

From: Yager, Amanda L
Sent: Wednesday, December 22, 2021 1:57 PM
To: ORSO
Cc: Moore, Anke Marga-Christa
Subject: 141061 FHI360 subaward
Attachments: subaward-initiation-form FHI360.pdf; 141061 FHI360.pdf

Dear ORSO and Anke,

Please find the attached subaward initiation form and FDP subaward for FHI360. FHI360 F&A rate is proprietary and so we will be working on a NDA with them for the information.

I would also ask that a few items be added to the email to FHI360 concerning the subaward.

1. They have requested a change to T&Cs #3 on page 1. Let them know that we are unable to change the FDP template.
2. That the appropriate links have been updated on page 3
3. That the correct reporting requirements have been checked since their review of the draft subaward agreement.

Let me know if you have any questions.

Thanks,
Amanda



Amanda Yager, CRA
Research Services Manager
Paul G. Allen School for Global Health
College of Veterinary Medicine
Washington State University
Email: ayager@wsu.edu

SUBAGREEMENT INITIATION FORM

Washington State University

Hover over each section for additional guidance

ORSO#: 141061

Project Title: PMU: Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)

Financial Overview:

1. Check if your subrecipient is listed as pre-approved, [here](#).
2. If not listed via the link above, please obtain and attach w/this form the subrecipient's most recent [Single Audit](#) for financial review. If unavailable, send recent tax record or certified financial statement.
3. No financial information? Please have subrecipient fill and return this [Subrecipient Questionnaire](#).

Attached with this form are the following:

☒ Statement of Work* ☒ Budget* ☐ Budget* Justification ☐ F&A Rate Agreement ☐ FCOI form ☐ RCR form ☒ Financial Documents
for New Supplier only: ☒ W9* Domestic ☐ W8* BEN/BENE Foreign

*Required attachments

WSU Information

PI: Felix Lankester Admin Contact: Amanda Yager
Phone: Phone:
Email: felix.lankester@wsu.edu Email: ayager@wsu.edu
Address: Paul G. Allen School for Global Animal Health PO Box 647090

☒ Federal Sponsor: USAID Prime Award #: 7200AA21CA00033
☐ Non-Fed Sponsor:

Funds set aside in AWD #: 003704 GR# 00008484 WD Supplier # SPC003578

Subrecipient Information

Legal Name: Family Health International Admin. Contact: Amber Sowa Phone: (919) 544-7040
DUNS/UEI#: 18 EIN#: 40 Email: ASowa@fhi360.org Remittance Address:
PI: Janet Robinson General Address: 359 Blackwell St., STE 200
Phone: (919) 321-3549 359 Blackwell St., STE 200
Email: JRobinson@fhi360.org Durham, NC 27701

Subagreement Information

Amount Funded this action: \$ 177,030.00 Total Est. Funding:
Cost Share this action: \$ 8,905.00 F&A Rate, if applicable: 49
Budget Period this action: 10/01/2021 — 09/30/2022 Est. Project Period: 10/01/2021 — 09/30/2026

Human Subjects ☒ Yes ☐ No

Subrecipient IRB not required for the following reason:

- ☐ IRB Exempt
☐ WSU acting as sIRB
☐ Other sIRB designated
☐ Approval will be sought after 1 year

Status of IRB:

- ☐ Approved
☒ Pending

Comments: These will be requested when the use of human subjects is approved by USAID

Animal Subjects ☒ Yes ☐ No

Status of IACUC approval

- ☐ Approved
☒ Pending

Comments: These will be requested when use of animals is approved by USAID

Technical/Progress Reporting requirement		
<input type="checkbox"/> Annual	<input type="checkbox"/> Monthly	
<input checked="" type="checkbox"/> Quarterly	<input checked="" type="checkbox"/> At the discretion of the PI to satisfy reporting REQs	
Other		
<input checked="" type="checkbox"/> Data Management/Sharing Plan	<input type="checkbox"/> Foreign subrecipient	<input type="checkbox"/> Select Agents Name/ Comments below:
<input checked="" type="checkbox"/> Human Subjects Data	<input type="checkbox"/> Carryforward restricted by PI	
<input type="checkbox"/> Fixed Priced Agreement	<input type="checkbox"/> Biohazardous materials	
Please list any special requirements or provide any other information you think might be useful for the person preparing this subagreement:		
Please work closely with Amanda Yager; Research Services Manager, Paul G. Allen School of Global Health, on any updates. Only partial budget at this time is being submitted until USAID approves the project workplan and budget detail. After approval budget and budget justification will be submitted.		
FHI360 F&A rate agreement is proprietary. We will be working on a NDA with them so we can have the agreement and open budget template so we can monitor their expenses properly.		

WSU PI Verification
By signing below, I certify that I have read the following statements and certify that they are accurate and true to the best of my knowledge:
<p>The subagency's proposed costs have been reviewed and are reasonable for the technical effort proposed.</p> <p>Funding is available for this subagreement and is an allowable cost under the terms of the prime.</p> <p><input type="checkbox"/> The project and relationship with this subagency present a potential conflict of interest or appearance thereof and a COI plan and explanation are attached.</p> <p style="text-align: center;">[OR]</p> <p><input checked="" type="checkbox"/> No conflict of interest as defined in Executive Policy #27 has been identified as a result of this project and relationship with the subagency.</p>
<p>Unavailable for Signature</p> <p>_____</p> <p>Signature of WSU PI</p>

For accounting purposes, please fill the below subrecipient budget template by WSU object code:

Salaries – 00	\$ 96,521.00
Wages - 01	
Personal Svc Contract – 02	
Goods/Services – 03	
Travel – 04	
Computer Services -05	
Equipment – 06	
Benefits – 07	\$ 29,930.00
Stipends/Subsides - 08	
SBCTs/Restricted – 14	
Small/Attractive Items – 16	
Total Direct Costs	
F&A - 13	49
Total Costs	\$ 177,030.00

Helpful Links:

Sam.gov:

<https://sam.gov/SAM/>

Federal Audit Clearinghouse:

<https://harvester.census.gov/facweb/>

ORSO Policy & Guidelines:

<https://orso.wsu.edu/wsu-policies-guidelines/>

For questions:

Please contact ORSO at 5-9661 or orso@wsu.edu.

FDP Cost Reimbursement Subaward

Federal Awarding Agency: Other [Type in Agency]		US Agency for International Development
Pass-Through Entity (PTE):		Subrecipient:
Washington State University		Family Health International
PTE PI: Felix Lankester		Sub PI: Janet Robinson
PTE Federal Award No: 7200AA21CA00033		Subaward No: 141061-SPC003578
Project Title: Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)		
Subaward Budget Period:		Amount Funded This Action (USD): \$ 177,030.00
Start: 10/01/2021	End: 09/30/2022	
Estimated Period of Performance:		Incrementally Estimated Total (USD): \$ 26,268,765.00
Start: 10/01/2021	End: 09/30/2026	

Terms and Conditions

1. PTE hereby awards a cost reimbursable subaward, (as determined by 2 CFR 200.331), to Subrecipient. The Statement of Work and budget for this Subaward are as shown in Attachment 5. In its performance of Subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.
2. Subrecipient shall submit invoices not more often than monthly and not less frequently than quarterly for allowable costs incurred. Upon the receipt of proper invoices, the PTE agrees to process payments in accordance with this Subaward and 2 CFR 200.305. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), breakdown by major cost category, Subaward number, and certification, as required in 2 CFR 200.415(a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments shall be directed to the party's Financial Contact, shown in Attachment 3A.
3. A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Financial Contact, as shown in Attachment 3A, not later than 60 days after the final Budget Period end date. The final statement of costs shall constitute Subrecipient's final financial report.
4. All payments shall be considered provisional and are subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Subrecipient.
5. Matters concerning the technical performance of this Subaward shall be directed to the appropriate party's Principal Investigator as shown in Attachments 3A and 3B. Technical reports are required as shown in Attachment 4.
6. Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this Subaward, and any changes requiring prior approval, shall be directed to the PTE's Authorized Official Contact and the Subrecipient's Authorized Official Contact shown in Attachments 3A and 3B. Any such change made to this Subaward requires the written approval of each party's Authorized Official as shown in Attachments 3A and 3B.
7. The PTE may issue non-substantive changes to the Budget Period(s) and Budget Bilaterally. Unilateral modification shall be considered valid 14 days after receipt unless otherwise indicated by Subrecipient when sent to Subrecipient's Authorized Official Contact, as shown in Attachment 3B.
8. Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.
9. Either party may terminate this Subaward with 30 days written notice. Notwithstanding, if the Awarding Agency terminates the Federal Award, PTE will terminate in accordance with Awarding Agency requirements. PTE notice shall be directed to the Authorized Official Contact, and Subrecipient notice shall be directed to the Authorized Official Contact as shown in Attachments 3A and 3B. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix IX, as applicable.
10. By signing this Subaward, including the attachments hereto which are hereby incorporated by reference, Subrecipient certifies that it will perform the Statement of Work in accordance with the terms and conditions of this Subaward and the applicable terms of the Federal Award, including the appropriate Research Terms and Conditions ("RTCs") of the Federal Awarding Agency, as referenced in Attachment 2. The parties further agree that they intend this subaward to comply with all applicable laws, regulations, and requirements.

By an Authorized Official of the PTE:		By an Authorized Official of the Subrecipient:	
<div style="border-bottom: 1px solid black; width: 100%;"></div> <div style="display: flex; justify-content: space-between;"> Name: <div style="border-bottom: 1px solid black; width: 80%;"></div> Date: <div style="border-bottom: 1px solid black; width: 15%;"></div> </div> <div style="border-bottom: 1px solid black; width: 100%;"></div>	<div style="border-bottom: 1px solid black; width: 100%;"></div> <div style="display: flex; justify-content: space-between;"> Name: <div style="border-bottom: 1px solid black; width: 80%;"></div> Date: <div style="border-bottom: 1px solid black; width: 15%;"></div> </div> <div style="border-bottom: 1px solid black; width: 100%;"></div>		
Title: <div style="border-bottom: 1px solid black; width: 100%;"></div>	Title: <div style="border-bottom: 1px solid black; width: 100%;"></div>		

Attachment 1

Certifications and Assurances

Subaward Number:

141061-SPC003578

Certification Regarding Lobbying (2 CFR 200.450)

By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief, that no Federal appropriated funds have been paid or will be paid, by or on behalf of the Subrecipient, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement in accordance with 2 CFR 200.450.

If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or intending to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the Subrecipient shall complete and submit Standard Form -LLL, "Disclosure Form to Report Lobbying," to the PTE.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by 31 U.S.C. 1352. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

Debarment, Suspension, and Other Responsibility Matters (2 CFR 200.214 and 2 CFR 180)

By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief that neither the Subrecipient nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this transaction by any federal department or agency, in accordance with 2 CFR 200.213 and 2 CFR 180.

Audit and Access to Records

Subrecipient certifies that it will provide PTE with notice of any adverse findings which impact this Subaward. Subrecipient certifies compliance with applicable provisions of 2 CFR 200.501-200.521. If Subrecipient is not required to have a Single Audit as defined by 200.501, Awarding Agency requirements, or the Single Audit Act, then Subrecipient will provide notice of the completion of any required audits and will provide access to such audits upon request. Subrecipient will provide access to records as required by parts 2 CFR 200.337 and 200.338 as applicable.

Program for Enhancement of Contractor Employee Protections (41 U.S.C 4712)

Subrecipient is hereby notified that they are required to: inform their employees working on any federal award that they are subject to the whistleblower rights and remedies of the program; inform their employees in writing of employee whistleblower protections under 41 U.S.C §4712 in the predominant native language of the workforce; and include such requirements in any agreement made with a subcontractor or subgrantee.

The Subrecipient shall require that the language of the certifications above in this Attachment 1 be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

Use of Name

Neither party shall use the other party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may use factual information regarding the existence and purpose of the relationship that is the subject of this Subaward for legitimate business purposes, to satisfy any reporting and funding obligations, or as required by applicable law or regulation without written permission from the other party. In any such statement, the relationship of the parties shall be accurately and appropriately described.

Prohibition on Certain Telecommunication and Video Surveillance Services or Equipment

Pursuant to 2 CFR 200.216, Subrecipient will not obligate or expend funds received under this Subaward to: (1) procure or obtain; (2) extend or renew a contract to procure or obtain; or (3) enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that uses covered telecommunications equipment or services (as described in Public Law 115-232, section 889) as a substantial or essential component of any system, or as a critical technology as part of any system.

Attachment 2

Federal Award Terms and Conditions

Subaward Number

141061-SPC003578

Required Data Elements

The data elements required by Uniform
Guidance are incorporated in the attached Federal Award.

This Subaward Is:

☒ Research & Development ☐ Subject to FFATA

Awarding Agency Institute (If Applicable)

USAID

Federal Award Issue Date FAIN Assistance Listing No.

09/22/21

7200AA21CA00033

98.001

Assistance Listing Program Title (ALPT)

USAID Foreign Assistance for Programs Overseas

Key Personnel Per NOA

Ch. Rabiner; B.T. Leader

General Terms and Conditions

By signing this Subaward, Subrecipient agrees to the following:

1. To abide by the conditions on activities and restrictions on expenditure of federal funds in appropriations acts that are applicable to this Subaward to the extent those restrictions are pertinent. This includes any recent legislation noted on the Federal Awarding Agency's website:

<https://www.usaid.gov/who-we-are/agency-policy>

2. 2 CFR 200

3. The Federal Awarding Agency's grants policy guidance, including addenda in effect as of the beginning date of the period of performance or as amended found at:

<https://www.usaid.gov/ads/policy/300/303>

4. Research Terms and Conditions, including any Federal Awarding Agency's Specific Requirements found at:

see attachment #6

except for the following :

- a. No-cost extensions require the written approval of the PTE. Any requests for a no-cost extension shall be directed to the Authorized Official Contact shown in Attachment 3A, not less than 30 days prior to the desired effective date of the requested change.
- b. Any payment mechanisms and financial reporting requirements described in the applicable Federal Awarding Agency Terms and Conditions and Agency-Specific Requirements are replaced with Terms and Conditions (1) through (4) of this Subaward; and
- c. Any prior approvals are to be sought from the PTE and not the Federal Awarding Agency.
- d. Title to equipment as defined in 2 CFR 200.1 that is purchased or fabricated with research funds or Subrecipient cost sharing funds, as direct costs of the project or program, shall vest in the Subrecipient subject to the conditions specified in 2 CFR 200.313.
- e. Prior approval must be sought for a change in Subrecipient PI or change in Key Personnel (defined as listed on the NOA).

5. Treatment of program income: Additive

Special Terms and Conditions:

Data Sharing and Access:

Subrecipient agrees to comply with the Federal Awarding Agency's data sharing and/or access requirements as reflected in the NOA or the Federal Awarding Agency's standard terms and conditions as referenced in General Terms and Conditions 1-4 above.

Provided upon request is a Data Management and/or Sharing Plan that incorporates additional requirements as submitted to the Federal Awarding Agency.

Data Rights:

Subrecipient grants to PTE the right to use data created in the performance of this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Copyrights:

Subrecipient Shall Grant to PTE an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted material (including any computer software and its documentation and/or databases) first developed and delivered under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Subrecipient grants to PTE the right to use any written progress reports and deliverables created under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its Federal Award.

Promoting Objectivity in Research (COI):

Subrecipient must designate herein which entity's Financial Conflicts of Interest policy (COI) will apply: Subrecipient

If applying its own COI policy, by execution of this Subaward, Subrecipient certifies that its policy complies with the requirements of the relevant Federal Awarding Agency as identified herein: US Agency for International Development

Subrecipient shall report any financial conflict of interest to PTE's Administrative Representative or COI contact, as designated on Attachment 3A. Any financial conflicts of interest identified shall, when applicable, subsequently be reported to Federal Awarding Agency. Such report shall be made before expenditure of funds authorized in this Subaward and within 45 days of any subsequently identified COI.

Work Involving Human or Vertebrate Animals (Select Applicable Options)☐ No Human or Vertebrate Animals**IRB**☒ Human Subjects**IACUC**☒ Vertebrate Animals

The PTE requires verification of IRB and/or IACUC approval be sent to the as required above:

Subrecipient agrees that any non-exempt human and/or vertebrate animal research protocol conducted under this Subaward shall be reviewed and approved by the appropriate Institutional Review Board (IRB) and/or its Institutional Animal Care and Use Committee (IACUC), as applicable and that it will maintain current and duly approved research protocols for all periods of the Subaward involving human and/or vertebrate animal research. Subrecipient certifies that the appropriate IRB and/or IACUC are in full compliance with applicable state and federal laws and regulations. The Subrecipient certifies that any submitted IRB / IACUC approval represents a valid, approved protocol that is entirely consistent with the Project associated with this Subaward. In no event shall Subrecipient invoice or be reimbursed for any human or vertebrate animals related expenses incurred in a period where any applicable IRB / IACUC approval is not properly in place.

Human Subjects Data (Select One)

Human Subjects Data will be exchanged under this Subaward (check all that apply):

- ☒ From Subrecipient to PTE
☒ From PTE to Subrecipient

The PTE will set forth the terms of the exchange of Human Subjects Data (Select One):

This section left intentionally blank

Additional Terms

Subawards issued under this award are subject to additional USAID approval.

If applicable, Subrecipient certifies that its Institutional Biosafety committee is in full compliance with applicable state and federal laws and regulations. Subrecipient agrees that any non-exempt research involving recombinant or synthetic nucleic acid molecules or select agents conducted under this agreement shall be reviewed and approved by its Institutional Biosafety Committee, as applicable. In Addition, Subrecipient will maintain current and duly approved research protocols for all periods of the Agreement involving recombinant or synthetic nucleic acid molecules or select agents.

The Subrecipient certifies that any submitted recombinant or synthetic nucleic acid molecules or select agents approval represents a valid, approved protocol that is entirely consistent with project associated with this subaward. In no event shall subrecipient invoice or be reimbursed for any recombinant or synthetic nucleic acid molecules or select agents related expense incurred in a period where any applicable IRB/IACUC approval is not properly in place.

In addition to other applicable provisions in the NOA, the mandatory provisions for U.S. Nongovernmental organizations found in the NOA as part of Attachment 6 (Pages 40-65 of this subaward) are incorporated by reference into this subaward.

Attachment 3A
Pass-Through Entity (PTE) Contacts

Subaward Number:

141061-SPC003578

PTE Information

Entity Name: Washington State University

Legal Address: Office of Research Support and Operations
280 Lighty
PO Box 641060
Pullman, WA 99164-1060

Website: <https://orso.wsu.edu/>

PTE Contacts

Central Email: orso@wsu.edu

Principal Investigator Name: Felix Lankester

Email: felix.lankester@wsu.edu

Telephone Number:

Administrative Contact Name: Chana Rabiner

Email: chana.rabiner@wsu.edu

Telephone Number:

COI Contact email (if different to above): orso@wsu.edu

Financial Contact Name: Casey St. Clair, Director, Sponsored Programs

Email: sps@wsu.edu

Telephone Number: (509) 335-2058

Email invoices? ☒ Yes ☐ No Invoice email (if different): ayager@wsu.edu

Authorized Official Name: Dan Nordquist, AVP ORSO

Email: orso@wsu.edu

Telephone Number: (509) 335-9661

PI Address:

Washington State University
Paul G. Allen School for Global Animal Health
PO Box 647090
Pullman WA 99164-7090

Administrative Address:

Washington State University
Office of Research Support and Operations
PO Box 641060
Pullman, WA 99164-1060

Invoice Address:

Washington State University
Sponsored Programs Services
PO Box 641025
Pullman, WA 99164-1025

Attachment 3B**Research Subaward Agreement
Subrecipient Contacts**

Subaward Number:

141061-SPC003578

Subrecipient Information for FFATA

reporting Entity's UEI/DUNS Name: Family Health International

EIN No.: 40 Institution Type: Nonprofit with 501c3 Status (other than Inst. of Higher Ed.)

UEI / DUNS: 40 Currently registered in SAM.gov: ☒ Yes ☐ No
Exempt from reporting executive compensation: ☒ Yes ☐ No (if no, complete 3Bpg2)Parent UEI / DUNS: This section for U.S. Entities: Zip Code Look-up
Congressional District: 4th Zip Code+4: 27701**Place of Performance Address**359 Blackwell St., STE 200
Durham, NC 27701**Subrecipient Contacts**

Central Email:

Website: www.fhi360.org

Principal Investigator Name: Janet Robinson

Email: JRobinson@fhi360.org Telephone Number: 919-321-3549

Administrative Contact Name:

Email: Telephone Number:

Financial Contact Name: Amber Sowa

Email: ASowa@fhi360.org Telephone Number: 919-544-7040 ext 1234

Invoice Email: ASowa@fhi360.org

Authorized Official Name: Amber Sowa

Email: ASowa@fhi360.org Telephone Number: 919-544-7040 ext 1234

Legal Address:359 Blackwell St., STE 200
Durham, NC 27701**Administrative Address:**359 Blackwell St., STE 200
Durham, NC 27701**Payment Address:**359 Blackwell St., STE 200
Durham, NC 27701

Attachment 3B Page 2
Research Subaward Agreement
Highest Compensated Officers

Subaward Number:
141061-SPC003578

Subrecipient

Entity Name:

PI Name:

Highest Compensated Officers

The names and total compensation of the five most highly compensated officers of the entity(ies) must be listed if the entity in the preceding fiscal year received 80 percent or more of its annual gross revenues in Federal awards; and \$25,000,000 or more in annual gross revenues from Federal awards; and the public does not have access to this information about the compensation of the senior executives of the entity through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. See FFATA § 2(b)(1) Internal Revenue Code of 1986.

Officer 1 Name:

Officer 1 Compensation:

Officer 2 Name:

Officer 2 Compensation:

Officer 3 Name:

Officer 3 Compensation:

Officer 4 Name:

Officer 4 Compensation:

Officer 5 Name:

Officer 5 Compensation:

Attachment 4
Reporting and Prior Approval Terms

Subaward Number:

141061-SPC003578

Subrecipient agrees to submit the following reports (PTE contacts are identified in Attachment 3A):

Technical Reports:

- ☐ Monthly technical/progress reports will be submitted to the PTE's within days of the end of the month.
- ☐ Quarterly technical/progress reports will be submitted within 30 days after the end of each project quarter to the PTE's .
- ☒ Annual technical / progress reports will be submitted within days prior to the end of each budget period to the PTE's . Such report shall also include a detailed budget for the next Budget Period, updated other support for key personnel, certification of appropriate education in the conduct of human subject research of any new key personnel, and annual IRB or IACUC approval, if applicable.
- ☒ A Final technical/progress report will be submitted to the PTE's within days of the end of the Project Period or after termination of this award, whichever comes first.
- ☒ Technical/progress reports on the project as may be required by PTE's in order for the PTE to satisfy its reporting obligations to the Federal Awarding Agency.

Prior Approvals:

Carryover:

Other Reports:

- ☒ In accordance with 37 CFR 401.14, Subrecipient agrees to notify both the Federal Awarding Agency via iEdison and PTE's within 60 days after Subrecipient's inventor discloses invention(s) in writing to Subrecipient's personnel responsible for patent matters. The Subrecipient will submit a final invention report using Federal Awarding Agency specific forms to the PTE's within 60 days of the end of the Project Period to be included as part of the PTE's final invention report to the Federal Awarding Agency.

A negative report is required:

- ☒ Property Inventory Report (only when required by Federal Awarding Agency), specific requirements below.

Additional cost sharing requirements included below:

Additional Technical and Reporting Requirements:

Subrecipients shall list each country included in the program and the total amount expended for each country when submitting financial reports. These will be noted to each partner as countries are onboarded.

Kenya 615-GH-W	141061-SPC003579
Senegal 685-GH-W	141061-SPC003580
Peru 527-GH-W	141061-SPC003581
Vietnam 440-GH-W	141061-SPC003582
Thailand 493-GH-W	141061-SPC003583

There may be additional reporting requirements and ad hoc information requests including, but not limited to, those associated with Mission buy-ins or additional sources of funding provided to DEEP VZN. Ad hoc refers to an unscheduled report for immediate, specific use. These requests will need to be approved by USAID.

Attachment 5
Statement of Work, Cost Sharing, Indirects & Budget

Subaward Number:

141061-SPC003578

Statement of Work

☐ Below ☒ Attached, pages

If award is FFATA eligible and SOW exceeds 4000 characters, include a *Subrecipient Federal Award Project Description*

- HQ Technical and Program Management: This includes costs to provide technical support to the global workplan and project implementation overall.
- EMMP/R: FHI 360 will lead the development of the DEEP VZN EMMP and annual EMMR. The associated LOE to develop the plan and report is included.
- Research Ethics Training: FHI 360 will lead the development of the Research Ethics training materials, which will be rolled out in all countries. The budget includes the LOE to develop/adapt the training materials and translation costs. No direct in-country training costs are included. It is assumed that costs to implement the training in-country will be included in the respective country budgets.
- QMS Training: FHI 360 will lead the development of the QMS training package, which will be rolled out in all countries. The budget includes the LOE and translation costs. No direct in-country training costs are included. It is assumed that costs to implement the training in-country will be included in the respective country budgets.
- Biosafety/biosecurity plan: WSU will lead development of the BSBS plan. FHI 360 has included LOE to provide any technical assistance to review and finalize the plan.

Budget Information

Indirect Information Indirect Cost Rate (IDC) Applied %

Rate Type:

Modified Total Direct Costs

Cost Sharing

Yes

If Yes, include Amount: \$ 8,905.00

Budget Details

☒ Below ☐ Attached, pages

Salaries - \$96,521

Benefits - \$29,930

F&A - \$ 49

Total - \$177,030

Only partial budget at this time is being submitted until USAID approves the project workplan and budget detail.

Budget Totals

Direct Costs \$ 126,450.00

Indirect Costs \$ 49

Total Costs \$ 177,030.00

All amounts are in United States Dollars

Attachment 6**Notice of Award (NOA) and any additional documents**

The following pages include the NOA and if applicable any additional documentation referenced throughout this Subaward.



Not incorporating the NOA or any additional documentation to this Subaward.



September 22, 2021

Dan Nordquist
Associate Vice President for Research
Washington State University
P.O. Box 641060
Pullman, WA 99164-1060
orso@wsu.edu

Reference: Award No. Titled "Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)" Cooperative Agreement 7200AA21CA00033

Dear Dan Nordquist:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, the U.S. Agency for International Development (USAID) hereby awards to Washington State University, hereinafter referred to as the "Recipient", the sum of \$124,679,896 to provide support for a program titled "Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)", as described in the Schedule of this award and in Attachment B, entitled "Program Description."

This Cooperative Agreement will be effective October 1, 2021. Obligation will be made upon receipt of the Recipient's acknowledgement and shall apply to expenditures made by the Recipient in furtherance of program objectives during the period beginning with the effective date October 1, 2021 and ending September 30, 2026. USAID will not be liable for reimbursing the Recipient for any costs in excess of the obligated amount.

This Cooperative Agreement is made to Washington State University, on condition that the funds will be administered in accordance with the terms and conditions as set forth in Attachment A (the Schedule), Attachment B (the Program Description), Attachment C (the Standard Provisions), and Attachment D (the Branding & Marking Plan) all of which have been agreed to by your organization.

Please sign the second page of this cover letter to acknowledge your receipt of this award and e-mail a copy of only the signed page to Anna Nelson at annelson@usaid.gov with a cc: to Patricia Bradley at pbradley@usaid.gov.

Sincerely,

Patricia Elena Bradley
(affiliate)
Patricia Bradley
Agreement Officer

Digitally signed by Patricia Elena
Bradley (affiliate)
Date: 2021.09.22 10:24:23 -04'00'

Attachments:

- A. Schedule
- B. Program Description
- C. Standard Provisions
- D. Branding & Marking Plan

ACKNOWLEDGED BY:

NAME: Christopher J. Keane



TITLE: Vice President for Research, WSU and Vice Chancellor for Research, WSU Pullman

DATE: 9/23/2021

ACCOUNTING AND APPROPRIATION DATA

A. GENERAL

1. Amount Obligated this Action: \$ 10,000,000
 2. Total Estimated USAID Amount: \$124,679,896
 3. Total Obligated USAID Amount: \$ 10,000,000
 4. Cost-Sharing Amount (Non-Federal): \$ 6,607,682
 5. Activity Title: “Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)”
 6. USAID Technical Office: GH/ID/ETD
 7. Tax I.D. Number: 40
 8. DUNS No.: 40
 9. LOC Number: 42A5P

B. SPECIFIC

GLAAS Requisition: REQ-GH-21-000020

Account ID	Accounting Template	BBFY	EBFY	Fund	Operating Unit	Prog Area	Program Name	Dist Code	BGA	SOC	Funded Amount
1-1	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	615-GH-W	615	4100201	\$2,000,000
1-2	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	685-GH-W	685	4100201	\$2,000,000
1-3	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	440-GH-W	440	4100201	\$2,000,000
1-4	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	527-GH-W	527	4100201	\$2,000,000
1-5	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	493-GH-W	493	4100201	\$2,000,000

C. PAYMENT OFFICE

M/CFO/CMP Letter of Credit Office
USAID/Washington

USAID Office of Financial Management (M/CFO/CMP) prefers the submittal of invoices to be electronic. In addition to the required submission to the Agreement Officer’s Representative (AOR), please submit a copy of the invoices to loc@usaid.gov.

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ATTACHMENT A - SCHEDULE

A.1 PURPOSE OF AWARD

The purpose of this Cooperative Agreement is to provide support for the program described in Attachment B to this Cooperative Agreement entitled "Program Description."

A.2 PERIOD OF AWARD

1. The effective date of this Award is **October 1, 2021**. The estimated completion date of this Award is **September 30, 2026**.

A.3 AMOUNT OF AWARD AND PAYMENT

1. The total estimated amount of this Award for the period shown in A.2.1 above is \$124,679,897, not including cost share.
2. USAID hereby obligates the amount of \$10,000,000 for program expenditures during the period set forth in A.2.1 above and as encompassed in the Budget below. The recipient must use funds obligated under this award and any subsequent amendments from the specific Operating Units (OU) and Program Areas (PA) for activities approved in the award and detailed in the work plan, as applicable. Program disbursements for each OU/PA must not exceed the amounts specified in the Accounting and Appropriates data for each Operating Unit (OU) and Program Area (PA). The Recipient will be given written notice by the Agreement Officer if additional funds will be added.
3. As the obligated amount for the program shall equal the total USAID estimated amount of this Agreement, additional increments of funds may be obligated by USAID under this Agreement (by a unilateral modification to this Agreement), subject to availability of funds, successful performance by the Recipient, possible evaluation of the program, program priorities at the time, and the requirements of the 2 CFR 200.308.
4. Payment will be made to the Recipient by Letter of Credit in accordance with procedures set forth in 2 CFR 200 and 2 CFR 700.

A.4 AWARD BUDGET

The following is the Award Budget, including local cost financing items, if authorized. Revisions to this budget shall be made in accordance with 2 CFR 200 and 2 CFR 700.

TOTAL BUDGET

Cost Element	USD
Direct Costs	\$116,474,256
Indirect Costs	\$ 49
Total Federal Contribution	\$124,679,897
Cost Share	\$6,607,682
Total Program Cost	\$131,287,579

Washington State University is responsible for managing available funds. This agreement includes a ceiling amount and obligated amount that the recipient exceeds at its own risk.

A.5 PLANNING, REPORTING, AND EVALUATION

1. Financial Reporting:

The recipient must submit the Federal Financial Form (SF-425) on a quarterly basis via electronic format to the U.S. Department of Health and Human Services. The recipient also must submit a copy of the SF-425 to the Agreement Officer (AO) and the Agreement Officer's Representative (AOR). These financial reports are due no later than 30 calendar days at the end of each quarter based on the federal fiscal calendar. The recipient must submit final financial reports to USAID/Washington, M/CFO/CMP-LOC Unit, the AO, and the AOR. The recipient must also submit an electronic version of the final financial report to the U.S. Department of Health and Human Services in accordance with the paragraph above.

2. Performance Planning:

Implementation Plans

Annual implementation plans serve as a guide to activity implementation and detail how the recipient will use the implementation year to achieve the objectives of DEEP VZN. The implementation plan is intended to be an annual roadmap for USAID and the recipient. With approval from the AOR, reasonable and justifiable modifications can be made to improve the chances of achieving the medium- and long-term results of the award. The recipient must submit the following implementation and reporting documents in English. The AOR and recipient will agree on the appropriate format and length.

Implementation plans include, but are not limited to, the following:

- Annual work plans, including planned activities for the following year and any subsequent revisions
- International travel plans
- Planned expenditures
- Event planning/management
- International meeting preparation
- Material Transfer Agreement (MTA) risk mitigation plan
- Country-level Level of Effort (LOE) chart, to include any oversight provided by headquarters
- Protocol Development and Review Plan
- Biosecurity and Biosafety (BSBS) Plan

USAID requires the AOR approval of implementation plans annually to ensure alignment with stated goals, milestones and outputs. The implementation plan communicates how and when the recipient will complete project activities and is drafted annually to describe new activities. The AOR will ensure that the implementation plans fit within the scope, terms and conditions of the agreement.

First Year Work Plan and Budget

The recipient will submit a draft work plan for the first year within the first 90 calendar days of executing the award. Depending on the start date of the agreement, the first-year work plan may be less than a full year or more than a full year. The first-year work plan must include a detailed budget and budget narrative for the first year. As part of the First Year Work Plan submission, the recipient will include a supplementary annual work plan describing planned contributions to the GHSA on a template designated by the AOR. All work plans and budgets, including

significant revisions thereto, must be approved by the AOR.

Annual Work Plan and Budget

Starting with the second year of the award and for each subsequent year of performance thereafter, the recipient will submit annual work plans, budgets, and budget narratives to the AOR for the next federal fiscal year within 30 calendar days prior to the end of the current federal fiscal year in a format agreed upon by the AOR and the recipient. The recipient also will submit supplementary annual work plans describing planned contributions to the Global Health Security Agenda (GHSa) within a timeframe and on a template designated by the AOR.

Monitoring, Evaluation and Learning (MEL) Plan

The recipient will finalize a MEL plan for the life of DEEP VZN that derives from the activities outlined in the Program Description and submit it to the AOR within 90 calendar days of the award for approval. The MEL plan will outline key program interventions, indicators of achievement, associated annual and life-of-Activity targets and a learning agenda. The learning agenda will outline key questions to be addressed, a plan for addressing these questions, and a process for incorporating findings into program implementation and the detection and characterization of unknown viruses. Where appropriate, the MEL plan must track gender equality issues in implementing activities. The recipient will update the MEL plan annually and submit it as an attachment to the annual report.

Biosecurity and Biosafety (BSBS) Plan

The recipient will finalize a BSBS plan for the life of DEEP VZN and submit it to the AOR within 90 calendar days of the award for approval. The BSBS will outline all program interventions that have biosafety/biosecurity implications and steps (e.g. protocols, training) that will be taken to minimize risk.

Gender Action Plan

The recipient will conduct a gender analysis that assesses context and gender needs, including time constraints and participation limitations. This analysis will inform a subsequent gender action plan, which will be developed in collaboration with the USAID management team and finalized within 90 calendar days of the award and updated annually. The gender action plan will inform the Activity's technical approach as it relates to gender throughout the life of the Activity. It also will be used to inform the design of activities that seek to reduce opportunity gaps between men and women or address power differentials to promote gender equity. The gender action plans should be developed in conjunction with the Activity's monitoring, evaluation and learning plan, and progress should be reflected in annual work plans and performance reports.

Data Management Plan

A Data Management Plan (DMP) is a document that describes how the recipient will manage data during the project and what happens to the data after the project ends. The initial DMP, which will be developed in collaboration with the USAID management team, will be finalized within 90 calendar days of the award and updated semi-annually and annually.

A comprehensive DMP will discuss the following aspects of the data life cycle:

- Collect - How the data is collected and processed by the researcher.
- Assure - How to make sure the data is high quality and free of errors.
- Describe - How the data will be documented so that other researchers can use it.
- Preserve - How and where the data will be stored so that researchers can access it forever.

The data management plan will inform the Activity's technical approach as it relates to data throughout the life of the Activity. The data management plan should be developed in conjunction with the Activity's monitoring, evaluation and learning plan, and progress should be reflected in annual work plans and performance reports.

Closeout Plan

No later than six (6) months prior to the completion date of the agreement, the recipient will submit a demobilization plan for Agreement Officer's approval. The demobilization plan shall include: 1) a draft property disposition plan, 2) a plan for the phase-out of in-country operations, 3) a staffing discharge plan, 4) a delivery schedule for all reports or other deliverables required under the agreement, and 5) a timetable for completing all required actions in the demobilization plan, including the submission date of the final property disposition plan to the Agreement Officer.

3. Performance Reporting:

The recipient must submit via email a copy of semi-annual, annual, and final performance reports, in English, to the AOR in accordance with 2 CFR 200.328.

Semi-Annual and Annual Reports

The recipient will submit semi-annual and annual progress reports based on the federal fiscal calendar. The semi-annual report will be due within 30 days after the end of the reporting period and will cover the first six months of the year (October 1 - March 31). The annual report will cover the entire fiscal year (October 1 - September 30) and will be due within 90 days of the end of the federal fiscal year.

At a minimum, both semi-annual and annual reports will contain:

- Narrative description of activities completed and major accomplishments achieved during the reporting period in all countries supported by DEEP VZN, presented by objective
- Qualitative and quantitative data on program achievements and results
- Progress on standard and agreed upon indicators, as outlined in the MEL plan, including status towards achieving targets and explanations for significant deviations
- An updated MEL plan, including progress on the learning agenda (annually)
- An updated BSBS plan
- An updated Data Management plan
- Problems encountered and whether they were solved or are still outstanding
- Proposed solutions to ongoing or new problems
- Success stories, blogs, articles, publications, press releases, and photographs, if available
- Update on expenditures for the reporting period against the pipeline
- Analysis and explanation of cost overruns or high unit costs, when applicable
- Planned activities for the next performance period

Global Health Security Agenda (GHS) reports

The Recipient will submit semi-annual GHS performance reports within a timeframe and on a template designated by the AOR. The Recipient will submit the GHS semi-annual reports to the AOR via email.

Ad Hoc Reports

There may be additional reporting requirements and ad hoc information requests including, but not limited to, those associated with Mission buy-ins or additional sources of funding provided to DEEP VZN. Ad hoc refers to an unscheduled report for immediate, specific use. USAID will define the purpose, content, and specific use for any ad hoc report.

Final Report

Within ninety (90) calendar days after the period performance date, the recipient will submit one (1) original and two (2) copies of the Final Report to the AOR and one (1) copy to the Agreement Officer. In addition, one (1) copy will be submitted to the Development Experience Clearinghouse:

- 1) Electronically: <http://www.usaid.gov/results-and-data/informationresources/developmentexperience-clearinghouse-dec>
or
- 2) By U.S. Postal Service delivery to:
U.S. Agency for International Development
Development Experience Clearinghouse
M/CIO/ITSD/KM
Ronald Reagan Building M. 01-010
Washington, DC 20523-6100

The Final Report must include a narrative report and summary table of results, a comparison of actual accomplishments to the objectives established for the period of performance, and a gender analysis that describes how gender equality issues were tracked and addressed. It should highlight accomplishments against implementation plans; outline progress of benchmarks against targets; describe results; and document lessons learned during implementation. The Final Report also must contain a three-page executive summary, an index of all reports and information products produced under the agreement, and a summary of the program's finances. More details on the format of the final report will be provided after the award.

A.6 INDIRECT COST RATE

Allowable indirect costs shall be reimbursed on the basis of the following negotiated Colleges and Universities Rate Agreement, dated August 20, 2019.

INDIRECT COST RATES:

TYPE	FROM	TO	LOCATION	RATE%	APPLICABLE TO
Predetermined	7/1/2019	6/30/2023	On-Campus	49	Organized Research
			Off-Campus	49	Organized Research
			On-Campus	49	Instruction
			Off-Campus	49	Instruction
			On-Campus	49	Other Sponsored Activities
			Off-Campus	49	Other Sponsored Activities
Provisional	7/1/2023	Until Amended	Use same rates and conditions as those cited for fiscal year ending June 30, 2023.		

Base

Modified total direct costs, consisting of all salaries and wages, fringe benefits, materials, supplies, services, travel and subgrants and subcontracts up to the first \$25,000 of each

subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). Modified total direct costs shall exclude equipment, capital expenditures, charges for patient care, student tuition remission, rental costs of off-site facilities, scholarships, and fellowships as well as the portion of each subgrant and subcontract in excess of \$25,000.

A.7 TITLE TO PROPERTY

Title of property financed under this award shall vest with the recipient subject to the requirements of 2 CFR 200.311-200.316, until such time as USAID issues disposition instructions.

Furthermore, the following requirements apply regarding the use, care, accountability, maintenance, and disposition thereof:

(a) Tangible Property

(1) Equipment: “Equipment” means an article of tangible nonexpendable personal property having a useful life of one year or more and a per-unit acquisition cost (purchase price) of \$5,000 or more. Equipment is subject to the requirements set forth in 2 CFR 200.313.

(2) Supplies and Other Expendable Equipment: “Supplies and other expendable equipment” means items of tangible personal property that do not meet the definition of “equipment” in paragraph (a)(1) above. Supplies and other expendable equipment are subject to the requirements set forth in 2 CFR 200.314.

(3) Real Property: “Real property” means land, land improvements, structures, and appurtenances thereto. Real property is subject to the requirements set forth in 2 CFR 200.311.

(b) Intangible (Intellectual) Property

“Intangible property” means, but is not limited to, copyrights, inventions and patents, and data first produced under this Agreement. Intangible property is subject to the requirements set forth in 2 CFR 200.315.

A.8 AUTHORIZED GEOGRAPHIC CODE

The authorized geographic code for procurement of goods and services under this award is 935.

A.9 COST SHARING

The Recipient will contribute 5.03% percent of the total obligated amount of the award, excluding the sub-awards to the networks, as cost share throughout the life of the project. The cost share contribution shall be listed per cost category and presented in the work plan budgets.

Description	USD
Federal Amount Subject to Cost Share	\$124,679,897
Proposed Cost Share Amount	\$6,607,682
Cost Share Percentage	5.03%
Total Project Amount	\$131,287,579

A.10 SUBSTANTIAL INVOLVEMENT

a. Approval of the Recipient's Annual Implementation Plans:

Implementation plans include, but are not limited to, annual work plans, budget and budget narrative, including planned activities for the following year and any subsequent revisions, international travel plans, planned expenditures, event planning/management, international meeting preparation, MTA risk mitigation plan, country-level LOE chart, to include any oversight provided by headquarters, and protocol development and review plan.

USAID requires AOR approval of implementation plans annually to ensure alignment with stated goals, milestones and outputs. Each implementation plan communicates how and when the recipient will complete project activities and is drafted annually to describe new activities. This plan will be developed in partnership between the recipient and the AOR team. The AOR will ensure that each implementation plan fits within the scope, terms and conditions of the agreement.

b. Approval of Specified Key Personnel:

Designation of key personnel positions, approval of key personnel and any changes for the positions listed below:

- Project Director
- Deputy Project Director/Operational Lead

All individuals proposed as Key Personnel in the Recipient's application are hereby approved. Any future approval of key personnel will be authorized by the Agreement Officer in a separate administrative letter. The Recipient must submit to the AOR, reasonably in advance, any proposed replacement (including proposed substitutions) along with written justification in sufficient detail to permit evaluation of the impact on the program. Any proposed replacement Key Personnel must meet the minimum requirements stated in the Notice of Funding Opportunity (NOFO) number 7200AA21RFA00005, Section D.5.g). No replacement shall be made by the Recipient without the written consent of the Agreement Officer.

c. Agency and Recipient Collaboration or Joint Participation:

- Collaborative involvement in the selection of advisory committee members, if the recipient establishes an advisory committee that provides advice to the recipient. The AOR may participate as a member of this committee. Advisory committees must only deal with programmatic or technical issues and not routine administrative matters.
- Collaborative involvement in the selection of countries, viruses, and interfaces.
- USAID review and approval of monitoring, evaluation, and learning plans.
- USAID review and approval of data management plans.
- USAID involvement in the substantive direction/re-direction of interrelationships with other projects.
- USAID involvement in monitoring progress toward achievement of the Objectives and Expected Achievements during the course of the Agreement(s) and in monitoring of financial expenditures.

d. Direction and Redirection:

USAID will be involved in the substantive direction/re-direction of inter-relationships with other projects.

A.11 PROGRAM INCOME

The Recipient shall account for Program Income in accordance with 2 CFR 200.307 (or the Standard Provision entitled Program Income for non-U.S. organizations). Program Income earned under this award shall be added to the project.

A.12 AGREEMENT OFFICER'S REPRESENTATIVE

The Agreement Officer's Representative (AOR) for this Agreement will be designated in a separate memorandum from the Agreement Officer to the AOR with copy to the Recipient and the payment office.

A.13 SPECIAL PROVISIONS

A.13.1 SUBAWARD APPROVAL

Pursuant to the approved budget of this cooperative agreement, the following sub-awards are approved. All other sub-awards are subject to additional USAID approval.

Sub-awardee

University of Washington – UW

Family Health International 360 – FHI 360

PATH

Washington University at Saint Louis – WUSTL

Duke University

A.13.2 COUNTRY-BY-COUNTRY BREAKDOWN OF EXPENDITURES

The Recipient shall list each country included in the program and the total amount expended for each country under the award for the reporting period in the "Remarks" block on the "Financial Status Report" SF 425, or on a separate sheet of paper with the "Request for Advance or Reimbursement" SF 270.

A.13.3 BRANDING STRATEGY & MARKING PLAN

The Recipient shall submit within 30 calendar days of award, a Branding Strategy and Marking Plan. Upon the approval of the AO and AOR, the plan shall be incorporated as Attachment D.

A.13.4 ENVIRONMENTAL COMPLIANCE

The Foreign Assistance Act of 1961, as amended, Section 117 requires that the impact of USAID's activities on the environment be considered and that USAID include environmental sustainability as a central consideration in designing and carrying out its development programs. This mandate is codified in Federal Regulations (22 CFR 216) and in USAID's Automated Directives System (ADS) Parts 201.5.10g and 204 (<http://www.usaid.gov/policy/ADS/200/>), which, in part, require that the potential environmental impacts of USAID-financed activities are

identified prior to a final decision to proceed and that appropriate environmental safeguards are adopted for all activities. The recipient's environmental compliance obligations under these regulations and procedures are specified in the following paragraphs of this cooperative agreement.

In addition, the recipient must comply with host country environmental regulations unless otherwise directed in writing by USAID. In case of conflict between host country and USAID regulations, the latter shall govern.

No activity funded under this cooperative agreement will be implemented unless an environmental threshold determination, as defined by 22 CFR 216, has been reached for that activity, as documented in a Request for Categorical Exclusion (RCE), Initial Environmental Examination (IEE), or Environmental Assessment (EA) duly signed by the Bureau Environmental Officer (BEO). (Hereinafter, such documents are described as "approved Regulation 216 environmental documentation.")

As part of its initial Work Plan, and all Annual Work Plans thereafter, the Recipient, in collaboration with the USAID AOR and Mission Environmental Officer or Bureau Environmental Officer, as appropriate, shall review all ongoing and planned activities under this cooperative agreement to determine if they are within the scope of the approved Regulation 216 environmental documentation.

If the Recipient plans any new activities outside the scope of the approved Regulation 216 environmental documentation, it shall prepare an amendment to the documentation for USAID review and approval. No such new activities shall be undertaken prior to receiving written USAID approval of environmental documentation amendments.

Any ongoing activities found to be outside the scope of the approved Regulation 216 environmental documentation shall be halted until an amendment to the documentation is submitted and written approval is received from USAID.

A.13.5 OPEN DATA AND DATA SHARING

The recipient will be expected to comply with the Office of Management and Budget's Open Data Policy, as well as any USAID open data policy. Relevant MEL related data, knowledge and specifically lessons learned from sampling, discovery, characterization, and data analysis and use will be documented. All final data sets that USAID and the recipient deem as valuable to its stakeholders shall be submitted to USAID in a reliable media prior to the award end date and will be available for dissemination as appropriate. During the term of the agreement, preliminary data and analysis will be submitted to USAID on a periodic basis, but no less than annually, as agreed upon by USAID and recipient during work planning.

A.13.6 ORGANIZATIONAL CONFLICT OF INTEREST

Recipient must adhere to conflict of interest regulations found in 2 CFR 200.112 and 2 CFR 200.318(c)(1).

A.13.7 COORDINATION, COMMUNICATION, AND COLLABORATION

Coordination, communication and collaboration among stakeholders facilitate trust and mutual understanding; reduce redundancy; increase synergy, scalability, and impact; and promote learning and mutual accountability. DEEP VZN is expected to build and enhance constructive

partnerships, as appropriate. DEEP VZN will collaborate and coordinate with a wide variety of stakeholders, including country National NTD Programs, Ministries of Health and other relevant government entities; USAID Missions and Country Offices, USG partners, bilateral and multilateral agencies; academic and research institutions; private sector and philanthropic organizations; and civil society organizations.

A.14 SPECIAL REQUIREMENTS

A.14.1 FOR U.S. ORGANIZATIONS -- SPECIAL AWARD REQUIREMENT RELATING TO THE PROHIBITION ON CERTAIN TELECOMMUNICATION AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUGUST 2020)

- a. 2 CFR 200.216, “Prohibition on certain telecommunications and video surveillance services or equipment” implements Pub. L. 115-232, Section 889.
- b. USAID has been granted a temporary, limited waiver under Section 889(d)(2) that will allow the recipient to use award funds for the duration of this award to procure internet, cellular and landline services from communication service-providers who use covered telecommunications. All other costs incurred for covered telecommunications and video surveillance services or equipment, such as phones, video surveillance, and cloud servers specified in 2 CFR 200.216 remain unallowable in accordance with 2 CFR 200.471.

[End of Special Award Requirement]

A.14.2 FOR NON-U.S. ORGANIZATIONS -- SPECIAL AWARD REQUIREMENT RELATING TO THE PROHIBITION ON CERTAIN TELECOMMUNICATION AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUGUST 2020)

- a. The mandatory standard provision “Prohibition on Certain Telecommunication and Video Surveillance Services or Equipment (AUGUST 2020)” implements Pub. L. 115-232, Section 889.
- b. USAID has been granted a temporary, limited waiver under Section 889(d)(2) that will allow the recipient to use award funds for the duration of this award to procure internet, cellular and landline services from communication service-providers who use covered telecommunications. All other costs incurred for covered telecommunications and video surveillance services or equipment, such as phones, video surveillance, and cloud servers specified in the standard provision in paragraph a. above remain unallowable in accordance with the mandatory standard provision “Allowable Costs” and 2 CFR 200.471.

[End of Special Award Requirement]

[END OF ATTACHMENT A]

ATTACHMENT B – PROGRAM DESCRIPTION

EXECUTIVE SUMMARY

With an overarching goal of detecting ‘known unknown’ viruses that might pose a pre-pandemic threat, we will carry out an innovative, sustainable, and responsive surveillance program for detection and characterization of novel animal viruses with zoonotic potential. Our consortium, which includes University of Washington (UW), PATH, FHI360, and Washington University in St. Louis (WUSTL) is led by Washington State University’s (WSU) Allen School for Global Health, whose approach of placing full-time faculty in global regions has seen it lead innovative emerging infectious disease studies in East and Central Africa that target landscapes inhabited by humans, their livestock and diverse wildlife populations in ecosystems ideal for the maintenance and transmission of emerging zoonotic pathogens. The consortium features strong in-country partners supported by world class virology reference laboratories at UW and WUSTL involved in novel virus discovery and characterization, unparalleled experience in laboratory strengthening, One Health epidemiology and social science, and global reach. Apart from collective presence and institutional links in countries located in the six DEEP VZN global regions, our consortium partners bring complementary expertise, including global field studies and sampling by WSU and UW, laboratory capacity by WUSTL and UW, and data management and in-country stewardship by PATH, FHI360 and WSU. We will build on the achievements of the USAID EPT programs, and our collective prominence in the global NIH-supported Centers for Research in Infectious Diseases (NIH-CREID), to enable partner labs in focus countries to fully sequence and characterize novel viruses in unprecedented breadth and depth. We will leverage scientific breakthroughs with SARS CoV2 and other emerging viruses to apply cutting edge technologies to prioritize potential for viral spillover and pandemics. In focus countries, we will target high-risk locations and subpopulations at the human-animal interface using a risk-based analytical approach to guide sample collection where there is evidence of previous spillover or high prevalence of zoonotic viruses. Additionally, we will establish an efficient sample collection and transportation system and align capacities at in-country laboratories to identify viruses of zoonotic potential in a timely manner, thus triggering additional targeted sampling focused up- and downstream of the transmission chain.

We plan to collect over 800,000 samples, of which approximately 60% will come from wildlife. Assuming a 1-1.5% yield, our in-country labs will provide near-real time screening and genome sequencing to detect and characterize between 8,000 and 12,000 novel viruses from the target families over the five years of the DEEP VZN program. To effectively characterize viruses of zoonotic potential from the detected pool, we will use a combination of innovative molecular, protein structure and receptor analyses, and serological techniques to generate evidence of spillover to humans, and potential for human-to-human transmission. This consortium will also strengthen capacity within focus countries for continued assessment of viruses of zoonotic potential and enhance response to future outbreaks. To enhance sustainability, we will build in-country stewardship of all surveillance, diagnostic and data management activities through the development of meaningful partnerships with focus country stakeholders. Through engagement and integration with other USAID EPT efforts, NIH CREID networks and other professionals across human, animal, and environmental health sectors, we will promote meaningful sharing of resources and data in an inclusive and cost-effective One Health-approach. The overall outcomes of this program will be the detection of an unprecedented number of unknown viruses of pandemic potential that can be monitored by public health institutions worldwide, and significant

advances in our collective ability to characterize zoonotic and pandemic potential of emerging viruses.

OBJECTIVE 1: Conduct Sampling for Unknown Viruses from the Priority Viral Families **We have designed an efficient, responsive, and sustainable program that uses existing data and models on spillover risk to guide initial sampling and interim data to refine sampling targets.**

Building on baseline detection of known viruses in the PREDICT, VIRION and EIDITH databases, our strategies will lead to the detection of previously unknown wildlife-origin viruses from the target families and identify a subset that pose a significant pandemic threat. Our

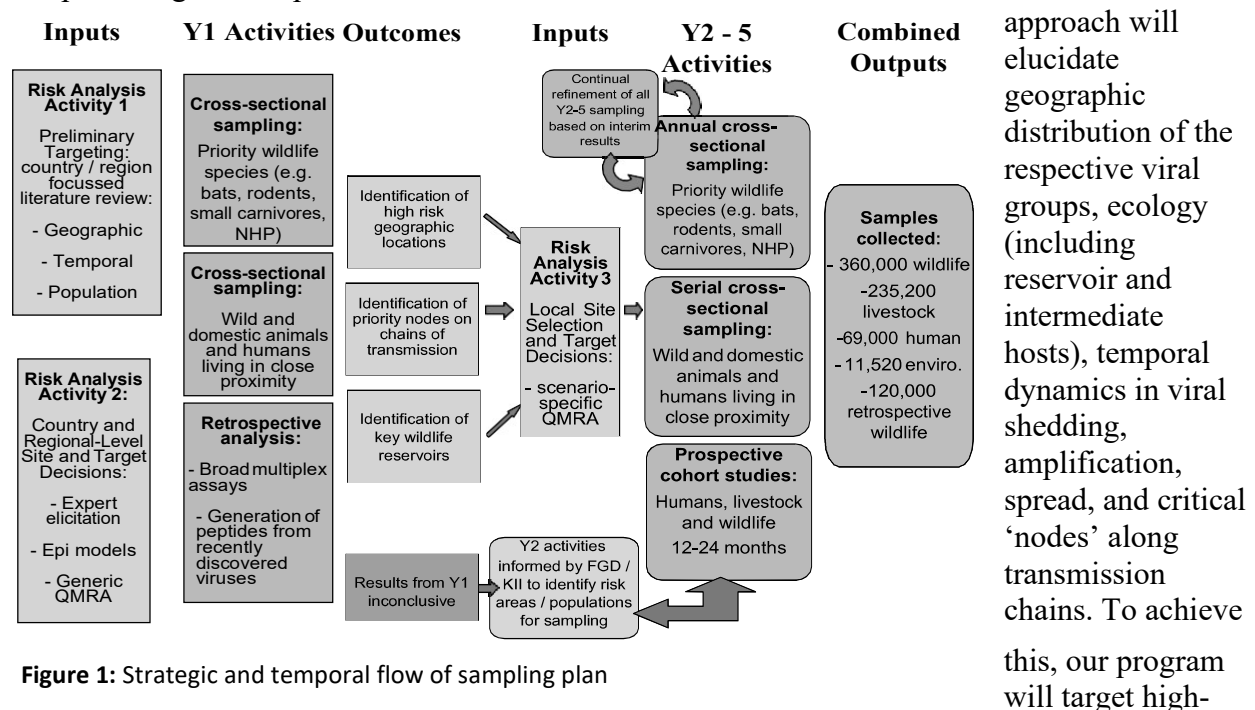


Figure 1: Strategic and temporal flow of sampling plan

risk locations and subpopulations at the human-animal interface, optimizing yield and resources (Fig. 1). This targeting will be adaptive, with locations identified through an iterative process informed by ongoing data collection. We will establish a pipeline of sample collection and transportation, aligned with capacities at existing in-country laboratories (utilizing a hub and spoke approach). Identification of a virus of zoonotic potential will trigger additional sampling focused up- and downstream on the transmission chain. Sampling will be guided by a risk-based analytical approach informed by evidence of a previous spillover event, a high prevalence of zoonotic viruses, or close contact between humans and reservoir hosts. Finally, we will employ a One Health-approach through engagement of human, animal, and environmental health sectors.

1.1 Sample Site and Species Selection

Focus 1: Preliminary Targeting - country/region focused literature review

To inform initial geographic, temporal, and species sampling plans and further risk-based targeting, we will carry out a rapid and comprehensive literature review (including grey literature and proceedings from meetings and One Health platforms) in Y1 to identify where prevalence and diversity of the target viral families are high, where critical nodes on chains of transmission are located, and key wildlife species are abundant (Focus 2 and Fig. 2).

Geographic Selection: We will use literature review, remote-sensed data, and existing risk maps of zoonotic disease emergence risk and its drivers to make a primary selection of geographic

areas of interest. Priority drivers of disease emergence will include human population density, land use change, density and diversity of wildlife species (focusing on mammalian species),

intensive farming of domestic and wild species, and live/wet wildlife markets. We will also leverage maps and data from PREDICT sampling data.

Temporal Selection: Viral (and host) seasonality and multiannual trends impact viral load and thus detection rates and will be critical determinants of sampling timeframes, particularly for wild animal sampling. The literature review will leverage existing knowledge of targeted viral families and host dynamics to inform our risk-based sampling strategies.

Population Selection: Country-specific literature review will identify wildlife and livestock species, human occupational groups, and value chains to consider for sampling.

Focus 2: Country and Regional-Level Site and Target Decisions - risk-based analysis Using a hybrid risk-based approach, we will refine geographic, temporal, and population targets defined by Focus 1 to plan the location and the timing of each sampling activity, with emphasis on identifying populations of wildlife, domestic animals, and humans on transmission chains. This approach will build upon existing knowledge from previous USAID-funded research projects, tailored to country-specific contexts. We will use available data and models and in-country stakeholder engagement, ensuring rapid site selection and start-up of project activities.

Epidemiological Models: In collaboration with key partners, such as the USAID-funded STOP Spillover project, in-country research institutions, and relevant government ministries, the team will review existing epidemiologic models (spatial and mathematical) of spillover risk parameterized to the geographic areas and populations identified in Focus 1. This work will both inform the structure of the epidemiologic models developed in Focus 3 and collate data for these later models. Existing models of viral and host seasonality, host dynamics in targeted wildlife populations, and seasonal trends in wild meat hunting will be used to plan sample timing. **Expert Elicitation:** If the absence of context- and site-specific data or relevant

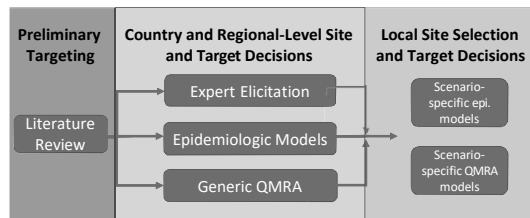


Fig. 2: Risk-based analytical approach to sample site selection

epidemiologic models preclude the use of modeling to refine sampling plans, we will use an expert elicitation-based risk ranking approach to scope initial rounds of sampling.

QMRA: As part of a multimodal strategy, the team will develop prospective probabilistic models utilizing a quantitative microbial risk assessment (QMRA) approach to identify populations and areas of greatest risk and uncertainty. Such approaches have been used to estimate environmental risk of zoonoses transmission and provide a way to include viral load data into our risk prioritization process. As the magnitude of risk will likely be driven by scenario-specific exposures, updated models will be developed at the onset of the project following literature review and subsequently tailored to specific exposure scenarios (Fig. 2).

Focus 3: Local Site Selection and Target Decisions

Based on site- and context-specific information and models generated in Focus 2, detailed exposure modules will be incorporated into location-specific QMRA models, the findings of which will be triangulated with spatial epidemiologic models. These models will be informed by geolocated data indicating prior spillover events, presence of immunocompromised wildlife species, disturbances that increase physiological stress, human activities that facilitate wildlife contact, and high population density. We will develop an initial set of location specific QMRA models based on the sampling sites and data from PREDICT 1 & 2 and evaluate these models to identify sites with the greatest estimated risks and/or uncertainty. In concert with our QMRA models, we will use the computationally efficient stochastic partial differential equations approach to Gaussian process modelling to generate high-resolution maps of spillover risk in the

target geographies identified in Focus 1 - 3. Both models will be continually iterated as new data become available, and sampling sites/targets will be adjusted.

1.2 Sampling Targets

To reduce delay, as soon as each of Focus 1-3 is completed decisions on site identification and timing for initial rounds of sample collection can begin. We will use pre-existing models and computational frameworks to complete these models while sampling approvals are pending. Targeted sampling locations, timelines, and species will be refined through participatory workshops, including representatives from wildlife, human, livestock, and environmental health sectors, and supply chain mapping integrated with network data. Retail outlets for wildlife products will be the terminus of this mapping, with focus on the movement of animals or their products from their points of origin to consumers. Eco-centric network data and value chain data will be collected at each node to identify priority nodes for viral transmission.

Once sampling targets have been identified, we will use sampling methods selected based on population sampled, risk characterization, and country-context, including serial cross-sectional sampling and prospective cohort sampling. Where possible, serial cross-sectional sampling will be repeated in the same population to determine which viruses are adapting to humans (pre-pandemic viruses) and to allow development of interventions to mitigate transmission. In addition, we will use composite sampling to screen samples, with follow-up testing of discrete samples from positive composites to decrease cost and increase throughput. We will also collect socio-anthropological data at these high-risk locations to better understand human-animal-ecosystem interactions relevant to viral transmission. Sampling targets will include:

Wildlife: Focus 1-3 will identify sites for initial sampling and priority mammalian species.

Supplementing risk characterization, trait-based statistical modelling will be used to prioritize bat species for each viral taxon, which will be iteratively improved as more host-virus data become available. Within these sites and species, sampling will focus on populations likely to impact the animal value chain (wildlife or livestock), including free-ranging wild animals living near areas of intensive livestock farming, wild mammals in ecosystems recently fragmented by expanding human communities, farmed wild mammals and wild mammals sold in live/wet markets.

Domestic animals: Sampling will focus primarily on intensively farmed domestic species that are reservoirs or amplifying hosts for the targeted viral families, characterized in Focus 1-3.

Industrialized farms with poor biosecurity or ecosystem encroachment will be prioritized.

Humans: Sampling will focus on country-specific occupational groups (and controls) at highest risk for spillover already geographically and temporally linked to wildlife described above.

1.3 Country-level Strategic Sampling Approach*

**Specific sampling targets will vary by target country based on in-country context*

Task 1.1: Cross-sectional sampling of wild animals (priority species): We will implement cross-sectional sampling of populations of free ranging wild animals likely to host unknown species of known virus families and target physiologically and immunologically stressed populations (migratory populations/ those living in areas of intense land use change). The highest proportion of samples collected will be fecal matter (e.g., under-roost excreta) to optimize efficiency and sensitivity for viral surveillance and discovery, particularly for henipaviruses and coronaviruses. We will also collect and test wildlife meat from markets and traders.

Year 1: Sample teams: 3 per country, sampling for 45 days/year, collecting 40 samples/day;

Aim Per country: 5000 samples; **Target species:** Bats, rodents, small carnivore species, non-human primates (NHP); **Sample type:** Feces, blood, oral/rectal swabs;

Years 2–5: Sample teams: 3 per country, sampling for 21 days / year, collecting 40 samples/day; Prospective sampling informed by Y1 results; **Aim per country:** 2500 total samples/year; **Target species** and **Sample type:** as in Y1

Task 1.2: Cross-sectional sampling of animals and humans living in proximity:

Humans are frequently in contact with large aggregations of wildlife, such as rodents, bats, and small carnivore species. Such synanthropic wildlife species provide opportunities for spillover to amplifying reservoir species that have greater opportunities for pathogen sharing with humans. We will sample wildlife species among or near areas of intensive livestock farming, farmed wild animals, and wild animals sold in live/wet markets. We will also carry out composite sampling of human and livestock species through collection of fecal slurry (livestock) and sewage (human) samples, prioritizing sampling of environments where animals/humans have recently displayed signs of illness and sites characterized by recent disturbances of neighboring ecosystems. We will also sample domestic carnivores (dogs and cats) as these species typically range widely, scavenge, have contact with wildlife, livestock, and humans and are accessible for sampling.

Year 1: Wild animal sample teams: 3 per country, sampling for 45 days/year, collecting 40 samples/day; **Domestic animal sample teams:** 3 per country, sampling for 30 days/year, collecting 40 samples/day; **Human sample teams:** 3 per country, sampling for 45 days/year, collecting 10 samples/day; **Per country aim:** 5000 wildlife, 3600 domestic animal, 1350 human samples; **Target species:** Rodents, bats, domestic and wild carnivore species (e.g. domestic dogs/cats, civet cats), ungulates, poultry, humans; **Sample type:** Wildlife species: feces, blood, oral/rectal swabs; humans, livestock: composite sampling of fecal slurry and sewage

Years 2–5: Prospective sampling informed by Y1 results; **Wild animal sample teams:** 3 per country, sampling for 21 days/year, collecting 40 samples/day; **Domestic animal sample teams:** 3 per country, sampling for 14 days/year, collecting 40 samples/day; **Human sample teams:** 3 per country, sampling for 20 days/year, collecting 10 samples/day; **Per country aim:** 2500 wildlife, 1600 domestic animal, 600 human samples.

Task 1.3: Retrospective analysis of bio-banked samples: We will request access to bio-banked sera collected from wildlife species, including from previous USAID-funded projects such as PREDICT, in areas determined by our risk analysis activities to be hot-spot zones. Broad multiplex assays will allow identification of all ‘known knowns’ and refinement of subsequent sampling strategies (in Y2-5) to increase the probability of detecting ‘known unknown’ viruses. Additionally, novel peptides generated from recently discovered focus family viruses will allow contemporary viruses to be detected.

Year 1: Per country aim: Collection of up to 10,000 wildlife serum samples from in-country biobanks; **Target species:** Bats, rodents, small carnivore species, NHP

Task 1.4: Prospective cohort studies of humans, livestock, and farmed wildlife

Per country aim: i) **animal workers (human):** 200 blood samples twice/year; 200 risk factor questionnaires monthly; 10 semi-structured interviews monthly; 200 nasal wash samples monthly; ii) **controls (human):** 50 blood samples twice/year; 50 questionnaire surveys monthly; 50 nasal wash samples monthly; iii) **farmed animals:** 200 composite samples monthly; iv) **environmental samples:** 20 samples monthly (1 per farm/month), for example, composited waste water sample or barn air; v) **workplace:** 20 (1 per farm/month) x Animal Workplace Enrolment and Animal Workplace Follow-up Questionnaire; **Target species:** Humans, ungulates, poultry, farmed wildlife

Task 1.5: Responsive sampling in the face of an outbreak: In the face of emerging epidemics, opportunities to understand the epidemiology of an outbreak are lost because of delays

mobilizing sample collecting activities. SOPs and sampling teams will be prepared to undertake rapid collection of samples from wildlife and domestic animals in the immediate geographic area around an index case. We will remain in close communication with public and animal health disease reporting agencies so that disease outbreaks can trigger localized investigations.

1.4 Sample Size and Detection of Known Viruses

The more samples collected and tested, the higher the likelihood of detecting a previously unknown member of the target viral families. Collecting 300 samples from a given target species provides a 95% probability of detecting a virus present in at least 1% of individuals; Therefore, a risk-based approach to selecting animal species is critically important to optimize project resources. We will tether our collected data to baseline detection of known viruses in the PREDICT and VIRION databases and a beta-coronavirus specific database (<https://www.viralemergence.org/betacov>). This will allow estimation of expected prevalence and diversity for comparison with observed values for each viral family and host species. Following Y1 collection, detection, and viral characterization activities, we will use cluster detection algorithms to identify hotspots of prevalence or diversity of known viruses, triggering further focused sampling. Detection of known viruses in the three families provides a positive control.

1.5 Contingency Plans

Although the sampling plan is ambitious in scope we are confident that we can collect the numbers of samples listed. Key reasons for this are that we will a) focus sampling efforts on the collection of fecal matter, including composite slurry/sewage samples, which is an excellent sample type for viral discovery and relatively easy to collect; b) exploit sampling synergies within and between sampling targets, for example, sampling of humans, domestic animals, environments, and farmed wildlife will be carried out by single teams that focus on multiple sampling targets. This will make sample collection more efficient; and c) increase the number of sampling teams and / or sampling days if targets are not met. Finally, the plan will allow sampling targets to be exceeded in countries where collection is efficient, which will counterbalance more modest sampling outputs in less productive countries. It is also important to note that, for restrained animals, multiple samples will be collected (fecal, blood, swabs) and as such the estimated total number of samples refers just that and not number of animals sampled.

1.6 Outcomes

The outcomes of Y1 will be used to inform the strategic planning of the sampling activities in Y2 – 5. This site selection review will be an iterative process to determine whether to add new sampling sites. If outcomes from Y1 activities are inconclusive, sampling activities in Y2 – 5 will be informed through iterative refinement of the epidemiological and QMRA models and detailed, in-country participatory workshops and interviews targeting workers in the human, animal and environmental health sectors. Samples collected will be studied with an array of molecular assays for previously identified as well as novel corona-, filo-, and paramyxoviruses. Where data show a prevalent emergent animal virus, we will identify the location and specific animal hosts of origin and collect data on supply chains and contact networks to target additional specimen collections and molecular studies along the chain of transmission.

1.7 Capacity Building and Sustainability

To facilitate sustainability, we will promote in-country stewardship of all Objective 1 activities, including risk-based analytical approaches, design of sampling strategies and collection of samples. Rapid assessment of in-country capabilities will be conducted to identify gaps in personnel, training and equipment. Training will be provided for each activity (utilizing virtual

methods and translation to local language), and location-appropriate equipment provided in order to allow activities to be performed within, and beyond, the lifetime of the program.

OBJECTIVE 2: Strengthen Detection for Novel Viruses from Priority Viral Families

Our sampling strategy is designed to collect as many specimens as possible. Using a strategically designed, risk-based approach to sampling, we will roll out serial cross-sectional and prospective cohort studies at nodes of potential transmission of novel viruses to collect and screen **~800,000 specimens, with >60% from wildlife**. We will build a detection and characterization program utilizing in-country labs to provide near-real time screening and genome sequencing and finishing. Assuming 1-1.5% yield, based on the yield in the PREDICT program in the 3 viral families targeted for DEEP VZN (DV), this approach is likely to **detect and characterize 8000 – 12,000 novel virus genomes** over the DV program. We estimate these genomes to comprise a total of 1,000 novel viral species, based on the number of novel sequence submissions from the PREDICT project (~2100 novel sequences from 3 highlighted viral families for DV, constituting ~250 novel viral species, or ~8 specimens/sequences per novel virus species).

2.1 Capacity Building and Sustainability

Our capacity building approach for in-country laboratories is summarized in **Fig 3**. *The goal is to ensure that each country independently conducts full virus screening (basic detection to whole-genome sequencing) and basic characterization that includes evaluation of spillover (serology) and later glycoprotein and receptor-binding assays.* We will ensure sustainable, in-country capacity to safely detect and characterize unknown novel viruses by providing high-throughput automated nucleic extraction, multiplex qRT-PCR screening instruments, and *NextSeq* Illumina next-generation sequencing (NGS) platform in each country. All 18 partner institutions we have identified in the 12 target countries have existing serology capacity, while 60% and 25% have qRT-PCR, and NGS capacities, respectively. Building on our consortium's >25 years of experience working in sub-Saharan Africa, Asia, and Latin America, including during the COVID-19 pandemic, we will address the recurrent problem of high cost and delayed delivery by establishing direct-buy credit accounts and service contracts with the manufacturers of equipment involved in the DV program. As illustrated in **Fig 3**, in Year 1 we will conduct rapid assessment of in-country labs to determine needs, followed by provision and installation of equipment to ensure they can conduct qRT-PCR, serology (ELISA and pseudotype viral neutralization test (pVNT)), and viral WGS.

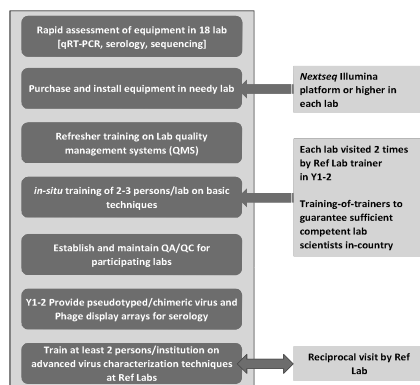


Fig 3. Flow chart of stepwise capacity-building for in-country labs

Reference Labs: We will establish and fund two Reference Labs in the US, tasked with building in-country lab capacity, and validate advanced virus characterization (*in-silico* glycoprotein and receptor, *in vitro* and *ex vivo* virus-cell studies). The D. Wang (WUSTL) and A. Greninger (UW) labs, supported by other virology, immunology, and protein chemistry labs at these institutions, will in the early phase of the program (Years 1-2) (i) Develop and supply novel virus detection and

characterization standard operating procedures (SOPs), (ii) Conduct *in situ* training to in-country labs on qRT-PCR, whole-genome sequencing (WGS), and serology technologies, including annual refresher trainings, (iii) Develop and supply qRT-PCR controls and standards, (iv) Develop and supply serology screening kits (phage display peptide libraries, pseudotyped and/or chimeric viruses, monoclonal antibodies), (v) Roll out and manage a QA/QC system to ensure

reproducible and comparable data (including proficiency panels and re-testing 10% of positive specimens from each country), (vi) Conduct advanced characterization (*in-silico* glycoprotein and receptor, *in vivo* and *ex vivo* studies with live virus), and (vii) travel and train at least two persons from each participating institution in their US reference labs on development of pseudotyped/chimeric virus and antibodies for serology, and advanced virus characterization. Based on our successful experience with lab capacity strengthening, it is essential that this will be accompanied by reciprocal training visits by reference laboratory trainers to in-country labs, with the goal of ensuring that in-country labs can independently conduct detection and significant advanced virus characterization (except virus culture, or *in vitro* and *ex vivo* studies with live virus that may require high biosecurity laboratories). We recognize that in-country laboratories will not acquire competency at the same rate because of factors such as additional needs to improve infrastructure, biosafety and biosecurity capacity, sub-contracting and procurement challenges, and staff turnover. We also anticipate that early in the DV program in-country labs will identify suspected novel virus samples that require urgent characterization methodologies not yet fully established and transitioned to the country. To address this, the project will expand U.S. based reference lab personnel who will be dedicated to implementing all aspects of in-country virus detection and characterization (as described). These personnel will transition for several month-long periods each year through the in-country laboratories to provide both structured and ad hoc in-country analysis support, including complete bioinformatic analysis of NGS data to identify novel viruses, basic *in-silico* viral glycoprotein and receptor-binding analyses, and serological analysis to determine novel virus spillover. Additionally, this response team may be deployed to work alongside in-country scientists in a country with suspected novel viruses until characterization is completed to the satisfaction of the consortium executive council and USAID. The Reference Laboratories will also validate in-country results by repeating a limited number of the characterization tests conducted on novel viruses. This validation will be achieved by shipping aliquots of not more than ~0.1% of collected samples (negative and positive) as shown in the textbox below.

ESTIMATED NUMBER OF SAMPLES SHIPPED TO REFERENCES LABS IN UNITED STATES

From ~800,000 specimens collected; we estimate at least 8,000 (1,600/year) will have suspected novel viruses. Of these, we expect to ship no more than 10 qRT-PCR positive and 10 negative specimens from each country in Years 1-2 (480 specimens) for validation, and 5 qRT-PCR positive and 5 negative specimens In Years 3-5 (360 specimens), bringing the total specimens shipped to 840 (0.1% of collected specimens) over the 5 years for the DEEP VZN program.

For purposes of virus culture, virus isolation, *in-vitro* and *ex-vivo* studies, we have established access to the Rocky Mountain BSL-4 laboratory (letter of commitment available).

2.2 Overall Detection Strategy

We will use both molecular and serological approaches to detect novel viruses. For maximum sensitivity and efficiency, our primary virus detection strategy will use broad-range qRT-PCR assays that specifically target the 3 virus families for initial screening of specimens. We will utilize consensus RT-PCR followed by sequencing of amplicons and interrogate positive specimens further to obtain complete genomes. Broad serology will be used to adjust the sampling strategy (Objective 1), and also to investigate spillover of novel viruses across the wildlife-livestock-human spectrum (Objective 3). Focusing primarily on sera collected from bats, rodents, NHP, and humans, we will screen for known and newly detected coronaviruses, paramyxoviruses and filoviruses using phage display serology. Evidence of high prevalence of diverse species of target virus families will indicate an ecosystem favourable to maintenance and

transmission of these viruses. *Serologic detection* of antibodies to a novel virus may also provide information on duration of exposure and affected animal species, with high seroprevalence in humans pointing to higher frequency of spillover events.

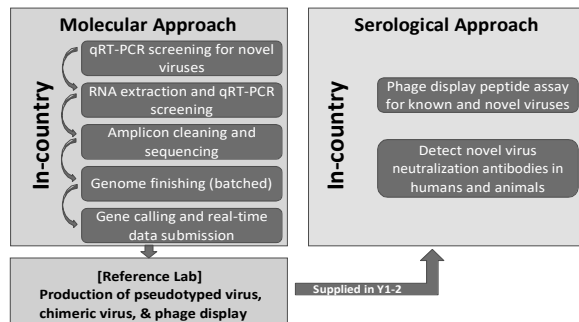


Fig 4. Virus detection flow chart

How our approach enhances efficiency to detect novel viruses: Our molecular screening strategy (Fig. 4) optimizes sensitivity, keeping the most expensive aspects (deep meta-genomic sequencing) to a minimum. All 3 viral families targeted for detection in the DV program are shed and detectable in stool reducing the need for animal trapping and handling. We have also integrated viral load measurement to our screening to improve chances of genome

finishing. During genome recovery from positive specimens, we will be able to infer hosts from environmental metadata and non-viral metagenomic sequencing data, which will be fed back to sampling teams to focus on particular animal species and areas where positives have been detected. The phage display approach is more cost-effective and efficient to serologically screen for known and novel viruses from target families than alternative multiplex serology approaches, such as peptide microarrays. Primarily because the phages self-replicate and thus are a renewable resource. Broad serology is costlier than qRT-PCR and this will limit its use.

2.3 Molecular Screening

Task 2.1: RNA extraction and broad-range qRT-PCR: RNA extraction methods will be standardized across all sites. Ideally, automated extraction instrumentation will be installed at each site. In addition, an alternative manual extraction method will be established as back-up. Our team has validated a family-specific, broad-range, single-well RT-PCR assay for *Orthocoronavirinae*, which enabled discovery of a novel coronavirus from a hospitalized patient in Malaysia. We will also make use of a published two-well pan-paramyxovirus and a one-well pan-filovirus qRT-PCRs to screen specimens. These family-specific primers amplify conserved portions of the RNA-dependent RNA-polymerase and allow for species determination after amplicon sequencing. We will integrate SYBR-Green into family-based RT-PCRs to allow for viral load quantitation at the same time we are detecting novel viruses along with melting curves to ensure appropriate-sized amplicons are generated without gel electrophoresis. As a backup strategy to the quantitative readout, a standard operating protocol for gel electrophoresis-based readout will be established. We will ensure in-country labs have instruments that can perform these assays with a throughput of 20-22 specimens per 96-well plate or 80-84 specimens per 384-well plate. We anticipate a throughput of at least 80 specimens per day per laboratory. Amplicons from qRT-PCR will be cleaned of PCR primers and sequenced on *Nextseq* biweekly, with up to 96 amplicons multiplexed. For further cost efficiency, we will explore the feasibility of multiplexing up to 384 amplicons. To identify novel viruses from the amplicons, all sequences will be aligned to a reference database composed of all target viruses from GenBank. Amplicon sequences that diverge significantly from all known viruses will be prioritized for whole genome sequencing. To standardize assays, the Reference Labs will provide positive and negative control standards for RT-PCR. Qualitative controls will be run through extraction and qRT-PCR on every plate, while quantitative controls will be run monthly. Quantitative controls will consist of a set of serial dilutions (10^7 - 10^0 copies/ul) of *in-vitro* transcribed RNA targets (2 different viruses in the family).

Task 2.2: Genome recovery and finishing: For maximal cost efficiency and timeliness, genome finishing will be performed in batches using *NextSeq* or *NovaSeq* equipment in each country. After identification of amplicons derived from novel viruses, we will ensure that complete genomes are recovered and finished to enable further screening and characterization. Complete genomes are also necessary for development of diagnostics, molecular epidemiology, vaccinology, and therapeutic development. Specimens will be prioritized for whole genome sequencing based on sequence divergence from known viruses and viral load estimates. We will use a variety of NGS methods as needed, including metatranscriptomics with rRNA depletion and/or poly-A enrichment approaches. Based on the identity of the virus, we can also use spike primers that bind the sequences recovered in the family-specific qRT-PCR or other highly conserved regions in that viral family into the cDNA synthesis prior to sequencing to increase coverage of viruses. New rRNA depletion reagents that cross-hybridize across metazoans will ensure fewer reads are spent on rRNA in rodents, bats, NHP, and humans, allowing for 8-150-fold enrichment of on-target reads. All targeted viral families poly-adenylate their transcripts, allowing classical RNA-Seq approaches to help in viral genome recovery. As a default, specimens will be targeted for 25 million reads to ensure genome recovery using high-throughput Illumina sequencers, which can allow recovery of near-complete genomes from specimens with Ct < 27. If needed, we will perform additional deeper sequencing, manually design PCR primers to close gaps, and perform 5' and 3' RACE to recover the viral genome termini. Our team has expertise sequencing whole genomes of novel RNA viruses. In Year 1, we endeavour to obtain and sequence specimens that have novel target virus from prior PREDICT projects. Small 400-500bp fragments of >150 novel paramyxoviruses and more than 60 novel coronaviruses were detected in PREDICT projects, but full genome sequences are not available. **Task 2.3: Genome calling and real-time data deposition:** Genome calling will be performed using a variety of automated and bespoke pipelines, including cloud based IDSeq for comprehensive assessment of viruses present in a specimen. As a complementary approach, we will also use well-described locally installed bioinformatic approaches, such as IRMA (an assembler specifically optimized for RNA virus genomes) and SURPI (pipeline optimized for unbiased metagenomic detection of all pathogens). Reads will be remapped to all draft genomes to ensure accuracy and manually reviewed in Geneious, especially if manual gap filling or 5' and 3' RACE is required. Importantly, our bioinformatics strategy also takes advantage of the global bioinformatics community and the wisdom of crowds by including real-time FASTQ and FASTA sequencing data deposition into NCBI Sequence Read Archive (SRA) and GenBank with **zero embargo time**. Our team has previously published software to facilitate rapid deposition of viral genomes into GenBank. SRA and GenBank accessions and brief initial analyses of sequencing data will be automatically communicated in real-time via our project-specific Twitter, so they are accessible to the global scientific community.

2.4. Broad Serology Screening

Zoonotic spillover is not considered a one-off event, and multiple small spillover events can potentially be detected by serological studies. For SARS-CoV, human serosurveys in south-eastern China found evidence of repeated spillover, with antibodies shown to persist for at least 2 years. To identify the animals or humans that had prior exposure to target viruses, our Reference Labs will generate phage display libraries covering 100,000 of the most conserved 60-mer peptides across all known filovirus, paramyxovirus, and coronavirus genomes following the VirScan protocol. The phage library will be amplified and validated using well-characterized positive control sera obtained from PREDICT labs, NIH-CREID network, in-country and CDC,

and Institute Pasteur labs. Reference Labs will develop kits consisting of phages that can be incubated with sera and protein A/G beads in in-country labs, with library preparation. Following incubation, the beads can be washed and library generation performed. The resultant DNA library is stable and can be sequenced at in-country laboratories. The phage library will be updated with novel viruses detected globally. The library will be used to screen high priority sera collected from bats, rodents, NHP, and humans sampled from nodes of potential transmission, serial cross-sectional samplings, and possibly archived sera. *Broad serology testing will be applied selectively and as a secondary approach, in part because of cost and the broader utility of genome recovery to enable further viral characterization work.* However, we envision that:

- (i) evidence of infection by novel viruses can be obtained from the serological profiles;
- (ii) unique signatures of epitopes distinct from those derived from known infections may suggest prior infection with a novel virus;
- (iii) high prevalence of diverse species of the target virus families may indicate an ecosystem favourable to maintenance and transmission of novel viruses of interest, and therefore point to a preferred sampling location;
- (iv) serologic detection of antibodies to a novel virus could inform the duration of exposure and affected animal species, with high prevalence in humans pointing to increased risk of spillover to humans.

We should point out that low or undetectable antibodies in humans may not indicate that a novel virus poses low risk to humans because other factors such as its recent introduction or potential for acquiring transmissibility to humans through minor mutations still exists.

As an orthogonal method to the broad serological screening, we will also perform binding ELISA serological assays against novel virus glycoproteins. Upon sequencing of a new virus, we will undertake codon-optimized gene synthesis to generate constructs for recombinant protein expression and pseudovirus generation. We expect to purify recombinant spike ectodomain trimers and/or receptor binding domain proteins for coronaviruses, GP trimers for filoviruses, and both fusion (F) trimers and G/H/HN tetramers for novel paramyxoviruses. We will use an antigen prediction pipeline to predict sensitive and specific viral protein antigens. Viral proteins and fragments predicted by this algorithm will be expressed for ELISA serodiagnosis. Negative-stain electron microscopy will be used to ensure the viral proteins are folded correctly after purification. Once viral protein antigens are purified, we will contract with GenScript for rapid generation of custom monoclonal antibody controls. We will then determine the specificity of the ELISA binding assay against a bank of >2,000 historical human serum specimens from UW Virology, including testing for cross-reactivity specifically against sera positive for IgGs to measles/mumps virus for paramyxoviruses, SARS-CoV-2 and all four endemic coronaviruses, and Ebola/Marburg viruses for filoviruses. Pending results from those specificity tests, we can iterate design of antigens for specific serological testing, including use of specific viral peptides, as required. Sensitivity will be tested against convalescent host animal sera as well as any human sera available from individuals known to be infected. This ELISA kit will then be provided to in-country labs with positive and negative controls, as well as host control proteins for testing for vaccine preventable illnesses (SARS-CoV-2 spike protein for coronaviruses; measles H for paramyxoviruses) and will be compatible with commonly available plate readers. Early in the COVID-19 pandemic, our UW Reference Lab provided recombinant SARS-CoV-2 nucleocapsid along with controls for binding ELISAs to laboratory partners in Senegal, Pakistan, Brazil, South Africa, Nigeria, Kenya, and other countries as part of the NIH CREID consortium. In addition to the binding assays described above, we will use pseudotyped lentivirus and chimeric vesicular

stomatitis virus (VSV) neutralization assays with the novel virus glycoproteins to functionally profile sera for neutralizing antibodies. These assays will benefit from the expertise of Dr. Whelan (WUSTL) and Dr. Veessler (UW) and allow for greater rigor and reproducibility of seropositivity identified by binding ELISA by providing an orthogonal and functional readout. Our primary approach will involve generating chimeric VSV reporter viruses (below). As these assays require cell lines permissive for viral entry, these efforts will create synergy between virus detection (Section 2.2) and characterization (Section 3.3) components.

Task 2.4: Generation of chimeric reporter viruses: We have extensive experience generating chimeric VSV reporter viruses where native viral glycoprotein (spike S, attachment glycoprotein G, fusion F, and hemagglutinin H) is replaced by those of heterologous viruses. Our experience with the coronaviruses indicates that either mutation of the endoplasmic reticulum retention sequence in the cytoplasmic tail of the spike, or truncation of the tail by approximately 20 residues can allow effective integration of the respective Spike gene into VSV, yielding viruses

that grow to titers of 10^8 pfu/ml. For filoviruses, we have not found it necessary to manipulate the cytoplasmic tail of the glycoprotein, although we have mutated the transcriptional editing sequence that is used for synthesis of soluble glycoproteins. Once an infectious clone of VSV-chimeras is assembled, we confirm sequences of the recovered virus, and characterize the growth of the respective viruses to establish the optimal conditions for the generation of seed stocks.

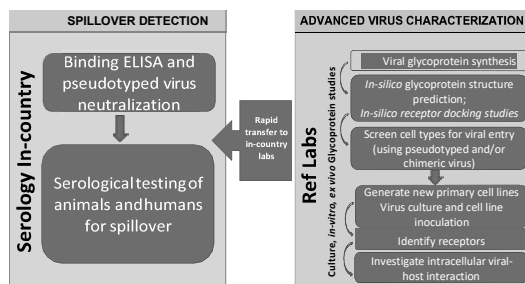


Fig 5. Flow chart for novel virus characterization

Task 2.5: Detection of neutralizing antibodies: We will use VSV-chimeric viruses to monitor levels of neutralizing antibodies in humans and sometimes animals. We are mindful of reports that bats inoculated with some filoviruses do not generate neutralizing antibodies that are detectable in neutralization assays. Accordingly, we will also use the VSV-chimeras to detect antibodies that recognize the respective envelope proteins displayed on the surface of virions. To do this, we will use purified virions that contain the respective envelope proteins on their surface and sera containing antibodies that bind to the virion identified by isolating the bound complexes. As an alternative approach to VSV chimeric viruses, we will use lentivirus-based pseudotyped neutralization assays. Pseudovirus neutralization assays against novel viruses will be optimized for expression and intracellular termini truncations as well as with monoclonal controls. The constructs, controls, and pseudotyped viruses will be made available to in-country partners once the assay is validated by Reference Labs. *These approaches will permit us to determine whether a given animal species has mounted an immune response to the envelope proteins of any novel virus and whether such immune responses include neutralizing antibodies.* The prevalence of such antibody responses may indicate potential risk for spillover into humans, even though low or undetectable antibodies may not mean that a virus is at low risk for human infection. These assays are compatible with BSL-2 settings widely available in in-country labs.

OBJECTIVE 3: Strengthen Characterization of Novel Viruses from Priority Viral Families

3.1. Overall Characterization Strategy

Guided by the understanding that, with timely and complete genome sequencing in Objective 2, >80% of novel virus characterization can be performed in the absence of virus isolation. We will start by characterizing selected novel viruses detected under the PREDICT program and identified as potentially important. Subsequently, we will use sequence data from novel viruses

we detected (Objective 2) to construct qRT-PCR screening kits and recombinantly express and purify viral proteins for reagents development (e.g., monoclonal antibodies) for serological assays and structural studies. We will use these sequences to create pseudotyped and chimeric viruses for serological assays and profiling viral entry. Pseudotyped and chimeric viruses can also be used to identify and screen for receptor usage and identify cell lines that support viral entry. These cell lines can be used to identify other determinants of tropism and to characterize viral entry mechanisms. We will attempt to isolate novel viruses and identify known or novel host genes that enable viral entry. Finally, we will determine the affinity of novel viral glycoproteins for human receptors and mechanisms of innate immunity antagonization to determine zoonotic/ pandemic potential (Fig. 5).

3.2 Profiling Viral Glycoproteins/Receptors to Assess Pandemic Risk of Novel Viruses

Task 3. 1: *In-silico* characterization of novel viruses. Our *in-silico* approach for profiling human transmission risk follows directly from the hypothesis that *affinity for human receptors of a novel viral glycoprotein indicates pandemic potential*. As soon as a novel virus genome is recovered, our UW Reference Lab will perform *in-silico structure prediction* of viral glycoproteins with Rosetta and trRosetta, as well as docking with known receptors for a given viral family to approximate affinity for human receptors. To support this effort, we will model the structures of the extracellular domains of all human proteins and compare these to structures of known host cell viral receptors to determine how closely they match as a way of generating hypotheses **for candidate** human host cell viral entry points. We will interrogate these predicted structures for specific changes in protease site activation. Our ability to determine high- resolution structures of viral glycoprotein-receptor complexes using world-class cryo-EM will be fed back to *in-silico* models to enhance protein structure prediction and viral-host protein-protein interactions. It is worth noting that to-date, no model has successfully predicted viral zoonoses and spread in humans. Therefore, our bias will be to perform as much wet laboratory characterization of novel virus glycoproteins. We will synthesize all viral glycoproteins recovered from novel viral genomes and screen in viral entry, biochemical, and biophysical assays because *in-silico* modelling is insufficient to capture risk.

Task 3.2: Biophysics and structures of viral glycoproteins. Divergent paramyxovirus, filovirus, and coronavirus genomes will be used to carry out structural studies of the corresponding glycoproteins in isolation and bound to target receptors to understand the mechanisms of viral entry into host cells. Our UW Reference Lab is world-renowned for expertise in viral glycoproteins and has developed a streamlined, high-resolution cryo-EM pipeline enabling high-throughput structural studies of viral glycoproteins bound to host receptors and neutralizing antibodies. It will be leveraged to provide atomic-level information of the infection machinery of discovered viral pathogens before they emerge. Novel viral glycoproteins and animal and human receptors will also be expressed and tested directly for binding kinetics and affinity using biolayer interferometry. These affinity measurements will provide biophysical confirmation of receptor interactions and direct biochemical evidence of the degree of pandemic risk of a novel virus. We will correlate binding affinity measurements and functional biochemical measurements of fusogenicity using cell-cell fusion assays.

Task 3.3: Viral isolation-independent viral entry characterization and receptor discovery. The VSV chimeras and pseudoviruses generated above will also be used to perform viral receptor discovery at a BSL-2 level. Previously, our WUSTL Reference Lab has used both VSV

SECURING MTAs FOR SHIPPING SPECIMENS: Our approach is to reduce the number and scope of MTAs. Each in-country lab will only sign one MTA with either UW or WUSTL reference laboratory

and pseudoviruses and a series of cell lines expressing canonical coronavirus receptors to rapidly screen for coronavirus receptor usage and to discover the human receptor of SARS-CoV-2. To establish neutralization assays, VSV chimeras and pseudoviruses will already be tested against a broad array of human, non-human primate, bat, and rodent cell lines that support paramyxovirus, filovirus, and coronavirus growth, including an initial screen of VeroE6, RHMK, CV-1, HAE, HuH-7.5, HEK293, HepG2, CaCo2, BHK (hamster), MEF (mouse), Aji (bat), RhiNi (bat) cell lines. This screen will be performed in the presence and absence of trypsin to determine if host restriction for viral entry exists at the level of proteolytic activation, as previously described for several bat coronaviruses. Canonical receptor usage (e.g., ACE2/DPP4/APN for coronaviruses, NPC1 for filoviruses, or SLAM/EphrinB2/3 for paramyxoviruses) will be confirmed at the protein-level using soluble receptor blocking and/or blocking monoclonal antibodies.

If viral entry into one of the above cell lines is not found to be caused by a known or canonical receptor, we will perform genome-wide CRISPRko screens to discover viral receptors. Using this and related genome-wide approaches, we have identified the receptors for multiple coronaviruses, paramyxoviruses and filoviruses validating this approach. We will carry out such screens to identify host genes that are potential determinants of infection and, armed with that information, we can determine the step of viral infection at which any given host gene functions as described in the rest of the proposal. This will allow us to compare the genomic sequence of entry factors between susceptible and non-susceptible host cells.

3.3 Viral Inhibition of Innate Immunity

Viral antagonization of innate immunity is an important component of viral pathogenesis in humans. Like glycoproteins, viral immuno-evasion proteins are often tailored specifically to the host they infect, and thus the zoonotic and pandemic potential of a new virus will be determined in part by how these genes affect human innate immunity pathways. West Nile and Zika virus spread in humans is in part determined by the degree of inhibition of the JAK/STAT pathway.

Infection in animal host species reservoirs can contribute to viral evolution strategies that facilitate evasion of host innate immunity. Bats have specifically downregulated inflammatory pathways while maintaining type I interferon pathways, leading to a unique evolutionary selection for viral antagonization of type I interferons.

Task 3.4: Testing for the degree of innate immune inhibition: The UW Lab will perform tests by all open reading frames from a novel virus in a host innate immune evasion screening platform. If throughput is limited, at a minimum we will characterize the major immuno-evasion genes from the different viral families. Here, the specific viral protein open reading frame is cloned and expressed ectopically in relevant host cell lines, 24 hours later cells are treated with exogenous interferon (IFN) and harvested over a time course to evaluate for possible reduction in innate immune signalling pathway activation compared to control cells treated with IFN but without ectopic expression of viral genes. Loss of innate immune activation will be evaluated by reduced IFIT1 and IFITM1 gene expression measured by RT-qPCR. We recognize that these approaches are limited to evaluating viral evasion from IFN responses and do not evaluate innate immune signalling components that occur prior to (upstream of) IFN induction. To address this, we will assess the ability of viral protein expression constructs to suppress the activation of interferon regulatory factor (IRF)3 activation induced by Sendai virus infection, a control virus that potently induces innate immune activation in infected cells. We will transfect cells with each viral protein expression construct, followed by infection with Sendai virus, and assess total and phospho/active IRF3 abundance. For a broader analysis of innate immune pathway regulation, we will infect relevant host cell lines with the virus panel of interest and evaluate innate immune

response pathways activated by each specific virus using assays (immunoblot and mRNA analyses) to measure the activation state of specific innate immune pathway markers as well as expression of downstream genes linked to each pathway.

3.4 Virus Isolation for Receptor and Intracellular Viral-Host Interaction Studies

Task 3.5: Viral isolation and receptor identification. As illustrated in Fig. 5, we may require virus isolation to conduct *in vitro* and *ex vivo* studies. Such studies will be conducted in BSL-3 and BSL-4 labs under proper biosafety protocols. Isolation of novel coronaviruses or paramyxoviruses (determined using sequencing data) when there is no concern of severe human disease can be attempted in certified BSL-3 labs located in-country, regionally, or at Reference Labs. Isolation of viruses of great concern of severe disease, such as filoviruses, will only be attempted in Rocky Mountain Laboratories BSL-4 lab (letter of commitment available on request). Positive specimens will be prioritized based on viral load, with a focus on specimens with >1 million copies per mL or gram. We will inoculate virus onto cells shown to be permissive to pseudovirus entry from above. Viral isolates will be expanded and deposited into central repositories with CDC, BEI, and/or WRCEVA, according to the appropriate biosecurity and national data sharing guidelines. Receptor usage determined in the pseudovirus screen will be confirmed using the viral isolate. For isolated novel viruses that do not show canonical receptor usage but cytopathic effect, we will screen for novel human receptors using genome wide CRISPRko libraries in cell lines that support viral growth as described above. Where possible, we will prefer viral isolate CRISPRko screens over pseudotype screens to identify potential intracellular viral-host interactions at the same time as identifying potential receptors.

Task 3.6: Host cell characterization and cell line generation for viral characterization.

Inoculating existing cell lines and primary cells with virus-positive specimens may not result in viral growth. The cell lines chosen may not contain the correct receptors, proteases, or other intracellular factors to support viral entry and/or growth. To support viral isolation and characterization for such viruses, we will generate primary cells from bat, rodent, and NHP tissues that are specifically sampled in DV and identified by host deep sequencing reads in Objective 2. Over the past decade, several new primary bat cell lines have been established that support growth of many viruses of high zoonotic potential *in vitro*, and yet bat species are so diverse that it is likely that no specific cell lines might be available for the bats sampled here. Should the approaches outlined above fail to support viral isolation, we will use scRNA-Seq sequencing of virus-positive primary specimens to help identify candidate host cells and host receptors to be targeted for cell line generation. scRNA-Seq is a powerful approach to link virus transcription and replication on a single cell level with candidate host cells and receptors should existing cell lines prove insufficient. If we are unable to specifically isolate the relevant host cell lines based on scRNA-Seq data, we will ectopically express candidate viral receptors identified by scRNA-Seq data into candidate host cell lines to determine viral receptor usage.

3.5 Algorithm for Ranking Viruses with Pandemic Potential

A proposed algorithm for ranking emerging viruses for potential spillover to humans was recently published by the PREDICT team (<https://spillover.global/ranking-comparison/>;doi.org/10.1073/pnas.2002324118). We will improve on this by applying the findings of our innovative and thorough stepwise virus characterization methodologies described in Section 3, and by rating each novel virus based on the following three questions:

- (i) Does the virus have potential for human transmission? This will be investigated using the glycoprotein modeling and functional viral entry studies described above.

- (ii) Is there evidence of its spillover to humans or a broad range of potential animal reservoirs? This will be addressed through serologic testing.
- (iii) Does the virus have capacity to inhibit host innate immunity? Evidence of immunoevasion is consistent with the potential for significant morbidity and/or mortality in humans and should trigger a higher level of public health concern, particularly if the virus rates high on criteria i & ii above.

We will summarize the results in prioritized lists that will be publicly accessible to both in-country partners and international stakeholders. Importantly, our findings, which will be disseminated in scientific publications, presentations, communication with USAID and other stakeholders, will add key metrics to evaluate the zoonotic and pandemic potential of novel viruses.

OBJECTIVE 4: Strengthen Focus Country Capacities for Data Management and the Viral Characterization Process

The proposed project will develop and implement improved data systems at the country and international level, building on learnings from the EIDITH system developed for PREDICT 2, and increasing interoperability and access for partners and stakeholders alike. We will also aim to enhance in-country data collection and use to accelerate detection and response to future public health threats. This will begin with an assessment of the data structure of the EIDITH system, defining a core set of standard variables to be collected across sampling locations for use in describing the distribution of pathogens/exposures. The importance of national-level data autonomy must be balanced with the need for widespread dissemination of data to aid in the prediction and prevention of emerging epidemics. We will work with countries to build on existing systems using an “Adopt-Adapt-Develop” approach while defining protocols for data sharing between the DV and local systems so that project data enhances existing systems while observing local policies and SOPs. The consortium will also draw on previous experience with local and global datasets to advance global surveillance of zoonotic threats. To allow rapid sharing of data across the consortium and with international databases such as NCBI, we will put in place MOUs and data use agreements using a “staged ring” approach, wherein data access can be conceptualized as a series of interlocking rings within which data ownership is retained by in-country stakeholders whilst standardized review, approval, and validation processes allow data to be rapidly shared to key stakeholders at national and international levels. This will ensure that, rather than creating parallel systems, the project builds upon (and integrates into) existing structures and data systems, while ensuring rapid release of validated data to project team, national, and international partners. Pending national approvals, aligned to standardized data sharing agreements supported by DV, and the removal of any sensitive information, data will matriculate across the data management structure, representing gradually more release of data (e.g., USAID staff, external partners, cross-border sharing and full public accessibility). This progression will represent not only increased access but also improved data quality: data sets made available to the public would represent those with well-documented dictionaries and curated metadata, while more incomplete data would remain with project and national stakeholders. In these endeavors, we will build on PREDICT, which has uploaded hundreds of sequences from newly discovered animal pathogens to the NCBI’s Short Read Archive (SRA) and GenBank. With USAID and local stakeholders, we will review and update the data use agreements where PREDICT has been active and use them as models.

4.1 Project Data Collection and Management

Task 4.1: Develop a project-wide data management plan. The consortium will use a data system based on principles of the EIDITH system to collect and manage data among the partners while respecting the need for data safety and ensuring in-country data ownership. This management system has the capability to import data for linkage with surveillance data systems in the host countries, USAID, and global systems such as healthmap, ProMED, NCBI.

Task 4.2 Monitor project implementation. PATH, leading Objective 4 and as a global leader in project monitoring and evaluation, will develop indicators and track project progress via systematic data analysis and review meetings, data quality assessments, technical working groups, and training of data managers at the facility, subnational, and national level.

Task 4.3 Data storage. Following national approvals described in section 4.2, data will be stored within the DV database with data security and access conforming to the FAIR Principles, as well as the Nagoya protocol for genomic data sharing.

4.2 Country Data Management

Task 4.4: Map the data management and policy landscape of each country. In Year 1 an early assessment of existing systems in use at the country and regional levels will be conducted in order to help support and define the architecture, connectivity, flow and human resource capacity to achieve rapid access to quality data at the country level. This assessment will identify gaps and areas that must be strengthened across the continuum from data collection, cleaning, and storage to analysis and presentation to key stakeholders and users and across relevant data sources including laboratory, human and animal clinical, and environmental data sets. This will also entail an extensive evaluation of the enabling environment, including existing health data privacy policies, data use regulations, digital workforce capacity, and information technology infrastructure. The goal is to develop a baseline for each country in terms of existing data agreements, identify adaptations that would enhance data sharing, and understand the policy environment for data sharing and use. Using these assessments, we will develop a roadmap for developing an integrated country-level data architecture with our country partners, including reporting from our DV data system and site- and laboratory-level data collection, as well as ensuring local data sharing through secure, interoperable data exchange.

Task 4.5: Evaluate lab information systems of DV lab and field data collection teams in focus countries. Our consortium will identify the capacity of partner labs in focus countries to support data capture for the project. Similarly, we will ensure that the field data collection teams are trained in data collection according to the data standards that we will extend based on EIDITH/PREDICT. We will build on the existing data structure from in-country data management systems and PREDICT/EIDITH, including sample tagging protocols, geolocation, and survey-based questionnaires.

Task 4.6: Incorporate knowledge and learnings from previous projects. We will use publicly available data, such as PREDICT data available through <https://data.usaid.gov> including readily available country-specific data sets from EIDITH (event animal production, event crop production, animals sampled, event dwellings, event value chain, PCR tests, and site/event characterization) and genomic information available through GenBank in national-level data use and analysis. This will ensure that our project database builds on successes and lessons learned from the EPT project to date. Our data management plan will be able to rapidly incorporate the metadata and genomic data of these samples when they become available.

Task 4.7: Establish data standards and governance. With our in-country partners, we will establish global data standards and assist with establishment of a data warehouse that includes

different collection and management aspects for analyzing, sharing, and storing data. The consortium has previous experience creating similar architecture (the POLIS system for polio eradication and analysis) which has been in use for over eight years. Technical working groups (TWG) will be developed to establish data governance and reporting plans for each target country. These TWG's will conduct regular monitoring of implementation and the assessment of whether goals are being met, while adhering to country needs to try to be more proactive, transparent, to share data rapidly, and be adaptable to addressing issues. We will engage existing standards bodies to ensure that data sharing formats leverage existing works and/or contribute to these standards. This will also address (and ensure) country/regional and local stakeholders' access to genomic/sequencing data from GenBank and other global repositories to build and strengthen research capabilities. We will work with country governments to ensure the timely sharing of information as described, while also recognizing sensitivities around data to avoid stigmatization that could lead to reluctance because of economic and societal pressures.

Task 4.8: Implement data collection using updated data system for focus countries. We will adapt existing technology for the DV digital tool to collect field-based data, including geolocation, animal or plant species, samples collected, unique sample identification, and so on. The tool will be based on an existing technological base, such as CommCare, RedCap or similar, with interfaces for data import, exchange, and interfacing with lab systems. The DV data system will collect necessary data, including accession information for genomic data, connected with sample and location data collected by the DV digital tool.

Task 4.9: Strengthen capacity of in-country partners to store, analyze, and share data. We will train in country partners on use of the DV data system and its linkages with existing in-country data system architecture, work with host governments and data users to identify the key questions they would like to answer with the data, as well intended purposes and requirements, and support implementation of solutions to improve country-level electronic data sharing capacities. Uploading viral sequences to NCBI will also facilitate data exchange between in-country labs and reference labs. We will work to establish harmonized bioinformatics techniques and pipelines across the DV project to ensure comparability of genomic data. User-friendly dashboards including GIS maps to show location of possible priority infectious agents or exposure will be developed to visualize and support interpretation of the data. The consortium will identify "local champions" at the different levels to accelerate this activity. We will work with our in-country partners to publish, supporting their capacity to act as lead authors in internationally recognized journals, and provide training and mentorship in scientific writing.

Task 4.10: Strengthen in-country data management processes for the viral detection and characterization processes. Our consortium will support in-country labs in the focus countries in training the necessary staff on laboratory data management, including genomic data, and to support staff in bioinformatics, monitoring, and maintaining data repositories and architecture.

Task 4.11: Develop an early warning system with country-level dashboards. Learning from tools such as Tableau, DHIS2 dashboards, and other existing AI platforms, by the end of Year 2 we will develop country-level dashboards of DV data to visualize data and identify potential emerging threats based on expert opinion. This will leverage work done under PREDICT 1 and 2 as well as the Spillover data tool (<https://spillover.global>).

4.3 Global Data Sharing

The consortium has identified key data sets to be collected across countries that may require augmentation to in-country systems. Sequencing data will be communicated in as close to real-time as feasible to make this information accessible to the global scientific community, while

also adhering to data governance requirements negotiated with local stakeholders. Sequencing data and correlation with other findings including advanced characterization will also be regularly shared with in-country partners and global stakeholders via published lists of prioritized novel viruses ranked on their pandemic potential. This release of high priority and high-risk pathogens will feed into other risk assessment activities at national and global levels such as STOP Spillover and the proposed WHO Berlin Hub for Pandemic and Epidemic Intelligence. The consortium is already engaging with these stakeholders to cultivate a new model of data solidarity and collaborative intelligence for risk assessment. Another emerging initiative supported by WHO - the International Pathogen Surveillance Network (IPSN) - will also work to support global exchange of genomic information. The consortium will ensure a close integration with and support for IPSN, leveraging this global structure and pathway for R&D. These examples demonstrate opportunities for improved and rapid data sharing in a quickly evolving landscape. The consortium, in collaboration with USAID, will continue to track and engage with these initiatives as appropriate. Wherever possible, the linkages between the consortium data and these international data sharing mechanisms will be built into the project system architecture and part of agreements with national stakeholders.

Task 4.13: Convene multisectoral networks at country and international level. We will build on existing data standards for PREDICT 2 and provide trainings across the consortium and with in-country stakeholders to ensure adherence to data standards.

Task 4.14: Develop improved data sharing processes across data systems at country and international levels and across stakeholders. The project will develop the DV digital tool “esign” – a data-sharing process that supports differing levels of staging and access – with the capability to move data from an internal-only level to internal plus USAID, external partners, and fully public, international levels. While aligning with host country requirements and global guidelines (e.g., WHO’s code of conduct for sharing of pathogen genetic sequence data), our consortium will also ensure appropriate data is made available in a rapid and responsible manner to benefit the global community. In keeping with our “Adopt-Adapt-Develop” approach, we propose a data storage structure that will include three related databases – one for raw sequencing reads, one for assembled data and one for sample metadata. This segregated structure will facilitate real-time reporting of raw sequence data (FASTQ and FASTA) accompanied by limited deidentified metadata to global repositories (NCBI SRA, etc.) while also ensuring that access to sensitive metadata remains restricted until validated and approved for release. This structure will support more routine release of raw sequencing data throughout the duration of the DV project, while enabling local investigators adequate time to complete genome assembly and perform data cleaning and validation prior to submission of finished genome sequences to public domain (NCBI, EMBL-EBI, DDBJ) or public access (e.g. GISAID) repositories, and/or alternative global platforms (e.g., GitHub). Finally, project results and analyses will be regularly communicated via scientific publications, presentations, and direct communication with USAID and other stakeholders. As appropriate, and in accordance with in-country data sharing agreements, outlets will be explored for more rapid dissemination of findings, particularly when novel viruses with high pandemic risk are identified. This includes sharing manuscripts within preprint servers, such as medRxiv or bioRxiv, prior to publication.

5 Capacity Strengthening

A key goal of our DV program is for every activity and outcome to be predicated on a foundation of sustainable capacity strengthening within focus countries. To achieve this, in-country partner organizations will play leading and participatory roles in the development and implementation of

all activities. Further, in-country nationals will coordinate and implement all planned activities, from sample collecting through to laboratory analyses, with language-specific training programs being provided where necessary. Moreover, when planning for the improvements in technical capacity through provision of equipment, care will be taken to ensure the utility of any equipment extends beyond the duration of the program by selecting location-appropriate equipment that can readily be maintained, resourced, and used. This will ensure that during and after the program maximal use is made of the virus detection and characterization capacity that the project will develop. Finally, it is critical that in-country stakeholders understand the value of the knowledge and resources generated. We plan to achieve this in two ways: (1) in-country partners will take leading roles in all aspects of data analysis and the preparation of peer-reviewed publications and (2) the DV project will engage a wide range of in-country stakeholders at project inception to begin the process of raising awareness about the potential value of the generated resources. This process will include multiple fora being hosted within focus countries with a variety of stakeholders to raise awareness of resources that will be generated by the program, and their use (Table 1).

Resource Generated	Resource Uses	Stakeholders
Data from wildlife sampling: species and abundance	Inform conservation efforts	National and international wildlife organizations
Viruses detected in wildlife and domestic animals	Prepare for animal health events	Animal health agencies
Spillover events detected in human populations	Determine risk to humans, control efforts	Human health clinicians, public health
Improved laboratory capacity for qRT-PCR	Improve detection of other infectious diseases	Human health, public health
Improved capacity for ELISA	Improve detection of other infectious diseases	Human health, public health
Improved sequencing and bioinformatics capacity	Application of whole genome sequencing to other pathogens	Laboratories, public health, surveillance

Table 1: Resources generated by the program, their utility, and the stakeholders who will benefit

6 Sample Monitoring and Learning Plan

The WSU-led consortium partners will work with USAID within the first 90 days of the grant to develop a comprehensive Monitoring Evaluation and Learning Plan inclusive of a Learning Agenda and Data Management plan that will describe the processes for monitoring project activities and progress towards achieving the desired results. A comprehensive indicator matrix with output, outcome, and impact indicators, annual and life of project targets, and baseline measures will be at the center of the MEL plan. Table 2 presents illustrative indicators for a subset of intended results and activities under each of the project's 4 objectives, with additional illustrative indicators in Annex 2. Quarterly team check-ins will be used as a venue for Objective Leads to review MEL data with the team to identify areas that are not achieving desired results and flag areas where implementation strategies might need to be adjusted. The team will use MEL data to inform project management and will report semi-annually and annually on progress towards achieving results under the agreed upon indicators in the MEL plan and explain any significant deviations from expected targets. The MEL plan will be reviewed for relevance semi-annually and the WSU-led consortium will work with USAID to revise if and when necessary. The team will collect and analyze data on gender to inform the project's gender action planning to identify opportunities for the project to reduce opportunity gaps between men and women or address power differentials to promote gender equity.

Table 2: Selected illustrative indicators linked to intended results and project activities

Objective 1: Conduct Sampling In Focus Countries For Unknown Viruses From Priority Viral Families		
Intended results	Project Activities/Tasks	Indicators/Milestones
In-country institutional and staff capacity to conduct risk modeling to identify and inform sampling efforts strengthened .	1.7 Capacity Building and Sustainability (cross cutting all Objective 1 activities and tasks)	#/% representatives from in-country wildlife, human, livestock, and environmental health sectors, trained and engaged in risk modeling, sample site and species selection, and sample target setting processes
Key species sampled at research sites.	1.3 Country-level Strategic Sampling	# of wildlife samples collected in each country % of archived wildlife samples of interest screened
Objective 2: Strengthen Detection In Focus Countries For Novel Viruses From The Priority Viral Families		
Detection and genomic sequencing of novel viruses from prospective samples safely conducted .	2.2 Overall Detection Strategy 2.3 Molecular Screening 2.4. Broad Serology Screening	# of in-country labs with instruments that can perform assays with a throughput of 20-22 specimens per 96- well plate or 80-84 specimens per 384-well plate # of genome finishing batches performed using NextSeqor NovaSequequipment in each country
Ability of select in-country laboratories to provide technical assistance and/or detection capabilities for viral discovery in- country and in the region improved .	2.1 Capacity Building and Sustainability	# of labs & # people trained by project on qRT-PCR, serology, next gen sequencing methods, bioinformatics platforms and methods for analysis; % of those trained demonstrating improved competency in new methods; % of laboratory capacity gaps identified in each country that are showing improvement as demonstrated by: % of labs with screening & sequencing instruments
Objective 3: Strengthen Characterization In Focus Countries Of Novel Viruses From Priority Viral Families		
Lab and bioinformatics capacity for characterizing unknown viruses in select in- country institutions strengthened .	3.1. Overall Characterization Strategy	# countries with improved characterization capacity as demonstrated by increased number of novel viruses characterized and fully sequenced by in-country laboratories that have staff who have participated in at least one of the project's capacity building activities.
Objective 4: Strengthen In-Country Capacities For Data Management And Viral Characterization Process		
Newly validated methodologies and protocols, data and analyses associated with viral detection and characterization shared .	4.2 Country Data Management Task 4.9: Strengthen capacity of in-country partners to store, analyze, and share data	# countries with validated protocols for data sharing, MOUs in place; # DV datasets, methodologies, and/or publications made publicly available; # of data managers providing data sets with reliability, accuracy, completeness, consistency and timeliness.

Learning Agenda: Our consortium is committed to utilizing a Collaborating, Learning and Adapting approach to implementing the DV project. The Learning Agenda (LA) will be developed in the first 90 days in collaboration with USAID and in-country technical experts and will be the primary tool for ensuring critical questions that can guide implementation are collaboratively agreed upon and used to inform project implementation. The LA will serve to contextualize project achievements and test assumptions regarding how implemented activities yield intended results. We will review and discuss LA assessments quarterly to ensure learning from identified failures and successes and to improve future implementation. Illustrative LA questions are provided in Table 3. The final LA will include learning activities, timelines, methods and a dissemination plan that will describe key audiences benefitting from the learning

produced by the project and products targeted at those audiences to ensure relevant information is shared back quickly to the right stakeholders in a useful format.

Table 3. Illustrative Learning Agenda questions:	
1	To what extent is the project successfully supporting the timely detection and complete characterization of known and un-known pathogens among the prioritized viral families within the in-country reference laboratories? Which approaches are leading to the most robust implementation in countries and greatest effects on timely detection and complete characterization? And what characteristics, differences or similarities do we see across successful vs. less successful reference laboratories or countries where DV is implemented?
2	What data have the project successfully made available for use by local, regional and global audiences, and how have the data generated by the project supported local, regional and global preparedness and response activities to the targeted viral families? Are the appropriate audiences receiving useful data more rapidly? What barriers are still delaying the processes of sharing data and findings as quickly as possible? And what differences or similarities do we see across countries where DV is implemented vs. Countries where DV is not implemented?
3	<p>a. In which areas of capacity building (a-d below), and with which cadres of the workforce, has the project been successful in strengthening in-country capacity? What capacity building strategies are showing greatest / least impact? What remain the biggest barriers to successfully unlocking in-country capacity? Are project activities leading to unexpected capacity improvements? Laboratory capacity in viral detection and characterization of unknown viruses</p> <p>b. Data management capacity, including data collection, quality, analysis, sharing and storage</p> <p>c. Timely dissemination of actionable data and research findings</p> <p>d. In-country capacity to use data and research findings</p>
4	What existing in-country and global data systems are most successfully being leveraged for sharing DV data to increase likelihood of sustainability and interoperability among sectors? How successful is the project with getting virus sequencing data into those data sources? What facilitators can be leveraged and barriers do we still need to overcome to integrate DV data into sustainable systems?

Mixed methods will be used to answer these learning questions. Desk reviews will compile existing evidence; project monitoring and evaluation data will be used to track progress towards achievement of results within the learning agenda topic areas and incorporate project M&E within the learning. Additional methods for collecting data to answer these learning questions will include surveys, checklists, observations, key informant interviews and review of secondary data extracted from existing databases. Data from these sources will be analyzed to answer these questions, help the project understand what is working, where immediate pivots are needed in current implementation strategies and what learning should be shared more broadly. Data collection tools will be stored in a central repository for re-use and continuous learning during the project and beyond. The plan to disseminate and use findings will differ depending on the learning question. In many cases the first audience will be internal team and management to inform activity planning and work planning. Learning exchange sessions, webinars or workshops will be planned to discuss findings with local experts and decision makers to explore the local context and use of the findings. On a global scale, we will develop white papers, blogs, conference presentations, global learning exchange webinars, or publications for peer review.

[END OF ATTACHMENT B]

ATTACHMENT C – STANDARD PROVISIONS

MANDATORY STANDARD PROVISIONS FOR U.S. NONGOVERNMENTAL ORGANIZATIONS

M1. APPLICABILITY OF 2 CFR 200 and 2 CFR 700 (NOVEMBER 2020)

- a. All provisions of 2 CFR 200 and 2 CFR 700 in effect on the date of this award, and all Standard Provisions attached to this agreement are applicable to the recipient and to subrecipients that meet the definition of “Non-Federal Entity” in part 2 CFR 200.1, unless a section specifically excludes a subrecipient from coverage. The recipient must assure that subrecipients have copies of all the attached standard provisions.
- b. For any subawards made with Non-U.S. subrecipients the recipient must include the applicable “Standard Provisions for Non-US Nongovernmental Organizations.” Recipients are required to ensure compliance with monitoring procedures in accordance with 2 CFR 200 and 2 CFR 700.

[END OF PROVISION]

M2. INELIGIBLE COUNTRIES (MAY 1986)

Unless otherwise approved by the USAID Agreement Officer, funds will only be expended for assistance to countries eligible for assistance under the Foreign Assistance Act of 1961, as amended, or under acts appropriating funds for foreign assistance.

[END OF PROVISION]

M3. NONDISCRIMINATION (JUNE 2012)

No U.S. citizen or legal resident shall be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination on the basis of race, color, national origin, age, disability, or sex under any program or activity funded by this award when work under the grant is performed in the U.S. or when employees are recruited from the U.S.

Additionally, USAID is committed to achieving and maintaining a diverse and representative workforce and a workplace free of discrimination. Based on law, Executive Order, and Agency policy, USAID prohibits discrimination, including harassment, in its own workplace on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, disability, age, veteran’s status, sexual orientation, genetic information, marital status, parental status, political affiliation, and any other conduct that does not adversely affect the performance of the employee.

In addition, the Agency strongly encourages its recipients and their subrecipients and vendors (at all tiers), performing both in the U.S. and overseas, to develop and enforce comprehensive nondiscrimination policies for their workplaces that include protection for all their employees on these expanded bases, subject to applicable law.

[END OF PROVISION]

M4. AMENDMENT OF AWARD (JUNE 2012)

This award may only be amended in writing, by formal amendment or letter, signed by the Agreement Officer (AO), and in the case of a bilateral amendment, by the AO and an authorized official of the recipient.

[END OF PROVISION]

M5. NOTICES (JUNE 2012)

Any notice given by USAID or the recipient is sufficient only if in writing and delivered in person, mailed or e-mailed as follows:

- (1) To the USAID Agreement Officer, at the address specified in this award; or
- (2) To the recipient, at the recipient's address shown in this award, or to such other address specified in this award.

[END OF PROVISION]

M6. SUBAWARDS AND CONTRACTS (DECEMBER 2014)

- a. Subawardees and contractors have no relationship with USAID under the terms of this award. All required USAID approvals must be directed through the recipient to USAID.
- b. Notwithstanding any other term of this award, subawardees and contractors have no right to submit claims directly to USAID and USAID assumes no liability for any third party claims against the recipient.

[END OF PROVISION]

M7. OMB APPROVAL UNDER THE PAPERWORK REDUCTION ACT (DECEMBER 2014)

Information collection requirements imposed by this award are covered by OMB approval number 0412-0510; the current expiration date is 04/30/2005. The Standard Provisions containing the requirement and an estimate of the public reporting burden (including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information) are

<u>Standard Provision</u>	<u>Burden Estimate</u>
Air Travel and Transportation	1 (hour)
Ocean Shipment of Goods	.5
Patent Rights	.5
Publications	.5
Negotiated Indirect Cost Rates - (Predetermined and Provisional)	1
Voluntary Population Planning	.5

Protection of the Individual as a Research Subject 1

<u>22 CFR 200</u>	<u>Burden Estimate</u>
2 CFR 200.318-326, Procurement Standards	1
2 CFR 200.310-315, Property Standards	1.5

Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, may be sent to the Bureau for Management, Office of Acquisition and Assistance, Policy Division (M/OAA/P), U.S. Agency for International Development, Washington, DC 20523 and to the Office of Management and Budget, Paperwork Reduction Project (0412-0510), Washington, DC 20503.

[END OF PROVISION]

M8. USAID ELIGIBILITY RULES FOR GOODS AND SERVICES (MAY 2020)

This provision is not applicable to commodities or services that the recipient provides with private funds as part of a cost-sharing requirement, or with Program Income generated under this award.

- a. Ineligible and Restricted Commodities and Services:
- (1) Ineligible Commodities and Services. The recipient must not, under any circumstances, procure any of the following under this award:
 - (i) Military equipment,
 - (ii) Surveillance equipment,
 - (iii) Commodities and services for support of police or other law enforcement activities,
 - (iv) Abortion equipment and services,
 - (v) Luxury goods and gambling equipment, or
 - (vi) Weather modification equipment.
 - (2) Ineligible Suppliers. Any firms or individuals that do not comply with the requirements in Standard Provision, “Debarment, Suspension and Other Responsibility Matters” and Standard Provision, “Preventing Transactions with, or the Provision of Resources or Support to, Sanctioned Groups and Individuals” must not be used to provide any commodities or services funded under this award.
 - (3) Restricted Commodities. The recipient must obtain prior written approval of the Agreement Officer (AO) or comply with required procedures under an applicable waiver, as provided by the AO when procuring any of the following commodities:
 - (i) Agricultural commodities,
 - (ii) Motor vehicles,

- (iii) Pharmaceuticals,
 - (iv) Pesticides,
 - (v) Used equipment,
 - (vi) U.S. Government-owned excess property, or
 - (vii) Fertilizer.
- b. Source and Nationality:
Except as may be specifically approved in advance by the AO, all commodities and services that will be reimbursed by USAID under this award must be from the authorized geographic code specified in this award and must meet the source and nationality requirements set forth in 22 CFR 228. If the geographic code is not specified, the authorized geographic code is 937. When the total value of procurement for commodities and services during the life of this award is valued at \$250,000 or less, the authorized geographic code for procurement of all goods and services to be reimbursed under this award is code 935. For a current list of countries within each geographic code, see: <http://www.usaid.gov/ads/policy/300/310>.
- c. Guidance on the eligibility of specific commodities and services may be obtained from the AO. If USAID determines that the recipient has procured any commodities or services under this award contrary to the requirements of this provision, and has received payment for such purposes, the AO may require the recipient to refund the entire amount of the purchase.
- d. This provision must be included in all subawards and contracts which include procurement of commodities or services.

[END OF PROVISION]

M9. DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS (JUNE 2012)

- a. The recipient agrees to notify the Agreement Officer (AO) immediately upon learning that it or any of its principals:
 - (1) Are presently excluded or disqualified from covered transactions by any Federal department or agency;
 - (2) Have been convicted within the preceding three-year period preceding this proposal; been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, receiving stolen property, making false claims, or obstruction of justice; commission of any other offense indicating a lack of business integrity or business honesty that seriously and directly affects your present responsibility;
 - (3) Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph a.(2); and
 - (4) Have had one or more public transactions (Federal, State, or local) terminated for cause

or default within the preceding three years.

- b. The recipient agrees that, unless authorized by the AO, it will not knowingly enter into any subawards or contracts under this award with a person or entity that has an active exclusion on the System for Award Management (SAM) (www.sam.gov). The recipient further agrees to include the following provision in any subawards or contracts entered into under this award:

.DEBARMENT, SUSPENSION, INELIGIBILITY, AND VOLUNTARY EXCLUSION
(JUNE 2012)

The recipient/contractor certifies that neither it nor its principals is presently excluded or disqualified from participation in this transaction by any Federal department or agency.

- c. The policies and procedures applicable to debarment, suspension, and ineligibility under USAID-financed transactions are set forth in Subpart C of 2 CFR Section 180, as supplemented by 2 CFR 780.

[END OF PROVISION]

M10. DRUG-FREE WORKPLACE (JUNE 2012)

The recipient must comply with drug-free workplace requirements in subpart B (or subpart C, if the recipient is an individual) of 2 CFR 782, which adopts the Government-wide implementation (2 CFR part 182) of sec. 5152–5158 of the Drug-Free Workplace Act of 1988 (Pub. L. 100–690, Title V, Subtitle D; 41 U.S.C. 701–707).

[END OF PROVISION]

M11. EQUAL PARTICIPATION BY FAITH-BASED ORGANIZATIONS (JUNE 2016)

a. Faith-Based Organizations Encouraged

Faith-based organizations are eligible, on the same basis as any other organization, to participate in any USAID program for which they are otherwise eligible. Neither USAID nor entities that make and administer subawards of USAID funds shall discriminate for or against an organization on the basis of the organization's religious character or affiliation. Additionally, religious organizations shall not be disqualified from participating in USAID programs because such organizations are motivated or influenced by religious faith to provide social services, or because of their religious character or affiliation.

Decisions about awards of USAID financial assistance must be free from political interference or even the appearance of such interference. Awards must be made on the basis of merit, not the basis of the religious affiliation of an applicant, or lack thereof. A faith-based organization may continue to carry out its mission, including the definition, development, practice, and expression of its religious beliefs, within the limits contained in this provision. For more information, see the **USAID Faith-Based and Community Initiatives Web site** and **22 CFR 205.1**.

b. Explicitly Religious Activities Prohibited.

- (1)** Explicitly religious activities include activities that involve overt religious content such as worship, religious instruction, prayer, or proselytization.
 - (2)** The recipient must not engage in explicitly religious activities as part of the programs or services directly funded with financial assistance from USAID. If the recipient engages in explicitly religious activities, the activities must be offered separately, in time or location, from any programs or services directly funded by this award, and participation must be voluntary for beneficiaries of the programs or services funded with USAID assistance.
 - (3)** These restrictions apply equally to religious and secular organizations. All organizations that participate in USAID programs, as recipients or subawardees, including religious ones, must carry out eligible activities in accordance with all program requirements and other applicable requirements governing USAID-funded activities.
 - (4)** Notwithstanding the restrictions of b.(1) and (2), a religious organization that participates in USAID-funded programs or services:
 - (i)** May retain its independence and may continue to carry out its mission, including the definition, development, practice, and expression of its religious beliefs, provided that it does not use direct financial assistance from USAID to support or engage in any explicitly religious activities or in any other manner prohibited by law;
 - (ii)** May use space in its facilities, without removing religious art, icons, scriptures, or other religious symbols; and
 - (iii)** May retain its authority over its internal governance, and may retain religious terms in its organization's name, select its board members on a religious basis, and include religious references in its organization's mission statements and other governing documents.
- c.** Implementation in accordance with the Establishment Clause: Nothing in this provision shall be construed as authorizing the use of USAID funds for activities that are not permitted by Establishment Clause jurisprudence or otherwise by law.
- d.** Discrimination Based on Religion Prohibited: The recipient must not, in providing services, discriminate against a program beneficiary or potential program beneficiary on the basis of religion or religious belief, refusal to hold a religious belief, or a refusal to attend or participate in a religious practice.
- e.** A religious organization's exemption from the Federal prohibition on employment discrimination on the basis of religion, set forth in Sec. 702(a) of the Civil Rights Act of

1964, 42 U.S.C. 2000e–1 is not forfeited when the organization receives financial assistance from USAID.

- f. The Secretary of State may waive the requirements of this section in whole or in part, on a case-by-case basis, where the Secretary determines that such waiver is necessary to further the national security or foreign policy interests of the United States.
- g. This provision must be included in all subawards under this award.

[END OF PROVISION]

M12. PREVENTING TRANSACTIONS WITH, OR THE PROVISION OF RESOURCES OR SUPPORT TO, SANCTIONED GROUPS AND INDIVIDUALS (MAY 2020)

- a. In carrying out activities under this award, except as authorized by a license issued by the Office of Foreign Assets Control (OFAC) of the U.S. Department of Treasury, the recipient will not engage in transactions with, or provide resources or support to, any individual or entity that is subject to sanctions administered by OFAC or the United Nations (UN), including any individual or entity that is included on the Specially Designated Nationals and Blocked Persons List maintained by OFAC (<https://www.treasury.gov/resource-center/sanctions/SDNList/Pages/default.aspx>) or on the UN Security Council consolidated list (<https://www.un.org/securitycouncil/content/un-sc-consolidated-list>).
- b. Any violation of the above will be grounds for unilateral termination of the agreement by USAID.
- c. The Recipient must include this provision in all subawards and contracts issued under this award.

[END OF PROVISION]

M13. MARKING AND PUBLIC COMMUNICATIONS UNDER USAID-FUNDED ASSISTANCE (DECEMBER 2014)

- a. The USAID Identity is the official marking for USAID, comprised of the USAID logo and landmark with the tagline “from the American people,” unless amended by USAID to include additional or substitute use of a logo or seal and tagline representing a presidential initiative or other high level interagency initiative. The USAID Identity (including any required presidential initiative or related identity) is on the USAID Web site at www.usaid.gov/branding. Recipients must use the USAID Identity, of a size and prominence equivalent to or greater than any other identity or logo displayed, to mark the following:
 - (1) Programs, projects, activities, public communications, and commodities partially or fully funded by USAID;
 - (2) Program, project, or activity sites funded by USAID, including visible infrastructure projects or other physical sites;

- (3) Technical assistance, studies, reports, papers, publications, audio-visual productions, public service announcements, Web sites/Internet activities, promotional, informational, media, or communications products funded by USAID;
 - (4) Commodities, equipment, supplies, and other materials funded by USAID, including commodities or equipment provided under humanitarian assistance or disaster relief programs; and
 - (5) Events financed by USAID, such as training courses, conferences, seminars, exhibitions, fairs, workshops, press conferences and other public activities. If the USAID Identity cannot be displayed, the recipient is encouraged to otherwise acknowledge USAID and the support of the American people.
- b. The recipient must implement the requirements of this provision following the approved Marking Plan in the award.
 - c. The AO may require a preproduction review of program materials and “public communications” (documents and messages intended for external distribution, including but not limited to correspondence; publications; studies; reports; audio visual productions; applications; forms; press; and promotional materials) used in connection with USAID-funded programs, projects or activities, for compliance with an approved Marking Plan.
 - d. The recipient is encouraged to give public notice of the receipt of this award and announce progress and accomplishments. The recipient must provide copies of notices or announcements to the Agreement Officer’s Representative (AOR) and to USAID’s Office of Legislative and Public Affairs in advance of release, as practicable. Press releases or other public notices must include a statement substantially as follows:

“The U.S. Agency for International Development administers the U.S. foreign assistance program providing economic and humanitarian assistance in more than 80 countries worldwide.”
 - e. Any “public communication” in which the content has not been approved by USAID must contain the following disclaimer:

“This study/report/audio/visual/other information/media product (specify) is made possible by the generous support of the American people through the United States Agency for International Development (USAID). The contents are the responsibility of [insert recipient name] and do not necessarily reflect the views of USAID or the United States Government.”
 - f. The recipient must provide the USAID AOR with two copies of all program and communications materials produced under this award.
 - g. The recipient may request an exception from USAID marking requirements when USAID

marking requirements would:

- (1) Compromise the intrinsic independence or neutrality of a program or materials where independence or neutrality is an inherent aspect of the program and materials;
 - (2) Diminish the credibility of audits, reports, analyses, studies, or policy recommendations whose data or findings must be seen as independent;
 - (3) Undercut host-country government “ownership” of constitutions, laws, regulations, policies, studies, assessments, reports, publications, surveys or audits, public service announcements, or other communications;
 - (4) Impair the functionality of an item;
 - (5) Incur substantial costs or be impractical;
 - (6) Offend local cultural or social norms, or be considered inappropriate; or
 - (7) Conflict with international law.
- h. The recipient may submit a waiver request of the marking requirements of this provision or the Marking Plan, through the AOR, when USAID-required marking would pose compelling political, safety, or security concerns, or have an adverse impact in the cooperating country.
- (1) Approved waivers “flow down” to subawards and contracts unless specified otherwise. The waiver may also include the removal of USAID markings already affixed, if circumstances warrant.
 - (2) USAID determinations regarding waiver requests are subject to appeal by the recipient, by submitting a written request to reconsider the determination to the cognizant Assistant Administrator.
- i. The recipient must include the following marking provision in any subawards entered into under this award:

“As a condition of receipt of this subaward, marking with the USAID Identity of a size and prominence equivalent to or greater than the recipient’s, subrecipient’s, other donor’s, or third party’s is required. In the event the recipient chooses not to require marking with its own identity or logo by the subrecipient, USAID may, at its discretion, require marking by the subrecipient with the USAID Identity.”

[END OF PROVISION]

M14. REGULATIONS GOVERNING EMPLOYEES (JUNE 2018)

- a. While working overseas, the recipient's employees who are not citizens of the cooperating

country must maintain private status, and may not rely on local U.S. Government offices or facilities for support while under this award.

- b. The sale of personal property or automobiles by the recipient's non-cooperating country citizen employees and their dependents in the foreign country to which they are assigned, are subject to the same limitations and prohibitions that apply to direct-hire USAID personnel employed by the Mission, including the rules contained in 22 CFR 136, except as this may conflict with host government regulations.
- c. Other than work to be performed under this award for which an employee is assigned by the recipient, employees of the recipient who are not citizens of the cooperating country must not engage directly or indirectly, either in the individual's own name or in the name or through an agency of another person, in any business, profession, or occupation in the foreign countries to which the individual is assigned. In addition, the individual must not make loans or investments to or in any business, profession, or occupation in the foreign countries to which the individual is assigned.
- d. The recipient's employees who are not citizens of the cooperating country, while in a foreign country, are expected to show respect for its conventions, customs, and institutions, to abide by its applicable laws and regulations, and not to interfere in its internal political affairs.
- e. In accordance with the internal control requirements in 2 CFR 200.303, which require the recipient to establish standards of conduct for its employees, the recipient must ensure that all its employees adhere to these standards of conduct in a manner consistent with the standards for United Nations (UN) employees in Section 3 of the UN Secretary-General's Bulletin - Special Measures for Protection from Sexual Exploitation and Sexual Abuse (ST/SGB/2003/13).
- f. If the recipient determines that the conduct of any recipient employee is not in accordance with the preceding paragraphs, the recipient's Chief of Party must consult with the Agreement Officer and the USAID Mission Director, and the employee involved, and must recommend to the recipient a course of action with regard to such employee.
- g. The parties recognize the rights of the U.S. Ambassador to direct the removal from a country of any U.S. citizen, or the discharge from this award of any individual (U.S., third-country, or cooperating-country national) when, in the discretion of the Ambassador, the interests of the United States so require.
- h. If it is determined, under paragraph (f) or (g) above, that the services of such employee should be terminated, the recipient must use its best efforts to cause the return of such employee to the United States, or third-country point of origin, as appropriate, and replace the employee with an acceptable substitute at no cost to USAID.
- i. Any matters relating to subrecipients, including the employees of subrecipients, must be coordinated through the recipient's Chief of Party.

[END OF PROVISION]

**M15. CONVERSION OF UNITED STATES DOLLARS TO LOCAL CURRENCY
(NOVEMBER 1985)**

(This provision applies when activities are undertaken outside the United States.)

Upon arrival in the cooperating country, and from time to time as appropriate, the recipient's chief of party must consult with the Mission Director who must provide, in writing, the procedure the recipient and its employees must follow in the conversion of United States dollars to local currency. This may include, but is not limited to, the conversion of currency through the cognizant United States Disbursing Officer or Mission Controller, as appropriate.

[END OF PROVISION]

M16. USE OF POUCH FACILITIES (AUGUST 1992)

(This provision applies when activities are undertaken outside the United States.)

- a. Use of diplomatic pouch is controlled by the Department of State. The Department of State has authorized the use of pouch facilities for USAID recipients and their employees as a general policy, as detailed in items (1) through (6) below. However, the final decision regarding use of pouch facilities rest with the Embassy or USAID Mission. In consideration of the use of pouch facilities, the recipient and its employees agree to indemnify and hold harmless, the Department of State and USAID for loss or damage occurring in pouch transmission:
 - (1) Recipients and their employees are authorized use of the pouch for transmission and receipt of up to a maximum of .9 kgs per shipment of correspondence and documents needed in the administration of assistance programs.
 - (2) U.S. citizen employees are authorized use of the pouch for personal mail up to a maximum of .45 kgs per shipment (but see a.(3) below).
 - (3) Merchandise, parcels, magazines, or newspapers are not considered to be personal mail for purposes of this standard provision and are not authorized to be sent or received by pouch.
 - (4) Official and personal mail pursuant to a.(1) and (2) above sent by pouch should be addressed as follows:

Name of individual or organization (followed by
letter symbol "G")
City Name of post (USAID/_____)
Agency for International Development
Washington, DC 20523-0001
 - (5) Mail sent via the diplomatic pouch may not be in violation of U.S. Postal laws and may

not contain material ineligible for pouch transmission.

(6) Recipient personnel are NOT authorized use of military postal facilities (APO/FPO).

This is an Adjutant General's decision based on existing laws and regulations governing military postal facilities and is being enforced worldwide.

- b. The recipient is responsible for advising its employees of this authorization, these guidelines, and limitations on use of pouch facilities.
- c. Specific additional guidance on grantee use of pouch facilities in accordance with this standard provision is available from the Post Communication Center at the Embassy or USAID Mission.

[END OF PROVISION]

M17. TRAVEL AND INTERNATIONAL AIR TRANSPORTATION (DECEMBER 2014)

a. TRAVEL COSTS

All travel costs must comply with the applicable cost principles and must be consistent with those normally allowed in like circumstances in the recipient's non-USAID-funded activities. Costs incurred by employees and officers for travel, including air fare, costs of lodging, other subsistence, and incidental expenses, may be considered reasonable and allowable only to the extent such costs do not exceed reasonable charges normally allowed by the recipient in its regular operations as the result of the recipient organization's written travel policy and are within the limits established by the applicable cost principles.

In the absence of a reasonable written policy regarding international travel costs, the standard for determining the reasonableness of reimbursement for international travel costs will be the Standardized Regulations (Government Civilians, Foreign Areas), published by the U.S. Department of State, as from time to time amended. The most current Standardized Regulations on international travel costs may be obtained from the AO. In the event that the cost for air fare exceeds the customary standard commercial airfare (coach or equivalent) or the lowest commercial discount airfare, the recipient must document one of the allowable exceptions from the applicable cost principles.

b. FLY AMERICA ACT RESTRICTIONS

- (1) The recipient must use U.S. Flag Air Carriers for all international air transportation (including personal effects) funded by this award pursuant to the Fly America Act and its implementing regulations to the extent service by such carriers is available.
- (2) In the event that the recipient selects a carrier other than a U.S. Flag Air Carrier for international air transportation, in order for the costs of such international air transportation to be allowable, the recipient must document such transportation in accordance with this provision and maintain such documentation pursuant to the

Standard Provision, “Accounting, Audit and Records.” The documentation must use one of the following reasons or other exception under the Fly America Act:

- (i) The recipient uses a European Union (EU) flag air carrier, which is an airline operating from an EU country that has signed the US-EU “Open Skies” agreement (<http://www.state.gov/e/eb/rls/othr/ata/i/ic/170684.htm>).
- (ii) Travel to or from one of the following countries on an airline of that country when no city pair fare is in effect for that leg (see <http://apps.fas.gsa.gov/citypairs/search/>):
 - a. Australia on an Australian airline,
 - b. Switzerland on a Swiss airline, or
 - c. Japan on a Japanese airline;
- (iii) Only for a particular leg of a route on which no US Flag Air Carrier provides service on that route;
- (iv) For a trip of 3 hours or less, the use of a US Flag Air Carrier at least doubles the travel time;
- (v) If the US Flag Air Carrier offers direct service, use of the US Flag Air Carrier would increase the travel time by more than 24 hours; or
- (vi) If the US Flag Air Carrier does not offer direct service,
 - a. Use of the US Flag Air Carrier increases the number of aircraft changes by 2 or more,
 - b. Use of the US Flag Air Carrier extends travel time by 6 hours or more, or
 - c. Use of the US Flag Air Carrier requires a layover at an overseas interchange of 4 hours or more.

c. DEFINITIONS

The terms used in this provision have the following meanings:

- (1) “Travel costs” means expenses for transportation, lodging, subsistence (meals and incidentals), and related expenses incurred by employees who are on travel status on official business of the recipient for any travel outside the country in which the organization is located. “Travel costs” do not include expenses incurred by employees who are not on official business of the recipient, such as rest and recuperation (R&R) travel offered as part of an employee’s benefits package that are consistent with the recipient’s personnel and travel policies and procedures.

- (2) "International air transportation" means international air travel by individuals (and their personal effects) or transportation of cargo by air between a place in the United States and a place outside thereof, or between two places both of which are outside the United States.
- (3) "U.S. Flag Air Carrier" means an air carrier on the list issued by the U.S. Department of Transportation at <http://ostpxweb.dot.gov/aviation/certific/certlist.htm>. U.S. Flag Air Carrier service also includes service provided under a code share agreement with another air carrier when the ticket, or documentation for an electronic ticket, identifies the U.S. flag air carrier's designator code and flight number.
- (4) For this provision, the term "United States" includes the fifty states, Commonwealth of Puerto Rico, possessions of the United States, and the District of Columbia.

d. SUBAWARDS AND CONTRACTS

This provision must be included in all subawards and contracts under which this award will finance international air transportation.

[END OF PROVISION]

M18. OCEAN SHIPMENT OF GOODS (JUNE 2012)

- a. Prior to contracting for ocean transportation to ship goods purchased or financed with USAID funds under this award, the recipient must contact the office below to determine the flag and class of vessel to be used for shipment:

U.S. Agency for International Development,
Bureau for Management
Office of Acquisition and Assistance, Transportation Division
1300 Pennsylvania Avenue, NW
Washington, DC 20523
Email: oceantransportation@usaid.gov

- b. This provision must be included in all subawards and contracts.

[END OF PROVISION]

M19. VOLUNTARY POPULATION PLANNING ACTIVITIES – MANDATORY REQUIREMENTS (MAY 2006)

Requirements for Voluntary Sterilization Programs

- (1) Funds made available under this award must not be used to pay for the performance of involuntary sterilization as a method of family planning or to coerce or provide any financial incentive to any individual to practice sterilization.

Prohibition on Abortion-Related Activities:

- (1) No funds made available under this award will be used to finance, support, or be attributed to the following activities: (i) procurement or distribution of equipment intended to be used for the purpose of inducing abortions as a method of family planning; (ii) special fees or incentives to any person to coerce or motivate them to have abortions; (iii) payments to persons to perform abortions or to solicit persons to undergo abortions; (iv) information, education, training, or communication programs that seek to promote abortion as a method of family planning; and (v) lobbying for or against abortion. The term “motivate,” as it relates to family planning assistance, must not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options.
- (2) No funds made available under this award will be used to pay for any biomedical research which relates, in whole or in part, to methods of, or the performance of, abortions or involuntary sterilizations as a means of family planning. Epidemiologic or descriptive research to assess the incidence, extent or consequences of abortions is not precluded.

[END OF PROVISION]

M20. TRAFFICKING IN PERSONS (April 2016)

- a. The recipient, subawardee, or contractor, at any tier, or their employees, labor recruiters, brokers or other agents, must not engage in:
 - (1) Trafficking in persons (as defined in the Protocol to Prevent, Suppress, and Punish Trafficking in Persons, especially Women and Children, supplementing the UN Convention against Transnational Organized Crime) during the period of this award;
 - (2) Procurement of a commercial sex act during the period of this award;
 - (3) Use of forced labor in the performance of this award;
 - (4) Acts that directly support or advance trafficking in persons, including the following acts:
 - i. Destroying, concealing, confiscating, or otherwise denying an employee access to that employee's identity or immigration documents;
 - ii. Failing to provide return transportation or pay for return transportation costs to an employee from a country outside the United States to the country from which the employee was recruited upon the end of employment if requested by the employee, unless:
 - a) exempted from the requirement to provide or pay for such return transportation by USAID under this award; or

- b) the employee is a victim of human trafficking seeking victim services or legal redress in the country of employment or a witness in a human trafficking enforcement action;
 - iii. Soliciting a person for the purpose of employment, or offering employment, by means of materially false or fraudulent pretenses, representations, or promises regarding that employment;
 - iv. Charging employees recruitment fees; or
 - v. Providing or arranging housing that fails to meet the host country housing and safety standards.
- b. In the event of a violation of section (a) of this provision, USAID is authorized to terminate this award, without penalty, and is also authorized to pursue any other remedial actions authorized as stated in section 1704(c) of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112-239, enacted January 2, 2013).
- c. If the estimated value of services required to be performed under the award outside the United States exceeds \$500,000, the recipient must submit to the Agreement Officer, the annual “Certification regarding Trafficking in Persons, Implementing Title XVII of the National Defense Authorization Act for Fiscal Year 2013” as required prior to this award, and must implement a compliance plan to prevent the activities described above in section (a) of this provision. The recipient must provide a copy of the compliance plan to the Agreement Officer upon request and must post the useful and relevant contents of the plan or related materials on its website (if one is maintained) and at the workplace.
- d. The recipient’s compliance plan must be appropriate to the size and complexity of the award and to the nature and scope of the activities, including the number of non-United States citizens expected to be employed. The plan must include, at a minimum, the following:
 - (1) An awareness program to inform employees about the trafficking related prohibitions included in this provision, the activities prohibited and the action that will be taken against the employee for violations.
 - (2) A reporting process for employees to report, without fear of retaliation, activity inconsistent with the policy prohibiting trafficking, including a means to make available to all employees the Global Human Trafficking Hotline at 1-844-888-FREE and its e-mail address at help@befree.org.
 - (3) A recruitment and wage plan that only permits the use of recruitment companies with trained employees, prohibits charging of recruitment fees to the employee, and ensures that wages meet applicable host-country legal requirements or explains any variance.

- (4) A housing plan, if the recipient or any subawardee intends to provide or arrange housing. The housing plan is required to meet any host-country housing and safety standards.
 - (5) Procedures for the recipient to prevent any agents or subawardee at any tier and at any dollar value from engaging in trafficking in persons activities described in section a of this provision. The recipient must also have procedures to monitor, detect, and terminate any agents or subawardee or subawardee employees that have engaged in such activities.
- e. If the Recipient receives any credible information regarding a violation listed in section a(1)-(4) of this provision, the recipient must immediately notify the cognizant Agreement Officer and the USAID Office of the Inspector General; and must fully cooperate with any Federal agencies responsible for audits, investigations, or corrective actions relating to trafficking in persons.
 - f. The Agreement Officer may direct the Recipient to take specific steps to abate an alleged violation or enforce the requirements of a compliance plan.
 - g. For purposes of this provision, “employee” means an individual who is engaged in the performance of this award as a direct employee, consultant, or volunteer of the recipient or any subrecipient.
 - h. The recipient must include in all subawards and contracts a provision prohibiting the conduct described in section a(1)-(4) by the subrecipient, contractor, or any of their employees, or any agents. The recipient must also include a provision authorizing the recipient to terminate the award as described in section b of this provision.

[END OF PROVISION]

M21. SUBMISSIONS TO THE DEVELOPMENT EXPERIENCE CLEARINGHOUSE AND PUBLICATIONS (JUNE 2012)

- a. Submissions to the Development Experience Clearinghouse (DEC).
 - 1) The recipient must provide the Agreement Officer’s Representative one copy of any Intellectual Work that is published, and a list of any Intellectual Work that is not published.
 - 2) In addition, the recipient must submit Intellectual Work, whether published or not, to the DEC, either on-line (preferred) or by mail. The recipient must review the DEC Web site for submission instructions, including document formatting and the types of documents to submit. Submission instructions can be found at: <http://dec.usaid.gov>.

- 3) For purposes of submissions to the DEC, Intellectual Work includes all works that document the implementation, evaluation, and results of international development assistance activities developed or acquired under this award, which may include program and communications materials, evaluations and assessments, information products, research and technical reports, progress and performance reports required under this award (excluding administrative financial information), and other reports, articles and papers prepared by the recipient under the award, whether published or not. The term does not include the recipient's information that is incidental to award administration, such as financial, administrative, cost or pricing, or management information.
 - 4) Each document submitted should contain essential bibliographic information, such as 1) descriptive title; 2) author(s) name; 3) award number; 4) sponsoring USAID office; 5) development objective; and 6) date of publication.
 - 5) The recipient must not submit to the DEC any financially sensitive information or personally identifiable information, such as social security numbers, home addresses and dates of birth. Such information must be removed prior to submission. The recipient must not submit classified documents to the DEC.
- b. In the event award funds are used to underwrite the cost of publishing, in lieu of the publisher assuming this cost as is the normal practice, any profits or royalties up to the amount of such cost must be credited to the award unless the schedule of the award has identified the profits or royalties as program income.

[END OF PROVISION]

M22. LIMITING CONSTRUCTION ACTIVITIES (AUGUST 2013)

- a) Construction is not eligible for reimbursement under this award unless specifically identified in paragraph d) below.
- b) Construction means —construction, alteration, or repair (including dredging and excavation) of buildings, structures, or other real property and includes, without limitation, improvements, renovation, alteration and refurbishment. The term includes, without limitation, roads, power plants, buildings, bridges, water treatment facilities, and vertical structures.
- c) Agreement Officers will not approve any subawards or procurements by recipients for construction activities that are not listed in paragraph d) below. USAID will reimburse allowable costs for only the construction activities listed in this provision not to exceed the amount specified in the construction line item of the award budget. The recipient must receive prior written approval from the AO to transfer funds allotted for construction activities to other cost categories, or vice versa.
- d) Description

Construction is not eligible for reimbursement under this award.

- e) The recipient must include this provision in all subawards and procurements and make vendors providing services under this award and subrecipients aware of the restrictions of this provision.

[END OF PROVISION]

M23. USAID IMPLEMENTING PARTNER NOTICES (IPN) PORTAL FOR ASSISTANCE (JULY 2014)

(a) Definitions

“USAID Implementing Partner Notices (IPN) Portal for Assistance (“IPN Portal)” means the single point where USAID posts proposed universal bilateral amendments for USAID awards, which can be accessed electronically by registered USAID recipients. The IPN Portal is located at <https://sites.google.com/site/usaaidipnforassistance/>. Universal amendments are those which affect all assistance awards or a designated class of awards as specified in each amendment by the IPN Portal Administrator.

“IPN Portal Administrator” means the USAID official designated by the Director, M/OAA, who has overall responsibility for managing the USAID Implementing Partner Notices Portal for Assistance.

“Universal bilateral amendment” means those amendments with revisions or new requirements or provisions that affect all awards or a designated class of awards, as specified in the Agency notification of such revisions or new requirements.

- (b)** By submission of an application and execution of an award, the Applicant/Recipient acknowledges the requirement to:

- (1)** Register with the IPN Portal if awarded an assistance award resulting from this solicitation, and
 - (2)** Receive universal bilateral amendments to this award and general notices via the IPN Portal.

- (c)** Procedure to register for notifications.

Go to <https://sites.google.com/site/usaaidipnforassistance/> and click the “Register” button at the top of the page. Recipient representatives must use their official organization email address when subscribing, not personal email addresses.

- (d)** Processing of IPN Portal Amendments

The Recipient may access the IPN Portal at any time to review all IPN Portal amendments; however, the system will also notify the Recipient by email when the USAID IPN Portal Administrator posts a universal bilateral amendment for Recipient's review and signature. Proposed USAID IPN Portal amendments distributed via the IPN Portal are applicable to all awards, unless otherwise noted in the proposed amendment.

Within 15 calendar days from receipt of the notification email from the IPN Portal, the Recipient must do one of the following:

- (1) (a) verify applicability of the proposed amendment for their award(s) per the instructions provided with each amendment; (b) download the amendment and incorporate the following information on the amendment form: award number, organization name, and organization mailing address as it appears in the basic award; (c) sign the hardcopy version; and (d) send the signed amendment (by email or hardcopy) to the AO for signature. The Recipient must not incorporate any other changes to the IPN Portal amendment. Bilateral amendments provided through the IPN Portal are not effective until the both the Recipient and the AO sign the amendment;
- (2) Notify the AO in writing if the amendment requires negotiation of additional changes to terms and conditions of the award; or
- (3) Notify the AO that the Recipient declines to sign the amendment.

Within 30 calendar days of receipt of a signed amendment from the Recipient, the AO must provide the fully executed amendment to the Recipient or initiate discussions with the Recipient.

[END OF PROVISION]

M24. PILOT PROGRAM FOR ENHANCEMENT OF GRANTEE EMPLOYEE WHISTLEBLOWER PROTECTIONS (SEPTEMBER 2014)

The requirement to comply with and inform all employees of the "Pilot Program for Enhancement of Contractor Employee Whistleblower Protections" is retroactively effective for all assistance awards and subawards (including subcontracts) issued beginning July 1, 2013.

The Grantee must:

1. Inform its employees working under this award in the predominant native language of the workforce that they are afforded the employee whistleblower rights and protections provided under 41 U.S.C. § 4712; and
2. Include such requirement in any subaward or subcontract made under this award.

41 U.S.C. § 4712 states that an employee of a Grantee may not be discharged, demoted, or otherwise discriminated against as a reprisal for "whistleblowing." In addition, whistleblower protections cannot be waived by any agreement, policy, form, or condition of employment.

Whistleblowing is defined as making a disclosure "that the employee reasonably believes" is evidence of any of the following:

- Gross mismanagement of a Federal contract or grant;
- A gross waste of Federal funds;
- An abuse of authority relating to a Federal contract or grant;
- A substantial and specific danger to public health or safety; or
- A violation of law, rule, or regulation related to a Federal contract or grant (including the competition for, or negotiation of, a contract or grant).

To qualify under the statute, the employee's disclosure must be made to:

- A Member of the U.S. Congress, or a representative of a U.S. Congressional Committee;
- A cognizant U.S. Inspector General;
- The U.S. Government Accountability Office;
- A Federal employee responsible for contract or grant oversight or management at the relevant agency;
- A U.S. court or grand jury; or,
- A management official or other employee of the Grantee who has the responsibility to investigate, discover, or address misconduct.

[END OF PROVISION]

M25. SUBMISSION OF DATASETS TO THE DEVELOPMENT DATA LIBRARY (OCTOBER 2014)

a. Definitions. For the purpose of submissions to the DDL:

- (1) "Dataset" is an organized collection of structured data, including data contained in spreadsheets, whether presented in tabular or non-tabular form. For example, a Dataset may represent a single spreadsheet, an extensible mark-up language (XML) file, a geospatial data file, or an organized collection of these. This requirement does not apply to aggregated performance reporting data that the recipient submits directly to a USAID portfolio management system or to unstructured data, such as email messages, PDF files, PowerPoint presentations, word processing documents, photos and graphic images, audio files, collaboration software, and instant messages. Neither does the requirement apply to the recipient's information that is incidental to award administration, such as financial, administrative, cost or pricing, or management information. Datasets submitted to the DDL will generally be those generated with USAID resources and created in support of Intellectual Work that is uploaded to the Development Experience Clearinghouse (DEC) (See M21. SUBMISSIONS TO THE DEVELOPMENT EXPERIENCE CLEARINGHOUSE AND PUBLICATIONS (JUNE 2012)).

- (2) “Intellectual Work” includes all works that document the implementation, monitoring, evaluation, and results of international development assistance activities developed or acquired under this award, which may include program and communications materials, evaluations and assessments, information products, research and technical reports, progress and performance reports required under this award (excluding administrative financial information), and other reports, articles and papers prepared by the recipient under the award, whether published or not. The term does not include the recipient’s information that is incidental to award administration, such as financial, administrative, cost or pricing, or management information.

b. Submissions to the Development Data Library (DDL)

- (1) The recipient must submit to the Development Data Library (DDL) at www.usaid.gov/data, in a machine-readable, non-proprietary format, a copy of any Dataset created or obtained in performance of this award, including Datasets produced by a subawardee or a contractor at any tier. The submission must include supporting documentation describing the Dataset, such as code books, data dictionaries, data gathering tools, notes on data quality, and explanations of redactions.
- (2) Unless otherwise directed by the Agreement Officer (AO) or the Agreement Officer Representative (AOR), the recipient must submit the Dataset and supporting documentation to the DDL within thirty (30) calendar days after the Dataset is first used to produce an Intellectual Work or is of sufficient quality to produce an Intellectual Work. Within thirty (30) calendar days after award completion, the recipient must submit to the DDL any Datasets and supporting documentation that have not previously been submitted to the DDL, along with an index of all Datasets and Intellectual Work created or obtained under the award. The recipient must also provide to the AOR an itemized list of any and all DDL submissions.

The recipient is not required to submit the data to the DDL, when, in accordance with the terms and conditions of this award, Datasets containing results of federally funded scientific research are submitted to a publicly accessible research database. However, the recipient must submit a notice to the DDL by following the instructions at www.usaid.gov/data, with a copy to the agreement officer representative, providing details on where and how to access the data. The direct results of federally funded scientific research must be reported no later than when the data are ready to be submitted to a peer-reviewed journal for publication, or no later than five calendar days prior to the conclusion of the award, whichever occurs earlier.

- (3) The recipient must submit the Datasets following the submission instructions and acceptable formats found at www.usaid.gov/data.
- (4) The recipient must ensure that any Dataset submitted to the DDL does not contain any proprietary or personally identifiable information, such as social security numbers, home

addresses, and dates of birth. Such information must be removed prior to submission.

- (5) The recipient must not submit classified data to the DDL.

[END OF PROVISION]

M26. PROHIBITION ON REQUIRING CERTAIN INTERNAL CONFIDENTIALITY AGREEMENTS OR STATEMENTS (MAY 2017)

- (a) Definitions.

“Contract” has the meaning given in 2 CFR Part 200.

“Contractor” means an entity that receives a contract as defined in 2 CFR Part 200.

“Internal confidentiality agreement or statement” means a confidentiality agreement or any other written statement that the recipient requires any of its employees or subrecipients to sign regarding nondisclosure of recipient information, except that it does not include confidentiality agreements arising out of civil litigation or confidentiality agreements that recipient employees or subrecipients sign at the behest of a Federal agency.

“Subaward” has the meaning given in 2 CFR Part 200.

“Subrecipient” has the meaning given in 2 CFR Part 200.

- (b) The recipient must not require its employees, subrecipients, or contractors to sign or comply with internal confidentiality agreements or statements that prohibit or otherwise restrict employees, subrecipients, or contractors from lawfully reporting waste, fraud, or abuse related to the performance of a Federal award to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (for example, the Agency Office of the Inspector General).
- (c) The recipient must notify current employees and subrecipients that prohibitions and restrictions of any preexisting internal confidentiality agreements or statements covered by this provision, to the extent that such prohibitions and restrictions are inconsistent with the prohibitions of this provision, are no longer in effect.
- (d) The prohibition in paragraph (b) of this provision does not contravene the requirements applicable to Standard Form 312 (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.
- (e) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further

Continuing Appropriations Act, 2015, (Pub. L. 113-235), and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions) use of funds appropriated (or otherwise made available) is prohibited, if the Government determines that the recipient is not in compliance with the requirements of this provision.

- (f) The recipient must include the substance of this provision, including this paragraph (f), in subawards and contracts under such awards.

[END OF PROVISION]

M27. CHILD SAFEGUARDING (JUNE 2015)

- (a) Because the activities to be funded under this award may involve children, or personnel engaged in the implementation of the award may come into contact with children, these activities could raise the risk of child abuse, exploitation, or neglect within USAID-funded programs. The organization agrees to abide by the following child safeguarding core principles:
- (1) Ensure compliance with host country and local child welfare and protection legislation or international standards, whichever gives greater protection, and with U.S. law where applicable;
 - (2) Prohibit all personnel from engaging in child abuse, exploitation, or neglect;
 - (3) Consider child safeguarding in project planning and implementation to determine potential risks to children that are associated with project activities and operations;
 - (4) Apply measures to reduce the risk of child abuse, exploitation, or neglect, including, but not limited to, limiting unsupervised interactions with children; prohibiting exposure to pornography; and complying with applicable laws, regulations, or customs regarding the photographing, filming, or other image-generating activities of children;
 - (5) Promote child-safe screening procedures for personnel, particularly personnel whose work brings them in direct contact with children; and
 - (6) Have a procedure for ensuring that personnel and others recognize child abuse, exploitation, or neglect; mandating that personnel and others report allegations; investigating and managing allegations; and taking appropriate action in response to such allegations, including, but not limited to, dismissal of personnel.
- (b) The organization must also include in their code of conduct for all personnel implementing USAID-funded activities the child safeguarding principles in (a) (1) through (6).
- (c) The following definitions apply for purposes of this provision:

- (1) Child: A child or children are defined as persons who have not attained 18 years of age.
 - (2) Child abuse, exploitation, or neglect: Constitutes any form of physical abuse; emotional ill-treatment; sexual abuse; neglect or insufficient supervision; trafficking; or commercial, transactional, labor, or other exploitation resulting in actual or potential harm to the child's health, well-being, survival, development, or dignity. It includes, but is not limited to: any act or failure to act which results in death, serious physical or emotional harm to a child, or an act or failure to act which presents an imminent risk of serious harm to a child.
 - (3) Physical abuse: Constitutes acts or failures to act resulting in injury (not necessarily visible), unnecessary or unjustified pain or suffering without causing injury, harm or risk of harm to a child's health or welfare, or death. Such acts may include, but are not limited to: punching, beating, kicking, biting, shaking, throwing, stabbing, choking, or hitting (regardless of object used), or burning. These acts are considered abuse regardless of whether they were intended to hurt the child.
 - (4) Sexual Abuse: Constitutes fondling a child's genitals, penetration, incest, rape, sodomy, indecent exposure, and exploitation through prostitution or the production of pornographic materials.
 - (5) Emotional abuse or ill treatment: Constitutes injury to the psychological capacity or emotional stability of the child caused by acts, threats of acts, or coercive tactics. Emotional abuse may include, but is not limited to: humiliation, control, isolation, withholding of information, or any other deliberate activity that makes the child feel diminished or embarrassed.
 - (6) Exploitation: Constitutes the abuse of a child where some form of remuneration is involved or whereby the perpetrators benefit in some manner. Exploitation represents a form of coercion and violence that is detrimental to the child's physical or mental health, development, education, or well-being.
 - (7) Neglect: Constitutes failure to provide for a child's basic needs within USAID-funded activities that are responsible for the care of a child in the absence of the child's parent or guardian.
- (d) The recipient must insert the provisions in (a) and (b) in all sub-awards under this award.

[END OF PROVISION]

M28. MANDATORY DISCLOSURES (JULY 2015)

Consistent with 2 CFR §200.113, applicants and recipients must disclose, in a timely manner, in writing to the USAID Office of the Inspector General, with a copy to the cognizant Agreement Officer, all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. Subrecipients must disclose, in a timely manner, in

writing to the USAID Office of the Inspector General and to the prime recipient (pass through entity) all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award.

Disclosures must be sent to:

U.S. Agency for International Development
Office of the Inspector General
P.O. Box 657
Washington, DC 20044-0657

Phone: 1-800-230-6539 or 202-712-1023

Email: ig.hotline@usaid.gov

URL: <https://oig.usaid.gov/content/usaid-contractor-reporting-form>.

Failure to make required disclosures can result in any of the remedies described in 2 CFR §200.338 Remedies for noncompliance, including suspension or debarment (See 2 CFR 180, 2 CFR 780 and 31 U.S.C. 3321).

The recipient must include this mandatory disclosure requirement in all subawards and contracts under this award.

[END OF PROVISION]

M29. NONDISCRIMINATION AGAINST BENEFICIARIES (NOVEMBER 2016)

- (a) USAID policy requires that the recipient not discriminate against any beneficiaries in implementation of this award, such as, but not limited to, by withholding, adversely impacting, or denying equitable access to the benefits provided through this award on the basis of any factor not expressly stated in the award. This includes, for example, race, color, religion, sex (including gender identity, sexual orientation, and pregnancy), national origin, disability, age, genetic information, marital status, parental status, political affiliation, or veteran's status. Nothing in this provision is intended to limit the ability of the recipient to target activities toward the assistance needs of certain populations as defined in the award.
- (b) The recipient must insert this provision, including this paragraph, in all subawards and contracts under this award.

[END OF PROVISION]

M30. CONFLICT OF INTEREST (AUGUST 2018)

- a. A conflict of interest in the award, administration, or monitoring of subawards arises when an employee, officer, or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of these parties, has a

financial or other interest in, or a tangible personal benefit from, a subrecipient considered for a subaward. The officers, employees, and agents of the recipient may neither solicit nor accept gratuities, favors, or anything of monetary value from subrecipients or parties to subawards. However, recipients may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value.

- b. The recipient must maintain written standards of conduct covering conflicts of interest and governing the actions of its employees engaged in the selection, award, and administration of subawards. The standards must prohibit employees from using their positions for a purpose that constitutes or presents the appearance of a conflict of interest. The standards of conduct must provide for disciplinary actions to be applied for violations of such standards by officers, employees, or agents of the recipient.
- c. The recipient must also maintain written standards of conduct covering organizational conflicts of interest. Organizational conflicts of interest means a situation in which the recipient is unable or appears to be unable to be impartial in conducting a subaward action involving a related organization because of relationships with a parent company, affiliate, or subsidiary organization.
- d. The recipient must have a system or systems in place to identify, address, resolve, and disclose to USAID any conflicts of interest as described in this provision that affect any subaward, regardless of the amount of funding.
- e. The recipient must disclose any conflict of interest, including organizational conflicts of interest, and the recipient's approach for resolving the conflict of interest to the cognizant Agreement Officer for the award within ten (10) calendar days of the discovery of the conflict of interest.
- f. Upon notice from the recipient of a potential conflict of interest and the approach for resolving it, the Agreement Officer will make a determination regarding the effectiveness of the recipient's actions to resolve the conflict of interest within thirty (30) calendar days of receipt of the recipient's notice, unless the Agreement Officer advises the recipient that a longer period is necessary.
- g. The recipient must not request payment from USAID for costs for transactions subject to the conflict of interest pending notification of USAID's determination. The recipient's failure to disclose a conflict of interest may result in cost disallowances by USAID.
- h. For conflicts of interest, including organizational conflicts of interest, involving contracts, the recipient must follow 2 CFR 200.318, general procurement standards.
- i. The recipient must insert the substance of this provision, including paragraph (i), in all subawards under this award, at any subaward tier.

[END OF PROVISION]

**REQUIRED AS APPLICABLE STANDARD PROVISIONS FOR U.S.
NONGOVERNMENTAL ORGANIZATIONS**

RAA1. NEGOTIATED INDIRECT COST RATES – PREDETERMINED (NOVEMBER 2020)

- a. The allowable indirect costs must be determined by applying the predetermined indirect cost rates to the bases specified in the schedule of this award.
- b. Except as otherwise provided in 2 CFR 200.414 Indirect (F&A) costs paragraph (e) and (f), a nonprofit organization which has not previously established an indirect cost rate with a Federal agency must submit its initial indirect cost proposal immediately after the organization is advised that a Federal award will be made and, in no event, later than three months after the effective date of the Federal award.

Organizations that have previously established indirect cost rates must submit a new indirect cost proposal to the cognizant agency for indirect costs within six months after the close of each fiscal year.

If USAID is the cognizant agency or no cognizant agency has been designated, the recipient must submit four copies of the audit report, the proposed predetermined indirect cost rates, and supporting cost data to the Overhead, Special Costs, and Closeout Branch, Management Bureau, Office of Acquisition and Assistance, USAID, Washington, DC 20523-7802. The proposed rates must be based on the recipient's actual cost experience during that fiscal year. Negotiations of predetermined indirect cost rates must begin soon after receipt of the recipient's proposal.

- c. Allowability of costs and acceptability of cost allocation methods must be determined in accordance with the applicable cost principles.
- d. The results of each negotiation must be set forth in an indirect cost rate agreement signed by both parties. Such agreement is automatically incorporated into this award and must specify (1) the agreed upon predetermined rates, (2) the bases to which the rates apply, and (3) the fiscal year for which the rates apply. The indirect cost rate agreement must not change any monetary ceiling, award obligation, or specific cost allowance or disallowance provided for in this award.
- e. Predetermined rate means an indirect cost rate, applicable to a specified current or future period, usually the organization's fiscal year. The rate is based on an estimate of the costs to be incurred during the period. A predetermined rate is not subject to adjustment.
- f. If a dispute arises in a negotiation of an indirect cost rate between the cognizant agency for indirect costs and the nonprofit organization, the dispute must be resolved in accordance with the appeals procedures of the cognizant agency for indirect costs.

[END OF PROVISION]

RAA5. EXCHANGE VISITORS AND PARTICIPANT TRAINING (JUNE 2012)

For any Exchange Visitor, Participant Training or Invitational Travel activities, the recipient must comply with this provision.

a. Definitions:

- (1) An **Exchange Visitor** is any host-country or third-country national traveling to the U.S., for any purpose, including Participant Training and Invitational Travel, funded by USAID in whole or in part, directly or indirectly.
- (2) A **Participant** is a host-country or third-country national sponsored by USAID for a Participant Training activity taking place in the U.S., a third country, or in the host country.
- (3) **Participant Training** is a learning activity conducted within the U.S., a third country, or in the host country for the purpose of furthering USAID development objectives. A learning activity takes place in a setting in which an individual (the Participant) interacts with a knowledgeable professional, predominantly for the purpose of acquiring knowledge or skills for the professional or technical enhancement of the individual. Learning activities may be formally structured, such as an academic program or a technical course, or they may be more informal, such as an observational study tour.
- (4) **Invitational Travel** is a type of travel that USAID funds for non-U.S. Government employees. This type of travel may be approved for both U.S. and foreign citizens who are not employed by the U.S. Government (USG), not receiving any type of compensation from the USG for such travel, and only when it is determined that the functions to be performed are essential to the interests of USAID.

b. Program Monitoring and Data Reporting: The recipient must monitor Exchange Visitors' and Participants' progress during their program and ensure that problems are identified and resolved quickly.

- (1) For U.S.-based activities, the recipient must use USAID's official Exchange Visitor and Participant Training information system, currently called "Training Results and Information Network – TraiNet" (see <http://trainethelp.usaid.gov/>), to report and manage Exchange Visitor and Participant Training data. The recipient must also use the USAID Visa Compliance System – VCS (see <http://trainethelp.usaid.gov/>) to transfer required data for USAID Exchange Visitors to the Department of Homeland Security's Student and Exchange Visitor Information System (SEVIS).
- (2) For all third-country activities, and for host-country activities of two consecutive days or 16 contact hours or more in duration, the recipient must use USAID's official

Exchange Visitor and Participant Training information system, currently called “Training Results and Information Network – TraiNet” (see <http://trainethelp.usaid.gov/>), to report and manage Participant Training data.

c. Health and Accident Insurance:

- (1) For Exchange Visitors traveling to the United States, the recipient must enroll Exchange Visitors in health and accident insurance coverage that meets or exceeds Department of State and USAID minimum coverage requirements as set forth in 22 CFR 62.14 and ADS 253.3.6.2. The requirements may be obtained from the Agreement Officer’s Representative.
- (2) For Participants traveling to a third country, the recipient must obtain health and accident insurance coverage for all Participants.
- (3) For Participants traveling within the host country, the recipient must determine whether specific in-country participant training activities subject them to any risk of health and accident liability for medical costs. Participants may incur, and if so, take appropriate steps according to the local situation, including obtaining health and accident insurance coverage for Participants.

d. Immigration Requirements:

- (1) For Exchange Visitors traveling to the United States, the recipient must ensure that all USAID-sponsored Exchange Visitors obtain, use, and comply with the terms of the J-1 visa, issued in conjunction with a USAID-issued Certificate of Eligibility for J-1 Visa Status (DS-2019).
- (2) For Participants traveling to a third country or within the host country, the recipient must ensure that all Participants obtain, use, and comply with the terms of all applicable immigration, visa and other similar requirements.

e. Language Proficiency: The recipient must verify language proficiency. Exchange Visitors must possess sufficient English language proficiency to participate in a U.S.-based activity. Participants of third-country or host-country training must be proficient in the language of training at a sufficient level for participation, unless an interpreter has been arranged. Language competency can be verified through a variety of means including proficiency assessments of interviews, publications, presentations, education conducted in English, and formal testing.

f. Pre-departure Orientation: The recipient must conduct pre-departure orientation for U.S.-bound Exchange Visitors and Participants of third-country training programs. Pre-departure orientation covers: program objectives; administrative and policy review; cultural aspects; and training/learning methods.

- g. **Conditions of Sponsorship:** The recipient must ensure that all Exchange Visitors read and sign the Conditions of Sponsorship for U.S.-Based Activities form (AID 1381-6). The recipient must also ensure that all Participants of long-term (six months or longer) third-country training read and sign the form Conditions of Sponsorship for Third-Country Training form (AID 1381-7). The recipient must report to the Agreement Officer any known violations by Exchange Visitors of visa or other immigration requirements or conditions.
- h. **Exchange Visitor Security Risk and Fraud Inquiry:** Each USAID Mission has an established process for conducting a Security Risk and Fraud Inquiry (SRFI) for Exchange Visitors. The recipient must be prepared to assist Missions in conducting the SRFI, if requested. However, the recipient's role is contributive, and the Mission is ultimately responsible for conducting the SRFI.
- i. **Fly America:** To the extent that participants travel by international air travel, the recipient must comply with the Standard Provision, "International Air Travel and Air Transportation of Property."
- j. **Use of Minority Serving Institutions:** For U.S.-based Participant Training, the recipient must, to the maximum extent possible, maintain their use of Historically Black Colleges and Universities (HBCUs) and other Minority Serving Institutions (MSIs), including Hispanic Serving Institutions and Tribal Colleges and Universities, as training or education providers.

[END OF PROVISION]

RAA7. PROTECTION OF THE INDIVIDUAL AS A RESEARCH SUBJECT (APRIL 1998)

- a. Safeguarding the rights and welfare of human subjects involved in research supported by USAID is the responsibility of the organization to which support is awarded. USAID has adopted the Common Federal Policy for the Protection of Human Subjects, Part 225 of Title 22 of the Code of Federal Regulations (the "Policy"). Additional interpretation, procedures, and implementation guidance of the Policy are found in USAID General Notice entitled "Procedures for the Protection of Human Subjects in Research Supported by USAID," issued April 19, 1995, as amended. USAID's Cognizant Human Subjects Officer (CHSO) in USAID/W has oversight, guidance, and interpretation responsibility for the Policy.
- b. Recipient organizations must comply with USAID policy when humans are the subject of research, as defined in 22 CFR 225.102(d), funded by the grant and recipients must provide "assurance," as required by 22 CFR 225.103, that they follow and abide by the procedures in the Policy. See also Section 5 of the April 19, 1995, USAID General Notice which sets forth activities to which the Policy is applicable. The existence of a bona fide, applicable assurance approved by the Department of Health and Human Services (HHS) such as the "multiple project assurance" (MPA) will satisfy this requirement. Alternatively, organizations can provide an acceptable written assurance to USAID as described in 22 CFR 225.103.

Such assurances must be determined by the CHSO to be acceptable prior to any applicable research being initiated or conducted under the award. In some limited instances outside the U.S., alternative systems for the protection of human subjects may be used provided they are deemed “at least equivalent” to those outlined in Part 225 (See 22 CFR 225.101[h]). Criteria and procedures for making this determination are described in the General Notice cited in the preceding paragraph.

- c. Since the welfare of the research subject is a matter of concern to USAID as well as to the organization, USAID staff consultants and advisory groups may independently review and inspect research and research processes and procedures involving human subjects, and based on such findings, the CHSO may prohibit research which presents unacceptable hazards or otherwise fails to comply with USAID procedures. Informed consent documents must include the stipulation that the subject's records may be subject to such review.

[END OF PROVISION]

RAA8. CARE OF LABORATORY ANIMALS (MARCH 2004)

CARE OF LABORATORY ANIMALS (MARCH 2004)

- a. Before undertaking performance of any grant involving the use of laboratory animals, the recipient must register with the Secretary of Agriculture of the United States in accordance with Section 6, Public Law 89-544, Laboratory Animal Welfare Act, August 24, 1966, as amended by Public Law 91-579, Animal Welfare Act of 1970, December 24, 1970. The recipient must furnish evidence of such registration to the Agreement Officer.
- b. The recipient must acquire animals used in research under this award only from dealers licensed by the Secretary of Agriculture, or from exempted sources in accordance with the Public Laws enumerated in a. above.
- c. In the care of any live animals used or intended for use in the performance of this grant, the recipient must adhere to the principles enunciated in the Guide for Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences - National Research Council (NAS-NRC), and in the United States Department of Agriculture's (USDA) regulations and standards issued under the Public Laws enumerated in a. above. In case of conflict between standards, the higher standard must be used. The recipient's reports on portions of the award in which animals were used must contain a certificate stating that the animals were cared for in accordance with the principles enunciated in the Guide for Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, NAS-NRC, and/or in the regulations and standards as promulgated by the Agricultural Research Service, USDA, pursuant to the Laboratory Animal Welfare Act of 24 August 1966, as amended (P.L. 89-544 and P.L. 91-579). NOTE: The recipient may request registration of the recipient's facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which the recipient's research facility is located. The location of the appropriate APHIS Regional Office as well as information concerning this program may be obtained by contacting the Senior Staff

Office, Animal Care Staff, USDA/APHIS, 4700 River Road, Unit 84, Riverdale, MD 20737-1234 and at www.aphis.usda.gov/animal_welfare/index.shtml.

[END OF PROVISION]

RAA10. COST SHARING (MATCHING) (FEBRUARY 2012)

COST SHARING (MATCHING) (FEBRUARY 2012)

- a. If at the end of any funding period, the recipient has expended an amount of non-Federal funds less than the agreed upon amount or percentage of total expenditures, the Agreement Officer may apply the difference to reduce the amount of USAID incremental funding in the following funding period. If the award has expired or has been terminated, the Agreement Officer may require the recipient to refund the difference to USAID.
- b. The source and nationality requirements and the restricted goods provision established in the Standard Provision entitled "USAID Eligibility Rules for Goods and Services" do not apply to cost sharing (matching) expenditures.

[END OF PROVISION]

RAA11. PROHIBITION OF ASSISTANCE TO DRUG TRAFFICKERS (JUNE 1999)

- a. USAID reserves the right to terminate assistance to, or take other appropriate measures with respect to, any participant approved by USAID who is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR 140.
- b.
 - (1) For any loan over \$1,000 made under this agreement, the recipient must insert a clause in the loan agreement stating that the loan is subject to immediate cancellation, acceleration, recall, or refund by the recipient if the borrower or a key individual of a borrower is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR 140.
 - (2) Upon notice by USAID of a determination under section (1) and at USAID's option, the recipient agrees to immediately cancel, accelerate, or recall the loan, including refund in full of the outstanding balance. USAID reserves the right to have the loan refund returned to USAID.
- c.
 - (1) The recipient agrees not to disburse, or sign documents committing the recipient to disburse, funds to a subrecipient designated by USAID ("Designated Subrecipient") until advised by USAID that: (i) any United States Government review of the Designated Subrecipient and its key individuals has been completed; (ii) any related certifications have been obtained; and (iii) the assistance to the Designated Subrecipient has been

approved. Designation means that the subrecipient has been unilaterally selected by USAID as the subrecipient. USAID approval of a subrecipient, selected by another party, or joint selection by USAID and another party is not designation.

- (2) The recipient must insert the following clause, or its substance, in its agreement with the Designated Subrecipient:

“The recipient reserves the right to terminate this [Agreement/Contract] or take other appropriate measures if the [Subrecipient] or a key individual of the [Subrecipient] is found to have been convicted of a narcotic offense or to have been engaged in drug trafficking as defined in 22 CFR 140.”

[END OF PROVISION]

RAA13. REPORTING HOST GOVERNMENT TAXES (DECEMBER 2014)

- a. By April 16 of each year, the recipient must submit a report containing:
- (1) Contractor/recipient name.
 - (2) Contact name with phone, fax and e-mail.
 - (3) Agreement number(s).
 - (4) The total amount of value-added taxes and customs duties (but not sales taxes) assessed by the host government (or any entity thereof) on purchases in excess of \$500 per transaction of supplies, materials, goods or equipment, during the 12 months ending on the preceding September 30, using funds provided under this contract/agreement.
 - (5) Any reimbursements received by April 1 of the current year on value-added taxes and customs duties reported in (iv).
 - (6) Reports are required even if the recipient did not pay any taxes or receive any reimbursements during the reporting period.
 - (7) Cumulative reports may be provided if the recipient is implementing more than one program in a foreign country.
- b. Submit the reports to: Agreement’s Officer Representative.
- a. Host government taxes are not allowable where the Agreement Officer provides the necessary means to the recipient to obtain an exemption or refund of such taxes, and the recipient fails to take reasonable steps to obtain such exemption or refund. Otherwise, taxes

are allowable in accordance with the Standard Provision, “Allowable Costs,” and must be reported as required in this provision.

- b. The recipient must include this reporting requirement in all applicable subawards and contracts.

[END OF PROVISION]

RAA14. FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)

FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)

- a. U.S. Government funds under this award must not be used to finance the travel, per diem, hotel expenses, meals, conference fees or other conference costs for any member of a foreign government’s delegation to an international conference sponsored by a multilateral organization, as defined below, unless approved by the Agreement Officer in writing.
- b. Definitions:
 - (1) A foreign government delegation is appointed by the national government (including ministries and agencies but excluding local, state and provincial entities) to act on behalf of the appointing authority at the international conference. A conference participant is a delegate for the purposes of this provision, only when there is an appointment or designation that the individual is authorized to officially represent the government or agency. A delegate may be a private citizen.
 - (2) An international conference is a meeting where there is an agenda, an organizational structure, and delegations from countries other than the conference location, in which country delegations participate through discussion, votes, etc.
 - (3) A multilateral organization is an organization established by international agreement and whose governing body is composed principally of foreign governments or other multilateral organizations.

[END OF PROVISION]

RAA18. USAID DISABILITY POLICY - ASSISTANCE (DECEMBER 2004)

- a. The objectives of the USAID Disability Policy are (1) to enhance the attainment of United States foreign assistance program goals by promoting the participation and equalization of opportunities of individuals with disabilities in USAID policy, country and sector strategies, activity designs and implementation; (2) to increase awareness of issues of people with disabilities both within USAID programs and in host countries; (3) to engage other U.S. Government agencies, host country counterparts, governments, implementing organizations

and other donors in fostering a climate of nondiscrimination against people with disabilities; and (4) to support international advocacy for people with disabilities.

- b. USAID therefore requires that the recipient not discriminate against people with disabilities in the implementation of USAID funded programs and that it make every effort to comply with the objectives of the USAID Disability Policy in performing the program under this grant or cooperative agreement. To that end and to the extent it can accomplish this goal within the scope of the program objectives, the recipient should demonstrate a comprehensive and consistent approach for including men, women, and children with disabilities.

[END OF PROVISION]

RAA23. UNIVERSAL IDENTIFIER AND SYSTEM OF AWARD MANAGEMENT (NOVEMBER 2020)

- a. **Requirement for System of Award Management (SAM).** Unless you are exempted from this requirement under 2 CFR 25.110, you as the recipient must maintain current information in the SAM. This includes information on your immediate and highest level owner and subsidiaries, as well as on all of your predecessors that have been awarded a Federal contract or Federal financial assistance within the last three years, if applicable, until you submit the final financial report required under this Federal award or receive the final payment, whichever is later. This requires that you review and update the information at least annually after the initial registration, and more frequently, if required by changes in your information or another Federal award term.
- b. **Requirement for Unique Entity Identifier.** If you are authorized to make subawards under this Federal award, you:
 - (1) Must notify potential subrecipients that no entity (see definition in paragraph c. of this award term) may receive a subaward from you until the entity has provided its Unique Entity Identifier to you.
 - (2) May not make a subaward to an entity unless the entity has provided its Unique Entity Identifier to you. Subrecipients are not required to obtain an active SAM registration but must obtain a Unique Entity Identifier.
- c. **Definitions.** For purposes of this award term:
 - (1) System of Award Management (SAM) means the Federal repository into which a recipient must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM Internet site (currently at <https://www.sam.gov>).

- (2) Unique Entity Identifier means the identifier assigned by SAM to uniquely identify business entities.
- (3) Entity includes non-Federal entities as defined in 2 CFR 200.1 and also includes all of the following, for purposes of this part:
 - a. A foreign organization;
 - b. A foreign public entity;
 - c. A domestic for-profit organization; and
 - d. A Federal agency.
- (4) Subaward has the meaning given in 2 CFR 200.1.
- (5) Subrecipient has the meaning given in 2 CFR 200.1.

ADDENDUM (NOVEMBER 2020):

- d. **Exceptions.** The requirements of this provision to obtain a Unique Entity Identifier and maintain a current registration in the SAM do not apply, at the prime award or subaward level, to:
 - (1) Awards to individuals
 - (2) Awards less than \$25,000 to foreign recipients to be performed outside the United States (based on a USAID determination)
 - (3) Awards where the Agreement Officer determines, in writing, that the Agency must protect entity information from disclosure due to national security or foreign policy interests of the United States or that these requirements would cause personal safety concerns.
- e. This provision does not need to be included in subawards.

[END OF PROVISION]

**RAA24. REPORTING SUBAWARDS AND EXECUTIVE COMPENSATION
(NOVEMBER 2020)**

- a. **Reporting of first-tier subawards.**
 - (1) Applicability. Unless you are exempt as provided in paragraph d. of this award term, you must report each action that equals or exceeds \$30,000 in Federal funds for a subaward to a non-Federal entity or Federal agency (see definitions in paragraph e. of this award term).

(2) Where and when to report.

- (i) The non-Federal entity or Federal agency must report each obligating action described in paragraph a.(1) of this award term to www.fsrs.gov.
- (ii) For subaward information, report no later than the end of the month following the month in which the obligation was made. (For example, if the obligation was made on November 7, 2010, the obligation must be reported by no later than December 31, 2010.)

(3) What to report. You must report the information about each obligating action that the submission instructions posted at www.fsrs.gov specify.

b. Reporting Total Compensation of Recipient Executives.

(1) Applicability and what to report. You must report total compensation for each of your five most highly compensated executives for the preceding completed fiscal year, if –

- (i) The total Federal funding authorized to date under this Federal award equals or exceeds \$30,000 as defined in 2 CFR 170.320;
- (ii) In the preceding fiscal year, you received—
 - (A) 80 percent or more of your annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
 - (B) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
- (iii) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at www.sec.gov/answers/execomp.htm.)

(2) Where and when to report. You must report executive total compensation described in paragraph b.(1) of this award term:

- (i) As part of your registration profile at www.sam.gov.
- (ii) By the end of the month following the month in which this award is made, and annually thereafter.

c. Reporting of Total Compensation of Subrecipient Executives.

- (1) Applicability and what to report. Unless you are exempt as provided in paragraph d. of this award term, for each first-tier subrecipient under this award, you must report the names and total compensation of each of the subrecipient's five most highly compensated executives for the subrecipient's preceding completed fiscal year, if—
 - (i) In the subrecipient's preceding fiscal year, the subrecipient received—
 - (A) 80 percent or more of its annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
 - (B) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts), and Federal financial assistance subject to the Transparency Act (and subawards); and
 - (ii) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at www.sec.gov/answers/execomp.htm.)
- (2) Where and when to report. You must report subrecipient executive total compensation described in paragraph c.(1) of this award term:
 - (i) To the recipient.
 - (ii) By the end of the month following the month during which you make the subaward. For example, if a subaward is obligated on any date during the month of October of a given year (for example, between October 1 and 31), you must report any required compensation information of the subrecipient by November 30 of that year.

d. Exemptions.

If, in the previous tax year, you had gross income, from all sources, under \$300,000, you are exempt from the requirements to report:

- (1) Subawards, and
- (2) The total compensation of the five most highly compensated executives of any subrecipient.

e. Definitions.

For purposes of this award term:

- (1) Federal Agency means a Federal agency as defined at 5 U.S.C. 551(1) and further clarified by 5 U.S.C. 552(f).
- (2) Entity means all of the following, as defined in 2 CFR 25:
 - (i) A governmental organization, which is a State, local government, or Indian tribe;
 - (ii) A foreign public entity;
 - (iii) A domestic or foreign nonprofit organization; and
 - (iv) A domestic or foreign for-profit organization.
- (3) Executive means officers, managing partners, or any other employees in management positions.
- (4) Subaward:
 - (i) This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.
 - (ii) The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see 2 CFR 200.331).
 - (iii) A subaward may be provided through any legal agreement, including an agreement that you or a subrecipient considers a contract.
- (5) Subrecipient means a non-Federal entity or Federal agency that:
 - (i) Receives a subaward from you (the recipient) under this award; and
 - (ii) Is accountable to you for the use of the Federal funds provided by the subaward.
- (6) Total compensation means the cash and noncash dollar value earned by the executive during the recipient's or subrecipient's preceding fiscal year and includes the following (for more information see 17 CFR 229.402(c)(2)):
 - (i) Salary and bonus.

- (ii) Awards of stock, stock options, and stock appreciation rights. Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Statement of Financial Accounting Standards No. 123 (Revised 2004) (FAS 123R), Shared Based Payments.
- (iii) Earnings for services under nonequity incentive plans. This does not include group life, health, hospitalization, or medical reimbursement plans that do not discriminate in favor of executives, and are available generally to all salaried employees.
- (iv) Change in pension value. This is the change in present value of defined benefit and actuarial pension plans.
- (v) Above-market earnings on deferred compensation which is not tax-qualified.
- (vi) Other compensation, if the aggregate value of all such other compensation (for example, severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property) for the executive exceeds \$10,000.

[END OF PROVISION]

RAA25. PATENT REPORTING PROCEDURES (NOVEMBER 2020)

As incorporated by 2 CFR 200.315 and the standard provision “APPLICABILITY OF 2 CFR 200 and 2 CFR 700,” the clause at 37 CFR 401.14 (“Standard Patent Rights”) is incorporated by reference into this award as if set forth in full text. The recipient must use the National Institutes of Health EDISON Patent Reporting and Tracking system (<http://www.iedison.gov>) to fulfill its disclosure obligations under 37 CFR 401.14(c)(1). The recipient must also submit reports on utilization of subject inventions annually to the Agreement Officer’s Representative under 37 CFR 401.14(h), and the last report must be provided within 90 days of the expiration of the agreement.

[END OF PROVISION]

RAA26. ACCESS TO USAID FACILITIES AND USAID’S INFORMATION SYSTEMS (AUGUST 2013)

- a. A U.S. citizen or resident alien engaged in the performance of this award as an employee, consultant, or volunteer of a U.S organization may obtain access to USAID facilities or logical access to USAID’s information systems only when and to the extent necessary to carry out this award and in accordance with this provision. The recipient’s employees, consultants, or volunteers who are not U.S. citizen as well as employees, consultants, or volunteers of non-U.S.

- b. organizations, irrespective of their citizenship, will not be granted logical access to U.S. Government information technology systems (such as Phoenix, GLAAS, etc.) and must be escorted to use U.S. Government facilities (such as office space).
- c. Before a U.S. citizen or resident alien engaged in the performance of this award as an employee, consultant, or volunteer of the recipient, subrecipient or contractor at any tier may obtain a USAID ID (new or replacement) authorizing the individual routine access to USAID facilities in the United States, or logical access to USAID's information systems, the individual must provide two forms of identity source documents in original form. One identity source document must be a valid Federal or State government-issued picture ID. The recipient must contact the USAID Office of Security to obtain the list of acceptable forms of documentation. Submission of these documents, and related background checks, are mandatory in order for the individual to receive a building access ID, and before access will be granted to any of USAID's information systems. All such individuals must physically present these two source documents for identity proofing at their Security Briefing. All individuals provided access under this provision must return any issued building access ID and remote authentication token to USAID custody upon termination of the individual's employment with the recipient or completion of the award, whichever occurs first.
- d. Individuals engaged in the performance of this award as an employee, consultant, or volunteer of the recipient must comply with all applicable Homeland Security Policy Directive-12 (HSPD-12) and Personal Identity Verification (PIV) procedures, as described above, as well as any subsequent USAID or government-wide HSPD-12 and PIV procedures/policies, including any
- e. HSPD-12 procedures established by the Office of Security in USAID/Washington.
- f. The recipient is required to include this provision in all subawards and contracts at any tier made to a U.S. organization/company, that require employees or consultants engaged in the performance of this award to have routine physical access to USAID facilities or logical access to USAID's information systems in order to perform this award.

[END OF PROVISION]

RAA27. CONTRACT PROVISION FOR DBA INSURANCE UNDER RECIPIENT PROCUREMENTS (DECEMBER 2014)

All contracts made by the recipient under this award for services to be performed overseas must contain the following provision, as applicable.

Workers' Compensation Insurance (Defense Base Act)

- (a) The Contractor must--

- (1) Before commencing performance under this contract, establish provisions to provide for the payment of disability compensation and medical benefits to covered employees and death benefits to their eligible survivors, by purchasing Defense Base Act (DBA) insurance pursuant to the terms of the contract between USAID and USAID's DBA insurance carrier unless the Contractor qualifies as a self-insurer under the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 932) as extended by the Defense Base Act (42 U.S.C. 1651, et seq.), or has an approved retrospective rating agreement for DBA. The Contractor must continue to maintain these provisions to provide such Defense Base Act benefits until contract performance is completed.
- (2) If USAID or the Contractor has secured a waiver of DBA coverage in accordance with AIDAR 728.305-70(a) for contractor's employees who are not citizens of, residents of, or hired in the United States, the contractor agrees to provide such employees with worker's compensation benefits as required by the laws of the country in which the employees are working, or by the laws of the employee's native country, whichever offers greater benefits. The Department of Labor has granted partial blanket waivers of DBA coverage applicable to USAID-financed contracts performed in countries listed in the DEFENSE BASE ACT (DBA) WAIVER LIST.
- (3) Within ten days of an employee's injury or death or from the date the Contractor has knowledge of the injury or death, submit Form LS-202 (Employee's First Report of Injury or Occupational Illness) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 930(a), 20 CFR 702.201 to 702.203).
- (4) Pay all compensation due for disability or death within the timeframes required by the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914, 20 CFR 702.231 and 703.232).
- (5) Provide for medical care as required by the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 907, 20 CFR 702.402 and 702.419).
- (6) If controverting the right to compensation, submit Form LS-207 (Notice of Controversion of Right to Compensation) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914(d), 20 CFR 702.251).
- (7) Immediately upon making the first payment of compensation in any case, submit Form LS-206 (Payment of Compensation Without Award) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914(c), 20 CFR 702.234).
- (8) When payments are suspended or when making the final payment, submit Form LS-208 (Notice of Final Payment or Suspension of Compensation Payments) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914 (c) and (g), 20 CFR 702.234 and 702.235).

- (9) Adhere to all other provisions of the Longshore and Harbor Workers' Compensation Act as extended by the Defense Base Act, and Department of Labor regulations at 20 CFR Parts 701 to 704.

For additional information on the Longshore and Harbor Workers' Compensation Act requirements see <http://www.dol.gov/owcp/dlhwc/lbdba.htm>.

The Contractor must insert the substance of this clause including this paragraph (c), in all subcontracts to which the Defense Base Act applies.

[END OF PROVISION]

RAA28. AWARD TERM AND CONDITION FOR RECIPIENT INTEGRITY AND PERFORMANCE MATTERS (APRIL 2016)

A. Reporting of Matters Related to Recipient Integrity and Performance

1. General Reporting Requirement

If the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds \$10,000,000 for any period of time during the period of performance of this Federal award, then you as the recipient during that period of time must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) about civil, criminal, or administrative proceedings described in paragraph 2 of this award term and condition. This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available.

2. Proceedings About Which You Must Report

Submit the information required about each proceeding that:

- a. Is in connection with the award or performance of a grant, cooperative agreement, or procurement contract from the Federal Government;
- b. Reached its final disposition during the most recent five year period; and
- c. Is one of the following:
 - (1) A criminal proceeding that resulted in a conviction, as defined in paragraph 5 of this award term and condition;

- (2) A civil proceeding that resulted in a finding of fault and liability and payment of a monetary fine, penalty, reimbursement, restitution, or damages of \$5,000 or more;
- (3) An administrative proceeding, as defined in paragraph 5. of this award term and condition, that resulted in a finding of fault and liability and your payment of either a monetary fine or penalty of \$5,000 or more or reimbursement, restitution, or damages in excess of \$100,000; or
- (4) Any other criminal, civil, or administrative proceeding if:
 - (i) It could have led to an outcome described in paragraph 2.c.(1), (2), or (3) of this award term and condition;
 - (ii) It had a different disposition arrived at by consent or compromise with an acknowledgment of fault on your part; and
 - (iii) The requirement in this award term and condition to disclose information about the proceeding does not conflict with applicable laws and regulations.

3. Reporting Procedures

Enter in the SAM Entity Management area the information that SAM requires about each proceeding described in paragraph 2 of this award term and condition. You do not need to submit the information a second time under assistance awards that you received if you already provided the information through SAM because you were required to do so under Federal procurement contracts that you were awarded.

4. Reporting Frequency

During any period of time when you are subject to the requirement in paragraph 1 of this award term and condition, you must report proceedings information through SAM for the most recent five year period, either to report new information about any proceeding(s) that you have not reported previously or affirm that there is no new information to report. Recipients that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 must disclose semiannually any information about the criminal, civil, and administrative proceedings.

5. Definitions

For purposes of this award term and condition:

- a. Administrative proceeding means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative proceedings, Civilian Board of Contract Appeals

proceedings, and Armed Services Board of Contract Appeals proceedings). This includes proceedings at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include audits, site visits, corrective plans, or inspection of deliverables.

- b. Conviction, for purposes of this award term and condition, means a judgment or conviction of a criminal offense by any court of competent jurisdiction, whether entered upon a verdict or a plea, and includes a conviction entered upon a plea of nolo contendere.
- c. Total value of currently active grants, cooperative agreements, and procurement contracts includes—
 - (1) Only the Federal share of the funding under any Federal award with a recipient cost share or match; and
 - (2) The value of all expected funding increments under a Federal award and options, even if not yet exercised.

B. [Reserved]

[END OF PROVISION]

[END OF PROVISION]

RAA30. PROGRAM INCOME (AUGUST 2020)

PROGRAM INCOME (August 2020)

- a. Program income is gross income earned by the recipient that is directly generated by a supported activity or earned as a result of the Federal award during the period of performance. Program income includes, but is not limited to: income from fees for services performed; the use or rental of real or personal property acquired under Federal awards; the sale of commodities or items fabricated under a Federal award; license fees and royalties on patents and copyrights; and principal and interest on loans made with Federal award funds. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, or interest earned on any of them.
- b. Program income must be used for the purposes, and under the conditions, of the award, to further project objectives, program objectives, or award activities. Program income must be used only for allowable program costs. Interest earned on program income is subject to the same conditions as program income.
- c. The recipient must apply the approach for use of program income as specified in the schedule of the award. This may include one of the three approaches listed below (see also **2 CFR**

200.307). The recipient must also follow the standards in this provision to account for gross income earned from Federally-supported activities under this award.

1) If the deduction approach is used, the recipient must use the program income for current costs, prior to drawdown of USAID funds under the award.

2) If the addition approach is used, the total award amount is increased by the amount of program income. If the award anticipates a specific program income amount, any program income in excess of such amount must be deducted from expenditures.

3) If the cost sharing approach is used, the amount of the award remains the same. If the award anticipates a specific program income amount, any program income in excess of such amount must be deducted from expenditures.

d. Costs subject to generating program income under this award may be deducted from gross income to calculate program income, provided these costs have not been charged to this award and comply with the standard provision, “Allowable Costs.”

e. The recipient must report program income using the **Federal Financial Report, SF-425**. Program income must be accounted for in the same ratio as USAID’s participation in the program. For example, if USAID funded 75 percent of a recipient’s program, then the recipient must report 75 percent of any program income earned under the award as “Federal program income earned” on the SF-425.

f. The recipient should continue to use program income earned after the period of the award to further award objectives, but is not subject to Federal requirements governing the disposition of program income earned after the end of the period of performance for the award.

[END OF PROVISION]

[END OF STANDARD PROVISIONS]

ATTACHMENT D – BRANDING AND MARKING PLAN

From: Yager, Amanda L
Sent: Friday, December 17, 2021 1:51 PM
To: ORSO
Cc: Moore, Anke Marga-Christa
Subject: 141061 PATH subaward
Attachments: subaward-initiation-form PATH.pdf; 141061 PATH.pdf; 2020-1231 PATH FS and SAR_12.14.21.pdf; 2021 PATH W-9 Form_12.14.21.pdf

Attached is the subaward information for PATH under 141061. Let me know if you have any questions.

Amanda



Amanda Yager
Research Services Manager
Paul G. Allen School for Global Health
College of Veterinary Medicine
Washington State University
Email: ayager@wsu.edu

SUBAGREEMENT INITIATION FORM

Washington State University

Hover over each section for additional guidance

ORSO#: 141061

Project Title: PMU: Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)

Financial Overview:

1. Check if your subrecipient is listed as pre-approved, [here](#).
2. If not listed via the link above, please obtain and attach w/this form the subrecipient's most recent [Single Audit](#) for financial review. If unavailable, send recent tax record or certified financial statement.
3. No financial information? Please have subrecipient fill and return this [Subrecipient Questionnaire](#).

Attached with this form are the following:

☒ Statement of Work* ☒ Budget* ☐ Budget* Justification ☐ F&A Rate Agreement ☐ FCOI form ☐ RCR form ☒ Financial Documents
for New Supplier only: ☒ W9* Domestic ☐ W8* BEN/BENE Foreign

*Required attachments

WSU Information

PI: Felix Lankester Admin Contact: Amanda Yager
Phone: Phone:
Email: felix.lankester@wsu.edu Email: ayager@wsu.edu
Address: Paul G. Allen School for Global Animal Health PO Box 647090

☒ Federal Sponsor: USAID Prime Award #: 7200AA21CA00033
☐ Non-Fed Sponsor:

Funds set aside in AWD #: 003704 GR# 00008484 WD Supplier #

Subrecipient Information

Legal Name: PATH Admin. Contact: Ashima Tandan Phone: (206) 285-3500
DUNS/UEI#: 40 EIN#: 40 Email: awards@path.org Remittance Address:
PI: Linda Venczel General Address: 2201 Westlake Avenue, Suite 200
Phone: (206) 830-0250 2201 Westlake Avenue, Suite 200
Email: lvenczel@path.org Seattle, WA 98121-2778
United States United States

Subagreement Information

Amount Funded this action: \$ 195,866.00 Total Est. Funding: \$ 24,922,805.00
Cost Share this action: \$ 9,852.00 F&A Rate, if applicable: 49 %
Budget Period this action: 10/01/2021 — 09/30/2022 Est. Project Period: 10/01/2021 — 09/30/2026

Human Subjects ☒ Yes ☐ No

Subrecipient IRB not required for the following reason:

- ☐ IRB Exempt
☐ WSU acting as sIRB
☐ Other sIRB designated
☐ Approval will be sought after 1 year

Status of IRB:

- ☐ Approved
☒ Pending

Comments: These will be requested when the use of human subjects is approved by USAID

Animal Subjects ☒ Yes ☐ No

Status of IACUC approval

- ☐ Approved
☒ Pending

Comments: These will be requested when use of animals is approved by USAID

Technical/Progress Reporting requirement		
<input type="checkbox"/> Annual	<input type="checkbox"/> Monthly	
<input checked="" type="checkbox"/> Quarterly	<input checked="" type="checkbox"/> At the discretion of the PI to satisfy reporting REQs	
Other		
<input checked="" type="checkbox"/> Data Management/Sharing Plan	<input type="checkbox"/> Foreign subrecipient	<input type="checkbox"/> Select Agents Name/ Comments below:
<input checked="" type="checkbox"/> Human Subjects Data	<input type="checkbox"/> Carryforward restricted by PI	
<input type="checkbox"/> Fixed Priced Agreement	<input type="checkbox"/> Biohazardous materials	
<p>Please list any special requirements or provide any other information you think might be useful for the person preparing this subagreement:</p> <p>Please work closely with Amanda Yager; Research Services Manager, Paul G. Allen School of Global Health, on any updates. Only partial budget at this time is being submitted until USAID approves the project workplan and budget detail. After approval budget and budget justification will be submitted.</p>		

WSU PI Verification
<p>By signing below, I certify that I have read the following statements and certify that they are accurate and true to the best of my knowledge:</p> <p>The subagency's proposed costs have been reviewed and are reasonable for the technical effort proposed. Funding is available for this subagreement and is an allowable cost under the terms of the prime.</p> <p><input type="checkbox"/> The project and relationship with this subagency present a potential conflict of interest or appearance thereof and a COI plan and explanation are attached. [OR]</p> <p><input checked="" type="checkbox"/> No conflict of interest as defined in <u>Executive Policy #27</u> has been identified as a result of this project and relationship with the subagency.</p>
<p>Unavailable for Signature</p> <p>_____ Signature of WSU PI</p>

For accounting purposes, please fill the below subrecipient budget template by WSU object code:

Salaries – 00	\$ 110,672.00
Wages - 01	
Personal Svc Contract – 02	
Goods/Services – 03	
Travel – 04	
Computer Services -05	
Equipment – 06	
Benefits – 07	\$ 31,368.00
Stipends/Subsides - 08	
SBCTs/Restricted – 14	
Small/Attractive Items – 16	
Total Direct Costs	
F&A - 13	\$ 49
Total Costs	\$ 195,866.00

Helpful Links:

Sam.gov:

<https://sam.gov/SAM/>

Federal Audit Clearinghouse:

<https://harvester.census.gov/facweb/>

ORSO Policy & Guidelines:

<https://orso.wsu.edu/wsu-policies-guidelines/>

For questions:

Please contact ORSO at **5-9661** or orso@wsu.edu.

FDP Cost Reimbursement Subaward

Federal Awarding Agency: Other [Type in Agency]		US Agency for International Development
Pass-Through Entity (PTE):		Subrecipient:
Washington State University		PATH
PTE PI: Felix Lankester	Sub PI: Linda Venczel	
PTE Federal Award No: 7200AA21CA00033	Subaward No: 141061	
Project Title: Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)		
Subaward Budget Period:		Amount Funded This Action (USD): \$ 195,866.00
Start: 10/01/2021	End: 09/30/2022	
Estimated Period of Performance:		Incrementally Estimated Total (USD): \$ 24,922,805.00
Start: 10/01/2021	End: 09/30/2026	

Terms and Conditions

1. PTE hereby awards a cost reimbursable subaward, (as determined by 2 CFR 200.331), to Subrecipient. The Statement of Work and budget for this Subaward are as shown in Attachment 5. In its performance of Subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.
2. Subrecipient shall submit invoices not more often than monthly and not less frequently than quarterly for allowable costs incurred. Upon the receipt of proper invoices, the PTE agrees to process payments in accordance with this Subaward and 2 CFR 200.305. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), breakdown by major cost category, Subaward number, and certification, as required in 2 CFR 200.415(a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments shall be directed to the party's Financial Contact, shown in Attachment 3A.
3. A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Financial Contact, as shown in Attachment 3A, not later than 60 days after the final Budget Period end date. The final statement of costs shall constitute Subrecipient's final financial report.
4. All payments shall be considered provisional and are subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Subrecipient.
5. Matters concerning the technical performance of this Subaward shall be directed to the appropriate party's Principal Investigator as shown in Attachments 3A and 3B. Technical reports are required as shown in Attachment 4.
6. Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this Subaward, and any changes requiring prior approval, shall be directed to the PTE's Authorized Official Contact and the Subrecipient's Authorized Official Contact shown in Attachments 3A and 3B. Any such change made to this Subaward requires the written approval of each party's Authorized Official as shown in Attachments 3A and 3B.
7. The PTE may issue non-substantive changes to the Budget Period(s) and Budget Bilaterally. Unilateral modification shall be considered valid 14 days after receipt unless otherwise indicated by Subrecipient when sent to Subrecipient's Authorized Official Contact, as shown in Attachment 3B.
8. Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.
9. Either party may terminate this Subaward with 30 days written notice. Notwithstanding, if the Awarding Agency terminates the Federal Award, PTE will terminate in accordance with Awarding Agency requirements. PTE notice shall be directed to the Authorized Official Contact, and Subrecipient notice shall be directed to the Authorized Official Contact as shown in Attachments 3A and 3B. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix IX, as applicable.
10. By signing this Subaward, including the attachments hereto which are hereby incorporated by reference, Subrecipient certifies that it will perform the Statement of Work in accordance with the terms and conditions of this Subaward and the applicable terms of the Federal Award, including the appropriate Research Terms and Conditions ("RTCs") of the Federal Awarding Agency, as referenced in Attachment 2. The parties further agree that they intend this subaward to comply with all applicable laws, regulations, and requirements.

By an Authorized Official of the PTE:		By an Authorized Official of the Subrecipient:	
<div style="border-bottom: 1px solid black; width: 100%;"></div> <div style="display: flex; justify-content: space-between;"> Name: <div style="border-bottom: 1px solid black; width: 80%;"></div> Date: <div style="border-bottom: 1px solid black; width: 15%;"></div> </div> <div style="border-bottom: 1px solid black; width: 100%;"></div> <div style="display: flex; justify-content: space-between;"> Title: <div style="border-bottom: 1px solid black; width: 80%;"></div> </div>	<div style="border-bottom: 1px solid black; width: 100%;"></div> <div style="display: flex; justify-content: space-between;"> Name: <div style="border-bottom: 1px solid black; width: 80%;"></div> Date: <div style="border-bottom: 1px solid black; width: 15%;"></div> </div> <div style="border-bottom: 1px solid black; width: 100%;"></div> <div style="display: flex; justify-content: space-between;"> Title: <div style="border-bottom: 1px solid black; width: 80%;"></div> </div>		

Attachment 1

Certifications and Assurances

Subaward Number:

141061

Certification Regarding Lobbying (2 CFR 200.450)

By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief, that no Federal appropriated funds have been paid or will be paid, by or on behalf of the Subrecipient, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement in accordance with 2 CFR 200.450.

If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or intending to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the Subrecipient shall complete and submit Standard Form -LLL, "Disclosure Form to Report Lobbying," to the PTE.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by 31 U.S.C. 1352. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

Debarment, Suspension, and Other Responsibility Matters (2 CFR 200.214 and 2 CFR 180)

By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief that neither the Subrecipient nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this transaction by any federal department or agency, in accordance with 2 CFR 200.213 and 2 CFR 180.

Audit and Access to Records

Subrecipient certifies that it will provide PTE with notice of any adverse findings which impact this Subaward. Subrecipient certifies compliance with applicable provisions of 2 CFR 200.501-200.521. If Subrecipient is not required to have a Single Audit as defined by 200.501, Awarding Agency requirements, or the Single Audit Act, then Subrecipient will provide notice of the completion of any required audits and will provide access to such audits upon request. Subrecipient will provide access to records as required by parts 2 CFR 200.337 and 200.338 as applicable.

Program for Enhancement of Contractor Employee Protections (41 U.S.C 4712)

Subrecipient is hereby notified that they are required to: inform their employees working on any federal award that they are subject to the whistleblower rights and remedies of the program; inform their employees in writing of employee whistleblower protections under 41 U.S.C §4712 in the predominant native language of the workforce; and include such requirements in any agreement made with a subcontractor or subgrantee.

The Subrecipient shall require that the language of the certifications above in this Attachment 1 be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

Use of Name

Neither party shall use the other party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may use factual information regarding the existence and purpose of the relationship that is the subject of this Subaward for legitimate business purposes, to satisfy any reporting and funding obligations, or as required by applicable law or regulation without written permission from the other party. In any such statement, the relationship of the parties shall be accurately and appropriately described.

Prohibition on Certain Telecommunication and Video Surveillance Services or Equipment

Pursuant to 2 CFR 200.216, Subrecipient will not obligate or expend funds received under this Subaward to: (1) procure or obtain; (2) extend or renew a contract to procure or obtain; or (3) enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that uses covered telecommunications equipment or services (as described in Public Law 115-232, section 889) as a substantial or essential component of any system, or as a critical technology as part of any system.

Attachment 2

Federal Award Terms and Conditions

Subaward Number

141061

Required Data Elements

The data elements required by Uniform
Guidance are incorporated in the attached Federal Award.

This Subaward Is:

☒ Research & Development ☐ Subject to FFATA

Awarding Agency Institute (If Applicable)

USAID

Federal Award Issue Date FAIN Assistance Listing No.

09/22/21

7200AA21CA00033

98.001

Assistance Listing Program Title (ALPT)

USAID Foreign Assistance for Programs Overseas

Key Personnel Per NOA

Ch. Rabiner; B.T. Leader

General Terms and Conditions

By signing this Subaward, Subrecipient agrees to the following:

1. To abide by the conditions on activities and restrictions on expenditure of federal funds in appropriations acts that are applicable to this Subaward to the extent those restrictions are pertinent. This includes any recent legislation noted on the Federal Awarding Agency's website:

<https://www.usaid.gov/who-we-are/agency-policy>

2. 2 CFR 200

3. The Federal Awarding Agency's grants policy guidance, including addenda in effect as of the beginning date of the period of performance or as amended found at:

<https://www.usaid.gov/ads/policy/300/303>

4. Research Terms and Conditions, including any Federal Awarding Agency's Specific Requirements found at:

see attachment #6

except for the following :

- a. No-cost extensions require the written approval of the PTE. Any requests for a no-cost extension shall be directed to the Authorized Official Contact shown in Attachment 3A, not less than 30 days prior to the desired effective date of the requested change.
- b. Any payment mechanisms and financial reporting requirements described in the applicable Federal Awarding Agency Terms and Conditions and Agency-Specific Requirements are replaced with Terms and Conditions (1) through (4) of this Subaward; and
- c. Any prior approvals are to be sought from the PTE and not the Federal Awarding Agency.
- d. Title to equipment as defined in 2 CFR 200.1 that is purchased or fabricated with research funds or Subrecipient cost sharing funds, as direct costs of the project or program, shall vest in the Subrecipient subject to the conditions specified in 2 CFR 200.313.
- e. Prior approval must be sought for a change in Subrecipient PI or change in Key Personnel (defined as listed on the NOA).

5. Treatment of program income: Additive

Special Terms and Conditions:

Data Sharing and Access:

Subrecipient agrees to comply with the Federal Awarding Agency's data sharing and/or access requirements as reflected in the NOA or the Federal Awarding Agency's standard terms and conditions as referenced in General Terms and Conditions 1-4 above.

Provided upon request is a Data Management and/or Sharing Plan that incorporates additional requirements as submitted to the Federal Awarding Agency.

Data Rights:

Subrecipient grants to PTE the right to use data created in the performance of this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Copyrights:

Subrecipient Shall Grant to PTE an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted material (including any computer software and its documentation and/or databases) first developed and delivered under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Subrecipient grants to PTE the right to use any written progress reports and deliverables created under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its Federal Award.

Promoting Objectivity in Research (COI):

Subrecipient must designate herein which entity's Financial Conflicts of Interest policy (COI) will apply: Subrecipient

If applying its own COI policy, by execution of this Subaward, Subrecipient certifies that its policy complies with the requirements of the relevant Federal Awarding Agency as identified herein: US Agency for International Development

Subrecipient shall report any financial conflict of interest to PTE's Administrative Representative or COI contact, as designated on Attachment 3A. Any financial conflicts of interest identified shall, when applicable, subsequently be reported to Federal Awarding Agency. Such report shall be made before expenditure of funds authorized in this Subaward and within 45 days of any subsequently identified COI.

Work Involving Human or Vertebrate Animals (Select Applicable Options)☐ No Human or Vertebrate Animals**IRB**☒ Human Subjects**IACUC**☒ Vertebrate Animals

The PTE requires verification of IRB and/or IACUC approval be sent to the as required above:

Subrecipient agrees that any non-exempt human and/or vertebrate animal research protocol conducted under this Subaward shall be reviewed and approved by the appropriate Institutional Review Board (IRB) and/or its Institutional Animal Care and Use Committee (IACUC), as applicable and that it will maintain current and duly approved research protocols for all periods of the Subaward involving human and/or vertebrate animal research. Subrecipient certifies that the appropriate IRB and/or IACUC are in full compliance with applicable state and federal laws and regulations. The Subrecipient certifies that any submitted IRB / IACUC approval represents a valid, approved protocol that is entirely consistent with the Project associated with this Subaward. In no event shall Subrecipient invoice or be reimbursed for any human or vertebrate animals related expenses incurred in a period where any applicable IRB / IACUC approval is not properly in place.

Human Subjects Data (Select One)

Human Subjects Data will be exchanged under this Subaward (check all that apply):

- ☒ From Subrecipient to PTE
☒ From PTE to Subrecipient

The PTE will set forth the terms of the exchange of Human Subjects Data (Select One):

This section left intentionally blank

Additional Terms

Subawards issued under this award are subject to additional USAID approval.

If applicable, Subrecipient certifies that its Institutional Biosafety committee is in full compliance with applicable state and federal laws and regulations. Subrecipient agrees that any non-exempt research involving recombinant or synthetic nucleic acid molecules or select agents conducted under this agreement shall be reviewed and approved by its Institutional Biosafety Committee, as applicable. In Addition, Subrecipient will maintain current and duly approved research protocols for all periods of the Agreement involving recombinant or synthetic nucleic acid molecules or select agents.

The Subrecipient certifies that any submitted recombinant or synthetic nucleic acid molecules or select agents approval represents a valid, approved protocol that is entirely consistent with project associated with this subaward. In no event shall subrecipient invoice or be reimbursed for any recombinant or synthetic nucleic acid molecules or select agents related expense incurred in a period where any applicable IRB/IACUC approval is not properly in place.

In addition to other applicable provisions in the NOA, the mandatory provisions for U.S. Nongovernmental organizations found in the NOA as part of Attachment 6 (Pages 40-65 of this subaward) are incorporated by reference into this subaward.

Attachment 3A
Pass-Through Entity (PTE) Contacts

Subaward Number:

141061

PTE Information

Entity Name: Washington State University

Legal Address: Office of Research Support and Operations
280 Lighty
PO Box 641060
Pullman, WA 99164-1060

Website: <https://orso.wsu.edu/>

PTE Contacts

Central Email: orso@wsu.edu

Principal Investigator Name: Felix Lankester

Email: felix.lankester@wsu.edu

Telephone Number:

Administrative Contact Name: Chana Rabiner

Email: chana.rabiner@wsu.edu

Telephone Number:

COI Contact email (if different to above): orso@wsu.edu

Financial Contact Name: Casey St. Clair, Director, Sponsored Programs

Email: sps@wsu.edu

Telephone Number: (509) 335-2058

Email invoices? ☒ Yes ☐ No Invoice email (if different): ayager@wsu.edu

Authorized Official Name: Dan Nordquist, AVP ORSO

Email: orso@wsu.edu

Telephone Number: (509) 335-9661

PI Address:

Washington State University
Paul G. Allen School for Global Animal Health
PO Box 647090
Pullman WA 99164-7090

Administrative Address:

Washington State University
Office of Research Support and Operations
PO Box 641060
Pullman, WA 99164-1060

Invoice Address:

Washington State University
Sponsored Programs Services
PO Box 641025
Pullman, WA 99164-1025

Attachment 3B**Research Subaward Agreement
Subrecipient Contacts**

Subaward Number:

141061

Subrecipient Information for FFATA

reporting Entity's UEI/DUNS Name: PATH

EIN No.:

40

Institution Type:

Nonprofit with 501c3 Status (other than Inst. of Higher Ed.)

UEI / DUNS:

DUNS: 18

UEI: 18

Currently registered in SAM.gov: ☒ Yes ☐ NoExempt from reporting executive compensation: ☒ Yes ☐ No (if no, complete 3Bpg2)

Parent UEI / DUNS: N/A

This section for U.S. Entities:

Zip Code Look-up

Congressional District: WA-007

Zip Code+4: 98121-2778

Place of Performance Address2201 Westlake Avenue, Suite 200
Seattle, WA 98121-2778
United States**Subrecipient Contacts**

Central Email:

awards@path.org

Website:

www.path.org

Principal Investigator Name:

Linda Venczel

Email:

lvenczel@path.org

Telephone Number:

206-830-0250

Administrative Contact Name:

Ashima Tandan

Email:

atandan@path.org

Telephone Number:

206-285-3500

Financial Contact Name:

Rosa Joncich

Email:

rjoncich@path.org

Telephone Number:

206-285-3500

Invoice Email:

accountspayable@path.org

Authorized Official Name:

Nikolaj Gilbert

Email:

awards@path.org

Telephone Number:

206-285-3500

Legal Address:2201 Westlake Avenue, Suite 200
Seattle, WA 98121-2778
United States**Administrative Address:**2201 Westlake Avenue, Suite 200
Seattle, WA 98121-2778
United States**Payment Address:**2201 Westlake Avenue, Suite 200
Seattle, WA 98121-2778
United States

Attachment 3B Page 2
Research Subaward Agreement
Highest Compensated Officers

Subaward Number:

141061

Subrecipient

Entity Name: PATH

PI Name: Linda Venczel

Highest Compensated Officers

The names and total compensation of the five most highly compensated officers of the entity(ies) must be listed if the entity in the preceding fiscal year received 80 percent or more of its annual gross revenues in Federal awards; and \$25,000,000 or more in annual gross revenues from Federal awards; and the public does not have access to this information about the compensation of the senior executives of the entity through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. See FFATA § 2(b)(1) Internal Revenue Code of 1986.

Officer 1 Name:

Officer 1 Compensation:

Officer 2 Name:

Officer 2 Compensation:

Officer 3 Name:

Officer 3 Compensation:

Officer 4 Name:

Officer 4 Compensation:

Officer 5 Name:

Officer 5 Compensation:

Attachment 4

Reporting and Prior Approval Terms

Subaward Number:

141061

Subrecipient agrees to submit the following reports (PTE contacts are identified in Attachment 3A):

Technical Reports:

- ☐ Monthly technical/progress reports will be submitted to the PTE's within days of the end of the month.
- ☐ Quarterly technical/progress reports will be submitted within 30 days after the end of each project quarter to the PTE's .
- ☒ Annual technical / progress reports will be submitted within days prior to the end of each budget period to the PTE's . Such report shall also include a detailed budget for the next Budget Period, updated other support for key personnel, certification of appropriate education in the conduct of human subject research of any new key personnel, and annual IRB or IACUC approval, if applicable.
- ☒ A Final technical/progress report will be submitted to the PTE's within days of the end of the Project Period or after termination of this award, whichever comes first.
- ☒ Technical/progress reports on the project as may be required by PTE's in order for the PTE to satisfy its reporting obligations to the Federal Awarding Agency.

Prior Approvals:

Carryover:

Other Reports:

- ☒ In accordance with 37 CFR 401.14, Subrecipient agrees to notify both the Federal Awarding Agency via iEdison and PTE's within 60 days after Subrecipient's inventor discloses invention(s) in writing to Subrecipient's personnel responsible for patent matters. The Subrecipient will submit a final invention report using Federal Awarding Agency specific forms to the PTE's within 60 days of the end of the Project Period to be included as part of the PTE's final invention report to the Federal Awarding Agency.

A negative report is required:

- ☒ Property Inventory Report (only when required by Federal Awarding Agency), specific requirements below.

Additional cost sharing requirements included below:

Additional Technical and Reporting Requirements:

Subrecipients shall list each country included in the program and the total amount expended for each country when submitting financial reports. These will be noted to each partner as countries are onboarded.

Kenya 615-GH-W

Senegal 685-GH-W

Peru 527-GH-W

Vietnam 440-GH-W

Thailand 493-GH-W

There may be additional reporting requirements and ad hoc information requests including, but not limited to, those associated with Mission buy-ins or additional sources of funding provided to DEEP VZN. Ad hoc refers to an unscheduled report for immediate, specific use. These requests will need to be approved by USAID.

Attachment 5
Statement of Work, Cost Sharing, Indirects & Budget

Subaward Number:

141061

Statement of Work

☐ Below ☒ Attached, pages

If award is FFATA eligible and SOW exceeds 4000 characters, include a *Subrecipient Federal Award Project Description*

PATH will leverage its strong country offices and national and local relationships to lead activities in Senegal, Vietnam, and India. PATH will also provide expertise and technical assistance throughout the four project objectives.

Objective 1: Provide technical input at global level and lead implementation of activities in PATH-led countries. PATH will design and implement One Health sampling strategies and activities, including along the value chain.

Objective 2: Contribute to defining stakeholder requirements for candidate detection technologies, identifying, and selecting appropriate technologies to best meet these needs, and providing technical assistance to laboratory sites during implementation and use of new methods for viral detection.

Objective 3: Contribute to the consortium's understanding of risk, which is essential for efficient use of resources for precision targeted surveillance, prevention, and preparedness through novel virus characterization. PATH will assist with method selection and facilitating an enabling environment to share samples and data among local, regional, and international partners.

Objective 4: Lead the objective, providing thought leadership for data management, system integration and interoperability, data analysis and sharing. This includes data, findings, and analyses from objectives 1, 2, and 3, using country data systems to avoid duplication, and sharing information across sectors to support a One Health approach.

Budget Information

Indirect Information Indirect Cost Rate (IDC) Applied

%

Cost Sharing

Rate Type:

If Yes, include Amount: \$

Budget Details

☒ Below ☐ Attached, pages

Salaries - \$110,672

Benefits - \$31,368

F&A - \$

Total - \$195,866

Only partial budget at this time is being submitted until USAID approves the project workplan and budget detail.

Budget Totals

Direct Costs \$

Indirect Costs \$

Total Costs \$

All amounts are in United States Dollars

Attachment 6**Notice of Award (NOA) and any additional documents**

The following pages include the NOA and if applicable any additional documentation referenced throughout this Subaward.



Not incorporating the NOA or any additional documentation to this Subaward.



September 22, 2021

Dan Nordquist
Associate Vice President for Research
Washington State University
P.O. Box 641060
Pullman, WA 99164-1060
orso@wsu.edu

Reference: Award No. Titled "Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)" Cooperative Agreement 7200AA21CA00033

Dear Dan Nordquist:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, the U.S. Agency for International Development (USAID) hereby awards to Washington State University, hereinafter referred to as the "Recipient", the sum of \$124,679,896 to provide support for a program titled "Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)", as described in the Schedule of this award and in Attachment B, entitled "Program Description."

This Cooperative Agreement will be effective October 1, 2021. Obligation will be made upon receipt of the Recipient's acknowledgement and shall apply to expenditures made by the Recipient in furtherance of program objectives during the period beginning with the effective date October 1, 2021 and ending September 30, 2026. USAID will not be liable for reimbursing the Recipient for any costs in excess of the obligated amount.

This Cooperative Agreement is made to Washington State University, on condition that the funds will be administered in accordance with the terms and conditions as set forth in Attachment A (the Schedule), Attachment B (the Program Description), Attachment C (the Standard Provisions), and Attachment D (the Branding & Marking Plan) all of which have been agreed to by your organization.

Please sign the second page of this cover letter to acknowledge your receipt of this award and e-mail a copy of only the signed page to Anna Nelson at annelson@usaid.gov with a cc: to Patricia Bradley at pbradley@usaid.gov.

Sincerely,

Patricia Elena Bradley
(affiliate)
Patricia Bradley
Agreement Officer

Digitally signed by Patricia Elena
Bradley (affiliate)
Date: 2021.09.22 10:24:23 -04'00'

Attachments:

- A. Schedule
- B. Program Description
- C. Standard Provisions
- D. Branding & Marking Plan

ACKNOWLEDGED BY:

NAME: Christopher J. Keane



TITLE: Vice President for Research, WSU and Vice Chancellor for Research, WSU Pullman

DATE: 9/23/2021

ACCOUNTING AND APPROPRIATION DATA

A. GENERAL

1. Amount Obligated this Action: \$ 10,000,000
 2. Total Estimated USAID Amount: \$124,679,896
 3. Total Obligated USAID Amount: \$ 10,000,000
 4. Cost-Sharing Amount (Non-Federal): \$ 6,607,682
 5. Activity Title: “Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)”
 6. USAID Technical Office: GH/ID/ETD
 7. Tax I.D. Number: 40
 8. DUNS No.: 40
 9. LOC Number: 42A5P

B. SPECIFIC

GLAAS Requisition: REQ-GH-21-000020

Account ID	Accounting Template	BBFY	EBFY	Fund	Operating Unit	Prog Area	Program Name	Dist Code	BGA	SOC	Funded Amount
1-1	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	615-GH-W	615	4100201	\$2,000,000
1-2	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	685-GH-W	685	4100201	\$2,000,000
1-3	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	440-GH-W	440	4100201	\$2,000,000
1-4	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	527-GH-W	527	4100201	\$2,000,000
1-5	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	493-GH-W	493	4100201	\$2,000,000

C. PAYMENT OFFICE

M/CFO/CMP Letter of Credit Office
USAID/Washington

USAID Office of Financial Management (M/CFO/CMP) prefers the submittal of invoices to be electronic. In addition to the required submission to the Agreement Officer’s Representative (AOR), please submit a copy of the invoices to loc@usaid.gov.

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ATTACHMENT A - SCHEDULE

A.1 PURPOSE OF AWARD

The purpose of this Cooperative Agreement is to provide support for the program described in Attachment B to this Cooperative Agreement entitled "Program Description."

A.2 PERIOD OF AWARD

1. The effective date of this Award is **October 1, 2021**. The estimated completion date of this Award is **September 30, 2026**.

A.3 AMOUNT OF AWARD AND PAYMENT

1. The total estimated amount of this Award for the period shown in A.2.1 above is \$124,679,897, not including cost share.
2. USAID hereby obligates the amount of \$10,000,000 for program expenditures during the period set forth in A.2.1 above and as encompassed in the Budget below. The recipient must use funds obligated under this award and any subsequent amendments from the specific Operating Units (OU) and Program Areas (PA) for activities approved in the award and detailed in the work plan, as applicable. Program disbursements for each OU/PA must not exceed the amounts specified in the Accounting and Appropriates data for each Operating Unit (OU) and Program Area (PA). The Recipient will be given written notice by the Agreement Officer if additional funds will be added.
3. As the obligated amount for the program shall equal the total USAID estimated amount of this Agreement, additional increments of funds may be obligated by USAID under this Agreement (by a unilateral modification to this Agreement), subject to availability of funds, successful performance by the Recipient, possible evaluation of the program, program priorities at the time, and the requirements of the 2 CFR 200.308.
4. Payment will be made to the Recipient by Letter of Credit in accordance with procedures set forth in 2 CFR 200 and 2 CFR 700.

A.4 AWARD BUDGET

The following is the Award Budget, including local cost financing items, if authorized. Revisions to this budget shall be made in accordance with 2 CFR 200 and 2 CFR 700.

TOTAL BUDGET

Cost Element	USD
Direct Costs	\$116,474,256
Indirect Costs	\$ 49
Total Federal Contribution	\$124,679,897
Cost Share	\$6,607,682
Total Program Cost	\$131,287,579

Washington State University is responsible for managing available funds. This agreement includes a ceiling amount and obligated amount that the recipient exceeds at its own risk.

A.5 PLANNING, REPORTING, AND EVALUATION

1. Financial Reporting:

The recipient must submit the Federal Financial Form (SF-425) on a quarterly basis via electronic format to the U.S. Department of Health and Human Services. The recipient also must submit a copy of the SF-425 to the Agreement Officer (AO) and the Agreement Officer's Representative (AOR). These financial reports are due no later than 30 calendar days at the end of each quarter based on the federal fiscal calendar. The recipient must submit final financial reports to USAID/Washington, M/CFO/CMP-LOC Unit, the AO, and the AOR. The recipient must also submit an electronic version of the final financial report to the U.S. Department of Health and Human Services in accordance with the paragraph above.

2. Performance Planning:

Implementation Plans

Annual implementation plans serve as a guide to activity implementation and detail how the recipient will use the implementation year to achieve the objectives of DEEP VZN. The implementation plan is intended to be an annual roadmap for USAID and the recipient. With approval from the AOR, reasonable and justifiable modifications can be made to improve the chances of achieving the medium- and long-term results of the award. The recipient must submit the following implementation and reporting documents in English. The AOR and recipient will agree on the appropriate format and length.

Implementation plans include, but are not limited to, the following:

- Annual work plans, including planned activities for the following year and any subsequent revisions
- International travel plans
- Planned expenditures
- Event planning/management
- International meeting preparation
- Material Transfer Agreement (MTA) risk mitigation plan
- Country-level Level of Effort (LOE) chart, to include any oversight provided by headquarters
- Protocol Development and Review Plan
- Biosecurity and Biosafety (BSBS) Plan

USAID requires the AOR approval of implementation plans annually to ensure alignment with stated goals, milestones and outputs. The implementation plan communicates how and when the recipient will complete project activities and is drafted annually to describe new activities. The AOR will ensure that the implementation plans fit within the scope, terms and conditions of the agreement.

First Year Work Plan and Budget

The recipient will submit a draft work plan for the first year within the first 90 calendar days of executing the award. Depending on the start date of the agreement, the first-year work plan may be less than a full year or more than a full year. The first-year work plan must include a detailed budget and budget narrative for the first year. As part of the First Year Work Plan submission, the recipient will include a supplementary annual work plan describing planned contributions to the GHSA on a template designated by the AOR. All work plans and budgets, including

significant revisions thereto, must be approved by the AOR.

Annual Work Plan and Budget

Starting with the second year of the award and for each subsequent year of performance thereafter, the recipient will submit annual work plans, budgets, and budget narratives to the AOR for the next federal fiscal year within 30 calendar days prior to the end of the current federal fiscal year in a format agreed upon by the AOR and the recipient. The recipient also will submit supplementary annual work plans describing planned contributions to the Global Health Security Agenda (GHSa) within a timeframe and on a template designated by the AOR.

Monitoring, Evaluation and Learning (MEL) Plan

The recipient will finalize a MEL plan for the life of DEEP VZN that derives from the activities outlined in the Program Description and submit it to the AOR within 90 calendar days of the award for approval. The MEL plan will outline key program interventions, indicators of achievement, associated annual and life-of-Activity targets and a learning agenda. The learning agenda will outline key questions to be addressed, a plan for addressing these questions, and a process for incorporating findings into program implementation and the detection and characterization of unknown viruses. Where appropriate, the MEL plan must track gender equality issues in implementing activities. The recipient will update the MEL plan annually and submit it as an attachment to the annual report.

Biosecurity and Biosafety (BSBS) Plan

The recipient will finalize a BSBS plan for the life of DEEP VZN and submit it to the AOR within 90 calendar days of the award for approval. The BSBS will outline all program interventions that have biosafety/biosecurity implications and steps (e.g. protocols, training) that will be taken to minimize risk.

Gender Action Plan

The recipient will conduct a gender analysis that assesses context and gender needs, including time constraints and participation limitations. This analysis will inform a subsequent gender action plan, which will be developed in collaboration with the USAID management team and finalized within 90 calendar days of the award and updated annually. The gender action plan will inform the Activity's technical approach as it relates to gender throughout the life of the Activity. It also will be used to inform the design of activities that seek to reduce opportunity gaps between men and women or address power differentials to promote gender equity. The gender action plans should be developed in conjunction with the Activity's monitoring, evaluation and learning plan, and progress should be reflected in annual work plans and performance reports.

Data Management Plan

A Data Management Plan (DMP) is a document that describes how the recipient will manage data during the project and what happens to the data after the project ends. The initial DMP, which will be developed in collaboration with the USAID management team, will be finalized within 90 calendar days of the award and updated semi-annually and annually.

A comprehensive DMP will discuss the following aspects of the data life cycle:

- Collect - How the data is collected and processed by the researcher.
- Assure - How to make sure the data is high quality and free of errors.
- Describe - How the data will be documented so that other researchers can use it.
- Preserve - How and where the data will be stored so that researchers can access it forever.

The data management plan will inform the Activity's technical approach as it relates to data throughout the life of the Activity. The data management plan should be developed in conjunction with the Activity's monitoring, evaluation and learning plan, and progress should be reflected in annual work plans and performance reports.

Closeout Plan

No later than six (6) months prior to the completion date of the agreement, the recipient will submit a demobilization plan for Agreement Officer's approval. The demobilization plan shall include: 1) a draft property disposition plan, 2) a plan for the phase-out of in-country operations, 3) a staffing discharge plan, 4) a delivery schedule for all reports or other deliverables required under the agreement, and 5) a timetable for completing all required actions in the demobilization plan, including the submission date of the final property disposition plan to the Agreement Officer.

3. Performance Reporting:

The recipient must submit via email a copy of semi-annual, annual, and final performance reports, in English, to the AOR in accordance with 2 CFR 200.328.

Semi-Annual and Annual Reports

The recipient will submit semi-annual and annual progress reports based on the federal fiscal calendar. The semi-annual report will be due within 30 days after the end of the reporting period and will cover the first six months of the year (October 1 - March 31). The annual report will cover the entire fiscal year (October 1 - September 30) and will be due within 90 days of the end of the federal fiscal year.

At a minimum, both semi-annual and annual reports will contain:

- Narrative description of activities completed and major accomplishments achieved during the reporting period in all countries supported by DEEP VZN, presented by objective
- Qualitative and quantitative data on program achievements and results
- Progress on standard and agreed upon indicators, as outlined in the MEL plan, including status towards achieving targets and explanations for significant deviations
- An updated MEL plan, including progress on the learning agenda (annually)
- An updated BSBS plan
- An updated Data Management plan
- Problems encountered and whether they were solved or are still outstanding
- Proposed solutions to ongoing or new problems
- Success stories, blogs, articles, publications, press releases, and photographs, if available
- Update on expenditures for the reporting period against the pipeline
- Analysis and explanation of cost overruns or high unit costs, when applicable
- Planned activities for the next performance period

Global Health Security Agenda (GHS) reports

The Recipient will submit semi-annual GHS performance reports within a timeframe and on a template designated by the AOR. The Recipient will submit the GHS semi-annual reports to the AOR via email.

Ad Hoc Reports

There may be additional reporting requirements and ad hoc information requests including, but not limited to, those associated with Mission buy-ins or additional sources of funding provided to DEEP VZN. Ad hoc refers to an unscheduled report for immediate, specific use. USAID will define the purpose, content, and specific use for any ad hoc report.

Final Report

Within ninety (90) calendar days after the period performance date, the recipient will submit one (1) original and two (2) copies of the Final Report to the AOR and one (1) copy to the Agreement Officer. In addition, one (1) copy will be submitted to the Development Experience Clearinghouse:

- 1) Electronically: <http://www.usaid.gov/results-and-data/informationresources/developmentexperience-clearinghouse-dec>
or
- 2) By U.S. Postal Service delivery to:
U.S. Agency for International Development
Development Experience Clearinghouse
M/CIO/ITSD/KM
Ronald Reagan Building M. 01-010
Washington, DC 20523-6100

The Final Report must include a narrative report and summary table of results, a comparison of actual accomplishments to the objectives established for the period of performance, and a gender analysis that describes how gender equality issues were tracked and addressed. It should highlight accomplishments against implementation plans; outline progress of benchmarks against targets; describe results; and document lessons learned during implementation. The Final Report also must contain a three-page executive summary, an index of all reports and information products produced under the agreement, and a summary of the program's finances. More details on the format of the final report will be provided after the award.

A.6 INDIRECT COST RATE

Allowable indirect costs shall be reimbursed on the basis of the following negotiated Colleges and Universities Rate Agreement, dated August 20, 2019.

INDIRECT COST RATES:

TYPE	FROM	TO	LOCATION	RATE%	APPLICABLE TO
Predetermined	7/1/2019	6/30/2023	On-Campus	49	Organized Research
			Off-Campus	49	Organized Research
			On-Campus	49	Instruction
			Off-Campus	49	Instruction
			On-Campus	49	Other Sponsored Activities
			Off-Campus	49	Other Sponsored Activities
Provisional	7/1/2023	Until Amended	Use same rates and conditions as those cited for fiscal year ending June 30, 2023.		

Base

Modified total direct costs, consisting of all salaries and wages, fringe benefits, materials, supplies, services, travel and subgrants and subcontracts up to the first \$25,000 of each

subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). Modified total direct costs shall exclude equipment, capital expenditures, charges for patient care, student tuition remission, rental costs of off-site facilities, scholarships, and fellowships as well as the portion of each subgrant and subcontract in excess of \$25,000.

A.7 TITLE TO PROPERTY

Title of property financed under this award shall vest with the recipient subject to the requirements of 2 CFR 200.311-200.316, until such time as USAID issues disposition instructions.

Furthermore, the following requirements apply regarding the use, care, accountability, maintenance, and disposition thereof:

(a) Tangible Property

(1) Equipment: “Equipment” means an article of tangible nonexpendable personal property having a useful life of one year or more and a per-unit acquisition cost (purchase price) of \$5,000 or more. Equipment is subject to the requirements set forth in 2 CFR 200.313.

(2) Supplies and Other Expendable Equipment: “Supplies and other expendable equipment” means items of tangible personal property that do not meet the definition of “equipment” in paragraph (a)(1) above. Supplies and other expendable equipment are subject to the requirements set forth in 2 CFR 200.314.

(3) Real Property: “Real property” means land, land improvements, structures, and appurtenances thereto. Real property is subject to the requirements set forth in 2 CFR 200.311.

(b) Intangible (Intellectual) Property

“Intangible property” means, but is not limited to, copyrights, inventions and patents, and data first produced under this Agreement. Intangible property is subject to the requirements set forth in 2 CFR 200.315.

A.8 AUTHORIZED GEOGRAPHIC CODE

The authorized geographic code for procurement of goods and services under this award is 935.

A.9 COST SHARING

The Recipient will contribute 5.03% percent of the total obligated amount of the award, excluding the sub-awards to the networks, as cost share throughout the life of the project. The cost share contribution shall be listed per cost category and presented in the work plan budgets.

Description	USD
Federal Amount Subject to Cost Share	\$124,679,897
Proposed Cost Share Amount	\$6,607,682
Cost Share Percentage	5.03%
Total Project Amount	\$131,287,579

A.10 SUBSTANTIAL INVOLVEMENT

a. Approval of the Recipient's Annual Implementation Plans:

Implementation plans include, but are not limited to, annual work plans, budget and budget narrative, including planned activities for the following year and any subsequent revisions, international travel plans, planned expenditures, event planning/management, international meeting preparation, MTA risk mitigation plan, country-level LOE chart, to include any oversight provided by headquarters, and protocol development and review plan.

USAID requires AOR approval of implementation plans annually to ensure alignment with stated goals, milestones and outputs. Each implementation plan communicates how and when the recipient will complete project activities and is drafted annually to describe new activities. This plan will be developed in partnership between the recipient and the AOR team. The AOR will ensure that each implementation plan fits within the scope, terms and conditions of the agreement.

b. Approval of Specified Key Personnel:

Designation of key personnel positions, approval of key personnel and any changes for the positions listed below:

- Project Director
- Deputy Project Director/Operational Lead

All individuals proposed as Key Personnel in the Recipient's application are hereby approved. Any future approval of key personnel will be authorized by the Agreement Officer in a separate administrative letter. The Recipient must submit to the AOR, reasonably in advance, any proposed replacement (including proposed substitutions) along with written justification in sufficient detail to permit evaluation of the impact on the program. Any proposed replacement Key Personnel must meet the minimum requirements stated in the Notice of Funding Opportunity (NOFO) number 7200AA21RFA00005, Section D.5.g). No replacement shall be made by the Recipient without the written consent of the Agreement Officer.

c. Agency and Recipient Collaboration or Joint Participation:

- Collaborative involvement in the selection of advisory committee members, if the recipient establishes an advisory committee that provides advice to the recipient. The AOR may participate as a member of this committee. Advisory committees must only deal with programmatic or technical issues and not routine administrative matters.
- Collaborative involvement in the selection of countries, viruses, and interfaces.
- USAID review and approval of monitoring, evaluation, and learning plans.
- USAID review and approval of data management plans.
- USAID involvement in the substantive direction/re-direction of interrelationships with other projects.
- USAID involvement in monitoring progress toward achievement of the Objectives and Expected Achievements during the course of the Agreement(s) and in monitoring of financial expenditures.

d. Direction and Redirection:

USAID will be involved in the substantive direction/re-direction of inter-relationships with other projects.

A.11 PROGRAM INCOME

The Recipient shall account for Program Income in accordance with 2 CFR 200.307 (or the Standard Provision entitled Program Income for non-U.S. organizations). Program Income earned under this award shall be added to the project.

A.12 AGREEMENT OFFICER'S REPRESENTATIVE

The Agreement Officer's Representative (AOR) for this Agreement will be designated in a separate memorandum from the Agreement Officer to the AOR with copy to the Recipient and the payment office.

A.13 SPECIAL PROVISIONS

A.13.1 SUBAWARD APPROVAL

Pursuant to the approved budget of this cooperative agreement, the following sub-awards are approved. All other sub-awards are subject to additional USAID approval.

Sub-awardee

University of Washington – UW

Family Health International 360 – FHI 360

PATH

Washington University at Saint Louis – WUSTL

Duke University

A.13.2 COUNTRY-BY-COUNTRY BREAKDOWN OF EXPENDITURES

The Recipient shall list each country included in the program and the total amount expended for each country under the award for the reporting period in the "Remarks" block on the "Financial Status Report" SF 425, or on a separate sheet of paper with the "Request for Advance or Reimbursement" SF 270.

A.13.3 BRANDING STRATEGY & MARKING PLAN

The Recipient shall submit within 30 calendar days of award, a Branding Strategy and Marking Plan. Upon the approval of the AO and AOR, the plan shall be incorporated as Attachment D.

A.13.4 ENVIRONMENTAL COMPLIANCE

The Foreign Assistance Act of 1961, as amended, Section 117 requires that the impact of USAID's activities on the environment be considered and that USAID include environmental sustainability as a central consideration in designing and carrying out its development programs. This mandate is codified in Federal Regulations (22 CFR 216) and in USAID's Automated Directives System (ADS) Parts 201.5.10g and 204 (<http://www.usaid.gov/policy/ADS/200/>), which, in part, require that the potential environmental impacts of USAID-financed activities are

identified prior to a final decision to proceed and that appropriate environmental safeguards are adopted for all activities. The recipient's environmental compliance obligations under these regulations and procedures are specified in the following paragraphs of this cooperative agreement.

In addition, the recipient must comply with host country environmental regulations unless otherwise directed in writing by USAID. In case of conflict between host country and USAID regulations, the latter shall govern.

No activity funded under this cooperative agreement will be implemented unless an environmental threshold determination, as defined by 22 CFR 216, has been reached for that activity, as documented in a Request for Categorical Exclusion (RCE), Initial Environmental Examination (IEE), or Environmental Assessment (EA) duly signed by the Bureau Environmental Officer (BEO). (Hereinafter, such documents are described as "approved Regulation 216 environmental documentation.")

As part of its initial Work Plan, and all Annual Work Plans thereafter, the Recipient, in collaboration with the USAID AOR and Mission Environmental Officer or Bureau Environmental Officer, as appropriate, shall review all ongoing and planned activities under this cooperative agreement to determine if they are within the scope of the approved Regulation 216 environmental documentation.

If the Recipient plans any new activities outside the scope of the approved Regulation 216 environmental documentation, it shall prepare an amendment to the documentation for USAID review and approval. No such new activities shall be undertaken prior to receiving written USAID approval of environmental documentation amendments.

Any ongoing activities found to be outside the scope of the approved Regulation 216 environmental documentation shall be halted until an amendment to the documentation is submitted and written approval is received from USAID.

A.13.5 OPEN DATA AND DATA SHARING

The recipient will be expected to comply with the Office of Management and Budget's Open Data Policy, as well as any USAID open data policy. Relevant MEL related data, knowledge and specifically lessons learned from sampling, discovery, characterization, and data analysis and use will be documented. All final data sets that USAID and the recipient deem as valuable to its stakeholders shall be submitted to USAID in a reliable media prior to the award end date and will be available for dissemination as appropriate. During the term of the agreement, preliminary data and analysis will be submitted to USAID on a periodic basis, but no less than annually, as agreed upon by USAID and recipient during work planning.

A.13.6 ORGANIZATIONAL CONFLICT OF INTEREST

Recipient must adhere to conflict of interest regulations found in 2 CFR 200.112 and 2 CFR 200.318(c)(1).

A.13.7 COORDINATION, COMMUNICATION, AND COLLABORATION

Coordination, communication and collaboration among stakeholders facilitate trust and mutual understanding; reduce redundancy; increase synergy, scalability, and impact; and promote learning and mutual accountability. DEEP VZN is expected to build and enhance constructive

partnerships, as appropriate. DEEP VZN will collaborate and coordinate with a wide variety of stakeholders, including country National NTD Programs, Ministries of Health and other relevant government entities; USAID Missions and Country Offices, USG partners, bilateral and multilateral agencies; academic and research institutions; private sector and philanthropic organizations; and civil society organizations.

A.14 SPECIAL REQUIREMENTS

A.14.1 FOR U.S. ORGANIZATIONS -- SPECIAL AWARD REQUIREMENT RELATING TO THE PROHIBITION ON CERTAIN TELECOMMUNICATION AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUGUST 2020)

- a. 2 CFR 200.216, “Prohibition on certain telecommunications and video surveillance services or equipment” implements Pub. L. 115-232, Section 889.
- b. USAID has been granted a temporary, limited waiver under Section 889(d)(2) that will allow the recipient to use award funds for the duration of this award to procure internet, cellular and landline services from communication service-providers who use covered telecommunications. All other costs incurred for covered telecommunications and video surveillance services or equipment, such as phones, video surveillance, and cloud servers specified in 2 CFR 200.216 remain unallowable in accordance with 2 CFR 200.471.

[End of Special Award Requirement]

A.14.2 FOR NON-U.S. ORGANIZATIONS -- SPECIAL AWARD REQUIREMENT RELATING TO THE PROHIBITION ON CERTAIN TELECOMMUNICATION AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUGUST 2020)

- a. The mandatory standard provision “Prohibition on Certain Telecommunication and Video Surveillance Services or Equipment (AUGUST 2020)” implements Pub. L. 115-232, Section 889.
- b. USAID has been granted a temporary, limited waiver under Section 889(d)(2) that will allow the recipient to use award funds for the duration of this award to procure internet, cellular and landline services from communication service-providers who use covered telecommunications. All other costs incurred for covered telecommunications and video surveillance services or equipment, such as phones, video surveillance, and cloud servers specified in the standard provision in paragraph a. above remain unallowable in accordance with the mandatory standard provision “Allowable Costs” and 2 CFR 200.471.

[End of Special Award Requirement]

[END OF ATTACHMENT A]

ATTACHMENT B – PROGRAM DESCRIPTION

EXECUTIVE SUMMARY

With an overarching goal of detecting ‘known unknown’ viruses that might pose a pre-pandemic threat, we will carry out an innovative, sustainable, and responsive surveillance program for detection and characterization of novel animal viruses with zoonotic potential. Our consortium, which includes University of Washington (UW), PATH, FHI360, and Washington University in St. Louis (WUSTL) is led by Washington State University’s (WSU) Allen School for Global Health, whose approach of placing full-time faculty in global regions has seen it lead innovative emerging infectious disease studies in East and Central Africa that target landscapes inhabited by humans, their livestock and diverse wildlife populations in ecosystems ideal for the maintenance and transmission of emerging zoonotic pathogens. The consortium features strong in-country partners supported by world class virology reference laboratories at UW and WUSTL involved in novel virus discovery and characterization, unparalleled experience in laboratory strengthening, One Health epidemiology and social science, and global reach. Apart from collective presence and institutional links in countries located in the six DEEP VZN global regions, our consortium partners bring complementary expertise, including global field studies and sampling by WSU and UW, laboratory capacity by WUSTL and UW, and data management and in-country stewardship by PATH, FHI360 and WSU. We will build on the achievements of the USAID EPT programs, and our collective prominence in the global NIH-supported Centers for Research in Infectious Diseases (NIH-CREID), to enable partner labs in focus countries to fully sequence and characterize novel viruses in unprecedented breadth and depth. We will leverage scientific breakthroughs with SARS CoV2 and other emerging viruses to apply cutting edge technologies to prioritize potential for viral spillover and pandemics. In focus countries, we will target high-risk locations and subpopulations at the human-animal interface using a risk-based analytical approach to guide sample collection where there is evidence of previous spillover or high prevalence of zoonotic viruses. Additionally, we will establish an efficient sample collection and transportation system and align capacities at in-country laboratories to identify viruses of zoonotic potential in a timely manner, thus triggering additional targeted sampling focused up- and downstream of the transmission chain.

We plan to collect over 800,000 samples, of which approximately 60% will come from wildlife. Assuming a 1-1.5% yield, our in-country labs will provide near-real time screening and genome sequencing to detect and characterize between 8,000 and 12,000 novel viruses from the target families over the five years of the DEEP VZN program. To effectively characterize viruses of zoonotic potential from the detected pool, we will use a combination of innovative molecular, protein structure and receptor analyses, and serological techniques to generate evidence of spillover to humans, and potential for human-to-human transmission. This consortium will also strengthen capacity within focus countries for continued assessment of viruses of zoonotic potential and enhance response to future outbreaks. To enhance sustainability, we will build in-country stewardship of all surveillance, diagnostic and data management activities through the development of meaningful partnerships with focus country stakeholders. Through engagement and integration with other USAID EPT efforts, NIH CREID networks and other professionals across human, animal, and environmental health sectors, we will promote meaningful sharing of resources and data in an inclusive and cost-effective One Health-approach. The overall outcomes of this program will be the detection of an unprecedented number of unknown viruses of pandemic potential that can be monitored by public health institutions worldwide, and significant

advances in our collective ability to characterize zoonotic and pandemic potential of emerging viruses.

OBJECTIVE 1: Conduct Sampling for Unknown Viruses from the Priority Viral Families
We have designed an efficient, responsive, and sustainable program that uses existing data and models on spillover risk to guide initial sampling and interim data to refine sampling targets.

Building on baseline detection of known viruses in the PREDICT, VIRION and EIDITH databases, our strategies will lead to the detection of previously unknown wildlife-origin viruses from the target families and identify a subset that pose a significant pandemic threat. Our

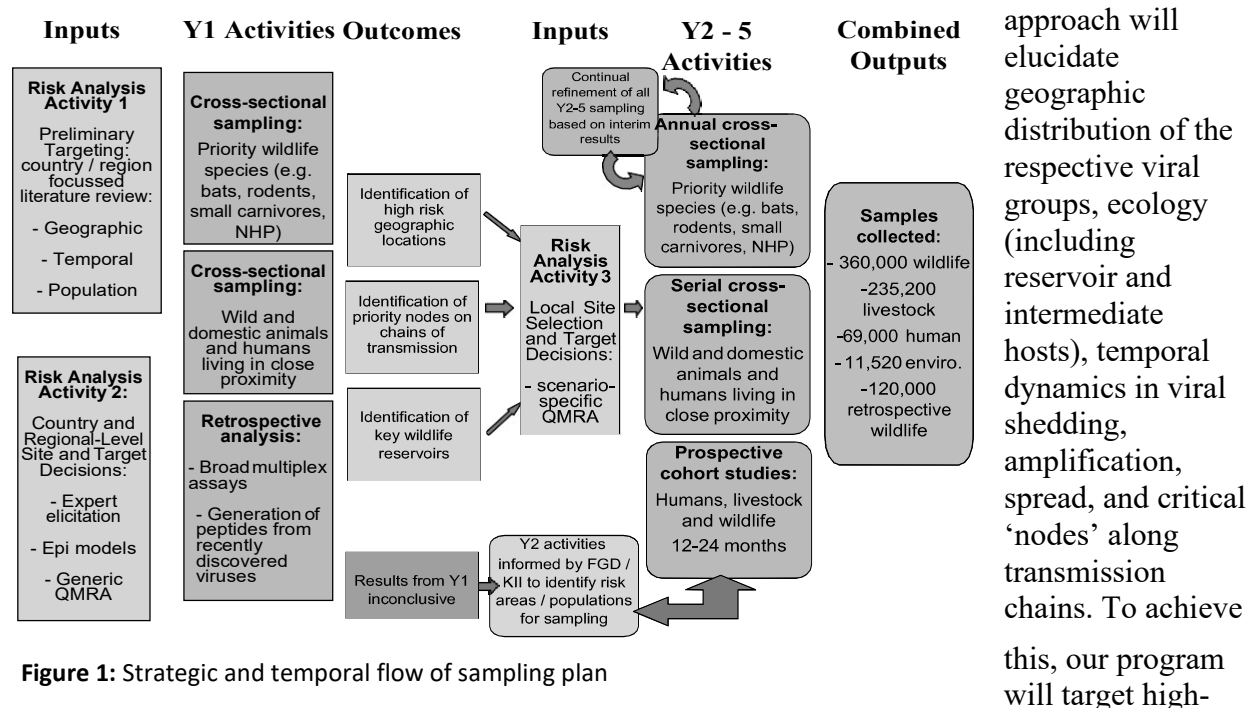


Figure 1: Strategic and temporal flow of sampling plan

risk locations and subpopulations at the human-animal interface, optimizing yield and resources (Fig. 1). This targeting will be adaptive, with locations identified through an iterative process informed by ongoing data collection. We will establish a pipeline of sample collection and transportation, aligned with capacities at existing in-country laboratories (utilizing a hub and spoke approach). Identification of a virus of zoonotic potential will trigger additional sampling focused up- and downstream on the transmission chain. Sampling will be guided by a risk-based analytical approach informed by evidence of a previous spillover event, a high prevalence of zoonotic viruses, or close contact between humans and reservoir hosts. Finally, we will employ a One Health-approach through engagement of human, animal, and environmental health sectors.

1.1 Sample Site and Species Selection

Focus 1: Preliminary Targeting - country/region focused literature review

To inform initial geographic, temporal, and species sampling plans and further risk-based targeting, we will carry out a rapid and comprehensive literature review (including grey literature and proceedings from meetings and One Health platforms) in Y1 to identify where prevalence and diversity of the target viral families are high, where critical nodes on chains of transmission are located, and key wildlife species are abundant (Focus 2 and Fig. 2).

Geographic Selection: We will use literature review, remote-sensed data, and existing risk maps of zoonotic disease emergence risk and its drivers to make a primary selection of geographic

areas of interest. Priority drivers of disease emergence will include human population density, land use change, density and diversity of wildlife species (focusing on mammalian species),

intensive farming of domestic and wild species, and live/wet wildlife markets. We will also leverage maps and data from PREDICT sampling data.

Temporal Selection: Viral (and host) seasonality and multiannual trends impact viral load and thus detection rates and will be critical determinants of sampling timeframes, particularly for wild animal sampling. The literature review will leverage existing knowledge of targeted viral families and host dynamics to inform our risk-based sampling strategies.

Population Selection: Country-specific literature review will identify wildlife and livestock species, human occupational groups, and value chains to consider for sampling.

Focus 2: Country and Regional-Level Site and Target Decisions - risk-based analysis Using a hybrid risk-based approach, we will refine geographic, temporal, and population targets defined by Focus 1 to plan the location and the timing of each sampling activity, with emphasis on identifying populations of wildlife, domestic animals, and humans on transmission chains. This approach will build upon existing knowledge from previous USAID-funded research projects, tailored to country-specific contexts. We will use available data and models and in-country stakeholder engagement, ensuring rapid site selection and start-up of project activities.

Epidemiological Models: In collaboration with key partners, such as the USAID-funded STOP Spillover project, in-country research institutions, and relevant government ministries, the team will review existing epidemiologic models (spatial and mathematical) of spillover risk parameterized to the geographic areas and populations identified in Focus 1. This work will both inform the structure of the epidemiologic models developed in Focus 3 and collate data for these later models. Existing models of viral and host seasonality, host dynamics in targeted wildlife populations, and seasonal trends in wild meat hunting will be used to plan sample timing. **Expert Elicitation:** If the absence of context- and site-specific data or relevant

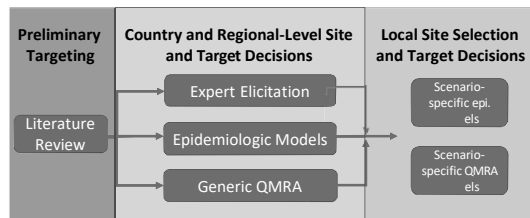


Fig. 2: Risk-based analytical approach to sample site selection

epidemiologic models preclude the use of modeling to refine sampling plans, we will use an expert elicitation-based risk ranking approach to scope initial rounds of sampling.

QMRA: As part of a multimodal strategy, the team will develop prospective probabilistic models utilizing a quantitative microbial risk assessment (QMRA) approach to identify populations and areas of greatest risk and uncertainty. Such approaches have been used to estimate environmental risk of zoonoses transmission and provide a way to include viral load data into our risk prioritization process. As the magnitude of risk will likely be driven by scenario-specific exposures, updated models will be developed at the onset of the project following literature review and subsequently tailored to specific exposure scenarios (Fig. 2).

Focus 3: Local Site Selection and Target Decisions

Based on site- and context-specific information and models generated in Focus 2, detailed exposure modules will be incorporated into location-specific QMRA models, the findings of which will be triangulated with spatial epidemiologic models. These models will be informed by geolocated data indicating prior spillover events, presence of immunocompromised wildlife species, disturbances that increase physiological stress, human activities that facilitate wildlife contact, and high population density. We will develop an initial set of location specific QMRA models based on the sampling sites and data from PREDICT 1 & 2 and evaluate these models to identify sites with the greatest estimated risks and/or uncertainty. In concert with our QMRA models, we will use the computationally efficient stochastic partial differential equations approach to Gaussian process modelling to generate high-resolution maps of spillover risk in the

target geographies identified in Focus 1 - 3. Both models will be continually iterated as new data become available, and sampling sites/targets will be adjusted.

1.2 Sampling Targets

To reduce delay, as soon as each of Focus 1-3 is completed decisions on site identification and timing for initial rounds of sample collection can begin. We will use pre-existing models and computational frameworks to complete these models while sampling approvals are pending. Targeted sampling locations, timelines, and species will be refined through participatory workshops, including representatives from wildlife, human, livestock, and environmental health sectors, and supply chain mapping integrated with network data. Retail outlets for wildlife products will be the terminus of this mapping, with focus on the movement of animals or their products from their points of origin to consumers. Eco-centric network data and value chain data will be collected at each node to identify priority nodes for viral transmission.

Once sampling targets have been identified, we will use sampling methods selected based on population sampled, risk characterization, and country-context, including serial cross-sectional sampling and prospective cohort sampling. Where possible, serial cross-sectional sampling will be repeated in the same population to determine which viruses are adapting to humans (pre-pandemic viruses) and to allow development of interventions to mitigate transmission. In addition, we will use composite sampling to screen samples, with follow-up testing of discrete samples from positive composites to decrease cost and increase throughput. We will also collect socio-anthropological data at these high-risk locations to better understand human-animal-ecosystem interactions relevant to viral transmission. Sampling targets will include:

Wildlife: Focus 1-3 will identify sites for initial sampling and priority mammalian species.

Supplementing risk characterization, trait-based statistical modelling will be used to prioritize bat species for each viral taxon, which will be iteratively improved as more host-virus data become available. Within these sites and species, sampling will focus on populations likely to impact the animal value chain (wildlife or livestock), including free-ranging wild animals living near areas of intensive livestock farming, wild mammals in ecosystems recently fragmented by expanding human communities, farmed wild mammals and wild mammals sold in live/wet markets.

Domestic animals: Sampling will focus primarily on intensively farmed domestic species that are reservoirs or amplifying hosts for the targeted viral families, characterized in Focus 1-3.

Industrialized farms with poor biosecurity or ecosystem encroachment will be prioritized.

Humans: Sampling will focus on country-specific occupational groups (and controls) at highest risk for spillover already geographically and temporally linked to wildlife described above.

1.3 Country-level Strategic Sampling Approach*

**Specific sampling targets will vary by target country based on in-country context*

Task 1.1: Cross-sectional sampling of wild animals (priority species): We will implement cross-sectional sampling of populations of free ranging wild animals likely to host unknown species of known virus families and target physiologically and immunologically stressed populations (migratory populations/ those living in areas of intense land use change). The highest proportion of samples collected will be fecal matter (e.g., under-roost excreta) to optimize efficiency and sensitivity for viral surveillance and discovery, particularly for henipaviruses and coronaviruses. We will also collect and test wildlife meat from markets and traders.

Year 1: Sample teams: 3 per country, sampling for 45 days/year, collecting 40 samples/day;

Aim Per country: 5000 samples; **Target species:** Bats, rodents, small carnivore species, non-human primates (NHP); **Sample type:** Feces, blood, oral/rectal swabs;

Years 2–5: Sample teams: 3 per country, sampling for 21 days / year, collecting 40 samples/day; Prospective sampling informed by Y1 results; **Aim per country:** 2500 total samples/year; **Target species** and **Sample type:** as in Y1

Task 1.2: Cross-sectional sampling of animals and humans living in proximity:

Humans are frequently in contact with large aggregations of wildlife, such as rodents, bats, and small carnivore species. Such synanthropic wildlife species provide opportunities for spillover to amplifying reservoir species that have greater opportunities for pathogen sharing with humans. We will sample wildlife species among or near areas of intensive livestock farming, farmed wild animals, and wild animals sold in live/wet markets. We will also carry out composite sampling of human and livestock species through collection of fecal slurry (livestock) and sewage (human) samples, prioritizing sampling of environments where animals/humans have recently displayed signs of illness and sites characterized by recent disturbances of neighboring ecosystems. We will also sample domestic carnivores (dogs and cats) as these species typically range widely, scavenge, have contact with wildlife, livestock, and humans and are accessible for sampling.

Year 1: Wild animal sample teams: 3 per country, sampling for 45 days/year, collecting 40 samples/day; **Domestic animal sample teams:** 3 per country, sampling for 30 days/year, collecting 40 samples/day; **Human sample teams:** 3 per country, sampling for 45 days/year, collecting 10 samples/day; **Per country aim:** 5000 wildlife, 3600 domestic animal, 1350 human samples; **Target species:** Rodents, bats, domestic and wild carnivore species (e.g. domestic dogs/cats, civet cats), ungulates, poultry, humans; **Sample type:** Wildlife species: feces, blood, oral/rectal swabs; humans, livestock: composite sampling of fecal slurry and sewage

Years 2–5: Prospective sampling informed by Y1 results; **Wild animal sample teams:** 3 per country, sampling for 21 days/year, collecting 40 samples/day; **Domestic animal sample teams:** 3 per country, sampling for 14 days/year, collecting 40 samples/day; **Human sample teams:** 3 per country, sampling for 20 days/year, collecting 10 samples/day; **Per country aim:** 2500 wildlife, 1600 domestic animal, 600 human samples.

Task 1.3: Retrospective analysis of bio-banked samples: We will request access to bio-banked sera collected from wildlife species, including from previous USAID-funded projects such as PREDICT, in areas determined by our risk analysis activities to be hot-spot zones. Broad multiplex assays will allow identification of all ‘known knowns’ and refinement of subsequent sampling strategies (in Y2-5) to increase the probability of detecting ‘known unknown’ viruses. Additionally, novel peptides generated from recently discovered focus family viruses will allow contemporary viruses to be detected.

Year 1: Per country aim: Collection of up to 10,000 wildlife serum samples from in-country biobanks; **Target species:** Bats, rodents, small carnivore species, NHP

Task 1.4: Prospective cohort studies of humans, livestock, and farmed wildlife

Per country aim: i) **animal workers (human):** 200 blood samples twice/year; 200 risk factor questionnaires monthly; 10 semi-structured interviews monthly; 200 nasal wash samples monthly; ii) **controls (human):** 50 blood samples twice/year; 50 questionnaire surveys monthly; 50 nasal wash samples monthly; iii) **farmed animals:** 200 composite samples monthly; iv) **environmental samples:** 20 samples monthly (1 per farm/month), for example, composited waste water sample or barn air; v) **workplace:** 20 (1 per farm/month) x Animal Workplace Enrolment and Animal Workplace Follow-up Questionnaire; **Target species:** Humans, ungulates, poultry, farmed wildlife

Task 1.5: Responsive sampling in the face of an outbreak: In the face of emerging epidemics, opportunities to understand the epidemiology of an outbreak are lost because of delays

mobilizing sample collecting activities. SOPs and sampling teams will be prepared to undertake rapid collection of samples from wildlife and domestic animals in the immediate geographic area around an index case. We will remain in close communication with public and animal health disease reporting agencies so that disease outbreaks can trigger localized investigations.

1.4 Sample Size and Detection of Known Viruses

The more samples collected and tested, the higher the likelihood of detecting a previously unknown member of the target viral families. Collecting 300 samples from a given target species provides a 95% probability of detecting a virus present in at least 1% of individuals; Therefore, a risk-based approach to selecting animal species is critically important to optimize project resources. We will tether our collected data to baseline detection of known viruses in the PREDICT and VIRION databases and a beta-coronavirus specific database (<https://www.viralemergence.org/betacov>). This will allow estimation of expected prevalence and diversity for comparison with observed values for each viral family and host species. Following Y1 collection, detection, and viral characterization activities, we will use cluster detection algorithms to identify hotspots of prevalence or diversity of known viruses, triggering further focused sampling. Detection of known viruses in the three families provides a positive control.

1.5 Contingency Plans

Although the sampling plan is ambitious in scope we are confident that we can collect the numbers of samples listed. Key reasons for this are that we will a) focus sampling efforts on the collection of fecal matter, including composite slurry/sewage samples, which is an excellent sample type for viral discovery and relatively easy to collect; b) exploit sampling synergies within and between sampling targets, for example, sampling of humans, domestic animals, environments, and farmed wildlife will be carried out by single teams that focus on multiple sampling targets. This will make sample collection more efficient; and c) increase the number of sampling teams and / or sampling days if targets are not met. Finally, the plan will allow sampling targets to be exceeded in countries where collection is efficient, which will counterbalance more modest sampling outputs in less productive countries. It is also important to note that, for restrained animals, multiple samples will be collected (fecal, blood, swabs) and as such the estimated total number of samples refers just that and not number of animals sampled.

1.6 Outcomes

The outcomes of Y1 will be used to inform the strategic planning of the sampling activities in Y2 – 5. This site selection review will be an iterative process to determine whether to add new sampling sites. If outcomes from Y1 activities are inconclusive, sampling activities in Y2 – 5 will be informed through iterative refinement of the epidemiological and QMRA models and detailed, in-country participatory workshops and interviews targeting workers in the human, animal and environmental health sectors. Samples collected will be studied with an array of molecular assays for previously identified as well as novel corona-, filo-, and paramyxoviruses. Where data show a prevalent emergent animal virus, we will identify the location and specific animal hosts of origin and collect data on supply chains and contact networks to target additional specimen collections and molecular studies along the chain of transmission.

1.7 Capacity Building and Sustainability

To facilitate sustainability, we will promote in-country stewardship of all Objective 1 activities, including risk-based analytical approaches, design of sampling strategies and collection of samples. Rapid assessment of in-country capabilities will be conducted to identify gaps in personnel, training and equipment. Training will be provided for each activity (utilizing virtual

methods and translation to local language), and location-appropriate equipment provided in order to allow activities to be performed within, and beyond, the lifetime of the program.

OBJECTIVE 2: Strengthen Detection for Novel Viruses from Priority Viral Families

Our sampling strategy is designed to collect as many specimens as possible. Using a strategically designed, risk-based approach to sampling, we will roll out serial cross-sectional and prospective cohort studies at nodes of potential transmission of novel viruses to collect and screen **~800,000 specimens, with >60% from wildlife**. We will build a detection and characterization program utilizing in-country labs to provide near-real time screening and genome sequencing and finishing. Assuming 1-1.5% yield, based on the yield in the PREDICT program in the 3 viral families targeted for DEEP VZN (DV), this approach is likely to **detect and characterize 8000 – 12,000 novel virus genomes** over the DV program. We estimate these genomes to comprise a total of 1,000 novel viral species, based on the number of novel sequence submissions from the PREDICT project (~2100 novel sequences from 3 highlighted viral families for DV, constituting ~250 novel viral species, or ~8 specimens/sequences per novel virus species).

2.1 Capacity Building and Sustainability

Our capacity building approach for in-country laboratories is summarized in **Fig 3**. *The goal is to ensure that each country independently conducts full virus screening (basic detection to whole-genome sequencing) and basic characterization that includes evaluation of spillover (serology) and later glycoprotein and receptor-binding assays.* We will ensure sustainable, in-country capacity to safely detect and characterize unknown novel viruses by providing high-throughput automated nucleic extraction, multiplex qRT-PCR screening instruments, and *NextSeq* Illumina next-generation sequencing (NGS) platform in each country. All 18 partner institutions we have identified in the 12 target countries have existing serology capacity, while 60% and 25% have qRT-PCR, and NGS capacities, respectively. Building on our consortium's >25 years of experience working in sub-Saharan Africa, Asia, and Latin America, including during the COVID-19 pandemic, we will address the recurrent problem of high cost and delayed delivery by establishing direct-buy credit accounts and service contracts with the manufacturers of equipment involved in the DV program. As illustrated in **Fig 3**, in Year 1 we will conduct rapid assessment of in-country labs to determine needs, followed by provision and installation of equipment to ensure they can conduct qRT-PCR, serology (ELISA and pseudotype viral neutralization test (pVNT)), and viral WGS.

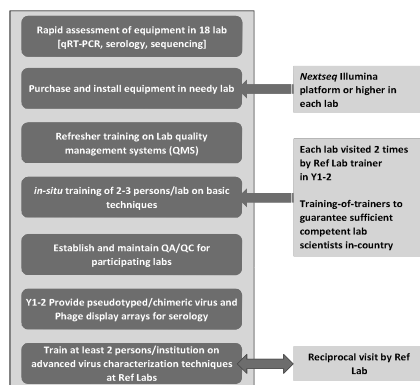


Fig 3. Flow chart of stepwise capacity-building for in-country labs

Reference Labs: We will establish and fund two Reference Labs in the US, tasked with building in-country lab capacity, and validate advanced virus characterization (*in-silico* glycoprotein and receptor, *in vitro* and *ex vivo* virus-cell studies). The D. Wang (WUSTL) and A. Greninger (UW) labs, supported by other virology, immunology, and protein chemistry labs at these institutions, will in the early phase of the program (Years 1-2) (i) Develop and supply novel virus detection and

characterization standard operating procedures (SOPs), (ii) Conduct *in situ* training to in-country labs on qRT-PCR, whole-genome sequencing (WGS), and serology technologies, including annual refresher trainings, (iii) Develop and supply qRT-PCR controls and standards, (iv) Develop and supply serology screening kits (phage display peptide libraries, pseudotyped and/or chimeric viruses, monoclonal antibodies), (v) Roll out and manage a QA/QC system to ensure

reproducible and comparable data (including proficiency panels and re-testing 10% of positive specimens from each country), (vi) Conduct advanced characterization (*in-silico* glycoprotein and receptor, *in vivo* and *ex vivo* studies with live virus), and (vii) travel and train at least two persons from each participating institution in their US reference labs on development of pseudotyped/chimeric virus and antibodies for serology, and advanced virus characterization. Based on our successful experience with lab capacity strengthening, it is essential that this will be accompanied by reciprocal training visits by reference laboratory trainers to in-country labs, with the goal of ensuring that in-country labs can independently conduct detection and significant advanced virus characterization (except virus culture, or *in vitro* and *ex vivo* studies with live virus that may require high biosecurity laboratories). We recognize that in-country laboratories will not acquire competency at the same rate because of factors such as additional needs to improve infrastructure, biosafety and biosecurity capacity, sub-contracting and procurement challenges, and staff turnover. We also anticipate that early in the DV program in-country labs will identify suspected novel virus samples that require urgent characterization methodologies not yet fully established and transitioned to the country. To address this, the project will expand U.S. based reference lab personnel who will be dedicated to implementing all aspects of in-country virus detection and characterization (as described). These personnel will transition for several month-long periods each year through the in-country laboratories to provide both structured and ad hoc in-country analysis support, including complete bioinformatic analysis of NGS data to identify novel viruses, basic *in-silico* viral glycoprotein and receptor-binding analyses, and serological analysis to determine novel virus spillover. Additionally, this response team may be deployed to work alongside in-country scientists in a country with suspected novel viruses until characterization is completed to the satisfaction of the consortium executive council and USAID. The Reference Laboratories will also validate in-country results by repeating a limited number of the characterization tests conducted on novel viruses. This validation will be achieved by shipping aliquots of not more than ~0.1% of collected samples (negative and positive) as shown in the textbox below.

ESTIMATED NUMBER OF SAMPLES SHIPPED TO REFERENCES LABS IN UNITED STATES

From ~800,000 specimens collected; we estimate at least 8,000 (1,600/year) will have suspected novel viruses. Of these, we expect to ship no more than 10 qRT-PCR positive and 10 negative specimens from each country in Years 1-2 (480 specimens) for validation, and 5 qRT-PCR positive and 5 negative specimens In Years 3-5 (360 specimens), bringing the total specimens shipped to 840 (0.1% of collected specimens) over the 5 years for the DEEP VZN program.

For purposes of virus culture, virus isolation, *in-vitro* and *ex-vivo* studies, we have established access to the Rocky Mountain BSL-4 laboratory (letter of commitment available).

2.2 Overall Detection Strategy

We will use both molecular and serological approaches to detect novel viruses. For maximum sensitivity and efficiency, our primary virus detection strategy will use broad-range qRT-PCR assays that specifically target the 3 virus families for initial screening of specimens. We will utilize consensus RT-PCR followed by sequencing of amplicons and interrogate positive specimens further to obtain complete genomes. Broad serology will be used to adjust the sampling strategy (Objective 1), and also to investigate spillover of novel viruses across the wildlife-livestock-human spectrum (Objective 3). Focusing primarily on sera collected from bats, rodents, NHP, and humans, we will screen for known and newly detected coronaviruses, paramyxoviruses and filoviruses using phage display serology. Evidence of high prevalence of diverse species of target virus families will indicate an ecosystem favourable to maintenance and

transmission of these viruses. *Serologic detection* of antibodies to a novel virus may also provide information on duration of exposure and affected animal species, with high seroprevalence in humans pointing to higher frequency of spillover events.

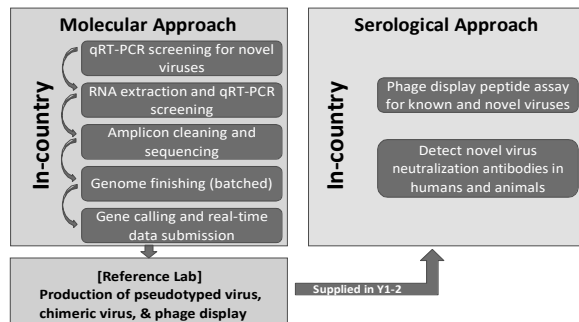


Fig 4. Virus detection flow chart

How our approach enhances efficiency to detect novel viruses: Our molecular screening strategy (Fig. 4) optimizes sensitivity, keeping the most expensive aspects (deep meta-genomic sequencing) to a minimum. All 3 viral families targeted for detection in the DV program are shed and detectable in stool reducing the need for animal trapping and handling. We have also integrated viral load measurement to our screening to improve chances of genome

finishing. During genome recovery from positive specimens, we will be able to infer hosts from environmental metadata and non-viral metagenomic sequencing data, which will be fed back to sampling teams to focus on particular animal species and areas where positives have been detected. The phage display approach is more cost-effective and efficient to serologically screen for known and novel viruses from target families than alternative multiplex serology approaches, such as peptide microarrays. Primarily because the phages self-replicate and thus are a renewable resource. Broad serology is costlier than qRT-PCR and this will limit its use.

2.3 Molecular Screening

Task 2.1: RNA extraction and broad-range qRT-PCR: RNA extraction methods will be standardized across all sites. Ideally, automated extraction instrumentation will be installed at each site. In addition, an alternative manual extraction method will be established as back-up. Our team has validated a family-specific, broad-range, single-well RT-PCR assay for *Orthocoronavirinae*, which enabled discovery of a novel coronavirus from a hospitalized patient in Malaysia. We will also make use of a published two-well pan-paramyxovirus and a one-well pan-filovirus qRT-PCRs to screen specimens. These family-specific primers amplify conserved portions of the RNA-dependent RNA-polymerase and allow for species determination after amplicon sequencing. We will integrate SYBR-Green into family-based RT-PCRs to allow for viral load quantitation at the same time we are detecting novel viruses along with melting curves to ensure appropriate-sized amplicons are generated without gel electrophoresis. As a backup strategy to the quantitative readout, a standard operating protocol for gel electrophoresis-based readout will be established. We will ensure in-country labs have instruments that can perform these assays with a throughput of 20-22 specimens per 96-well plate or 80-84 specimens per 384-well plate. We anticipate a throughput of at least 80 specimens per day per laboratory. Amplicons from qRT-PCR will be cleaned of PCR primers and sequenced on *Nextseq* biweekly, with up to 96 amplicons multiplexed. For further cost efficiency, we will explore the feasibility of multiplexing up to 384 amplicons. To identify novel viruses from the amplicons, all sequences will be aligned to a reference database composed of all target viruses from GenBank. Amplicon sequences that diverge significantly from all known viruses will be prioritized for whole genome sequencing. To standardize assays, the Reference Labs will provide positive and negative control standards for RT-PCR. Qualitative controls will be run through extraction and qRT-PCR on every plate, while quantitative controls will be run monthly. Quantitative controls will consist of a set of serial dilutions (10^7 - 10^0 copies/ul) of *in-vitro* transcribed RNA targets (2 different viruses in the family).

Task 2.2: Genome recovery and finishing: For maximal cost efficiency and timeliness, genome finishing will be performed in batches using *NextSeq* or *NovaSeq* equipment in each country. After identification of amplicons derived from novel viruses, we will ensure that complete genomes are recovered and finished to enable further screening and characterization. Complete genomes are also necessary for development of diagnostics, molecular epidemiology, vaccinology, and therapeutic development. Specimens will be prioritized for whole genome sequencing based on sequence divergence from known viruses and viral load estimates. We will use a variety of NGS methods as needed, including metatranscriptomics with rRNA depletion and/or poly-A enrichment approaches. Based on the identity of the virus, we can also use spike primers that bind the sequences recovered in the family-specific qRT-PCR or other highly conserved regions in that viral family into the cDNA synthesis prior to sequencing to increase coverage of viruses. New rRNA depletion reagents that cross-hybridize across metazoans will ensure fewer reads are spent on rRNA in rodents, bats, NHP, and humans, allowing for 8-150-fold enrichment of on-target reads. All targeted viral families poly-adenylate their transcripts, allowing classical RNA-Seq approaches to help in viral genome recovery. As a default, specimens will be targeted for 25 million reads to ensure genome recovery using high-throughput Illumina sequencers, which can allow recovery of near-complete genomes from specimens with Ct < 27. If needed, we will perform additional deeper sequencing, manually design PCR primers to close gaps, and perform 5' and 3' RACE to recover the viral genome termini. Our team has expertise sequencing whole genomes of novel RNA viruses. In Year 1, we endeavour to obtain and sequence specimens that have novel target virus from prior PREDICT projects. Small 400-500bp fragments of >150 novel paramyxoviruses and more than 60 novel coronaviruses were detected in PREDICT projects, but full genome sequences are not available. **Task 2.3: Genome calling and real-time data deposition:** Genome calling will be performed using a variety of automated and bespoke pipelines, including cloud based IDSeq for comprehensive assessment of viruses present in a specimen. As a complementary approach, we will also use well-described locally installed bioinformatic approaches, such as IRMA (an assembler specifically optimized for RNA virus genomes) and SURPI (pipeline optimized for unbiased metagenomic detection of all pathogens). Reads will be remapped to all draft genomes to ensure accuracy and manually reviewed in Geneious, especially if manual gap filling or 5' and 3' RACE is required. Importantly, our bioinformatics strategy also takes advantage of the global bioinformatics community and the wisdom of crowds by including real-time FASTQ and FASTA sequencing data deposition into NCBI Sequence Read Archive (SRA) and GenBank with **zero embargo time**. Our team has previously published software to facilitate rapid deposition of viral genomes into GenBank. SRA and GenBank accessions and brief initial analyses of sequencing data will be automatically communicated in real-time via our project-specific Twitter, so they are accessible to the global scientific community.

2.4. Broad Serology Screening

Zoonotic spillover is not considered a one-off event, and multiple small spillover events can potentially be detected by serological studies. For SARS-CoV, human serosurveys in south-eastern China found evidence of repeated spillover, with antibodies shown to persist for at least 2 years. To identify the animals or humans that had prior exposure to target viruses, our Reference Labs will generate phage display libraries covering 100,000 of the most conserved 60-mer peptides across all known filovirus, paramyxovirus, and coronavirus genomes following the VirScan protocol. The phage library will be amplified and validated using well-characterized positive control sera obtained from PREDICT labs, NIH-CREID network, in-country and CDC,

and Institute Pasteur labs. Reference Labs will develop kits consisting of phages that can be incubated with sera and protein A/G beads in in-country labs, with library preparation. Following incubation, the beads can be washed and library generation performed. The resultant DNA library is stable and can be sequenced at in-country laboratories. The phage library will be updated with novel viruses detected globally. The library will be used to screen high priority sera collected from bats, rodents, NHP, and humans sampled from nodes of potential transmission, serial cross-sectional samplings, and possibly archived sera. *Broad serology testing will be applied selectively and as a secondary approach, in part because of cost and the broader utility of genome recovery to enable further viral characterization work.* However, we envision that:

- (i) evidence of infection by novel viruses can be obtained from the serological profiles;
- (ii) unique signatures of epitopes distinct from those derived from known infections may suggest prior infection with a novel virus;
- (iii) high prevalence of diverse species of the target virus families may indicate an ecosystem favourable to maintenance and transmission of novel viruses of interest, and therefore point to a preferred sampling location;
- (iv) serologic detection of antibodies to a novel virus could inform the duration of exposure and affected animal species, with high prevalence in humans pointing to increased risk of spillover to humans.

We should point out that low or undetectable antibodies in humans may not indicate that a novel virus poses low risk to humans because other factors such as its recent introduction or potential for acquiring transmissibility to humans through minor mutations still exists.

As an orthogonal method to the broad serological screening, we will also perform binding ELISA serological assays against novel virus glycoproteins. Upon sequencing of a new virus, we will undertake codon-optimized gene synthesis to generate constructs for recombinant protein expression and pseudovirus generation. We expect to purify recombinant spike ectodomain trimers and/or receptor binding domain proteins for coronaviruses, GP trimers for filoviruses, and both fusion (F) trimers and G/H/HN tetramers for novel paramyxoviruses. We will use an antigen prediction pipeline to predict sensitive and specific viral protein antigens. Viral proteins and fragments predicted by this algorithm will be expressed for ELISA serodiagnosis. Negative-stain electron microscopy will be used to ensure the viral proteins are folded correctly after purification. Once viral protein antigens are purified, we will contract with GenScript for rapid generation of custom monoclonal antibody controls. We will then determine the specificity of the ELISA binding assay against a bank of >2,000 historical human serum specimens from UW Virology, including testing for cross-reactivity specifically against sera positive for IgGs to measles/mumps virus for paramyxoviruses, SARS-CoV-2 and all four endemic coronaviruses, and Ebola/Marburg viruses for filoviruses. Pending results from those specificity tests, we can iterate design of antigens for specific serological testing, including use of specific viral peptides, as required. Sensitivity will be tested against convalescent host animal sera as well as any human sera available from individuals known to be infected. This ELISA kit will then be provided to in-country labs with positive and negative controls, as well as host control proteins for testing for vaccine preventable illnesses (SARS-CoV-2 spike protein for coronaviruses; measles H for paramyxoviruses) and will be compatible with commonly available plate readers. Early in the COVID-19 pandemic, our UW Reference Lab provided recombinant SARS-CoV-2 nucleocapsid along with controls for binding ELISAs to laboratory partners in Senegal, Pakistan, Brazil, South Africa, Nigeria, Kenya, and other countries as part of the NIH CREID consortium. In addition to the binding assays described above, we will use pseudotyped lentivirus and chimeric vesicular

stomatitis virus (VSV) neutralization assays with the novel virus glycoproteins to functionally profile sera for neutralizing antibodies. These assays will benefit from the expertise of Dr. Whelan (WUSTL) and Dr. Veessler (UW) and allow for greater rigor and reproducibility of seropositivity identified by binding ELISA by providing an orthogonal and functional readout. Our primary approach will involve generating chimeric VSV reporter viruses (below). As these assays require cell lines permissive for viral entry, these efforts will create synergy between virus detection (Section 2.2) and characterization (Section 3.3) components.

Task 2.4: Generation of chimeric reporter viruses: We have extensive experience generating chimeric VSV reporter viruses where native viral glycoprotein (spike S, attachment glycoprotein G, fusion F, and hemagglutinin H) is replaced by those of heterologous viruses. Our experience with the coronaviruses indicates that either mutation of the endoplasmic reticulum retention sequence in the cytoplasmic tail of the spike, or truncation of the tail by approximately 20 residues can allow effective integration of the respective Spike gene into VSV, yielding viruses

that grow to titers of 10^8 pfu/ml. For filoviruses, we have not found it necessary to manipulate the cytoplasmic tail of the glycoprotein, although we have mutated the transcriptional editing sequence that is used for synthesis of soluble glycoproteins. Once an infectious clone of VSV-chimeras is assembled, we confirm sequences of the recovered virus, and characterize the growth of the respective viruses to establish the optimal conditions for the generation of seed stocks.

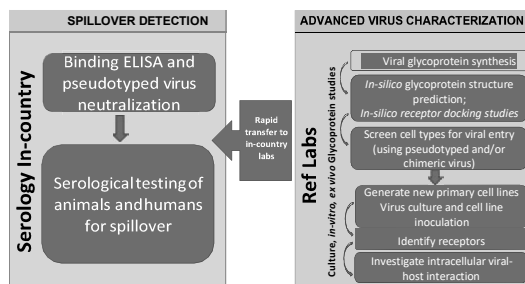


Fig 5. Flow chart for novel virus characterization

Task 2.5: Detection of neutralizing antibodies: We will use VSV-chimeric viruses to monitor levels of neutralizing antibodies in humans and sometimes animals. We are mindful of reports that bats inoculated with some filoviruses do not generate neutralizing antibodies that are detectable in neutralization assays. Accordingly, we will also use the VSV-chimeras to detect antibodies that recognize the respective envelope proteins displayed on the surface of virions. To do this, we will use purified virions that contain the respective envelope proteins on their surface and sera containing antibodies that bind to the virion identified by isolating the bound complexes. As an alternative approach to VSV chimeric viruses, we will use lentivirus-based pseudotyped neutralization assays. Pseudovirus neutralization assays against novel viruses will be optimized for expression and intracellular termini truncations as well as with monoclonal controls. The constructs, controls, and pseudotyped viruses will be made available to in-country partners once the assay is validated by Reference Labs. *These approaches will permit us to determine whether a given animal species has mounted an immune response to the envelope proteins of any novel virus and whether such immune responses include neutralizing antibodies.* The prevalence of such antibody responses may indicate potential risk for spillover into humans, even though low or undetectable antibodies may not mean that a virus is at low risk for human infection. These assays are compatible with BSL-2 settings widely available in in-country labs.

OBJECTIVE 3: Strengthen Characterization of Novel Viruses from Priority Viral Families

3.1. Overall Characterization Strategy

Guided by the understanding that, with timely and complete genome sequencing in Objective 2, >80% of novel virus characterization can be performed in the absence of virus isolation. We will start by characterizing selected novel viruses detected under the PREDICT program and identified as potentially important. Subsequently, we will use sequence data from novel viruses

we detected (Objective 2) to construct qRT-PCR screening kits and recombinantly express and purify viral proteins for reagents development (e.g., monoclonal antibodies) for serological assays and structural studies. We will use these sequences to create pseudotyped and chimeric viruses for serological assays and profiling viral entry. Pseudotyped and chimeric viruses can also be used to identify and screen for receptor usage and identify cell lines that support viral entry. These cell lines can be used to identify other determinants of tropism and to characterize viral entry mechanisms. We will attempt to isolate novel viruses and identify known or novel host genes that enable viral entry. Finally, we will determine the affinity of novel viral glycoproteins for human receptors and mechanisms of innate immunity antagonization to determine zoonotic/ pandemic potential (Fig. 5).

3.2 Profiling Viral Glycoproteins/Receptors to Assess Pandemic Risk of Novel Viruses

Task 3. 1: *In-silico* characterization of novel viruses. Our *in-silico* approach for profiling human transmission risk follows directly from the hypothesis that *affinity for human receptors of a novel viral glycoprotein indicates pandemic potential*. As soon as a novel virus genome is recovered, our UW Reference Lab will perform *in-silico structure prediction* of viral glycoproteins with Rosetta and trRosetta, as well as docking with known receptors for a given viral family to approximate affinity for human receptors. To support this effort, we will model the structures of the extracellular domains of all human proteins and compare these to structures of known host cell viral receptors to determine how closely they match as a way of generating hypotheses **for candidate** human host cell viral entry points. We will interrogate these predicted structures for specific changes in protease site activation. Our ability to determine high- resolution structures of viral glycoprotein-receptor complexes using world-class cryo-EM will be fed back to *in-silico* models to enhance protein structure prediction and viral-host protein-protein interactions. It is worth noting that to-date, no model has successfully predicted viral zoonoses and spread in humans. Therefore, our bias will be to perform as much wet laboratory characterization of novel virus glycoproteins. We will synthesize all viral glycoproteins recovered from novel viral genomes and screen in viral entry, biochemical, and biophysical assays because *in-silico* modelling is insufficient to capture risk.

Task 3.2: Biophysics and structures of viral glycoproteins. Divergent paramyxovirus, filovirus, and coronavirus genomes will be used to carry out structural studies of the corresponding glycoproteins in isolation and bound to target receptors to understand the mechanisms of viral entry into host cells. Our UW Reference Lab is world-renowned for expertise in viral glycoproteins and has developed a streamlined, high-resolution cryo-EM pipeline enabling high-throughput structural studies of viral glycoproteins bound to host receptors and neutralizing antibodies. It will be leveraged to provide atomic-level information of the infection machinery of discovered viral pathogens before they emerge. Novel viral glycoproteins and animal and human receptors will also be expressed and tested directly for binding kinetics and affinity using biolayer interferometry. These affinity measurements will provide biophysical confirmation of receptor interactions and direct biochemical evidence of the degree of pandemic risk of a novel virus. We will correlate binding affinity measurements and functional biochemical measurements of fusogenicity using cell-cell fusion assays.

Task 3.3: Viral isolation-independent viral entry characterization and receptor discovery. The VSV chimeras and pseudoviruses generated above will also be used to perform viral receptor discovery at a BSL-2 level. Previously, our WUSTL Reference Lab has used both VSV

SECURING MTAs FOR SHIPPING SPECIMENS: Our approach is to reduce the number and scope of MTAs. Each in-country lab will only sign one MTA with either UW or WUSTL reference laboratory

and pseudoviruses and a series of cell lines expressing canonical coronavirus receptors to rapidly screen for coronavirus receptor usage and to discover the human receptor of SARS-CoV-2. To establish neutralization assays, VSV chimeras and pseudoviruses will already be tested against a broad array of human, non-human primate, bat, and rodent cell lines that support paramyxovirus, filovirus, and coronavirus growth, including an initial screen of VeroE6, RHMK, CV-1, HAE, HuH-7.5, HEK293, HepG2, CaCo2, BHK (hamster), MEF (mouse), Aji (bat), RhiNi (bat) cell lines. This screen will be performed in the presence and absence of trypsin to determine if host restriction for viral entry exists at the level of proteolytic activation, as previously described for several bat coronaviruses. Canonical receptor usage (e.g., ACE2/DPP4/APN for coronaviruses, NPC1 for filoviruses, or SLAM/EphrinB2/3 for paramyxoviruses) will be confirmed at the protein-level using soluble receptor blocking and/or blocking monoclonal antibodies.

If viral entry into one of the above cell lines is not found to be caused by a known or canonical receptor, we will perform genome-wide CRISPRko screens to discover viral receptors. Using this and related genome-wide approaches, we have identified the receptors for multiple coronaviruses, paramyxoviruses and filoviruses validating this approach. We will carry out such screens to identify host genes that are potential determinants of infection and, armed with that information, we can determine the step of viral infection at which any given host gene functions as described in the rest of the proposal. This will allow us to compare the genomic sequence of entry factors between susceptible and non-susceptible host cells.

3.3 Viral Inhibition of Innate Immunity

Viral antagonization of innate immunity is an important component of viral pathogenesis in humans. Like glycoproteins, viral immuno-evasion proteins are often tailored specifically to the host they infect, and thus the zoonotic and pandemic potential of a new virus will be determined in part by how these genes affect human innate immunity pathways. West Nile and Zika virus spread in humans is in part determined by the degree of inhibition of the JAK/STAT pathway.

Infection in animal host species reservoirs can contribute to viral evolution strategies that facilitate evasion of host innate immunity. Bats have specifically downregulated inflammatory pathways while maintaining type I interferon pathways, leading to a unique evolutionary selection for viral antagonization of type I interferons.

Task 3.4: Testing for the degree of innate immune inhibition: The UW Lab will perform tests by all open reading frames from a novel virus in a host innate immune evasion screening platform. If throughput is limited, at a minimum we will characterize the major immuno-evasion genes from the different viral families. Here, the specific viral protein open reading frame is cloned and expressed ectopically in relevant host cell lines, 24 hours later cells are treated with exogenous interferon (IFN) and harvested over a time course to evaluate for possible reduction in innate immune signalling pathway activation compared to control cells treated with IFN but without ectopic expression of viral genes. Loss of innate immune activation will be evaluated by reduced IFIT1 and IFITM1 gene expression measured by RT-qPCR. We recognize that these approaches are limited to evaluating viral evasion from IFN responses and do not evaluate innate immune signalling components that occur prior to (upstream of) IFN induction. To address this, we will assess the ability of viral protein expression constructs to suppress the activation of interferon regulatory factor (IRF)3 activation induced by Sendai virus infection, a control virus that potently induces innate immune activation in infected cells. We will transfect cells with each viral protein expression construct, followed by infection with Sendai virus, and assess total and phospho/active IRF3 abundance. For a broader analysis of innate immune pathway regulation, we will infect relevant host cell lines with the virus panel of interest and evaluate innate immune

response pathways activated by each specific virus using assays (immunoblot and mRNA analyses) to measure the activation state of specific innate immune pathway markers as well as expression of downstream genes linked to each pathway.

3.4 Virus Isolation for Receptor and Intracellular Viral-Host Interaction Studies

Task 3.5: Viral isolation and receptor identification. As illustrated in Fig. 5, we may require virus isolation to conduct *in vitro* and *ex vivo* studies. Such studies will be conducted in BSL-3 and BSL-4 labs under proper biosafety protocols. Isolation of novel coronaviruses or paramyxoviruses (determined using sequencing data) when there is no concern of severe human disease can be attempted in certified BSL-3 labs located in-country, regionally, or at Reference Labs. Isolation of viruses of great concern of severe disease, such as filoviruses, will only be attempted in Rocky Mountain Laboratories BSL-4 lab (letter of commitment available on request). Positive specimens will be prioritized based on viral load, with a focus on specimens with >1 million copies per mL or gram. We will inoculate virus onto cells shown to be permissive to pseudovirus entry from above. Viral isolates will be expanded and deposited into central repositories with CDC, BEI, and/or WRCEVA, according to the appropriate biosecurity and national data sharing guidelines. Receptor usage determined in the pseudovirus screen will be confirmed using the viral isolate. For isolated novel viruses that do not show canonical receptor usage but cytopathic effect, we will screen for novel human receptors using genome wide CRISPRko libraries in cell lines that support viral growth as described above. Where possible, we will prefer viral isolate CRISPRko screens over pseudotype screens to identify potential intracellular viral-host interactions at the same time as identifying potential receptors.

Task 3.6: Host cell characterization and cell line generation for viral characterization.

Inoculating existing cell lines and primary cells with virus-positive specimens may not result in viral growth. The cell lines chosen may not contain the correct receptors, proteases, or other intracellular factors to support viral entry and/or growth. To support viral isolation and characterization for such viruses, we will generate primary cells from bat, rodent, and NHP tissues that are specifically sampled in DV and identified by host deep sequencing reads in Objective 2. Over the past decade, several new primary bat cell lines have been established that support growth of many viruses of high zoonotic potential *in vitro*, and yet bat species are so diverse that it is likely that no specific cell lines might be available for the bats sampled here. Should the approaches outlined above fail to support viral isolation, we will use scRNA-Seq sequencing of virus-positive primary specimens to help identify candidate host cells and host receptors to be targeted for cell line generation. scRNA-Seq is a powerful approach to link virus transcription and replication on a single cell level with candidate host cells and receptors should existing cell lines prove insufficient. If we are unable to specifically isolate the relevant host cell lines based on scRNA-Seq data, we will ectopically express candidate viral receptors identified by scRNA-Seq data into candidate host cell lines to determine viral receptor usage.

3.5 Algorithm for Ranking Viruses with Pandemic Potential

A proposed algorithm for ranking emerging viruses for potential spillover to humans was recently published by the PREDICT team (<https://spillover.global/ranking-comparison/>;doi.org/10.1073/pnas.2002324118). We will improve on this by applying the findings of our innovative and thorough stepwise virus characterization methodologies described in Section 3, and by rating each novel virus based on the following three questions:

- (i) Does the virus have potential for human transmission? This will be investigated using the glycoprotein modeling and functional viral entry studies described above.

- (ii) Is there evidence of its spillover to humans or a broad range of potential animal reservoirs? This will be addressed through serologic testing.
- (iii) Does the virus have capacity to inhibit host innate immunity? Evidence of immunoevasion is consistent with the potential for significant morbidity and/or mortality in humans and should trigger a higher level of public health concern, particularly if the virus rates high on criteria i & ii above.

We will summarize the results in prioritized lists that will be publicly accessible to both in-country partners and international stakeholders. Importantly, our findings, which will be disseminated in scientific publications, presentations, communication with USAID and other stakeholders, will add key metrics to evaluate the zoonotic and pandemic potential of novel viruses.

OBJECTIVE 4: Strengthen Focus Country Capacities for Data Management and the Viral Characterization Process

The proposed project will develop and implement improved data systems at the country and international level, building on learnings from the EIDITH system developed for PREDICT 2, and increasing interoperability and access for partners and stakeholders alike. We will also aim to enhance in-country data collection and use to accelerate detection and response to future public health threats. This will begin with an assessment of the data structure of the EIDITH system, defining a core set of standard variables to be collected across sampling locations for use in describing the distribution of pathogens/exposures. The importance of national-level data autonomy must be balanced with the need for widespread dissemination of data to aid in the prediction and prevention of emerging epidemics. We will work with countries to build on existing systems using an “Adopt-Adapt-Develop” approach while defining protocols for data sharing between the DV and local systems so that project data enhances existing systems while observing local policies and SOPs. The consortium will also draw on previous experience with local and global datasets to advance global surveillance of zoonotic threats. To allow rapid sharing of data across the consortium and with international databases such as NCBI, we will put in place MOUs and data use agreements using a “staged ring” approach, wherein data access can be conceptualized as a series of interlocking rings within which data ownership is retained by in-country stakeholders whilst standardized review, approval, and validation processes allow data to be rapidly shared to key stakeholders at national and international levels. This will ensure that, rather than creating parallel systems, the project builds upon (and integrates into) existing structures and data systems, while ensuring rapid release of validated data to project team, national, and international partners. Pending national approvals, aligned to standardized data sharing agreements supported by DV, and the removal of any sensitive information, data will matriculate across the data management structure, representing gradually more release of data (e.g., USAID staff, external partners, cross-border sharing and full public accessibility). This progression will represent not only increased access but also improved data quality: data sets made available to the public would represent those with well-documented dictionaries and curated metadata, while more incomplete data would remain with project and national stakeholders. In these endeavors, we will build on PREDICT, which has uploaded hundreds of sequences from newly discovered animal pathogens to the NCBI’s Short Read Archive (SRA) and GenBank. With USAID and local stakeholders, we will review and update the data use agreements where PREDICT has been active and use them as models.

4.1 Project Data Collection and Management

Task 4.1: Develop a project-wide data management plan. The consortium will use a data system based on principles of the EIDITH system to collect and manage data among the partners while respecting the need for data safety and ensuring in-country data ownership. This management system has the capability to import data for linkage with surveillance data systems in the host countries, USAID, and global systems such as healthmap, ProMED, NCBI.

Task 4.2 Monitor project implementation. PATH, leading Objective 4 and as a global leader in project monitoring and evaluation, will develop indicators and track project progress via systematic data analysis and review meetings, data quality assessments, technical working groups, and training of data managers at the facility, subnational, and national level.

Task 4.3 Data storage. Following national approvals described in section 4.2, data will be stored within the DV database with data security and access conforming to the FAIR Principles, as well as the Nagoya protocol for genomic data sharing.

4.2 Country Data Management

Task 4.4: Map the data management and policy landscape of each country. In Year 1 an early assessment of existing systems in use at the country and regional levels will be conducted in order to help support and define the architecture, connectivity, flow and human resource capacity to achieve rapid access to quality data at the country level. This assessment will identify gaps and areas that must be strengthened across the continuum from data collection, cleaning, and storage to analysis and presentation to key stakeholders and users and across relevant data sources including laboratory, human and animal clinical, and environmental data sets. This will also entail an extensive evaluation of the enabling environment, including existing health data privacy policies, data use regulations, digital workforce capacity, and information technology infrastructure. The goal is to develop a baseline for each country in terms of existing data agreements, identify adaptations that would enhance data sharing, and understand the policy environment for data sharing and use. Using these assessments, we will develop a roadmap for developing an integrated country-level data architecture with our country partners, including reporting from our DV data system and site- and laboratory-level data collection, as well as ensuring local data sharing through secure, interoperable data exchange.

Task 4.5: Evaluate lab information systems of DV lab and field data collection teams in focus countries. Our consortium will identify the capacity of partner labs in focus countries to support data capture for the project. Similarly, we will ensure that the field data collection teams are trained in data collection according to the data standards that we will extend based on EIDITH/PREDICT. We will build on the existing data structure from in-country data management systems and PREDICT/EIDITH, including sample tagging protocols, geolocation, and survey-based questionnaires.

Task 4.6: Incorporate knowledge and learnings from previous projects. We will use publicly available data, such as PREDICT data available through <https://data.usaid.gov> including readily available country-specific data sets from EIDITH (event animal production, event crop production, animals sampled, event dwellings, event value chain, PCR tests, and site/event characterization) and genomic information available through GenBank in national-level data use and analysis. This will ensure that our project database builds on successes and lessons learned from the EPT project to date. Our data management plan will be able to rapidly incorporate the metadata and genomic data of these samples when they become available.

Task 4.7: Establish data standards and governance. With our in-country partners, we will establish global data standards and assist with establishment of a data warehouse that includes

different collection and management aspects for analyzing, sharing, and storing data. The consortium has previous experience creating similar architecture (the POLIS system for polio eradication and analysis) which has been in use for over eight years. Technical working groups (TWG) will be developed to establish data governance and reporting plans for each target country. These TWG's will conduct regular monitoring of implementation and the assessment of whether goals are being met, while adhering to country needs to try to be more proactive, transparent, to share data rapidly, and be adaptable to addressing issues. We will engage existing standards bodies to ensure that data sharing formats leverage existing works and/or contribute to these standards. This will also address (and ensure) country/regional and local stakeholders' access to genomic/sequencing data from GenBank and other global repositories to build and strengthen research capabilities. We will work with country governments to ensure the timely sharing of information as described, while also recognizing sensitivities around data to avoid stigmatization that could lead to reluctance because of economic and societal pressures.

Task 4.8: Implement data collection using updated data system for focus countries. We will adapt existing technology for the DV digital tool to collect field-based data, including geolocation, animal or plant species, samples collected, unique sample identification, and so on. The tool will be based on an existing technological base, such as CommCare, RedCap or similar, with interfaces for data import, exchange, and interfacing with lab systems. The DV data system will collect necessary data, including accession information for genomic data, connected with sample and location data collected by the DV digital tool.

Task 4.9: Strengthen capacity of in-country partners to store, analyze, and share data. We will train in country partners on use of the DV data system and its linkages with existing in-country data system architecture, work with host governments and data users to identify the key questions they would like to answer with the data, as well intended purposes and requirements, and support implementation of solutions to improve country-level electronic data sharing capacities. Uploading viral sequences to NCBI will also facilitate data exchange between in-country labs and reference labs. We will work to establish harmonized bioinformatics techniques and pipelines across the DV project to ensure comparability of genomic data. User-friendly dashboards including GIS maps to show location of possible priority infectious agents or exposure will be developed to visualize and support interpretation of the data. The consortium will identify "local champions" at the different levels to accelerate this activity. We will work with our in-country partners to publish, supporting their capacity to act as lead authors in internationally recognized journals, and provide training and mentorship in scientific writing.

Task 4.10: Strengthen in-country data management processes for the viral detection and characterization processes. Our consortium will support in-country labs in the focus countries in training the necessary staff on laboratory data management, including genomic data, and to support staff in bioinformatics, monitoring, and maintaining data repositories and architecture.

Task 4.11: Develop an early warning system with country-level dashboards. Learning from tools such as Tableau, DHIS2 dashboards, and other existing AI platforms, by the end of Year 2 we will develop country-level dashboards of DV data to visualize data and identify potential emerging threats based on expert opinion. This will leverage work done under PREDICT 1 and 2 as well as the Spillover data tool (<https://spillover.global>).

4.3 Global Data Sharing

The consortium has identified key data sets to be collected across countries that may require augmentation to in-country systems. Sequencing data will be communicated in as close to real-time as feasible to make this information accessible to the global scientific community, while

also adhering to data governance requirements negotiated with local stakeholders. Sequencing data and correlation with other findings including advanced characterization will also be regularly shared with in-country partners and global stakeholders via published lists of prioritized novel viruses ranked on their pandemic potential. This release of high priority and high-risk pathogens will feed into other risk assessment activities at national and global levels such as STOP Spillover and the proposed WHO Berlin Hub for Pandemic and Epidemic Intelligence. The consortium is already engaging with these stakeholders to cultivate a new model of data solidarity and collaborative intelligence for risk assessment. Another emerging initiative supported by WHO - the International Pathogen Surveillance Network (IPSN) - will also work to support global exchange of genomic information. The consortium will ensure a close integration with and support for IPSN, leveraging this global structure and pathway for R&D. These examples demonstrate opportunities for improved and rapid data sharing in a quickly evolving landscape. The consortium, in collaboration with USAID, will continue to track and engage with these initiatives as appropriate. Wherever possible, the linkages between the consortium data and these international data sharing mechanisms will be built into the project system architecture and part of agreements with national stakeholders.

Task 4.13: Convene multisectoral networks at country and international level. We will build on existing data standards for PREDICT 2 and provide trainings across the consortium and with in-country stakeholders to ensure adherence to data standards.

Task 4.14: Develop improved data sharing processes across data systems at country and international levels and across stakeholders. The project will develop the DV digital tool “esign” – a data-sharing process that supports differing levels of staging and access – with the capability to move data from an internal-only level to internal plus USAID, external partners, and fully public, international levels. While aligning with host country requirements and global guidelines (e.g., WHO’s code of conduct for sharing of pathogen genetic sequence data), our consortium will also ensure appropriate data is made available in a rapid and responsible manner to benefit the global community. In keeping with our “Adopt-Adapt-Develop” approach, we propose a data storage structure that will include three related databases – one for raw sequencing reads, one for assembled data and one for sample metadata. This segregated structure will facilitate real-time reporting of raw sequence data (FASTQ and FASTA) accompanied by limited deidentified metadata to global repositories (NCBI SRA, etc.) while also ensuring that access to sensitive metadata remains restricted until validated and approved for release. This structure will support more routine release of raw sequencing data throughout the duration of the DV project, while enabling local investigators adequate time to complete genome assembly and perform data cleaning and validation prior to submission of finished genome sequences to public domain (NCBI, EMBL-EBI, DDBJ) or public access (e.g. GISAID) repositories, and/or alternative global platforms (e.g., GitHub). Finally, project results and analyses will be regularly communicated via scientific publications, presentations, and direct communication with USAID and other stakeholders. As appropriate, and in accordance with in-country data sharing agreements, outlets will be explored for more rapid dissemination of findings, particularly when novel viruses with high pandemic risk are identified. This includes sharing manuscripts within preprint servers, such as medRxiv or bioRxiv, prior to publication.

5 Capacity Strengthening

A key goal of our DV program is for every activity and outcome to be predicated on a foundation of sustainable capacity strengthening within focus countries. To achieve this, in-country partner organizations will play leading and participatory roles in the development and implementation of

all activities. Further, in-country nationals will coordinate and implement all planned activities, from sample collecting through to laboratory analyses, with language-specific training programs being provided where necessary. Moreover, when planning for the improvements in technical capacity through provision of equipment, care will be taken to ensure the utility of any equipment extends beyond the duration of the program by selecting location-appropriate equipment that can readily be maintained, resourced, and used. This will ensure that during and after the program maximal use is made of the virus detection and characterization capacity that the project will develop. Finally, it is critical that in-country stakeholders understand the value of the knowledge and resources generated. We plan to achieve this in two ways: (1) in-country partners will take leading roles in all aspects of data analysis and the preparation of peer-reviewed publications and (2) the DV project will engage a wide range of in-country stakeholders at project inception to begin the process of raising awareness about the potential value of the generated resources. This process will include multiple fora being hosted within focus countries with a variety of stakeholders to raise awareness of resources that will be generated by the program, and their use (Table 1).

Resource Generated	Resource Uses	Stakeholders
Data from wildlife sampling: species and abundance	Inform conservation efforts	National and international wildlife organizations
Viruses detected in wildlife and domestic animals	Prepare for animal health events	Animal health agencies
Spillover events detected in human populations	Determine risk to humans, control efforts	Human health clinicians, public health
Improved laboratory capacity for qRT-PCR	Improve detection of other infectious diseases	Human health, public health
Improved capacity for ELISA	Improve detection of other infectious diseases	Human health, public health
Improved sequencing and bioinformatics capacity	Application of whole genome sequencing to other pathogens	Laboratories, public health, surveillance

Table 1: Resources generated by the program, their utility, and the stakeholders who will benefit

6 Sample Monitoring and Learning Plan

The WSU-led consortium partners will work with USAID within the first 90 days of the grant to develop a comprehensive Monitoring Evaluation and Learning Plan inclusive of a Learning Agenda and Data Management plan that will describe the processes for monitoring project activities and progress towards achieving the desired results. A comprehensive indicator matrix with output, outcome, and impact indicators, annual and life of project targets, and baseline measures will be at the center of the MEL plan. Table 2 presents illustrative indicators for a subset of intended results and activities under each of the project's 4 objectives, with additional illustrative indicators in Annex 2. Quarterly team check-ins will be used as a venue for Objective Leads to review MEL data with the team to identify areas that are not achieving desired results and flag areas where implementation strategies might need to be adjusted. The team will use MEL data to inform project management and will report semi-annually and annually on progress towards achieving results under the agreed upon indicators in the MEL plan and explain any significant deviations from expected targets. The MEL plan will be reviewed for relevance semi-annually and the WSU-led consortium will work with USAID to revise if and when necessary. The team will collect and analyze data on gender to inform the project's gender action planning to identify opportunities for the project to reduce opportunity gaps between men and women or address power differentials to promote gender equity.

Table 2: Selected illustrative indicators linked to intended results and project activities

Objective 1: Conduct Sampling In Focus Countries For Unknown Viruses From Priority Viral Families		
Intended results	Project Activities/Tasks	Indicators/Milestones
In-country institutional and staff capacity to conduct risk modeling to identify and inform sampling efforts strengthened .	1.7 Capacity Building and Sustainability (cross cutting all Objective 1 activities and tasks)	#/% representatives from in-country wildlife, human, livestock, and environmental health sectors, trained and engaged in risk modeling, sample site and species selection, and sample target setting processes
Key species sampled at research sites.	1.3 Country-level Strategic Sampling	# of wildlife samples collected in each country % of archived wildlife samples of interest screened
Objective 2: Strengthen Detection In Focus Countries For Novel Viruses From The Priority Viral Families		
Detection and genomic sequencing of novel viruses from prospective samples safely conducted .	2.2 Overall Detection Strategy 2.3 Molecular Screening 2.4. Broad Serology Screening	# of in-country labs with instruments that can perform assays with a throughput of 20-22 specimens per 96- well plate or 80-84 specimens per 384-well plate # of genome finishing batches performed using NextSeqor NovaSequequipment in each country
Ability of select in-country laboratories to provide technical assistance and/or detection capabilities for viral discovery in- country and in the region improved .	2.1 Capacity Building and Sustainability	# of labs & # people trained by project on qRT-PCR, serology, next gen sequencing methods, bioinformatics platforms and methods for analysis; % of those trained demonstrating improved competency in new methods; % of laboratory capacity gaps identified in each country that are showing improvement as demonstrated by: % of labs with screening & sequencing instruments
Objective 3: Strengthen Characterization In Focus Countries Of Novel Viruses From Priority Viral Families		
Lab and bioinformatics capacity for characterizing unknown viruses in select in- country institutions strengthened .	3.1. Overall Characterization Strategy	# countries with improved characterization capacity as demonstrated by increased number of novel viruses characterized and fully sequenced by in-country laboratories that have staff who have participated in at least one of the project's capacity building activities.
Objective 4: Strengthen In-Country Capacities For Data Management And Viral Characterization Process		
Newly validated methodologies and protocols, data and analyses associated with viral detection and characterization shared .	4.2 Country Data Management Task 4.9: Strengthen capacity of in-country partners to store, analyze, and share data	# countries with validated protocols for data sharing, MOUs in place; # DV datasets, methodologies, and/or publications made publicly available; # of data managers providing data sets with reliability, accuracy, completeness, consistency and timeliness.

Learning Agenda: Our consortium is committed to utilizing a Collaborating, Learning and Adapting approach to implementing the DV project. The Learning Agenda (LA) will be developed in the first 90 days in collaboration with USAID and in-country technical experts and will be the primary tool for ensuring critical questions that can guide implementation are collaboratively agreed upon and used to inform project implementation. The LA will serve to contextualize project achievements and test assumptions regarding how implemented activities yield intended results. We will review and discuss LA assessments quarterly to ensure learning from identified failures and successes and to improve future implementation. Illustrative LA questions are provided in Table 3. The final LA will include learning activities, timelines, methods and a dissemination plan that will describe key audiences benefitting from the learning

produced by the project and products targeted at those audiences to ensure relevant information is shared back quickly to the right stakeholders in a useful format.

Table 3. Illustrative Learning Agenda questions:	
1	To what extent is the project successfully supporting the timely detection and complete characterization of known and un-known pathogens among the prioritized viral families within the in-country reference laboratories? Which approaches are leading to the most robust implementation in countries and greatest effects on timely detection and complete characterization? And what characteristics, differences or similarities do we see across successful vs. less successful reference laboratories or countries where DV is implemented?
2	What data have the project successfully made available for use by local, regional and global audiences, and how have the data generated by the project supported local, regional and global preparedness and response activities to the targeted viral families? Are the appropriate audiences receiving useful data more rapidly? What barriers are still delaying the processes of sharing data and findings as quickly as possible? And what differences or similarities do we see across countries where DV is implemented vs. Countries where DV is not implemented?
3	<p>a. In which areas of capacity building (a-d below), and with which cadres of the workforce, has the project been successful in strengthening in-country capacity? What capacity building strategies are showing greatest / least impact? What remain the biggest barriers to successfully unlocking in-country capacity? Are project activities leading to unexpected capacity improvements? Laboratory capacity in viral detection and characterization of unknown viruses</p> <p>b. Data management capacity, including data collection, quality, analysis, sharing and storage</p> <p>c. Timely dissemination of actionable data and research findings</p> <p>d. In-country capacity to use data and research findings</p>
4	What existing in-country and global data systems are most successfully being leveraged for sharing DV data to increase likelihood of sustainability and interoperability among sectors? How successful is the project with getting virus sequencing data into those data sources? What facilitators can be leveraged and barriers do we still need to overcome to integrate DV data into sustainable systems?

Mixed methods will be used to answer these learning questions. Desk reviews will compile existing evidence; project monitoring and evaluation data will be used to track progress towards achievement of results within the learning agenda topic areas and incorporate project M&E within the learning. Additional methods for collecting data to answer these learning questions will include surveys, checklists, observations, key informant interviews and review of secondary data extracted from existing databases. Data from these sources will be analyzed to answer these questions, help the project understand what is working, where immediate pivots are needed in current implementation strategies and what learning should be shared more broadly. Data collection tools will be stored in a central repository for re-use and continuous learning during the project and beyond. The plan to disseminate and use findings will differ depending on the learning question. In many cases the first audience will be internal team and management to inform activity planning and work planning. Learning exchange sessions, webinars or workshops will be planned to discuss findings with local experts and decision makers to explore the local context and use of the findings. On a global scale, we will develop white papers, blogs, conference presentations, global learning exchange webinars, or publications for peer review.

[END OF ATTACHMENT B]

ATTACHMENT C – STANDARD PROVISIONS

MANDATORY STANDARD PROVISIONS FOR U.S. NONGOVERNMENTAL ORGANIZATIONS

M1. APPLICABILITY OF 2 CFR 200 and 2 CFR 700 (NOVEMBER 2020)

- a. All provisions of 2 CFR 200 and 2 CFR 700 in effect on the date of this award, and all Standard Provisions attached to this agreement are applicable to the recipient and to subrecipients that meet the definition of “Non-Federal Entity” in part 2 CFR 200.1, unless a section specifically excludes a subrecipient from coverage. The recipient must assure that subrecipients have copies of all the attached standard provisions.
- b. For any subawards made with Non-U.S. subrecipients the recipient must include the applicable “Standard Provisions for Non-US Nongovernmental Organizations.” Recipients are required to ensure compliance with monitoring procedures in accordance with 2 CFR 200 and 2 CFR 700.

[END OF PROVISION]

M2. INELIGIBLE COUNTRIES (MAY 1986)

Unless otherwise approved by the USAID Agreement Officer, funds will only be expended for assistance to countries eligible for assistance under the Foreign Assistance Act of 1961, as amended, or under acts appropriating funds for foreign assistance.

[END OF PROVISION]

M3. NONDISCRIMINATION (JUNE 2012)

No U.S. citizen or legal resident shall be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination on the basis of race, color, national origin, age, disability, or sex under any program or activity funded by this award when work under the grant is performed in the U.S. or when employees are recruited from the U.S.

Additionally, USAID is committed to achieving and maintaining a diverse and representative workforce and a workplace free of discrimination. Based on law, Executive Order, and Agency policy, USAID prohibits discrimination, including harassment, in its own workplace on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, disability, age, veteran’s status, sexual orientation, genetic information, marital status, parental status, political affiliation, and any other conduct that does not adversely affect the performance of the employee.

In addition, the Agency strongly encourages its recipients and their subrecipients and vendors (at all tiers), performing both in the U.S. and overseas, to develop and enforce comprehensive nondiscrimination policies for their workplaces that include protection for all their employees on these expanded bases, subject to applicable law.

[END OF PROVISION]

M4. AMENDMENT OF AWARD (JUNE 2012)

This award may only be amended in writing, by formal amendment or letter, signed by the Agreement Officer (AO), and in the case of a bilateral amendment, by the AO and an authorized official of the recipient.

[END OF PROVISION]

M5. NOTICES (JUNE 2012)

Any notice given by USAID or the recipient is sufficient only if in writing and delivered in person, mailed or e-mailed as follows:

- (1) To the USAID Agreement Officer, at the address specified in this award; or
- (2) To the recipient, at the recipient's address shown in this award, or to such other address specified in this award.

[END OF PROVISION]

M6. SUBAWARDS AND CONTRACTS (DECEMBER 2014)

- a. Subawardees and contractors have no relationship with USAID under the terms of this award. All required USAID approvals must be directed through the recipient to USAID.
- b. Notwithstanding any other term of this award, subawardees and contractors have no right to submit claims directly to USAID and USAID assumes no liability for any third party claims against the recipient.

[END OF PROVISION]

M7. OMB APPROVAL UNDER THE PAPERWORK REDUCTION ACT (DECEMBER 2014)

Information collection requirements imposed by this award are covered by OMB approval number 0412-0510; the current expiration date is 04/30/2005. The Standard Provisions containing the requirement and an estimate of the public reporting burden (including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information) are

<u>Standard Provision</u>	<u>Burden Estimate</u>
Air Travel and Transportation	1 (hour)
Ocean Shipment of Goods	.5
Patent Rights	.5
Publications	.5
Negotiated Indirect Cost Rates - (Predetermined and Provisional)	1
Voluntary Population Planning	.5

Protection of the Individual as a Research Subject 1

<u>22 CFR 200</u>	<u>Burden Estimate</u>
2 CFR 200.318-326, Procurement Standards	1
2 CFR 200.310-315, Property Standards	1.5

Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, may be sent to the Bureau for Management, Office of Acquisition and Assistance, Policy Division (M/OAA/P), U.S. Agency for International Development, Washington, DC 20523 and to the Office of Management and Budget, Paperwork Reduction Project (0412-0510), Washington, DC 20503.

[END OF PROVISION]

M8. USAID ELIGIBILITY RULES FOR GOODS AND SERVICES (MAY 2020)

This provision is not applicable to commodities or services that the recipient provides with private funds as part of a cost-sharing requirement, or with Program Income generated under this award.

- a. Ineligible and Restricted Commodities and Services:
- (1) Ineligible Commodities and Services. The recipient must not, under any circumstances, procure any of the following under this award:
 - (i) Military equipment,
 - (ii) Surveillance equipment,
 - (iii) Commodities and services for support of police or other law enforcement activities,
 - (iv) Abortion equipment and services,
 - (v) Luxury goods and gambling equipment, or
 - (vi) Weather modification equipment.
 - (2) Ineligible Suppliers. Any firms or individuals that do not comply with the requirements in Standard Provision, “Debarment, Suspension and Other Responsibility Matters” and Standard Provision, “Preventing Transactions with, or the Provision of Resources or Support to, Sanctioned Groups and Individuals” must not be used to provide any commodities or services funded under this award.
 - (3) Restricted Commodities. The recipient must obtain prior written approval of the Agreement Officer (AO) or comply with required procedures under an applicable waiver, as provided by the AO when procuring any of the following commodities:
 - (i) Agricultural commodities,
 - (ii) Motor vehicles,

- (iii) Pharmaceuticals,
 - (iv) Pesticides,
 - (v) Used equipment,
 - (vi) U.S. Government-owned excess property, or
 - (vii) Fertilizer.
- b. Source and Nationality:
Except as may be specifically approved in advance by the AO, all commodities and services that will be reimbursed by USAID under this award must be from the authorized geographic code specified in this award and must meet the source and nationality requirements set forth in 22 CFR 228. If the geographic code is not specified, the authorized geographic code is 937. When the total value of procurement for commodities and services during the life of this award is valued at \$250,000 or less, the authorized geographic code for procurement of all goods and services to be reimbursed under this award is code 935. For a current list of countries within each geographic code, see: <http://www.usaid.gov/ads/policy/300/310>.
- c. Guidance on the eligibility of specific commodities and services may be obtained from the AO. If USAID determines that the recipient has procured any commodities or services under this award contrary to the requirements of this provision, and has received payment for such purposes, the AO may require the recipient to refund the entire amount of the purchase.
- d. This provision must be included in all subawards and contracts which include procurement of commodities or services.

[END OF PROVISION]

**M9. DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS
(JUNE 2012)**

- a. The recipient agrees to notify the Agreement Officer (AO) immediately upon learning that it or any of its principals:
 - (1) Are presently excluded or disqualified from covered transactions by any Federal department or agency;
 - (2) Have been convicted within the preceding three-year period preceding this proposal; been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, receiving stolen property, making false claims, or obstruction of justice; commission of any other offense indicating a lack of business integrity or business honesty that seriously and directly affects your present responsibility;
 - (3) Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph a.(2); and
 - (4) Have had one or more public transactions (Federal, State, or local) terminated for cause

or default within the preceding three years.

- b. The recipient agrees that, unless authorized by the AO, it will not knowingly enter into any subawards or contracts under this award with a person or entity that has an active exclusion on the System for Award Management (SAM) (www.sam.gov). The recipient further agrees to include the following provision in any subawards or contracts entered into under this award:

.DEBARMENT, SUSPENSION, INELIGIBILITY, AND VOLUNTARY EXCLUSION
(JUNE 2012)

The recipient/contractor certifies that neither it nor its principals is presently excluded or disqualified from participation in this transaction by any Federal department or agency.

- c. The policies and procedures applicable to debarment, suspension, and ineligibility under USAID-financed transactions are set forth in Subpart C of 2 CFR Section 180, as supplemented by 2 CFR 780.

[END OF PROVISION]

M10. DRUG-FREE WORKPLACE (JUNE 2012)

The recipient must comply with drug-free workplace requirements in subpart B (or subpart C, if the recipient is an individual) of 2 CFR 782, which adopts the Government-wide implementation (2 CFR part 182) of sec. 5152–5158 of the Drug-Free Workplace Act of 1988 (Pub. L. 100–690, Title V, Subtitle D; 41 U.S.C. 701–707).

[END OF PROVISION]

M11. EQUAL PARTICIPATION BY FAITH-BASED ORGANIZATIONS (JUNE 2016)

a. Faith-Based Organizations Encouraged

Faith-based organizations are eligible, on the same basis as any other organization, to participate in any USAID program for which they are otherwise eligible. Neither USAID nor entities that make and administer subawards of USAID funds shall discriminate for or against an organization on the basis of the organization's religious character or affiliation. Additionally, religious organizations shall not be disqualified from participating in USAID programs because such organizations are motivated or influenced by religious faith to provide social services, or because of their religious character or affiliation.

Decisions about awards of USAID financial assistance must be free from political interference or even the appearance of such interference. Awards must be made on the basis of merit, not the basis of the religious affiliation of an applicant, or lack thereof. A faith-based organization may continue to carry out its mission, including the definition, development, practice, and expression of its religious beliefs, within the limits contained in this provision. For more information, see the **USAID Faith-Based and Community Initiatives Web site** and **22 CFR 205.1**.

b. Explicitly Religious Activities Prohibited.

- (1)** Explicitly religious activities include activities that involve overt religious content such as worship, religious instruction, prayer, or proselytization.
 - (2)** The recipient must not engage in explicitly religious activities as part of the programs or services directly funded with financial assistance from USAID. If the recipient engages in explicitly religious activities, the activities must be offered separately, in time or location, from any programs or services directly funded by this award, and participation must be voluntary for beneficiaries of the programs or services funded with USAID assistance.
 - (3)** These restrictions apply equally to religious and secular organizations. All organizations that participate in USAID programs, as recipients or subawardees, including religious ones, must carry out eligible activities in accordance with all program requirements and other applicable requirements governing USAID-funded activities.
 - (4)** Notwithstanding the restrictions of b.(1) and (2), a religious organization that participates in USAID-funded programs or services:
 - (i)** May retain its independence and may continue to carry out its mission, including the definition, development, practice, and expression of its religious beliefs, provided that it does not use direct financial assistance from USAID to support or engage in any explicitly religious activities or in any other manner prohibited by law;
 - (ii)** May use space in its facilities, without removing religious art, icons, scriptures, or other religious symbols; and
 - (iii)** May retain its authority over its internal governance, and may retain religious terms in its organization's name, select its board members on a religious basis, and include religious references in its organization's mission statements and other governing documents.
- c.** Implementation in accordance with the Establishment Clause: Nothing in this provision shall be construed as authorizing the use of USAID funds for activities that are not permitted by Establishment Clause jurisprudence or otherwise by law.
- d.** Discrimination Based on Religion Prohibited: The recipient must not, in providing services, discriminate against a program beneficiary or potential program beneficiary on the basis of religion or religious belief, refusal to hold a religious belief, or a refusal to attend or participate in a religious practice.
- e.** A religious organization's exemption from the Federal prohibition on employment discrimination on the basis of religion, set forth in Sec. 702(a) of the Civil Rights Act of

1964, 42 U.S.C. 2000e–1 is not forfeited when the organization receives financial assistance from USAID.

- f. The Secretary of State may waive the requirements of this section in whole or in part, on a case-by-case basis, where the Secretary determines that such waiver is necessary to further the national security or foreign policy interests of the United States.
- g. This provision must be included in all subawards under this award.

[END OF PROVISION]

M12. PREVENTING TRANSACTIONS WITH, OR THE PROVISION OF RESOURCES OR SUPPORT TO, SANCTIONED GROUPS AND INDIVIDUALS (MAY 2020)

- a. In carrying out activities under this award, except as authorized by a license issued by the Office of Foreign Assets Control (OFAC) of the U.S. Department of Treasury, the recipient will not engage in transactions with, or provide resources or support to, any individual or entity that is subject to sanctions administered by OFAC or the United Nations (UN), including any individual or entity that is included on the Specially Designated Nationals and Blocked Persons List maintained by OFAC (<https://www.treasury.gov/resource-center/sanctions/SDNList/Pages/default.aspx>) or on the UN Security Council consolidated list (<https://www.un.org/securitycouncil/content/un-sc-consolidated-list>).
- b. Any violation of the above will be grounds for unilateral termination of the agreement by USAID.
- c. The Recipient must include this provision in all subawards and contracts issued under this award.

[END OF PROVISION]

M13. MARKING AND PUBLIC COMMUNICATIONS UNDER USAID-FUNDED ASSISTANCE (DECEMBER 2014)

- a. The USAID Identity is the official marking for USAID, comprised of the USAID logo and landmark with the tagline “from the American people,” unless amended by USAID to include additional or substitute use of a logo or seal and tagline representing a presidential initiative or other high level interagency initiative. The USAID Identity (including any required presidential initiative or related identity) is on the USAID Web site at www.usaid.gov/branding. Recipients must use the USAID Identity, of a size and prominence equivalent to or greater than any other identity or logo displayed, to mark the following:
 - (1) Programs, projects, activities, public communications, and commodities partially or fully funded by USAID;
 - (2) Program, project, or activity sites funded by USAID, including visible infrastructure projects or other physical sites;

- (3) Technical assistance, studies, reports, papers, publications, audio-visual productions, public service announcements, Web sites/Internet activities, promotional, informational, media, or communications products funded by USAID;
 - (4) Commodities, equipment, supplies, and other materials funded by USAID, including commodities or equipment provided under humanitarian assistance or disaster relief programs; and
 - (5) Events financed by USAID, such as training courses, conferences, seminars, exhibitions, fairs, workshops, press conferences and other public activities. If the USAID Identity cannot be displayed, the recipient is encouraged to otherwise acknowledge USAID and the support of the American people.
- b. The recipient must implement the requirements of this provision following the approved Marking Plan in the award.
 - c. The AO may require a preproduction review of program materials and “public communications” (documents and messages intended for external distribution, including but not limited to correspondence; publications; studies; reports; audio visual productions; applications; forms; press; and promotional materials) used in connection with USAID-funded programs, projects or activities, for compliance with an approved Marking Plan.
 - d. The recipient is encouraged to give public notice of the receipt of this award and announce progress and accomplishments. The recipient must provide copies of notices or announcements to the Agreement Officer’s Representative (AOR) and to USAID’s Office of Legislative and Public Affairs in advance of release, as practicable. Press releases or other public notices must include a statement substantially as follows:

“The U.S. Agency for International Development administers the U.S. foreign assistance program providing economic and humanitarian assistance in more than 80 countries worldwide.”
 - e. Any “public communication” in which the content has not been approved by USAID must contain the following disclaimer:

“This study/report/audio/visual/other information/media product (specify) is made possible by the generous support of the American people through the United States Agency for International Development (USAID). The contents are the responsibility of [insert recipient name] and do not necessarily reflect the views of USAID or the United States Government.”
 - f. The recipient must provide the USAID AOR with two copies of all program and communications materials produced under this award.
 - g. The recipient may request an exception from USAID marking requirements when USAID

marking requirements would:

- (1) Compromise the intrinsic independence or neutrality of a program or materials where independence or neutrality is an inherent aspect of the program and materials;
 - (2) Diminish the credibility of audits, reports, analyses, studies, or policy recommendations whose data or findings must be seen as independent;
 - (3) Undercut host-country government “ownership” of constitutions, laws, regulations, policies, studies, assessments, reports, publications, surveys or audits, public service announcements, or other communications;
 - (4) Impair the functionality of an item;
 - (5) Incur substantial costs or be impractical;
 - (6) Offend local cultural or social norms, or be considered inappropriate; or
 - (7) Conflict with international law.
- h. The recipient may submit a waiver request of the marking requirements of this provision or the Marking Plan, through the AOR, when USAID-required marking would pose compelling political, safety, or security concerns, or have an adverse impact in the cooperating country.
- (1) Approved waivers “flow down” to subawards and contracts unless specified otherwise. The waiver may also include the removal of USAID markings already affixed, if circumstances warrant.
 - (2) USAID determinations regarding waiver requests are subject to appeal by the recipient, by submitting a written request to reconsider the determination to the cognizant Assistant Administrator.
- i. The recipient must include the following marking provision in any subawards entered into under this award:

“As a condition of receipt of this subaward, marking with the USAID Identity of a size and prominence equivalent to or greater than the recipient’s, subrecipient’s, other donor’s, or third party’s is required. In the event the recipient chooses not to require marking with its own identity or logo by the subrecipient, USAID may, at its discretion, require marking by the subrecipient with the USAID Identity.”

[END OF PROVISION]

M14. REGULATIONS GOVERNING EMPLOYEES (JUNE 2018)

- a. While working overseas, the recipient's employees who are not citizens of the cooperating

country must maintain private status, and may not rely on local U.S. Government offices or facilities for support while under this award.

- b. The sale of personal property or automobiles by the recipient's non-cooperating country citizen employees and their dependents in the foreign country to which they are assigned, are subject to the same limitations and prohibitions that apply to direct-hire USAID personnel employed by the Mission, including the rules contained in 22 CFR 136, except as this may conflict with host government regulations.
- c. Other than work to be performed under this award for which an employee is assigned by the recipient, employees of the recipient who are not citizens of the cooperating country must not engage directly or indirectly, either in the individual's own name or in the name or through an agency of another person, in any business, profession, or occupation in the foreign countries to which the individual is assigned. In addition, the individual must not make loans or investments to or in any business, profession, or occupation in the foreign countries to which the individual is assigned.
- d. The recipient's employees who are not citizens of the cooperating country, while in a foreign country, are expected to show respect for its conventions, customs, and institutions, to abide by its applicable laws and regulations, and not to interfere in its internal political affairs.
- e. In accordance with the internal control requirements in 2 CFR 200.303, which require the recipient to establish standards of conduct for its employees, the recipient must ensure that all its employees adhere to these standards of conduct in a manner consistent with the standards for United Nations (UN) employees in Section 3 of the UN Secretary-General's Bulletin - Special Measures for Protection from Sexual Exploitation and Sexual Abuse (ST/SGB/2003/13).
- f. If the recipient determines that the conduct of any recipient employee is not in accordance with the preceding paragraphs, the recipient's Chief of Party must consult with the Agreement Officer and the USAID Mission Director, and the employee involved, and must recommend to the recipient a course of action with regard to such employee.
- g. The parties recognize the rights of the U.S. Ambassador to direct the removal from a country of any U.S. citizen, or the discharge from this award of any individual (U.S., third-country, or cooperating-country national) when, in the discretion of the Ambassador, the interests of the United States so require.
- h. If it is determined, under paragraph (f) or (g) above, that the services of such employee should be terminated, the recipient must use its best efforts to cause the return of such employee to the United States, or third-country point of origin, as appropriate, and replace the employee with an acceptable substitute at no cost to USAID.
- i. Any matters relating to subrecipients, including the employees of subrecipients, must be coordinated through the recipient's Chief of Party.

[END OF PROVISION]

**M15. CONVERSION OF UNITED STATES DOLLARS TO LOCAL CURRENCY
(NOVEMBER 1985)**

(This provision applies when activities are undertaken outside the United States.)

Upon arrival in the cooperating country, and from time to time as appropriate, the recipient's chief of party must consult with the Mission Director who must provide, in writing, the procedure the recipient and its employees must follow in the conversion of United States dollars to local currency. This may include, but is not limited to, the conversion of currency through the cognizant United States Disbursing Officer or Mission Controller, as appropriate.

[END OF PROVISION]

M16. USE OF POUCH FACILITIES (AUGUST 1992)

(This provision applies when activities are undertaken outside the United States.)

- a. Use of diplomatic pouch is controlled by the Department of State. The Department of State has authorized the use of pouch facilities for USAID recipients and their employees as a general policy, as detailed in items (1) through (6) below. However, the final decision regarding use of pouch facilities rest with the Embassy or USAID Mission. In consideration of the use of pouch facilities, the recipient and its employees agree to indemnify and hold harmless, the Department of State and USAID for loss or damage occurring in pouch transmission:
 - (1) Recipients and their employees are authorized use of the pouch for transmission and receipt of up to a maximum of .9 kgs per shipment of correspondence and documents needed in the administration of assistance programs.
 - (2) U.S. citizen employees are authorized use of the pouch for personal mail up to a maximum of .45 kgs per shipment (but see a.(3) below).
 - (3) Merchandise, parcels, magazines, or newspapers are not considered to be personal mail for purposes of this standard provision and are not authorized to be sent or received by pouch.
 - (4) Official and personal mail pursuant to a.(1) and (2) above sent by pouch should be addressed as follows:

Name of individual or organization (followed by
letter symbol "G")
City Name of post (USAID/_____)
Agency for International Development
Washington, DC 20523-0001
 - (5) Mail sent via the diplomatic pouch may not be in violation of U.S. Postal laws and may

not contain material ineligible for pouch transmission.

(6) Recipient personnel are NOT authorized use of military postal facilities (APO/FPO).

This is an Adjutant General's decision based on existing laws and regulations governing military postal facilities and is being enforced worldwide.

- b. The recipient is responsible for advising its employees of this authorization, these guidelines, and limitations on use of pouch facilities.
- c. Specific additional guidance on grantee use of pouch facilities in accordance with this standard provision is available from the Post Communication Center at the Embassy or USAID Mission.

[END OF PROVISION]

M17. TRAVEL AND INTERNATIONAL AIR TRANSPORTATION (DECEMBER 2014)

a. TRAVEL COSTS

All travel costs must comply with the applicable cost principles and must be consistent with those normally allowed in like circumstances in the recipient's non-USAID-funded activities. Costs incurred by employees and officers for travel, including air fare, costs of lodging, other subsistence, and incidental expenses, may be considered reasonable and allowable only to the extent such costs do not exceed reasonable charges normally allowed by the recipient in its regular operations as the result of the recipient organization's written travel policy and are within the limits established by the applicable cost principles.

In the absence of a reasonable written policy regarding international travel costs, the standard for determining the reasonableness of reimbursement for international travel costs will be the Standardized Regulations (Government Civilians, Foreign Areas), published by the U.S. Department of State, as from time to time amended. The most current Standardized Regulations on international travel costs may be obtained from the AO. In the event that the cost for air fare exceeds the customary standard commercial airfare (coach or equivalent) or the lowest commercial discount airfare, the recipient must document one of the allowable exceptions from the applicable cost principles.

b. FLY AMERICA ACT RESTRICTIONS

- (1) The recipient must use U.S. Flag Air Carriers for all international air transportation (including personal effects) funded by this award pursuant to the Fly America Act and its implementing regulations to the extent service by such carriers is available.
- (2) In the event that the recipient selects a carrier other than a U.S. Flag Air Carrier for international air transportation, in order for the costs of such international air transportation to be allowable, the recipient must document such transportation in accordance with this provision and maintain such documentation pursuant to the

Standard Provision, “Accounting, Audit and Records.” The documentation must use one of the following reasons or other exception under the Fly America Act:

- (i) The recipient uses a European Union (EU) flag air carrier, which is an airline operating from an EU country that has signed the US-EU “Open Skies” agreement (<http://www.state.gov/e/eb/rls/othr/ata/i/ic/170684.htm>).
- (ii) Travel to or from one of the following countries on an airline of that country when no city pair fare is in effect for that leg (see <http://apps.fas.gsa.gov/citypairs/search/>):
 - a. Australia on an Australian airline,
 - b. Switzerland on a Swiss airline, or
 - c. Japan on a Japanese airline;
- (iii) Only for a particular leg of a route on which no US Flag Air Carrier provides service on that route;
- (iv) For a trip of 3 hours or less, the use of a US Flag Air Carrier at least doubles the travel time;
- (v) If the US Flag Air Carrier offers direct service, use of the US Flag Air Carrier would increase the travel time by more than 24 hours; or
- (vi) If the US Flag Air Carrier does not offer direct service,
 - a. Use of the US Flag Air Carrier increases the number of aircraft changes by 2 or more,
 - b. Use of the US Flag Air Carrier extends travel time by 6 hours or more, or
 - c. Use of the US Flag Air Carrier requires a layover at an overseas interchange of 4 hours or more.

c. DEFINITIONS

The terms used in this provision have the following meanings:

- (1) “Travel costs” means expenses for transportation, lodging, subsistence (meals and incidentals), and related expenses incurred by employees who are on travel status on official business of the recipient for any travel outside the country in which the organization is located. “Travel costs” do not include expenses incurred by employees who are not on official business of the recipient, such as rest and recuperation (R&R) travel offered as part of an employee’s benefits package that are consistent with the recipient’s personnel and travel policies and procedures.

- (2) "International air transportation" means international air travel by individuals (and their personal effects) or transportation of cargo by air between a place in the United States and a place outside thereof, or between two places both of which are outside the United States.
- (3) "U.S. Flag Air Carrier" means an air carrier on the list issued by the U.S. Department of Transportation at <http://ostpxweb.dot.gov/aviation/certific/certlist.htm>. U.S. Flag Air Carrier service also includes service provided under a code share agreement with another air carrier when the ticket, or documentation for an electronic ticket, identifies the U.S. flag air carrier's designator code and flight number.
- (4) For this provision, the term "United States" includes the fifty states, Commonwealth of Puerto Rico, possessions of the United States, and the District of Columbia.

d. SUBAWARDS AND CONTRACTS

This provision must be included in all subawards and contracts under which this award will finance international air transportation.

[END OF PROVISION]

M18. OCEAN SHIPMENT OF GOODS (JUNE 2012)

- a. Prior to contracting for ocean transportation to ship goods purchased or financed with USAID funds under this award, the recipient must contact the office below to determine the flag and class of vessel to be used for shipment:

U.S. Agency for International Development,
Bureau for Management
Office of Acquisition and Assistance, Transportation Division
1300 Pennsylvania Avenue, NW
Washington, DC 20523
Email: oceantransportation@usaid.gov

- b. This provision must be included in all subawards and contracts.

[END OF PROVISION]

M19. VOLUNTARY POPULATION PLANNING ACTIVITIES – MANDATORY REQUIREMENTS (MAY 2006)

Requirements for Voluntary Sterilization Programs

- (1) Funds made available under this award must not be used to pay for the performance of involuntary sterilization as a method of family planning or to coerce or provide any financial incentive to any individual to practice sterilization.

Prohibition on Abortion-Related Activities:

- (1) No funds made available under this award will be used to finance, support, or be attributed to the following activities: (i) procurement or distribution of equipment intended to be used for the purpose of inducing abortions as a method of family planning; (ii) special fees or incentives to any person to coerce or motivate them to have abortions; (iii) payments to persons to perform abortions or to solicit persons to undergo abortions; (iv) information, education, training, or communication programs that seek to promote abortion as a method of family planning; and (v) lobbying for or against abortion. The term “motivate,” as it relates to family planning assistance, must not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options.
- (2) No funds made available under this award will be used to pay for any biomedical research which relates, in whole or in part, to methods of, or the performance of, abortions or involuntary sterilizations as a means of family planning. Epidemiologic or descriptive research to assess the incidence, extent or consequences of abortions is not precluded.

[END OF PROVISION]

M20. TRAFFICKING IN PERSONS (April 2016)

- a. The recipient, subawardee, or contractor, at any tier, or their employees, labor recruiters, brokers or other agents, must not engage in:
 - (1) Trafficking in persons (as defined in the Protocol to Prevent, Suppress, and Punish Trafficking in Persons, especially Women and Children, supplementing the UN Convention against Transnational Organized Crime) during the period of this award;
 - (2) Procurement of a commercial sex act during the period of this award;
 - (3) Use of forced labor in the performance of this award;
 - (4) Acts that directly support or advance trafficking in persons, including the following acts:
 - i. Destroying, concealing, confiscating, or otherwise denying an employee access to that employee's identity or immigration documents;
 - ii. Failing to provide return transportation or pay for return transportation costs to an employee from a country outside the United States to the country from which the employee was recruited upon the end of employment if requested by the employee, unless:
 - a) exempted from the requirement to provide or pay for such return transportation by USAID under this award; or

- b) the employee is a victim of human trafficking seeking victim services or legal redress in the country of employment or a witness in a human trafficking enforcement action;
 - iii. Soliciting a person for the purpose of employment, or offering employment, by means of materially false or fraudulent pretenses, representations, or promises regarding that employment;
 - iv. Charging employees recruitment fees; or
 - v. Providing or arranging housing that fails to meet the host country housing and safety standards.
- b. In the event of a violation of section (a) of this provision, USAID is authorized to terminate this award, without penalty, and is also authorized to pursue any other remedial actions authorized as stated in section 1704(c) of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112-239, enacted January 2, 2013).
- c. If the estimated value of services required to be performed under the award outside the United States exceeds \$500,000, the recipient must submit to the Agreement Officer, the annual “Certification regarding Trafficking in Persons, Implementing Title XVII of the National Defense Authorization Act for Fiscal Year 2013” as required prior to this award, and must implement a compliance plan to prevent the activities described above in section (a) of this provision. The recipient must provide a copy of the compliance plan to the Agreement Officer upon request and must post the useful and relevant contents of the plan or related materials on its website (if one is maintained) and at the workplace.
- d. The recipient’s compliance plan must be appropriate to the size and complexity of the award and to the nature and scope of the activities, including the number of non-United States citizens expected to be employed. The plan must include, at a minimum, the following:
 - (1) An awareness program to inform employees about the trafficking related prohibitions included in this provision, the activities prohibited and the action that will be taken against the employee for violations.
 - (2) A reporting process for employees to report, without fear of retaliation, activity inconsistent with the policy prohibiting trafficking, including a means to make available to all employees the Global Human Trafficking Hotline at 1-844-888-FREE and its e-mail address at help@befree.org.
 - (3) A recruitment and wage plan that only permits the use of recruitment companies with trained employees, prohibits charging of recruitment fees to the employee, and ensures that wages meet applicable host-country legal requirements or explains any variance.

- (4) A housing plan, if the recipient or any subawardee intends to provide or arrange housing. The housing plan is required to meet any host-country housing and safety standards.
 - (5) Procedures for the recipient to prevent any agents or subawardee at any tier and at any dollar value from engaging in trafficking in persons activities described in section a of this provision. The recipient must also have procedures to monitor, detect, and terminate any agents or subawardee or subawardee employees that have engaged in such activities.
- e. If the Recipient receives any credible information regarding a violation listed in section a(1)-(4) of this provision, the recipient must immediately notify the cognizant Agreement Officer and the USAID Office of the Inspector General; and must fully cooperate with any Federal agencies responsible for audits, investigations, or corrective actions relating to trafficking in persons.
 - f. The Agreement Officer may direct the Recipient to take specific steps to abate an alleged violation or enforce the requirements of a compliance plan.
 - g. For purposes of this provision, “employee” means an individual who is engaged in the performance of this award as a direct employee, consultant, or volunteer of the recipient or any subrecipient.
 - h. The recipient must include in all subawards and contracts a provision prohibiting the conduct described in section a(1)-(4) by the subrecipient, contractor, or any of their employees, or any agents. The recipient must also include a provision authorizing the recipient to terminate the award as described in section b of this provision.

[END OF PROVISION]

M21. SUBMISSIONS TO THE DEVELOPMENT EXPERIENCE CLEARINGHOUSE AND PUBLICATIONS (JUNE 2012)

- a. Submissions to the Development Experience Clearinghouse (DEC).
 - 1) The recipient must provide the Agreement Officer’s Representative one copy of any Intellectual Work that is published, and a list of any Intellectual Work that is not published.
 - 2) In addition, the recipient must submit Intellectual Work, whether published or not, to the DEC, either on-line (preferred) or by mail. The recipient must review the DEC Web site for submission instructions, including document formatting and the types of documents to submit. Submission instructions can be found at: <http://dec.usaid.gov>.

- 3) For purposes of submissions to the DEC, Intellectual Work includes all works that document the implementation, evaluation, and results of international development assistance activities developed or acquired under this award, which may include program and communications materials, evaluations and assessments, information products, research and technical reports, progress and performance reports required under this award (excluding administrative financial information), and other reports, articles and papers prepared by the recipient under the award, whether published or not. The term does not include the recipient's information that is incidental to award administration, such as financial, administrative, cost or pricing, or management information.
 - 4) Each document submitted should contain essential bibliographic information, such as 1) descriptive title; 2) author(s) name; 3) award number; 4) sponsoring USAID office; 5) development objective; and 6) date of publication.
 - 5) The recipient must not submit to the DEC any financially sensitive information or personally identifiable information, such as social security numbers, home addresses and dates of birth. Such information must be removed prior to submission. The recipient must not submit classified documents to the DEC.
- b. In the event award funds are used to underwrite the cost of publishing, in lieu of the publisher assuming this cost as is the normal practice, any profits or royalties up to the amount of such cost must be credited to the award unless the schedule of the award has identified the profits or royalties as program income.

[END OF PROVISION]

M22. LIMITING CONSTRUCTION ACTIVITIES (AUGUST 2013)

- a) Construction is not eligible for reimbursement under this award unless specifically identified in paragraph d) below.
- b) Construction means —construction, alteration, or repair (including dredging and excavation) of buildings, structures, or other real property and includes, without limitation, improvements, renovation, alteration and refurbishment. The term includes, without limitation, roads, power plants, buildings, bridges, water treatment facilities, and vertical structures.
- c) Agreement Officers will not approve any subawards or procurements by recipients for construction activities that are not listed in paragraph d) below. USAID will reimburse allowable costs for only the construction activities listed in this provision not to exceed the amount specified in the construction line item of the award budget. The recipient must receive prior written approval from the AO to transfer funds allotted for construction activities to other cost categories, or vice versa.
- d) Description

Construction is not eligible for reimbursement under this award.

- e) The recipient must include this provision in all subawards and procurements and make vendors providing services under this award and subrecipients aware of the restrictions of this provision.

[END OF PROVISION]

M23. USAID IMPLEMENTING PARTNER NOTICES (IPN) PORTAL FOR ASSISTANCE (JULY 2014)

(a) Definitions

“USAID Implementing Partner Notices (IPN) Portal for Assistance (“IPN Portal)” means the single point where USAID posts proposed universal bilateral amendments for USAID awards, which can be accessed electronically by registered USAID recipients. The IPN Portal is located at <https://sites.google.com/site/usaaidipnforassistance/>. Universal amendments are those which affect all assistance awards or a designated class of awards as specified in each amendment by the IPN Portal Administrator.

“IPN Portal Administrator” means the USAID official designated by the Director, M/OAA, who has overall responsibility for managing the USAID Implementing Partner Notices Portal for Assistance.

“Universal bilateral amendment” means those amendments with revisions or new requirements or provisions that affect all awards or a designated class of awards, as specified in the Agency notification of such revisions or new requirements.

- (b)** By submission of an application and execution of an award, the Applicant/Recipient acknowledges the requirement to:

- (1)** Register with the IPN Portal if awarded an assistance award resulting from this solicitation, and
 - (2)** Receive universal bilateral amendments to this award and general notices via the IPN Portal.

- (c)** Procedure to register for notifications.

Go to <https://sites.google.com/site/usaaidipnforassistance/> and click the “Register” button at the top of the page. Recipient representatives must use their official organization email address when subscribing, not personal email addresses.

- (d)** Processing of IPN Portal Amendments

The Recipient may access the IPN Portal at any time to review all IPN Portal amendments; however, the system will also notify the Recipient by email when the USAID IPN Portal Administrator posts a universal bilateral amendment for Recipient's review and signature. Proposed USAID IPN Portal amendments distributed via the IPN Portal are applicable to all awards, unless otherwise noted in the proposed amendment.

Within 15 calendar days from receipt of the notification email from the IPN Portal, the Recipient must do one of the following:

- (1) (a) verify applicability of the proposed amendment for their award(s) per the instructions provided with each amendment; (b) download the amendment and incorporate the following information on the amendment form: award number, organization name, and organization mailing address as it appears in the basic award; (c) sign the hardcopy version; and (d) send the signed amendment (by email or hardcopy) to the AO for signature. The Recipient must not incorporate any other changes to the IPN Portal amendment. Bilateral amendments provided through the IPN Portal are not effective until the both the Recipient and the AO sign the amendment;
- (2) Notify the AO in writing if the amendment requires negotiation of additional changes to terms and conditions of the award; or
- (3) Notify the AO that the Recipient declines to sign the amendment.

Within 30 calendar days of receipt of a signed amendment from the Recipient, the AO must provide the fully executed amendment to the Recipient or initiate discussions with the Recipient.

[END OF PROVISION]

M24. PILOT PROGRAM FOR ENHANCEMENT OF GRANTEE EMPLOYEE WHISTLEBLOWER PROTECTIONS (SEPTEMBER 2014)

The requirement to comply with and inform all employees of the "Pilot Program for Enhancement of Contractor Employee Whistleblower Protections" is retroactively effective for all assistance awards and subawards (including subcontracts) issued beginning July 1, 2013.

The Grantee must:

1. Inform its employees working under this award in the predominant native language of the workforce that they are afforded the employee whistleblower rights and protections provided under 41 U.S.C. § 4712; and
2. Include such requirement in any subaward or subcontract made under this award.

41 U.S.C. § 4712 states that an employee of a Grantee may not be discharged, demoted, or otherwise discriminated against as a reprisal for "whistleblowing." In addition, whistleblower protections cannot be waived by any agreement, policy, form, or condition of employment.

Whistleblowing is defined as making a disclosure "that the employee reasonably believes" is evidence of any of the following:

- Gross mismanagement of a Federal contract or grant;
- A gross waste of Federal funds;
- An abuse of authority relating to a Federal contract or grant;
- A substantial and specific danger to public health or safety; or
- A violation of law, rule, or regulation related to a Federal contract or grant (including the competition for, or negotiation of, a contract or grant).

To qualify under the statute, the employee's disclosure must be made to:

- A Member of the U.S. Congress, or a representative of a U.S. Congressional Committee;
- A cognizant U.S. Inspector General;
- The U.S. Government Accountability Office;
- A Federal employee responsible for contract or grant oversight or management at the relevant agency;
- A U.S. court or grand jury; or,
- A management official or other employee of the Grantee who has the responsibility to investigate, discover, or address misconduct.

[END OF PROVISION]

M25. SUBMISSION OF DATASETS TO THE DEVELOPMENT DATA LIBRARY (OCTOBER 2014)

a. Definitions. For the purpose of submissions to the DDL:

- (1) "Dataset" is an organized collection of structured data, including data contained in spreadsheets, whether presented in tabular or non-tabular form. For example, a Dataset may represent a single spreadsheet, an extensible mark-up language (XML) file, a geospatial data file, or an organized collection of these. This requirement does not apply to aggregated performance reporting data that the recipient submits directly to a USAID portfolio management system or to unstructured data, such as email messages, PDF files, PowerPoint presentations, word processing documents, photos and graphic images, audio files, collaboration software, and instant messages. Neither does the requirement apply to the recipient's information that is incidental to award administration, such as financial, administrative, cost or pricing, or management information. Datasets submitted to the DDL will generally be those generated with USAID resources and created in support of Intellectual Work that is uploaded to the Development Experience Clearinghouse (DEC) (See M21. SUBMISSIONS TO THE DEVELOPMENT EXPERIENCE CLEARINGHOUSE AND PUBLICATIONS (JUNE 2012)).

- (2) “Intellectual Work” includes all works that document the implementation, monitoring, evaluation, and results of international development assistance activities developed or acquired under this award, which may include program and communications materials, evaluations and assessments, information products, research and technical reports, progress and performance reports required under this award (excluding administrative financial information), and other reports, articles and papers prepared by the recipient under the award, whether published or not. The term does not include the recipient’s information that is incidental to award administration, such as financial, administrative, cost or pricing, or management information.

b. Submissions to the Development Data Library (DDL)

- (1) The recipient must submit to the Development Data Library (DDL) at www.usaid.gov/data, in a machine-readable, non-proprietary format, a copy of any Dataset created or obtained in performance of this award, including Datasets produced by a subawardee or a contractor at any tier. The submission must include supporting documentation describing the Dataset, such as code books, data dictionaries, data gathering tools, notes on data quality, and explanations of redactions.
- (2) Unless otherwise directed by the Agreement Officer (AO) or the Agreement Officer Representative (AOR), the recipient must submit the Dataset and supporting documentation to the DDL within thirty (30) calendar days after the Dataset is first used to produce an Intellectual Work or is of sufficient quality to produce an Intellectual Work. Within thirty (30) calendar days after award completion, the recipient must submit to the DDL any Datasets and supporting documentation that have not previously been submitted to the DDL, along with an index of all Datasets and Intellectual Work created or obtained under the award. The recipient must also provide to the AOR an itemized list of any and all DDL submissions.

The recipient is not required to submit the data to the DDL, when, in accordance with the terms and conditions of this award, Datasets containing results of federally funded scientific research are submitted to a publicly accessible research database. However, the recipient must submit a notice to the DDL by following the instructions at www.usaid.gov/data, with a copy to the agreement officer representative, providing details on where and how to access the data. The direct results of federally funded scientific research must be reported no later than when the data are ready to be submitted to a peer-reviewed journal for publication, or no later than five calendar days prior to the conclusion of the award, whichever occurs earlier.

- (3) The recipient must submit the Datasets following the submission instructions and acceptable formats found at www.usaid.gov/data.
- (4) The recipient must ensure that any Dataset submitted to the DDL does not contain any proprietary or personally identifiable information, such as social security numbers, home

addresses, and dates of birth. Such information must be removed prior to submission.

- (5) The recipient must not submit classified data to the DDL.

[END OF PROVISION]

M26. PROHIBITION ON REQUIRING CERTAIN INTERNAL CONFIDENTIALITY AGREEMENTS OR STATEMENTS (MAY 2017)

- (a) Definitions.

“Contract” has the meaning given in 2 CFR Part 200.

“Contractor” means an entity that receives a contract as defined in 2 CFR Part 200.

“Internal confidentiality agreement or statement” means a confidentiality agreement or any other written statement that the recipient requires any of its employees or subrecipients to sign regarding nondisclosure of recipient information, except that it does not include confidentiality agreements arising out of civil litigation or confidentiality agreements that recipient employees or subrecipients sign at the behest of a Federal agency.

“Subaward” has the meaning given in 2 CFR Part 200.

“Subrecipient” has the meaning given in 2 CFR Part 200.

- (b) The recipient must not require its employees, subrecipients, or contractors to sign or comply with internal confidentiality agreements or statements that prohibit or otherwise restrict employees, subrecipients, or contractors from lawfully reporting waste, fraud, or abuse related to the performance of a Federal award to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (for example, the Agency Office of the Inspector General).
- (c) The recipient must notify current employees and subrecipients that prohibitions and restrictions of any preexisting internal confidentiality agreements or statements covered by this provision, to the extent that such prohibitions and restrictions are inconsistent with the prohibitions of this provision, are no longer in effect.
- (d) The prohibition in paragraph (b) of this provision does not contravene the requirements applicable to Standard Form 312 (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.
- (e) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further

Continuing Appropriations Act, 2015, (Pub. L. 113-235), and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions) use of funds appropriated (or otherwise made available) is prohibited, if the Government determines that the recipient is not in compliance with the requirements of this provision.

- (f) The recipient must include the substance of this provision, including this paragraph (f), in subawards and contracts under such awards.

[END OF PROVISION]

M27. CHILD SAFEGUARDING (JUNE 2015)

- (a) Because the activities to be funded under this award may involve children, or personnel engaged in the implementation of the award may come into contact with children, these activities could raise the risk of child abuse, exploitation, or neglect within USAID-funded programs. The organization agrees to abide by the following child safeguarding core principles:
- (1) Ensure compliance with host country and local child welfare and protection legislation or international standards, whichever gives greater protection, and with U.S. law where applicable;
 - (2) Prohibit all personnel from engaging in child abuse, exploitation, or neglect;
 - (3) Consider child safeguarding in project planning and implementation to determine potential risks to children that are associated with project activities and operations;
 - (4) Apply measures to reduce the risk of child abuse, exploitation, or neglect, including, but not limited to, limiting unsupervised interactions with children; prohibiting exposure to pornography; and complying with applicable laws, regulations, or customs regarding the photographing, filming, or other image-generating activities of children;
 - (5) Promote child-safe screening procedures for personnel, particularly personnel whose work brings them in direct contact with children; and
 - (6) Have a procedure for ensuring that personnel and others recognize child abuse, exploitation, or neglect; mandating that personnel and others report allegations; investigating and managing allegations; and taking appropriate action in response to such allegations, including, but not limited to, dismissal of personnel.
- (b) The organization must also include in their code of conduct for all personnel implementing USAID-funded activities the child safeguarding principles in (a) (1) through (6).
- (c) The following definitions apply for purposes of this provision:

- (1) Child: A child or children are defined as persons who have not attained 18 years of age.
 - (2) Child abuse, exploitation, or neglect: Constitutes any form of physical abuse; emotional ill-treatment; sexual abuse; neglect or insufficient supervision; trafficking; or commercial, transactional, labor, or other exploitation resulting in actual or potential harm to the child's health, well-being, survival, development, or dignity. It includes, but is not limited to: any act or failure to act which results in death, serious physical or emotional harm to a child, or an act or failure to act which presents an imminent risk of serious harm to a child.
 - (3) Physical abuse: Constitutes acts or failures to act resulting in injury (not necessarily visible), unnecessary or unjustified pain or suffering without causing injury, harm or risk of harm to a child's health or welfare, or death. Such acts may include, but are not limited to: punching, beating, kicking, biting, shaking, throwing, stabbing, choking, or hitting (regardless of object used), or burning. These acts are considered abuse regardless of whether they were intended to hurt the child.
 - (4) Sexual Abuse: Constitutes fondling a child's genitals, penetration, incest, rape, sodomy, indecent exposure, and exploitation through prostitution or the production of pornographic materials.
 - (5) Emotional abuse or ill treatment: Constitutes injury to the psychological capacity or emotional stability of the child caused by acts, threats of acts, or coercive tactics. Emotional abuse may include, but is not limited to: humiliation, control, isolation, withholding of information, or any other deliberate activity that makes the child feel diminished or embarrassed.
 - (6) Exploitation: Constitutes the abuse of a child where some form of remuneration is involved or whereby the perpetrators benefit in some manner. Exploitation represents a form of coercion and violence that is detrimental to the child's physical or mental health, development, education, or well-being.
 - (7) Neglect: Constitutes failure to provide for a child's basic needs within USAID-funded activities that are responsible for the care of a child in the absence of the child's parent or guardian.
- (d) The recipient must insert the provisions in (a) and (b) in all sub-awards under this award.

[END OF PROVISION]

M28. MANDATORY DISCLOSURES (JULY 2015)

Consistent with 2 CFR §200.113, applicants and recipients must disclose, in a timely manner, in writing to the USAID Office of the Inspector General, with a copy to the cognizant Agreement Officer, all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. Subrecipients must disclose, in a timely manner, in

writing to the USAID Office of the Inspector General and to the prime recipient (pass through entity) all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award.

Disclosures must be sent to:

U.S. Agency for International Development
Office of the Inspector General
P.O. Box 657
Washington, DC 20044-0657

Phone: 1-800-230-6539 or 202-712-1023

Email: ig.hotline@usaid.gov

URL: <https://oig.usaid.gov/content/usaid-contractor-reporting-form>.

Failure to make required disclosures can result in any of the remedies described in 2 CFR §200.338 Remedies for noncompliance, including suspension or debarment (See 2 CFR 180, 2 CFR 780 and 31 U.S.C. 3321).

The recipient must include this mandatory disclosure requirement in all subawards and contracts under this award.

[END OF PROVISION]

M29. NONDISCRIMINATION AGAINST BENEFICIARIES (NOVEMBER 2016)

- (a) USAID policy requires that the recipient not discriminate against any beneficiaries in implementation of this award, such as, but not limited to, by withholding, adversely impacting, or denying equitable access to the benefits provided through this award on the basis of any factor not expressly stated in the award. This includes, for example, race, color, religion, sex (including gender identity, sexual orientation, and pregnancy), national origin, disability, age, genetic information, marital status, parental status, political affiliation, or veteran's status. Nothing in this provision is intended to limit the ability of the recipient to target activities toward the assistance needs of certain populations as defined in the award.
- (b) The recipient must insert this provision, including this paragraph, in all subawards and contracts under this award.

[END OF PROVISION]

M30. CONFLICT OF INTEREST (AUGUST 2018)

- a. A conflict of interest in the award, administration, or monitoring of subawards arises when an employee, officer, or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of these parties, has a

financial or other interest in, or a tangible personal benefit from, a subrecipient considered for a subaward. The officers, employees, and agents of the recipient may neither solicit nor accept gratuities, favors, or anything of monetary value from subrecipients or parties to subawards. However, recipients may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value.

- b. The recipient must maintain written standards of conduct covering conflicts of interest and governing the actions of its employees engaged in the selection, award, and administration of subawards. The standards must prohibit employees from using their positions for a purpose that constitutes or presents the appearance of a conflict of interest. The standards of conduct must provide for disciplinary actions to be applied for violations of such standards by officers, employees, or agents of the recipient.
- c. The recipient must also maintain written standards of conduct covering organizational conflicts of interest. Organizational conflicts of interest means a situation in which the recipient is unable or appears to be unable to be impartial in conducting a subaward action involving a related organization because of relationships with a parent company, affiliate, or subsidiary organization.
- d. The recipient must have a system or systems in place to identify, address, resolve, and disclose to USAID any conflicts of interest as described in this provision that affect any subaward, regardless of the amount of funding.
- e. The recipient must disclose any conflict of interest, including organizational conflicts of interest, and the recipient's approach for resolving the conflict of interest to the cognizant Agreement Officer for the award within ten (10) calendar days of the discovery of the conflict of interest.
- f. Upon notice from the recipient of a potential conflict of interest and the approach for resolving it, the Agreement Officer will make a determination regarding the effectiveness of the recipient's actions to resolve the conflict of interest within thirty (30) calendar days of receipt of the recipient's notice, unless the Agreement Officer advises the recipient that a longer period is necessary.
- g. The recipient must not request payment from USAID for costs for transactions subject to the conflict of interest pending notification of USAID's determination. The recipient's failure to disclose a conflict of interest may result in cost disallowances by USAID.
- h. For conflicts of interest, including organizational conflicts of interest, involving contracts, the recipient must follow 2 CFR 200.318, general procurement standards.
- i. The recipient must insert the substance of this provision, including paragraph (i), in all subawards under this award, at any subaward tier.

[END OF PROVISION]

**REQUIRED AS APPLICABLE STANDARD PROVISIONS FOR U.S.
NONGOVERNMENTAL ORGANIZATIONS**

RAA1. NEGOTIATED INDIRECT COST RATES – PREDETERMINED (NOVEMBER 2020)

- a. The allowable indirect costs must be determined by applying the predetermined indirect cost rates to the bases specified in the schedule of this award.
- b. Except as otherwise provided in 2 CFR 200.414 Indirect (F&A) costs paragraph (e) and (f), a nonprofit organization which has not previously established an indirect cost rate with a Federal agency must submit its initial indirect cost proposal immediately after the organization is advised that a Federal award will be made and, in no event, later than three months after the effective date of the Federal award.

Organizations that have previously established indirect cost rates must submit a new indirect cost proposal to the cognizant agency for indirect costs within six months after the close of each fiscal year.

If USAID is the cognizant agency or no cognizant agency has been designated, the recipient must submit four copies of the audit report, the proposed predetermined indirect cost rates, and supporting cost data to the Overhead, Special Costs, and Closeout Branch, Management Bureau, Office of Acquisition and Assistance, USAID, Washington, DC 20523-7802. The proposed rates must be based on the recipient's actual cost experience during that fiscal year. Negotiations of predetermined indirect cost rates must begin soon after receipt of the recipient's proposal.

- c. Allowability of costs and acceptability of cost allocation methods must be determined in accordance with the applicable cost principles.
- d. The results of each negotiation must be set forth in an indirect cost rate agreement signed by both parties. Such agreement is automatically incorporated into this award and must specify (1) the agreed upon predetermined rates, (2) the bases to which the rates apply, and (3) the fiscal year for which the rates apply. The indirect cost rate agreement must not change any monetary ceiling, award obligation, or specific cost allowance or disallowance provided for in this award.
- e. Predetermined rate means an indirect cost rate, applicable to a specified current or future period, usually the organization's fiscal year. The rate is based on an estimate of the costs to be incurred during the period. A predetermined rate is not subject to adjustment.
- f. If a dispute arises in a negotiation of an indirect cost rate between the cognizant agency for indirect costs and the nonprofit organization, the dispute must be resolved in accordance with the appeals procedures of the cognizant agency for indirect costs.

[END OF PROVISION]

RAA5. EXCHANGE VISITORS AND PARTICIPANT TRAINING (JUNE 2012)

For any Exchange Visitor, Participant Training or Invitational Travel activities, the recipient must comply with this provision.

a. Definitions:

- (1) An **Exchange Visitor** is any host-country or third-country national traveling to the U.S., for any purpose, including Participant Training and Invitational Travel, funded by USAID in whole or in part, directly or indirectly.
- (2) A **Participant** is a host-country or third-country national sponsored by USAID for a Participant Training activity taking place in the U.S., a third country, or in the host country.
- (3) **Participant Training** is a learning activity conducted within the U.S., a third country, or in the host country for the purpose of furthering USAID development objectives. A learning activity takes place in a setting in which an individual (the Participant) interacts with a knowledgeable professional, predominantly for the purpose of acquiring knowledge or skills for the professional or technical enhancement of the individual. Learning activities may be formally structured, such as an academic program or a technical course, or they may be more informal, such as an observational study tour.
- (4) **Invitational Travel** is a type of travel that USAID funds for non-U.S. Government employees. This type of travel may be approved for both U.S. and foreign citizens who are not employed by the U.S. Government (USG), not receiving any type of compensation from the USG for such travel, and only when it is determined that the functions to be performed are essential to the interests of USAID.

b. Program Monitoring and Data Reporting: The recipient must monitor Exchange Visitors' and Participants' progress during their program and ensure that problems are identified and resolved quickly.

- (1) For U.S.-based activities, the recipient must use USAID's official Exchange Visitor and Participant Training information system, currently called "Training Results and Information Network – TraiNet" (see <http://trainethelp.usaid.gov/>), to report and manage Exchange Visitor and Participant Training data. The recipient must also use the USAID Visa Compliance System – VCS (see <http://trainethelp.usaid.gov/>) to transfer required data for USAID Exchange Visitors to the Department of Homeland Security's Student and Exchange Visitor Information System (SEVIS).
- (2) For all third-country activities, and for host-country activities of two consecutive days or 16 contact hours or more in duration, the recipient must use USAID's official

Exchange Visitor and Participant Training information system, currently called “Training Results and Information Network – TraiNet” (see <http://trainethelp.usaid.gov/>), to report and manage Participant Training data.

c. Health and Accident Insurance:

- (1) For Exchange Visitors traveling to the United States, the recipient must enroll Exchange Visitors in health and accident insurance coverage that meets or exceeds Department of State and USAID minimum coverage requirements as set forth in 22 CFR 62.14 and ADS 253.3.6.2. The requirements may be obtained from the Agreement Officer’s Representative.
- (2) For Participants traveling to a third country, the recipient must obtain health and accident insurance coverage for all Participants.
- (3) For Participants traveling within the host country, the recipient must determine whether specific in-country participant training activities subject them to any risk of health and accident liability for medical costs. Participants may incur, and if so, take appropriate steps according to the local situation, including obtaining health and accident insurance coverage for Participants.

d. Immigration Requirements:

- (1) For Exchange Visitors traveling to the United States, the recipient must ensure that all USAID-sponsored Exchange Visitors obtain, use, and comply with the terms of the J-1 visa, issued in conjunction with a USAID-issued Certificate of Eligibility for J-1 Visa Status (DS-2019).
- (2) For Participants traveling to a third country or within the host country, the recipient must ensure that all Participants obtain, use, and comply with the terms of all applicable immigration, visa and other similar requirements.

e. Language Proficiency: The recipient must verify language proficiency. Exchange Visitors must possess sufficient English language proficiency to participate in a U.S.-based activity. Participants of third-country or host-country training must be proficient in the language of training at a sufficient level for participation, unless an interpreter has been arranged. Language competency can be verified through a variety of means including proficiency assessments of interviews, publications, presentations, education conducted in English, and formal testing.

f. Pre-departure Orientation: The recipient must conduct pre-departure orientation for U.S.-bound Exchange Visitors and Participants of third-country training programs. Pre-departure orientation covers: program objectives; administrative and policy review; cultural aspects; and training/learning methods.

- g. **Conditions of Sponsorship:** The recipient must ensure that all Exchange Visitors read and sign the Conditions of Sponsorship for U.S.-Based Activities form (AID 1381-6). The recipient must also ensure that all Participants of long-term (six months or longer) third-country training read and sign the form Conditions of Sponsorship for Third-Country Training form (AID 1381-7). The recipient must report to the Agreement Officer any known violations by Exchange Visitors of visa or other immigration requirements or conditions.
- h. **Exchange Visitor Security Risk and Fraud Inquiry:** Each USAID Mission has an established process for conducting a Security Risk and Fraud Inquiry (SRFI) for Exchange Visitors. The recipient must be prepared to assist Missions in conducting the SRFI, if requested. However, the recipient's role is contributive, and the Mission is ultimately responsible for conducting the SRFI.
- i. **Fly America:** To the extent that participants travel by international air travel, the recipient must comply with the Standard Provision, "International Air Travel and Air Transportation of Property."
- j. **Use of Minority Serving Institutions:** For U.S.-based Participant Training, the recipient must, to the maximum extent possible, maintain their use of Historically Black Colleges and Universities (HBCUs) and other Minority Serving Institutions (MSIs), including Hispanic Serving Institutions and Tribal Colleges and Universities, as training or education providers.

[END OF PROVISION]

RAA7. PROTECTION OF THE INDIVIDUAL AS A RESEARCH SUBJECT (APRIL 1998)

- a. Safeguarding the rights and welfare of human subjects involved in research supported by USAID is the responsibility of the organization to which support is awarded. USAID has adopted the Common Federal Policy for the Protection of Human Subjects, Part 225 of Title 22 of the Code of Federal Regulations (the "Policy"). Additional interpretation, procedures, and implementation guidance of the Policy are found in USAID General Notice entitled "Procedures for the Protection of Human Subjects in Research Supported by USAID," issued April 19, 1995, as amended. USAID's Cognizant Human Subjects Officer (CHSO) in USAID/W has oversight, guidance, and interpretation responsibility for the Policy.
- b. Recipient organizations must comply with USAID policy when humans are the subject of research, as defined in 22 CFR 225.102(d), funded by the grant and recipients must provide "assurance," as required by 22 CFR 225.103, that they follow and abide by the procedures in the Policy. See also Section 5 of the April 19, 1995, USAID General Notice which sets forth activities to which the Policy is applicable. The existence of a bona fide, applicable assurance approved by the Department of Health and Human Services (HHS) such as the "multiple project assurance" (MPA) will satisfy this requirement. Alternatively, organizations can provide an acceptable written assurance to USAID as described in 22 CFR 225.103.

Such assurances must be determined by the CHSO to be acceptable prior to any applicable research being initiated or conducted under the award. In some limited instances outside the U.S., alternative systems for the protection of human subjects may be used provided they are deemed “at least equivalent” to those outlined in Part 225 (See 22 CFR 225.101[h]). Criteria and procedures for making this determination are described in the General Notice cited in the preceding paragraph.

- c. Since the welfare of the research subject is a matter of concern to USAID as well as to the organization, USAID staff consultants and advisory groups may independently review and inspect research and research processes and procedures involving human subjects, and based on such findings, the CHSO may prohibit research which presents unacceptable hazards or otherwise fails to comply with USAID procedures. Informed consent documents must include the stipulation that the subject's records may be subject to such review.

[END OF PROVISION]

RAA8. CARE OF LABORATORY ANIMALS (MARCH 2004)

CARE OF LABORATORY ANIMALS (MARCH 2004)

- a. Before undertaking performance of any grant involving the use of laboratory animals, the recipient must register with the Secretary of Agriculture of the United States in accordance with Section 6, Public Law 89-544, Laboratory Animal Welfare Act, August 24, 1966, as amended by Public Law 91-579, Animal Welfare Act of 1970, December 24, 1970. The recipient must furnish evidence of such registration to the Agreement Officer.
- b. The recipient must acquire animals used in research under this award only from dealers licensed by the Secretary of Agriculture, or from exempted sources in accordance with the Public Laws enumerated in a. above.
- c. In the care of any live animals used or intended for use in the performance of this grant, the recipient must adhere to the principles enunciated in the Guide for Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences - National Research Council (NAS-NRC), and in the United States Department of Agriculture's (USDA) regulations and standards issued under the Public Laws enumerated in a. above. In case of conflict between standards, the higher standard must be used. The recipient's reports on portions of the award in which animals were used must contain a certificate stating that the animals were cared for in accordance with the principles enunciated in the Guide for Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, NAS-NRC, and/or in the regulations and standards as promulgated by the Agricultural Research Service, USDA, pursuant to the Laboratory Animal Welfare Act of 24 August 1966, as amended (P.L. 89-544 and P.L. 91-579). NOTE: The recipient may request registration of the recipient's facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which the recipient's research facility is located. The location of the appropriate APHIS Regional Office as well as information concerning this program may be obtained by contacting the Senior Staff

Office, Animal Care Staff, USDA/APHIS, 4700 River Road, Unit 84, Riverdale, MD 20737-1234 and at www.aphis.usda.gov/animal_welfare/index.shtml.

[END OF PROVISION]

RAA10. COST SHARING (MATCHING) (FEBRUARY 2012)

COST SHARING (MATCHING) (FEBRUARY 2012)

- a. If at the end of any funding period, the recipient has expended an amount of non-Federal funds less than the agreed upon amount or percentage of total expenditures, the Agreement Officer may apply the difference to reduce the amount of USAID incremental funding in the following funding period. If the award has expired or has been terminated, the Agreement Officer may require the recipient to refund the difference to USAID.
- b. The source and nationality requirements and the restricted goods provision established in the Standard Provision entitled "USAID Eligibility Rules for Goods and Services" do not apply to cost sharing (matching) expenditures.

[END OF PROVISION]

RAA11. PROHIBITION OF ASSISTANCE TO DRUG TRAFFICKERS (JUNE 1999)

- a. USAID reserves the right to terminate assistance to, or take other appropriate measures with respect to, any participant approved by USAID who is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR 140.
- b.
 - (1) For any loan over \$1,000 made under this agreement, the recipient must insert a clause in the loan agreement stating that the loan is subject to immediate cancellation, acceleration, recall, or refund by the recipient if the borrower or a key individual of a borrower is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR 140.
 - (2) Upon notice by USAID of a determination under section (1) and at USAID's option, the recipient agrees to immediately cancel, accelerate, or recall the loan, including refund in full of the outstanding balance. USAID reserves the right to have the loan refund returned to USAID.
- c.
 - (1) The recipient agrees not to disburse, or sign documents committing the recipient to disburse, funds to a subrecipient designated by USAID ("Designated Subrecipient") until advised by USAID that: (i) any United States Government review of the Designated Subrecipient and its key individuals has been completed; (ii) any related certifications have been obtained; and (iii) the assistance to the Designated Subrecipient has been

approved. Designation means that the subrecipient has been unilaterally selected by USAID as the subrecipient. USAID approval of a subrecipient, selected by another party, or joint selection by USAID and another party is not designation.

- (2) The recipient must insert the following clause, or its substance, in its agreement with the Designated Subrecipient:

“The recipient reserves the right to terminate this [Agreement/Contract] or take other appropriate measures if the [Subrecipient] or a key individual of the [Subrecipient] is found to have been convicted of a narcotic offense or to have been engaged in drug trafficking as defined in 22 CFR 140.”

[END OF PROVISION]

RAA13. REPORTING HOST GOVERNMENT TAXES (DECEMBER 2014)

- a. By April 16 of each year, the recipient must submit a report containing:
- (1) Contractor/recipient name.
 - (2) Contact name with phone, fax and e-mail.
 - (3) Agreement number(s).
 - (4) The total amount of value-added taxes and customs duties (but not sales taxes) assessed by the host government (or any entity thereof) on purchases in excess of \$500 per transaction of supplies, materials, goods or equipment, during the 12 months ending on the preceding September 30, using funds provided under this contract/agreement.
 - (5) Any reimbursements received by April 1 of the current year on value-added taxes and customs duties reported in (iv).
 - (6) Reports are required even if the recipient did not pay any taxes or receive any reimbursements during the reporting period.
 - (7) Cumulative reports may be provided if the recipient is implementing more than one program in a foreign country.
- b. Submit the reports to: Agreement’s Officer Representative.
- a. Host government taxes are not allowable where the Agreement Officer provides the necessary means to the recipient to obtain an exemption or refund of such taxes, and the recipient fails to take reasonable steps to obtain such exemption or refund. Otherwise, taxes

are allowable in accordance with the Standard Provision, “Allowable Costs,” and must be reported as required in this provision.

- b. The recipient must include this reporting requirement in all applicable subawards and contracts.

[END OF PROVISION]

RAA14. FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)

FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)

- a. U.S. Government funds under this award must not be used to finance the travel, per diem, hotel expenses, meals, conference fees or other conference costs for any member of a foreign government’s delegation to an international conference sponsored by a multilateral organization, as defined below, unless approved by the Agreement Officer in writing.
- b. Definitions:
 - (1) A foreign government delegation is appointed by the national government (including ministries and agencies but excluding local, state and provincial entities) to act on behalf of the appointing authority at the international conference. A conference participant is a delegate for the purposes of this provision, only when there is an appointment or designation that the individual is authorized to officially represent the government or agency. A delegate may be a private citizen.
 - (2) An international conference is a meeting where there is an agenda, an organizational structure, and delegations from countries other than the conference location, in which country delegations participate through discussion, votes, etc.
 - (3) A multilateral organization is an organization established by international agreement and whose governing body is composed principally of foreign governments or other multilateral organizations.

[END OF PROVISION]

RAA18. USAID DISABILITY POLICY - ASSISTANCE (DECEMBER 2004)

- a. The objectives of the USAID Disability Policy are (1) to enhance the attainment of United States foreign assistance program goals by promoting the participation and equalization of opportunities of individuals with disabilities in USAID policy, country and sector strategies, activity designs and implementation; (2) to increase awareness of issues of people with disabilities both within USAID programs and in host countries; (3) to engage other U.S. Government agencies, host country counterparts, governments, implementing organizations

and other donors in fostering a climate of nondiscrimination against people with disabilities; and (4) to support international advocacy for people with disabilities.

- b. USAID therefore requires that the recipient not discriminate against people with disabilities in the implementation of USAID funded programs and that it make every effort to comply with the objectives of the USAID Disability Policy in performing the program under this grant or cooperative agreement. To that end and to the extent it can accomplish this goal within the scope of the program objectives, the recipient should demonstrate a comprehensive and consistent approach for including men, women, and children with disabilities.

[END OF PROVISION]

RAA23. UNIVERSAL IDENTIFIER AND SYSTEM OF AWARD MANAGEMENT (NOVEMBER 2020)

- a. **Requirement for System of Award Management (SAM).** Unless you are exempted from this requirement under 2 CFR 25.110, you as the recipient must maintain current information in the SAM. This includes information on your immediate and highest level owner and subsidiaries, as well as on all of your predecessors that have been awarded a Federal contract or Federal financial assistance within the last three years, if applicable, until you submit the final financial report required under this Federal award or receive the final payment, whichever is later. This requires that you review and update the information at least annually after the initial registration, and more frequently, if required by changes in your information or another Federal award term.
- b. **Requirement for Unique Entity Identifier.** If you are authorized to make subawards under this Federal award, you:
 - (1) Must notify potential subrecipients that no entity (see definition in paragraph c. of this award term) may receive a subaward from you until the entity has provided its Unique Entity Identifier to you.
 - (2) May not make a subaward to an entity unless the entity has provided its Unique Entity Identifier to you. Subrecipients are not required to obtain an active SAM registration but must obtain a Unique Entity Identifier.
- c. **Definitions.** For purposes of this award term:
 - (1) System of Award Management (SAM) means the Federal repository into which a recipient must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM Internet site (currently at <https://www.sam.gov>).

- (2) Unique Entity Identifier means the identifier assigned by SAM to uniquely identify business entities.
- (3) Entity includes non-Federal entities as defined in 2 CFR 200.1 and also includes all of the following, for purposes of this part:
 - a. A foreign organization;
 - b. A foreign public entity;
 - c. A domestic for-profit organization; and
 - d. A Federal agency.
- (4) Subaward has the meaning given in 2 CFR 200.1.
- (5) Subrecipient has the meaning given in 2 CFR 200.1.

ADDENDUM (NOVEMBER 2020):

- d. **Exceptions.** The requirements of this provision to obtain a Unique Entity Identifier and maintain a current registration in the SAM do not apply, at the prime award or subaward level, to:
 - (1) Awards to individuals
 - (2) Awards less than \$25,000 to foreign recipients to be performed outside the United States (based on a USAID determination)
 - (3) Awards where the Agreement Officer determines, in writing, that the Agency must protect entity information from disclosure due to national security or foreign policy interests of the United States or that these requirements would cause personal safety concerns.
- e. This provision does not need to be included in subawards.

[END OF PROVISION]

**RAA24. REPORTING SUBAWARDS AND EXECUTIVE COMPENSATION
(NOVEMBER 2020)**

- a. **Reporting of first-tier subawards.**
 - (1) Applicability. Unless you are exempt as provided in paragraph d. of this award term, you must report each action that equals or exceeds \$30,000 in Federal funds for a subaward to a non-Federal entity or Federal agency (see definitions in paragraph e. of this award term).

(2) Where and when to report.

- (i) The non-Federal entity or Federal agency must report each obligating action described in paragraph a.(1) of this award term to www.fsrs.gov.
- (ii) For subaward information, report no later than the end of the month following the month in which the obligation was made. (For example, if the obligation was made on November 7, 2010, the obligation must be reported by no later than December 31, 2010.)

(3) What to report. You must report the information about each obligating action that the submission instructions posted at www.fsrs.gov specify.

b. Reporting Total Compensation of Recipient Executives.

(1) Applicability and what to report. You must report total compensation for each of your five most highly compensated executives for the preceding completed fiscal year, if –

- (i) The total Federal funding authorized to date under this Federal award equals or exceeds \$30,000 as defined in 2 CFR 170.320;
- (ii) In the preceding fiscal year, you received—
 - (A) 80 percent or more of your annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
 - (B) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
- (iii) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at www.sec.gov/answers/execomp.htm.)

(2) Where and when to report. You must report executive total compensation described in paragraph b.(1) of this award term:

- (i) As part of your registration profile at www.sam.gov.
- (ii) By the end of the month following the month in which this award is made, and annually thereafter.

c. Reporting of Total Compensation of Subrecipient Executives.

- (1) Applicability and what to report. Unless you are exempt as provided in paragraph d. of this award term, for each first-tier subrecipient under this award, you must report the names and total compensation of each of the subrecipient's five most highly compensated executives for the subrecipient's preceding completed fiscal year, if—
 - (i) In the subrecipient's preceding fiscal year, the subrecipient received—
 - (A) 80 percent or more of its annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
 - (B) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts), and Federal financial assistance subject to the Transparency Act (and subawards); and
 - (ii) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at www.sec.gov/answers/execomp.htm.)
- (2) Where and when to report. You must report subrecipient executive total compensation described in paragraph c.(1) of this award term:
 - (i) To the recipient.
 - (ii) By the end of the month following the month during which you make the subaward. For example, if a subaward is obligated on any date during the month of October of a given year (for example, between October 1 and 31), you must report any required compensation information of the subrecipient by November 30 of that year.

d. Exemptions.

If, in the previous tax year, you had gross income, from all sources, under \$300,000, you are exempt from the requirements to report:

- (1) Subawards, and
- (2) The total compensation of the five most highly compensated executives of any subrecipient.

e. Definitions.

For purposes of this award term:

- (1) Federal Agency means a Federal agency as defined at 5 U.S.C. 551(1) and further clarified by 5 U.S.C. 552(f).
- (2) Entity means all of the following, as defined in 2 CFR 25:
 - (i) A governmental organization, which is a State, local government, or Indian tribe;
 - (ii) A foreign public entity;
 - (iii) A domestic or foreign nonprofit organization; and
 - (iv) A domestic or foreign for-profit organization.
- (3) Executive means officers, managing partners, or any other employees in management positions.
- (4) Subaward:
 - (i) This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.
 - (ii) The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see 2 CFR 200.331).
 - (iii) A subaward may be provided through any legal agreement, including an agreement that you or a subrecipient considers a contract.
- (5) Subrecipient means a non-Federal entity or Federal agency that:
 - (i) Receives a subaward from you (the recipient) under this award; and
 - (ii) Is accountable to you for the use of the Federal funds provided by the subaward.
- (6) Total compensation means the cash and noncash dollar value earned by the executive during the recipient's or subrecipient's preceding fiscal year and includes the following (for more information see 17 CFR 229.402(c)(2)):
 - (i) Salary and bonus.

- (ii) Awards of stock, stock options, and stock appreciation rights. Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Statement of Financial Accounting Standards No. 123 (Revised 2004) (FAS 123R), Shared Based Payments.
- (iii) Earnings for services under nonequity incentive plans. This does not include group life, health, hospitalization, or medical reimbursement plans that do not discriminate in favor of executives, and are available generally to all salaried employees.
- (iv) Change in pension value. This is the change in present value of defined benefit and actuarial pension plans.
- (v) Above-market earnings on deferred compensation which is not tax-qualified.
- (vi) Other compensation, if the aggregate value of all such other compensation (for example, severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property) for the executive exceeds \$10,000.

[END OF PROVISION]

RAA25. PATENT REPORTING PROCEDURES (NOVEMBER 2020)

As incorporated by 2 CFR 200.315 and the standard provision “APPLICABILITY OF 2 CFR 200 and 2 CFR 700,” the clause at 37 CFR 401.14 (“Standard Patent Rights”) is incorporated by reference into this award as if set forth in full text. The recipient must use the National Institutes of Health EDISON Patent Reporting and Tracking system (<http://www.iedison.gov>) to fulfill its disclosure obligations under 37 CFR 401.14(c)(1). The recipient must also submit reports on utilization of subject inventions annually to the Agreement Officer’s Representative under 37 CFR 401.14(h), and the last report must be provided within 90 days of the expiration of the agreement.

[END OF PROVISION]

RAA26. ACCESS TO USAID FACILITIES AND USAID’S INFORMATION SYSTEMS (AUGUST 2013)

- a. A U.S. citizen or resident alien engaged in the performance of this award as an employee, consultant, or volunteer of a U.S organization may obtain access to USAID facilities or logical access to USAID’s information systems only when and to the extent necessary to carry out this award and in accordance with this provision. The recipient’s employees, consultants, or volunteers who are not U.S. citizen as well as employees, consultants, or volunteers of non-U.S.

- b. organizations, irrespective of their citizenship, will not be granted logical access to U.S. Government information technology systems (such as Phoenix, GLAAS, etc.) and must be escorted to use U.S. Government facilities (such as office space).
- c. Before a U.S. citizen or resident alien engaged in the performance of this award as an employee, consultant, or volunteer of the recipient, subrecipient or contractor at any tier may obtain a USAID ID (new or replacement) authorizing the individual routine access to USAID facilities in the United States, or logical access to USAID's information systems, the individual must provide two forms of identity source documents in original form. One identity source document must be a valid Federal or State government-issued picture ID. The recipient must contact the USAID Office of Security to obtain the list of acceptable forms of documentation. Submission of these documents, and related background checks, are mandatory in order for the individual to receive a building access ID, and before access will be granted to any of USAID's information systems. All such individuals must physically present these two source documents for identity proofing at their Security Briefing. All individuals provided access under this provision must return any issued building access ID and remote authentication token to USAID custody upon termination of the individual's employment with the recipient or completion of the award, whichever occurs first.
- d. Individuals engaged in the performance of this award as an employee, consultant, or volunteer of the recipient must comply with all applicable Homeland Security Policy Directive-12 (HSPD-12) and Personal Identity Verification (PIV) procedures, as described above, as well as any subsequent USAID or government-wide HSPD-12 and PIV procedures/policies, including any
- e. HSPD-12 procedures established by the Office of Security in USAID/Washington.
- f. The recipient is required to include this provision in all subawards and contracts at any tier made to a U.S. organization/company, that require employees or consultants engaged in the performance of this award to have routine physical access to USAID facilities or logical access to USAID's information systems in order to perform this award.

[END OF PROVISION]

RAA27. CONTRACT PROVISION FOR DBA INSURANCE UNDER RECIPIENT PROCUREMENTS (DECEMBER 2014)

All contracts made by the recipient under this award for services to be performed overseas must contain the following provision, as applicable.

Workers' Compensation Insurance (Defense Base Act)

(a) The Contractor must--

- (1) Before commencing performance under this contract, establish provisions to provide for the payment of disability compensation and medical benefits to covered employees and death benefits to their eligible survivors, by purchasing Defense Base Act (DBA) insurance pursuant to the terms of the contract between USAID and USAID's DBA insurance carrier unless the Contractor qualifies as a self-insurer under the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 932) as extended by the Defense Base Act (42 U.S.C. 1651, et seq.), or has an approved retrospective rating agreement for DBA. The Contractor must continue to maintain these provisions to provide such Defense Base Act benefits until contract performance is completed.
- (2) If USAID or the Contractor has secured a waiver of DBA coverage in accordance with AIDAR 728.305-70(a) for contractor's employees who are not citizens of, residents of, or hired in the United States, the contractor agrees to provide such employees with worker's compensation benefits as required by the laws of the country in which the employees are working, or by the laws of the employee's native country, whichever offers greater benefits. The Department of Labor has granted partial blanket waivers of DBA coverage applicable to USAID-financed contracts performed in countries listed in the DEFENSE BASE ACT (DBA) WAIVER LIST.
- (3) Within ten days of an employee's injury or death or from the date the Contractor has knowledge of the injury or death, submit Form LS-202 (Employee's First Report of Injury or Occupational Illness) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 930(a), 20 CFR 702.201 to 702.203).
- (4) Pay all compensation due for disability or death within the timeframes required by the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914, 20 CFR 702.231 and 703.232).
- (5) Provide for medical care as required by the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 907, 20 CFR 702.402 and 702.419).
- (6) If controverting the right to compensation, submit Form LS-207 (Notice of Controversion of Right to Compensation) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914(d), 20 CFR 702.251).
- (7) Immediately upon making the first payment of compensation in any case, submit Form LS-206 (Payment of Compensation Without Award) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914(c), 20 CFR 702.234).
- (8) When payments are suspended or when making the final payment, submit Form LS-208 (Notice of Final Payment or Suspension of Compensation Payments) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914 (c) and (g), 20 CFR 702.234 and 702.235).

- (9) Adhere to all other provisions of the Longshore and Harbor Workers' Compensation Act as extended by the Defense Base Act, and Department of Labor regulations at 20 CFR Parts 701 to 704.

For additional information on the Longshore and Harbor Workers' Compensation Act requirements see <http://www.dol.gov/owcp/dlhwc/lbdba.htm>.

The Contractor must insert the substance of this clause including this paragraph (c), in all subcontracts to which the Defense Base Act applies.

[END OF PROVISION]

RAA28. AWARD TERM AND CONDITION FOR RECIPIENT INTEGRITY AND PERFORMANCE MATTERS (APRIL 2016)

A. Reporting of Matters Related to Recipient Integrity and Performance

1. General Reporting Requirement

If the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds \$10,000,000 for any period of time during the period of performance of this Federal award, then you as the recipient during that period of time must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) about civil, criminal, or administrative proceedings described in paragraph 2 of this award term and condition. This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available.

2. Proceedings About Which You Must Report

Submit the information required about each proceeding that:

- a. Is in connection with the award or performance of a grant, cooperative agreement, or procurement contract from the Federal Government;
- b. Reached its final disposition during the most recent five year period; and
- c. Is one of the following:
 - (1) A criminal proceeding that resulted in a conviction, as defined in paragraph 5 of this award term and condition;

- (2) A civil proceeding that resulted in a finding of fault and liability and payment of a monetary fine, penalty, reimbursement, restitution, or damages of \$5,000 or more;
- (3) An administrative proceeding, as defined in paragraph 5. of this award term and condition, that resulted in a finding of fault and liability and your payment of either a monetary fine or penalty of \$5,000 or more or reimbursement, restitution, or damages in excess of \$100,000; or
- (4) Any other criminal, civil, or administrative proceeding if:
 - (i) It could have led to an outcome described in paragraph 2.c.(1), (2), or (3) of this award term and condition;
 - (ii) It had a different disposition arrived at by consent or compromise with an acknowledgment of fault on your part; and
 - (iii) The requirement in this award term and condition to disclose information about the proceeding does not conflict with applicable laws and regulations.

3. Reporting Procedures

Enter in the SAM Entity Management area the information that SAM requires about each proceeding described in paragraph 2 of this award term and condition. You do not need to submit the information a second time under assistance awards that you received if you already provided the information through SAM because you were required to do so under Federal procurement contracts that you were awarded.

4. Reporting Frequency

During any period of time when you are subject to the requirement in paragraph 1 of this award term and condition, you must report proceedings information through SAM for the most recent five year period, either to report new information about any proceeding(s) that you have not reported previously or affirm that there is no new information to report. Recipients that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 must disclose semiannually any information about the criminal, civil, and administrative proceedings.

5. Definitions

For purposes of this award term and condition:

- a. Administrative proceeding means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative proceedings, Civilian Board of Contract Appeals

proceedings, and Armed Services Board of Contract Appeals proceedings). This includes proceedings at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include audits, site visits, corrective plans, or inspection of deliverables.

- b. Conviction, for purposes of this award term and condition, means a judgment or conviction of a criminal offense by any court of competent jurisdiction, whether entered upon a verdict or a plea, and includes a conviction entered upon a plea of nolo contendere.
- c. Total value of currently active grants, cooperative agreements, and procurement contracts includes—
 - (1) Only the Federal share of the funding under any Federal award with a recipient cost share or match; and
 - (2) The value of all expected funding increments under a Federal award and options, even if not yet exercised.

B. [Reserved]

[END OF PROVISION]

[END OF PROVISION]

RAA30. PROGRAM INCOME (AUGUST 2020)

PROGRAM INCOME (August 2020)

- a. Program income is gross income earned by the recipient that is directly generated by a supported activity or earned as a result of the Federal award during the period of performance. Program income includes, but is not limited to: income from fees for services performed; the use or rental of real or personal property acquired under Federal awards; the sale of commodities or items fabricated under a Federal award; license fees and royalties on patents and copyrights; and principal and interest on loans made with Federal award funds. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, or interest earned on any of them.
- b. Program income must be used for the purposes, and under the conditions, of the award, to further project objectives, program objectives, or award activities. Program income must be used only for allowable program costs. Interest earned on program income is subject to the same conditions as program income.
- c. The recipient must apply the approach for use of program income as specified in the schedule of the award. This may include one of the three approaches listed below (see also **2 CFR**

200.307). The recipient must also follow the standards in this provision to account for gross income earned from Federally-supported activities under this award.

1) If the deduction approach is used, the recipient must use the program income for current costs, prior to drawdown of USAID funds under the award.

2) If the addition approach is used, the total award amount is increased by the amount of program income. If the award anticipates a specific program income amount, any program income in excess of such amount must be deducted from expenditures.

3) If the cost sharing approach is used, the amount of the award remains the same. If the award anticipates a specific program income amount, any program income in excess of such amount must be deducted from expenditures.

d. Costs subject to generating program income under this award may be deducted from gross income to calculate program income, provided these costs have not been charged to this award and comply with the standard provision, “Allowable Costs.”

e. The recipient must report program income using the **Federal Financial Report, SF-425**. Program income must be accounted for in the same ratio as USAID’s participation in the program. For example, if USAID funded 75 percent of a recipient’s program, then the recipient must report 75 percent of any program income earned under the award as “Federal program income earned” on the SF-425.

f. The recipient should continue to use program income earned after the period of the award to further award objectives, but is not subject to Federal requirements governing the disposition of program income earned after the end of the period of performance for the award.

[END OF PROVISION]

[END OF STANDARD PROVISIONS]

ATTACHMENT D – BRANDING AND MARKING PLAN

PATH Consolidated Financial Statements and Single Audit Report



For the Year Ended
December 31, 2020

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Independent Auditor's Report

To the Board of Directors
PATH

REPORT ON THE FINANCIAL STATEMENTS

We have audited the accompanying consolidated financial statements of PATH and Subsidiaries (collectively, the Organization), which comprise the consolidated statements of financial position as of December 31, 2020 and 2019 and the related consolidated statements of activities and changes in net assets, functional expenses, and cash flows for the years then ended, and the related notes to the consolidated financial statements.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America and the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the Organization's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Organization's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.



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We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Organization as of December 31, 2020 and 2019, and the changes in its net assets and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

Report on Supplementary Information

Our audit was conducted for the purpose of forming an opinion on the financial statements as a whole. The accompanying schedule of expenditures of federal awards, as required by the audit requirements of Title 2 U.S. Code of Federal Regulations (CFR) Part 200, *Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards* (Uniform Guidance), on pages 27 through 32 is presented for purposes of additional analysis and is not a required part of the financial statements. Such information is the responsibility of management and was derived from and relates directly to the underlying accounting and other records used to prepare the financial statements. The information has been subjected to the auditing procedures applied in the audit of the financial statements and certain additional procedures, including comparing and reconciling such information directly to the underlying accounting and other records used to prepare the financial statements or to the financial statements themselves, and other additional procedures in accordance with auditing standards generally accepted in the United States of America. In our opinion, the information is fairly stated in all material respects in relation to the financial statements as a whole.

OTHER REPORTING REQUIRED BY GOVERNMENT AUDITING STANDARDS

In accordance with *Government Auditing Standards*, we have also issued our report June 3, 2021 on our consideration of the Organization's internal control over financial reporting and on our tests of its compliance with certain provisions of laws, regulations, contracts, and grant agreements and other matters. The purpose of that report is to describe the scope of our testing of internal control over financial reporting and compliance and the results of that testing, and not to provide an opinion on the effectiveness of the Organization's internal control over financial reporting or on compliance. That report is an integral part of an audit performed in accordance with *Government Auditing Standards* in considering the Organization's internal control over financial reporting and compliance.

Clark Nuber P.S.

Certified Public Accountants
June 3, 2021

PATH AND SUBSIDIARIES

Consolidated Statements of Financial Position **December 31, 2020 and 2019** **(In Thousands)**

	2020	2019
Assets		
Cash and cash equivalents	\$ 17,141	\$ 26,554
Investments	211,221	177,558
Awards and contributions receivable, net	39,743	43,347
Prepaid expenses and other	7,324	7,506
Furniture, equipment and leasehold improvements, net	8,432	10,035
Total Assets	\$ 283,861	\$ 265,000
Liabilities and Net Assets		
Accounts payable	\$ 23,825	\$ 17,930
Accrued expenses and other liabilities	26,619	25,688
Deferred revenue	182,853	179,438
Total Liabilities	233,297	223,056
Net Assets:		
Without donor restrictions	23,544	21,320
With donor restrictions	27,020	20,624
Total Net Assets	50,564	41,944
Total Liabilities and Net Assets	\$ 283,861	\$ 265,000

See accompanying notes to the consolidated financial statements.

PATH AND SUBSIDIARIES

Consolidated Statement of Activities and Changes in Net Assets For the Years Ended December 31, 2020 and 2019 (In Thousands)

	2020			2019		
	Without Donor Restrictions	With Donor Restrictions	Total	Without Donor Restrictions	With Donor Restrictions	Total
Operating Revenues:						
Awards and contributions						
Private foundations	\$ 157,000	\$ -	\$ 157,000	\$ 166,509	\$ -	\$ 166,509
U.S. government	64,169	-	64,169	71,817	-	71,817
Other governments	34,599	-	34,599	34,392	-	34,392
Other awards and in-kind	25,898	314	26,212	12,830	2,277	15,107
Private campaign contributions	4,392	913	5,305	1,728	2,904	4,632
	286,058	1,227	287,285	287,276	5,181	292,457
Other income-						
Income and funding from invested funds	4,549	10,323	14,872	7,714	2,665	10,379
Other	708	358	1,066	353	306	659
	5,257	10,681	15,938	8,067	2,971	11,038
Net assets released from restrictions-						
Satisfaction of program restrictions	4,633	(4,633)	-	2,147	(2,147)	-
Private campaign - pledges released from restriction	879	(879)	-	619	(619)	-
	5,512	(5,512)	-	2,766	(2,766)	-
Total Operating Revenues	296,827	6,396	303,223	298,109	5,386	303,495
Expenses:						
Program services	252,136	-	252,136	252,307	-	252,307
Support services-						
Management and general	37,600	-	37,600	36,989	-	36,989
Bid and proposal	2,308	-	2,308	2,618	-	2,618
Fundraising	2,325	-	2,325	2,535	-	2,535
Total Expenses	294,369	-	294,369	294,449	-	294,449
Change in Net Assets From Operations	2,458	6,396	8,854	3,660	5,386	9,046
Non-Operating Activity:						
Loss on foreign currency exchange	(234)	-	(234)	(2,181)	-	(2,181)
Total Change in Net Assets	2,224	6,396	8,620	1,479	5,386	6,865
Net assets, beginning of year	21,320	20,624	41,944	19,841	15,238	35,079
Net Assets, End of Year	\$ 23,544	\$ 27,020	\$ 50,564	\$ 21,320	\$ 20,624	\$ 41,944

See accompanying notes to the consolidated financial statements.

PATH AND SUBSIDIARIES

Consolidated Statement of Functional Expenses For the Year Ended December 31, 2020 (In Thousands)

	Program Services					Support Services				
	Essential Medicines	Global Health Programs	Technology, Analytics and Market Innovation	Other	Total Program Services	Management and General	Fundraising	Bid and Proposal	Total	
Salaries	\$ 26,896	\$ 36,800	\$ 13,638	\$ 2,674	\$ 80,008	\$ 18,569	\$ 1,213	\$ 1,309	\$ 101,099	
Sub-agreements	35,407	20,352	7,574	35	63,368	-	-	-	63,368	
Fringe benefits and payroll tax	7,066	13,433	3,607	957	25,063	4,401	320	405	30,189	
Sub-contracts	19,114	8,072	1,661	133	28,980	3	-	-	28,983	
Occupancy	4,710	6,133	2,533	508	13,884	4,106	213	255	18,458	
Professional services	1,479	6,945	1,439	480	10,343	2,861	161	285	13,650	
Travel	685	5,833	622	362	7,502	194	5	40	7,741	
Meetings, education and workshops	166	4,187	259	162	4,774	504	5	8	5,291	
Supplies and other	137	3,308	960	21	4,426	65	13	-	4,504	
Equipment rental and maintenance	164	2,595	235	47	3,041	1,174	4	-	4,219	
Consultants	110	2,620	256	51	3,037	844	50	6	3,937	
Project procurement	18	2,105	138	-	2,261	-	-	-	2,261	
Unrecoverable costs	-	-	-	-	-	1,910	-	-	1,910	
Donations, sponsorships and memberships	77	158	25	17	277	1,075	135	-	1,487	
Taxes, licenses and fees	503	321	10	24	858	588	29	-	1,475	
Direct aid to beneficiaries	-	1,266	4	123	1,393	-	-	-	1,393	
Telecommunications	163	677	70	51	961	134	6	-	1,101	
In-kind contributions	32	13	362	-	407	562	108	-	1,077	
Printing and copying	41	649	12	26	728	140	45	-	913	
Postage and freight	123	378	112	1	614	30	18	-	662	
Insurance	126	85	-	-	211	440	-	-	651	
	\$ 97,017	\$ 115,930	\$ 33,517	\$ 5,672	\$ 252,136	\$ 37,600	\$ 2,325	\$ 2,308	\$ 294,369	

See accompanying notes to the consolidated financial statements.

PATH AND SUBSIDIARIES

Consolidated Statement of Functional Expenses For the Year Ended December 31, 2019 (In Thousands)

	Program Services					Support Services				
	Essential Medicines	Global Health Programs	Technology, Analytics and Market Innovation	Other	Total Program Services	Management and General	Fundraising	Bid and Proposal	Total	
Salaries	\$ 25,753	\$ 37,672	\$ 11,453	\$ 2,478	\$ 77,356	\$ 17,806	\$ 1,114	\$ 1,418	\$ 97,694	
Sub-agreements	30,851	18,555	4,676	207	54,289	(1)	-	-	54,288	
Fringe benefits and payroll tax	8,974	13,865	3,956	899	27,694	6,060	406	413	34,573	
Sub-contracts	15,812	9,187	1,404	428	26,831	116	-	7	26,954	
Occupancy	4,835	6,417	2,170	499	13,921	4,625	222	226	18,994	
Professional services	1,123	5,111	1,007	415	7,656	2,499	312	239	10,706	
Travel	4,701	10,898	1,580	614	17,793	1,222	27	201	19,243	
Meetings, education and workshops	611	6,874	204	465	8,154	51	57	14	8,276	
Supplies and other	279	2,015	662	38	2,994	350	252	1	3,597	
Equipment rental and maintenance	157	1,059	163	43	1,422	1,172	3	1	2,598	
Consultants	194	4,572	205	65	5,036	956	48	93	6,133	
Project procurement	70	503	258	-	831	-	-	-	831	
Donations, sponsorships and memberships	80	123	23	33	259	147	10	-	416	
Taxes, licenses and fees	185	375	33	28	621	552	29	1	1,203	
Direct aid to beneficiaries	-	3,033	2	-	3,035	-	-	-	3,035	
Telecommunications	241	647	58	54	1,000	197	11	2	1,210	
In-kind contributions	18	1,055	450	-	1,523	739	-	-	2,262	
Printing and copying	140	843	26	55	1,064	178	33	2	1,277	
Postage and freight	130	309	130	6	575	50	11	-	636	
Insurance	175	75	3	-	253	270	-	-	523	
	<u>\$ 94,329</u>	<u>\$ 123,188</u>	<u>\$ 28,463</u>	<u>\$ 6,327</u>	<u>\$ 252,307</u>	<u>\$ 36,989</u>	<u>\$ 2,535</u>	<u>\$ 2,618</u>	<u>\$ 294,449</u>	

See accompanying notes to the consolidated financial statements.

PATH AND SUBSIDIARIES

Consolidated Statements of Cash Flows For the Years Ended December 31, 2020 and 2019 (In Thousands)

	2020	2019
Cash Flows From Operating Activities:		
Change in net assets	\$ 8,620	\$ 6,865
Adjustments to reconcile change in net assets to net cash provided (used) by operating activities-		
Depreciation and amortization	3,114	3,227
Unrealized gains and accrued interest on investments	(2,388)	(2,722)
(Gain) loss on hedging activity	(260)	1,103
Loss on sale and disposal of equipment	14	150
Contributions restricted for endowment	(3)	(2)
Changes in assets and liabilities:		
Contributions and awards receivable	3,604	(6,236)
Prepaid expenses and other	450	(2,063)
Accounts payable	5,895	(330)
Accrued expenses and other liabilities	931	(274)
Deferred revenue	3,415	(7,400)
Net Cash Provided (Used) by Operating Activities	23,392	(7,682)
Cash Flows From Investing Activities:		
Purchases of furniture, equipment and leasehold improvements	(1,547)	(2,320)
Proceeds from sale of equipment	22	38
Net purchases from hedging activity	(8)	(1,073)
Purchases of investments	(88,358)	(124,093)
Proceeds from maturity/sales of investments	57,083	140,199
Net Cash (Used) Provided by Investing Activities	(32,808)	12,751
Cash Flows From Financing Activities:		
Payments on notes payable	-	(194)
Proceeds from contributions restricted for endowment	3	2
Net Cash Provided (Used) by Financing Activities	3	(192)
Net Change in Cash and Cash Equivalents	(9,413)	4,877
Cash and cash equivalents, beginning of year	26,554	21,677
Cash and Cash Equivalents, End of Year	\$ 17,141	\$ 26,554
Supplementary Disclosure of Cash Flow Information:		
Property and equipment purchases included in accounts payable	\$ -	\$ 14

See accompanying notes to the consolidated financial statements.

PATH AND SUBSIDIARIES

Notes to Consolidated Financial Statements For the Years Ended December 31, 2020 and 2019

Note 1 - Organization and Summary of Accounting Policies

Organization - PATH, along with its Subsidiaries (collectively, the Organization) is a global non-profit accelerating health equity and access to good health so people and communities can thrive. PATH advises and partners with public institutions, businesses, grassroots groups and investors to solve the world's most pressing health challenges. Headquartered in Seattle, PATH has close to 1,380 employees that work in more than 60 countries and with 20 offices worldwide, PATH delivers through a model that is both global and local. With leading global capabilities in primary health care, malaria, vaccines and data and digital solution development, its team of professionals that includes scientists, health professionals, business leaders, advocate and experts from dozens of specialties, transform bold ideas into sustainable solutions that improve health and well-being.

PATH's solution areas include: advocacy and policy; development of easy to use and affordable device and diagnostics tools; invention and advancement of affordable and effective medicines, as well as partnering with countries to assess and design appropriate demand and supply markets for affordable and available quality health products and services. As a global health organization addressing health problems facing people and communities around the world, the breadth and scope of the health areas covered by PATH are broad, encompassing: cancer, diabetes, diarrheal disease, early childhood development, Ebola, epidemic preparedness, heart disease, HIV/AIDS, HPV, Influenza, Japanese Encephalitis, malaria, maternal and newborn care, meningitis, tropical diseases, nutrition, pneumonia, polio, sexual and reproductive health, tuberculosis, water sanitation and hygiene.

Basis of Presentation - The consolidated financial statements of the Organization have been prepared on the accrual basis of accounting under accounting principles generally accepted in the United States of America (U.S. GAAP). The consolidated financial statements include the accounts of PATH and PATH's controlled subsidiaries, including:

- Foundation for Appropriate Technologies in Health - Switzerland (FATH), a Swiss Foundation.
- Program for Appropriate Technology in Health (PATH - Kenya), an organization registered under the Non-Governmental Organizations Co-ordination Act, 1990 in Kenya.
- PATH Vaccine Solutions (PVS), a 501(c)(3) nonprofit corporation, incorporated in the state of Washington. The entity was dissolved effective July 31, 2020 and its assets were transferred to PATH.

All inter-entity accounts and transactions have been eliminated in consolidation.

For the purposes of financial reporting, the Organization classifies resources into two net asset categories pursuant to any donor-imposed restrictions. Accordingly, the net assets of the Organization are classified and reported as follows:

Net Assets Without Donor Restrictions - Net assets that are not subject to donor-imposed stipulations.

PATH AND SUBSIDIARIES

Notes to Consolidated Financial Statements For the Years Ended December 31, 2020 and 2019

Note 1 - Continued

Net Assets With Donor Restrictions - Net assets subject to donor-imposed stipulations to be invested in perpetuity, restricted for specific purposes, or that may or will be met by actions of the Organization and/or the passage of time.

Award and contribution revenues are reported as increases in net assets without donor restrictions unless the use of the related assets is limited by donor-imposed restrictions. Expenses are reported as decreases in net assets without donor restrictions. Gains and losses on investments and other assets or liabilities are reported as increases or decreases in net assets without donor restrictions unless their use is restricted by explicit donor stipulation or by law. Donor stipulated restrictions expire when the stipulated purpose has been fulfilled and/or the stipulated time period has elapsed. Expirations of restrictions related to the passage of time result in the reclassification of net assets with donor restrictions to net assets without donor restrictions and are reported in the consolidated statements of activities and changes in net assets as net assets released from restrictions. The Organization has elected to report donor-restricted contributions whose restrictions are met in the same period that the condition is met as revenue within net assets without donor restriction.

Cash and Cash Equivalents - For purposes of the consolidated statements of cash flows, the Organization considers all highly liquid debt instruments purchased with an original maturity of three months or less, other than those held in the Organization's investment portfolio, to be cash equivalents.

Investments - Investments in equity securities with readily determinable market values and all debt securities are recorded at fair value. Unrealized and realized gains and losses on these investments are reported in the consolidated statements of activities and changes in net assets. Securities are generally held in custodial investment accounts administered by certain financial institutions.

Investment securities, in general, are exposed to various risks, including interest rate, credit and overall market volatility. Due to the level of risk associated with certain long-term investments, it is possible that changes in the values of these investments will occur in the near term and that such changes could materially affect the amounts reported in the consolidated statements of financial position.

Investment return consists primarily of income and gains and losses earned on cash, cash equivalents and investments. Where directed by the donor or grantor, investment return on award advances is credited to deferred revenue for future use as specified in the award agreement. All other investment return is credited to net assets with or without donor restrictions as is appropriate.

Awards and Contributions Revenue Recognition - Awards and contributions from United States and foreign government agencies, foundations and public and private funders are recognized as revenue when the donor-imposed conditions, if any, have been met. Revenue from contracts with customers are recognized at the time the service or good is provided.

PATH AND SUBSIDIARIES

Notes to Consolidated Financial Statements For the Years Ended December 31, 2020 and 2019

Note 1 - Continued

Contributions and awards receivable are stated at the amount management expects to collect from outstanding balances. Awards receivable represents expenditures made in accordance with the terms of the awards not yet reimbursed in cash. Deferred revenue represents funding received in advance of the incurrence of project expenditures. Management provides for probable uncollectible amounts through a charge to expense and a credit to a valuation allowance based on its assessment of the current status of individual accounts. Balances that are still outstanding after management has used reasonable collection efforts are written off through a charge to the valuation allowance and a credit to awards contributions receivable.

Furniture, Equipment and Leasehold Improvements - The Organization capitalizes furniture, equipment and leasehold improvements with a cost of \$5,000 or greater. The cost of furniture and equipment is depreciated over the estimated useful life of the asset and is computed using the straight-line method. Leasehold improvements are amortized over the lives of the respective leases or the service lives of the improvements, whichever is shorter. Maintenance and repairs are charged to expense as incurred. Computer software purchases of \$25,000 or greater are capitalized and depreciated. Internally developed software and internally developed enhancements and modifications to existing or purchased software that result in additional functionality with a total development cost in excess of \$500,000 are capitalized and depreciated.

Vulnerability From Certain Concentrations - Financial instruments that potentially subject the Organization to concentrations of credit and market risk consist primarily of cash and cash equivalents and investments. Cash and cash equivalents and investments held by financial institutions at times exceed Federal Deposit Insurance Corporation and Securities Investor Protection Corporation insured limits.

For the year ended December 31, 2020, total revenues, gains and other support of 54% were from one private foundation and 22% were from agencies of the United States government (57% and 24%, respectively in 2019). Management is aware of the related vulnerabilities but does not anticipate material losses in connection with these concentrations. The Organization actively pursues a broad based of donors and funding sources.

Donated Goods and Services - Donations of goods, including property and equipment and software licenses, are recorded as support at their estimated fair values at the date of donation. Such donations are reported as support without restrictions unless the donor has restricted the donated asset to a specific purpose. Donated services are recognized if the services received (i) create or enhance nonfinancial assets or (ii) require specialized skills, are provided by individuals possessing those skills and would need to be purchased if not provided by donation.

Functional Allocation of Expenses - The financial statements report certain categories of expenses that are attributable to one or more program or supporting services of the Organization. Those expenses include fringe benefits, payroll taxes, occupancy, and overhead expenses. Fringe benefits, payroll taxes, and occupancy expenses are allocated to program and supporting services categories based on salary expense. Overhead expenses are allocated to program and supporting services categories based on modified direct costs.

PATH AND SUBSIDIARIES

Notes to Consolidated Financial Statements For the Years Ended December 31, 2020 and 2019

Note 1 - Continued

Operating and Non-Operating Activities - Operating activities represent all sources of revenue and expenses except those designated as non-operating. Non-operating activities are the gains and losses related to foreign currency exchange.

Sub-Agreements and Sub-Contracts - In connection with projects funded through awards and contributions, the Organization works with collaborating partners to assess health problems, identify and implement solutions and evaluate results. Accordingly, the Organization enters into funding agreements and cooperative agreements with these collaborating partners including international agencies, ministries of health, nongovernmental organizations, commercial entities and universities. Subagreements and subcontracts awarded from these projects are funded by contributions with conditions from other organizations and recorded as expense, which totaled \$92.4 million and \$81.2 million for the years ended December 31, 2020 and 2019, respectively.

Tax Exempt Status - The Internal Revenue Service has determined that PATH and PVS are exempt from federal income taxes under provisions of Section 501(c)(3) of the Internal Revenue Code (IRC). They are classified as organizations that are not private foundations under Section 501(a) of the IRC. PATH, as an independent nonprofit foundation within the meaning of Article 80 et seq of the Swiss Civil Code, has been granted certain exemptions from tax by the Switzerland Department of Finance, Cantonal Tax Administration. PATH Kenya is a not-for-profit organization registered under section 10 of the Non-Governmental Organizations Co-ordination Act, 1990 in Kenya. PATH Kenya qualifies for exemption from income tax in Kenya under Paragraph 10 of the First Schedule to the Income Tax Act CAP 470.

Foreign Currency Translation - Substantially all assets and liabilities of the Organization that are held in foreign currencies are translated at year end exchange rates. Revenues and expenses are translated using a rate based upon the funding rate the Organization receives from banks when transferring money between currencies, which approximates the exchange rate at the transaction date. Gains and losses from foreign currency translation for the year are included in the consolidated statements of activities and changes in net assets.

Use of Estimates - The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Subsequent Events - The Organization has evaluated subsequent events through June 3, 2021, the date on which the consolidated financial statements were available to be issued.

PATH AND SUBSIDIARIES

Notes to Consolidated Financial Statements For the Years Ended December 31, 2020 and 2019

Note 2 - Cash and Cash Equivalents

Cash and cash equivalents consisted of the following at December 31:

	(In Thousands)	
	2020	2019
Cash	\$ 7,422	\$ 9,036
Money market accounts and other cash equivalents	9,719	17,518
	<u>\$ 17,141</u>	<u>\$ 26,554</u>

Cash and cash equivalents held in bank accounts outside of the United States totaled \$6.3 million and \$8.1 million at December 31, 2020 and 2019, respectively. When specified by funding agreement, the Organization holds project-related funds in separate bank accounts.

Note 3 - Investments

Investments consisted of the following at December 31:

	(In Thousands)	
	2020	2019
Corporate bonds	\$ 130,189	\$ 88,047
U.S., state and foreign government securities	68,194	48,918
Asset-backed securities	-	4,412
Equity mutual funds	6,159	6,740
Money market investment funds	6,679	29,441
	<u>\$ 211,221</u>	<u>\$ 177,558</u>

PATH AND SUBSIDIARIES

Notes to Consolidated Financial Statements For the Years Ended December 31, 2020 and 2019

Note 3 - Continued

Where directed by the donor or grantor, investment return on award advances is credited to deferred revenue for future use as specified in the award agreement. Investment return utilized for specific awards is included in investment return on the consolidated statement of activities and changes in net assets. A reconciliation of investment return earned for the year and investment return reported on the consolidated statement of activities and changes in net assets for the years ended December 31 is presented below:

	(In Thousands)	
	2020	2019
Interest and dividends	\$ 3,519	\$ 3,792
Unrealized gains	1,628	2,722
Realized gains	835	751
Investment management services	(225)	(244)
Investment return	5,757	7,021
Investment return added to deferred revenues	(2,366)	(3,163)
Use of investment return from deferred revenues	11,481	6,521
Income and Funding From Invested Funds Reported on the Consolidated Statement of Activities and Changes in Net Assets	<u>\$ 14,872</u>	<u>\$ 10,379</u>

Note 4 - Fair Value Measurements

U.S. GAAP provides a framework for measuring fair value. To increase consistency and comparability in fair value measurements, the framework requires fair value to be determined based on the exchange price that would be received for an asset or paid to transfer a liability (exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants.

The framework uses a three-level valuation hierarchy based on observable and nonobservable inputs. Observable inputs consist of data obtained from independent sources. Nonobservable inputs reflect market assumptions. These two types of inputs are used to create the fair value hierarchy, giving preference to observable inputs.

Assets and liabilities classified as Level 1 have fair values based on unadjusted quoted market prices for identical instruments in active markets. Assets and liabilities classified as Level 2 have fair values based on quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in inactive markets, or model-derived valuations whose inputs are observable. Assets and liabilities classified as Level 3 have fair values based on value drivers that are unobservable.

PATH AND SUBSIDIARIES

Notes to Consolidated Financial Statements For the Years Ended December 31, 2020 and 2019

Note 4 - Continued

Following is a description of the valuation methodologies used for assets measured at fair value. There have been no changes in the methodologies used at December 31, 2020 and 2019.

Money Market Investment Funds - Valued at cost plus accrued interest, which approximates fair value.

Equity and Debt Mutual Funds - Valued at quoted market prices in active markets, which represent the net asset value (NAV) of shares held by the Organization at year end.

Debt Securities - Valued using bid evaluations from similar instruments in actively traded markets.

Foreign Exchange Derivative Contracts - Valued based primarily on the exchange rates effective at the measurement date.

Assets and liabilities recorded at fair value on a recurring basis were as follows at December 31, 2020:

	(In Thousands)		
	Level 1	Level 2	Total
Debt securities and debt mutual funds-			
U.S., state and foreign government securities	\$ 68,194	\$ -	\$ 68,194
Corporate	130,189	-	130,189
Asset-backed securities	-	-	-
Total debt securities and debt mutual funds	198,383	-	198,383
Equity mutual funds	6,159	-	6,159
Money market investment funds	6,679	-	6,679
Total investments	211,221	-	211,221
Foreign exchange derivative contracts	-	149	149
Total Assets and Liabilities at Fair Value	\$ 211,221	\$ 149	\$ 211,370

PATH AND SUBSIDIARIES

Notes to Consolidated Financial Statements For the Years Ended December 31, 2020 and 2019

Note 4 - Continued

Assets and liabilities recorded at fair value on a recurring basis were as follows at December 31, 2019:

	(In Thousands)		
	Level 1	Level 2	Total
Debt securities and debt mutual funds-			
U.S., state and foreign government securities	\$ 48,918	\$ -	\$ 48,918
Corporate	88,047	-	88,047
Asset-backed securities	4,412	-	4,412
Total debt securities and debt mutual funds	141,377	-	141,377
Equity mutual funds	6,740	-	6,740
Money market investment funds	29,441	-	29,441
Total investments	177,558	-	177,558
Foreign exchange derivative contracts	-	(119)	(119)
Total Assets and Liabilities at Fair Value	\$ 177,558	\$ (119)	\$ 177,439

Note 5 - Awards and Contributions Receivable

Awards and contributions receivable consisted of amounts due in less than one year and are recorded net of an allowance for doubtful accounts of \$349,000 and \$297,000, respectively, at December 31, 2020 and 2019.

Awards from the United States government and certain nongovernmental organizations are recorded as revenue when costs are incurred, which may not reflect the full amount awarded. The total amount of unrecognized awards pending for active projects was \$1.098 billion and \$1.107 billion at December 31, 2020 and 2019, respectively. At December 31, 2020, 48% of the Organization's unrecognized awards were from one private foundation and 38% were from agencies of the United States government (65% and 13%, respectively at December 31, 2019).

Note 6 - Furniture, Equipment and Leasehold Improvements

The Organization funds purchases of furniture, equipment and leasehold improvements from two sources: net assets without donor restriction, or project funds with donor restrictions.

PATH AND SUBSIDIARIES

Notes to Consolidated Financial Statements For the Years Ended December 31, 2020 and 2019

Note 6 - Continued

Furniture, equipment and leasehold improvements consisted of the following at December 31:

	2020 (In Thousands)		
	Without Donor Restrictions	Project Funds	Total
Furniture	\$ 3,733	\$ -	\$ 3,733
Equipment	3,977	6,532	10,509
Software	1,548	-	1,548
Leasehold improvements	22,137	67	22,204
Assets not yet in service	-	146	146
	31,395	6,745	38,140
Less accumulated depreciation and amortization	(24,390)	(5,318)	(29,708)
	<u><u>\$ 7,005</u></u>	<u><u>\$ 1,427</u></u>	<u><u>\$ 8,432</u></u>
	2019 (In Thousands)		
	Without Donor Restrictions	Project Funds	Total
Furniture	\$ 3,712	\$ -	\$ 3,712
Equipment	3,944	6,763	10,707
Software	1,548	-	1,548
Leasehold improvements	20,423	67	20,490
Assets not yet in service	837	-	837
	30,464	6,830	37,294
Less accumulated depreciation and amortization	(22,446)	(4,813)	(27,259)
	<u><u>\$ 8,018</u></u>	<u><u>\$ 2,017</u></u>	<u><u>\$ 10,035</u></u>

Note 7 - Self-Insurance Reserve

The Organization maintains a research insurance program made up of a Self-Insured Retention (SIR) reserve fund and an excess insurance policy. The Organization's SIR program covers claims up to \$125,000 per incident and is funded by allocations to programs that are conducting clinical trials involving human subjects. As of December 31, 2020 and 2019, \$2.03 million and \$2.17 million, respectively, has been funded and set aside in the reserve. It is anticipated that additional planned annual allocations and interest income will add to the reserve going forward. Additionally, the Organization carries an excess insurance policy to cover any potential claims from \$125,000 to \$10 million.

PATH AND SUBSIDIARIES

Notes to Consolidated Financial Statements For the Years Ended December 31, 2020 and 2019

Note 8 - Net Assets Without Donor Restrictions

Net assets without donor restrictions consisted of the following at December 31:

	(In Thousands)	
	2020	2019
Board designations-		
Contingency reserve fund	\$ 8,000	\$ -
Quasi-endowment fund*	-	3,670
Capital fund	4,400	4,400
Self-insured retention reserve	2,031	2,166
Total board designated	14,431	10,236
Undesignated	9,113	11,084
Total Net Assets Without Donor Restrictions	\$ 23,544	\$ 21,320

The following is a description of board designated net assets without donor restrictions:

Contingency Reserve Fund - The board has established an \$8 million contingency reserve effective January 1, 2020 to help ensure PATH's long-term financial stability and position the Organization to respond to varying economic conditions and changes that affect its financial position and ability to continuously carry out its mission. The main objectives of this reserve are to protect against sudden and significant disruptions to the Organization's business continuity and operative capital requirements, and to promote public and funder confidence in the long-term stability of the Organization. This reserve is comprised of:

*Quasi-endowment	\$ 3,898
Contingency reserve balance	4,102
Contingency Reserve Fund	\$ 8,000

* Quasi-Endowment Fund - Amounts designated to function as an endowment which provide general support for the Organization (Note 10). In 2020 the Quasi-endowment fund became a component of the Contingency reserve fund.

Capital Fund - A reserve amount set aside for furniture, equipment or leasehold improvements generally set not less than the anticipated net book value of the Organization's assets, less tenant improvement allowances.

Self-Insurance Retention Reserve - A reserve set aside for uninsured portion of claims resulting from settlement of judgment of actions related to clinical trials (Note 7).

PATH AND SUBSIDIARIES

Notes to Consolidated Financial Statements For the Years Ended December 31, 2020 and 2019

Note 9 - Net Assets With Donor Restrictions

Net assets with donor restrictions were available for the following purposes at December 31:

	(In Thousands)	
	2020	2019
Project equipment	\$ 1,427	\$ 2,017
Private campaign - donor-restricted	17,208	10,173
Donor-restricted endowment funds	7,033	6,618
Prepaid licenses	1,352	1,816
Total Net Assets With Donor Restrictions	\$ 27,020	\$ 20,624

Restricted funds are available primarily for global health initiatives.

Note 10 - Endowment

The Organization's endowment includes donor-restricted endowment funds and funds designated by the Board to function as an endowment (quasi-endowment), both of which provide general support for the Organization. As required by U.S. GAAP, net assets associated with endowment funds, including quasi-endowments, are classified and reported based on the existence or absence of donor-imposed restrictions.

The Board of Directors of the Organization has interpreted the Washington Prudent Management of Institutional Funds Act (PMIFA) as making it advisable for the Organization to track fair value of the original gift as of the gift date of the donor-restricted endowment funds absent explicit donor stipulations to the contrary. As a result of this interpretation, the Organization considers the value of a fund to be deficient if the fair value of the fund is less than the sum of (a) the original value of gifts donated to the endowment, (b) the original value of subsequent gifts to the endowment and (c) accumulations to the endowment made in accordance with the direction of the applicable donor gift instrument at the time the accumulation is added to the fund.

The remaining portion of the donor-restricted endowment fund is classified as donor restricted net assets until those amounts are appropriated for expenditure by the Foundation in a manner consistent with the standard of prudence prescribed by PMIFA. In accordance with PMIFA, the Organization considers the following factors in making a determination to appropriate or accumulate donor-restricted endowment funds: the duration and preservation of the fund, the purposes of the Organization and the donor-restricted endowment fund, general economic conditions, the possible effect of inflation and deflation, the expected total return from income and the appreciation of investments, other resources of the Organization and the investment policies of the Organization.

PATH AND SUBSIDIARIES

Notes to Consolidated Financial Statements For the Years Ended December 31, 2020 and 2019

Note 10 - Continued

Endowment net assets consisted of the following at December 31:

	2020 (In Thousands)		
	Without Donor Restrictions	With Donor Restrictions	Total
Board designated quasi-endowment funds	\$ 3,898	\$ -	\$ 3,898
Donor-restricted endowment funds-			
Original donor-restricted gift amount			
and amounts required to be retained			
by donor	-	3,403	3,403
Accumulated investment return	-	3,630	3,630
	<u>\$ 3,898</u>	<u>\$ 7,033</u>	<u>\$ 10,931</u>

	2019 (In Thousands)		
	Without Donor Restrictions	With Donor Restrictions	Total
Board designated quasi-endowment funds	\$ 3,670	\$ -	\$ 3,670
Donor-restricted endowment funds-			
Original donor-restricted gift amount			
and amounts required to be retained			
by donor	-	3,400	3,400
Accumulated investment return	-	3,218	3,218
	<u>\$ 3,670</u>	<u>\$ 6,618</u>	<u>\$ 10,288</u>

PATH AND SUBSIDIARIES

Notes to Consolidated Financial Statements For the Years Ended December 31, 2020 and 2019

Note 10 - Continued

Changes to endowment net assets were as follows for the years ended December 31, 2020 and 2019:

	(In Thousands)		
	Without Donor Restrictions	With Donor Restrictions	Total
Endowment net assets, January 1, 2019	\$ 3,246	\$ 5,851	\$ 9,097
Endowment investment return	604	1,088	1,692
Contributions	-	2	2
Earnings appropriated for expenditure	(180)	(323)	(503)
Endowment Net Assets, December 31, 2019	3,670	6,618	10,288
Endowment investment return	390	705	1,095
Contributions	-	3	3
Earnings appropriated for expenditure	(162)	(293)	(455)
Endowment Net Assets, December 31, 2020	\$ 3,898	\$ 7,033	\$ 10,931

The Organization has adopted investment and spending policies for endowment assets that attempt to provide a predictable stream of funding to programs supported by its endowment while seeking to maintain the purchasing power of the endowment assets. Endowment assets include those assets of donor-restricted funds that the Organization must hold in perpetuity or for donor-specified periods as well as board designated funds. Under this policy, as approved by the Board of Directors, the endowment assets are invested in mutual funds to ensure a broad diversification among investment styles, sectors, industries, market capitalizations and credit quality. These vehicles offer the advantages of economies of scale, greater liquidity, broader diversification, cost efficiency, lower transaction costs and low minimum investment requirements not available through separate account management.

The performance objective for the total endowment investment portfolio is to achieve an annualized investment return, net of fees, which will exceed a composite index composed of 40% Barclays Capital U.S. Aggregate Index and 60% MSCI All Country World IMI Net Total Return Index. The Organization expects its endowment funds, over time, to provide an average rate of return of approximately 5% annually. Actual returns in any given year may vary from this amount based on current market conditions.

PATH AND SUBSIDIARIES

Notes to Consolidated Financial Statements For the Years Ended December 31, 2020 and 2019

Note 10 - Continued

To satisfy its long-term rate-of-return objectives, the Organization relies on a total return strategy in which investment returns are achieved through both capital appreciation (realized and unrealized) and current yield (interest and dividends). The Organization targets a diversified asset allocation between two asset classes: 40% fixed income and 60% equity investments to achieve its long-term return objectives within prudent risk constraints.

The Organization has established an endowment spending policy for appropriating a maximum distribution in support of PATH's programs each year. In establishing this policy, the Organization considered the long-term expected return on its endowment and the need for that return to provide additional protection for any necessary adjustment to the value of the endowment for inflation. In order to sustain the real value of the endowment, the long-term return of the endowment should meet or exceed spending plus inflation as measured by an appropriate benchmark, such as the Consumer Price Index (CPI). To protect the essential value of the endowment against the expected impact of inflation, the Finance Committee sets a payout rate for the endowment's income that provides a prudent rate of real growth of endowment funds while also providing a relatively constant funding stream in support of PATH's current expenditures for programs.

In determining each year's level of distribution, PATH is governed by a spending policy which seeks to distribute up to 5% of the market value of the endowment investment portfolio, calculated based on the prior year's ending balance. This is consistent with the Organization's objective to maintain the purchasing power of the endowment assets held in perpetuity or for a specified term as well as to provide additional real growth through new gifts and investment return.

PATH AND SUBSIDIARIES

Notes to Consolidated Financial Statements For the Years Ended December 31, 2020 and 2019

Note 11 - Awards from the Foreign, Commonwealth & Development Office

The Organization has received several awards from the Foreign, Commonwealth & Development Office (FCDO), United Kingdom of Great Britain and Northern Ireland, to support specific projects. FCDO requires separate disclosure of revenue recognized in the Organization's financial statements. Revenue recognized, for each of these projects was as follows for the years ended December 31, 2020 and 2019:

	(In Thousands)	
	2020	2019
Technical Assistance for Nutrition 2016 to 2020	\$ 2,388	\$ 4,301
Product Development Partnership Programme 2017 to 2021	10,682	11,990
Strengthening Supply: shaping markets and supply chains for quality reproductive health for quality reproductive health commodities for the poorest and the most marginalized	81	1,812
New Health Technologies (MAPS)	1,441	1,067
Development of New Health Technologies (DAWN)	1,938	2,214
Reducing Maternal and Newborn Health	113	-
Improving outcome of future transmission assessment surveys and community compliance for MDA in LF patients	116	-
AMR in Sri Lanka	453	-
The Fleming Fund Country Grants	1,714	-
Reproductive Health Supplies Coalition (2020-2025)	1,128	-
ASCEND DFID - RFP for MMDP Services of LF in Bangladesh	46	-
National consultation on COVID-19 vaccine development in Vietnam	8	-
National workshop for COVID-19 vaccine introduction	8	-
Consultation meeting with stakeholders on protocol synopsis of COVID-19 vaccine clinical trial	6	-
Integrating Human Milk Banking into Newborn Care	-	192
	<u>\$ 20,122</u>	<u>\$ 21,576</u>

As disclosed in Note 1, revenue for these awards is recognized as related allowable project costs are incurred and is included in award and contribution revenue on the consolidated statements of activities and changes in net assets.

PATH AND SUBSIDIARIES

Notes to Consolidated Financial Statements For the Years Ended December 31, 2020 and 2019

Note 12 - Employee Benefits

The Organization sponsors a defined contribution 401(k) plan (the Plan) for US employees. Under the Plan, eligible PATH employees may elect to contribute up to 75% of their pre-tax compensation, subject to certain limits under the IRC. The Organization will match the employee's contribution monthly at a ratio of 1:1 for the first 2%, and 1:2 for the next 4%, with a maximum employer contribution equal to 4% of pre-tax salary. Employer matching contributions to the Plan are fully vested after one year of completed service. Employee optional contributions in the Plan vest immediately. In addition, the Organization may make a voluntary employer contribution of up to 8% of employees' base compensation. Voluntary employer contributions to the Plan vest at a rate of 20% for each completed year of service. All regular U.S. hire employees are eligible to enter the Plan on the first of the month after completing three months of employment. The Organization also offers an optional Roth 401(k) plan.

Within the various countries in which PATH operates outside the United States, most employees are citizens of the host country. These employees are eligible for plans, including local government sponsored plans, appropriate for that country.

Employer contributions for US based plans totaled \$7.9 million and \$8.0 million, for years ended December 31, 2020 and 2019; total global pension contributions totaled \$10.3 million for the years ended December 31, 2020 and 2019.

Note 13 - Private Campaign Contributions

Private campaign contributions consist of contributions and pledges both with and without donor restrictions. Donor restricted contributions and pledges are to be used for specific purposes and/or will be paid over a period of time. Private campaign contribution revenue for the years ended December 31 consisted of:

	(In Thousands)	
	2020	2019
Contributions without donor restrictions	\$ 4,392	\$ 1,728
Contributions with donor restrictions-		
Time restricted	22	2,506
Purpose restricted	888	396
Endowment	3	2
Total contributions with donor restrictions	913	2,904
	<u>\$ 5,305</u>	<u>\$ 4,632</u>

PATH AND SUBSIDIARIES

Notes to Consolidated Financial Statements For the Years Ended December 31, 2020 and 2019

Note 14 - Derivative Instruments and Hedging Activities

The Organization's risk management strategies include the use of foreign exchange (FX) derivative contracts. The goal of these strategies is to mitigate both market and economic risk so that movements in currency fluctuations do not adversely affect the value of the Organization or its ability to deliver on its contractual obligations and overall mission. The net fair value of the FX derivative contracts, reported at market value, is included in prepaid expenses or in accounts payable on the consolidated statements of financial position, depending on whether the net position is positive or negative at year end.

The Organization had in place foreign currency contracts for purchases of U.S. dollars (USD) with notional amounts totaling \$6.7 million and \$6.3 million, respectively, and sales of USD for foreign currencies with notional amounts totaling \$11.0 million and \$3.6 million, respectively, for the years ended December 31, 2020 and 2019. At December 31, 2020 and 2019, the fair value of FX contracts recognized in the consolidated statement of financial position is an asset of \$0.15 million and a liability of \$0.1 million, respectively. The currencies being hedged are the Euro, British Pound Sterling, Japanese Yen, Kenyan Shillings, South African Rand, and Swiss Franc.

Note 15 - Liquidity and Availability of Financial Assets

As part of the Organization's liquidity management, it has a policy to structure its financial assets to be available as its general expenditures, liabilities, and other obligations come due. In addition, the Organization invests cash in excess of daily requirements in short-term investments.

The Organization has Contingency reserve and undesignated funds within its net assets without donor restrictions, which serve as operating reserves. The Contingency reserve fund, which was established in 2020, had a balance of \$8 million at December 31, 2020. The undesignated fund had a balance of \$9.1 million and \$11.0 million at December 31, 2020 and 2019 respectively. These funds can be drawn upon in the event of financial distress or an immediate liquidity need resulting from events outside the typical life cycle of converting financial assets to cash or settling financial liabilities.

PATH AND SUBSIDIARIES

Notes to Consolidated Financial Statements For the Years Ended December 31, 2020 and 2019

Note 15 - Continued

The following reflects the Organization's financial assets as of the date of the consolidated statement of financial position, reduced by amounts not available for general use within one year of the date of the consolidated statement of financial position because of contractual or donor-imposed restrictions.

	(In Thousands)	
	2020	2019
Financial assets, at year end-		
Cash and cash equivalents	\$ 17,141	\$ 26,554
Investments	211,221	177,558
Contributions and awards receivable	39,743	43,347
Total financial assets	268,105	247,459
Less those unavailable for general expenditures within one year, due to contractual or donor-imposed restrictions-		
Restricted by donor with time or purpose restrictions	(24,241)	(16,791)
Deferred revenue subject to meeting award conditions	(182,853)	(179,438)
Financial Assets Available to Meet Cash Needs for General Expenditures Within One Year	\$ 61,011	\$ 51,230

Note 16 - Commitments and Contingencies

Operating Leases - A summary of annual non-cancelable minimum commitments under operating leases for office space and equipment is as follows:

For the Year Ending December 31,	(In Thousands)
2021	\$ 9,887
2022	9,173
2023	9,113
2024	9,116
2025	3,690
Thereafter	25,012
	\$ 65,991

Rental expense was \$11.7 million and \$10.6 million for the years ended December 31, 2020 and 2019, respectively.

PATH AND SUBSIDIARIES

Notes to Consolidated Financial Statements For the Years Ended December 31, 2020 and 2019

Note 16 - Continued

Standby Letter of Credit - The Organization has Standby Letters of Credit (SBLC) associated with its lease commitments, with total available credit of \$263,000 at December 31, 2020 and 2019. There were no outstanding balances owed on the SBLCs as of December 31, 2020 and 2019.

Awards - PATH participates in several federal and other grant programs that are governed by various rules and regulations of the grantor agencies. Costs charged to the respective grant programs are subject to audit and adjustment by the grantor agencies; therefore, to the extent that PATH has not complied with the rules and regulations governing the grants, refunds of any money received may be required and the collectability of any related receivable at December 31, 2020 and 2019 may be impaired. Liabilities are accrued for any amounts where management assesses a probability of adjustment or refund to funders.

Conditional Grants and Contracts - PATH has awarded conditional grants and contracts to subrecipients related to performance of these sponsored projects, which have outstanding commitments of up to \$231 million and \$229.7 million as of December 31, 2020 and 2019, respectively.

Contingencies - In the normal course of business, the Organization has various claims in process, matters in litigation and other contingencies. In management's opinion, the outcome from these matters will not materially impact the Organization's financial position or results of activities.

SUPPLEMENTARY INFORMATION

PATH AND SUBSIDIARIES

Schedule of Expenditures of Federal Awards For the Year Ended December 31, 2020

Federal Grantor/Pass-Through Grantor/Program Title	Federal Assistance Listing Number	Award/Pass-Through Number	Passed-Through to Subrecipients	Fiscal Year Expenditures
Research and Development Cluster				
Department of Health and Human Services				
Pass-through from University of Washington- Discovery and Applied Research for Technological Innovations To Improve Human Health	93 286	1R01EB022630-01A1	\$ -	\$ 67,739
Subtotal - Assitance Listing No. 93.286				67,739
Pass-through from University of Washington- Institute of Translational Health Sciences Advisership	93 350	5UL1TR002319-03		9,065
Subtotal - Assitance Listing No. 93.350				9,065
Pass-through from Fred Hutchinson Cancer Research Center Cervical Cancer Prevention in Peru and the Dominican Republic	93 399	1 U54 CA242977-01	29,733	158,821
Subtotal - Assitance Listing No. 93.399			29,733	158,821
Allergy and Infectious Diseases Research (ARV MAPs--Long-acting Drug Delivery Systems for ART Optimization in HIV-1 Infected Children)	93 855	1R61AI149642-01		157,132
Pass-through from University of Washington- Allergy and Infectious Diseases Research (Optimization of Methionyl-tRNA Synthetase Inhibitors for Human African Trypanosomiasis)	93 855	2R01A1097177-05		13,417
(Implementing Assisted Partner Services to HIV Test and Treat Men in Western Kenya)	93 855	1R01AI134130-01		416,402
(Bumped Kinase Inhibitors: Novel Therapeutics for Cryptosporidiosis & Toxoplasmosis)	93 855	1 R01 AI 111341-01		(355)
Pass-through from Population Council- Novel pre-coital, non-hormonal multipurpose prevention technology (MPT)	93 855	1R01AI150324-01		609
Pass-through from Colorado State University- (Repeat Ivermectin Mass Drug Administrations for Malaria Control II (RIMDAMALII))	93 855	1U01AI138910-02		5,538
Pass-through from State University of New York at Buffalo- (Rationally-Designed, Spontaneously-Particleized Pfs48/45 for a Multivalent Malaria Vaccine)	93 855	R01AI148557		11,073
Subtotal - Assitance Listing No. 93.855				603,816
Pass-through from Fred Hutchinson Cancer Research Center Child Health and Human Development Extramural Research (Predicting PrEP Uptake and Adherence Among Adolescent Girls and Young Women in Sub-Saharan Africa: Leveraging Programmatic Clinical Trials Data)	93 865	1 R01 HD094682-01	223	98,253
(Year 2 Supplemental Funding: Predicting PrEP Uptake Among Girls and Women in Sub-Saharan Africa: Leveraging Programmatic Clinical Trials Data)	93 865	1 R01 HD094682-01		(402)
Subtotal - Assitance Listing No. 93.865			223	97,851
Pass-through from Icahn School of Medicine At Mount Sinai- (Collaborative Influenza Vaccine Innovation Center (CIVIC))	93.75N93019C00051	75N93019C00051		42,437
Subtotal - Assitance Listing No. 93.75N93019C00051				42,437

See independent auditor's report and notes to schedule of expenditures of federal awards.

PATH AND SUBSIDIARIES

Schedule of Expenditures of Federal Awards For the Year Ended December 31, 2020

Federal Grantor/Pass-Through Grantor/Program Title	Federal Assistance Listing Number	Award/Pass-Through Number	Passed-Through to Subrecipients	Fiscal Year Expenditures
Biomedical Advanced Research and Development Authority (BARDA), Biodefense Medical Countermeasure Development (Chemistry, Manufacturing, and Control (CMC) and Clinical Trial Technical Support for Influenza)	93.360	IDSEP130018-01-00	350	446
Subtotal - Assistance Listing No. 93.360			350	446
Total - Department of Health and Human Services			30,306	980,175
United States Agency for International Development (USAID)				
USAID Foreign Assistance for Programs Overseas (Malaria Vaccine)	98.001	7200AA20C00017	50,000	613,512
USAID Foreign Assistance for Programs Overseas PMI Evaluation & Research-to-Use Implementation Project	98.001	7200AA20CA00031	20,794	156,715
Pass-through from The Population Council USAID Foreign Assistance for Programs Overseas (Griffithsin Fast-Dissolving Insert for Microbicide Delivery)	98.001	AID-OAA-A-14-00009		6,203
Total - USAID/Assistance Listing No. 98.001			70,794	776,430
United States Department of Defense (DOD)				
Research and Technology Development (Thermostable Formulation of Gastric-Resistant Lipid Coated Insulin for Treatment and Management of Diabetes)	12.420	W81XWH-19-1-0085	49,345	161,827
Total - DOD/Assistance Listing No. 12.420			49,345	161,827
Total Research and Development Cluster			150,445	1,918,432
Other Programs				
Department of Health and Human Services:				
Global AIDS				
(Strengthening India's Strategic Information Management Systems under the President's Emergency Plan for AIDS Relief (PEPFAR))	93.067	1 NU2GGH002129-01-00		(4,572)
(Strengthening India's Strategic Information Management Systems under the President's Emergency Plan for AIDS Relief (PEPFAR))	93.067	5 NU2GGH002129-02-00	3,969	97,531
(Strengthening India's Strategic Information Management Systems under the President's Emergency Plan for AIDS Relief (PEPFAR))	93.067	5 NU2GGH002129-03-00		80,017
(M&E Capacity Building for Aurum Institute)	93.067	1 NU2GGH002304-01-00	20,000	223,649
Subtotal - Assistance Listing No. 93.067			23,969	396,625
Protecting and Improving Health Globally: Building and Strengthening Public Health Impact, Systems, Capacity and Security (Expanding Efforts and Strategies to Protect and Improve Public Health in Vietnam)				
(Global Health Security Partner Engagement: Expanding Efforts and Strategies to Project and Improve Public Health Globally)	93.318	1 NU2HGH000009-01-00		98,982
(Tanzania Global Health Security Partner Engagement: Advancing Efforts and Strategies to Protect and Improve Public Health)	93.318	5 NU2GGH001812-03-00	450,678	2,909,107
(CDC country Grant for Senegal)	93.318	1 NU2HGH000052-01-00		64,389
	93.318	1 NU2HGH000058-01-00		92,486

See independent auditor's report and notes to schedule of expenditures of federal awards.

PATH AND SUBSIDIARIES

Schedule of Expenditures of Federal Awards For the Year Ended December 31, 2020

Federal Grantor/Pass-Through Grantor/Program Title	Federal Assistance Listing Number	Award/Pass-Through Number	Passed-Through to Subrecipients	Fiscal Year Expenditures
Pass-through from the Family Health International 360 Enhancing Global Health Security: Expanding Efforts and Strategies to Protect and Improve Public Health Globally	93.318	1 NU2HGH000074-01-00		24,580
Subtotal - Assitance Listing No. 93.318			450,678	3,189,544
Total Department of Health and Human Services			474,647	3,586,169
USAID:				
USAID Foreign Assistance for Programs Overseas (APHIAPlus Health Service Delivery Project - Zone 1 Western and Nyanza Provinces)	98.001	AID-623-A-11-00002	29,236	1,123,231
(Healthy Markets)	98.001	AID-440-A-14-00002	812,465	3,904,438
(USAID/Uganda Advocacy for Better Health)	98.001	AID-617-A-14-00004	45	342
(Integrated HIV/AIDS Project, IHAP-Haut Katanga/Lualaba)	98.001	AID-660-A-17-00001	1,270,498	6,277,974
(MAPs for PrEP: Dissolving Microarray Patches (MAPs) for long acting HIV and pregnancy prevention)	98.001	AID-OAA-A-17-00015	464,969	1,132,757
(Serving Life Ukraine)	98.001	AID-121-A-17-00001	1,135,968	2,311,190
(Digital Health Initiative Accelerating the Cycle of Investment to Impact in Global Digital Health)	98.001	AID-OAA-A-16-00084	6,034,286	11,700,027
USAID End Malaria Program (EMP) Activity	98.001	72061120CA00005		47,875
(Support TB Control Efforts in Ukraine)	98.001	72012119CA00002	477,203	3,175,150
(COVID-19 - Support TB Control Efforts in Ukraine)	98.001	72012119CA00002		430,959
Total - Support TB Control Efforts in Ukraine			477,203	3,606,109
Pass-through from JHPIEGO Corporation- USAID Foreign Assistance for Programs Overseas (Comprehensive Health Services Delivery (CHSD)-LOA)	98.001	AID-621-A-16-00003		686,941
Pass-through from JSI Research and Training Institute- USAID MOMENTUM Round 3b: Overcoming Entrenched Obstacles	98.001	7200AA20CA00017		149,339
Pass-through from KNCV Tuberculosis Foundation- USAID Foreign Assistance for Programs Overseas (Challenge TB)	98.001	AID-OAA-A-14-00029	14,584	411,664
Pass-through from Pathfinder International- USAID Foreign Assistance for Programs Overseas (Evidence to Action for Strengthened Family Planning and Reproductive Health for Women and Girls)	98.001	AID-OAA-A-11-00024		136,750
Pass-through from Palladium (PAL) Health Informatics, Governance, Data, and Analytics (HIGDA)	98.001	AID-615-A-16-00007		(661)
USAID RHSC 2020-21 Funding (Core, GFPVAN, LAC)	98.001	AID-OAA-A-15-00051		810,739
Pass-through from Population Services International- USAID Foreign Assistance for Programs Overseas (Madagascar Improving Market Partnerships and Access to Commodities Together (IMPACT))	98.001	72068718CA00001		338,942
Pass-through from Abt Associates- USAID Foreign Assistance for Programs Overseas (Expanding Tuberculosis Identification, Treatment and Prevention in Central Asia)	98.001	72011519C00002	18,750	374,722
Pass-through from Task Force for Global Health Second generation multi-antigen Onchocerciasis Rapid Serology Test	98.001	AID-OAA-G-14-00008		529
Subtotal - Assitance Listing No. 98.001			10,258,004	33,012,908

See independent auditor's report and notes to schedule of expenditures of federal awards.

PATH AND SUBSIDIARIES

Schedule of Expenditures of Federal Awards For the Year Ended December 31, 2020

Federal Grantor/Pass-Through Grantor/Program Title	Federal Assistance Listing Number	Award/Pass-Through Number	Passed-Through to Subrecipients	Fiscal Year Expenditures
Pass-through from United Nations Foundation Food for Peace Development Assistance Program (DAP) (Demonstrating How Mobile Network Operator Data Can Improve The Reach and Efficiency of Immunization Programs)	98 007	AID-OAA-A-14-00067		79,110
Subtotal - Assistance Listing No. 98.007				79,110
THRIVE	98.AID-611-C-13-00001	AID-611-C-13-00001	(8,561)	(8,561)
Program for the Advancement of Malaria Outcomes (USAID PAMO)	98.AID-611-C-15-00002	AID-611-C-15-00002	446,075	5,477,965
Eradicate TB Activity	98 AID-611-C-17-00003	AID-611-C-17-00003	180,597	3,771,958
HIV Service Delivery Support Activity (HSDSA)	98 AID-615-C-17-00002	AID-615-C-17-00002	1,778,449	6,477,389
Pass-through from Family Health International- USAID Global Health Quality Assurance (GHQC) Program Testing and Technical Assistance for Rapid Test Kits	98.AID-OAA-C-15-00001 98.AID-OAA-C-15-00001	AID-OAA-C-15-00001 AID-OAA-C-15-00001		39,958 148,872
Pass-through from National Malaria Control Program- Senegal: Scale up of Malaria Case Investigations Senegal: Scale up of Malaria Case Investigations III (FARA)	98.685-012-12 98.685-12-12-07	685-012-12 685-12-12-07		9,508 189,637
Pass-through from ICF International- Infectious Disease Detection and Surveillance (IDDS) The Demographics and Health Surveys Program (DHS-8)	98.GS00Q14OADU19 98.7200AA18M00010	GS00Q14OADU19 7200AA18M00010	1,833 13,467	3,945,470 180,047
Pass-through from Abt Associates- Prevention of Mosquito-Borne Diseases Through Vector Control IDIQ/Task Order #1	98.AID-OAA-I-17-00008	AID-OAA-I-17-00008		724,850
Pass-through from McKinsey & Company - USAID Foreign Assistance for Programs Overseas (Accelerating Uptake and Adherence of Oral PrEP through "V)	98.AID-7200AA18M00011	7200AA18M00011		34,255
Total United States Agency for International Development			12,669,864	54,083,366
Total Federal Expenditures			\$ 13,294,956	\$ 59,587,967

See independent auditor's report and notes to schedule of expenditures of federal awards.

PATH AND SUBSIDIARIES

Schedule of Expenditures of Federal Awards For the Year Ended December 31, 2020

Federal Grantor/Program Title	Federal Assistance Listing Number	Research and Development	Passed-Through to Subrecipients	Fiscal Year Expenditures
Recap by Federal Agency				
Department of Defense:				
Research and Technology Development	12.420	R&D	\$ 49,345	\$ 161,827
Total Department of Defense			49,345	161,827
Department of Health and Human Services:				
Global AIDS	93.067		23,969	396,625 00
Discovery and Applied Research for Technological Innovations To Improve Human Health	93.286	R&D		67,739
Protecting and Improving Health Globally: Building and Strengthening Public Health Impact, Systems, Capacity and Security	93.318		450,678	3,189,544
Prevention of HPV-related Cancers in HIV-infected individuals	93.399	R&D	29,733	158,821
Institute of Translational Health Sciences Advisership	93.350	R&D		9,065
Biomedical Advanced Research and Development Authority (BARDA)	93.360	R&D	350	446
Allergy and Infectious Diseases Research	93.855	R&D		603,816
Child Health and Human Development Extramural Research	93.865	R&D	223	97,851
Contracts		R&D		42,437
Total Department of Health and Human Services			504,953	4,566,344
United States Agency for International Development:				
USAID Foreign Assistance for Programs Overseas- Co-operative agreements	98.001	R&D	70,794	776,430
USAID Foreign Assistance for Programs Overseas- Co-operative agreements	98.001		10,258,004	33,012,908
Food for Peace Development Assistance Program (DAP) Co-operative agreements	98.007			79,110
Contracts			2,411,860	20,991,348
Total United States Agency for International Development			12,740,658	54,859,796
Total Federal Expenditures			\$ 13,294,956	\$ 59,587,967

See independent auditor's report and notes to schedule of expenditures of federal awards.

PATH AND SUBSIDIARIES

Schedule of Expenditures of Federal Awards For the Year Ended December 31, 2020

Note 1 - Basis of Presentation

The accompanying schedule of expenditures of federal awards (the Schedule) includes the federal award activity of PATH and Subsidiaries (collectively, the Organization) under programs of the federal government for the year ended December 31, 2020. The information in this Schedule is presented in accordance with the requirements of Title 2 U.S. Code of Federal Regulations Part 200, *Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards* (Uniform Guidance). Because the Schedule presents only a selected portion of the operations of the Organization, it is not intended to and does not present the financial position, changes in net assets or cash flows of the Organization.

Note 2 - Summary of Significant Accounting Policies

Expenditures reported on the Schedule are reported on the accrual basis of accounting. Such expenditures are recognized following, as applicable, either the cost principles contained in the Uniform Guidance, wherein certain types of expenditures are not allowable or are limited as to reimbursement. Negative amounts shown on the Schedule represent adjustments or credits made in the normal course of business to amounts reported as expenditures in prior years.

Pass-through entity identifying numbers are presented where available.

The Organization has not elected to use the 10-percent de minimis indirect cost rate as allowed under the Uniform Guidance.

SINGLE AUDIT REPORT

**Report on Internal Control Over Financial Reporting
and on Compliance and Other Matters Based on an
Audit of Financial Statements Performed in
Accordance With *Government Auditing Standards***

Independent Auditor's Report

**To the Board of Directors
PATH**

We have audited, in accordance with the auditing standards generally accepted in the United States of America and the standards applicable to financial audits contained in *Government Auditing Standards* issued by the Comptroller General of the United States, the financial statements of PATH and Subsidiaries (collectively, the Organization), which comprise the consolidated statement of financial position as of December 31, 2020, and the related consolidated statements of activities and changes in net assets, functional expenses and cash flows for the year then ended, and the related notes to the financial statements, and have issued our report thereon dated June 3, 2021.

INTERNAL CONTROL OVER FINANCIAL REPORTING

In planning and performing our audit of the financial statements, we considered the Organization's internal control over financial reporting (internal control) as a basis for designing audit procedures that are appropriate in the circumstances for the purpose of expressing our opinion on the financial statements but not for the purpose of expressing an opinion on the effectiveness of the Organization's internal control. Accordingly, we do not express an opinion on the effectiveness of the Organization's internal control.

A deficiency in internal control exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct, misstatements on a timely basis. *A material weakness* is a deficiency, or combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the Organization's financial statements will not be prevented, or detected and corrected, on a timely basis. *A significant deficiency* is a deficiency, or a combination of deficiencies, in internal control that is less severe than a material weakness, yet important enough to merit attention by those charged with governance.



T: 425-454-4919
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F: 425-454-4620

10900 NE 4th St
Suite 1400
Bellevue WA
98004

clarknuber.com

Our consideration of internal control was for the limited purpose described in the first paragraph of this section and was not designed to identify all deficiencies in internal control that might be material weaknesses or significant deficiencies. Given these limitations, during our audit we did not identify any deficiencies in internal control that we consider to be material weaknesses. However, material weaknesses may exist that have not been identified.

COMPLIANCE AND OTHER MATTERS

As part of obtaining reasonable assurance about whether the Organization's financial statements are free of material misstatement, we performed tests of its compliance with certain provisions of laws, regulations, contracts and grant agreements, noncompliance with which could have a direct and material effect on the financial statements. However, providing an opinion on compliance with those provisions was not an objective of our audit, and accordingly, we do not express such an opinion. The results of our tests disclosed no instances of noncompliance or other matters that are required to be reported under *Government Auditing Standards*.

PURPOSE OF THIS REPORT

The purpose of this report is solely to describe the scope of our testing of internal control and compliance and the result of that testing, and not to provide an opinion on the effectiveness of the Organization's internal control or on compliance. This report is an integral part of an audit performed in accordance with *Government Auditing Standards* in considering the Organization's internal control and compliance. Accordingly, this communication is not suitable for any other purpose.

Clark Nuber P.S.

Certified Public Accountants
June 3, 2021

**Report on Compliance for Each Major Federal
Program and Report on Internal Control Over Compliance
Required by the Uniform Guidance**

Independent Auditor's Report

**To the Board of Directors
PATH**

REPORT ON COMPLIANCE FOR EACH MAJOR FEDERAL PROGRAM

We have audited PATH and Subsidiaries' (collectively, the Organization) compliance with the types of compliance requirements described in the OMB *Compliance Supplement* that could have a direct and material effect on each of the Organization's major federal programs for the year ended December 31, 2020. The Organization's major federal programs are identified in the summary of auditor's results section of the accompanying schedule of findings and questioned costs.

Management's Responsibility

Management is responsible for compliance with federal statutes, regulations and the terms and conditions of its federal awards applicable to its federal programs.

Auditor's Responsibility

Our responsibility is to express an opinion on compliance for each of the Organization's major federal programs based on our audit of the types of compliance requirements referred to above. We conducted our audit of compliance in accordance with auditing standards generally accepted in the United States of America; the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States; and the audit requirements of Title 2 U.S. Code of Federal Regulations (CFR) Part 200, *Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards* (Uniform Guidance). Those standards and the Uniform Guidance require that we plan and perform the audit to obtain reasonable assurance about whether noncompliance with the types of compliance requirements referred to above that could have a direct and material effect on a major federal program occurred. An audit includes examining, on a test basis, evidence about the Organization's compliance with those requirements and performing such other procedures as we considered necessary in the circumstances.



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We believe that our audit provides a reasonable basis for our opinion on compliance for each major federal program. However, our audit does not provide a legal determination of the Organization's compliance.

Opinion on Each Major Federal Program

In our opinion, the Organization complied, in all material respects, with the compliance requirements referred to above that could have a direct and material effect on each of its major federal programs for the year ended December 31, 2020.

REPORT ON INTERNAL CONTROL OVER COMPLIANCE

Management of the Organization is responsible for establishing and maintaining effective internal control over compliance with the types of compliance requirements referred to above. In planning and performing our audit of compliance, we considered the Organization's internal control over compliance with the types of requirements that could have a direct and material effect on each major federal program to determine the auditing procedures that are appropriate in the circumstances for the purpose of expressing an opinion on compliance for each major program and to test and report on internal control over compliance in accordance with the Uniform Guidance, but not for the purpose of expressing an opinion on the effectiveness of internal control over compliance. Accordingly, we do not express an opinion on the effectiveness of the Organization's internal control over compliance.

A deficiency in internal control over compliance exists when the design or operation of a control over compliance does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct, noncompliance with a type of compliance requirement of a federal program on a timely basis. A *material weakness in internal control over compliance* is a deficiency, or combination of deficiencies, in internal control over compliance, such that there is a reasonable possibility that material noncompliance with a type of compliance requirement of a federal program will not be prevented, or detected and corrected, on a timely basis. A *significant deficiency in internal control over compliance* is a deficiency, or a combination of deficiencies, in internal control over compliance with a type of compliance requirement of a federal program that is less severe than a material weakness in internal control over compliance, yet important enough to merit attention by those charged with governance.

Our consideration of internal control over compliance was for the limited purpose described in the first paragraph of this section and was not designed to identify all deficiencies in internal control over compliance that might be material weaknesses or significant deficiencies, and therefore, material weaknesses or significant deficiencies may exist that were not identified. We did not identify any deficiencies in internal control over compliance that we consider to be material weaknesses. However, material weaknesses may exist that have not been identified.

The purpose of this report on internal control over compliance is solely to describe the scope of our testing of internal control over compliance and the results of that testing based on the requirements of the Uniform Guidance. Accordingly, this report is not suitable for any other purpose.

Clark Nuber P.S.

Certified Public Accountants

June 3, 2021

PATH AND SUBSIDIARIES

Schedule of Findings and Questioned Costs For the Year Ended December 31, 2020

Section I - Summary of Auditor's Results

Financial Statements

Type of auditor's report issued:

Unmodified

Internal control over financial reporting:

- Material weaknesses identified?

☐ Yes

☒ No

- Significant deficiencies identified?

☐ Yes

☒ None reported.

Noncompliance material to financial statements noted?

☐ Yes

☒ No

Federal Awards

Internal control over major programs:

- Material weaknesses identified?

☐ Yes

☒ No

- Significant deficiencies identified?

☐ Yes

☒ None reported.

Type of auditor's report issued on compliance
for major federal programs:

Unmodified

Any audit findings disclosed that are required to
be reported in accordance with 2 CFR 200.516(a)?

☐ Yes

☒ No

Identification of Major Programs

Assistance Listing Numbers

Name of Federal Program or Cluster

98.AID-611-C-15-00002

Program for the Advancement of
Malaria Outcomes (USAID PAMO)

98.GS00Q14OADU19

Infectious Diseases Detection and
Surveillance (IDDS)

98.AID-615-C-17-00002

HIV Service Delivery Support Activity (HSDSA)

Dollar threshold used to distinguish between
Type A and Type B programs:

\$ 1,787,639

Auditee qualified as low-risk auditee?

☒ Yes

☐ No

PATH AND SUBSIDIARIES

Schedule of Findings and Questioned Costs For the Year Ended December 31, 2020

Section II - Financial Statement Findings

No matters were reported.

Section III - Federal Award Findings and Questioned Costs

No matters were reported.

**MANAGEMENT'S
SUMMARY SCHEDULE OF PRIOR AUDIT FINDINGS**

Finding 2019-001 – Corrective Action Completed

PATH's internal control over salaries costs charged to a Federal award requires that only allowable time be charged to Federal award or leave cost pools. Internal control also requires that timesheets be completed by each employee and reviewed and approved by appropriate supervisor for accuracy and proper allocation. As result of the finding, PATH implemented additional controls over the timecard review process to ensure holidays are correctly captured in the leave cost pool. PATH also reinforced the timecard policy to staff in the DRC offices on the appropriateness and accuracy for recording holiday hours in their timecards. PATH to fully mitigated this finding in 2020.

Following is the status of the corrective action plan.

<i>Action</i>	<i>Responsible Staff Member</i>	<i>Due Date</i>	<i>Status of Action</i>
Reclassify \$48,378.21 from the Federal Program to the appropriate holiday leave code	Assistant Controller	Action completed (reclassification was made in the 2019 financial year, and as such the 2019 SEFA reflects corrected figures)	Complete
Reinforce the timecard policy and procedures on the appropriateness and accuracy for recording holiday hours	Direct of Finance and Administration, DRC Kinshasa	Throughout 2020	Complete
Ensure the timecard policy is clearly communicated and adhered to	Country Director, DRC		
Leveraging expertise of PATH's International Accounting Services team, implement additional monthly control over timecards review specifically focusing on reviewing holiday hours charged	International Accounting Services Team Lead	Throughout 2020	Complete

Finding 2019-002 – Corrective Action Completed

PATH currently has a process to review all incoming awards and amendments to determine whether the incoming award is R&D, and subsequently flow down the provisions to subrecipients. Per 2CFR200.331 - requirements for pass-through entities, PATH is required to include in the subaward document the characteristics of the Federal award it is issued under so that the subrecipient is aware of the funding requirements and can fully comply. One of those requirements, 200.331(a)(xxi), is whether the award is R&D – this is a classification that is assigned by the awarding agency and should not be modified as the funding is passed to other organizations. Although all other aspects of 2CFR200.331 were followed, for these three subawards were identified as R&D in error, as noted by the three exceptions. PATH fully mitigated this finding in 2020.

Following is the status of the corrective action plan.

<i>Action</i>	<i>Responsible Staff Member</i>	<i>Due Date</i>	<i>Status of Action</i>
Amend relevant sections of subaward template by including “Is Prime Award Research and Development” to clarify and ensure that PATH’s OGC (Office of Grants and Compliance) and Legal teams check to ensure whether the prime Award is classified as “Research and Development” and thereby flow down the right provisions to subrecipients	Subrecipient Monitoring and Compliance Manager	May 2020	Complete
Conduct trainings for PATH’s OGC and Legal teams on proper classification of what “research and development” award is and when to flow it down to subrecipients	Subrecipient Monitoring and Compliance Manager	Throughout 2020	Complete

Request for Taxpayer Identification Number and Certification

Give Form to the
requester. Do not
send to the IRS.

► Go to www.irs.gov/FormW9 for instructions and the latest information.

Print or type. See Specific Instructions on page 3.	1 Name (as shown on your income tax return). Name is required on this line; do not leave this line blank. PATH	
	2 Business name/disregarded entity name, if different from above	
	3 Check appropriate box for federal tax classification of the person whose name is entered on line 1. Check only one of the following seven boxes. <input type="checkbox"/> Individual/sole proprietor or single-member LLC <input type="checkbox"/> Limited liability company. Enter the tax classification (C=C corporation, S=S corporation, P=Partnership) ► Note: Check the appropriate box in the line above for the tax classification of the single-member owner. Do not check LLC if the LLC is classified as a single-member LLC that is disregarded from the owner unless the owner of the LLC is another LLC that is not disregarded from the owner for U.S. federal tax purposes. Otherwise, a single-member LLC that is disregarded from the owner should check the appropriate box for the tax classification of its owner. <input checked="" type="checkbox"/> Other (see instructions) ► Exempt 501 (c) (3) Corporation	4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3): Exempt payee code (if any) 5 Exemption from FATCA reporting code (if any) _____ <small>(Applies to accounts maintained outside the U.S.)</small>
	5 Address (number, street, and apt. or suite no.) See instructions. 2201 Westlake Avenue, Suite 200	Requester's name and address (optional)
	6 City, state, and ZIP code Seattle, WA 98121	
	7 List account number(s) here (optional)	

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

Note: If the account is in more than one name, see the instructions for line 1. Also see *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number									
				-			-		
or									
Employer identification number									

Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here	Signature of U.S. person ► <i>Kelly Priestley</i>	Date ► February 24, 2021
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General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to www.irs.gov/FormW9.

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS must obtain your correct taxpayer identification number (TIN) which may be your social security number (SSN), individual taxpayer identification number (ITIN), adoption taxpayer identification number (ATIN), or employer identification number (EIN), to report on an information return the amount paid to you, or other amount reportable on an information return. Examples of information returns include, but are not limited to, the following.

- Form 1099-INT (interest earned or paid)

- Form 1099-DIV (dividends, including those from stocks or mutual funds)
- Form 1099-MISC (various types of income, prizes, awards, or gross proceeds)
- Form 1099-B (stock or mutual fund sales and certain other transactions by brokers)
- Form 1099-S (proceeds from real estate transactions)
- Form 1099-K (merchant card and third party network transactions)
- Form 1098 (home mortgage interest), 1098-E (student loan interest), 1098-T (tuition)
- Form 1099-C (canceled debt)
- Form 1099-A (acquisition or abandonment of secured property)

Use Form W-9 only if you are a U.S. person (including a resident alien), to provide your correct TIN.

If you do not return Form W-9 to the requester with a TIN, you might be subject to backup withholding. See What is backup withholding, later.

From: ORSO <ORSO@wsu.edu>
Sent: Thursday, December 23, 2021 5:00 PM
To: filimus@uw.edu; osp@uw.edu
Cc: Yager, Amanda L; Moore, Anke Marga-Christa
Subject: Fully executed SPC003515
Attachments: 141061 SPC003515 AM DB.pdf

Hello,

Attached is the fully executed agreement for your records.

Thank you,



KATE MARTINSON

e-RESEARCH ADMINISTRATION COORDINATOR
Office of Research Support and Operations
Office of Research
Washington State University
Office: 509-335-9661
Email: katharine.martinson@wsu.edu
orso.wsu.edu
Pronouns: She/Her/Hers

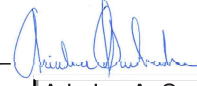
ORSO will be closed during the 2021-2022 winter reduced operations from 5pm on December 23rd 2021 and reopening at 8am on January 3rd 2022. Please work with your departments to plan ahead for any deadlines during the closure and have all items submitted to us by December 17th.

FDP Cost Reimbursement Subaward

Federal Awarding Agency: Other [Type in Agency]		US Agency for International Development
Pass-Through Entity (PTE):		Subrecipient:
Washington State University		University of Washington
PTE PI: Felix Lankester	Sub PI: Peter Rabinowitz	
PTE Federal Award No: 7200AA21CA00033	Subaward No: 141061 SPC003515	
Project Title: Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)		
Subaward Budget Period:		Amount Funded This Action (USD): \$ 260,323.00
Start: 10/01/2021	End: 09/30/2022	
Estimated Period of Performance:		Incrementally Estimated Total (USD): \$ 28,753,546.00
Start: 10/01/2021	End: 09/30/2026	

Terms and Conditions

1. PTE hereby awards a cost reimbursable subaward, (as determined by 2 CFR 200.331), to Subrecipient. The Statement of Work and budget for this Subaward are as shown in Attachment 5. In its performance of Subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.
2. Subrecipient shall submit invoices not more often than monthly and not less frequently than quarterly for allowable costs incurred. Upon the receipt of proper invoices, the PTE agrees to process payments in accordance with this Subaward and 2 CFR 200.305. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), breakdown by major cost category, Subaward number, and certification, as required in 2 CFR 200.415(a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments shall be directed to the party's Financial Contact, shown in Attachment 3A.
3. A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Financial Contact, as shown in Attachment 3A, not later than 60 days after the final Budget Period end date. The final statement of costs shall constitute Subrecipient's final financial report.
4. All payments shall be considered provisional and are subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Subrecipient.
5. Matters concerning the technical performance of this Subaward shall be directed to the appropriate party's Principal Investigator as shown in Attachments 3A and 3B. Technical reports are required as shown in Attachment 4.
6. Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this Subaward, and any changes requiring prior approval, shall be directed to the PTE's Authorized Official Contact and the Subrecipient's Authorized Official Contact shown in Attachments 3A and 3B. Any such change made to this Subaward requires the written approval of each party's Authorized Official as shown in Attachments 3A and 3B.
7. The PTE may issue non-substantive changes to the Budget Period(s) and Budget Bilaterally. Unilateral modification shall be considered valid 14 days after receipt unless otherwise indicated by Subrecipient when sent to Subrecipient's Authorized Official Contact, as shown in Attachment 3B.
8. Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.
9. Either party may terminate this Subaward with 30 days written notice. Notwithstanding, if the Awarding Agency terminates the Federal Award, PTE will terminate in accordance with Awarding Agency requirements. PTE notice shall be directed to the Authorized Official Contact, and Subrecipient notice shall be directed to the Authorized Official Contact as shown in Attachments 3A and 3B. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix IX, as applicable.
10. By signing this Subaward, including the attachments hereto which are hereby incorporated by reference, Subrecipient certifies that it will perform the Statement of Work in accordance with the terms and conditions of this Subaward and the applicable terms of the Federal Award, including the appropriate Research Terms and Conditions ("RTCs") of the Federal Awarding Agency, as referenced in Attachment 2. The parties further agree that they intend this subaward to comply with all applicable laws, regulations, and requirements.

By an Authorized Official of the PTE:		By an Authorized Official of the Subrecipient:	
<div style="display: flex; justify-content: space-between;"> <div>Name: _____</div> <div>Date: _____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Title: _____</div> <div></div> </div>		<div style="display: flex; justify-content: space-between;"> <div>  Digitally signed by Ariadna A. Santander Date: 2021.12.23 10:59:37 -08'00' </div> <div>Date: _____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Name: Ariadna A. Santander</div> <div></div> </div> <div style="display: flex; justify-content: space-between;"> <div>Title: Manager, Office of Sponsored Programs</div> <div></div> </div>	

Attachment 1

Certifications and Assurances

Subaward Number:

141061 SPC003515

Certification Regarding Lobbying (2 CFR 200.450)

By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief, that no Federal appropriated funds have been paid or will be paid, by or on behalf of the Subrecipient, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement in accordance with 2 CFR 200.450.

If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or intending to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the Subrecipient shall complete and submit Standard Form -LLL, "Disclosure Form to Report Lobbying," to the PTE.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by 31 U.S.C. 1352. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

Debarment, Suspension, and Other Responsibility Matters (2 CFR 200.214 and 2 CFR 180)

By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief that neither the Subrecipient nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this transaction by any federal department or agency, in accordance with 2 CFR 200.213 and 2 CFR 180.

Audit and Access to Records

Subrecipient certifies that it will provide PTE with notice of any adverse findings which impact this Subaward. Subrecipient certifies compliance with applicable provisions of 2 CFR 200.501-200.521. If Subrecipient is not required to have a Single Audit as defined by 200.501, Awarding Agency requirements, or the Single Audit Act, then Subrecipient will provide notice of the completion of any required audits and will provide access to such audits upon request. Subrecipient will provide access to records as required by parts 2 CFR 200.337 and 200.338 as applicable.

Program for Enhancement of Contractor Employee Protections (41 U.S.C 4712)

Subrecipient is hereby notified that they are required to: inform their employees working on any federal award that they are subject to the whistleblower rights and remedies of the program; inform their employees in writing of employee whistleblower protections under 41 U.S.C §4712 in the predominant native language of the workforce; and include such requirements in any agreement made with a subcontractor or subgrantee.

The Subrecipient shall require that the language of the certifications above in this Attachment 1 be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

Use of Name

Neither party shall use the other party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may use factual information regarding the existence and purpose of the relationship that is the subject of this Subaward for legitimate business purposes, to satisfy any reporting and funding obligations, or as required by applicable law or regulation without written permission from the other party. In any such statement, the relationship of the parties shall be accurately and appropriately described.

Prohibition on Certain Telecommunication and Video Surveillance Services or Equipment

Pursuant to 2 CFR 200.216, Subrecipient will not obligate or expend funds received under this Subaward to: (1) procure or obtain; (2) extend or renew a contract to procure or obtain; or (3) enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that uses covered telecommunications equipment or services (as described in Public Law 115-232, section 889) as a substantial or essential component of any system, or as a critical technology as part of any system.

Attachment 2
Federal Award Terms and Conditions

Subaward Number
141061 SPC003515

Required Data Elements

The data elements required by Uniform
Guidance are incorporated **in the attached Federal Award.**

This Subaward Is:

☒ Research & Development ☐ Subject to FFATA

Awarding Agency Institute (If Applicable)

USAID		
Federal Award Issue Date	FAIN	Assistance Listing No.
09/22/21	7200AA21CA00033	98.001
Assistance Listing Program Title (ALPT)		
USAID Foreign Assistance for Programs Overseas		
Key Personnel Per NOA		
Ch. Rabiner; B.T. Leader		

General Terms and Conditions

By signing this Subaward, Subrecipient agrees to the following:

1. To abide by the conditions on activities and restrictions on expenditure of federal funds in appropriations acts that are applicable to this Subaward to the extent those restrictions are pertinent. This includes any recent legislation noted on the Federal Awarding Agency's website:
<https://www.usaid.gov/who-we-are/agency-policy>
2. 2 CFR 200
3. The Federal Awarding Agency's grants policy guidance, including addenda in effect as of the beginning date of the period of performance or as amended found at:
<https://www.usaid.gov/ads/policy/300/303>
4. Research Terms and Conditions, including any Federal Awarding Agency's Specific Requirements found at:
see attachment #6 except for the following :
 - a. No-cost extensions require the written approval of the PTE. Any requests for a no-cost extension shall be directed to the **Authorized Official** Contact shown in Attachment 3A, not less than 30 days prior to the desired effective date of the requested change.
 - b. Any payment mechanisms and financial reporting requirements described in the applicable Federal Awarding Agency Terms and Conditions and Agency-Specific Requirements are replaced with Terms and Conditions (1) through (4) of this Subaward; and
 - c. Any prior approvals are to be sought from the PTE and not the Federal Awarding Agency.
 - d. Title to equipment as defined in 2 CFR 200.1 that is purchased or fabricated with research funds or Subrecipient cost sharing funds, as direct costs of the project or program, shall vest in the Subrecipient subject to the conditions specified in 2 CFR 200.313.
 - e. Prior approval must be sought for a change in Subrecipient PI or change in Key Personnel (defined as listed on the NOA).
5. Treatment of program income: **Additive**

Special Terms and Conditions:

Data Sharing and Access:

Subrecipient agrees to comply with the Federal Awarding Agency's data sharing and/or access requirements as reflected in the NOA or the Federal Awarding Agency's standard terms and conditions as referenced in General Terms and Conditions 1-4 above.

Provided upon request is a Data Management and/or Sharing Plan that incorporates additional requirements as submitted to the Federal Awarding Agency.

Data Rights:

Subrecipient grants to PTE the right to use data created in the performance of this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Copyrights:

Subrecipient Shall Grant to PTE an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted material (including any computer software and its documentation and/or databases) first developed and delivered under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Subrecipient grants to PTE the right to use any written progress reports and deliverables created under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its Federal Award.

Promoting Objectivity in Research (COI):

Subrecipient must designate herein which entity's Financial Conflicts of Interest policy (COI) will apply: **Subrecipient**

If applying its own COI policy, by execution of this Subaward, Subrecipient certifies that its policy complies with the requirements of the relevant Federal Awarding Agency as identified herein: **US Agency for International Development**

Subrecipient shall report any financial conflict of interest to PTE's Administrative Representative or COI contact, as designated on Attachment 3A. Any financial conflicts of interest identified shall, when applicable, subsequently be reported to Federal Awarding Agency. Such report shall be made before expenditure of funds authorized in this Subaward and within 45 days of any subsequently identified COI.

Work Involving Human or Vertebrate Animals (Select Applicable Options)☐ No Human or Vertebrate Animals**IRB**☒ Human Subjects**IACUC**☒ Vertebrate Animals

The PTE requires verification of IRB and/or IACUC approval be sent to the as required above:

Subrecipient agrees that any non-exempt human and/or vertebrate animal research protocol conducted under this Subaward shall be reviewed and approved by the appropriate Institutional Review Board (IRB) and/or its Institutional Animal Care and Use Committee (IACUC), as applicable and that it will maintain current and duly approved research protocols for all periods of the Subaward involving human and/or vertebrate animal research. Subrecipient certifies that the appropriate IRB and/or IACUC are in full compliance with applicable state and federal laws and regulations. The Subrecipient certifies that any submitted IRB / IACUC approval represents a valid, approved protocol that is entirely consistent with the Project associated with this Subaward. In no event shall Subrecipient invoice or be reimbursed for any human or vertebrate animals related expenses incurred in a period where any applicable IRB / IACUC approval is not properly in place.

Human Subjects Data (Select One)

Human Subjects Data will be exchanged under this Subaward (check all that apply):

- ☒ From Subrecipient to PTE
☒ From PTE to Subrecipient

The PTE will set forth the terms of the exchange of Human Subjects Data (Select One):

This section left intentionally blank

Additional Terms

Subawards issued under this award are subject to additional USAID approval.

If applicable, Subrecipient certifies that its Institutional Biosafety committee is in full compliance with applicable state and federal laws and regulations. Subrecipient agrees that any non-exempt research involving recombinant or synthetic nucleic acid molecules or select agents conducted under this agreement shall be reviewed and approved by its Institutional Biosafety Committee, as applicable. In Addition, Subrecipient will maintain current and duly approved research protocols for all periods of the Agreement involving recombinant or synthetic nucleic acid molecules or select agents.

The Subrecipient certifies that any submitted recombinant or synthetic nucleic acid molecules or select agents approval represents a valid, approved protocol that is entirely consistent with project associated with this subaward. In no event shall subrecipient invoice or be reimbursed for any recombinant or synthetic nucleic acid molecules or select agents related expense incurred in a period where any applicable IRB/IACUC approval is not properly in place.

In addition to other applicable provisions in the NOA, the mandatory standard provisions for U.S. Nongovernmental organizations found in the NOA as part of Attachment 6 (Pages 40-65 of this subaward) are incorporated by reference into this subaward.

Attachment 3A
Pass-Through Entity (PTE) Contacts

Subaward Number:

141061 SPC003515

PTE Information

Entity Name: Washington State University

Legal Address: Office of Research Support and Operations
280 Lighty
PO Box 641060
Pullman, WA 99164-1060

Website: <https://orso.wsu.edu/>

PTE Contacts

Central Email: orso@wsu.edu

Principal Investigator Name: Felix Lankester

Email: felix.lankester@wsu.edu

Telephone Number:

Administrative Contact Name: Chana Rabiner

Email: chana.rabiner@wsu.edu

Telephone Number:

COI Contact email (if different to above): orso@wsu.edu

Financial Contact Name: Casey St. Clair, Director, Sponsored Programs

Email: sps@wsu.edu

Telephone Number: (509) 335-2058

Email invoices? ☒ Yes ☐ No Invoice email (if different): ayager@wsu.edu

Authorized Official Name: Dan Nordquist, AVP ORSO

Email: orso@wsu.edu

Telephone Number: (509) 335-9661

PI Address:

Washington State University
Paul G. Allen School for Global Animal Health
PO Box 647090
Pullman WA 99164-7090

Administrative Address:

Washington State University
Office of Research Support and Operations
PO Box 641060
Pullman, WA 99164-1060

Invoice Address:

Washington State University
Sponsored Programs Services
PO Box 641025
Pullman, WA 99164-1025

Attachment 3B**Research Subaward Agreement
Subrecipient Contacts**

Subaward Number:

141061 SPC003515

Subrecipient Information for [FFATA](#)**reporting** Entity's UEI/DUNS Name: University of Washington

EIN No.: 40 Institution Type: Public/State Controlled Inst of Higher Ed.

UEI / DUNS: 18 Currently registered in SAM.gov: ☒ Yes ☐ No
Exempt from reporting executive compensation: ☒ Yes ☐ No (if no, complete 3Bpg2)Parent UEI / DUNS: This section for U.S. Entities: Zip Code [Look-up](#)
Congressional District: WA-007 Zip Code+4: 98195-9472**Place of Performance Address**International Training and Education Center for Health (I-TECH)
HMC#359932
325 9th Avenue
Seattle, WA 98104-2499
USA**Subrecipient Contacts**

Central Email: osp@uw.edu

Website: https://www.washington.edu/research/osp/

Principal Investigator Name: Peter Rabinowitz, Professor

Email: peterr7@uw.edu Telephone Number: 206-616-0598

Administrative Contact Name: John Fields, I-TECH Grant and Contract Specialist

Email: jtfields@uw.edu Telephone Number: 206-616-4831

Financial Contact Name: Lily Gebrenegus, Director, Grant and Contract Accounting

Email: gcahelp@uw.edu Telephone Number: 206-616-9995

Invoice Email: gcahelp@uw.edu

Authorized Official Name: Carol Rhodes, Director, Office of Sponsored Programs

Email: osp@uw.edu Telephone Number: 206-543-4043

Legal Address:University of Washington
4333 Brooklyn Ave NE
Box 359472
Seattle, WA
98195-9472**Administrative Address:**University of Washington
4333 Brooklyn Ave NE
Box 359472
Seattle, WA
98195-9472**Payment Address:**University of Washington
Grant and Contract Accounting
12455 Collections Drive
Chicago, IL 60693

Attachment 3B Page 2
Research Subaward Agreement
Highest Compensated Officers

Subaward Number:

141061 SPC003515

Subrecipient

Entity Name: University of Washington

PI Name: Peter Rabinowitz, Professor

Highest Compensated Officers

The names and total compensation of the five most highly compensated officers of the entity(ies) must be listed if the entity in the preceding fiscal year received 80 percent or more of its annual gross revenues in Federal awards; and \$25,000,000 or more in annual gross revenues from Federal awards; and the public does not have access to this information about the compensation of the senior executives of the entity through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. See FFATA § 2(b)(1) Internal Revenue Code of 1986.

Officer 1 Name:

Officer 1 Compensation:

Officer 2 Name:

Officer 2 Compensation:

Officer 3 Name:

Officer 3 Compensation:

Officer 4 Name:

Officer 4 Compensation:

Officer 5 Name:

Officer 5 Compensation:

Attachment 4

Reporting and Prior Approval Terms

Subaward Number:

141061 SPC003515

Subrecipient agrees to submit the following reports (PTE contacts are identified in Attachment 3A):

Technical Reports:

- ☐ Monthly technical/progress reports will be submitted to the PTE's within days of the end of the month.
- ☐ Quarterly technical/progress reports will be submitted within 30 days after the end of each project quarter to the PTE's .
- ☒ Annual technical / progress reports will be submitted within days prior to the end of each budget period to the PTE's . Such report shall also include a detailed budget for the next Budget Period, updated other support for key personnel, certification of appropriate education in the conduct of human subject research of any new key personnel, and annual IRB or IACUC approval, if applicable.
- ☒ A Final technical/progress report will be submitted to the PTE's within days of the end of the Project Period or after termination of this award, whichever comes first.
- ☒ Technical/progress reports on the project as may be required by PTE's in order for the PTE to satisfy its reporting obligations to the Federal Awarding Agency.

Prior Approvals:

Carryover:

Other Reports:

- ☒ In accordance with 37 CFR 401.14, Subrecipient agrees to notify both the Federal Awarding Agency via iEdison and PTE's within 60 days after Subrecipient's inventor discloses invention(s) in writing to Subrecipient's personnel responsible for patent matters. The Subrecipient will submit a final invention report using Federal Awarding Agency specific forms to the PTE's within 60 days of the end of the Project Period to be included as part of the PTE's final invention report to the Federal Awarding Agency.

A negative report is required:

- ☒ Property Inventory Report (only when required by Federal Awarding Agency), specific requirements below.

Additional cost sharing requirements included below:

Additional Technical and Reporting Requirements:

Subrecipients shall list each country included in the program and the total amount expended for each country when submitting financial reports. These will be noted to each partner as countries are onboarded.

Kenya 615-GH-W	141061-SPC003516
Senegal 685-GH-W	141061-SPC003517
Peru 527-GH-W	141061-SPC003518
Vietnam 440-GH-W	141061-SPC003519
Thailand 493-GH-W	141061-SPC003520

There may be additional reporting requirements and ad hoc information requests including, but not limited to, those associated with Mission buy-ins or additional sources of funding provided to DEEP VZN. Ad hoc refers to an unscheduled report for immediate, specific use. These requests will need to be approved by USAID.

Attachment 5
Statement of Work, Cost Sharing, Indirects & Budget

Subaward Number:

141061 SPC003515

Statement of Work

☐ Below ☒ Attached, pages

If award is FFATA eligible and SOW exceeds 4000 characters, include a *Subrecipient Federal Award Project Description*

Through this proposal, UW is one of two Universities with DEEP VZN reference laboratories that will provide high-level support across all participating country laboratory activities. Five globally-renowned laboratories from the UW will work together to provide support to viral detection and characterization efforts in countries, working with the larger consortium to ensure that each country can independently conduct full virus screening (qRT-PCR, sequencing), basic characterization that includes phylogenetic analysis and some evaluation of host plasticity (serology), and rapid sharing of data. By pairing UW technical experts directly with in-country laboratories, we ensure that we are strengthening local capacity to sustainably absorb program activities to detect and characterize unknown zoonotic viruses before they cause outbreaks, epidemics, or pandemics in human populations. This approach also enables countries to be more efficient and effective in preparedness, prevention, and response efforts ultimately saving lives and reducing economic damage.

Budget Information

Indirect Information Indirect Cost Rate (IDC) Applied

%

Cost Sharing

Rate Type:

If Yes, include Amount: \$

Budget Details

☒ Below ☐ Attached, pages

Salaries - \$152,700

Benefits - \$37,317

F&A - \$

Total - \$260,323

Only partial budget at this time is being submitted until USAID approves the project workplan and budget detail.

Budget Totals

Direct Costs \$

Indirect Costs \$

Total Costs \$

All amounts are in United States Dollars

Attachment 6

Notice of Award (NOA) and any additional documents



The following pages include the NOA and if applicable any additional documentation referenced throughout this Subaward.



Not incorporating the NOA or any additional documentation to this Subaward.



September 22, 2021

Dan Nordquist
Associate Vice President for Research
Washington State University
P.O. Box 641060
Pullman, WA 99164-1060
orso@wsu.edu

Reference: Award No. Titled "Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)" Cooperative Agreement 7200AA21CA00033

Dear Dan Nordquist:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, the U.S. Agency for International Development (USAID) hereby awards to Washington State University, hereinafter referred to as the "Recipient", the sum of \$124,679,896 to provide support for a program titled "Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)", as described in the Schedule of this award and in Attachment B, entitled "Program Description."

This Cooperative Agreement will be effective October 1, 2021. Obligation will be made upon receipt of the Recipient's acknowledgement and shall apply to expenditures made by the Recipient in furtherance of program objectives during the period beginning with the effective date October 1, 2021 and ending September 30, 2026. USAID will not be liable for reimbursing the Recipient for any costs in excess of the obligated amount.

This Cooperative Agreement is made to Washington State University, on condition that the funds will be administered in accordance with the terms and conditions as set forth in Attachment A (the Schedule), Attachment B (the Program Description), Attachment C (the Standard Provisions), and Attachment D (the Branding & Marking Plan) all of which have been agreed to by your organization.

Please sign the second page of this cover letter to acknowledge your receipt of this award and e-mail a copy of only the signed page to Anna Nelson at annelson@usaid.gov with a cc: to Patricia Bradley at pbradley@usaid.gov.

Sincerely,

Patricia Elena Bradley
(affiliate)
Patricia Bradley
Agreement Officer

Digitally signed by Patricia Elena
Bradley (affiliate)
Date: 2021.09.22 10:24:23 -04'00'

Attachments:

- A. Schedule
- B. Program Description
- C. Standard Provisions
- D. Branding & Marking Plan

ACKNOWLEDGED BY:

NAME: Christopher J. Keane



TITLE: Vice President for Research, WSU and Vice Chancellor for Research, WSU Pullman

DATE: 9/23/2021

ACCOUNTING AND APPROPRIATION DATA

A. GENERAL

1. Amount Obligated this Action: \$ 10,000,000
 2. Total Estimated USAID Amount: \$124,679,896
 3. Total Obligated USAID Amount: \$ 10,000,000
 4. Cost-Sharing Amount (Non-Federal): \$ 6,607,682
 5. Activity Title: “Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)”
 6. USAID Technical Office: GH/ID/ETD
 7. Tax I.D. Number: 40
 8. DUNS No.: 18
 9. LOC Number: 42A5P

B. SPECIFIC

GLAAS Requisition: REQ-GH-21-000020

Account ID	Accounting Template	BBFY	EBFY	Fund	Operating Unit	Prog Area	Program Name	Dist Code	BGA	SOC	Funded Amount
1-1	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	615-GH-W	615	4100201	\$2,000,000
1-2	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	685-GH-W	685	4100201	\$2,000,000
1-3	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	440-GH-W	440	4100201	\$2,000,000
1-4	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	527-GH-W	527	4100201	\$2,000,000
1-5	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	493-GH-W	493	4100201	\$2,000,000

C. PAYMENT OFFICE

M/CFO/CMP Letter of Credit Office
USAID/Washington

USAID Office of Financial Management (M/CFO/CMP) prefers the submittal of invoices to be electronic. In addition to the required submission to the Agreement Officer’s Representative (AOR), please submit a copy of the invoices to loc@usaid.gov.

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ATTACHMENT A - SCHEDULE

A.1 PURPOSE OF AWARD

The purpose of this Cooperative Agreement is to provide support for the program described in Attachment B to this Cooperative Agreement entitled "Program Description."

A.2 PERIOD OF AWARD

1. The effective date of this Award is **October 1, 2021**. The estimated completion date of this Award is ~~September 30, 2026~~.

A.3 AMOUNT OF AWARD AND PAYMENT

1. The total estimated amount of this Award for the period shown in A.2.1 above is ~~\$124,679,897~~, not including cost share.
2. USAID hereby obligates the amount of ~~\$10,000,000~~ for program expenditures during the period set forth in A.2.1 above and as encompassed in the Budget below. The recipient must use funds obligated under this award and any subsequent amendments from the specific Operating Units (OU) and Program Areas (PA) for activities approved in the award and detailed in the work plan, as applicable. Program disbursements for each OU/PA must not exceed the amounts specified in the Accounting and Appropriates data for each Operating Unit (OU) and Program Area (PA). The Recipient will be given written notice by the Agreement Officer if additional funds will be added.
3. As the obligated amount for the program shall equal the total USAID estimated amount of this Agreement, additional increments of funds may be obligated by USAID under this Agreement (by a unilateral modification to this Agreement), subject to availability of funds, successful performance by the Recipient, possible evaluation of the program, program priorities at the time, and the requirements of the 2 CFR 200.308.
4. Payment will be made to the Recipient by Letter of Credit in accordance with procedures set forth in 2 CFR 200 and 2 CFR 700.

A.4 AWARD BUDGET

The following is the Award Budget, including local cost financing items, if authorized. Revisions to this budget shall be made in accordance with 2 CFR 200 and 2 CFR 700.

TOTAL BUDGET

Cost Element	USD
Direct Costs	\$116,474,256
Indirect Costs	\$ 49
Total Federal Contribution	\$124,679,897
Cost Share	\$6,607,682
Total Program Cost	\$131,287,579

Washington State University is responsible for managing available funds. This agreement includes a ceiling amount and obligated amount that the recipient exceeds at its own risk.

A.5 PLANNING, REPORTING, AND EVALUATION

1. Financial Reporting:

The recipient must submit the Federal Financial Form (SF-425) on a quarterly basis via electronic format to the U.S. Department of Health and Human Services. The recipient also must submit a copy of the SF-425 to the Agreement Officer (AO) and the Agreement Officer's Representative (AOR). These financial reports are due no later than 30 calendar days at the end of each quarter based on the federal fiscal calendar. The recipient must submit final financial reports to USAID/Washington, M/CFO/CMP-LOC Unit, the AO, and the AOR. The recipient must also submit an electronic version of the final financial report to the U.S. Department of Health and Human Services in accordance with the paragraph above.

2. Performance Planning:

Implementation Plans

Annual implementation plans serve as a guide to activity implementation and detail how the recipient will use the implementation year to achieve the objectives of DEEP VZN. The implementation plan is intended to be an annual roadmap for USAID and the recipient. With approval from the AOR, reasonable and justifiable modifications can be made to improve the chances of achieving the medium- and long-term results of the award. The recipient must submit the following implementation and reporting documents in English. The AOR and recipient will agree on the appropriate format and length.

Implementation plans include, but are not limited to, the following:

- Annual work plans, including planned activities for the following year and any subsequent revisions
- International travel plans
- Planned expenditures
- Event planning/management
- International meeting preparation
- Material Transfer Agreement (MTA) risk mitigation plan
- Country-level Level of Effort (LOE) chart, to include any oversight provided by headquarters
- Protocol Development and Review Plan
- Biosecurity and Biosafety (BSBS) Plan

USAID requires the AOR approval of implementation plans annually to ensure alignment with stated goals, milestones and outputs. The implementation plan communicates how and when the recipient will complete project activities and is drafted annually to describe new activities. The AOR will ensure that the implementation plans fit within the scope, terms and conditions of the agreement.

First Year Work Plan and Budget

The recipient will submit a draft work plan for the first year within the first 90 calendar days of executing the award. Depending on the start date of the agreement, the first-year work plan may be less than a full year or more than a full year. The first-year work plan must include a detailed budget and budget narrative for the first year. As part of the First Year Work Plan submission, the recipient will include a supplementary annual work plan describing planned contributions to the GHSA on a template designated by the AOR. All work plans and budgets, including

significant revisions thereto, must be approved by the AOR.

Annual Work Plan and Budget

Starting with the second year of the award and for each subsequent year of performance thereafter, the recipient will submit annual work plans, budgets, and budget narratives to the AOR for the next federal fiscal year within 30 calendar days prior to the end of the current federal fiscal year in a format agreed upon by the AOR and the recipient. The recipient also will submit supplementary annual work plans describing planned contributions to the Global Health Security Agenda (GHSa) within a timeframe and on a template designated by the AOR.

Monitoring, Evaluation and Learning (MEL) Plan

The recipient will finalize a MEL plan for the life of DEEP VZN that derives from the activities outlined in the Program Description and submit it to the AOR within 90 calendar days of the award for approval. The MEL plan will outline key program interventions, indicators of achievement, associated annual and life-of-Activity targets and a learning agenda. The learning agenda will outline key questions to be addressed, a plan for addressing these questions, and a process for incorporating findings into program implementation and the detection and characterization of unknown viruses. Where appropriate, the MEL plan must track gender equality issues in implementing activities. The recipient will update the MEL plan annually and submit it as an attachment to the annual report.

Biosecurity and Biosafety (BSBS) Plan

The recipient will finalize a BSBS plan for the life of DEEP VZN and submit it to the AOR within 90 calendar days of the award for approval. The BSBS will outline all program interventions that have biosafety/biosecurity implications and steps (e.g. protocols, training) that will be taken to minimize risk.

Gender Action Plan

The recipient will conduct a gender analysis that assesses context and gender needs, including time constraints and participation limitations. This analysis will inform a subsequent gender action plan, which will be developed in collaboration with the USAID management team and finalized within 90 calendar days of the award and updated annually. The gender action plan will inform the Activity's technical approach as it relates to gender throughout the life of the Activity. It also will be used to inform the design of activities that seek to reduce opportunity gaps between men and women or address power differentials to promote gender equity. The gender action plans should be developed in conjunction with the Activity's monitoring, evaluation and learning plan, and progress should be reflected in annual work plans and performance reports.

Data Management Plan

A Data Management Plan (DMP) is a document that describes how the recipient will manage data during the project and what happens to the data after the project ends. The initial DMP, which will be developed in collaboration with the USAID management team, will be finalized within 90 calendar days of the award and updated semi-annually and annually.

A comprehensive DMP will discuss the following aspects of the data life cycle:

- Collect - How the data is collected and processed by the researcher.
- Assure - How to make sure the data is high quality and free of errors.
- Describe - How the data will be documented so that other researchers can use it.
- Preserve - How and where the data will be stored so that researchers can access it forever.

The data management plan will inform the Activity's technical approach as it relates to data throughout the life of the Activity. The data management plan should be developed in conjunction with the Activity's monitoring, evaluation and learning plan, and progress should be reflected in annual work plans and performance reports.

Closeout Plan

No later than six (6) months prior to the completion date of the agreement, the recipient will submit a demobilization plan for Agreement Officer's approval. The demobilization plan shall include: 1) a draft property disposition plan, 2) a plan for the phase-out of in-country operations, 3) a staffing discharge plan, 4) a delivery schedule for all reports or other deliverables required under the agreement, and 5) a timetable for completing all required actions in the demobilization plan, including the submission date of the final property disposition plan to the Agreement Officer.

3. Performance Reporting:

The recipient must submit via email a copy of semi-annual, annual, and final performance reports, in English, to the AOR in accordance with 2 CFR 200.328.

Semi-Annual and Annual Reports

The recipient will submit semi-annual and annual progress reports based on the federal fiscal calendar. The semi-annual report will be due within 30 days after the end of the reporting period and will cover the first six months of the year (October 1 - March 31). The annual report will cover the entire fiscal year (October 1 - September 30) and will be due within 90 days of the end of the federal fiscal year.

At a minimum, both semi-annual and annual reports will contain:

- Narrative description of activities completed and major accomplishments achieved during the reporting period in all countries supported by DEEP VZN, presented by objective
- Qualitative and quantitative data on program achievements and results
- Progress on standard and agreed upon indicators, as outlined in the MEL plan, including status towards achieving targets and explanations for significant deviations
- An updated MEL plan, including progress on the learning agenda (annually)
- An updated BSBS plan
- An updated Data Management plan
- Problems encountered and whether they were solved or are still outstanding
- Proposed solutions to ongoing or new problems
- Success stories, blogs, articles, publications, press releases, and photographs, if available
- Update on expenditures for the reporting period against the pipeline
- Analysis and explanation of cost overruns or high unit costs, when applicable
- Planned activities for the next performance period

Global Health Security Agenda (GHS) reports

The Recipient will submit semi-annual GHS performance reports within a timeframe and on a template designated by the AOR. The Recipient will submit the GHS semi-annual reports to the AOR via email.

Ad Hoc Reports

There may be additional reporting requirements and ad hoc information requests including, but not limited to, those associated with Mission buy-ins or additional sources of funding provided to DEEP VZN. Ad hoc refers to an unscheduled report for immediate, specific use. USAID will define the purpose, content, and specific use for any ad hoc report.

Final Report

Within ninety (90) calendar days after the period performance date, the recipient will submit one (1) original and two (2) copies of the Final Report to the AOR and one (1) copy to the Agreement Officer. In addition, one (1) copy will be submitted to the Development Experience Clearinghouse:

- 1) Electronically: <http://www.usaid.gov/results-and-data/informationresources/developmentexperience-clearinghouse-dec>
or
- 2) By U.S. Postal Service delivery to:
U.S. Agency for International Development
Development Experience Clearinghouse
M/CIO/ITSD/KM
Ronald Reagan Building M. 01-010
Washington, DC 20523-6100

The Final Report must include a narrative report and summary table of results, a comparison of actual accomplishments to the objectives established for the period of performance, and a gender analysis that describes how gender equality issues were tracked and addressed. It should highlight accomplishments against implementation plans; outline progress of benchmarks against targets; describe results; and document lessons learned during implementation. The Final Report also must contain a three-page executive summary, an index of all reports and information products produced under the agreement, and a summary of the program's finances. More details on the format of the final report will be provided after the award.

A.6 INDIRECT COST RATE

Allowable indirect costs shall be reimbursed on the basis of the following negotiated Colleges and Universities Rate Agreement, dated August 20, 2019.

INDIRECT COST RATES:

TYPE	FROM	TO	LOCATION	RATE%	APPLICABLE TO
Predetermined	7/1/2019	6/30/2023	On-Campus	49	Organized Research
			Off-Campus	49	Organized Research
			On-Campus	49	Instruction
			Off-Campus	49	Instruction
			On-Campus	49	Other Sponsored Activities
			Off-Campus	49	Other Sponsored Activities
Provisional	7/1/2023	Until Amended	Use same rates and conditions as those cited for fiscal year ending June 30, 2023.		

Base

Modified total direct costs, consisting of all salaries and wages, fringe benefits, materials, supplies, services, travel and subgrants and subcontracts up to the first \$25,000 of each

subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). Modified total direct costs shall exclude equipment, capital expenditures, charges for patient care, student tuition remission, rental costs of off-site facilities, scholarships, and fellowships as well as the portion of each subgrant and subcontract in excess of \$25,000.

A.7 TITLE TO PROPERTY

Title of property financed under this award shall vest with the recipient subject to the requirements of 2 CFR 200.311-200.316, until such time as USAID issues disposition instructions.

Furthermore, the following requirements apply regarding the use, care, accountability, maintenance, and disposition thereof:

(a) Tangible Property

(1) Equipment: “Equipment” means an article of tangible nonexpendable personal property having a useful life of one year or more and a per-unit acquisition cost (purchase price) of \$5,000 or more. Equipment is subject to the requirements set forth in 2 CFR 200.313.

(2) Supplies and Other Expendable Equipment: “Supplies and other expendable equipment” means items of tangible personal property that do not meet the definition of “equipment” in paragraph (a)(1) above. Supplies and other expendable equipment are subject to the requirements set forth in 2 CFR 200.314.

(3) Real Property: “Real property” means land, land improvements, structures, and appurtenances thereto. Real property is subject to the requirements set forth in 2 CFR 200.311.

(b) Intangible (Intellectual) Property

“Intangible property” means, but is not limited to, copyrights, inventions and patents, and data first produced under this Agreement. Intangible property is subject to the requirements set forth in 2 CFR 200.315.

A.8 AUTHORIZED GEOGRAPHIC CODE

The authorized geographic code for procurement of goods and services under this award is 935.

A.9 COST SHARING

The Recipient will contribute 5.03% percent of the total obligated amount of the award, excluding the sub-awards to the networks, as cost share throughout the life of the project. The cost share contribution shall be listed per cost category and presented in the work plan budgets.

Description	USD
Federal Amount Subject to Cost Share	\$124,679,897
Proposed Cost Share Amount	\$6,607,682
Cost Share Percentage	5.03%
Total Project Amount	\$131,287,579

A.10 SUBSTANTIAL INVOLVEMENT

a. Approval of the Recipient's Annual Implementation Plans:

Implementation plans include, but are not limited to, annual work plans, budget and budget narrative, including planned activities for the following year and any subsequent revisions, international travel plans, planned expenditures, event planning/management, international meeting preparation, MTA risk mitigation plan, country-level LOE chart, to include any oversight provided by headquarters, and protocol development and review plan.

USAID requires AOR approval of implementation plans annually to ensure alignment with stated goals, milestones and outputs. Each implementation plan communicates how and when the recipient will complete project activities and is drafted annually to describe new activities. This plan will be developed in partnership between the recipient and the AOR team. The AOR will ensure that each implementation plan fits within the scope, terms and conditions of the agreement.

b. Approval of Specified Key Personnel:

Designation of key personnel positions, approval of key personnel and any changes for the positions listed below:

- Project Director
- Deputy Project Director/Operational Lead

All individuals proposed as Key Personnel in the Recipient's application are hereby approved. Any future approval of key personnel will be authorized by the Agreement Officer in a separate administrative letter. The Recipient must submit to the AOR, reasonably in advance, any proposed replacement (including proposed substitutions) along with written justification in sufficient detail to permit evaluation of the impact on the program. Any proposed replacement Key Personnel must meet the minimum requirements stated in the Notice of Funding Opportunity (NOFO) number 7200AA21RFA00005, Section D.5.g). No replacement shall be made by the Recipient without the written consent of the Agreement Officer.

c. Agency and Recipient Collaboration or Joint Participation:

- Collaborative involvement in the selection of advisory committee members, if the recipient establishes an advisory committee that provides advice to the recipient. The AOR may participate as a member of this committee. Advisory committees must only deal with programmatic or technical issues and not routine administrative matters.
- Collaborative involvement in the selection of countries, viruses, and interfaces.
- USAID review and approval of monitoring, evaluation, and learning plans.
- USAID review and approval of data management plans.
- USAID involvement in the substantive direction/re-direction of interrelationships with other projects.
- USAID involvement in monitoring progress toward achievement of the Objectives and Expected Achievements during the course of the Agreement(s) and in monitoring of financial expenditures.

d. Direction and Redirection:

USAID will be involved in the substantive direction/re-direction of inter-relationships with other projects.

A.11 PROGRAM INCOME

The Recipient shall account for Program Income in accordance with 2 CFR 200.307 (or the Standard Provision entitled Program Income for non-U.S. organizations). Program Income earned under this award shall be added to the project.

A.12 AGREEMENT OFFICER'S REPRESENTATIVE

The Agreement Officer's Representative (AOR) for this Agreement will be designated in a separate memorandum from the Agreement Officer to the AOR with copy to the Recipient and the payment office.

A.13 SPECIAL PROVISIONS

A.13.1 SUBAWARD APPROVAL

Pursuant to the approved budget of this cooperative agreement, the following sub-awards are approved. All other sub-awards are subject to additional USAID approval.

Sub-awardee

University of Washington – UW
Family Health International 360 – FHI 360
PATH
Washington University at Saint Louis – WUSTL
Duke University

A.13.2 COUNTRY-BY-COUNTRY BREAKDOWN OF EXPENDITURES

The Recipient shall list each country included in the program and the total amount expended for each country under the award for the reporting period in the "Remarks" block on the "Financial Status Report" SF 425, or on a separate sheet of paper with the "Request for Advance or Reimbursement" SF 270.

A.13.3 BRANDING STRATEGY & MARKING PLAN

The Recipient shall submit within 30 calendar days of award, a Branding Strategy and Marking Plan. Upon the approval of the AO and AOR, the plan shall be incorporated as Attachment D.

A.13.4 ENVIRONMENTAL COMPLIANCE

The Foreign Assistance Act of 1961, as amended, Section 117 requires that the impact of USAID's activities on the environment be considered and that USAID include environmental sustainability as a central consideration in designing and carrying out its development programs. This mandate is codified in Federal Regulations (22 CFR 216) and in USAID's Automated Directives System (ADS) Parts 201.5.10g and 204 (<http://www.usaid.gov/policy/ADS/200/>), which, in part, require that the potential environmental impacts of USAID-financed activities are

identified prior to a final decision to proceed and that appropriate environmental safeguards are adopted for all activities. The recipient's environmental compliance obligations under these regulations and procedures are specified in the following paragraphs of this cooperative agreement.

In addition, the recipient must comply with host country environmental regulations unless otherwise directed in writing by USAID. In case of conflict between host country and USAID regulations, the latter shall govern.

No activity funded under this cooperative agreement will be implemented unless an environmental threshold determination, as defined by 22 CFR 216, has been reached for that activity, as documented in a Request for Categorical Exclusion (RCE), Initial Environmental Examination (IEE), or Environmental Assessment (EA) duly signed by the Bureau Environmental Officer (BEO). (Hereinafter, such documents are described as "approved Regulation 216 environmental documentation.")

As part of its initial Work Plan, and all Annual Work Plans thereafter, the Recipient, in collaboration with the USAID AOR and Mission Environmental Officer or Bureau Environmental Officer, as appropriate, shall review all ongoing and planned activities under this cooperative agreement to determine if they are within the scope of the approved Regulation 216 environmental documentation.

If the Recipient plans any new activities outside the scope of the approved Regulation 216 environmental documentation, it shall prepare an amendment to the documentation for USAID review and approval. No such new activities shall be undertaken prior to receiving written USAID approval of environmental documentation amendments.

Any ongoing activities found to be outside the scope of the approved Regulation 216 environmental documentation shall be halted until an amendment to the documentation is submitted and written approval is received from USAID.

A.13.5 OPEN DATA AND DATA SHARING

The recipient will be expected to comply with the Office of Management and Budget's Open Data Policy, as well as any USAID open data policy. Relevant MEL related data, knowledge and specifically lessons learned from sampling, discovery, characterization, and data analysis and use will be documented. All final data sets that USAID and the recipient deem as valuable to its stakeholders shall be submitted to USAID in a reliable media prior to the award end date and will be available for dissemination as appropriate. During the term of the agreement, preliminary data and analysis will be submitted to USAID on a periodic basis, but no less than annually, as agreed upon by USAID and recipient during work planning.

A.13.6 ORGANIZATIONAL CONFLICT OF INTEREST

Recipient must adhere to conflict of interest regulations found in 2 CFR 200.112 and 2 CFR 200.318(c)(1).

A.13.7 COORDINATION, COMMUNICATION, AND COLLABORATION

Coordination, communication and collaboration among stakeholders facilitate trust and mutual understanding; reduce redundancy; increase synergy, scalability, and impact; and promote learning and mutual accountability. DEEP VZN is expected to build and enhance constructive

partnerships, as appropriate. DEEP VZN will collaborate and coordinate with a wide variety of stakeholders, including country National NTD Programs, Ministries of Health and other relevant government entities; USAID Missions and Country Offices, USG partners, bilateral and multilateral agencies; academic and research institutions; private sector and philanthropic organizations; and civil society organizations.

A.14 SPECIAL REQUIREMENTS

A.14.1 FOR U.S. ORGANIZATIONS -- SPECIAL AWARD REQUIREMENT RELATING TO THE PROHIBITION ON CERTAIN TELECOMMUNICATION AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUGUST 2020)

- a. 2 CFR 200.216, “Prohibition on certain telecommunications and video surveillance services or equipment” implements Pub. L. 115-232, Section 889.
- b. USAID has been granted a temporary, limited waiver under Section 889(d)(2) that will allow the recipient to use award funds for the duration of this award to procure internet, cellular and landline services from communication service-providers who use covered telecommunications. All other costs incurred for covered telecommunications and video surveillance services or equipment, such as phones, video surveillance, and cloud servers specified in 2 CFR 200.216 remain unallowable in accordance with 2 CFR 200.471.

[End of Special Award Requirement]

A.14.2 FOR NON-U.S. ORGANIZATIONS -- SPECIAL AWARD REQUIREMENT RELATING TO THE PROHIBITION ON CERTAIN TELECOMMUNICATION AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUGUST 2020)

- a. The mandatory standard provision “Prohibition on Certain Telecommunication and Video Surveillance Services or Equipment (AUGUST 2020)” implements Pub. L. 115-232, Section 889.
- b. USAID has been granted a temporary, limited waiver under Section 889(d)(2) that will allow the recipient to use award funds for the duration of this award to procure internet, cellular and landline services from communication service-providers who use covered telecommunications. All other costs incurred for covered telecommunications and video surveillance services or equipment, such as phones, video surveillance, and cloud servers specified in the standard provision in paragraph a. above remain unallowable in accordance with the mandatory standard provision “Allowable Costs” and 2 CFR 200.471.

[End of Special Award Requirement]

[END OF ATTACHMENT A]

ATTACHMENT B – PROGRAM DESCRIPTION

EXECUTIVE SUMMARY

With an overarching goal of detecting ‘known unknown’ viruses that might pose a pre-pandemic threat, we will carry out an innovative, sustainable, and responsive surveillance program for detection and characterization of novel animal viruses with zoonotic potential. Our consortium, which includes University of Washington (UW), PATH, FHI360, and Washington University in St. Louis (WUSTL) is led by Washington State University’s (WSU) Allen School for Global Health, whose approach of placing full-time faculty in global regions has seen it lead innovative emerging infectious disease studies in East and Central Africa that target landscapes inhabited by humans, their livestock and diverse wildlife populations in ecosystems ideal for the maintenance and transmission of emerging zoonotic pathogens. The consortium features strong in-country partners supported by world class virology reference laboratories at UW and WUSTL involved in novel virus discovery and characterization, unparalleled experience in laboratory strengthening, One Health epidemiology and social science, and global reach. Apart from collective presence and institutional links in countries located in the six DEEP VZN global regions, our consortium partners bring complementary expertise, including global field studies and sampling by WSU and UW, laboratory capacity by WUSTL and UW, and data management and in-country stewardship by PATH, FHI360 and WSU. We will build on the achievements of the USAID EPT programs, and our collective prominence in the global NIH-supported Centers for Research in Infectious Diseases (NIH-CREID), to enable partner labs in focus countries to fully sequence and characterize novel viruses in unprecedented breadth and depth. We will leverage scientific breakthroughs with SARS CoV2 and other emerging viruses to apply cutting edge technologies to prioritize potential for viral spillover and pandemics. In focus countries, we will target high-risk locations and subpopulations at the human-animal interface using a risk-based analytical approach to guide sample collection where there is evidence of previous spillover or high prevalence of zoonotic viruses. Additionally, we will establish an efficient sample collection and transportation system and align capacities at in-country laboratories to identify viruses of zoonotic potential in a timely manner, thus triggering additional targeted sampling focused up- and downstream of the transmission chain.

We plan to collect over 800,000 samples, of which approximately 60% will come from wildlife. Assuming a 1-1.5% yield, our in-country labs will provide near-real time screening and genome sequencing to detect and characterize between 8,000 and 12,000 novel viruses from the target families over the five years of the DEEP VZN program. To effectively characterize viruses of zoonotic potential from the detected pool, we will use a combination of innovative molecular, protein structure and receptor analyses, and serological techniques to generate evidence of spillover to humans, and potential for human-to-human transmission. This consortium will also strengthen capacity within focus countries for continued assessment of viruses of zoonotic potential and enhance response to future outbreaks. To enhance sustainability, we will build in-country stewardship of all surveillance, diagnostic and data management activities through the development of meaningful partnerships with focus country stakeholders. Through engagement and integration with other USAID EPT efforts, NIH CREID networks and other professionals across human, animal, and environmental health sectors, we will promote meaningful sharing of resources and data in an inclusive and cost-effective One Health-approach. The overall outcomes of this program will be the detection of an unprecedented number of unknown viruses of pandemic potential that can be monitored by public health institutions worldwide, and significant

advances in our collective ability to characterize zoonotic and pandemic potential of emerging viruses.

OBJECTIVE 1: Conduct Sampling for Unknown Viruses from the Priority Viral Families

We have designed an efficient, responsive, and sustainable program that uses existing data and models on spillover risk to guide initial sampling and interim data to refine sampling targets.

Building on baseline detection of known viruses in the PREDICT, VIRION and EIDITH databases, our strategies will lead to the detection of previously unknown wildlife-origin viruses from the target families and identify a subset that pose a significant pandemic threat. Our

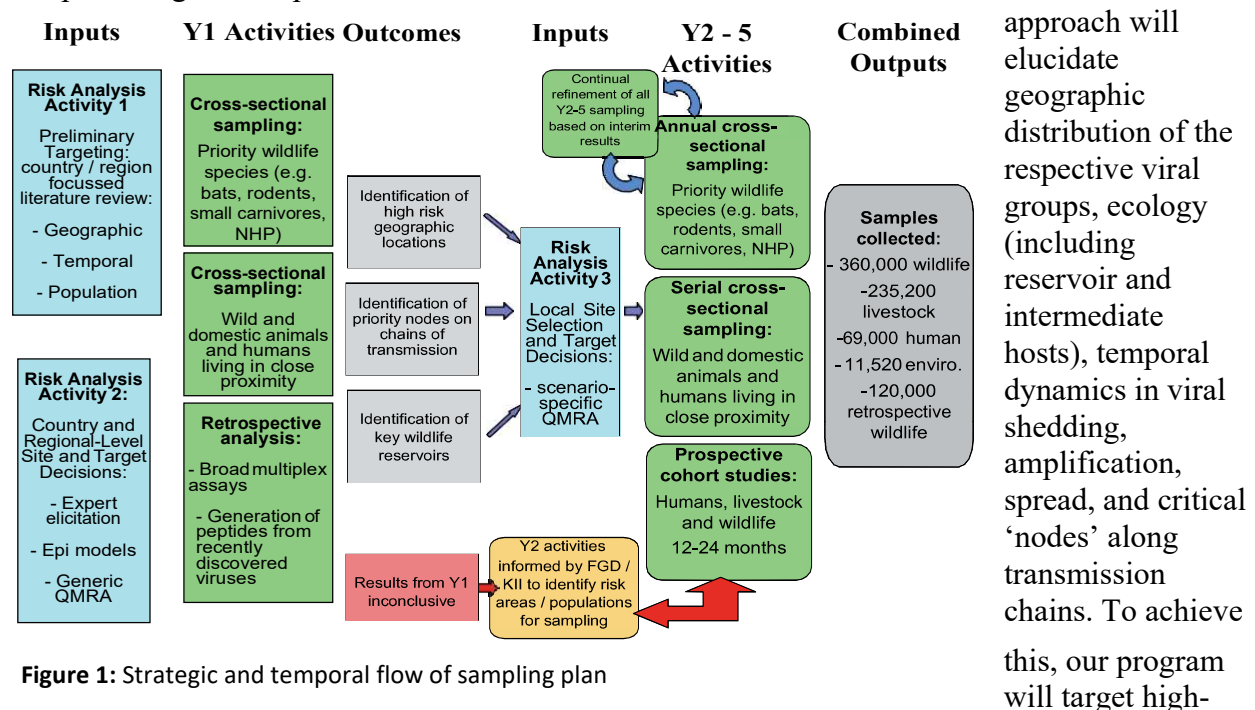


Figure 1: Strategic and temporal flow of sampling plan

risk locations and subpopulations at the human-animal interface, optimizing yield and resources (Fig. 1). This targeting will be adaptive, with locations identified through an iterative process informed by ongoing data collection. We will establish a pipeline of sample collection and transportation, aligned with capacities at existing in-country laboratories (utilizing a hub and spoke approach). Identification of a virus of zoonotic potential will trigger additional sampling focused up- and downstream on the transmission chain. Sampling will be guided by a risk-based analytical approach informed by evidence of a previous spillover event, a high prevalence of zoonotic viruses, or close contact between humans and reservoir hosts. Finally, we will employ a One Health-approach through engagement of human, animal, and environmental health sectors.

1.1 Sample Site and Species Selection

Focus 1: Preliminary Targeting - country/region focused literature review

To inform initial geographic, temporal, and species sampling plans and further risk-based targeting, we will carry out a rapid and comprehensive literature review (including grey literature and proceedings from meetings and One Health platforms) in Y1 to identify where prevalence and diversity of the target viral families are high, where critical nodes on chains of transmission are located, and key wildlife species are abundant (Focus 2 and Fig. 2).

Geographic Selection: We will use literature review, remote-sensed data, and existing risk maps of zoonotic disease emergence risk and its drivers to make a primary selection of geographic

areas of interest. Priority drivers of disease emergence will include human population density, land use change, density and diversity of wildlife species (focusing on mammalian species),

intensive farming of domestic and wild species, and live/wet wildlife markets. We will also leverage maps and data from PREDICT sampling data.

Temporal Selection: Viral (and host) seasonality and multiannual trends impact viral load and thus detection rates and will be critical determinants of sampling timeframes, particularly for wild animal sampling. The literature review will leverage existing knowledge of targeted viral families and host dynamics to inform our risk-based sampling strategies.

Population Selection: Country-specific literature review will identify wildlife and livestock species, human occupational groups, and value chains to consider for sampling.

Focus 2: Country and Regional-Level Site and Target Decisions - risk-based analysis Using a hybrid risk-based approach, we will refine geographic, temporal, and population targets defined by Focus 1 to plan the location and the timing of each sampling activity, with emphasis on identifying populations of wildlife, domestic animals, and humans on transmission chains. This approach will build upon existing knowledge from previous USAID-funded research projects, tailored to country-specific contexts. We will use available data and models and in-country stakeholder engagement, ensuring rapid site selection and start-up of project activities.

Epidemiological Models: In collaboration with key partners, such as the USAID-funded STOP Spillover project, in-country research institutions, and relevant government ministries, the team will review existing epidemiologic models (spatial and mathematical) of spillover risk parameterized to the geographic areas and populations identified in Focus 1. This work will both

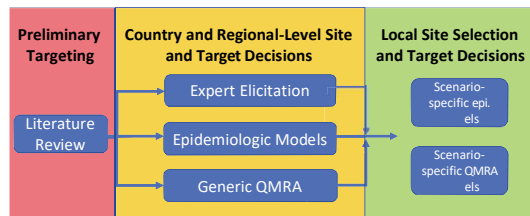


Fig. 2: Risk-based analytical approach to sample site selection

inform the structure of the epidemiologic models developed in Focus 3 and collate data for these later models. Existing models of viral and host seasonality, host dynamics in targeted wildlife populations, and seasonal trends in wild meat hunting will be used to plan sample timing. **Expert Elicitation:** If the absence of context- and site-specific data or relevant

epidemiologic models preclude the use of modeling to refine sampling plans, we will use an expert elicitation-based risk ranking approach to scope initial rounds of sampling.

QMRA: As part of a multimodal strategy, the team will develop prospective probabilistic models utilizing a quantitative microbial risk assessment (QMRA) approach to identify populations and areas of greatest risk and uncertainty. Such approaches have been used to estimate environmental risk of zoonoses transmission and provide a way to include viral load data into our risk prioritization process. As the magnitude of risk will likely be driven by scenario-specific exposures, updated models will be developed at the onset of the project following literature review and subsequently tailored to specific exposure scenarios (Fig. 2).

Focus 3: Local Site Selection and Target Decisions

Based on site- and context-specific information and models generated in Focus 2, detailed exposure modules will be incorporated into location-specific QMRA models, the findings of which will be triangulated with spatial epidemiologic models. These models will be informed by geolocated data indicating prior spillover events, presence of immunocompromised wildlife species, disturbances that increase physiological stress, human activities that facilitate wildlife contact, and high population density. We will develop an initial set of location specific QMRA models based on the sampling sites and data from PREDICT 1 & 2 and evaluate these models to identify sites with the greatest estimated risks and/or uncertainty. In concert with our QMRA models, we will use the computationally efficient stochastic partial differential equations approach to Gaussian process modelling to generate high-resolution maps of spillover risk in the

target geographies identified in Focus 1 - 3. Both models will be continually iterated as new data become available, and sampling sites/targets will be adjusted.

1.2 Sampling Targets

To reduce delay, as soon as each of Focus 1-3 is completed decisions on site identification and timing for initial rounds of sample collection can begin. We will use pre-existing models and computational frameworks to complete these models while sampling approvals are pending. Targeted sampling locations, timelines, and species will be refined through participatory workshops, including representatives from wildlife, human, livestock, and environmental health sectors, and supply chain mapping integrated with network data. Retail outlets for wildlife products will be the terminus of this mapping, with focus on the movement of animals or their products from their points of origin to consumers. Eco-centric network data and value chain data will be collected at each node to identify priority nodes for viral transmission.

Once sampling targets have been identified, we will use sampling methods selected based on population sampled, risk characterization, and country-context, including serial cross-sectional sampling and prospective cohort sampling. Where possible, serial cross-sectional sampling will be repeated in the same population to determine which viruses are adapting to humans (pre-pandemic viruses) and to allow development of interventions to mitigate transmission. In addition, we will use composite sampling to screen samples, with follow-up testing of discrete samples from positive composites to decrease cost and increase throughput. We will also collect socio-anthropological data at these high-risk locations to better understand human-animal-ecosystem interactions relevant to viral transmission. Sampling targets will include:

Wildlife: Focus 1-3 will identify sites for initial sampling and priority mammalian species.

Supplementing risk characterization, trait-based statistical modelling will be used to prioritize bat species for each viral taxon, which will be iteratively improved as more host-virus data become available. Within these sites and species, sampling will focus on populations likely to impact the animal value chain (wildlife or livestock), including free-ranging wild animals living near areas of intensive livestock farming, wild mammals in ecosystems recently fragmented by expanding human communities, farmed wild mammals and wild mammals sold in live/wet markets.

Domestic animals: Sampling will focus primarily on intensively farmed domestic species that are reservoirs or amplifying hosts for the targeted viral families, characterized in Focus 1-3.

Industrialized farms with poor biosecurity or ecosystem encroachment will be prioritized.

Humans: Sampling will focus on country-specific occupational groups (and controls) at highest risk for spillover already geographically and temporally linked to wildlife described above.

1.3 Country-level Strategic Sampling Approach*

**Specific sampling targets will vary by target country based on in-country context*

Task 1.1: Cross-sectional sampling of wild animals (priority species): We will implement cross-sectional sampling of populations of free ranging wild animals likely to host unknown species of known virus families and target physiologically and immunologically stressed populations (migratory populations/ those living in areas of intense land use change). The highest proportion of samples collected will be fecal matter (e.g., under-roost excreta) to optimize efficiency and sensitivity for viral surveillance and discovery, particularly for henipaviruses and coronaviruses. We will also collect and test wildlife meat from markets and traders.

Year 1: Sample teams: 3 per country, sampling for 45 days/year, collecting 40 samples/day;

Aim Per country: 5000 samples; **Target species:** Bats, rodents, small carnivore species, non-human primates (NHP); **Sample type:** Feces, blood, oral/rectal swabs;

Years 2–5: Sample teams: 3 per country, sampling for 21 days / year, collecting 40 samples/day; Prospective sampling informed by Y1 results; **Aim per country:** 2500 total samples/year; **Target species** and **Sample type:** as in Y1

Task 1.2: Cross-sectional sampling of animals and humans living in proximity:

Humans are frequently in contact with large aggregations of wildlife, such as rodents, bats, and small carnivore species. Such synanthropic wildlife species provide opportunities for spillover to amplifying reservoir species that have greater opportunities for pathogen sharing with humans. We will sample wildlife species among or near areas of intensive livestock farming, farmed wild animals, and wild animals sold in live/wet markets. We will also carry out composite sampling of human and livestock species through collection of fecal slurry (livestock) and sewage (human) samples, prioritizing sampling of environments where animals/humans have recently displayed signs of illness and sites characterized by recent disturbances of neighboring ecosystems. We will also sample domestic carnivores (dogs and cats) as these species typically range widely, scavenge, have contact with wildlife, livestock, and humans and are accessible for sampling.

Year 1: Wild animal sample teams: 3 per country, sampling for 45 days/year, collecting 40 samples/day; **Domestic animal sample teams:** 3 per country, sampling for 30 days/year, collecting 40 samples/day; **Human sample teams:** 3 per country, sampling for 45 days/year, collecting 10 samples/day; **Per country aim:** 5000 wildlife, 3600 domestic animal, 1350 human samples; **Target species:** Rodents, bats, domestic and wild carnivore species (e.g. domestic dogs/cats, civet cats), ungulates, poultry, humans; **Sample type:** Wildlife species: feces, blood, oral/rectal swabs; humans, livestock: composite sampling of fecal slurry and sewage

Years 2–5: Prospective sampling informed by Y1 results; **Wild animal sample teams:** 3 per country, sampling for 21 days/year, collecting 40 samples/day; **Domestic animal sample teams:** 3 per country, sampling for 14 days/year, collecting 40 samples/day; **Human sample teams:** 3 per country, sampling for 20 days/year, collecting 10 samples/day; **Per country aim:** 2500 wildlife, 1600 domestic animal, 600 human samples.

Task 1.3: Retrospective analysis of bio-banked samples: We will request access to bio-banked sera collected from wildlife species, including from previous USAID-funded projects such as PREDICT, in areas determined by our risk analysis activities to be hot-spot zones. Broad multiplex assays will allow identification of all ‘known knowns’ and refinement of subsequent sampling strategies (in Y2-5) to increase the probability of detecting ‘known unknown’ viruses. Additionally, novel peptides generated from recently discovered focus family viruses will allow contemporary viruses to be detected.

Year 1: Per country aim: Collection of up to 10,000 wildlife serum samples from in-country biobanks; **Target species:** Bats, rodents, small carnivore species, NHP

Task 1.4: Prospective cohort studies of humans, livestock, and farmed wildlife

Per country aim: i) **animal workers (human):** 200 blood samples twice/year; 200 risk factor questionnaires monthly; 10 semi-structured interviews monthly; 200 nasal wash samples monthly; ii) **controls (human):** 50 blood samples twice/year; 50 questionnaire surveys monthly; 50 nasal wash samples monthly; iii) **farmed animals:** 200 composite samples monthly; iv) **environmental samples:** 20 samples monthly (1 per farm/month), for example, composited waste water sample or barn air; v) **workplace:** 20 (1 per farm/month) x Animal Workplace Enrolment and Animal Workplace Follow-up Questionnaire; **Target species:** Humans, ungulates, poultry, farmed wildlife

Task 1.5: Responsive sampling in the face of an outbreak: In the face of emerging epidemics, opportunities to understand the epidemiology of an outbreak are lost because of delays

mobilizing sample collecting activities. SOPs and sampling teams will be prepared to undertake rapid collection of samples from wildlife and domestic animals in the immediate geographic area around an index case. We will remain in close communication with public and animal health disease reporting agencies so that disease outbreaks can trigger localized investigations.

1.4 Sample Size and Detection of Known Viruses

The more samples collected and tested, the higher the likelihood of detecting a previously unknown member of the target viral families. Collecting 300 samples from a given target species provides a 95% probability of detecting a virus present in at least 1% of individuals; Therefore, a risk-based approach to selecting animal species is critically important to optimize project resources. We will tether our collected data to baseline detection of known viruses in the PREDICT and VIRION databases and a beta-coronavirus specific database (<https://www.viralemergence.org/betacov>). This will allow estimation of expected prevalence and diversity for comparison with observed values for each viral family and host species. Following Y1 collection, detection, and viral characterization activities, we will use cluster detection algorithms to identify hotspots of prevalence or diversity of known viruses, triggering further focused sampling. Detection of known viruses in the three families provides a positive control.

1.5 Contingency Plans

Although the sampling plan is ambitious in scope we are confident that we can collect the numbers of samples listed. Key reasons for this are that we will a) focus sampling efforts on the collection of fecal matter, including composite slurry/sewage samples, which is an excellent sample type for viral discovery and relatively easy to collect; b) exploit sampling synergies within and between sampling targets, for example, sampling of humans, domestic animals, environments, and farmed wildlife will be carried out by single teams that focus on multiple sampling targets. This will make sample collection more efficient; and c) increase the number of sampling teams and / or sampling days if targets are not met. Finally, the plan will allow sampling targets to be exceeded in countries where collection is efficient, which will counterbalance more modest sampling outputs in less productive countries. It is also important to note that, for restrained animals, multiple samples will be collected (fecal, blood, swabs) and as such the estimated total number of samples refers just that and not number of animals sampled.

1.6 Outcomes

The outcomes of Y1 will be used to inform the strategic planning of the sampling activities in Y2 – 5. This site selection review will be an iterative process to determine whether to add new sampling sites. If outcomes from Y1 activities are inconclusive, sampling activities in Y2 – 5 will be informed through iterative refinement of the epidemiological and QMRA models and detailed, in-country participatory workshops and interviews targeting workers in the human, animal and environmental health sectors. Samples collected will be studied with an array of molecular assays for previously identified as well as novel corona-, filo-, and paramyxoviruses. Where data show a prevalent emergent animal virus, we will identify the location and specific animal hosts of origin and collect data on supply chains and contact networks to target additional specimen collections and molecular studies along the chain of transmission.

1.7 Capacity Building and Sustainability

To facilitate sustainability, we will promote in-country stewardship of all Objective 1 activities, including risk-based analytical approaches, design of sampling strategies and collection of samples. Rapid assessment of in-country capabilities will be conducted to identify gaps in personnel, training and equipment. Training will be provided for each activity (utilizing virtual

methods and translation to local language), and location-appropriate equipment provided in order to allow activities to be performed within, and beyond, the lifetime of the program.

OBJECTIVE 2: Strengthen Detection for Novel Viruses from Priority Viral Families

Our sampling strategy is designed to collect as many specimens as possible. Using a strategically designed, risk-based approach to sampling, we will roll out serial cross-sectional and prospective cohort studies at nodes of potential transmission of novel viruses to collect and screen **~800,000 specimens, with >60% from wildlife**. We will build a detection and characterization program utilizing in-country labs to provide near-real time screening and genome sequencing and finishing. Assuming 1-1.5% yield, based on the yield in the PREDICT program in the 3 viral families targeted for DEEP VZN (DV), this approach is likely to **detect and characterize 8000 – 12,000 novel virus genomes** over the DV program. We estimate these genomes to comprise a total of 1,000 novel viral species, based on the number of novel sequence submissions from the PREDICT project (~2100 novel sequences from 3 highlighted viral families for DV, constituting ~250 novel viral species, or ~8 specimens/sequences per novel virus species).

2.1 Capacity Building and Sustainability

Our capacity building approach for in-country laboratories is summarized in **Fig 3**. *The goal is to ensure that each country independently conducts full virus screening (basic detection to whole-genome sequencing) and basic characterization that includes evaluation of spillover (serology) and later glycoprotein and receptor-binding assays.* We will ensure sustainable, in-country capacity to safely detect and characterize unknown novel viruses by providing high-throughput automated nucleic extraction, multiplex qRT-PCR screening instruments, and *NextSeq* Illumina next-generation sequencing (NGS) platform in each country. All 18 partner institutions we have identified in the 12 target countries have existing serology capacity, while 60% and 25% have qRT-PCR, and NGS capacities, respectively. Building on our consortium's >25 years of experience working in sub-Saharan Africa, Asia, and Latin America, including during the COVID-19 pandemic, we will address the recurrent problem of high cost and delayed delivery by establishing direct-buy credit accounts and service contracts with the manufacturers of equipment involved in the DV program. As illustrated in **Fig 3**, in Year 1 we will conduct rapid assessment of in-country labs to determine needs, followed by provision and installation of

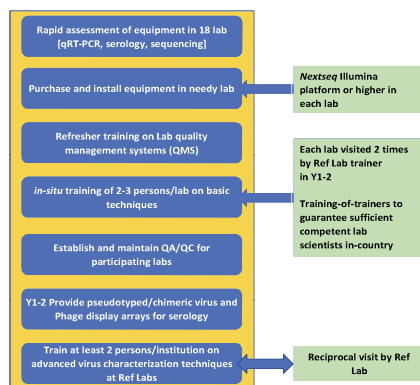


Fig 3. Flow chart of stepwise capacity-building for in-country labs

equipment to ensure they can conduct qRT-PCR, serology (ELISA and pseudotype viral neutralization test (pVNT)), and viral WGS.

Reference Labs: We will establish and fund two Reference Labs in the US, tasked with building in-country lab capacity, and validate advanced virus characterization (*in-silico* glycoprotein and receptor, *in vitro* and *ex vivo* virus-cell studies). The D. Wang (WUSTL) and A. Greninger (UW) labs, supported by other virology, immunology, and protein chemistry labs at these institutions, will in the early phase of the program (Years 1-2) (i) Develop and supply novel virus detection and

characterization standard operating procedures (SOPs), (ii) Conduct *in situ* training to in-country labs on qRT-PCR, whole-genome sequencing (WGS), and serology technologies, including annual refresher trainings, (iii) Develop and supply qRT-PCR controls and standards, (iv) Develop and supply serology screening kits (phage display peptide libraries, pseudotyped and/or chimeric viruses, monoclonal antibodies), (v) Roll out and manage a QA/QC system to ensure

reproducible and comparable data (including proficiency panels and re-testing 10% of positive specimens from each country), (vi) Conduct advanced characterization (*in-silico* glycoprotein and receptor, *in vivo* and *ex vivo* studies with live virus), and (vii) travel and train at least two persons from each participating institution in their US reference labs on development of pseudotyped/chimeric virus and antibodies for serology, and advanced virus characterization. Based on our successful experience with lab capacity strengthening, it is essential that this will be accompanied by reciprocal training visits by reference laboratory trainers to in-country labs, with the goal of ensuring that in-country labs can independently conduct detection and significant advanced virus characterization (except virus culture, or *in vitro* and *ex vivo* studies with live virus that may require high biosecurity laboratories). We recognize that in-country laboratories will not acquire competency at the same rate because of factors such as additional needs to improve infrastructure, biosafety and biosecurity capacity, sub-contracting and procurement challenges, and staff turnover. We also anticipate that early in the DV program in-country labs will identify suspected novel virus samples that require urgent characterization methodologies not yet fully established and transitioned to the country. To address this, the project will expand U.S. based reference lab personnel who will be dedicated to implementing all aspects of in-country virus detection and characterization (as described). These personnel will transition for several month-long periods each year through the in-country laboratories to provide both structured and ad hoc in-country analysis support, including complete bioinformatic analysis of NGS data to identify novel viruses, basic *in-silico* viral glycoprotein and receptor-binding analyses, and serological analysis to determine novel virus spillover. Additionally, this response team may be deployed to work alongside in-country scientists in a country with suspected novel viruses until characterization is completed to the satisfaction of the consortium executive council and USAID. The Reference Laboratories will also validate in-country results by repeating a limited number of the characterization tests conducted on novel viruses. This validation will be achieved by shipping aliquots of not more than ~0.1% of collected samples (negative and positive) as shown in the textbox below.

ESTIMATED NUMBER OF SAMPLES SHIPPED TO REFERENCES LABS IN UNITED STATES

From ~800,000 specimens collected; we estimate at least 8,000 (1,600/year) will have suspected novel viruses. Of these, we expect to ship no more than 10 qRT-PCR positive and 10 negative specimens from each country in Years 1-2 (480 specimens) for validation, and 5 qRT-PCR positive and 5 negative specimens In Years 3-5 (360 specimens), bringing the total specimens shipped to 840 (0.1% of collected specimens) over the 5 years for the DEEP VZN program.

For purposes of virus culture, virus isolation, *in-vitro* and *ex-vivo* studies, we have established access to the Rocky Mountain BSL-4 laboratory (letter of commitment available).

2.2 Overall Detection Strategy

We will use both molecular and serological approaches to detect novel viruses. For maximum sensitivity and efficiency, our primary virus detection strategy will use broad-range qRT-PCR assays that specifically target the 3 virus families for initial screening of specimens. We will utilize consensus RT-PCR followed by sequencing of amplicons and interrogate positive specimens further to obtain complete genomes. Broad serology will be used to adjust the sampling strategy (Objective 1), and also to investigate spillover of novel viruses across the wildlife-livestock-human spectrum (Objective 3). Focusing primarily on sera collected from bats, rodents, NHP, and humans, we will screen for known and newly detected coronaviruses, paramyxoviruses and filoviruses using phage display serology. Evidence of high prevalence of diverse species of target virus families will indicate an ecosystem favourable to maintenance and

transmission of these viruses. *Serologic detection of* antibodies to a novel virus may also provide information on duration of exposure and affected animal species, with high seroprevalence in humans pointing to higher frequency of spillover events.

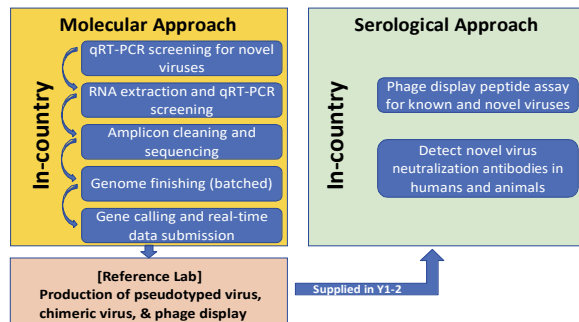


Fig 4. Virus detection flow chart

How our approach enhances efficiency to detect novel viruses: Our molecular screening strategy (Fig. 4) optimizes sensitivity, keeping the most expensive aspects (deep meta-genomic sequencing) to a minimum. All 3 viral families targeted for detection in the DV program are shed and detectable in stool reducing the need for animal trapping and handling. We have also integrated viral load measurement to our screening to improve chances of genome

finishing. During genome recovery from positive specimens, we will be able to infer hosts from environmental metadata and non-viral metagenomic sequencing data, which will be fed back to sampling teams to focus on particular animal species and areas where positives have been detected. The phage display approach is more cost-effective and efficient to serologically screen for known and novel viruses from target families than alternative multiplex serology approaches, such as peptide microarrays. Primarily because the phages self-replicate and thus are a renewable resource. Broad serology is costlier than qRT-PCR and this will limit its use.

2.3 Molecular Screening

Task 2.1: RNA extraction and broad-range qRT-PCR: RNA extraction methods will be standardized across all sites. Ideally, automated extraction instrumentation will be installed at each site. In addition, an alternative manual extraction method will be established as back-up. Our team has validated a family-specific, broad-range, single-well RT-PCR assay for *Orthocoronavirinae*, which enabled discovery of a novel coronavirus from a hospitalized patient in Malaysia. We will also make use of a published two-well pan-paramyxovirus and a one-well pan-filovirus qRT-PCRs to screen specimens. These family-specific primers amplify conserved portions of the RNA-dependent RNA-polymerase and allow for species determination after amplicon sequencing. We will integrate SYBR-Green into family-based RT-PCRs to allow for viral load quantitation at the same time we are detecting novel viruses along with melting curves to ensure appropriate-sized amplicons are generated without gel electrophoresis. As a backup strategy to the quantitative readout, a standard operating protocol for gel electrophoresis-based readout will be established. We will ensure in-country labs have instruments that can perform these assays with a throughput of 20-22 specimens per 96-well plate or 80-84 specimens per 384-well plate. We anticipate a throughput of at least 80 specimens per day per laboratory. Amplicons from qRT-PCR will be cleaned of PCR primers and sequenced on *Nextseq* biweekly, with up to 96 amplicons multiplexed. For further cost efficiency, we will explore the feasibility of multiplexing up to 384 amplicons. To identify novel viruses from the amplicons, all sequences will be aligned to a reference database composed of all target viruses from GenBank. Amplicon sequences that diverge significantly from all known viruses will be prioritized for whole genome sequencing. To standardize assays, the Reference Labs will provide positive and negative control standards for RT-PCR. Qualitative controls will be run through extraction and qRT-PCR on every plate, while quantitative controls will be run monthly. Quantitative controls will consist of a set of serial dilutions (10^7 - 10^0 copies/ul) of *in-vitro* transcribed RNA targets (2 different viruses in the family).

Task 2.2: Genome recovery and finishing: For maximal cost efficiency and timeliness, genome finishing will be performed in batches using *NextSeq* or *NovaSeq* equipment in each country. After identification of amplicons derived from novel viruses, we will ensure that complete genomes are recovered and finished to enable further screening and characterization. Complete genomes are also necessary for development of diagnostics, molecular epidemiology, vaccinology, and therapeutic development. Specimens will be prioritized for whole genome sequencing based on sequence divergence from known viruses and viral load estimates. We will use a variety of NGS methods as needed, including metatranscriptomics with rRNA depletion and/or poly-A enrichment approaches. Based on the identity of the virus, we can also use spike primers that bind the sequences recovered in the family-specific qRT-PCR or other highly conserved regions in that viral family into the cDNA synthesis prior to sequencing to increase coverage of viruses. New rRNA depletion reagents that cross-hybridize across metazoans will ensure fewer reads are spent on rRNA in rodents, bats, NHP, and humans, allowing for 8-150-fold enrichment of on-target reads. All targeted viral families poly-adenylate their transcripts, allowing classical RNA-Seq approaches to help in viral genome recovery. As a default, specimens will be targeted for 25 million reads to ensure genome recovery using high-throughput Illumina sequencers, which can allow recovery of near-complete genomes from specimens with Ct < 27. If needed, we will perform additional deeper sequencing, manually design PCR primers to close gaps, and perform 5' and 3' RACE to recover the viral genome termini. Our team has expertise sequencing whole genomes of novel RNA viruses. In Year 1, we endeavour to obtain and sequence specimens that have novel target virus from prior PREDICT projects. Small 400-500bp fragments of >150 novel paramyxoviruses and more than 60 novel coronaviruses were detected in PREDICT projects, but full genome sequences are not available. **Task 2.3: Genome calling and real-time data deposition:** Genome calling will be performed using a variety of automated and bespoke pipelines, including cloud based IDSeq for comprehensive assessment of viruses present in a specimen. As a complementary approach, we will also use well-described locally installed bioinformatic approaches, such as IRMA (an assembler specifically optimized for RNA virus genomes) and SURPI (pipeline optimized for unbiased metagenomic detection of all pathogens). Reads will be remapped to all draft genomes to ensure accuracy and manually reviewed in Geneious, especially if manual gap filling or 5' and 3' RACE is required. Importantly, our bioinformatics strategy also takes advantage of the global bioinformatics community and the wisdom of crowds by including real-time FASTQ and FASTA sequencing data deposition into NCBI Sequence Read Archive (SRA) and GenBank with **zero embargo time**. Our team has previously published software to facilitate rapid deposition of viral genomes into GenBank. SRA and GenBank accessions and brief initial analyses of sequencing data will be automatically communicated in real-time via our project-specific Twitter, so they are accessible to the global scientific community.

2.4. Broad Serology Screening

Zoonotic spillover is not considered a one-off event, and multiple small spillover events can potentially be detected by serological studies. For SARS-CoV, human serosurveys in south-eastern China found evidence of repeated spillover, with antibodies shown to persist for at least 2 years. To identify the animals or humans that had prior exposure to target viruses, our Reference Labs will generate phage display libraries covering 100,000 of the most conserved 60-mer peptides across all known filovirus, paramyxovirus, and coronavirus genomes following the VirScan protocol. The phage library will be amplified and validated using well-characterized positive control sera obtained from PREDICT labs, NIH-CREID network, in-country and CDC,

and Institute Pasteur labs. Reference Labs will develop kits consisting of phages that can be incubated with sera and protein A/G beads in in-country labs, with library preparation. Following incubation, the beads can be washed and library generation performed. The resultant DNA library is stable and can be sequenced at in-country laboratories. The phage library will be updated with novel viruses detected globally. The library will be used to screen high priority sera collected from bats, rodents, NHP, and humans sampled from nodes of potential transmission, serial cross-sectional samplings, and possibly archived sera. *Broad serology testing will be applied selectively and as a secondary approach, in part because of cost and the broader utility of genome recovery to enable further viral characterization work.* However, we envision that:

- (i) evidence of infection by novel viruses can be obtained from the serological profiles;
- (ii) unique signatures of epitopes distinct from those derived from known infections may suggest prior infection with a novel virus;
- (iii) high prevalence of diverse species of the target virus families may indicate an ecosystem favourable to maintenance and transmission of novel viruses of interest, and therefore point to a preferred sampling location;
- (iv) serologic detection of antibodies to a novel virus could inform the duration of exposure and affected animal species, with high prevalence in humans pointing to increased risk of spillover to humans.

We should point out that low or undetectable antibodies in humans may not indicate that a novel virus poses low risk to humans because other factors such as its recent introduction or potential for acquiring transmissibility to humans through minor mutations still exists.

As an orthogonal method to the broad serological screening, we will also perform binding ELISA serological assays against novel virus glycoproteins. Upon sequencing of a new virus, we will undertake codon-optimized gene synthesis to generate constructs for recombinant protein expression and pseudovirus generation. We expect to purify recombinant spike ectodomain trimers and/or receptor binding domain proteins for coronaviruses, GP trimers for filoviruses, and both fusion (F) trimers and G/H/HN tetramers for novel paramyxoviruses. We will use an antigen prediction pipeline to predict sensitive and specific viral protein antigens. Viral proteins and fragments predicted by this algorithm will be expressed for ELISA serodiagnosis. Negative-stain electron microscopy will be used to ensure the viral proteins are folded correctly after purification. Once viral protein antigens are purified, we will contract with GenScript for rapid generation of custom monoclonal antibody controls. We will then determine the specificity of the ELISA binding assay against a bank of >2,000 historical human serum specimens from UW Virology, including testing for cross-reactivity specifically against sera positive for IgGs to measles/mumps virus for paramyxoviruses, SARS-CoV-2 and all four endemic coronaviruses, and Ebola/Marburg viruses for filoviruses. Pending results from those specificity tests, we can iterate design of antigens for specific serological testing, including use of specific viral peptides, as required. Sensitivity will be tested against convalescent host animal sera as well as any human sera available from individuals known to be infected. This ELISA kit will then be provided to in-country labs with positive and negative controls, as well as host control proteins for testing for vaccine preventable illnesses (SARS-CoV-2 spike protein for coronaviruses; measles H for paramyxoviruses) and will be compatible with commonly available plate readers. Early in the COVID-19 pandemic, our UW Reference Lab provided recombinant SARS-CoV-2 nucleocapsid along with controls for binding ELISAs to laboratory partners in Senegal, Pakistan, Brazil, South Africa, Nigeria, Kenya, and other countries as part of the NIH CREID consortium. In addition to the binding assays described above, we will use pseudotyped lentivirus and chimeric vesicular

stomatitis virus (VSV) neutralization assays with the novel virus glycoproteins to functionally profile sera for neutralizing antibodies. These assays will benefit from the expertise of Dr. Whelan (WUSTL) and Dr. Veessler (UW) and allow for greater rigor and reproducibility of seropositivity identified by binding ELISA by providing an orthogonal and functional readout. Our primary approach will involve generating chimeric VSV reporter viruses (below). As these assays require cell lines permissive for viral entry, these efforts will create synergy between virus detection (Section 2.2) and characterization (Section 3.3) components.

Task 2.4: Generation of chimeric reporter viruses: We have extensive experience generating chimeric VSV reporter viruses where native viral glycoprotein (spike S, attachment glycoprotein G, fusion F, and hemagglutinin H) is replaced by those of heterologous viruses. Our experience with the coronaviruses indicates that either mutation of the endoplasmic reticulum retention sequence in the cytoplasmic tail of the spike, or truncation of the tail by approximately 20 residues can allow effective integration of the respective Spike gene into VSV, yielding viruses

that grow to titers of 10^8 pfu/ml. For filoviruses, we have not found it necessary to manipulate the cytoplasmic tail of the glycoprotein, although we have mutated the transcriptional editing sequence that is used for synthesis of soluble glycoproteins. Once an infectious clone of VSV-chimeras is assembled, we confirm sequences of the recovered virus, and characterize the growth of the respective viruses to establish the optimal conditions for the generation of seed stocks.

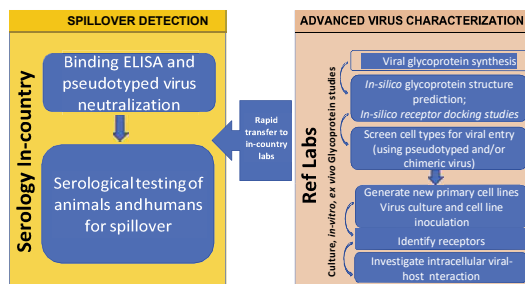


Fig 5. Flow chart for novel virus characterization

Task 2.5: Detection of neutralizing antibodies: We will use VSV-chimeric viruses to monitor levels of neutralizing antibodies in humans and sometimes animals. We are mindful of reports that bats inoculated with some filoviruses do not generate neutralizing antibodies that are detectable in neutralization assays. Accordingly, we will also use the VSV-chimeras to detect antibodies that recognize the respective envelope proteins displayed on the surface of virions. To do this, we will use purified virions that contain the respective envelope proteins on their surface and sera containing antibodies that bind to the virion identified by isolating the bound complexes. As an alternative approach to VSV chimeric viruses, we will use lentivirus-based pseudotyped neutralization assays. Pseudovirus neutralization assays against novel viruses will be optimized for expression and intracellular termini truncations as well as with monoclonal controls. The constructs, controls, and pseudotyped viruses will be made available to in-country partners once the assay is validated by Reference Labs. *These approaches will permit us to determine whether a given animal species has mounted an immune response to the envelope proteins of any novel virus and whether such immune responses include neutralizing antibodies.* The prevalence of such antibody responses may indicate potential risk for spillover into humans, even though low or undetectable antibodies may not mean that a virus is at low risk for human infection. These assays are compatible with BSL-2 settings widely available in in-country labs.

OBJECTIVE 3: Strengthen Characterization of Novel Viruses from Priority Viral Families

3.1. Overall Characterization Strategy

Guided by the understanding that, with timely and complete genome sequencing in Objective 2, >80% of novel virus characterization can be performed in the absence of virus isolation. We will start by characterizing selected novel viruses detected under the PREDICT program and identified as potentially important. Subsequently, we will use sequence data from novel viruses

we detected (Objective 2) to construct qRT-PCR screening kits and recombinantly express and purify viral proteins for reagents development (e.g., monoclonal antibodies) for serological assays and structural studies. We will use these sequences to create pseudotyped and chimeric viruses for serological assays and profiling viral entry. Pseudotyped and chimeric viruses can also be used to identify and screen for receptor usage and identify cell lines that support viral entry. These cell lines can be used to identify other determinants of tropism and to characterize viral entry mechanisms. We will attempt to isolate novel viruses and identify known or novel host genes that enable viral entry. Finally, we will determine the affinity of novel viral glycoproteins for human receptors and mechanisms of innate immunity antagonization to determine zoonotic/ pandemic potential (Fig. 5).

3.2 Profiling Viral Glycoproteins/Receptors to Assess Pandemic Risk of Novel Viruses

Task 3. 1: *In-silico* characterization of novel viruses. Our *in-silico* approach for profiling human transmission risk follows directly from the hypothesis that *affinity for human receptors of a novel viral glycoprotein indicates pandemic potential*. As soon as a novel virus genome is recovered, our UW Reference Lab will perform *in-silico structure prediction* of viral glycoproteins with Rosetta and trRosetta, as well as docking with known receptors for a given viral family to approximate affinity for human receptors. To support this effort, we will model the structures of the extracellular domains of all human proteins and compare these to structures of known host cell viral receptors to determine how closely they match as a way of generating hypotheses **for candidate** human host cell viral entry points. We will interrogate these predicted structures for specific changes in protease site activation. Our ability to determine high- resolution structures of viral glycoprotein-receptor complexes using world-class cryo-EM will be fed back to *in-silico* models to enhance protein structure prediction and viral-host protein-protein interactions. It is worth noting that to-date, no model has successfully predicted viral zoonoses and spread in humans. Therefore, our bias will be to perform as much wet laboratory characterization of novel virus glycoproteins. We will synthesize all viral glycoproteins recovered from novel viral genomes and screen in viral entry, biochemical, and biophysical assays because *in-silico* modelling is insufficient to capture risk.

Task 3.2: Biophysics and structures of viral glycoproteins. Divergent paramyxovirus, filovirus, and coronavirus genomes will be used to carry out structural studies of the corresponding glycoproteins in isolation and bound to target receptors to understand the mechanisms of viral entry into host cells. Our UW Reference Lab is world-renowned for expertise in viral glycoproteins and has developed a streamlined, high-resolution cryo-EM pipeline enabling high-throughput structural studies of viral glycoproteins bound to host receptors and neutralizing antibodies. It will be leveraged to provide atomic-level information of the infection machinery of discovered viral pathogens before they emerge. Novel viral glycoproteins and animal and human receptors will also be expressed and tested directly for binding kinetics and affinity using biolayer interferometry. These affinity measurements will provide biophysical confirmation of receptor interactions and direct biochemical evidence of the degree of pandemic risk of a novel virus. We will correlate binding affinity measurements and functional biochemical measurements of fusogenicity using cell-cell fusion assays.

Task 3.3: Viral isolation-independent viral entry characterization and receptor discovery. The VSV chimeras and pseudoviruses generated above will also be used to perform viral receptor discovery at a BSL-2 level. Previously, our WUSTL Reference Lab has used both VSV

SECURING MTAs FOR SHIPPING SPECIMENS: Our approach is to reduce the number and scope of MTAs. Each in-country lab will only sign one MTA with either UW or WUSTL reference laboratory

and pseudoviruses and a series of cell lines expressing canonical coronavirus receptors to rapidly screen for coronavirus receptor usage and to discover the human receptor of SARS-CoV-2. To establish neutralization assays, VSV chimeras and pseudoviruses will already be tested against a broad array of human, non-human primate, bat, and rodent cell lines that support paramyxovirus, filovirus, and coronavirus growth, including an initial screen of VeroE6, RHMK, CV-1, HAE, HuH-7.5, HEK293, HepG2, CaCo2, BHK (hamster), MEF (mouse), Aji (bat), RhiNi (bat) cell lines. This screen will be performed in the presence and absence of trypsin to determine if host restriction for viral entry exists at the level of proteolytic activation, as previously described for several bat coronaviruses. Canonical receptor usage (e.g., ACE2/DPP4/APN for coronaviruses, NPC1 for filoviruses, or SLAM/EphrinB2/3 for paramyxoviruses) will be confirmed at the protein-level using soluble receptor blocking and/or blocking monoclonal antibodies.

If viral entry into one of the above cell lines is not found to be caused by a known or canonical receptor, we will perform genome-wide CRISPRko screens to discover viral receptors. Using this and related genome-wide approaches, we have identified the receptors for multiple coronaviruses, paramyxoviruses and filoviruses validating this approach. We will carry out such screens to identify host genes that are potential determinants of infection and, armed with that information, we can determine the step of viral infection at which any given host gene functions as described in the rest of the proposal. This will allow us to compare the genomic sequence of entry factors between susceptible and non-susceptible host cells.

3.3 Viral Inhibition of Innate Immunity

Viral antagonization of innate immunity is an important component of viral pathogenesis in humans. Like glycoproteins, viral immuno-evasion proteins are often tailored specifically to the host they infect, and thus the zoonotic and pandemic potential of a new virus will be determined in part by how these genes affect human innate immunity pathways. West Nile and Zika virus spread in humans is in part determined by the degree of inhibition of the JAK/STAT pathway.

Infection in animal host species reservoirs can contribute to viral evolution strategies that facilitate evasion of host innate immunity. Bats have specifically downregulated inflammatory pathways while maintaining type I interferon pathways, leading to a unique evolutionary selection for viral antagonization of type I interferons.

Task 3.4: Testing for the degree of innate immune inhibition: The UW Lab will perform tests by all open reading frames from a novel virus in a host innate immune evasion screening platform. If throughput is limited, at a minimum we will characterize the major immuno-evasion genes from the different viral families. Here, the specific viral protein open reading frame is cloned and expressed ectopically in relevant host cell lines, 24 hours later cells are treated with exogenous interferon (IFN) and harvested over a time course to evaluate for possible reduction in innate immune signalling pathway activation compared to control cells treated with IFN but without ectopic expression of viral genes. Loss of innate immune activation will be evaluated by reduced IFIT1 and IFITM1 gene expression measured by RT-qPCR. We recognize that these approaches are limited to evaluating viral evasion from IFN responses and do not evaluate innate immune signalling components that occur prior to (upstream of) IFN induction. To address this, we will assess the ability of viral protein expression constructs to suppress the activation of interferon regulatory factor (IRF)3 activation induced by Sendai virus infection, a control virus that potently induces innate immune activation in infected cells. We will transfect cells with each viral protein expression construct, followed by infection with Sendai virus, and assess total and phospho/active IRF3 abundance. For a broader analysis of innate immune pathway regulation, we will infect relevant host cell lines with the virus panel of interest and evaluate innate immune

response pathways activated by each specific virus using assays (immunoblot and mRNA analyses) to measure the activation state of specific innate immune pathway markers as well as expression of downstream genes linked to each pathway.

3.4 Virus Isolation for Receptor and Intracellular Viral-Host Interaction Studies

Task 3.5: Viral isolation and receptor identification. As illustrated in Fig. 5, we may require virus isolation to conduct *in vitro* and *ex vivo* studies. Such studies will be conducted in BSL-3 and BSL-4 labs under proper biosafety protocols. Isolation of novel coronaviruses or paramyxoviruses (determined using sequencing data) when there is no concern of severe human disease can be attempted in certified BSL-3 labs located in-country, regionally, or at Reference Labs. Isolation of viruses of great concern of severe disease, such as filoviruses, will only be attempted in Rocky Mountain Laboratories BSL-4 lab (letter of commitment available on request). Positive specimens will be prioritized based on viral load, with a focus on specimens with >1 million copies per mL or gram. We will inoculate virus onto cells shown to be permissive to pseudovirus entry from above. Viral isolates will be expanded and deposited into central repositories with CDC, BEI, and/or WRCEVA, according to the appropriate biosecurity and national data sharing guidelines. Receptor usage determined in the pseudovirus screen will be confirmed using the viral isolate. For isolated novel viruses that do not show canonical receptor usage but cytopathic effect, we will screen for novel human receptors using genome wide CRISPRko libraries in cell lines that support viral growth as described above. Where possible, we will prefer viral isolate CRISPRko screens over pseudotype screens to identify potential intracellular viral-host interactions at the same time as identifying potential receptors.

Task 3.6: Host cell characterization and cell line generation for viral characterization.

Inoculating existing cell lines and primary cells with virus-positive specimens may not result in viral growth. The cell lines chosen may not contain the correct receptors, proteases, or other intracellular factors to support viral entry and/or growth. To support viral isolation and characterization for such viruses, we will generate primary cells from bat, rodent, and NHP tissues that are specifically sampled in DV and identified by host deep sequencing reads in Objective 2. Over the past decade, several new primary bat cell lines have been established that support growth of many viruses of high zoonotic potential *in vitro*, and yet bat species are so diverse that it is likely that no specific cell lines might be available for the bats sampled here. Should the approaches outlined above fail to support viral isolation, we will use scRNA-Seq sequencing of virus-positive primary specimens to help identify candidate host cells and host receptors to be targeted for cell line generation. scRNA-Seq is a powerful approach to link virus transcription and replication on a single cell level with candidate host cells and receptors should existing cell lines prove insufficient. If we are unable to specifically isolate the relevant host cell lines based on scRNA-Seq data, we will ectopically express candidate viral receptors identified by scRNA-Seq data into candidate host cell lines to determine viral receptor usage.

3.5 Algorithm for Ranking Viruses with Pandemic Potential

A proposed algorithm for ranking emerging viruses for potential spillover to humans was recently published by the PREDICT team (<https://spillover.global/ranking-comparison/doi.org/10.1073/pnas.2002324118>). We will improve on this by applying the findings of our innovative and thorough stepwise virus characterization methodologies described in Section 3, and by rating each novel virus based on the following three questions:

- (i) Does the virus have potential for human transmission? This will be investigated using the glycoprotein modeling and functional viral entry studies described above.

- (ii) Is there evidence of its spillover to humans or a broad range of potential animal reservoirs? This will be addressed through serologic testing.
- (iii) Does the virus have capacity to inhibit host innate immunity? Evidence of immunoevasion is consistent with the potential for significant morbidity and/or mortality in humans and should trigger a higher level of public health concern, particularly if the virus rates high on criteria i & ii above.

We will summarize the results in prioritized lists that will be publicly accessible to both in-country partners and international stakeholders. Importantly, our findings, which will be disseminated in scientific publications, presentations, communication with USAID and other stakeholders, will add key metrics to evaluate the zoonotic and pandemic potential of novel viruses.

OBJECTIVE 4: Strengthen Focus Country Capacities for Data Management and the Viral Characterization Process

The proposed project will develop and implement improved data systems at the country and international level, building on learnings from the EIDITH system developed for PREDICT 2, and increasing interoperability and access for partners and stakeholders alike. We will also aim to enhance in-country data collection and use to accelerate detection and response to future public health threats. This will begin with an assessment of the data structure of the EIDITH system, defining a core set of standard variables to be collected across sampling locations for use in describing the distribution of pathogens/exposures. The importance of national-level data autonomy must be balanced with the need for widespread dissemination of data to aid in the prediction and prevention of emerging epidemics. We will work with countries to build on existing systems using an “Adopt-Adapt-Develop” approach while defining protocols for data sharing between the DV and local systems so that project data enhances existing systems while observing local policies and SOPs. The consortium will also draw on previous experience with local and global datasets to advance global surveillance of zoonotic threats. To allow rapid sharing of data across the consortium and with international databases such as NCBI, we will put in place MOUs and data use agreements using a “staged ring” approach, wherein data access can be conceptualized as a series of interlocking rings within which data ownership is retained by in-country stakeholders whilst standardized review, approval, and validation processes allow data to be rapidly shared to key stakeholders at national and international levels. This will ensure that, rather than creating parallel systems, the project builds upon (and integrates into) existing structures and data systems, while ensuring rapid release of validated data to project team, national, and international partners. Pending national approvals, aligned to standardized data sharing agreements supported by DV, and the removal of any sensitive information, data will matriculate across the data management structure, representing gradually more release of data (e.g., USAID staff, external partners, cross-border sharing and full public accessibility). This progression will represent not only increased access but also improved data quality: data sets made available to the public would represent those with well-documented dictionaries and curated metadata, while more incomplete data would remain with project and national stakeholders. In these endeavors, we will build on PREDICT, which has uploaded hundreds of sequences from newly discovered animal pathogens to the NCBI’s Short Read Archive (SRA) and GenBank. With USAID and local stakeholders, we will review and update the data use agreements where PREDICT has been active and use them as models.

4.1 Project Data Collection and Management

Task 4.1: Develop a project-wide data management plan. The consortium will use a data system based on principles of the EIDITH system to collect and manage data among the partners while respecting the need for data safety and ensuring in-country data ownership. This management system has the capability to import data for linkage with surveillance data systems in the host countries, USAID, and global systems such as healthmap, ProMED, NCBI.

Task 4.2 Monitor project implementation. PATH, leading Objective 4 and as a global leader in project monitoring and evaluation, will develop indicators and track project progress via systematic data analysis and review meetings, data quality assessments, technical working groups, and training of data managers at the facility, subnational, and national level.

Task 4.3 Data storage. Following national approvals described in section 4.2, data will be stored within the DV database with data security and access conforming to the FAIR Principles, as well as the Nagoya protocol for genomic data sharing.

4.2 Country Data Management

Task 4.4: Map the data management and policy landscape of each country. In Year 1 an early assessment of existing systems in use at the country and regional levels will be conducted in order to help support and define the architecture, connectivity, flow and human resource capacity to achieve rapid access to quality data at the country level. This assessment will identify gaps and areas that must be strengthened across the continuum from data collection, cleaning, and storage to analysis and presentation to key stakeholders and users and across relevant data sources including laboratory, human and animal clinical, and environmental data sets. This will also entail an extensive evaluation of the enabling environment, including existing health data privacy policies, data use regulations, digital workforce capacity, and information technology infrastructure. The goal is to develop a baseline for each country in terms of existing data agreements, identify adaptations that would enhance data sharing, and understand the policy environment for data sharing and use. Using these assessments, we will develop a roadmap for developing an integrated country-level data architecture with our country partners, including reporting from our DV data system and site- and laboratory-level data collection, as well as ensuring local data sharing through secure, interoperable data exchange.

Task 4.5: Evaluate lab information systems of DV lab and field data collection teams in focus countries. Our consortium will identify the capacity of partner labs in focus countries to support data capture for the project. Similarly, we will ensure that the field data collection teams are trained in data collection according to the data standards that we will extend based on EIDITH/PREDICT. We will build on the existing data structure from in-country data management systems and PREDICT/EIDITH, including sample tagging protocols, geolocation, and survey-based questionnaires.

Task 4.6: Incorporate knowledge and learnings from previous projects. We will use publicly available data, such as PREDICT data available through <https://data.usaid.gov> including readily available country-specific data sets from EIDITH (event animal production, event crop production, animals sampled, event dwellings, event value chain, PCR tests, and site/event characterization) and genomic information available through GenBank in national-level data use and analysis. This will ensure that our project database builds on successes and lessons learned from the EPT project to date. Our data management plan will be able to rapidly incorporate the metadata and genomic data of these samples when they become available.

Task 4.7: Establish data standards and governance. With our in-country partners, we will establish global data standards and assist with establishment of a data warehouse that includes

different collection and management aspects for analyzing, sharing, and storing data. The consortium has previous experience creating similar architecture (the POLIS system for polio eradication and analysis) which has been in use for over eight years. Technical working groups (TWG) will be developed to establish data governance and reporting plans for each target country. These TWG's will conduct regular monitoring of implementation and the assessment of whether goals are being met, while adhering to country needs to try to be more proactive, transparent, to share data rapidly, and be adaptable to addressing issues. We will engage existing standards bodies to ensure that data sharing formats leverage existing works and/or contribute to these standards. This will also address (and ensure) country/regional and local stakeholders' access to genomic/sequencing data from GenBank and other global repositories to build and strengthen research capabilities. We will work with country governments to ensure the timely sharing of information as described, while also recognizing sensitivities around data to avoid stigmatization that could lead to reluctance because of economic and societal pressures.

Task 4.8: Implement data collection using updated data system for focus countries. We will adapt existing technology for the DV digital tool to collect field-based data, including geolocation, animal or plant species, samples collected, unique sample identification, and so on. The tool will be based on an existing technological base, such as CommCare, RedCap or similar, with interfaces for data import, exchange, and interfacing with lab systems. The DV data system will collect necessary data, including accession information for genomic data, connected with sample and location data collected by the DV digital tool.

Task 4.9: Strengthen capacity of in-country partners to store, analyze, and share data. We will train in country partners on use of the DV data system and its linkages with existing in-country data system architecture, work with host governments and data users to identify the key questions they would like to answer with the data, as well intended purposes and requirements, and support implementation of solutions to improve country-level electronic data sharing capacities. Uploading viral sequences to NCBI will also facilitate data exchange between in-country labs and reference labs. We will work to establish harmonized bioinformatics techniques and pipelines across the DV project to ensure comparability of genomic data. User-friendly dashboards including GIS maps to show location of possible priority infectious agents or exposure will be developed to visualize and support interpretation of the data. The consortium will identify "local champions" at the different levels to accelerate this activity. We will work with our in-country partners to publish, supporting their capacity to act as lead authors in internationally recognized journals, and provide training and mentorship in scientific writing.

Task 4.10: Strengthen in-country data management processes for the viral detection and characterization processes. Our consortium will support in-country labs in the focus countries in training the necessary staff on laboratory data management, including genomic data, and to support staff in bioinformatics, monitoring, and maintaining data repositories and architecture.

Task 4.11: Develop an early warning system with country-level dashboards. Learning from tools such as Tableau, DHIS2 dashboards, and other existing AI platforms, by the end of Year 2 we will develop country-level dashboards of DV data to visualize data and identify potential emerging threats based on expert opinion. This will leverage work done under PREDICT 1 and 2 as well as the Spillover data tool (<https://spillover.global>).

4.3 Global Data Sharing

The consortium has identified key data sets to be collected across countries that may require augmentation to in-country systems. Sequencing data will be communicated in as close to real-time as feasible to make this information accessible to the global scientific community, while

also adhering to data governance requirements negotiated with local stakeholders. Sequencing data and correlation with other findings including advanced characterization will also be regularly shared with in-country partners and global stakeholders via published lists of prioritized novel viruses ranked on their pandemic potential. This release of high priority and high-risk pathogens will feed into other risk assessment activities at national and global levels such as STOP Spillover and the proposed WHO Berlin Hub for Pandemic and Epidemic Intelligence. The consortium is already engaging with these stakeholders to cultivate a new model of data solidarity and collaborative intelligence for risk assessment. Another emerging initiative supported by WHO - the International Pathogen Surveillance Network (IPSN) - will also work to support global exchange of genomic information. The consortium will ensure a close integration with and support for IPSN, leveraging this global structure and pathway for R&D. These examples demonstrate opportunities for improved and rapid data sharing in a quickly evolving landscape. The consortium, in collaboration with USAID, will continue to track and engage with these initiatives as appropriate. Wherever possible, the linkages between the consortium data and these international data sharing mechanisms will be built into the project system architecture and part of agreements with national stakeholders.

Task 4.13: Convene multisectoral networks at country and international level. We will build on existing data standards for PREDICT 2 and provide trainings across the consortium and with in-country stakeholders to ensure adherence to data standards.

Task 4.14: Develop improved data sharing processes across data systems at country and international levels and across stakeholders. The project will develop the DV digital tool “esign” – a data-sharing process that supports differing levels of staging and access – with the capability to move data from an internal-only level to internal plus USAID, external partners, and fully public, international levels. While aligning with host country requirements and global guidelines (e.g., WHO’s code of conduct for sharing of pathogen genetic sequence data), our consortium will also ensure appropriate data is made available in a rapid and responsible manner to benefit the global community. In keeping with our “Adopt-Adapt-Develop” approach, we propose a data storage structure that will include three related databases – one for raw sequencing reads, one for assembled data and one for sample metadata. This segregated structure will facilitate real-time reporting of raw sequence data (FASTQ and FASTA) accompanied by limited deidentified metadata to global repositories (NCBI SRA, etc.) while also ensuring that access to sensitive metadata remains restricted until validated and approved for release. This structure will support more routine release of raw sequencing data throughout the duration of the DV project, while enabling local investigators adequate time to complete genome assembly and perform data cleaning and validation prior to submission of finished genome sequences to public domain (NCBI, EMBL-EBI, DDBJ) or public access (e.g. GISAID) repositories, and/or alternative global platforms (e.g., GitHub). Finally, project results and analyses will be regularly communicated via scientific publications, presentations, and direct communication with USAID and other stakeholders. As appropriate, and in accordance with in-country data sharing agreements, outlets will be explored for more rapid dissemination of findings, particularly when novel viruses with high pandemic risk are identified. This includes sharing manuscripts within preprint servers, such as medRxiv or bioRxiv, prior to publication.

5 Capacity Strengthening

A key goal of our DV program is for every activity and outcome to be predicated on a foundation of sustainable capacity strengthening within focus countries. To achieve this, in-country partner organizations will play leading and participatory roles in the development and implementation of

all activities. Further, in-country nationals will coordinate and implement all planned activities, from sample collecting through to laboratory analyses, with language-specific training programs being provided where necessary. Moreover, when planning for the improvements in technical capacity through provision of equipment, care will be taken to ensure the utility of any equipment extends beyond the duration of the program by selecting location-appropriate equipment that can readily be maintained, resourced, and used. This will ensure that during and after the program maximal use is made of the virus detection and characterization capacity that the project will develop. Finally, it is critical that in-country stakeholders understand the value of the knowledge and resources generated. We plan to achieve this in two ways: (1) in-country partners will take leading roles in all aspects of data analysis and the preparation of peer-reviewed publications and (2) the DV project will engage a wide range of in-country stakeholders at project inception to begin the process of raising awareness about the potential value of the generated resources. This process will include multiple fora being hosted within focus countries with a variety of stakeholders to raise awareness of resources that will be generated by the program, and their use (Table 1).

Resource Generated	Resource Uses	Stakeholders
Data from wildlife sampling: species and abundance	Inform conservation efforts	National and international wildlife organizations
Viruses detected in wildlife and domestic animals	Prepare for animal health events	Animal health agencies
Spillover events detected in human populations	Determine risk to humans, control efforts	Human health clinicians, public health
Improved laboratory capacity for qRT-PCR	Improve detection of other infectious diseases	Human health, public health
Improved capacity for ELISA	Improve detection of other infectious diseases	Human health, public health
Improved sequencing and bioinformatics capacity	Application of whole genome sequencing to other pathogens	Laboratories, public health, surveillance

Table 1: Resources generated by the program, their utility, and the stakeholders who will benefit

6 Sample Monitoring and Learning Plan

The WSU-led consortium partners will work with USAID within the first 90 days of the grant to develop a comprehensive Monitoring Evaluation and Learning Plan inclusive of a Learning Agenda and Data Management plan that will describe the processes for monitoring project activities and progress towards achieving the desired results. A comprehensive indicator matrix with output, outcome, and impact indicators, annual and life of project targets, and baseline measures will be at the center of the MEL plan. Table 2 presents illustrative indicators for a subset of intended results and activities under each of the project's 4 objectives, with additional illustrative indicators in Annex 2. Quarterly team check-ins will be used as a venue for Objective Leads to review MEL data with the team to identify areas that are not achieving desired results and flag areas where implementation strategies might need to be adjusted. The team will use MEL data to inform project management and will report semi-annually and annually on progress towards achieving results under the agreed upon indicators in the MEL plan and explain any significant deviations from expected targets. The MEL plan will be reviewed for relevance semi-annually and the WSU-led consortium will work with USAID to revise if and when necessary. The team will collect and analyze data on gender to inform the project's gender action planning to identify opportunities for the project to reduce opportunity gaps between men and women or address power differentials to promote gender equity.

Table 2: Selected illustrative indicators linked to intended results and project activities

Objective 1: Conduct Sampling In Focus Countries For Unknown Viruses From Priority Viral Families		
Intended results	Project Activities/Tasks	Indicators/Milestones
In-country institutional and staff capacity to conduct risk modeling to identify and inform sampling efforts strengthened.	1.7 Capacity Building and Sustainability (cross cutting all Objective 1 activities and tasks)	#/% representatives from in-country wildlife, human, livestock, and environmental health sectors, trained and engaged in risk modeling, sample site and species selection, and sample target setting processes
Key species sampled at research sites.	1.3 Country-level Strategic Sampling	# of wildlife samples collected in each country % of archived wildlife samples of interest screened
Objective 2: Strengthen Detection In Focus Countries For Novel Viruses From The Priority Viral Families		
Detection and genomic sequencing of novel viruses from prospective samples safely conducted.	2.2 Overall Detection Strategy 2.3 Molecular Screening 2.4. Broad Serology Screening	# of in-country labs with instruments that can perform assays with a throughput of 20-22 specimens per 96- well plate or 80-84 specimens per 384-well plate # of genome finishing batches performed using NextSeqor NovaSequequipment in each country
Ability of select in-country laboratories to provide technical assistance and/or detection capabilities for viral discovery in- country and in the region improved.	2.1 Capacity Building and Sustainability	# of labs & # people trained by project on qRT-PCR, serology, next gen sequencing methods, bioinformatics platforms and methods for analysis; % of those trained demonstrating improved competency in new methods; % of laboratory capacity gaps identified in each country that are showing improvement as demonstrated by: % of labs with screening & sequencing instruments
Objective 3: Strengthen Characterization In Focus Countries Of Novel Viruses From Priority Viral Families		
Lab and bioinformatics capacity for characterizing unknown viruses in select in- country institutions strengthened.	3.1. Overall Characterization Strategy	# countries with improved characterization capacity as demonstrated by increased number of novel viruses characterized and fully sequenced by in-country laboratories that have staff who have participated in at least one of the project's capacity building activities.
Objective 4: Strengthen In-Country Capacities For Data Management And Viral Characterization Process		
Newly validated methodologies and protocols, data and analyses associated with viral detection and characterization shared.	4.2 Country Data Management Task 4.9: Strengthen capacity of in-country partners to store, analyze, and share data	# countries with validated protocols for data sharing, MOUs in place; # DV datasets, methodologies, and/or publications made publicly available; # of data managers providing data sets with reliability, accuracy, completeness, consistency and timeliness.

Learning Agenda: Our consortium is committed to utilizing a Collaborating, Learning and Adapting approach to implementing the DV project. The Learning Agenda (LA) will be developed in the first 90 days in collaboration with USAID and in-country technical experts and will be the primary tool for ensuring critical questions that can guide implementation are collaboratively agreed upon and used to inform project implementation. The LA will serve to contextualize project achievements and test assumptions regarding how implemented activities yield intended results. We will review and discuss LA assessments quarterly to ensure learning from identified failures and successes and to improve future implementation. Illustrative LA questions are provided in Table 3. The final LA will include learning activities, timelines, methods and a dissemination plan that will describe key audiences benefitting from the learning

produced by the project and products targeted at those audiences to ensure relevant information is shared back quickly to the right stakeholders in a useful format.

Table 3. Illustrative Learning Agenda questions:	
1	To what extent is the project successfully supporting the timely detection and complete characterization of known and un-known pathogens among the prioritized viral families within the in-country reference laboratories? Which approaches are leading to the most robust implementation in countries and greatest effects on timely detection and complete characterization? And what characteristics, differences or similarities do we see across successful vs. less successful reference laboratories or countries where DV is implemented?
2	What data have the project successfully made available for use by local, regional and global audiences, and how have the data generated by the project supported local, regional and global preparedness and response activities to the targeted viral families? Are the appropriate audiences receiving useful data more rapidly? What barriers are still delaying the processes of sharing data and findings as quickly as possible? And what differences or similarities do we see across countries where DV is implemented vs. Countries where DV is not implemented?
3	<p>a. In which areas of capacity building (a-d below), and with which cadres of the workforce, has the project been successful in strengthening in-country capacity? What capacity building strategies are showing greatest / least impact? What remain the biggest barriers to successfully unlocking in-country capacity? Are project activities leading to unexpected capacity improvements? Laboratory capacity in viral detection and characterization of unknown viruses</p> <p>b. Data management capacity, including data collection, quality, analysis, sharing and storage</p> <p>c. Timely dissemination of actionable data and research findings</p> <p>d. In-country capacity to use data and research findings</p>
4	What existing in-country and global data systems are most successfully being leveraged for sharing DV data to increase likelihood of sustainability and interoperability among sectors? How successful is the project with getting virus sequencing data into those data sources? What facilitators can be leveraged and barriers do we still need to overcome to integrate DV data into sustainable systems?

Mixed methods will be used to answer these learning questions. Desk reviews will compile existing evidence; project monitoring and evaluation data will be used to track progress towards achievement of results within the learning agenda topic areas and incorporate project M&E within the learning. Additional methods for collecting data to answer these learning questions will include surveys, checklists, observations, key informant interviews and review of secondary data extracted from existing databases. Data from these sources will be analyzed to answer these questions, help the project understand what is working, where immediate pivots are needed in current implementation strategies and what learning should be shared more broadly. Data collection tools will be stored in a central repository for re-use and continuous learning during the project and beyond. The plan to disseminate and use findings will differ depending on the learning question. In many cases the first audience will be internal team and management to inform activity planning and work planning. Learning exchange sessions, webinars or workshops will be planned to discuss findings with local experts and decision makers to explore the local context and use of the findings. On a global scale, we will develop white papers, blogs, conference presentations, global learning exchange webinars, or publications for peer review.

[END OF ATTACHMENT B]

ATTACHMENT C – STANDARD PROVISIONS

MANDATORY STANDARD PROVISIONS FOR U.S. NONGOVERNMENTAL ORGANIZATIONS

M1. APPLICABILITY OF 2 CFR 200 and 2 CFR 700 (NOVEMBER 2020)

- a. All provisions of 2 CFR 200 and 2 CFR 700 in effect on the date of this award, and all Standard Provisions attached to this agreement are applicable to the recipient and to subrecipients that meet the definition of “Non-Federal Entity” in part 2 CFR 200.1, unless a section specifically excludes a subrecipient from coverage. The recipient must assure that subrecipients have copies of all the attached standard provisions.
- b. For any subawards made with Non-U.S. subrecipients the recipient must include the applicable “Standard Provisions for Non-US Nongovernmental Organizations.” Recipients are required to ensure compliance with monitoring procedures in accordance with 2 CFR 200 and 2 CFR 700.

[END OF PROVISION]

M2. INELIGIBLE COUNTRIES (MAY 1986)

Unless otherwise approved by the USAID Agreement Officer, funds will only be expended for assistance to countries eligible for assistance under the Foreign Assistance Act of 1961, as amended, or under acts appropriating funds for foreign assistance.

[END OF PROVISION]

M3. NONDISCRIMINATION (JUNE 2012)

No U.S. citizen or legal resident shall be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination on the basis of race, color, national origin, age, disability, or sex under any program or activity funded by this award when work under the grant is performed in the U.S. or when employees are recruited from the U.S.

Additionally, USAID is committed to achieving and maintaining a diverse and representative workforce and a workplace free of discrimination. Based on law, Executive Order, and Agency policy, USAID prohibits discrimination, including harassment, in its own workplace on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, disability, age, veteran’s status, sexual orientation, genetic information, marital status, parental status, political affiliation, and any other conduct that does not adversely affect the performance of the employee.

In addition, the Agency strongly encourages its recipients and their subrecipients and vendors (at all tiers), performing both in the U.S. and overseas, to develop and enforce comprehensive nondiscrimination policies for their workplaces that include protection for all their employees on these expanded bases, subject to applicable law.

[END OF PROVISION]

M4. AMENDMENT OF AWARD (JUNE 2012)

This award may only be amended in writing, by formal amendment or letter, signed by the Agreement Officer (AO), and in the case of a bilateral amendment, by the AO and an authorized official of the recipient.

[END OF PROVISION]

M5. NOTICES (JUNE 2012)

Any notice given by USAID or the recipient is sufficient only if in writing and delivered in person, mailed or e-mailed as follows:

- (1) To the USAID Agreement Officer, at the address specified in this award; or
- (2) To the recipient, at the recipient's address shown in this award, or to such other address specified in this award.

[END OF PROVISION]

M6. SUBAWARDS AND CONTRACTS (DECEMBER 2014)

- a. Subawardees and contractors have no relationship with USAID under the terms of this award. All required USAID approvals must be directed through the recipient to USAID.
- b. Notwithstanding any other term of this award, subawardees and contractors have no right to submit claims directly to USAID and USAID assumes no liability for any third party claims against the recipient.

[END OF PROVISION]

M7. OMB APPROVAL UNDER THE PAPERWORK REDUCTION ACT (DECEMBER 2014)

Information collection requirements imposed by this award are covered by OMB approval number 0412-0510; the current expiration date is 04/30/2005. The Standard Provisions containing the requirement and an estimate of the public reporting burden (including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information) are

<u>Standard Provision</u>	<u>Burden Estimate</u>
Air Travel and Transportation	1 (hour)
Ocean Shipment of Goods	.5
Patent Rights	.5
Publications	.5
Negotiated Indirect Cost Rates - (Predetermined and Provisional)	1
Voluntary Population Planning	.5

Protection of the Individual as a Research Subject 1

<u>22 CFR 200</u>	<u>Burden Estimate</u>
2 CFR 200.318-326, Procurement Standards	1
2 CFR 200.310-315, Property Standards	1.5

Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, may be sent to the Bureau for Management, Office of Acquisition and Assistance, Policy Division (M/OAA/P), U.S. Agency for International Development, Washington, DC 20523 and to the Office of Management and Budget, Paperwork Reduction Project (0412-0510), Washington, DC 20503.

[END OF PROVISION]

M8. USAID ELIGIBILITY RULES FOR GOODS AND SERVICES (MAY 2020)

This provision is not applicable to commodities or services that the recipient provides with private funds as part of a cost-sharing requirement, or with Program Income generated under this award.

- a. Ineligible and Restricted Commodities and Services:
- (1) Ineligible Commodities and Services. The recipient must not, under any circumstances, procure any of the following under this award:
 - (i) Military equipment,
 - (ii) Surveillance equipment,
 - (iii) Commodities and services for support of police or other law enforcement activities,
 - (iv) Abortion equipment and services,
 - (v) Luxury goods and gambling equipment, or
 - (vi) Weather modification equipment.
 - (2) Ineligible Suppliers. Any firms or individuals that do not comply with the requirements in Standard Provision, “Debarment, Suspension and Other Responsibility Matters” and Standard Provision, “Preventing Transactions with, or the Provision of Resources or Support to, Sanctioned Groups and Individuals” must not be used to provide any commodities or services funded under this award.
 - (3) Restricted Commodities. The recipient must obtain prior written approval of the Agreement Officer (AO) or comply with required procedures under an applicable waiver, as provided by the AO when procuring any of the following commodities:
 - (i) Agricultural commodities,
 - (ii) Motor vehicles,

- (iii) Pharmaceuticals,
 - (iv) Pesticides,
 - (v) Used equipment,
 - (vi) U.S. Government-owned excess property, or
 - (vii) Fertilizer.
- b. Source and Nationality:
Except as may be specifically approved in advance by the AO, all commodities and services that will be reimbursed by USAID under this award must be from the authorized geographic code specified in this award and must meet the source and nationality requirements set forth in 22 CFR 228. If the geographic code is not specified, the authorized geographic code is 937. When the total value of procurement for commodities and services during the life of this award is valued at \$250,000 or less, the authorized geographic code for procurement of all goods and services to be reimbursed under this award is code 935. For a current list of countries within each geographic code, see: <http://www.usaid.gov/ads/policy/300/310>.
- c. Guidance on the eligibility of specific commodities and services may be obtained from the AO. If USAID determines that the recipient has procured any commodities or services under this award contrary to the requirements of this provision, and has received payment for such purposes, the AO may require the recipient to refund the entire amount of the purchase.
- d. This provision must be included in all subawards and contracts which include procurement of commodities or services.

[END OF PROVISION]

**M9. DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS
(JUNE 2012)**

- a. The recipient agrees to notify the Agreement Officer (AO) immediately upon learning that it or any of its principals:
 - (1) Are presently excluded or disqualified from covered transactions by any Federal department or agency;
 - (2) Have been convicted within the preceding three-year period preceding this proposal; been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, receiving stolen property, making false claims, or obstruction of justice; commission of any other offense indicating a lack of business integrity or business honesty that seriously and directly affects your present responsibility;
 - (3) Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph a.(2); and
 - (4) Have had one or more public transactions (Federal, State, or local) terminated for cause

or default within the preceding three years.

- b. The recipient agrees that, unless authorized by the AO, it will not knowingly enter into any subawards or contracts under this award with a person or entity that has an active exclusion on the System for Award Management (SAM) (www.sam.gov). The recipient further agrees to include the following provision in any subawards or contracts entered into under this award:

.DEBARMENT, SUSPENSION, INELIGIBILITY, AND VOLUNTARY EXCLUSION
(JUNE 2012)

The recipient/contractor certifies that neither it nor its principals is presently excluded or disqualified from participation in this transaction by any Federal department or agency.

- c. The policies and procedures applicable to debarment, suspension, and ineligibility under USAID-financed transactions are set forth in Subpart C of 2 CFR Section 180, as supplemented by 2 CFR 780.

[END OF PROVISION]

M10. DRUG-FREE WORKPLACE (JUNE 2012)

The recipient must comply with drug-free workplace requirements in subpart B (or subpart C, if the recipient is an individual) of 2 CFR 782, which adopts the Government-wide implementation (2 CFR part 182) of sec. 5152–5158 of the Drug-Free Workplace Act of 1988 (Pub. L. 100–690, Title V, Subtitle D; 41 U.S.C. 701–707).

[END OF PROVISION]

M11. EQUAL PARTICIPATION BY FAITH-BASED ORGANIZATIONS (JUNE 2016)

a. Faith-Based Organizations Encouraged

Faith-based organizations are eligible, on the same basis as any other organization, to participate in any USAID program for which they are otherwise eligible. Neither USAID nor entities that make and administer subawards of USAID funds shall discriminate for or against an organization on the basis of the organization's religious character or affiliation. Additionally, religious organizations shall not be disqualified from participating in USAID programs because such organizations are motivated or influenced by religious faith to provide social services, or because of their religious character or affiliation.

Decisions about awards of USAID financial assistance must be free from political interference or even the appearance of such interference. Awards must be made on the basis of merit, not the basis of the religious affiliation of an applicant, or lack thereof. A faith-based organization may continue to carry out its mission, including the definition, development, practice, and expression of its religious beliefs, within the limits contained in this provision. For more information, see the [USAID Faith-Based and Community Initiatives Web site](#) and [22 CFR 205.1](#).

b. Explicitly Religious Activities Prohibited.

- (1)** Explicitly religious activities include activities that involve overt religious content such as worship, religious instruction, prayer, or proselytization.
 - (2)** The recipient must not engage in explicitly religious activities as part of the programs or services directly funded with financial assistance from USAID. If the recipient engages in explicitly religious activities, the activities must be offered separately, in time or location, from any programs or services directly funded by this award, and participation must be voluntary for beneficiaries of the programs or services funded with USAID assistance.
 - (3)** These restrictions apply equally to religious and secular organizations. All organizations that participate in USAID programs, as recipients or subawardees, including religious ones, must carry out eligible activities in accordance with all program requirements and other applicable requirements governing USAID-funded activities.
 - (4)** Notwithstanding the restrictions of b.(1) and (2), a religious organization that participates in USAID-funded programs or services:
 - (i)** May retain its independence and may continue to carry out its mission, including the definition, development, practice, and expression of its religious beliefs, provided that it does not use direct financial assistance from USAID to support or engage in any explicitly religious activities or in any other manner prohibited by law;
 - (ii)** May use space in its facilities, without removing religious art, icons, scriptures, or other religious symbols; and
 - (iii)** May retain its authority over its internal governance, and may retain religious terms in its organization's name, select its board members on a religious basis, and include religious references in its organization's mission statements and other governing documents.
- c.** Implementation in accordance with the Establishment Clause: Nothing in this provision shall be construed as authorizing the use of USAID funds for activities that are not permitted by Establishment Clause jurisprudence or otherwise by law.
- d.** Discrimination Based on Religion Prohibited: The recipient must not, in providing services, discriminate against a program beneficiary or potential program beneficiary on the basis of religion or religious belief, refusal to hold a religious belief, or a refusal to attend or participate in a religious practice.
- e.** A religious organization's exemption from the Federal prohibition on employment discrimination on the basis of religion, set forth in Sec. 702(a) of the Civil Rights Act of

1964, 42 U.S.C. 2000e–1 is not forfeited when the organization receives financial assistance from USAID.

- f. The Secretary of State may waive the requirements of this section in whole or in part, on a case-by-case basis, where the Secretary determines that such waiver is necessary to further the national security or foreign policy interests of the United States.
- g. This provision must be included in all subawards under this award.

[END OF PROVISION]

M12. PREVENTING TRANSACTIONS WITH, OR THE PROVISION OF RESOURCES OR SUPPORT TO, SANCTIONED GROUPS AND INDIVIDUALS (MAY 2020)

- a. In carrying out activities under this award, except as authorized by a license issued by the Office of Foreign Assets Control (OFAC) of the U.S. Department of Treasury, the recipient will not engage in transactions with, or provide resources or support to, any individual or entity that is subject to sanctions administered by OFAC or the United Nations (UN), including any individual or entity that is included on the Specially Designated Nationals and Blocked Persons List maintained by OFAC (<https://www.treasury.gov/resource-center/sanctions/SDNList/Pages/default.aspx>) or on the UN Security Council consolidated list (<https://www.un.org/securitycouncil/content/un-sc-consolidated-list>).
- b. Any violation of the above will be grounds for unilateral termination of the agreement by USAID.
- c. The Recipient must include this provision in all subawards and contracts issued under this award.

[END OF PROVISION]

M13. MARKING AND PUBLIC COMMUNICATIONS UNDER USAID-FUNDED ASSISTANCE (DECEMBER 2014)

- a. The USAID Identity is the official marking for USAID, comprised of the USAID logo and landmark with the tagline “from the American people,” unless amended by USAID to include additional or substitute use of a logo or seal and tagline representing a presidential initiative or other high level interagency initiative. The USAID Identity (including any required presidential initiative or related identity) is on the USAID Web site at www.usaid.gov/branding. Recipients must use the USAID Identity, of a size and prominence equivalent to or greater than any other identity or logo displayed, to mark the following:
 - (1) Programs, projects, activities, public communications, and commodities partially or fully funded by USAID;
 - (2) Program, project, or activity sites funded by USAID, including visible infrastructure projects or other physical sites;

- (3) Technical assistance, studies, reports, papers, publications, audio-visual productions, public service announcements, Web sites/Internet activities, promotional, informational, media, or communications products funded by USAID;
 - (4) Commodities, equipment, supplies, and other materials funded by USAID, including commodities or equipment provided under humanitarian assistance or disaster relief programs; and
 - (5) Events financed by USAID, such as training courses, conferences, seminars, exhibitions, fairs, workshops, press conferences and other public activities. If the USAID Identity cannot be displayed, the recipient is encouraged to otherwise acknowledge USAID and the support of the American people.
- b. The recipient must implement the requirements of this provision following the approved Marking Plan in the award.
 - c. The AO may require a preproduction review of program materials and “public communications” (documents and messages intended for external distribution, including but not limited to correspondence; publications; studies; reports; audio visual productions; applications; forms; press; and promotional materials) used in connection with USAID-funded programs, projects or activities, for compliance with an approved Marking Plan.
 - d. The recipient is encouraged to give public notice of the receipt of this award and announce progress and accomplishments. The recipient must provide copies of notices or announcements to the Agreement Officer’s Representative (AOR) and to USAID’s Office of Legislative and Public Affairs in advance of release, as practicable. Press releases or other public notices must include a statement substantially as follows:

“The U.S. Agency for International Development administers the U.S. foreign assistance program providing economic and humanitarian assistance in more than 80 countries worldwide.”
 - e. Any “public communication” in which the content has not been approved by USAID must contain the following disclaimer:

“This study/report/audio/visual/other information/media product (specify) is made possible by the generous support of the American people through the United States Agency for International Development (USAID). The contents are the responsibility of [insert recipient name] and do not necessarily reflect the views of USAID or the United States Government.”
 - f. The recipient must provide the USAID AOR with two copies of all program and communications materials produced under this award.
 - g. The recipient may request an exception from USAID marking requirements when USAID

marking requirements would:

- (1) Compromise the intrinsic independence or neutrality of a program or materials where independence or neutrality is an inherent aspect of the program and materials;
 - (2) Diminish the credibility of audits, reports, analyses, studies, or policy recommendations whose data or findings must be seen as independent;
 - (3) Undercut host-country government “ownership” of constitutions, laws, regulations, policies, studies, assessments, reports, publications, surveys or audits, public service announcements, or other communications;
 - (4) Impair the functionality of an item;
 - (5) Incur substantial costs or be impractical;
 - (6) Offend local cultural or social norms, or be considered inappropriate; or
 - (7) Conflict with international law.
- h. The recipient may submit a waiver request of the marking requirements of this provision or the Marking Plan, through the AOR, when USAID-required marking would pose compelling political, safety, or security concerns, or have an adverse impact in the cooperating country.
- (1) Approved waivers “flow down” to subawards and contracts unless specified otherwise. The waiver may also include the removal of USAID markings already affixed, if circumstances warrant.
 - (2) USAID determinations regarding waiver requests are subject to appeal by the recipient, by submitting a written request to reconsider the determination to the cognizant Assistant Administrator.
- i. The recipient must include the following marking provision in any subawards entered into under this award:

“As a condition of receipt of this subaward, marking with the USAID Identity of a size and prominence equivalent to or greater than the recipient’s, subrecipient’s, other donor’s, or third party’s is required. In the event the recipient chooses not to require marking with its own identity or logo by the subrecipient, USAID may, at its discretion, require marking by the subrecipient with the USAID Identity.”

[END OF PROVISION]

M14. REGULATIONS GOVERNING EMPLOYEES (JUNE 2018)

- a. While working overseas, the recipient's employees who are not citizens of the cooperating

country must maintain private status, and may not rely on local U.S. Government offices or facilities for support while under this award.

- b. The sale of personal property or automobiles by the recipient's non-cooperating country citizen employees and their dependents in the foreign country to which they are assigned, are subject to the same limitations and prohibitions that apply to direct-hire USAID personnel employed by the Mission, including the rules contained in 22 CFR 136, except as this may conflict with host government regulations.
- c. Other than work to be performed under this award for which an employee is assigned by the recipient, employees of the recipient who are not citizens of the cooperating country must not engage directly or indirectly, either in the individual's own name or in the name or through an agency of another person, in any business, profession, or occupation in the foreign countries to which the individual is assigned. In addition, the individual must not make loans or investments to or in any business, profession, or occupation in the foreign countries to which the individual is assigned.
- d. The recipient's employees who are not citizens of the cooperating country, while in a foreign country, are expected to show respect for its conventions, customs, and institutions, to abide by its applicable laws and regulations, and not to interfere in its internal political affairs.
- e. In accordance with the internal control requirements in 2 CFR 200.303, which require the recipient to establish standards of conduct for its employees, the recipient must ensure that all its employees adhere to these standards of conduct in a manner consistent with the standards for United Nations (UN) employees in Section 3 of the UN Secretary-General's Bulletin - Special Measures for Protection from Sexual Exploitation and Sexual Abuse (ST/SGB/2003/13).
- f. If the recipient determines that the conduct of any recipient employee is not in accordance with the preceding paragraphs, the recipient's Chief of Party must consult with the Agreement Officer and the USAID Mission Director, and the employee involved, and must recommend to the recipient a course of action with regard to such employee.
- g. The parties recognize the rights of the U.S. Ambassador to direct the removal from a country of any U.S. citizen, or the discharge from this award of any individual (U.S., third-country, or cooperating-country national) when, in the discretion of the Ambassador, the interests of the United States so require.
- h. If it is determined, under paragraph (f) or (g) above, that the services of such employee should be terminated, the recipient must use its best efforts to cause the return of such employee to the United States, or third-country point of origin, as appropriate, and replace the employee with an acceptable substitute at no cost to USAID.
- i. Any matters relating to subrecipients, including the employees of subrecipients, must be coordinated through the recipient's Chief of Party.

[END OF PROVISION]

**M15. CONVERSION OF UNITED STATES DOLLARS TO LOCAL CURRENCY
(NOVEMBER 1985)**

(This provision applies when activities are undertaken outside the United States.)

Upon arrival in the cooperating country, and from time to time as appropriate, the recipient's chief of party must consult with the Mission Director who must provide, in writing, the procedure the recipient and its employees must follow in the conversion of United States dollars to local currency. This may include, but is not limited to, the conversion of currency through the cognizant United States Disbursing Officer or Mission Controller, as appropriate.

[END OF PROVISION]

M16. USE OF POUCH FACILITIES (AUGUST 1992)

(This provision applies when activities are undertaken outside the United States.)

- a. Use of diplomatic pouch is controlled by the Department of State. The Department of State has authorized the use of pouch facilities for USAID recipients and their employees as a general policy, as detailed in items (1) through (6) below. However, the final decision regarding use of pouch facilities rest with the Embassy or USAID Mission. In consideration of the use of pouch facilities, the recipient and its employees agree to indemnify and hold harmless, the Department of State and USAID for loss or damage occurring in pouch transmission:
 - (1) Recipients and their employees are authorized use of the pouch for transmission and receipt of up to a maximum of .9 kgs per shipment of correspondence and documents needed in the administration of assistance programs.
 - (2) U.S. citizen employees are authorized use of the pouch for personal mail up to a maximum of .45 kgs per shipment (but see a.(3) below).
 - (3) Merchandise, parcels, magazines, or newspapers are not considered to be personal mail for purposes of this standard provision and are not authorized to be sent or received by pouch.
 - (4) Official and personal mail pursuant to a.(1) and (2) above sent by pouch should be addressed as follows:

Name of individual or organization (followed by
letter symbol "G")
City Name of post (USAID/_____)
Agency for International Development
Washington, DC 20523-0001
 - (5) Mail sent via the diplomatic pouch may not be in violation of U.S. Postal laws and may

not contain material ineligible for pouch transmission.

(6) Recipient personnel are NOT authorized use of military postal facilities (APO/FPO). This is an Adjutant General's decision based on existing laws and regulations governing military postal facilities and is being enforced worldwide.

- b. The recipient is responsible for advising its employees of this authorization, these guidelines, and limitations on use of pouch facilities.
- c. Specific additional guidance on grantee use of pouch facilities in accordance with this standard provision is available from the Post Communication Center at the Embassy or USAID Mission.

[END OF PROVISION]

M17. TRAVEL AND INTERNATIONAL AIR TRANSPORTATION (DECEMBER 2014)

a. TRAVEL COSTS

All travel costs must comply with the applicable cost principles and must be consistent with those normally allowed in like circumstances in the recipient's non-USAID-funded activities. Costs incurred by employees and officers for travel, including air fare, costs of lodging, other subsistence, and incidental expenses, may be considered reasonable and allowable only to the extent such costs do not exceed reasonable charges normally allowed by the recipient in its regular operations as the result of the recipient organization's written travel policy and are within the limits established by the applicable cost principles.

In the absence of a reasonable written policy regarding international travel costs, the standard for determining the reasonableness of reimbursement for international travel costs will be the Standardized Regulations (Government Civilians, Foreign Areas), published by the U.S. Department of State, as from time to time amended. The most current Standardized Regulations on international travel costs may be obtained from the AO. In the event that the cost for air fare exceeds the customary standard commercial airfare (coach or equivalent) or the lowest commercial discount airfare, the recipient must document one of the allowable exceptions from the applicable cost principles.

b. FLY AMERICA ACT RESTRICTIONS

- (1) The recipient must use U.S. Flag Air Carriers for all international air transportation (including personal effects) funded by this award pursuant to the Fly America Act and its implementing regulations to the extent service by such carriers is available.
- (2) In the event that the recipient selects a carrier other than a U.S. Flag Air Carrier for international air transportation, in order for the costs of such international air transportation to be allowable, the recipient must document such transportation in accordance with this provision and maintain such documentation pursuant to the

Standard Provision, “Accounting, Audit and Records.” The documentation must use one of the following reasons or other exception under the Fly America Act:

- (i) The recipient uses a European Union (EU) flag air carrier, which is an airline operating from an EU country that has signed the US-EU “Open Skies” agreement (<http://www.state.gov/e/eb/rls/othr/ata/i/ic/170684.htm>).
- (ii) Travel to or from one of the following countries on an airline of that country when no city pair fare is in effect for that leg (see <http://apps.fas.gsa.gov/citypairs/search/>):
 - a. Australia on an Australian airline,
 - b. Switzerland on a Swiss airline, or
 - c. Japan on a Japanese airline;
- (iii) Only for a particular leg of a route on which no US Flag Air Carrier provides service on that route;
- (iv) For a trip of 3 hours or less, the use of a US Flag Air Carrier at least doubles the travel time;
- (v) If the US Flag Air Carrier offers direct service, use of the US Flag Air Carrier would increase the travel time by more than 24 hours; or
- (vi) If the US Flag Air Carrier does not offer direct service,
 - a. Use of the US Flag Air Carrier increases the number of aircraft changes by 2 or more,
 - b. Use of the US Flag Air Carrier extends travel time by 6 hours or more, or
 - c. Use of the US Flag Air Carrier requires a layover at an overseas interchange of 4 hours or more.

c. DEFINITIONS

The terms used in this provision have the following meanings:

- (1) “Travel costs” means expenses for transportation, lodging, subsistence (meals and incidentals), and related expenses incurred by employees who are on travel status on official business of the recipient for any travel outside the country in which the organization is located. “Travel costs” do not include expenses incurred by employees who are not on official business of the recipient, such as rest and recuperation (R&R) travel offered as part of an employee’s benefits package that are consistent with the recipient’s personnel and travel policies and procedures.

- (2) "International air transportation" means international air travel by individuals (and their personal effects) or transportation of cargo by air between a place in the United States and a place outside thereof, or between two places both of which are outside the United States.
- (3) "U.S. Flag Air Carrier" means an air carrier on the list issued by the U.S. Department of Transportation at <http://ostpxweb.dot.gov/aviation/certific/certlist.htm>. U.S. Flag Air Carrier service also includes service provided under a code share agreement with another air carrier when the ticket, or documentation for an electronic ticket, identifies the U.S. flag air carrier's designator code and flight number.
- (4) For this provision, the term "United States" includes the fifty states, Commonwealth of Puerto Rico, possessions of the United States, and the District of Columbia.

d. SUBAWARDS AND CONTRACTS

This provision must be included in all subawards and contracts under which this award will finance international air transportation.

[END OF PROVISION]

M18. OCEAN SHIPMENT OF GOODS (JUNE 2012)

- a. Prior to contracting for ocean transportation to ship goods purchased or financed with USAID funds under this award, the recipient must contact the office below to determine the flag and class of vessel to be used for shipment:

U.S. Agency for International Development,
Bureau for Management
Office of Acquisition and Assistance, Transportation Division
1300 Pennsylvania Avenue, NW
Washington, DC 20523
Email: oceantransportation@usaid.gov

- b. This provision must be included in all subawards and contracts.

[END OF PROVISION]

M19. VOLUNTARY POPULATION PLANNING ACTIVITIES – MANDATORY REQUIREMENTS (MAY 2006)

Requirements for Voluntary Sterilization Programs

- (1) Funds made available under this award must not be used to pay for the performance of involuntary sterilization as a method of family planning or to coerce or provide any financial incentive to any individual to practice sterilization.

Prohibition on Abortion-Related Activities:

- (1) No funds made available under this award will be used to finance, support, or be attributed to the following activities: (i) procurement or distribution of equipment intended to be used for the purpose of inducing abortions as a method of family planning; (ii) special fees or incentives to any person to coerce or motivate them to have abortions; (iii) payments to persons to perform abortions or to solicit persons to undergo abortions; (iv) information, education, training, or communication programs that seek to promote abortion as a method of family planning; and (v) lobbying for or against abortion. The term “motivate,” as it relates to family planning assistance, must not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options.
- (2) No funds made available under this award will be used to pay for any biomedical research which relates, in whole or in part, to methods of, or the performance of, abortions or involuntary sterilizations as a means of family planning. Epidemiologic or descriptive research to assess the incidence, extent or consequences of abortions is not precluded.

[END OF PROVISION]

M20. TRAFFICKING IN PERSONS (April 2016)

- a. The recipient, subawardee, or contractor, at any tier, or their employees, labor recruiters, brokers or other agents, must not engage in:
 - (1) Trafficking in persons (as defined in the Protocol to Prevent, Suppress, and Punish Trafficking in Persons, especially Women and Children, supplementing the UN Convention against Transnational Organized Crime) during the period of this award;
 - (2) Procurement of a commercial sex act during the period of this award;
 - (3) Use of forced labor in the performance of this award;
 - (4) Acts that directly support or advance trafficking in persons, including the following acts:
 - i. Destroying, concealing, confiscating, or otherwise denying an employee access to that employee's identity or immigration documents;
 - ii. Failing to provide return transportation or pay for return transportation costs to an employee from a country outside the United States to the country from which the employee was recruited upon the end of employment if requested by the employee, unless:
 - a) exempted from the requirement to provide or pay for such return transportation by USAID under this award; or

- b) the employee is a victim of human trafficking seeking victim services or legal redress in the country of employment or a witness in a human trafficking enforcement action;
 - iii. Soliciting a person for the purpose of employment, or offering employment, by means of materially false or fraudulent pretenses, representations, or promises regarding that employment;
 - iv. Charging employees recruitment fees; or
 - v. Providing or arranging housing that fails to meet the host country housing and safety standards.
- b. In the event of a violation of section (a) of this provision, USAID is authorized to terminate this award, without penalty, and is also authorized to pursue any other remedial actions authorized as stated in section 1704(c) of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112-239, enacted January 2, 2013).
- c. If the estimated value of services required to be performed under the award outside the United States exceeds \$500,000, the recipient must submit to the Agreement Officer, the annual “Certification regarding Trafficking in Persons, Implementing Title XVII of the National Defense Authorization Act for Fiscal Year 2013” as required prior to this award, and must implement a compliance plan to prevent the activities described above in section (a) of this provision. The recipient must provide a copy of the compliance plan to the Agreement Officer upon request and must post the useful and relevant contents of the plan or related materials on its website (if one is maintained) and at the workplace.
- d. The recipient’s compliance plan must be appropriate to the size and complexity of the award and to the nature and scope of the activities, including the number of non-United States citizens expected to be employed. The plan must include, at a minimum, the following:
 - (1) An awareness program to inform employees about the trafficking related prohibitions included in this provision, the activities prohibited and the action that will be taken against the employee for violations.
 - (2) A reporting process for employees to report, without fear of retaliation, activity inconsistent with the policy prohibiting trafficking, including a means to make available to all employees the Global Human Trafficking Hotline at 1-844-888-FREE and its e-mail address at help@befree.org.
 - (3) A recruitment and wage plan that only permits the use of recruitment companies with trained employees, prohibits charging of recruitment fees to the employee, and ensures that wages meet applicable host-country legal requirements or explains any variance.

- (4) A housing plan, if the recipient or any subawardee intends to provide or arrange housing. The housing plan is required to meet any host-country housing and safety standards.
 - (5) Procedures for the recipient to prevent any agents or subawardee at any tier and at any dollar value from engaging in trafficking in persons activities described in section a of this provision. The recipient must also have procedures to monitor, detect, and terminate any agents or subawardee or subawardee employees that have engaged in such activities.
- e. If the Recipient receives any credible information regarding a violation listed in section a(1)-(4) of this provision, the recipient must immediately notify the cognizant Agreement Officer and the USAID Office of the Inspector General; and must fully cooperate with any Federal agencies responsible for audits, investigations, or corrective actions relating to trafficking in persons.
 - f. The Agreement Officer may direct the Recipient to take specific steps to abate an alleged violation or enforce the requirements of a compliance plan.
 - g. For purposes of this provision, “employee” means an individual who is engaged in the performance of this award as a direct employee, consultant, or volunteer of the recipient or any subrecipient.
 - h. The recipient must include in all subawards and contracts a provision prohibiting the conduct described in section a(1)-(4) by the subrecipient, contractor, or any of their employees, or any agents. The recipient must also include a provision authorizing the recipient to terminate the award as described in section b of this provision.

[END OF PROVISION]

M21. SUBMISSIONS TO THE DEVELOPMENT EXPERIENCE CLEARINGHOUSE AND PUBLICATIONS (JUNE 2012)

- a. Submissions to the Development Experience Clearinghouse (DEC).
 - 1) The recipient must provide the Agreement Officer’s Representative one copy of any Intellectual Work that is published, and a list of any Intellectual Work that is not published.
 - 2) In addition, the recipient must submit Intellectual Work, whether published or not, to the DEC, either on-line (preferred) or by mail. The recipient must review the DEC Web site for submission instructions, including document formatting and the types of documents to submit. Submission instructions can be found at: <http://dec.usaid.gov>.

- 3) For purposes of submissions to the DEC, Intellectual Work includes all works that document the implementation, evaluation, and results of international development assistance activities developed or acquired under this award, which may include program and communications materials, evaluations and assessments, information products, research and technical reports, progress and performance reports required under this award (excluding administrative financial information), and other reports, articles and papers prepared by the recipient under the award, whether published or not. The term does not include the recipient's information that is incidental to award administration, such as financial, administrative, cost or pricing, or management information.
 - 4) Each document submitted should contain essential bibliographic information, such as 1) descriptive title; 2) author(s) name; 3) award number; 4) sponsoring USAID office; 5) development objective; and 6) date of publication.
 - 5) The recipient must not submit to the DEC any financially sensitive information or personally identifiable information, such as social security numbers, home addresses and dates of birth. Such information must be removed prior to submission. The recipient must not submit classified documents to the DEC.
- b. In the event award funds are used to underwrite the cost of publishing, in lieu of the publisher assuming this cost as is the normal practice, any profits or royalties up to the amount of such cost must be credited to the award unless the schedule of the award has identified the profits or royalties as program income.

[END OF PROVISION]

M22. LIMITING CONSTRUCTION ACTIVITIES (AUGUST 2013)

- a) Construction is not eligible for reimbursement under this award unless specifically identified in paragraph d) below.
- b) Construction means —construction, alteration, or repair (including dredging and excavation) of buildings, structures, or other real property and includes, without limitation, improvements, renovation, alteration and refurbishment. The term includes, without limitation, roads, power plants, buildings, bridges, water treatment facilities, and vertical structures.
- c) Agreement Officers will not approve any subawards or procurements by recipients for construction activities that are not listed in paragraph d) below. USAID will reimburse allowable costs for only the construction activities listed in this provision not to exceed the amount specified in the construction line item of the award budget. The recipient must receive prior written approval from the AO to transfer funds allotted for construction activities to other cost categories, or vice versa.
- d) Description

Construction is not eligible for reimbursement under this award.

- e) The recipient must include this provision in all subawards and procurements and make vendors providing services under this award and subrecipients aware of the restrictions of this provision.

[END OF PROVISION]

M23. USAID IMPLEMENTING PARTNER NOTICES (IPN) PORTAL FOR ASSISTANCE (JULY 2014)

(a) Definitions

“USAID Implementing Partner Notices (IPN) Portal for Assistance (“IPN Portal)” means the single point where USAID posts proposed universal bilateral amendments for USAID awards, which can be accessed electronically by registered USAID recipients. The IPN Portal is located at <https://sites.google.com/site/usaaidipnforassistance/>. Universal amendments are those which affect all assistance awards or a designated class of awards as specified in each amendment by the IPN Portal Administrator.

“IPN Portal Administrator” means the USAID official designated by the Director, M/OAA, who has overall responsibility for managing the USAID Implementing Partner Notices Portal for Assistance.

“Universal bilateral amendment” means those amendments with revisions or new requirements or provisions that affect all awards or a designated class of awards, as specified in the Agency notification of such revisions or new requirements.

- (b)** By submission of an application and execution of an award, the Applicant/Recipient acknowledges the requirement to:

- (1)** Register with the IPN Portal if awarded an assistance award resulting from this solicitation, and
- (2)** Receive universal bilateral amendments to this award and general notices via the IPN Portal.

- (c)** Procedure to register for notifications.

Go to <https://sites.google.com/site/usaaidipnforassistance/> and click the “Register” button at the top of the page. Recipient representatives must use their official organization email address when subscribing, not personal email addresses.

- (d)** Processing of IPN Portal Amendments

The Recipient may access the IPN Portal at any time to review all IPN Portal amendments; however, the system will also notify the Recipient by email when the USAID IPN Portal Administrator posts a universal bilateral amendment for Recipient's review and signature. Proposed USAID IPN Portal amendments distributed via the IPN Portal are applicable to all awards, unless otherwise noted in the proposed amendment.

Within 15 calendar days from receipt of the notification email from the IPN Portal, the Recipient must do one of the following:

- (1) (a) verify applicability of the proposed amendment for their award(s) per the instructions provided with each amendment; (b) download the amendment and incorporate the following information on the amendment form: award number, organization name, and organization mailing address as it appears in the basic award; (c) sign the hardcopy version; and (d) send the signed amendment (by email or hardcopy) to the AO for signature. The Recipient must not incorporate any other changes to the IPN Portal amendment. Bilateral amendments provided through the IPN Portal are not effective until the both the Recipient and the AO sign the amendment;
- (2) Notify the AO in writing if the amendment requires negotiation of additional changes to terms and conditions of the award; or
- (3) Notify the AO that the Recipient declines to sign the amendment.

Within 30 calendar days of receipt of a signed amendment from the Recipient, the AO must provide the fully executed amendment to the Recipient or initiate discussions with the Recipient.

[END OF PROVISION]

M24. PILOT PROGRAM FOR ENHANCEMENT OF GRANTEE EMPLOYEE WHISTLEBLOWER PROTECTIONS (SEPTEMBER 2014)

The requirement to comply with and inform all employees of the "Pilot Program for Enhancement of Contractor Employee Whistleblower Protections" is retroactively effective for all assistance awards and subawards (including subcontracts) issued beginning July 1, 2013.

The Grantee must:

1. Inform its employees working under this award in the predominant native language of the workforce that they are afforded the employee whistleblower rights and protections provided under 41 U.S.C. § 4712; and
2. Include such requirement in any subaward or subcontract made under this award.

41 U.S.C. § 4712 states that an employee of a Grantee may not be discharged, demoted, or otherwise discriminated against as a reprisal for "whistleblowing." In addition, whistleblower protections cannot be waived by any agreement, policy, form, or condition of employment.

Whistleblowing is defined as making a disclosure "that the employee reasonably believes" is evidence of any of the following:

- Gross mismanagement of a Federal contract or grant;
- A gross waste of Federal funds;
- An abuse of authority relating to a Federal contract or grant;
- A substantial and specific danger to public health or safety; or
- A violation of law, rule, or regulation related to a Federal contract or grant (including the competition for, or negotiation of, a contract or grant).

To qualify under the statute, the employee's disclosure must be made to:

- A Member of the U.S. Congress, or a representative of a U.S. Congressional Committee;
- A cognizant U.S. Inspector General;
- The U.S. Government Accountability Office;
- A Federal employee responsible for contract or grant oversight or management at the relevant agency;
- A U.S. court or grand jury; or,
- A management official or other employee of the Grantee who has the responsibility to investigate, discover, or address misconduct.

[END OF PROVISION]

M25. SUBMISSION OF DATASETS TO THE DEVELOPMENT DATA LIBRARY (OCTOBER 2014)

a. Definitions. For the purpose of submissions to the DDL:

- (1) "Dataset" is an organized collection of structured data, including data contained in spreadsheets, whether presented in tabular or non-tabular form. For example, a Dataset may represent a single spreadsheet, an extensible mark-up language (XML) file, a geospatial data file, or an organized collection of these. This requirement does not apply to aggregated performance reporting data that the recipient submits directly to a USAID portfolio management system or to unstructured data, such as email messages, PDF files, PowerPoint presentations, word processing documents, photos and graphic images, audio files, collaboration software, and instant messages. Neither does the requirement apply to the recipient's information that is incidental to award administration, such as financial, administrative, cost or pricing, or management information. Datasets submitted to the DDL will generally be those generated with USAID resources and created in support of Intellectual Work that is uploaded to the Development Experience Clearinghouse (DEC) (See M21. SUBMISSIONS TO THE DEVELOPMENT EXPERIENCE CLEARINGHOUSE AND PUBLICATIONS (JUNE 2012)).

- (2) “Intellectual Work” includes all works that document the implementation, monitoring, evaluation, and results of international development assistance activities developed or acquired under this award, which may include program and communications materials, evaluations and assessments, information products, research and technical reports, progress and performance reports required under this award (excluding administrative financial information), and other reports, articles and papers prepared by the recipient under the award, whether published or not. The term does not include the recipient’s information that is incidental to award administration, such as financial, administrative, cost or pricing, or management information.

b. Submissions to the Development Data Library (DDL)

- (1) The recipient must submit to the Development Data Library (DDL) at www.usaid.gov/data, in a machine-readable, non-proprietary format, a copy of any Dataset created or obtained in performance of this award, including Datasets produced by a subawardee or a contractor at any tier. The submission must include supporting documentation describing the Dataset, such as code books, data dictionaries, data gathering tools, notes on data quality, and explanations of redactions.
- (2) Unless otherwise directed by the Agreement Officer (AO) or the Agreement Officer Representative (AOR), the recipient must submit the Dataset and supporting documentation to the DDL within thirty (30) calendar days after the Dataset is first used to produce an Intellectual Work or is of sufficient quality to produce an Intellectual Work. Within thirty (30) calendar days after award completion, the recipient must submit to the DDL any Datasets and supporting documentation that have not previously been submitted to the DDL, along with an index of all Datasets and Intellectual Work created or obtained under the award. The recipient must also provide to the AOR an itemized list of any and all DDL submissions.

The recipient is not required to submit the data to the DDL, when, in accordance with the terms and conditions of this award, Datasets containing results of federally funded scientific research are submitted to a publicly accessible research database. However, the recipient must submit a notice to the DDL by following the instructions at www.usaid.gov/data, with a copy to the agreement officer representative, providing details on where and how to access the data. The direct results of federally funded scientific research must be reported no later than when the data are ready to be submitted to a peer-reviewed journal for publication, or no later than five calendar days prior to the conclusion of the award, whichever occurs earlier.

- (3) The recipient must submit the Datasets following the submission instructions and acceptable formats found at www.usaid.gov/data.
- (4) The recipient must ensure that any Dataset submitted to the DDL does not contain any proprietary or personally identifiable information, such as social security numbers, home

addresses, and dates of birth. Such information must be removed prior to submission.

- (5) The recipient must not submit classified data to the DDL.

[END OF PROVISION]

M26. PROHIBITION ON REQUIRING CERTAIN INTERNAL CONFIDENTIALITY AGREEMENTS OR STATEMENTS (MAY 2017)

- (a) Definitions.

“Contract” has the meaning given in 2 CFR Part 200.

“Contractor” means an entity that receives a contract as defined in 2 CFR Part 200.

“Internal confidentiality agreement or statement” means a confidentiality agreement or any other written statement that the recipient requires any of its employees or subrecipients to sign regarding nondisclosure of recipient information, except that it does not include confidentiality agreements arising out of civil litigation or confidentiality agreements that recipient employees or subrecipients sign at the behest of a Federal agency.

“Subaward” has the meaning given in 2 CFR Part 200.

“Subrecipient” has the meaning given in 2 CFR Part 200.

- (b) The recipient must not require its employees, subrecipients, or contractors to sign or comply with internal confidentiality agreements or statements that prohibit or otherwise restrict employees, subrecipients, or contractors from lawfully reporting waste, fraud, or abuse related to the performance of a Federal award to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (for example, the Agency Office of the Inspector General).
- (c) The recipient must notify current employees and subrecipients that prohibitions and restrictions of any preexisting internal confidentiality agreements or statements covered by this provision, to the extent that such prohibitions and restrictions are inconsistent with the prohibitions of this provision, are no longer in effect.
- (d) The prohibition in paragraph (b) of this provision does not contravene the requirements applicable to Standard Form 312 (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.
- (e) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further

Continuing Appropriations Act, 2015, (Pub. L. 113-235), and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions) use of funds appropriated (or otherwise made available) is prohibited, if the Government determines that the recipient is not in compliance with the requirements of this provision.

- (f) The recipient must include the substance of this provision, including this paragraph (f), in subawards and contracts under such awards.

[END OF PROVISION]

M27. CHILD SAFEGUARDING (JUNE 2015)

- (a) Because the activities to be funded under this award may involve children, or personnel engaged in the implementation of the award may come into contact with children, these activities could raise the risk of child abuse, exploitation, or neglect within USAID-funded programs. The organization agrees to abide by the following child safeguarding core principles:
- (1) Ensure compliance with host country and local child welfare and protection legislation or international standards, whichever gives greater protection, and with U.S. law where applicable;
 - (2) Prohibit all personnel from engaging in child abuse, exploitation, or neglect;
 - (3) Consider child safeguarding in project planning and implementation to determine potential risks to children that are associated with project activities and operations;
 - (4) Apply measures to reduce the risk of child abuse, exploitation, or neglect, including, but not limited to, limiting unsupervised interactions with children; prohibiting exposure to pornography; and complying with applicable laws, regulations, or customs regarding the photographing, filming, or other image-generating activities of children;
 - (5) Promote child-safe screening procedures for personnel, particularly personnel whose work brings them in direct contact with children; and
 - (6) Have a procedure for ensuring that personnel and others recognize child abuse, exploitation, or neglect; mandating that personnel and others report allegations; investigating and managing allegations; and taking appropriate action in response to such allegations, including, but not limited to, dismissal of personnel.
- (b) The organization must also include in their code of conduct for all personnel implementing USAID-funded activities the child safeguarding principles in (a) (1) through (6).
- (c) The following definitions apply for purposes of this provision:

- (1) Child: A child or children are defined as persons who have not attained 18 years of age.
 - (2) Child abuse, exploitation, or neglect: Constitutes any form of physical abuse; emotional ill-treatment; sexual abuse; neglect or insufficient supervision; trafficking; or commercial, transactional, labor, or other exploitation resulting in actual or potential harm to the child's health, well-being, survival, development, or dignity. It includes, but is not limited to: any act or failure to act which results in death, serious physical or emotional harm to a child, or an act or failure to act which presents an imminent risk of serious harm to a child.
 - (3) Physical abuse: Constitutes acts or failures to act resulting in injury (not necessarily visible), unnecessary or unjustified pain or suffering without causing injury, harm or risk of harm to a child's health or welfare, or death. Such acts may include, but are not limited to: punching, beating, kicking, biting, shaking, throwing, stabbing, choking, or hitting (regardless of object used), or burning. These acts are considered abuse regardless of whether they were intended to hurt the child.
 - (4) Sexual Abuse: Constitutes fondling a child's genitals, penetration, incest, rape, sodomy, indecent exposure, and exploitation through prostitution or the production of pornographic materials.
 - (5) Emotional abuse or ill treatment: Constitutes injury to the psychological capacity or emotional stability of the child caused by acts, threats of acts, or coercive tactics. Emotional abuse may include, but is not limited to: humiliation, control, isolation, withholding of information, or any other deliberate activity that makes the child feel diminished or embarrassed.
 - (6) Exploitation: Constitutes the abuse of a child where some form of remuneration is involved or whereby the perpetrators benefit in some manner. Exploitation represents a form of coercion and violence that is detrimental to the child's physical or mental health, development, education, or well-being.
 - (7) Neglect: Constitutes failure to provide for a child's basic needs within USAID-funded activities that are responsible for the care of a child in the absence of the child's parent or guardian.
- (d) The recipient must insert the provisions in (a) and (b) in all sub-awards under this award.

[END OF PROVISION]

M28. MANDATORY DISCLOSURES (JULY 2015)

Consistent with 2 CFR §200.113, applicants and recipients must disclose, in a timely manner, in writing to the USAID Office of the Inspector General, with a copy to the cognizant Agreement Officer, all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. Subrecipients must disclose, in a timely manner, in

writing to the USAID Office of the Inspector General and to the prime recipient (pass through entity) all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award.

Disclosures must be sent to:

U.S. Agency for International Development
Office of the Inspector General
P.O. Box 657
Washington, DC 20044-0657

Phone: 1-800-230-6539 or 202-712-1023

Email: ig.hotline@usaid.gov

URL: <https://oig.usaid.gov/content/usaid-contractor-reporting-form>.

Failure to make required disclosures can result in any of the remedies described in 2 CFR §200.338 Remedies for noncompliance, including suspension or debarment (See 2 CFR 180, 2 CFR 780 and 31 U.S.C. 3321).

The recipient must include this mandatory disclosure requirement in all subawards and contracts under this award.

[END OF PROVISION]

M29. NONDISCRIMINATION AGAINST BENEFICIARIES (NOVEMBER 2016)

- (a) USAID policy requires that the recipient not discriminate against any beneficiaries in implementation of this award, such as, but not limited to, by withholding, adversely impacting, or denying equitable access to the benefits provided through this award on the basis of any factor not expressly stated in the award. This includes, for example, race, color, religion, sex (including gender identity, sexual orientation, and pregnancy), national origin, disability, age, genetic information, marital status, parental status, political affiliation, or veteran's status. Nothing in this provision is intended to limit the ability of the recipient to target activities toward the assistance needs of certain populations as defined in the award.
- (b) The recipient must insert this provision, including this paragraph, in all subawards and contracts under this award.

[END OF PROVISION]

M30. CONFLICT OF INTEREST (AUGUST 2018)

- a. A conflict of interest in the award, administration, or monitoring of subawards arises when an employee, officer, or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of these parties, has a

financial or other interest in, or a tangible personal benefit from, a subrecipient considered for a subaward. The officers, employees, and agents of the recipient may neither solicit nor accept gratuities, favors, or anything of monetary value from subrecipients or parties to subawards. However, recipients may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value.

- b. The recipient must maintain written standards of conduct covering conflicts of interest and governing the actions of its employees engaged in the selection, award, and administration of subawards. The standards must prohibit employees from using their positions for a purpose that constitutes or presents the appearance of a conflict of interest. The standards of conduct must provide for disciplinary actions to be applied for violations of such standards by officers, employees, or agents of the recipient.
- c. The recipient must also maintain written standards of conduct covering organizational conflicts of interest. Organizational conflicts of interest means a situation in which the recipient is unable or appears to be unable to be impartial in conducting a subaward action involving a related organization because of relationships with a parent company, affiliate, or subsidiary organization.
- d. The recipient must have a system or systems in place to identify, address, resolve, and disclose to USAID any conflicts of interest as described in this provision that affect any subaward, regardless of the amount of funding.
- e. The recipient must disclose any conflict of interest, including organizational conflicts of interest, and the recipient's approach for resolving the conflict of interest to the cognizant Agreement Officer for the award within ten (10) calendar days of the discovery of the conflict of interest.
- f. Upon notice from the recipient of a potential conflict of interest and the approach for resolving it, the Agreement Officer will make a determination regarding the effectiveness of the recipient's actions to resolve the conflict of interest within thirty (30) calendar days of receipt of the recipient's notice, unless the Agreement Officer advises the recipient that a longer period is necessary.
- g. The recipient must not request payment from USAID for costs for transactions subject to the conflict of interest pending notification of USAID's determination. The recipient's failure to disclose a conflict of interest may result in cost disallowances by USAID.
- h. For conflicts of interest, including organizational conflicts of interest, involving contracts, the recipient must follow 2 CFR 200.318, general procurement standards.
- i. The recipient must insert the substance of this provision, including paragraph (i), in all subawards under this award, at any subaward tier.

[END OF PROVISION]

**REQUIRED AS APPLICABLE STANDARD PROVISIONS FOR U.S.
NONGOVERNMENTAL ORGANIZATIONS**

RAA1. NEGOTIATED INDIRECT COST RATES – PREDETERMINED (NOVEMBER 2020)

- a. The allowable indirect costs must be determined by applying the predetermined indirect cost rates to the bases specified in the schedule of this award.
- b. Except as otherwise provided in 2 CFR 200.414 Indirect (F&A) costs paragraph (e) and (f), a nonprofit organization which has not previously established an indirect cost rate with a Federal agency must submit its initial indirect cost proposal immediately after the organization is advised that a Federal award will be made and, in no event, later than three months after the effective date of the Federal award.

Organizations that have previously established indirect cost rates must submit a new indirect cost proposal to the cognizant agency for indirect costs within six months after the close of each fiscal year.

If USAID is the cognizant agency or no cognizant agency has been designated, the recipient must submit four copies of the audit report, the proposed predetermined indirect cost rates, and supporting cost data to the Overhead, Special Costs, and Closeout Branch, Management Bureau, Office of Acquisition and Assistance, USAID, Washington, DC 20523-7802. The proposed rates must be based on the recipient's actual cost experience during that fiscal year. Negotiations of predetermined indirect cost rates must begin soon after receipt of the recipient's proposal.

- c. Allowability of costs and acceptability of cost allocation methods must be determined in accordance with the applicable cost principles.
- d. The results of each negotiation must be set forth in an indirect cost rate agreement signed by both parties. Such agreement is automatically incorporated into this award and must specify (1) the agreed upon predetermined rates, (2) the bases to which the rates apply, and (3) the fiscal year for which the rates apply. The indirect cost rate agreement must not change any monetary ceiling, award obligation, or specific cost allowance or disallowance provided for in this award.
- e. Predetermined rate means an indirect cost rate, applicable to a specified current or future period, usually the organization's fiscal year. The rate is based on an estimate of the costs to be incurred during the period. A predetermined rate is not subject to adjustment.
- f. If a dispute arises in a negotiation of an indirect cost rate between the cognizant agency for indirect costs and the nonprofit organization, the dispute must be resolved in accordance with the appeals procedures of the cognizant agency for indirect costs.

[END OF PROVISION]

RAA5. EXCHANGE VISITORS AND PARTICIPANT TRAINING (JUNE 2012)

For any Exchange Visitor, Participant Training or Invitational Travel activities, the recipient must comply with this provision.

a. Definitions:

- (1) An **Exchange Visitor** is any host-country or third-country national traveling to the U.S., for any purpose, including Participant Training and Invitational Travel, funded by USAID in whole or in part, directly or indirectly.
- (2) A **Participant** is a host-country or third-country national sponsored by USAID for a Participant Training activity taking place in the U.S., a third country, or in the host country.
- (3) **Participant Training** is a learning activity conducted within the U.S., a third country, or in the host country for the purpose of furthering USAID development objectives. A learning activity takes place in a setting in which an individual (the Participant) interacts with a knowledgeable professional, predominantly for the purpose of acquiring knowledge or skills for the professional or technical enhancement of the individual. Learning activities may be formally structured, such as an academic program or a technical course, or they may be more informal, such as an observational study tour.
- (4) **Invitational Travel** is a type of travel that USAID funds for non-U.S. Government employees. This type of travel may be approved for both U.S. and foreign citizens who are not employed by the U.S. Government (USG), not receiving any type of compensation from the USG for such travel, and only when it is determined that the functions to be performed are essential to the interests of USAID.

b. Program Monitoring and Data Reporting: The recipient must monitor Exchange Visitors' and Participants' progress during their program and ensure that problems are identified and resolved quickly.

- (1) For U.S.-based activities, the recipient must use USAID's official Exchange Visitor and Participant Training information system, currently called "Training Results and Information Network – TraiNet" (see <http://trainethelp.usaid.gov/>), to report and manage Exchange Visitor and Participant Training data. The recipient must also use the USAID Visa Compliance System – VCS (see <http://trainethelp.usaid.gov/>) to transfer required data for USAID Exchange Visitors to the Department of Homeland Security's Student and Exchange Visitor Information System (SEVIS).
- (2) For all third-country activities, and for host-country activities of two consecutive days or 16 contact hours or more in duration, the recipient must use USAID's official

Exchange Visitor and Participant Training information system, currently called “Training Results and Information Network – TraiNet” (see <http://trainethelp.usaid.gov/>), to report and manage Participant Training data.

c. Health and Accident Insurance:

- (1) For Exchange Visitors traveling to the United States, the recipient must enroll Exchange Visitors in health and accident insurance coverage that meets or exceeds Department of State and USAID minimum coverage requirements as set forth in 22 CFR 62.14 and ADS 253.3.6.2. The requirements may be obtained from the Agreement Officer’s Representative.
- (2) For Participants traveling to a third country, the recipient must obtain health and accident insurance coverage for all Participants.
- (3) For Participants traveling within the host country, the recipient must determine whether specific in-country participant training activities subject them to any risk of health and accident liability for medical costs. Participants may incur, and if so, take appropriate steps according to the local situation, including obtaining health and accident insurance coverage for Participants.

d. Immigration Requirements:

- (1) For Exchange Visitors traveling to the United States, the recipient must ensure that all USAID-sponsored Exchange Visitors obtain, use, and comply with the terms of the J-1 visa, issued in conjunction with a USAID-issued Certificate of Eligibility for J-1 Visa Status (DS-2019).
- (2) For Participants traveling to a third country or within the host country, the recipient must ensure that all Participants obtain, use, and comply with the terms of all applicable immigration, visa and other similar requirements.

e. Language Proficiency: The recipient must verify language proficiency. Exchange Visitors must possess sufficient English language proficiency to participate in a U.S.-based activity. Participants of third-country or host-country training must be proficient in the language of training at a sufficient level for participation, unless an interpreter has been arranged. Language competency can be verified through a variety of means including proficiency assessments of interviews, publications, presentations, education conducted in English, and formal testing.

f. Pre-departure Orientation: The recipient must conduct pre-departure orientation for U.S.-bound Exchange Visitors and Participants of third-country training programs. Pre-departure orientation covers: program objectives; administrative and policy review; cultural aspects; and training/learning methods.

- g. **Conditions of Sponsorship:** The recipient must ensure that all Exchange Visitors read and sign the Conditions of Sponsorship for U.S.-Based Activities form (AID 1381-6). The recipient must also ensure that all Participants of long-term (six months or longer) third-country training read and sign the form Conditions of Sponsorship for Third-Country Training form (AID 1381-7). The recipient must report to the Agreement Officer any known violations by Exchange Visitors of visa or other immigration requirements or conditions.
- h. **Exchange Visitor Security Risk and Fraud Inquiry:** Each USAID Mission has an established process for conducting a Security Risk and Fraud Inquiry (SRFI) for Exchange Visitors. The recipient must be prepared to assist Missions in conducting the SRFI, if requested. However, the recipient's role is contributive, and the Mission is ultimately responsible for conducting the SRFI.
- i. **Fly America:** To the extent that participants travel by international air travel, the recipient must comply with the Standard Provision, "International Air Travel and Air Transportation of Property."
- j. **Use of Minority Serving Institutions:** For U.S.-based Participant Training, the recipient must, to the maximum extent possible, maintain their use of Historically Black Colleges and Universities (HBCUs) and other Minority Serving Institutions (MSIs), including Hispanic Serving Institutions and Tribal Colleges and Universities, as training or education providers.

[END OF PROVISION]

RAA7. PROTECTION OF THE INDIVIDUAL AS A RESEARCH SUBJECT (APRIL 1998)

- a. Safeguarding the rights and welfare of human subjects involved in research supported by USAID is the responsibility of the organization to which support is awarded. USAID has adopted the Common Federal Policy for the Protection of Human Subjects, Part 225 of Title 22 of the Code of Federal Regulations (the "Policy"). Additional interpretation, procedures, and implementation guidance of the Policy are found in USAID General Notice entitled "Procedures for the Protection of Human Subjects in Research Supported by USAID," issued April 19, 1995, as amended. USAID's Cognizant Human Subjects Officer (CHSO) in USAID/W has oversight, guidance, and interpretation responsibility for the Policy.
- b. Recipient organizations must comply with USAID policy when humans are the subject of research, as defined in 22 CFR 225.102(d), funded by the grant and recipients must provide "assurance," as required by 22 CFR 225.103, that they follow and abide by the procedures in the Policy. See also Section 5 of the April 19, 1995, USAID General Notice which sets forth activities to which the Policy is applicable. The existence of a bona fide, applicable assurance approved by the Department of Health and Human Services (HHS) such as the "multiple project assurance" (MPA) will satisfy this requirement. Alternatively, organizations can provide an acceptable written assurance to USAID as described in 22 CFR 225.103.

Such assurances must be determined by the CHSO to be acceptable prior to any applicable research being initiated or conducted under the award. In some limited instances outside the U.S., alternative systems for the protection of human subjects may be used provided they are deemed “at least equivalent” to those outlined in Part 225 (See 22 CFR 225.101[h]). Criteria and procedures for making this determination are described in the General Notice cited in the preceding paragraph.

- c. Since the welfare of the research subject is a matter of concern to USAID as well as to the organization, USAID staff consultants and advisory groups may independently review and inspect research and research processes and procedures involving human subjects, and based on such findings, the CHSO may prohibit research which presents unacceptable hazards or otherwise fails to comply with USAID procedures. Informed consent documents must include the stipulation that the subject's records may be subject to such review.

[END OF PROVISION]

RAA8. CARE OF LABORATORY ANIMALS (MARCH 2004)

CARE OF LABORATORY ANIMALS (MARCH 2004)

- a. Before undertaking performance of any grant involving the use of laboratory animals, the recipient must register with the Secretary of Agriculture of the United States in accordance with Section 6, Public Law 89-544, Laboratory Animal Welfare Act, August 24, 1966, as amended by Public Law 91-579, Animal Welfare Act of 1970, December 24, 1970. The recipient must furnish evidence of such registration to the Agreement Officer.
- b. The recipient must acquire animals used in research under this award only from dealers licensed by the Secretary of Agriculture, or from exempted sources in accordance with the Public Laws enumerated in a. above.
- c. In the care of any live animals used or intended for use in the performance of this grant, the recipient must adhere to the principles enunciated in the Guide for Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences - National Research Council (NAS-NRC), and in the United States Department of Agriculture's (USDA) regulations and standards issued under the Public Laws enumerated in a. above. In case of conflict between standards, the higher standard must be used. The recipient's reports on portions of the award in which animals were used must contain a certificate stating that the animals were cared for in accordance with the principles enunciated in the Guide for Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, NAS-NRC, and/or in the regulations and standards as promulgated by the Agricultural Research Service, USDA, pursuant to the Laboratory Animal Welfare Act of 24 August 1966, as amended (P.L. 89-544 and P.L. 91-579). NOTE: The recipient may request registration of the recipient's facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which the recipient's research facility is located. The location of the appropriate APHIS Regional Office as well as information concerning this program may be obtained by contacting the Senior Staff

Office, Animal Care Staff, USDA/APHIS, 4700 River Road, Unit 84, Riverdale, MD 20737-1234 and at www.aphis.usda.gov/animal_welfare/index.shtml.

[END OF PROVISION]

RAA10. COST SHARING (MATCHING) (FEBRUARY 2012)

COST SHARING (MATCHING) (FEBRUARY 2012)

- a. If at the end of any funding period, the recipient has expended an amount of non-Federal funds less than the agreed upon amount or percentage of total expenditures, the Agreement Officer may apply the difference to reduce the amount of USAID incremental funding in the following funding period. If the award has expired or has been terminated, the Agreement Officer may require the recipient to refund the difference to USAID.
- b. The source and nationality requirements and the restricted goods provision established in the Standard Provision entitled "USAID Eligibility Rules for Goods and Services" do not apply to cost sharing (matching) expenditures.

[END OF PROVISION]

RAA11. PROHIBITION OF ASSISTANCE TO DRUG TRAFFICKERS (JUNE 1999)

- a. USAID reserves the right to terminate assistance to, or take other appropriate measures with respect to, any participant approved by USAID who is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR 140.
- b.
 - (1) For any loan over \$1,000 made under this agreement, the recipient must insert a clause in the loan agreement stating that the loan is subject to immediate cancellation, acceleration, recall, or refund by the recipient if the borrower or a key individual of a borrower is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR 140.
 - (2) Upon notice by USAID of a determination under section (1) and at USAID's option, the recipient agrees to immediately cancel, accelerate, or recall the loan, including refund in full of the outstanding balance. USAID reserves the right to have the loan refund returned to USAID.
- c.
 - (1) The recipient agrees not to disburse, or sign documents committing the recipient to disburse, funds to a subrecipient designated by USAID ("Designated Subrecipient") until advised by USAID that: (i) any United States Government review of the Designated Subrecipient and its key individuals has been completed; (ii) any related certifications have been obtained; and (iii) the assistance to the Designated Subrecipient has been

approved. Designation means that the subrecipient has been unilaterally selected by USAID as the subrecipient. USAID approval of a subrecipient, selected by another party, or joint selection by USAID and another party is not designation.

- (2) The recipient must insert the following clause, or its substance, in its agreement with the Designated Subrecipient:

“The recipient reserves the right to terminate this [Agreement/Contract] or take other appropriate measures if the [Subrecipient] or a key individual of the [Subrecipient] is found to have been convicted of a narcotic offense or to have been engaged in drug trafficking as defined in 22 CFR 140.”

[END OF PROVISION]

RAA13. REPORTING HOST GOVERNMENT TAXES (DECEMBER 2014)

- a. By April 16 of each year, the recipient must submit a report containing:
- (1) Contractor/recipient name.
 - (2) Contact name with phone, fax and e-mail.
 - (3) Agreement number(s).
 - (4) The total amount of value-added taxes and customs duties (but not sales taxes) assessed by the host government (or any entity thereof) on purchases in excess of \$500 per transaction of supplies, materials, goods or equipment, during the 12 months ending on the preceding September 30, using funds provided under this contract/agreement.
 - (5) Any reimbursements received by April 1 of the current year on value-added taxes and customs duties reported in (iv).
 - (6) Reports are required even if the recipient did not pay any taxes or receive any reimbursements during the reporting period.
 - (7) Cumulative reports may be provided if the recipient is implementing more than one program in a foreign country.
- b. Submit the reports to: Agreement’s Officer Representative.
- a. Host government taxes are not allowable where the Agreement Officer provides the necessary means to the recipient to obtain an exemption or refund of such taxes, and the recipient fails to take reasonable steps to obtain such exemption or refund. Otherwise, taxes

are allowable in accordance with the Standard Provision, “Allowable Costs,” and must be reported as required in this provision.

- b. The recipient must include this reporting requirement in all applicable subawards and contracts.

[END OF PROVISION]

RAA14. FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)

FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)

- a. U.S. Government funds under this award must not be used to finance the travel, per diem, hotel expenses, meals, conference fees or other conference costs for any member of a foreign government’s delegation to an international conference sponsored by a multilateral organization, as defined below, unless approved by the Agreement Officer in writing.
- b. Definitions:
 - (1) A foreign government delegation is appointed by the national government (including ministries and agencies but excluding local, state and provincial entities) to act on behalf of the appointing authority at the international conference. A conference participant is a delegate for the purposes of this provision, only when there is an appointment or designation that the individual is authorized to officially represent the government or agency. A delegate may be a private citizen.
 - (2) An international conference is a meeting where there is an agenda, an organizational structure, and delegations from countries other than the conference location, in which country delegations participate through discussion, votes, etc.
 - (3) A multilateral organization is an organization established by international agreement and whose governing body is composed principally of foreign governments or other multilateral organizations.

[END OF PROVISION]

RAA18. USAID DISABILITY POLICY - ASSISTANCE (DECEMBER 2004)

- a. The objectives of the USAID Disability Policy are (1) to enhance the attainment of United States foreign assistance program goals by promoting the participation and equalization of opportunities of individuals with disabilities in USAID policy, country and sector strategies, activity designs and implementation; (2) to increase awareness of issues of people with disabilities both within USAID programs and in host countries; (3) to engage other U.S. Government agencies, host country counterparts, governments, implementing organizations

and other donors in fostering a climate of nondiscrimination against people with disabilities; and (4) to support international advocacy for people with disabilities.

- b. USAID therefore requires that the recipient not discriminate against people with disabilities in the implementation of USAID funded programs and that it make every effort to comply with the objectives of the USAID Disability Policy in performing the program under this grant or cooperative agreement. To that end and to the extent it can accomplish this goal within the scope of the program objectives, the recipient should demonstrate a comprehensive and consistent approach for including men, women, and children with disabilities.

[END OF PROVISION]

RAA23. UNIVERSAL IDENTIFIER AND SYSTEM OF AWARD MANAGEMENT (NOVEMBER 2020)

- a. **Requirement for System of Award Management (SAM).** Unless you are exempted from this requirement under 2 CFR 25.110, you as the recipient must maintain current information in the SAM. This includes information on your immediate and highest level owner and subsidiaries, as well as on all of your predecessors that have been awarded a Federal contract or Federal financial assistance within the last three years, if applicable, until you submit the final financial report required under this Federal award or receive the final payment, whichever is later. This requires that you review and update the information at least annually after the initial registration, and more frequently, if required by changes in your information or another Federal award term.
- b. **Requirement for Unique Entity Identifier.** If you are authorized to make subawards under this Federal award, you:
 - (1) Must notify potential subrecipients that no entity (see definition in paragraph c. of this award term) may receive a subaward from you until the entity has provided its Unique Entity Identifier to you.
 - (2) May not make a subaward to an entity unless the entity has provided its Unique Entity Identifier to you. Subrecipients are not required to obtain an active SAM registration but must obtain a Unique Entity Identifier.
- c. **Definitions.** For purposes of this award term:
 - (1) System of Award Management (SAM) means the Federal repository into which a recipient must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM Internet site (currently at <https://www.sam.gov>).

- (2) Unique Entity Identifier means the identifier assigned by SAM to uniquely identify business entities.
- (3) Entity includes non-Federal entities as defined in 2 CFR 200.1 and also includes all of the following, for purposes of this part:
 - a. A foreign organization;
 - b. A foreign public entity;
 - c. A domestic for-profit organization; and
 - d. A Federal agency.
- (4) Subaward has the meaning given in 2 CFR 200.1.
- (5) Subrecipient has the meaning given in 2 CFR 200.1.

ADDENDUM (NOVEMBER 2020):

- d. **Exceptions.** The requirements of this provision to obtain a Unique Entity Identifier and maintain a current registration in the SAM do not apply, at the prime award or subaward level, to:
 - (1) Awards to individuals
 - (2) Awards less than \$25,000 to foreign recipients to be performed outside the United States (based on a USAID determination)
 - (3) Awards where the Agreement Officer determines, in writing, that the Agency must protect entity information from disclosure due to national security or foreign policy interests of the United States or that these requirements would cause personal safety concerns.
- e. This provision does not need to be included in subawards.

[END OF PROVISION]

**RAA24. REPORTING SUBAWARDS AND EXECUTIVE COMPENSATION
(NOVEMBER 2020)**

- a. **Reporting of first-tier subawards.**
 - (1) Applicability. Unless you are exempt as provided in paragraph d. of this award term, you must report each action that equals or exceeds \$30,000 in Federal funds for a subaward to a non-Federal entity or Federal agency (see definitions in paragraph e. of this award term).

(2) Where and when to report.

- (i) The non-Federal entity or Federal agency must report each obligating action described in paragraph a.(1) of this award term to www.fsrs.gov.
- (ii) For subaward information, report no later than the end of the month following the month in which the obligation was made. (For example, if the obligation was made on November 7, 2010, the obligation must be reported by no later than December 31, 2010.)

(3) What to report. You must report the information about each obligating action that the submission instructions posted at www.fsrs.gov specify.

b. Reporting Total Compensation of Recipient Executives.

(1) Applicability and what to report. You must report total compensation for each of your five most highly compensated executives for the preceding completed fiscal year, if –

- (i) The total Federal funding authorized to date under this Federal award equals or exceeds \$30,000 as defined in 2 CFR 170.320;
- (ii) In the preceding fiscal year, you received—
 - (A) 80 percent or more of your annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
 - (B) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
- (iii) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at www.sec.gov/answers/excomp.htm.)

(2) Where and when to report. You must report executive total compensation described in paragraph b.(1) of this award term:

- (i) As part of your registration profile at www.sam.gov.
- (ii) By the end of the month following the month in which this award is made, and annually thereafter.

c. Reporting of Total Compensation of Subrecipient Executives.

- (1) Applicability and what to report. Unless you are exempt as provided in paragraph d. of this award term, for each first-tier subrecipient under this award, you must report the names and total compensation of each of the subrecipient's five most highly compensated executives for the subrecipient's preceding completed fiscal year, if—
 - (i) In the subrecipient's preceding fiscal year, the subrecipient received—
 - (A) 80 percent or more of its annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
 - (B) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts), and Federal financial assistance subject to the Transparency Act (and subawards); and
 - (ii) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at www.sec.gov/answers/execomp.htm.)
- (2) Where and when to report. You must report subrecipient executive total compensation described in paragraph c.(1) of this award term:
 - (i) To the recipient.
 - (ii) By the end of the month following the month during which you make the subaward. For example, if a subaward is obligated on any date during the month of October of a given year (for example, between October 1 and 31), you must report any required compensation information of the subrecipient by November 30 of that year.

d. Exemptions.

If, in the previous tax year, you had gross income, from all sources, under \$300,000, you are exempt from the requirements to report:

- (1) Subawards, and
- (2) The total compensation of the five most highly compensated executives of any subrecipient.

e. Definitions.

For purposes of this award term:

- (1) Federal Agency means a Federal agency as defined at 5 U.S.C. 551(1) and further clarified by 5 U.S.C. 552(f).
- (2) Entity means all of the following, as defined in 2 CFR 25:
 - (i) A governmental organization, which is a State, local government, or Indian tribe;
 - (ii) A foreign public entity;
 - (iii) A domestic or foreign nonprofit organization; and
 - (iv) A domestic or foreign for-profit organization.
- (3) Executive means officers, managing partners, or any other employees in management positions.
- (4) Subaward:
 - (i) This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.
 - (ii) The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see 2 CFR 200.331).
 - (iii) A subaward may be provided through any legal agreement, including an agreement that you or a subrecipient considers a contract.
- (5) Subrecipient means a non-Federal entity or Federal agency that:
 - (i) Receives a subaward from you (the recipient) under this award; and
 - (ii) Is accountable to you for the use of the Federal funds provided by the subaward.
- (6) Total compensation means the cash and noncash dollar value earned by the executive during the recipient's or subrecipient's preceding fiscal year and includes the following (for more information see 17 CFR 229.402(c)(2)):
 - (i) Salary and bonus.

- (ii) Awards of stock, stock options, and stock appreciation rights. Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Statement of Financial Accounting Standards No. 123 (Revised 2004) (FAS 123R), Shared Based Payments.
- (iii) Earnings for services under nonequity incentive plans. This does not include group life, health, hospitalization, or medical reimbursement plans that do not discriminate in favor of executives, and are available generally to all salaried employees.
- (iv) Change in pension value. This is the change in present value of defined benefit and actuarial pension plans.
- (v) Above-market earnings on deferred compensation which is not tax-qualified.
- (vi) Other compensation, if the aggregate value of all such other compensation (for example, severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property) for the executive exceeds \$10,000.

[END OF PROVISION]

RAA25. PATENT REPORTING PROCEDURES (NOVEMBER 2020)

As incorporated by 2 CFR 200.315 and the standard provision “APPLICABILITY OF 2 CFR 200 and 2 CFR 700,” the clause at 37 CFR 401.14 (“Standard Patent Rights”) is incorporated by reference into this award as if set forth in full text. The recipient must use the National Institutes of Health EDISON Patent Reporting and Tracking system (<http://www.iedison.gov>) to fulfill its disclosure obligations under 37 CFR 401.14(c)(1). The recipient must also submit reports on utilization of subject inventions annually to the Agreement Officer’s Representative under 37 CFR 401.14(h), and the last report must be provided within 90 days of the expiration of the agreement.

[END OF PROVISION]

RAA26. ACCESS TO USAID FACILITIES AND USAID’S INFORMATION SYSTEMS (AUGUST 2013)

- a. A U.S. citizen or resident alien engaged in the performance of this award as an employee, consultant, or volunteer of a U.S organization may obtain access to USAID facilities or logical access to USAID’s information systems only when and to the extent necessary to carry out this award and in accordance with this provision. The recipient’s employees, consultants, or volunteers who are not U.S. citizen as well as employees, consultants, or volunteers of non-U.S.

- b. organizations, irrespective of their citizenship, will not be granted logical access to U.S. Government information technology systems (such as Phoenix, GLAAS, etc.) and must be escorted to use U.S. Government facilities (such as office space).
- c. Before a U.S. citizen or resident alien engaged in the performance of this award as an employee, consultant, or volunteer of the recipient, subrecipient or contractor at any tier may obtain a USAID ID (new or replacement) authorizing the individual routine access to USAID facilities in the United States, or logical access to USAID's information systems, the individual must provide two forms of identity source documents in original form. One identity source document must be a valid Federal or State government-issued picture ID. The recipient must contact the USAID Office of Security to obtain the list of acceptable forms of documentation. Submission of these documents, and related background checks, are mandatory in order for the individual to receive a building access ID, and before access will be granted to any of USAID's information systems. All such individuals must physically present these two source documents for identity proofing at their Security Briefing. All individuals provided access under this provision must return any issued building access ID and remote authentication token to USAID custody upon termination of the individual's employment with the recipient or completion of the award, whichever occurs first.
- d. Individuals engaged in the performance of this award as an employee, consultant, or volunteer of the recipient must comply with all applicable Homeland Security Policy Directive-12 (HSPD-12) and Personal Identity Verification (PIV) procedures, as described above, as well as any subsequent USAID or government-wide HSPD-12 and PIV procedures/policies, including any
- e. HSPD-12 procedures established by the Office of Security in USAID/Washington.
- f. The recipient is required to include this provision in all subawards and contracts at any tier made to a U.S. organization/company, that require employees or consultants engaged in the performance of this award to have routine physical access to USAID facilities or logical access to USAID's information systems in order to perform this award.

[END OF PROVISION]

RAA27. CONTRACT PROVISION FOR DBA INSURANCE UNDER RECIPIENT PROCUREMENTS (DECEMBER 2014)

All contracts made by the recipient under this award for services to be performed overseas must contain the following provision, as applicable.

Workers' Compensation Insurance (Defense Base Act)

- (a) The Contractor must--

- (1) Before commencing performance under this contract, establish provisions to provide for the payment of disability compensation and medical benefits to covered employees and death benefits to their eligible survivors, by purchasing Defense Base Act (DBA) insurance pursuant to the terms of the contract between USAID and USAID's DBA insurance carrier unless the Contractor qualifies as a self-insurer under the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 932) as extended by the Defense Base Act (42 U.S.C. 1651, et seq.), or has an approved retrospective rating agreement for DBA. The Contractor must continue to maintain these provisions to provide such Defense Base Act benefits until contract performance is completed.
- (2) If USAID or the Contractor has secured a waiver of DBA coverage in accordance with AIDAR 728.305-70(a) for contractor's employees who are not citizens of, residents of, or hired in the United States, the contractor agrees to provide such employees with worker's compensation benefits as required by the laws of the country in which the employees are working, or by the laws of the employee's native country, whichever offers greater benefits. The Department of Labor has granted partial blanket waivers of DBA coverage applicable to USAID-financed contracts performed in countries listed in the DEFENSE BASE ACT (DBA) WAIVER LIST.
- (3) Within ten days of an employee's injury or death or from the date the Contractor has knowledge of the injury or death, submit Form LS-202 (Employee's First Report of Injury or Occupational Illness) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 930(a), 20 CFR 702.201 to 702.203).
- (4) Pay all compensation due for disability or death within the timeframes required by the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914, 20 CFR 702.231 and 703.232).
- (5) Provide for medical care as required by the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 907, 20 CFR 702.402 and 702.419).
- (6) If controverting the right to compensation, submit Form LS-207 (Notice of Controversion of Right to Compensation) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914(d), 20 CFR 702.251).
- (7) Immediately upon making the first payment of compensation in any case, submit Form LS-206 (Payment of Compensation Without Award) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914(c), 20 CFR 702.234).
- (8) When payments are suspended or when making the final payment, submit Form LS-208 (Notice of Final Payment or Suspension of Compensation Payments) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914 (c) and (g), 20 CFR 702.234 and 702.235).

- (9) Adhere to all other provisions of the Longshore and Harbor Workers' Compensation Act as extended by the Defense Base Act, and Department of Labor regulations at 20 CFR Parts 701 to 704.

For additional information on the Longshore and Harbor Workers' Compensation Act requirements see <http://www.dol.gov/owcp/dlhwc/lbdba.htm>.

The Contractor must insert the substance of this clause including this paragraph (c), in all subcontracts to which the Defense Base Act applies.

[END OF PROVISION]

RAA28. AWARD TERM AND CONDITION FOR RECIPIENT INTEGRITY AND PERFORMANCE MATTERS (APRIL 2016)

A. Reporting of Matters Related to Recipient Integrity and Performance

1. General Reporting Requirement

If the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds \$10,000,000 for any period of time during the period of performance of this Federal award, then you as the recipient during that period of time must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) about civil, criminal, or administrative proceedings described in paragraph 2 of this award term and condition. This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available.

2. Proceedings About Which You Must Report

Submit the information required about each proceeding that:

- a. Is in connection with the award or performance of a grant, cooperative agreement, or procurement contract from the Federal Government;
- b. Reached its final disposition during the most recent five year period; and
- c. Is one of the following:
 - (1) A criminal proceeding that resulted in a conviction, as defined in paragraph 5 of this award term and condition;

- (2) A civil proceeding that resulted in a finding of fault and liability and payment of a monetary fine, penalty, reimbursement, restitution, or damages of \$5,000 or more;
- (3) An administrative proceeding, as defined in paragraph 5. of this award term and condition, that resulted in a finding of fault and liability and your payment of either a monetary fine or penalty of \$5,000 or more or reimbursement, restitution, or damages in excess of \$100,000; or
- (4) Any other criminal, civil, or administrative proceeding if:
 - (i) It could have led to an outcome described in paragraph 2.c.(1), (2), or (3) of this award term and condition;
 - (ii) It had a different disposition arrived at by consent or compromise with an acknowledgment of fault on your part; and
 - (iii) The requirement in this award term and condition to disclose information about the proceeding does not conflict with applicable laws and regulations.

3. Reporting Procedures

Enter in the SAM Entity Management area the information that SAM requires about each proceeding described in paragraph 2 of this award term and condition. You do not need to submit the information a second time under assistance awards that you received if you already provided the information through SAM because you were required to do so under Federal procurement contracts that you were awarded.

4. Reporting Frequency

During any period of time when you are subject to the requirement in paragraph 1 of this award term and condition, you must report proceedings information through SAM for the most recent five year period, either to report new information about any proceeding(s) that you have not reported previously or affirm that there is no new information to report. Recipients that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 must disclose semiannually any information about the criminal, civil, and administrative proceedings.

5. Definitions

For purposes of this award term and condition:

- a. Administrative proceeding means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative proceedings, Civilian Board of Contract Appeals

proceedings, and Armed Services Board of Contract Appeals proceedings). This includes proceedings at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include audits, site visits, corrective plans, or inspection of deliverables.

- b. Conviction, for purposes of this award term and condition, means a judgment or conviction of a criminal offense by any court of competent jurisdiction, whether entered upon a verdict or a plea, and includes a conviction entered upon a plea of nolo contendere.
- c. Total value of currently active grants, cooperative agreements, and procurement contracts includes—
 - (1) Only the Federal share of the funding under any Federal award with a recipient cost share or match; and
 - (2) The value of all expected funding increments under a Federal award and options, even if not yet exercised.

B. [Reserved]

[END OF PROVISION]

[END OF PROVISION]

RAA30. PROGRAM INCOME (AUGUST 2020)

PROGRAM INCOME (August 2020)

- a. Program income is gross income earned by the recipient that is directly generated by a supported activity or earned as a result of the Federal award during the period of performance. Program income includes, but is not limited to: income from fees for services performed; the use or rental of real or personal property acquired under Federal awards; the sale of commodities or items fabricated under a Federal award; license fees and royalties on patents and copyrights; and principal and interest on loans made with Federal award funds. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, or interest earned on any of them.
- b. Program income must be used for the purposes, and under the conditions, of the award, to further project objectives, program objectives, or award activities. Program income must be used only for allowable program costs. Interest earned on program income is subject to the same conditions as program income.
- c. The recipient must apply the approach for use of program income as specified in the schedule of the award. This may include one of the three approaches listed below (see also [2 CFR](#)

200.307). The recipient must also follow the standards in this provision to account for gross income earned from Federally-supported activities under this award.

1) If the deduction approach is used, the recipient must use the program income for current costs, prior to drawdown of USAID funds under the award.

2) If the addition approach is used, the total award amount is increased by the amount of program income. If the award anticipates a specific program income amount, any program income in excess of such amount must be deducted from expenditures.

3) If the cost sharing approach is used, the amount of the award remains the same. If the award anticipates a specific program income amount, any program income in excess of such amount must be deducted from expenditures.

d. Costs subject to generating program income under this award may be deducted from gross income to calculate program income, provided these costs have not been charged to this award and comply with the standard provision, “Allowable Costs.”

e. The recipient must report program income using the **Federal Financial Report, SF-425**. Program income must be accounted for in the same ratio as USAID’s participation in the program. For example, if USAID funded 75 percent of a recipient’s program, then the recipient must report 75 percent of any program income earned under the award as “Federal program income earned” on the SF-425.

f. The recipient should continue to use program income earned after the period of the award to further award objectives, but is not subject to Federal requirements governing the disposition of program income earned after the end of the period of performance for the award.

[END OF PROVISION]

[END OF STANDARD PROVISIONS]

ATTACHMENT D – BRANDING AND MARKING PLAN

Institutional Certification Detail

The institution below has certified on the FDP Clearinghouse that they are compliant with PHS FCOI Regulations.

Institution Name	University of Washington
Authorized Representative	Sinh Simmons
Authorized Representative Title	Associate Director
Authorized Representative Email Address	ssimmons@uw.edu
Primary DUNS Number Optional	18

Sub-Recipient:	
Name	
Address	
Telephone	
Fax	
Email	

Invoice Number: _____	Subaward (G00 _____) Number: _____
Invoice Date: _____	Award Number: _____
Invoice Amount: <u>\$0.00</u>	Subaward PI Name: _____
Cost Share Amount: <u>\$0.00</u>	Subrecipient email address: _____
In Account with:	Subrecipient phone number: _____
Sponsored Programs Services Washington State University PO Box 641025 240 French Administration Building Pullman, WA 99164-1025 (509)-335-2058, sps@wsu.edu	Invoice Period: _____ to _____ <input type="checkbox"/> Check if Final Invoice

Expense Categories	Expenditures for Invoice Period	Cumulative Expenditures	Cost Share Expenditures for Invoice Period	Cost Share Cumulative Expenditures
Project Costs				
Personnel Salaries				
Personnel Wages				
Fringe Benefits				
Supplies & Materials				
Domestic Travel				
International Travel				
Equipment*				
Contractual Services				
Tuition				
Stipends				
Other Direct Costs				
Total Direct Costs	\$0.00	\$0.00	\$0.00	\$0.00
F&A Costs: Rate _____				
Total Costs	\$0.00	\$0.00	\$0.00	\$0.00

*Equipment definition: refer to PART 200—UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR FEDERAL AWARDS, Subpart A, §200.33 Equipment.

http://www.ecfr.gov/cgi-bin/text-idx?SID=421d3e3a239e70bdcef843df7113da50&mc=true&node=se2.1.200_133&rgn=div8

By signing this report, I certify to the best of my knowledge and belief that the report is true, complete, and accurate, and the expenditures, disbursements and cash receipts are for the purposes and objectives set forth in the terms and conditions of the Federal award. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims or otherwise. (U.S. Code Title 18, Section 1001 and Title 31, Sections 3729-3730 and 3801-3812).

Subrecipient authorized representative name and title _____

Phone Number _____

Email Address: _____

Subrecipient authorized representative signature _____

Date _____

Voucher# _____

Date Invoice received: _____

PR: _____

Date paid: _____

Attachment 7
Standard Invoice
REPORT OF MATCHING FUNDS EXPENDED

Subcontractor Name: _____

Invoice #: _____

Vendor's Certificate: I hereby certify under penalty of perjury the items and totals listed herein are proper charges for materials, merchandise or services furnished and/or services rendered and reported as match.

Prepared by: _____

Date: _____

Expenses for period: _____ to _____

Salaries/Wages (examples below)	CASH	IN-KIND	WAIVED F&A	PLEDGED
_____ \$	-	\$ -	\$ -	\$ -
_____ \$	-	\$ -	\$ -	\$ -
_____ \$	-	\$ -	\$ -	\$ -
Total	\$ -	\$ -	\$ -	\$ -
Fringe Benefits				
_____ \$	-	\$ -	\$ -	\$ -
_____ \$	-	\$ -	\$ -	\$ -
_____ \$	-	\$ -	\$ -	\$ -
Total	\$ -	\$ -	\$ -	\$ -
Travel				
Domestic _____ \$	-	\$ -	\$ -	\$ -
International _____ \$	-	\$ -	\$ -	\$ -
Total	\$ -	\$ -	\$ -	\$ -
Goods & Services (examples below)				
_____ \$	-	\$ -	\$ -	\$ -
_____ \$	-	\$ -	\$ -	\$ -
_____ \$	-	\$ -	\$ -	\$ -
Equipment (over \$5,000)				
_____ \$	-	\$ -	\$ -	\$ -
_____ \$	-	\$ -	\$ -	\$ -
_____ \$	-	\$ -	\$ -	\$ -
_____ \$	-	\$ -	\$ -	\$ -
Contractual/Consultants				
_____ \$	-	\$ -	\$ -	\$ -
_____ \$	-	\$ -	\$ -	\$ -
_____ \$	-	\$ -	\$ -	\$ -
F&A @	\$ -	\$ -	\$ -	\$ -
TOTAL - THIS REPORT	\$ -	\$ -	\$ -	\$ -
Previously Reported	\$ -	\$ -	\$ -	\$ -
CUMULATIVE-TO-DATE	\$ -	\$ -	\$ -	\$ -
TOTAL AMOUNT PLEDGED:	\$ -			
BALANCE OF COST SHARE	\$ -			
PERCENT of COST SHARE MET	#DIV/0!			

This report shows the cash and in-kind match by the subcontractor.
Match must be met from non-federal funds and must not be used as match on any other grant.
The time frame of match, whether purchase or work, must be within the time frame of the grant.
Any item submitted as match must also be considered an "allowable" cost on the grant.

From: ORSO <ORSO@wsu.edu>
Sent: Wednesday, May 25, 2022 10:34 AM
To: filimus@uw.edu; osp@uw.edu
Cc: Yager, Amanda L; Howard, Tyler J; Boni, Troy; Moore, Anke Marga-Christa
Subject: Fully executed SPC003515A
Attachments: 141061_SPC003515A AM DN.pdf

Hello,

Attached is the fully executed agreement.

Thank you,



KATE MARTINSON

e-RESEARCH ADMINISTRATION COORDINATOR
Office of Research Support and Operations
Office of Research
Washington State University
Office: 509-335-9661
Work email: orso@wsu.edu
Personal email: katharine.martinson@wsu.edu
orso.wsu.edu
Pronouns: She/Her/Hers

FDP Subaward Amendment			
Amendment No 1		Subaward No 141061 SPC003515	
Pass-Through Entity (PTE)		Subrecipient	
Washington State University		Entity Name University of Washington	
orso@wsu.edu		Contact Email osp@wsu.edu	
Felix Lankester		Principal Investigator Peter Rabinowitz	
Project Title Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)			
PTE/Prime Award No. 7200AA21CA00033		Awarding Agency US Agency for International Development	
Cumulative Budget Period(s) <small>(Agreement Start Date) (End Date of Latest Budget Period)</small> Start Date: 10/01/2021 End Date: 09/30/2022		Amount Funded This Action \$ 1,989,675.00	
Total Amount of Funds Obligated to Date \$ 2,250,000.00			
Subrecipient Cost Share <input type="checkbox"/>		Subject to FFATA <input type="checkbox"/>	
Subrecipient UEI <small>(Unique Entity Identifier - May leave blank if unchanged from prior Agreement)</small>		18	
Amendment(s) to Original Terms and Conditions This Amendment revises the above-referenced Subaward Agreement as follows:			
<div style="margin-bottom: 10px;"><input type="checkbox"/> Additional Budget Period</div> <div style="margin-bottom: 10px;"><input type="checkbox"/> No Cost Extension</div> <div style="margin-bottom: 10px;"><input checked="" type="checkbox"/> Additional Funding Additional funding in the amount of \$ 1,989,675.00 is hereby obligated to this Subaward. </div> <div style="margin-bottom: 10px;"><input type="checkbox"/> Deobligation</div> <div style="margin-bottom: 10px;">Carryover is Automatic Carryover is allowed across all budget periods.</div> <div style="margin-bottom: 10px;"><input type="checkbox"/> Carryover Authorized</div> <div style="margin-bottom: 10px;"><input checked="" type="checkbox"/> Detailed Budget/Scope of Work/Notice of Award Attached <small>(Specify if the Budget and Scope of Work are "New", "Revised", or "Supplemental" in dropdown or "Other")</small> A Detailed Budget is incorporated by attachment to this Amendment. </div> <div style="margin-bottom: 10px;"><input checked="" type="checkbox"/> Other (See Below)</div> <div style="font-size: small; padding-top: 10px;"> Additional cost share of \$100,081 is incorporated. Monthly technical/progress reports will be submitted to the PTE's Administrator contact Chana Rabiner. Approval for subawards issued under this award are no longer subject to additional USAID approval. If applicable, Subrecipient certifies that its Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), and Institutional Review Board (IRB) are in full compliance with applicable state and federal laws and regulations. Subrecipient agrees that any non-exempt research involving animals, recombinant or synthetic nucleic acid molecules or select agents, and human subjects conducted under this agreement shall be reviewed and approved by its IACUC/IBC/IRB, as applicable. In Addition, Subrecipient will maintain current and duly approved research protocols for all periods of the Agreement involving animals, recombinant or synthetic nucleic acid molecules or select agents, and human subjects. The Subrecipient certifies that any submitted animal protocol, recombinant or synthetic nucleic acid molecules or select agents protocol, and human subjects protocol approval represents a valid, approved protocol that is entirely consistent with project associated with this subaward. In no event shall subrecipient invoice or be reimbursed for any research involving animals, recombinant or synthetic nucleic acid molecules or select agents, or human subject related expense incurred in a period where any applicable approval is not properly in place. In addition to other applicable provisions in the NOA, the mandatory standard provisions for U.S. Nongovernmental organizations found in the NOA are incorporated by reference into this subaward. Washington State University is an educational institution of the state of Washington, WSU is subject to Washington State laws and regulations including the Washington Public Records Act, RCW 42.56 et seq. </div>			
<i>For clarity: all amounts stated in this amendment are in United States Dollars.</i>			
All other terms and conditions of this Subaward Agreement remain in full force and effect.			
By an Authorized Official of PTE:		By an Authorized Official of Subrecipient:	
<div style="text-align: right; margin-right: 50px;">Date </div> <div style="border: 1px solid black; height: 20px; width: 100%;"></div>		<div style="text-align: right; margin-right: 50px;">Date </div> <div style="border: 1px solid black; height: 20px; width: 100%;"></div>	
Name 		Name Ariadna A. Santander	
Title 		Title Manager, Office of Sponsored Programs	

PI Name(s): Lankester, Felix		YR1
		2nd Allotment
Agency Name: USAID		Cognizant Agency
Approved By: Troy Boni Date: 4/17*/22	Category/Object	Year 1
	Salaries - 00	621,551
	Wages - 01	
	Personal Svc Contract - 02	
	Goods/Services - 03	194,315
	Travel - 04	63,340
	Computer Services - 05	
	Equipment - 06	186,900
	Benefits - 07	170,813
	Tuition (QTR) - 07QT	
	Stipends/Subsides - 08	
	SBCTs - 14	355,000
	Small/Attractive Items - 16	
Total Direct Costs		49
F&A - 13		397,756
Total Costs		1,989,675
Cost Share		100,081

University of Washington

Budget Item ID		Esc Factor	Unit Cost, \$	Unit	YR 1 Units	Year 1 BUDGET \$	Yr 1 1st Allotment \$	Yr 1 2nd Allotment \$
a.	Personnel							
	<i>Co-PI</i>							
	Peter Rabinowitz	0	\$ 217,092	LOE	0.10	\$ 21,709.00	\$ 4,987.00	\$ 16,722.00
	<i>Emerging Pathogen Specialist</i>							
	Noelle Benzekri	0	\$ 164,400	LOE	0.08	\$ 13,700.00	\$ 3,147.00	\$ 10,553.00
	<i>Risk Assessment and Sampling Technical Advisor</i>							\$ -
	John Scott Meschke	0	\$ 191,640	LOE	0.13	\$ 23,955.00	\$ 5,502.00	\$ 18,453.00
	<i>One Health Epidemiologist</i>							\$ -
	Julianne Meisner	0	\$ 110,400	LOE	0.33	\$ 36,800.00	\$ 8,453.00	\$ 28,347.00
	<i>One Health Social Scientist</i>							\$ -
	Kevin Bardosh	0	\$ 122,766	LOE	0.17	\$ 20,461.00	\$ 4,700.00	\$ 15,761.00
	<i>Data Manager and Analyst</i>							\$ -
	Anna Baines	0	\$ 78,000	LOE	0.42	\$ 32,500.00	\$ 7,465.00	\$ 25,035.00
	<i>Manager</i>							\$ -
	Vickie Ramirez	0	\$ 84,852	LOE	0.42	\$ 35,355.00	\$ 8,121.00	\$ 27,234.00
	<i>Co-PI</i>							\$ -
	Judy Wasserheit	0	\$ 396,324	LOE	0.04	\$ 16,514.00	\$ 3,793.00	\$ 12,721.00
	<i>Senior Program and Technical Manager</i>							\$ -
	Fernanda Freistadt	0	\$ 104,280	LOE	0.58	\$ 60,830.00	\$ 13,973.00	\$ 46,857.00
	<i>Co-PI (Lab)</i>							\$ -
	Alex Greninger	0	\$ 211,440	LOE	0.25	\$ 52,860.00	\$ 12,142.00	\$ 40,718.00
	<i>Research Faculty</i>							\$ -
	Pavitra Roychoudhury	0	\$ 76,560	LOE	0.14	\$ 10,718.00	\$ 2,462.00	\$ 8,256.00
	<i>Research Scientist</i>							\$ -
	Nicole Lieberman	0	\$ 86,712	LOE	0.20	\$ 17,342.00	\$ 3,983.00	\$ 13,359.00
	<i>Research Scientist</i>							\$ -
	Mee-li Huang	0	\$ 114,408	LOE	0.05	\$ 5,720.00	\$ 1,314.00	\$ 4,406.00
	<i>Research Scientist</i>							\$ -
	Jonathan Reed,	0	\$ 91,800	LOE	0.20	\$ 18,360.00	\$ 4,217.00	\$ 14,143.00
	<i>Research Scientist</i>							\$ -
	Hong Xie	0	\$ 78,864	LOE	0.20	\$ 15,773.00	\$ 3,623.00	\$ 12,150.00
	<i>Research Scientist</i>							\$ -
	Quynh Phung	0	\$ 51,576	LOE	0.25	\$ 12,894.00	\$ 2,962.00	\$ 9,932.00
	<i>Computer Scientist</i>							\$ -
	Paul (Kurtis) Cruz,	0	\$ 71,388	LOE	0.20	\$ 14,278.00	\$ 3,280.00	\$ 10,998.00
	<i>Co-Investigator</i>							\$ -
	Michael Gale	0	\$ 318,336	LOE	0.08	\$ 23,875.00	\$ 5,484.00	\$ 18,391.00
	<i>Research Scientist</i>							\$ -
	Linhui Hao	0	\$ 72,000	LOE	0.13	\$ 9,000.00	\$ 2,067.00	\$ 6,933.00
	<i>Research Scientist</i>							\$ -
	Tien-Ying Hsiang	0	\$ 70,764	LOE	0.13	\$ 8,846.00	\$ 2,032.00	\$ 6,814.00
	<i>Research Technician</i>							\$ -
	James (Bryan) Turnbull,	0	\$ 53,052	LOE	0.18	\$ 9,284.00	\$ 2,133.00	\$ 7,151.00
	<i>Co-Investigator</i>							\$ -
	Wesley C. Van Voorhis	0	\$ 269,448	LOE	0.15	\$ 40,417.00	\$ 9,284.00	\$ 31,133.00
	<i>Lab Research Manager</i>							\$ -
	Lynn Barrett	0	\$ 133,584	LOE	0.15	\$ 20,038.00	\$ 4,603.00	\$ 15,435.00
	<i>Research Scientist</i>							\$ -
	TBD	0	\$ 68,640	LOE	0.13	\$ 8,580.00	\$ 1,971.00	\$ 6,609.00
	<i>Bioinformatics Specialist</i>							\$ -
	TBD	0	\$ 110,240	LOE	0.10	\$ 11,024.00	\$ 2,532.00	\$ 8,492.00
	<i>Program Coordinator</i>							\$ -
	Sasha Tilles	0	\$ 58,140	LOE	0.25	\$ 14,535.00	\$ 3,339.00	\$ 11,196.00
	<i>Co-Investigator</i>							\$ -
	David Veessler	0	\$ 145,260	LOE	0.04	\$ 5,447.00	\$ 1,251.00	\$ 4,196.00
	<i>Research Scientist</i>							\$ -
	Alexandra (Lexi) Walls	0	\$ 102,012	LOE	0.15	\$ 15,302.00	\$ 3,515.00	\$ 11,787.00
	<i>Research Scientist</i>							\$ -
	Young-Jun Park	0	\$ 78,240	LOE	0.13	\$ 9,780.00	\$ 2,246.00	\$ 7,534.00
	<i>Research Scientist</i>							\$ -
	Kaitlin Sprouse,	0	\$ 66,216	LOE	0.38	\$ 24,831.00	\$ 5,704.00	\$ 19,127.00
	<i>Research Technician</i>							\$ -
	Mary-Jane Navarro	0	\$ 51,900	LOE	0.25	\$ 12,975.00	\$ 2,980.00	\$ 9,995.00
	<i>Co-Investigator</i>							\$ -
	David Baker,	0	\$ 409,320	LOE	0.02	\$ 6,140.00	\$ 1,410.00	\$ 4,730.00
	<i>Acting Instructor</i>							\$ -
	Ivan Anishchanka,	0	\$ 102,012	LOE	0.13	\$ 12,752.00	\$ 2,929.00	\$ 9,823.00
	<i>Post Doctoral Scholar</i>							\$ -
	Minkyng Baek	0	\$ 59,160	LOE	0.25	\$ 14,790.00	\$ 3,397.00	\$ 11,393.00
	<i>Post Doctoral Scholar</i>							\$ -
	Justas Dauparas	0	\$ 59,160	LOE	0.13	\$ 7,395.00	\$ 1,699.00	\$ 5,696.00
	Total Personnel					\$ 664,780.00	\$ 152,700.00	\$ 512,080.00

University of Washington

Budget Item ID		Esc Factor	Unit Cost, \$	Unit	YR 1 Units	Year 1 BUDGET \$	Yr 1 1st Allotment \$	Yr 1 2nd Allotment \$
b.	Fringe Benefits							
	Co-PI		23.20%	percent		\$ 5,036.00	\$ 1,081.00	\$ 3,955.00
	Emerging Pathogen Specialist		23.20%	percent		\$ 3,178.00	\$ 682.00	\$ 2,496.00
	Risk Assessment and Sampling Technical Advisor		23.20%	percent		\$ 5,558.00	\$ 1,192.00	\$ 4,366.00
	One Health Epidemiologist		23.20%	percent		\$ 8,538.00	\$ 1,833.00	\$ 6,705.00
	One Health Social Scientist		23.20%	percent		\$ 4,747.00	\$ 1,019.00	\$ 3,728.00
	Data Manager and Analyst		29.40%	percent		\$ 9,555.00	\$ 2,051.00	\$ 7,504.00
	Manager		29.40%	percent		\$ 10,394.00	\$ 2,232.00	\$ 8,162.00
	Co-PI		23.20%	percent		\$ 3,831.00	\$ 822.00	\$ 3,009.00
	Senior Program and Technical Manager		29.40%	percent		\$ 17,884.00	\$ 3,839.00	\$ 14,045.00
	Co-PI (Lab)		23.20%	percent		\$ 12,264.00	\$ 2,632.00	\$ 9,632.00
	Research Faculty		23.20%	percent		\$ 2,487.00	\$ 534.00	\$ 1,953.00
	Research Scientist		29.40%	percent		\$ 5,099.00	\$ 1,094.00	\$ 4,005.00
	Research Scientist		29.40%	percent		\$ 1,682.00	\$ 361.00	\$ 1,321.00
	Research Scientist		29.40%	percent		\$ 5,398.00	\$ 677.00	\$ 4,721.00
	Research Scientist		29.40%	percent		\$ 4,637.00	\$ 1,094.00	\$ 3,543.00
	Research Scientist		29.40%	percent		\$ 3,791.00	\$ 361.00	\$ 3,430.00
	Computer Scientist		29.40%	percent		\$ 4,198.00	\$ 901.00	\$ 3,297.00
	Co-Investigator		23.20%	percent		\$ 5,539.00	\$ 1,189.00	\$ 4,350.00
	Research Scientist		29.40%	percent		\$ 2,646.00	\$ 568.00	\$ 2,078.00
	Research Scientist		29.40%	percent		\$ 2,601.00	\$ 558.00	\$ 2,043.00
	Research Technician		29.40%	percent		\$ 2,729.00	\$ 586.00	\$ 2,143.00
	Co-Investigator		23.20%	percent		\$ 9,377.00	\$ 2,013.00	\$ 7,364.00
	Lab Research Manager		29.40%	percent		\$ 5,891.00	\$ 1,264.00	\$ 4,627.00
	Research Scientist		29.40%	percent		\$ 2,523.00	\$ 541.00	\$ 1,982.00
	Bioinformatics Specialist		29.40%	percent		\$ 3,241.00	\$ 695.00	\$ 2,546.00
	Program Coordinator		29.40%	percent		\$ 4,273.00	\$ 918.00	\$ 3,355.00
	Co-Investigator		23.20%	percent		\$ 1,264.00	\$ 271.00	\$ 993.00
	Research Scientist		29.40%	percent		\$ 4,499.00	\$ 965.00	\$ 3,534.00
	Research Scientist		29.40%	percent		\$ 2,875.00	\$ 617.00	\$ 2,258.00
	Research Scientist		29.40%	percent		\$ 7,300.00	\$ 1,567.00	\$ 5,733.00
	Research Technician		29.40%	percent		\$ 3,815.00	\$ 819.00	\$ 2,996.00
	Co-Investigator		23.20%	percent		\$ 1,424.00	\$ 306.00	\$ 1,118.00
	Acting Instructor		23.20%	percent		\$ 2,958.00	\$ 635.00	\$ 2,323.00
	Post Doctoral Scholar		29.40%	percent		\$ 4,348.00	\$ 934.00	\$ 3,414.00
	Post Doctoral Scholar		29.40%	percent		\$ 2,174.00	\$ 467.00	\$ 1,707.00
Total Fringe Benefits						\$ 177,754.00	\$ 37,318.00	\$ 140,436.00
c.	Travel							
	Travel 1 - Sampling Group - 5 trips 8 days each		\$ 4,780	trip	5	\$ 23,900.00	\$ -	\$ 23,900.00
	Travel 2 - Detection Group - 5 trips 8 days each		\$ 4,064	trip	5	\$ 20,320.00	\$ -	\$ 20,320.00
Total Travel						\$ 44,220.00	\$ -	\$ 44,220.00
d.	Equipment							
	Equipment 1	0		each		\$ -	\$ -	\$ -
Total Equipment						\$ -	\$ -	\$ -
e.	Materials and Supplies							
	Supplies 1 - Office Supplies		\$ 234	lot	12.00	\$ 2,808.00	\$ -	\$ 2,808.00
	Supplies 2 - Laptops		\$ 1,153	lot	2.00	\$ 2,306.00	\$ -	\$ 2,306.00
	Supplies 3 - Sequencing kits (Greninger Lab)		\$ 25,000	lot	0.25	\$ 6,250.00	\$ -	\$ 6,250.00
	Supplies 4 - Molecular biology (Greninger Lab)		\$ 25,000	lot	0.25	\$ 6,250.00	\$ -	\$ 6,250.00
	Supplies 5 - Serology materials, cell culture (Greninger Lab)		\$ 25,000	lot	0.25	\$ 6,250.00	\$ -	\$ 6,250.00
	Supplies 6 - Lab supplies (Michael Gale Lab)		\$ 68,274	lot	0.50	\$ 34,137.00	\$ -	\$ 34,137.00
	Supplies 7 - Lab supplies (Van Voorhis Lab)		\$ 13,490	lot	1	\$ 13,490.00	\$ -	\$ 13,490.00
	Supplies 8 Lab supplies (Veesler Labs)		\$ 17,983	lot	1	\$ 17,983.00	\$ -	\$ 17,983.00
Total Supplies						\$ 89,474.00	\$ -	\$ 89,474.00
f.	Contractual Services							
				lot		\$ -	\$ -	\$ -
Total Contractual Services						\$ -	\$ -	\$ -
g.	US subawards							
Sub 1			\$ -			\$ -	\$ -	\$ -
Total US Subawards						\$ -	\$ -	\$ -
h.	Tuition							
	GRA Tuition			lot		\$ -	\$ -	\$ -
Total Tuition						\$ -	\$ -	\$ -
i.	Other Direct Costs							
	ODC 1 - Publishing Costs	0	\$ 600	lot	1	\$ 600.00	\$ -	\$ 600.00

University of Washington

Budget Item ID		Esc Factor	Unit Cost, \$	Unit	YR 1 Units	Year 1 BUDGET \$	Yr 1 1st Allotment \$	Yr 1 2nd Allotment \$
	ODC 2 - SLU Shared Equipment Maintenance Fund	0	\$ 250,000	lot	0.010	\$ 2,500.00	\$ -	\$ 2,500.00
	ODC 3 - BSL3 fees	0	\$ 8,141	lot	1	\$ 8,141.00	\$ -	\$ 8,141.00
	ODC 4 - BSL2 glassware washing and biohazard waste fees	0	\$ 800	lot	0.50	\$ 400.00	\$ -	\$ 400.00
	ODC 5 - Lab equipment service contracts	0	\$ 35,052	lot	0.13	\$ 4,382.00	\$ -	\$ 4,382.00
	ODC 6 - Nebula	0	\$ 300	lot	5	\$ 1,647.00	\$ -	\$ 1,647.00
	ODC 7 - 'I-TECH Center Support (ICS)	0	\$ 28,000	lot	1	\$ 28,000.00	\$ -	\$ 28,000.00
	Total Other Direct Costs					\$ 45,670.00	\$ -	\$ 45,670.00
j.	Total Direct Cost					\$ 1,021,898.00	\$ 190,018.00	\$ 831,880.00
	Modified Total Direct Costs					\$ 1,021,898.00	\$ 190,018.00	\$ 831,880.00
k.1	Indirect Cost (MTDC base)		49%	Percent		\$ 49	\$ 49	\$ 49
			0%	Percent		\$ -	\$ -	\$ -
k.	Total Indirect Cost					\$ 49	\$ 49	\$ 49
l.	Total					\$ 1,400,000.00	\$ 260,325.00	\$ 1,139,675.00

University of Washington

UW Peru

Peru

Budget Item ID	Esc Factor	Unit Cost, \$	Unit	YR 1 Units	Year 1 Budget Total \$	Total, \$
a. Personnel						
Senior Program and Technical Manager						
Fernanda Freistadt	0	\$ 104,280	LOE	0.30	31,284.00	31,284.00
Instructional Designer						
TBD	0	\$ 93,000	LOE	0.50	46,500.00	46,500.00
Contracts Manager						
Maya Beal	0	\$ 102,240	LOE	0.03	2,556.00	2,556.00
Co-PI						
Peter Rabinowitz	0	\$ 217,092	LOE	0.08	18,091.00	18,091.00
One Health Epidemiologist						
Julianne Meisner	0	\$ 110,400	LOE	0.10	11,040.00	11,040.00
Total Personnel					109,471.00	109,471.00
b. Fringe Benefits						
Senior Program and Technical Manager		29.40%	percent		9,197.00	9,197.00
Instructional Designer		29.40%	percent		13,671.00	13,671.00
Contracts Manager		29.40%	percent		751.00	751.00
Co-PI		23.20%	percent		4,197.00	4,197.00
One Health Epidemiologist		23.20%	percent		2,561.00	2,561.00
Total Fringe Benefits					30,377.00	30,377.00
c. Travel						
Planning and Assessment		\$ 4,780	trip	4	19,120.00	19,120.00
Total Travel					19,120.00	19,120.00
d. Equipment						
Equipment 1 - Thermo Scientific TSX Series Ultra-Low Tempera	0	\$ 11,900	each	1	11,900.00	11,900.00
Equipment 2 - Quantstudio qRT-PCR platforms	0	\$ 67,000	each	1	67,000.00	67,000.00
Equipment 3 - ELISA plate and washer systems - Synergy LX M	0	\$ 23,000	each	1	23,000.00	23,000.00
Equipment 4 - KingFisher Flex RNA extraction & purification ma	0	\$ 85,000	each	1	85,000.00	85,000.00
Total Equipment					186,900.00	186,900.00
e. Materials and Supplies						
Supplies 1 - Lab test kits		\$ 96	lot	125	12,000.00	12,000.00
Supplies 2 - Office Supplies		\$ 280	lot	6	1,680.00	1,680.00
Supplies 3 - Laptops		\$ 1,155	lot	2	2,310.00	2,310.00
Supplies 4 - Planful Analytics Software License		\$ 968	lot	1	968.00	968.00
Total Supplies					16,958.00	16,958.00
f. Contractual Services/Secondary Focus Country Partners						
			lot		-	-
Total Contractual Services					-	-
g. US subawards						
Sub 1 Universidad Peruana Cayetano Heredia		\$ 355,000		1	355,000.00	355,000.00
Total US Subawards					355,000.00	355,000.00
h. Tuition						
Tuition 1	0		lot		-	-
Total Tuition					-	-
i. Other Direct Costs						
ODC 1 - Sample transport and shipping	0	\$ 150	lot	40	6,000.00	6,000.00
ODC 2 - Biosafety and Security Training Costs	0	\$ 294	lot	21	6,180.00	6,180.00
ODC 3 - Nebula Services	0	\$ 300	FTE	1	409.00	409.00
ODC 4 - I-TECH Center Support (ICS)	0	\$ 17,000	lot	1	17,000.00	17,000.00
ODC 8 - Shipping Equipment from USA to Peru	0	\$ 12,624	lot	1	12,624.00	12,624.00
Total Other Direct Costs					42,213.00	42,213.00
j. Total Direct Cost					760,039.00	760,039.00
MTDC					243,139.00	243,139.00
k.1 Indirect Cost (MTDC base)		49%	Percent		49	49
		0%	Percent		-	-
k. Total Indirect Cost					49	49
l. Total					850,000.00	850,000.00

From: ORSO <ORSO@wsu.edu>
Sent: Friday, January 7, 2022 3:01 PM
To: mrodden@wustl.edu; Yager, Amanda L; Moore, Anke Marga-Christa
Subject: Fully executed SPC003545
Attachments: 141061 SPC003545 AM DB.pdf

Hello,

Attached is the fully executed agreement for your records.

Thank you,



KATE MARTINSON

e-RESEARCH ADMINISTRATION COORDINATOR

Office of Research Support and Operations

Office of Research

Washington State University

Office: 509-335-9661

Email: katharine.martinson@wsu.edu

orso.wsu.edu

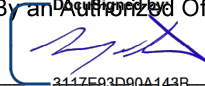
Pronouns: She/Her/Hers

FDP Cost Reimbursement Subaward

Federal Awarding Agency: Other [Type in Agency]		US Agency for International Development
Pass-Through Entity (PTE):		Subrecipient:
Washington State University		The Washington University
PTE PI: Felix Lankester	Sub PI: David Wang	
PTE Federal Award No: 18	Subaward No: 141061 - SPC003545	
Project Title: Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)		
Subaward Budget Period:		Amount Funded This Action (USD): \$ 91,051.00
Start: 10/01/2021	End: 09/30/2022	
Estimated Period of Performance:		Incrementally Estimated Total (USD): \$ 7,500,000.00
Start: 10/01/2021	End: 09/30/2026	

Terms and Conditions

1. PTE hereby awards a cost reimbursable subaward, (as determined by 2 CFR 200.331), to Subrecipient. The Statement of Work and budget for this Subaward are as shown in Attachment 5. In its performance of Subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.
2. Subrecipient shall submit invoices not more often than monthly and not less frequently than quarterly for allowable costs incurred. Upon the receipt of proper invoices, the PTE agrees to process payments in accordance with this Subaward and 2 CFR 200.305. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), breakdown by major cost category, Subaward number, and certification, as required in 2 CFR 200.415(a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments shall be directed to the party's Financial Contact, shown in Attachment 3A.
3. A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Financial Contact, as shown in Attachment 3A, not later than 60 days after the final Budget Period end date. The final statement of costs shall constitute Subrecipient's final financial report.
4. All payments shall be considered provisional and are subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Subrecipient.
5. Matters concerning the technical performance of this Subaward shall be directed to the appropriate party's Principal Investigator as shown in Attachments 3A and 3B. Technical reports are required as shown in Attachment 4.
6. Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this Subaward, and any changes requiring prior approval, shall be directed to the PTE's Authorized Official Contact and the Subrecipient's Authorized Official Contact shown in Attachments 3A and 3B. Any such change made to this Subaward requires the written approval of each party's Authorized Official as shown in Attachments 3A and 3B.
7. The PTE may issue non-substantive changes to the Budget Period(s) and Budget Bilaterally. Unilateral modification shall be considered valid 14 days after receipt unless otherwise indicated by Subrecipient when sent to Subrecipient's Authorized Official Contact, as shown in Attachment 3B.
8. Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.
9. Either party may terminate this Subaward with 30 days written notice. Notwithstanding, if the Awarding Agency terminates the Federal Award, PTE will terminate in accordance with Awarding Agency requirements. PTE notice shall be directed to the Authorized Official Contact, and Subrecipient notice shall be directed to the Authorized Official Contact as shown in Attachments 3A and 3B. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix IX, as applicable.
10. By signing this Subaward, including the attachments hereto which are hereby incorporated by reference, Subrecipient certifies that it will perform the Statement of Work in accordance with the terms and conditions of this Subaward and the applicable terms of the Federal Award, including the appropriate Research Terms and Conditions ("RTCs") of the Federal Awarding Agency, as referenced in Attachment 2. The parties further agree that they intend this subaward to comply with all applicable laws, regulations, and requirements.

By an Authorized Official of the PTE:		By an Authorized Official of the Subrecipient:	
		 <small>3147E93D90A143B...</small>	
Name: _____	Date: _____	Name: Megan M. White	Date: 1/6/2022 10:43 AM
Title: _____		Title: Director, Research Contracts	

Attachment 1

Certifications and Assurances

Subaward Number:

141061 - SPC003545

Certification Regarding Lobbying (2 CFR 200.450)

By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief, that no Federal appropriated funds have been paid or will be paid, by or on behalf of the Subrecipient, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement in accordance with 2 CFR 200.450.

If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or intending to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the Subrecipient shall complete and submit Standard Form -LLL, "Disclosure Form to Report Lobbying," to the PTE.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by 31 U.S.C. 1352. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

Debarment, Suspension, and Other Responsibility Matters (2 CFR 200.214 and 2 CFR 180)

By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief that neither the Subrecipient nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this transaction by any federal department or agency, in accordance with 2 CFR 200.213 and 2 CFR 180.

Audit and Access to Records

Subrecipient certifies that it will provide PTE with notice of any adverse findings which impact this Subaward. Subrecipient certifies compliance with applicable provisions of 2 CFR 200.501-200.521. If Subrecipient is not required to have a Single Audit as defined by 200.501, Awarding Agency requirements, or the Single Audit Act, then Subrecipient will provide notice of the completion of any required audits and will provide access to such audits upon request. Subrecipient will provide access to records as required by parts 2 CFR 200.337 and 200.338 as applicable.

Program for Enhancement of Contractor Employee Protections (41 U.S.C 4712)

Subrecipient is hereby notified that they are required to: inform their employees working on any federal award that they are subject to the whistleblower rights and remedies of the program; inform their employees in writing of employee whistleblower protections under 41 U.S.C §4712 in the predominant native language of the workforce; and include such requirements in any agreement made with a subcontractor or subgrantee.

The Subrecipient shall require that the language of the certifications above in this Attachment 1 be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

Use of Name

Neither party shall use the other party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may use factual information regarding the existence and purpose of the relationship that is the subject of this Subaward for legitimate business purposes, to satisfy any reporting and funding obligations, or as required by applicable law or regulation without written permission from the other party. In any such statement, the relationship of the parties shall be accurately and appropriately described.

Prohibition on Certain Telecommunication and Video Surveillance Services or Equipment

Pursuant to 2 CFR 200.216, Subrecipient will not obligate or expend funds received under this Subaward to: (1) procure or obtain; (2) extend or renew a contract to procure or obtain; or (3) enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that uses covered telecommunications equipment or services (as described in Public Law 115-232, section 889) as a substantial or essential component of any system, or as a critical technology as part of any system.

Attachment 2

Federal Award Terms and Conditions

Subaward Number

141061 - SPC003545

Required Data Elements

The data elements required by Uniform
Guidance are incorporated in the attached Federal Award.

Awarding Agency Institute (If Applicable)

USAID

Federal Award Issue Date FAIN Assistance Listing No.

09/22/21

7200AA21CA00033

98.001

Assistance Listing Program Title (ALPT)

USAID Foreign Assistance for Programs Overseas

Key Personnel Per NOA

Ch. Rabiner; B.T. Leader

This Subaward Is:

Research & Development



Subject to FFATA

General Terms and Conditions

By signing this Subaward, Subrecipient agrees to the following:

1. To abide by the conditions on activities and restrictions on expenditure of federal funds in appropriations acts that are applicable to this Subaward to the extent those restrictions are pertinent. This includes any recent legislation noted on the Federal Awarding Agency's website:

<https://www.usaid.gov/who-we-are/agency-policy>

2. 2 CFR 200

3. The Federal Awarding Agency's grants policy guidance, including addenda in effect as of the beginning date of the period of performance or as amended found at:

<https://www.usaid.gov/ads/policy/300/303>

4. Research Terms and Conditions, including any Federal Awarding Agency's Specific Requirements found at:

see attachment #6

except for the following :

- a. No-cost extensions require the written approval of the PTE. Any requests for a no-cost extension shall be directed to the Authorized Official Contact shown in Attachment 3A, not less than 30 days prior to the desired effective date of the requested change.
- b. Any payment mechanisms and financial reporting requirements described in the applicable Federal Awarding Agency Terms and Conditions and Agency-Specific Requirements are replaced with Terms and Conditions (1) through (4) of this Subaward; and
- c. Any prior approvals are to be sought from the PTE and not the Federal Awarding Agency.
- d. Title to equipment as defined in 2 CFR 200.1 that is purchased or fabricated with research funds or Subrecipient cost sharing funds, as direct costs of the project or program, shall vest in the Subrecipient subject to the conditions specified in 2 CFR 200.313.
- e. Prior approval must be sought for a change in Subrecipient PI or change in Key Personnel (defined as listed on the NOA).

5. Treatment of program income: Additive

Special Terms and Conditions:**Data Sharing and Access:**

Subrecipient agrees to comply with the Federal Awarding Agency's data sharing and/or access requirements as reflected in the NOA or the Federal Awarding Agency's standard terms and conditions as referenced in General Terms and Conditions 1-4 above.

Provided upon request

is a Data Management and/or Sharing Plan that incorporates additional requirements as submitted to the Federal Awarding Agency.

Data Rights:

Subrecipient grants to PTE the right to use data created in the performance of this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Copyrights:

Subrecipient Shall Grant

to PTE an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted material (including any computer software and its documentation and/or databases) first developed and delivered under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Subrecipient grants to PTE the right to use any written progress reports and deliverables created under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its Federal Award.

Promoting Objectivity in Research (COI):

Subrecipient must designate herein which entity's Financial Conflicts of Interest policy (COI) will apply: Subrecipient

If applying its own COI policy, by execution of this Subaward, Subrecipient certifies that its policy complies with the requirements of the relevant Federal Awarding Agency as identified herein: US Agency for International Development

Subrecipient shall report any financial conflict of interest to PTE's Administrative Representative or COI contact, as designated on Attachment 3A. Any financial conflicts of interest identified shall, when applicable, subsequently be reported to Federal Awarding Agency. Such report shall be made before expenditure of funds authorized in this Subaward and within 45 days of any subsequently identified COI.

Work Involving Human or Vertebrate Animals (Select Applicable Options)☐ No Human or Vertebrate Animals

IRB

Upon Request

☒ Human Subjects

IACUC

Upon Request

☒ Vertebrate Animals*The PTE requires verification of IRB and/or IACUC approval be sent to the **Administrative Contact** as required above:*

Subrecipient agrees that any non-exempt human and/or vertebrate animal research protocol conducted under this Subaward shall be reviewed and approved by the appropriate Institutional Review Board (IRB) and/or its Institutional Animal Care and Use Committee (IACUC), as applicable and that it will maintain current and duly approved research protocols for all periods of the Subaward involving human and/or vertebrate animal research. Subrecipient certifies that the appropriate IRB and/or IACUC are in full compliance with applicable state and federal laws and regulations. The Subrecipient certifies that any submitted IRB / IACUC approval represents a valid, approved protocol that is entirely consistent with the Project associated with this Subaward. In no event shall Subrecipient invoice or be reimbursed for any human or vertebrate animals related expenses incurred in a period where any applicable IRB / IACUC approval is not properly in place.

Human Subjects Data (Select One)

Applicable

Human Subjects Data will be exchanged under this Subaward (check all that apply):

The PTE will set forth the terms of the exchange of Human Subjects Data (Select One):

☒ From Subrecipient to PTE☒ From PTE to Subrecipient

Via a separate Data Use Agreement

This section left intentionally blank

Additional Terms

Subawards issued under this award are subject to additional USAID approval.

If applicable, Subrecipient certifies that its Institutional Biosafety committee is in full compliance with applicable state and federal laws and regulations. Subrecipient agrees that any non-exempt research involving recombinant or synthetic nucleic acid molecules or select agents conducted under this agreement shall be reviewed and approved by its Institutional Biosafety Committee, as applicable. In Addition, Subrecipient will maintain current and duly approved research protocols for all periods of the Agreement involving recombinant or synthetic nucleic acid molecules or select agents.

The Subrecipient certifies that any submitted recombinant or synthetic nucleic acid molecules or select agents approval represents a valid, approved protocol that is entirely consistent with project associated with this subaward. In no event shall subrecipient invoice or be reimbursed for any recombinant or synthetic nucleic acid molecules or select agents related expense incurred in a period where any applicable IRB/IACUC approval is not properly in place.

In addition to other applicable provisions in the NOA, the mandatory provisions for U.S. Nongovernmental organizations found in the NOA as part of Attachment 6 (Pages 40-65 of this subaward) are incorporated by reference into this subaward.

Attachment 3A
Pass-Through Entity (PTE) Contacts

Subaward Number:

141061 - SPC003545

PTE Information

Entity Name: Washington State University

Legal Address: Office of Research Support and Operations
280 Lighty
PO Box 641060
Pullman, WA 99164-1060Website: <https://orso.wsu.edu/>**PTE Contacts**

Central Email: orso@wsu.edu

Principal Investigator Name: Felix Lankester

Email: felix.lankester@wsu.edu

Telephone Number:

Administrative Contact Name: Chana Rabiner

Email: chana.rabiner@wsu.edu

Telephone Number:

COI Contact email (if different to above): orso@wsu.edu

Financial Contact Name: Casey St. Clair, Director, Sponsored Programs

Email: sps@wsu.edu

Telephone Number: (509) 335-2058

Email invoices? ☒ Yes ☐ No Invoice email (if different): ayager@wsu.edu

Authorized Official Name: Dan Nordquist, AVP ORSO

Email: orso@wsu.edu

Telephone Number: (509) 335-9661

PI Address:Washington State University
Paul G. Allen School for Global Animal Health
PO Box 647090
Pullman WA 99164-7090**Administrative Address:**Washington State University
Office of Research Support and Operations
PO Box 641060
Pullman, WA 99164-1060**Invoice Address:**Washington State University
Sponsored Programs Services
PO Box 641025
Pullman, WA 99164-1025

Attachment 3B**Research Subaward Agreement
Subrecipient Contacts**

Subaward Number:

141061 - SPC003545

**Subrecipient Information for FFATA
reporting**

Entity's UEI/DUNS Name: The Washington University

EIN No.:

40

Institution Type:

Private Institution of Higher Education

UEI / DUNS:

18

Currently registered in SAM.gov: ☒ Yes ☐ NoExempt from reporting executive compensation: ☒ Yes ☐ No (if no, complete 3Bpg2)

Parent UEI / DUNS:

18

This section for U.S. Entities:

Zip Code [Look-up](#)

Congressional District: MO-001

Zip Code+4:

63130-4862

Place of Performance AddressWashington University
Campus Box 1054
One Brookings Drive
St. Louis, MO 63130-4862**Subrecipient Contacts**

Central Email:

researchcontracts@wusm.wustl.edu

Website:

Principal Investigator Name:

David Wang

Email:

davewang@wustl.edu

Telephone Number:

314-286-1123

Administrative Contact Name:

Maria Guzman

Email:

mguzman@wustl.edu

Telephone Number:

314-362-4829

Financial Contact Name:

Joseph M Gindhart, Assoc VC for Finance & Sponsored Projects

Email:

jgindhart@wustl.edu

Telephone Number:

314-935-7089

Invoice Email:

Authorized Official Name:

Megan White

Email:

researchcontracts@wusm.wustl.edu

Telephone Number:

314-747-5292

Legal Address:The Washington University
Campus Box 1054
One Brookings Drive
St. Louis, MO 63130-4862**Administrative Address:**Campus Box 1054
One Brookings Drive
St. Louis, MO 63130-4862**Payment Address:**Washington University in St. Louis
Sponsored Projects Accounting
Campus Box 1034, 700 Rosedale Avenue
St. Louis, MO 63112-1408

Attachment 3B Page 2
Research Subaward Agreement
Highest Compensated Officers

Subaward Number:
141061 - SPC003545

Subrecipient

Entity Name: The Washington University

PI Name: David Wang

Highest Compensated Officers

The names and total compensation of the five most highly compensated officers of the entity(ies) must be listed if the entity in the preceding fiscal year received 80 percent or more of its annual gross revenues in Federal awards; and \$25,000,000 or more in annual gross revenues from Federal awards; and the public does not have access to this information about the compensation of the senior executives of the entity through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. See FFATA § 2(b)(1) Internal Revenue Code of 1986.

Officer 1 Name:

Officer 1 Compensation:

Officer 2 Name:

Officer 2 Compensation:

Officer 3 Name:

Officer 3 Compensation:

Officer 4 Name:

Officer 4 Compensation:

Officer 5 Name:

Officer 5 Compensation:

Attachment 4

Reporting and Prior Approval Terms

Subaward Number:

141061 - SPC003545

Subrecipient agrees to submit the following reports (PTE contacts are identified in Attachment 3A):

Technical Reports:

- ☐ Monthly technical/progress reports will be submitted to the PTE's Administrative Contact within 15 days of the end of the month.
- ☐ Quarterly technical/progress reports will be submitted within 30 days after the end of each project quarter to the PTE's Administrative Contact.
- ☒ Annual technical / progress reports will be submitted within 60 days prior to the end of each budget period to the PTE's Administrative Contact. Such report shall also include a detailed budget for the next Budget Period, updated other support for key personnel, certification of appropriate education in the conduct of human subject research of any new key personnel, and annual IRB or IACUC approval, if applicable.
- ☒ A Final technical/progress report will be submitted to the PTE's Administrative Contact within 45 days of the end of the Project Period or after termination of this award, whichever comes first.
- ☒ Technical/progress reports on the project as may be required by PTE's Administrative Contact in order for the PTE to satisfy its reporting obligations to the Federal Awarding Agency.

Prior Approvals:

Carryover:

Carryover is automatic

Other Reports:

- ☒ In accordance with 37 CFR 401.14, Subrecipient agrees to notify both the Federal Awarding Agency via iEdison and PTE's Financial Contact within 60 days after Subrecipient's inventor discloses invention(s) in writing to Subrecipient's personnel responsible for patent matters. The Subrecipient will submit a final invention report using Federal Awarding Agency specific forms to the PTE's Financial Contact within 60 days of the end of the Project Period to be included as part of the PTE's final invention report to the Federal Awarding Agency.

A negative report is required: Yes

- ☒ Property Inventory Report (only when required by Federal Awarding Agency), specific requirements below.

Additional cost sharing requirements included below:

Additional Technical and Reporting Requirements:

Subrecipients shall list each country included in the program and the total amount expended for each country when submitting financial reports. These will be noted to each partner as countries are onboarded.

Kenya 615-GH-W 141061-SPC003546

Senegal 685-GH-W 141061-SPC003547

Peru 527-GH-W 141061-SPC003548

Vietnam 440-GH-W 141061-SPC003549

Thailand 493-GH-W 141061-SPC003550

There may be additional reporting requirements and ad hoc information requests including, but not limited to, those associated with Mission buy-ins or additional sources of funding provided to DEEP VZN. Ad hoc refers to an unscheduled report for immediate, specific use. These requests will need to be approved by USAID.

Subaward Number:

141061 - SPC003545

Attachment 5
Statement of Work, Cost Sharing, Indirects & Budget**Statement of Work**☒ Below ☐ Attached, pagesIf award is FFATA eligible and SOW exceeds 4000 characters, include a *Subrecipient Federal Award Project Description*

Washington University at Saint Louis will provide laboratory and training services. Specifically, they will develop SOPs for broad RT-PCR screening, amplicon sequencing, genome finishing and highly parallel phage display based viral serology. They will optimize and validate protocols, perform proficiency testing to ensure quality and standardization across the sites, and perform highly specialized characterization of novel viruses that cannot be done in-country. Additionally, they will hire four new personnel to travel to the in-country regional laboratories and provide training for in-country scientists to conduct cross-validation in the latter years of the project. These personnel will work with the in-country teams to troubleshoot challenges as country teams develop or strengthen their laboratory techniques.

Budget Information**Indirect Information** Indirect Cost Rate (IDC) Applied

%

Rate Type:

Cost SharingIf Yes, include Amount: \$ **Budget Details**☒ Below ☐ Attached, pages

Salaries and Benefits - \$57,810

Indirect - \$

Total - \$91,051

Only partial budget at this time is being submitted until USAID approves the project workplan and budget detail.

Budget TotalsDirect Costs \$ Indirect Costs \$ Total Costs \$ *All amounts are in United States Dollars*

Attachment 6

Notice of Award (NOA) and any additional documents



The following pages include the NOA and if applicable any additional documentation referenced throughout this Subaward.



Not incorporating the NOA or any additional documentation to this Subaward.



September 22, 2021

Dan Nordquist
Associate Vice President for Research
Washington State University
P.O. Box 641060
Pullman, WA 99164-1060
orso@wsu.edu

Reference: Award No. Titled "Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)" Cooperative Agreement 7200AA21CA00033

Dear Dan Nordquist:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, the U.S. Agency for International Development (USAID) hereby awards to Washington State University, hereinafter referred to as the "Recipient", the sum of \$124,679,896 to provide support for a program titled "Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)", as described in the Schedule of this award and in Attachment B, entitled "Program Description."

This Cooperative Agreement will be effective October 1, 2021. Obligation will be made upon receipt of the Recipient's acknowledgement and shall apply to expenditures made by the Recipient in furtherance of program objectives during the period beginning with the effective date October 1, 2021 and ending September 30, 2026. USAID will not be liable for reimbursing the Recipient for any costs in excess of the obligated amount.

This Cooperative Agreement is made to Washington State University, on condition that the funds will be administered in accordance with the terms and conditions as set forth in Attachment A (the Schedule), Attachment B (the Program Description), Attachment C (the Standard Provisions), and Attachment D (the Branding & Marking Plan) all of which have been agreed to by your organization.

Please sign the second page of this cover letter to acknowledge your receipt of this award and e-mail a copy of only the signed page to Anna Nelson at annelson@usaid.gov with a cc: to Patricia Bradley at pbradley@usaid.gov.

Sincerely,

Patricia Elena Bradley
(affiliate)
Patricia Bradley
Agreement Officer

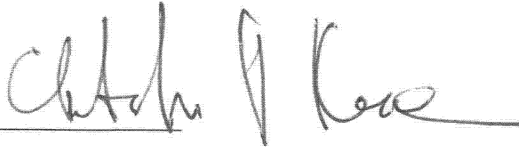
Digitally signed by Patricia Elena
Bradley (affiliate)
Date: 2021.09.22 10:24:23 -04'00'

Attachments:

- A. Schedule
- B. Program Description
- C. Standard Provisions
- D. Branding & Marking Plan

ACKNOWLEDGED BY:

NAME: Christopher J. Keane



TITLE: Vice President for Research, WSU and Vice Chancellor for Research, WSU Pullman

DATE: 9/23/2021

ACCOUNTING AND APPROPRIATION DATA

A. GENERAL

1. Amount Obligated this Action: \$ 10,000,000
 2. Total Estimated USAID Amount: \$124,679,896
 3. Total Obligated USAID Amount: \$ 10,000,000
 4. Cost-Sharing Amount (Non-Federal): \$ 6,607,682
 5. Activity Title: “Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)”
 6. USAID Technical Office: GH/ID/ETD
 7. Tax I.D. Number: 40
 8. DUNS No.: 18
 9. LOC Number: 42A5P

B. SPECIFIC

GLAAS Requisition: REQ-GH-21-000020

Account ID	Accounting Template	BBFY	EBFY	Fund	Operating Unit	Prog Area	Program Name	Dist Code	BGA	SOC	Funded Amount
1-1	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	615-GH-W	615	4100201	\$2,000,000
1-2	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	685-GH-W	685	4100201	\$2,000,000
1-3	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	440-GH-W	440	4100201	\$2,000,000
1-4	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	527-GH-W	527	4100201	\$2,000,000
1-5	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	493-GH-W	493	4100201	\$2,000,000

C. PAYMENT OFFICE

M/CFO/CMP Letter of Credit Office
USAID/Washington

USAID Office of Financial Management (M/CFO/CMP) prefers the submittal of invoices to be electronic. In addition to the required submission to the Agreement Officer’s Representative (AOR), please submit a copy of the invoices to loc@usaid.gov.

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ATTACHMENT A - SCHEDULE

A.1 PURPOSE OF AWARD

The purpose of this Cooperative Agreement is to provide support for the program described in Attachment B to this Cooperative Agreement entitled "Program Description."

A.2 PERIOD OF AWARD

1. The effective date of this Award is **October 1, 2021**. The estimated completion date of this Award is ~~September 30, 2026~~.

A.3 AMOUNT OF AWARD AND PAYMENT

1. The total estimated amount of this Award for the period shown in A.2.1 above is ~~\$124,679,897~~, not including cost share.
2. USAID hereby obligates the amount of ~~\$10,000,000~~ for program expenditures during the period set forth in A.2.1 above and as encompassed in the Budget below. The recipient must use funds obligated under this award and any subsequent amendments from the specific Operating Units (OU) and Program Areas (PA) for activities approved in the award and detailed in the work plan, as applicable. Program disbursements for each OU/PA must not exceed the amounts specified in the Accounting and Appropriates data for each Operating Unit (OU) and Program Area (PA). The Recipient will be given written notice by the Agreement Officer if additional funds will be added.
3. As the obligated amount for the program shall equal the total USAID estimated amount of this Agreement, additional increments of funds may be obligated by USAID under this Agreement (by a unilateral modification to this Agreement), subject to availability of funds, successful performance by the Recipient, possible evaluation of the program, program priorities at the time, and the requirements of the 2 CFR 200.308.
4. Payment will be made to the Recipient by Letter of Credit in accordance with procedures set forth in 2 CFR 200 and 2 CFR 700.

A.4 AWARD BUDGET

The following is the Award Budget, including local cost financing items, if authorized. Revisions to this budget shall be made in accordance with 2 CFR 200 and 2 CFR 700.

TOTAL BUDGET

Cost Element	USD
Direct Costs	\$116,474,256
Indirect Costs	\$ 49
Total Federal Contribution	\$124,679,897
Cost Share	\$6,607,682
Total Program Cost	\$131,287,579

Washington State University is responsible for managing available funds. This agreement includes a ceiling amount and obligated amount that the recipient exceeds at its own risk.

A.5 PLANNING, REPORTING, AND EVALUATION

1. Financial Reporting:

The recipient must submit the Federal Financial Form (SF-425) on a quarterly basis via electronic format to the U.S. Department of Health and Human Services. The recipient also must submit a copy of the SF-425 to the Agreement Officer (AO) and the Agreement Officer's Representative (AOR). These financial reports are due no later than 30 calendar days at the end of each quarter based on the federal fiscal calendar. The recipient must submit final financial reports to USAID/Washington, M/CFO/CMP-LOC Unit, the AO, and the AOR. The recipient must also submit an electronic version of the final financial report to the U.S. Department of Health and Human Services in accordance with the paragraph above.

2. Performance Planning:

Implementation Plans

Annual implementation plans serve as a guide to activity implementation and detail how the recipient will use the implementation year to achieve the objectives of DEEP VZN. The implementation plan is intended to be an annual roadmap for USAID and the recipient. With approval from the AOR, reasonable and justifiable modifications can be made to improve the chances of achieving the medium- and long-term results of the award. The recipient must submit the following implementation and reporting documents in English. The AOR and recipient will agree on the appropriate format and length.

Implementation plans include, but are not limited to, the following:

- Annual work plans, including planned activities for the following year and any subsequent revisions
- International travel plans
- Planned expenditures
- Event planning/management
- International meeting preparation
- Material Transfer Agreement (MTA) risk mitigation plan
- Country-level Level of Effort (LOE) chart, to include any oversight provided by headquarters
- Protocol Development and Review Plan
- Biosecurity and Biosafety (BSBS) Plan

USAID requires the AOR approval of implementation plans annually to ensure alignment with stated goals, milestones and outputs. The implementation plan communicates how and when the recipient will complete project activities and is drafted annually to describe new activities. The AOR will ensure that the implementation plans fit within the scope, terms and conditions of the agreement.

First Year Work Plan and Budget

The recipient will submit a draft work plan for the first year within the first 90 calendar days of executing the award. Depending on the start date of the agreement, the first-year work plan may be less than a full year or more than a full year. The first-year work plan must include a detailed budget and budget narrative for the first year. As part of the First Year Work Plan submission, the recipient will include a supplementary annual work plan describing planned contributions to the GHSA on a template designated by the AOR. All work plans and budgets, including

significant revisions thereto, must be approved by the AOR.

Annual Work Plan and Budget

Starting with the second year of the award and for each subsequent year of performance thereafter, the recipient will submit annual work plans, budgets, and budget narratives to the AOR for the next federal fiscal year within 30 calendar days prior to the end of the current federal fiscal year in a format agreed upon by the AOR and the recipient. The recipient also will submit supplementary annual work plans describing planned contributions to the Global Health Security Agenda (GHSa) within a timeframe and on a template designated by the AOR.

Monitoring, Evaluation and Learning (MEL) Plan

The recipient will finalize a MEL plan for the life of DEEP VZN that derives from the activities outlined in the Program Description and submit it to the AOR within 90 calendar days of the award for approval. The MEL plan will outline key program interventions, indicators of achievement, associated annual and life-of-Activity targets and a learning agenda. The learning agenda will outline key questions to be addressed, a plan for addressing these questions, and a process for incorporating findings into program implementation and the detection and characterization of unknown viruses. Where appropriate, the MEL plan must track gender equality issues in implementing activities. The recipient will update the MEL plan annually and submit it as an attachment to the annual report.

Biosecurity and Biosafety (BSBS) Plan

The recipient will finalize a BSBS plan for the life of DEEP VZN and submit it to the AOR within 90 calendar days of the award for approval. The BSBS will outline all program interventions that have biosafety/biosecurity implications and steps (e.g. protocols, training) that will be taken to minimize risk.

Gender Action Plan

The recipient will conduct a gender analysis that assesses context and gender needs, including time constraints and participation limitations. This analysis will inform a subsequent gender action plan, which will be developed in collaboration with the USAID management team and finalized within 90 calendar days of the award and updated annually. The gender action plan will inform the Activity's technical approach as it relates to gender throughout the life of the Activity. It also will be used to inform the design of activities that seek to reduce opportunity gaps between men and women or address power differentials to promote gender equity. The gender action plans should be developed in conjunction with the Activity's monitoring, evaluation and learning plan, and progress should be reflected in annual work plans and performance reports.

Data Management Plan

A Data Management Plan (DMP) is a document that describes how the recipient will manage data during the project and what happens to the data after the project ends. The initial DMP, which will be developed in collaboration with the USAID management team, will be finalized within 90 calendar days of the award and updated semi-annually and annually.

A comprehensive DMP will discuss the following aspects of the data life cycle:

- Collect - How the data is collected and processed by the researcher.
- Assure - How to make sure the data is high quality and free of errors.
- Describe - How the data will be documented so that other researchers can use it.
- Preserve - How and where the data will be stored so that researchers can access it forever.

The data management plan will inform the Activity's technical approach as it relates to data throughout the life of the Activity. The data management plan should be developed in conjunction with the Activity's monitoring, evaluation and learning plan, and progress should be reflected in annual work plans and performance reports.

Closeout Plan

No later than six (6) months prior to the completion date of the agreement, the recipient will submit a demobilization plan for Agreement Officer's approval. The demobilization plan shall include: 1) a draft property disposition plan, 2) a plan for the phase-out of in-country operations, 3) a staffing discharge plan, 4) a delivery schedule for all reports or other deliverables required under the agreement, and 5) a timetable for completing all required actions in the demobilization plan, including the submission date of the final property disposition plan to the Agreement Officer.

3. Performance Reporting:

The recipient must submit via email a copy of semi-annual, annual, and final performance reports, in English, to the AOR in accordance with 2 CFR 200.328.

Semi-Annual and Annual Reports

The recipient will submit semi-annual and annual progress reports based on the federal fiscal calendar. The semi-annual report will be due within 30 days after the end of the reporting period and will cover the first six months of the year (October 1 - March 31). The annual report will cover the entire fiscal year (October 1 - September 30) and will be due within 90 days of the end of the federal fiscal year.

At a minimum, both semi-annual and annual reports will contain:

- Narrative description of activities completed and major accomplishments achieved during the reporting period in all countries supported by DEEP VZN, presented by objective
- Qualitative and quantitative data on program achievements and results
- Progress on standard and agreed upon indicators, as outlined in the MEL plan, including status towards achieving targets and explanations for significant deviations
- An updated MEL plan, including progress on the learning agenda (annually)
- An updated BSBS plan
- An updated Data Management plan
- Problems encountered and whether they were solved or are still outstanding
- Proposed solutions to ongoing or new problems
- Success stories, blogs, articles, publications, press releases, and photographs, if available
- Update on expenditures for the reporting period against the pipeline
- Analysis and explanation of cost overruns or high unit costs, when applicable
- Planned activities for the next performance period

Global Health Security Agenda (GHS) reports

The Recipient will submit semi-annual GHS performance reports within a timeframe and on a template designated by the AOR. The Recipient will submit the GHS semi-annual reports to the AOR via email.

Ad Hoc Reports

There may be additional reporting requirements and ad hoc information requests including, but not limited to, those associated with Mission buy-ins or additional sources of funding provided to DEEP VZN. Ad hoc refers to an unscheduled report for immediate, specific use. USAID will define the purpose, content, and specific use for any ad hoc report.

Final Report

Within ninety (90) calendar days after the period performance date, the recipient will submit one (1) original and two (2) copies of the Final Report to the AOR and one (1) copy to the Agreement Officer. In addition, one (1) copy will be submitted to the Development Experience Clearinghouse:

- 1) Electronically: <http://www.usaid.gov/results-and-data/informationresources/developmentexperience-clearinghouse-dec>
or
- 2) By U.S. Postal Service delivery to:
U.S. Agency for International Development
Development Experience Clearinghouse
M/CIO/ITSD/KM
Ronald Reagan Building M. 01-010
Washington, DC 20523-6100

The Final Report must include a narrative report and summary table of results, a comparison of actual accomplishments to the objectives established for the period of performance, and a gender analysis that describes how gender equality issues were tracked and addressed. It should highlight accomplishments against implementation plans; outline progress of benchmarks against targets; describe results; and document lessons learned during implementation. The Final Report also must contain a three-page executive summary, an index of all reports and information products produced under the agreement, and a summary of the program's finances. More details on the format of the final report will be provided after the award.

A.6 INDIRECT COST RATE

Allowable indirect costs shall be reimbursed on the basis of the following negotiated Colleges and Universities Rate Agreement, dated August 20, 2019.

INDIRECT COST RATES:

TYPE	FROM	TO	LOCATION	RATE%	APPLICABLE TO
Predetermined	7/1/2019	6/30/2023	On-Campus	49	Organized Research
			Off-Campus	49	Organized Research
			On-Campus	49	Instruction
			Off-Campus	49	Instruction
			On-Campus	49	Other Sponsored Activities
			Off-Campus	49	Other Sponsored Activities
Provisional	7/1/2023	Until Amended	Use same rates and conditions as those cited for fiscal year ending June 30, 2023.		

Base

Modified total direct costs, consisting of all salaries and wages, fringe benefits, materials, supplies, services, travel and subgrants and subcontracts up to the first \$25,000 of each

subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). Modified total direct costs shall exclude equipment, capital expenditures, charges for patient care, student tuition remission, rental costs of off-site facilities, scholarships, and fellowships as well as the portion of each subgrant and subcontract in excess of \$25,000.

A.7 TITLE TO PROPERTY

Title of property financed under this award shall vest with the recipient subject to the requirements of 2 CFR 200.311-200.316, until such time as USAID issues disposition instructions.

Furthermore, the following requirements apply regarding the use, care, accountability, maintenance, and disposition thereof:

(a) Tangible Property

(1) Equipment: “Equipment” means an article of tangible nonexpendable personal property having a useful life of one year or more and a per-unit acquisition cost (purchase price) of \$5,000 or more. Equipment is subject to the requirements set forth in 2 CFR 200.313.

(2) Supplies and Other Expendable Equipment: “Supplies and other expendable equipment” means items of tangible personal property that do not meet the definition of “equipment” in paragraph (a)(1) above. Supplies and other expendable equipment are subject to the requirements set forth in 2 CFR 200.314.

(3) Real Property: “Real property” means land, land improvements, structures, and appurtenances thereto. Real property is subject to the requirements set forth in 2 CFR 200.311.

(b) Intangible (Intellectual) Property

“Intangible property” means, but is not limited to, copyrights, inventions and patents, and data first produced under this Agreement. Intangible property is subject to the requirements set forth in 2 CFR 200.315.

A.8 AUTHORIZED GEOGRAPHIC CODE

The authorized geographic code for procurement of goods and services under this award is 935.

A.9 COST SHARING

The Recipient will contribute 5.03% percent of the total obligated amount of the award, excluding the sub-awards to the networks, as cost share throughout the life of the project. The cost share contribution shall be listed per cost category and presented in the work plan budgets.

Description	USD
Federal Amount Subject to Cost Share	\$124,679,897
Proposed Cost Share Amount	\$6,607,682
Cost Share Percentage	5.03%
Total Project Amount	\$131,287,579

A.10 SUBSTANTIAL INVOLVEMENT

a. Approval of the Recipient’s Annual Implementation Plans:

Implementation plans include, but are not limited to, annual work plans, budget and budget narrative, including planned activities for the following year and any subsequent revisions, international travel plans, planned expenditures, event planning/management, international meeting preparation, MTA risk mitigation plan, country-level LOE chart, to include any oversight provided by headquarters, and protocol development and review plan.

USAID requires AOR approval of implementation plans annually to ensure alignment with stated goals, milestones and outputs. Each implementation plan communicates how and when the recipient will complete project activities and is drafted annually to describe new activities. This plan will be developed in partnership between the recipient and the AOR team. The AOR will ensure that each implementation plan fits within the scope, terms and conditions of the agreement.

b. Approval of Specified Key Personnel:

Designation of key personnel positions, approval of key personnel and any changes for the positions listed below:

- Project Director
- Deputy Project Director/Operational Lead

All individuals proposed as Key Personnel in the Recipient’s application are hereby approved. Any future approval of key personnel will be authorized by the Agreement Officer in a separate administrative letter. The Recipient must submit to the AOR, reasonably in advance, any proposed replacement (including proposed substitutions) along with written justification in sufficient detail to permit evaluation of the impact on the program. Any proposed replacement Key Personnel must meet the minimum requirements stated in the Notice of Funding Opportunity (NOFO) number 7200AA21RFA00005, Section D.5.g). No replacement shall be made by the Recipient without the written consent of the Agreement Officer.

c. Agency and Recipient Collaboration or Joint Participation:

- Collaborative involvement in the selection of advisory committee members, if the recipient establishes an advisory committee that provides advice to the recipient. The AOR may participate as a member of this committee. Advisory committees must only deal with programmatic or technical issues and not routine administrative matters.
- Collaborative involvement in the selection of countries, viruses, and interfaces.
- USAID review and approval of monitoring, evaluation, and learning plans.
- USAID review and approval of data management plans.
- USAID involvement in the substantive direction/re-direction of interrelationships with other projects.
- USAID involvement in monitoring progress toward achievement of the Objectives and Expected Achievements during the course of the Agreement(s) and in monitoring of financial expenditures.

d. Direction and Redirection:

USAID will be involved in the substantive direction/re-direction of inter-relationships with other projects.

A.11 PROGRAM INCOME

The Recipient shall account for Program Income in accordance with 2 CFR 200.307 (or the Standard Provision entitled Program Income for non-U.S. organizations). Program Income earned under this award shall be added to the project.

A.12 AGREEMENT OFFICER'S REPRESENTATIVE

The Agreement Officer's Representative (AOR) for this Agreement will be designated in a separate memorandum from the Agreement Officer to the AOR with copy to the Recipient and the payment office.

A.13 SPECIAL PROVISIONS

A.13.1 SUBAWARD APPROVAL

Pursuant to the approved budget of this cooperative agreement, the following sub-awards are approved. All other sub-awards are subject to additional USAID approval.

Sub-awardee

University of Washington – UW
Family Health International 360 – FHI 360
PATH
Washington University at Saint Louis – WUSTL
Duke University

A.13.2 COUNTRY-BY-COUNTRY BREAKDOWN OF EXPENDITURES

The Recipient shall list each country included in the program and the total amount expended for each country under the award for the reporting period in the "Remarks" block on the "Financial Status Report" SF 425, or on a separate sheet of paper with the "Request for Advance or Reimbursement" SF 270.

A.13.3 BRANDING STRATEGY & MARKING PLAN

The Recipient shall submit within 30 calendar days of award, a Branding Strategy and Marking Plan. Upon the approval of the AO and AOR, the plan shall be incorporated as Attachment D.

A.13.4 ENVIRONMENTAL COMPLIANCE

The Foreign Assistance Act of 1961, as amended, Section 117 requires that the impact of USAID's activities on the environment be considered and that USAID include environmental sustainability as a central consideration in designing and carrying out its development programs. This mandate is codified in Federal Regulations (22 CFR 216) and in USAID's Automated Directives System (ADS) Parts 201.5.10g and 204 (<http://www.usaid.gov/policy/ADS/200/>), which, in part, require that the potential environmental impacts of USAID-financed activities are

identified prior to a final decision to proceed and that appropriate environmental safeguards are adopted for all activities. The recipient's environmental compliance obligations under these regulations and procedures are specified in the following paragraphs of this cooperative agreement.

In addition, the recipient must comply with host country environmental regulations unless otherwise directed in writing by USAID. In case of conflict between host country and USAID regulations, the latter shall govern.

No activity funded under this cooperative agreement will be implemented unless an environmental threshold determination, as defined by 22 CFR 216, has been reached for that activity, as documented in a Request for Categorical Exclusion (RCE), Initial Environmental Examination (IEE), or Environmental Assessment (EA) duly signed by the Bureau Environmental Officer (BEO). (Hereinafter, such documents are described as "approved Regulation 216 environmental documentation.")

As part of its initial Work Plan, and all Annual Work Plans thereafter, the Recipient, in collaboration with the USAID AOR and Mission Environmental Officer or Bureau Environmental Officer, as appropriate, shall review all ongoing and planned activities under this cooperative agreement to determine if they are within the scope of the approved Regulation 216 environmental documentation.

If the Recipient plans any new activities outside the scope of the approved Regulation 216 environmental documentation, it shall prepare an amendment to the documentation for USAID review and approval. No such new activities shall be undertaken prior to receiving written USAID approval of environmental documentation amendments.

Any ongoing activities found to be outside the scope of the approved Regulation 216 environmental documentation shall be halted until an amendment to the documentation is submitted and written approval is received from USAID.

A.13.5 OPEN DATA AND DATA SHARING

The recipient will be expected to comply with the Office of Management and Budget's Open Data Policy, as well as any USAID open data policy. Relevant MEL related data, knowledge and specifically lessons learned from sampling, discovery, characterization, and data analysis and use will be documented. All final data sets that USAID and the recipient deem as valuable to its stakeholders shall be submitted to USAID in a reliable media prior to the award end date and will be available for dissemination as appropriate. During the term of the agreement, preliminary data and analysis will be submitted to USAID on a periodic basis, but no less than annually, as agreed upon by USAID and recipient during work planning.

A.13.6 ORGANIZATIONAL CONFLICT OF INTEREST

Recipient must adhere to conflict of interest regulations found in 2 CFR 200.112 and 2 CFR 200.318(c)(1).

A.13.7 COORDINATION, COMMUNICATION, AND COLLABORATION

Coordination, communication and collaboration among stakeholders facilitate trust and mutual understanding; reduce redundancy; increase synergy, scalability, and impact; and promote learning and mutual accountability. DEEP VZN is expected to build and enhance constructive

partnerships, as appropriate. DEEP VZN will collaborate and coordinate with a wide variety of stakeholders, including country National NTD Programs, Ministries of Health and other relevant government entities; USAID Missions and Country Offices, USG partners, bilateral and multilateral agencies; academic and research institutions; private sector and philanthropic organizations; and civil society organizations.

A.14 SPECIAL REQUIREMENTS

A.14.1 FOR U.S. ORGANIZATIONS -- SPECIAL AWARD REQUIREMENT RELATING TO THE PROHIBITION ON CERTAIN TELECOMMUNICATION AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUGUST 2020)

- a. 2 CFR 200.216, “Prohibition on certain telecommunications and video surveillance services or equipment” implements Pub. L. 115-232, Section 889.
- b. USAID has been granted a temporary, limited waiver under Section 889(d)(2) that will allow the recipient to use award funds for the duration of this award to procure internet, cellular and landline services from communication service-providers who use covered telecommunications. All other costs incurred for covered telecommunications and video surveillance services or equipment, such as phones, video surveillance, and cloud servers specified in 2 CFR 200.216 remain unallowable in accordance with 2 CFR 200.471.

[End of Special Award Requirement]

A.14.2 FOR NON-U.S. ORGANIZATIONS -- SPECIAL AWARD REQUIREMENT RELATING TO THE PROHIBITION ON CERTAIN TELECOMMUNICATION AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUGUST 2020)

- a. The mandatory standard provision “Prohibition on Certain Telecommunication and Video Surveillance Services or Equipment (AUGUST 2020)” implements Pub. L. 115-232, Section 889.
- b. USAID has been granted a temporary, limited waiver under Section 889(d)(2) that will allow the recipient to use award funds for the duration of this award to procure internet, cellular and landline services from communication service-providers who use covered telecommunications. All other costs incurred for covered telecommunications and video surveillance services or equipment, such as phones, video surveillance, and cloud servers specified in the standard provision in paragraph a. above remain unallowable in accordance with the mandatory standard provision “Allowable Costs” and 2 CFR 200.471.

[End of Special Award Requirement]

[END OF ATTACHMENT A]

ATTACHMENT B – PROGRAM DESCRIPTION

EXECUTIVE SUMMARY

With an overarching goal of detecting ‘known unknown’ viruses that might pose a pre-pandemic threat, we will carry out an innovative, sustainable, and responsive surveillance program for detection and characterization of novel animal viruses with zoonotic potential. Our consortium, which includes University of Washington (UW), PATH, FHI360, and Washington University in St. Louis (WUSTL) is led by Washington State University’s (WSU) Allen School for Global Health, whose approach of placing full-time faculty in global regions has seen it lead innovative emerging infectious disease studies in East and Central Africa that target landscapes inhabited by humans, their livestock and diverse wildlife populations in ecosystems ideal for the maintenance and transmission of emerging zoonotic pathogens. The consortium features strong in-country partners supported by world class virology reference laboratories at UW and WUSTL involved in novel virus discovery and characterization, unparalleled experience in laboratory strengthening, One Health epidemiology and social science, and global reach. Apart from collective presence and institutional links in countries located in the six DEEP VZN global regions, our consortium partners bring complementary expertise, including global field studies and sampling by WSU and UW, laboratory capacity by WUSTL and UW, and data management and in-country stewardship by PATH, FHI360 and WSU. We will build on the achievements of the USAID EPT programs, and our collective prominence in the global NIH-supported Centers for Research in Infectious Diseases (NIH-CREID), to enable partner labs in focus countries to fully sequence and characterize novel viruses in unprecedented breadth and depth. We will leverage scientific breakthroughs with SARS CoV2 and other emerging viruses to apply cutting edge technologies to prioritize potential for viral spillover and pandemics. In focus countries, we will target high-risk locations and subpopulations at the human-animal interface using a risk-based analytical approach to guide sample collection where there is evidence of previous spillover or high prevalence of zoonotic viruses. Additionally, we will establish an efficient sample collection and transportation system and align capacities at in-country laboratories to identify viruses of zoonotic potential in a timely manner, thus triggering additional targeted sampling focused up- and downstream of the transmission chain.

We plan to collect over 800,000 samples, of which approximately 60% will come from wildlife. Assuming a 1-1.5% yield, our in-country labs will provide near-real time screening and genome sequencing to detect and characterize between 8,000 and 12,000 novel viruses from the target families over the five years of the DEEP VZN program. To effectively characterize viruses of zoonotic potential from the detected pool, we will use a combination of innovative molecular, protein structure and receptor analyses, and serological techniques to generate evidence of spillover to humans, and potential for human-to-human transmission. This consortium will also strengthen capacity within focus countries for continued assessment of viruses of zoonotic potential and enhance response to future outbreaks. To enhance sustainability, we will build in-country stewardship of all surveillance, diagnostic and data management activities through the development of meaningful partnerships with focus country stakeholders. Through engagement and integration with other USAID EPT efforts, NIH CREID networks and other professionals across human, animal, and environmental health sectors, we will promote meaningful sharing of resources and data in an inclusive and cost-effective One Health-approach. The overall outcomes of this program will be the detection of an unprecedented number of unknown viruses of pandemic potential that can be monitored by public health institutions worldwide, and significant

advances in our collective ability to characterize zoonotic and pandemic potential of emerging viruses.

OBJECTIVE 1: Conduct Sampling for Unknown Viruses from the Priority Viral Families

We have designed an efficient, responsive, and sustainable program that uses existing data and models on spillover risk to guide initial sampling and interim data to refine sampling targets.

Building on baseline detection of known viruses in the PREDICT, VIRION and EIDITH databases, our strategies will lead to the detection of previously unknown wildlife-origin viruses from the target families and identify a subset that pose a significant pandemic threat. Our

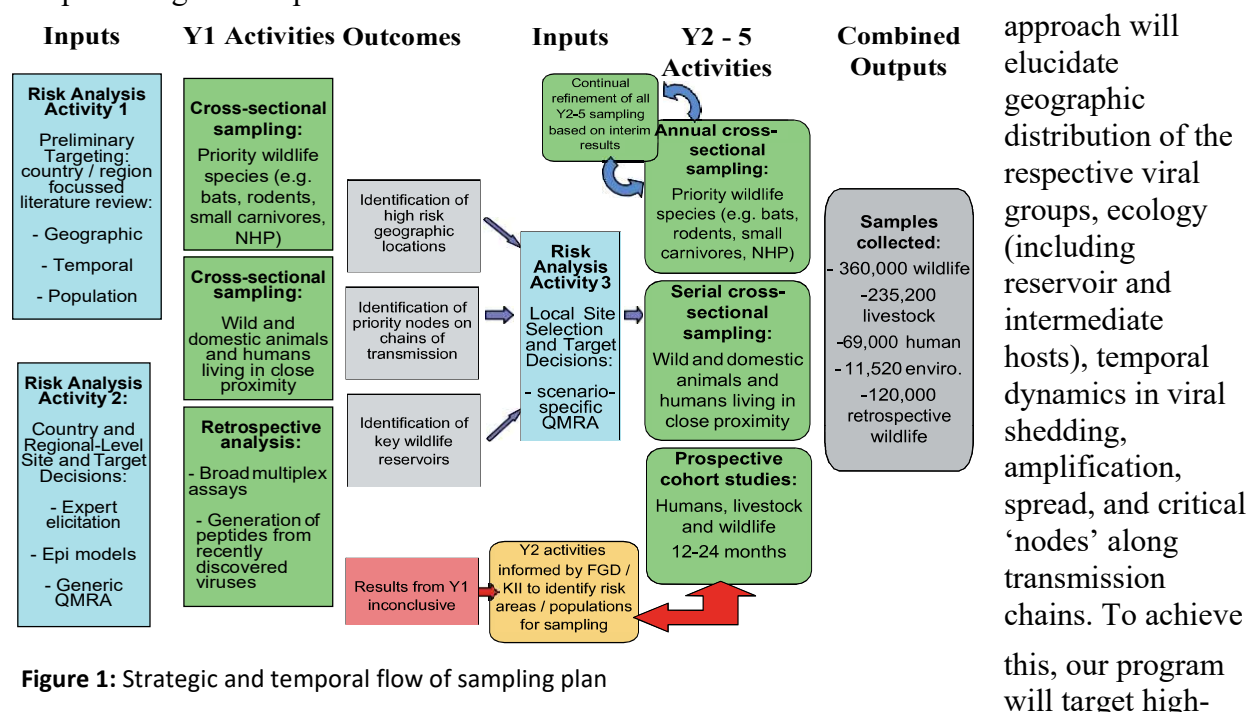


Figure 1: Strategic and temporal flow of sampling plan

risk locations and subpopulations at the human-animal interface, optimizing yield and resources (Fig. 1). This targeting will be adaptive, with locations identified through an iterative process informed by ongoing data collection. We will establish a pipeline of sample collection and transportation, aligned with capacities at existing in-country laboratories (utilizing a hub and spoke approach). Identification of a virus of zoonotic potential will trigger additional sampling focused up- and downstream on the transmission chain. Sampling will be guided by a risk-based analytical approach informed by evidence of a previous spillover event, a high prevalence of zoonotic viruses, or close contact between humans and reservoir hosts. Finally, we will employ a One Health-approach through engagement of human, animal, and environmental health sectors.

1.1 Sample Site and Species Selection

Focus 1: Preliminary Targeting - country/region focused literature review

To inform initial geographic, temporal, and species sampling plans and further risk-based targeting, we will carry out a rapid and comprehensive literature review (including grey literature and proceedings from meetings and One Health platforms) in Y1 to identify where prevalence and diversity of the target viral families are high, where critical nodes on chains of transmission are located, and key wildlife species are abundant (Focus 2 and Fig. 2).

Geographic Selection: We will use literature review, remote-sensed data, and existing risk maps of zoonotic disease emergence risk and its drivers to make a primary selection of geographic

areas of interest. Priority drivers of disease emergence will include human population density, land use change, density and diversity of wildlife species (focusing on mammalian species),

intensive farming of domestic and wild species, and live/wet wildlife markets. We will also leverage maps and data from PREDICT sampling data.

Temporal Selection: Viral (and host) seasonality and multiannual trends impact viral load and thus detection rates and will be critical determinants of sampling timeframes, particularly for wild animal sampling. The literature review will leverage existing knowledge of targeted viral families and host dynamics to inform our risk-based sampling strategies.

Population Selection: Country-specific literature review will identify wildlife and livestock species, human occupational groups, and value chains to consider for sampling.

Focus 2: Country and Regional-Level Site and Target Decisions - risk-based analysis Using a hybrid risk-based approach, we will refine geographic, temporal, and population targets defined by Focus 1 to plan the location and the timing of each sampling activity, with emphasis on identifying populations of wildlife, domestic animals, and humans on transmission chains. This approach will build upon existing knowledge from previous USAID-funded research projects, tailored to country-specific contexts. We will use available data and models and in-country stakeholder engagement, ensuring rapid site selection and start-up of project activities.

Epidemiological Models: In collaboration with key partners, such as the USAID-funded STOP Spillover project, in-country research institutions, and relevant government ministries, the team will review existing epidemiologic models (spatial and mathematical) of spillover risk parameterized to the geographic areas and populations identified in Focus 1. This work will both

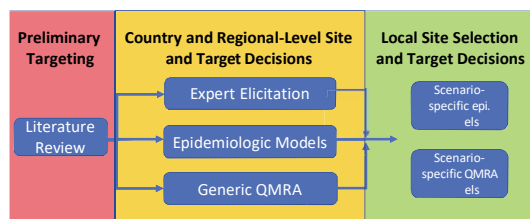


Fig. 2: Risk-based analytical approach to sample site selection

inform the structure of the epidemiologic models developed in Focus 3 and collate data for these later models. Existing models of viral and host seasonality, host dynamics in targeted wildlife populations, and seasonal trends in wild meat hunting will be used to plan sample timing. **Expert Elicitation:** If the absence of context- and site-specific data or relevant

epidemiologic models preclude the use of modeling to refine sampling plans, we will use an expert elicitation-based risk ranking approach to scope initial rounds of sampling.

QMRA: As part of a multimodal strategy, the team will develop prospective probabilistic models utilizing a quantitative microbial risk assessment (QMRA) approach to identify populations and areas of greatest risk and uncertainty. Such approaches have been used to estimate environmental risk of zoonoses transmission and provide a way to include viral load data into our risk prioritization process. As the magnitude of risk will likely be driven by scenario-specific exposures, updated models will be developed at the onset of the project following literature review and subsequently tailored to specific exposure scenarios (Fig. 2).

Focus 3: Local Site Selection and Target Decisions

Based on site- and context-specific information and models generated in Focus 2, detailed exposure modules will be incorporated into location-specific QMRA models, the findings of which will be triangulated with spatial epidemiologic models. These models will be informed by geolocated data indicating prior spillover events, presence of immunocompromised wildlife species, disturbances that increase physiological stress, human activities that facilitate wildlife contact, and high population density. We will develop an initial set of location specific QMRA models based on the sampling sites and data from PREDICT 1 & 2 and evaluate these models to identify sites with the greatest estimated risks and/or uncertainty. In concert with our QMRA models, we will use the computationally efficient stochastic partial differential equations approach to Gaussian process modelling to generate high-resolution maps of spillover risk in the

target geographies identified in Focus 1 - 3. Both models will be continually iterated as new data become available, and sampling sites/targets will be adjusted.

1.2 Sampling Targets

To reduce delay, as soon as each of Focus 1-3 is completed decisions on site identification and timing for initial rounds of sample collection can begin. We will use pre-existing models and computational frameworks to complete these models while sampling approvals are pending. Targeted sampling locations, timelines, and species will be refined through participatory workshops, including representatives from wildlife, human, livestock, and environmental health sectors, and supply chain mapping integrated with network data. Retail outlets for wildlife products will be the terminus of this mapping, with focus on the movement of animals or their products from their points of origin to consumers. Eco-centric network data and value chain data will be collected at each node to identify priority nodes for viral transmission.

Once sampling targets have been identified, we will use sampling methods selected based on population sampled, risk characterization, and country-context, including serial cross-sectional sampling and prospective cohort sampling. Where possible, serial cross-sectional sampling will be repeated in the same population to determine which viruses are adapting to humans (pre-pandemic viruses) and to allow development of interventions to mitigate transmission. In addition, we will use composite sampling to screen samples, with follow-up testing of discrete samples from positive composites to decrease cost and increase throughput. We will also collect socio-anthropological data at these high-risk locations to better understand human-animal-ecosystem interactions relevant to viral transmission. Sampling targets will include:

Wildlife: Focus 1-3 will identify sites for initial sampling and priority mammalian species.

Supplementing risk characterization, trait-based statistical modelling will be used to prioritize bat species for each viral taxon, which will be iteratively improved as more host-virus data become available. Within these sites and species, sampling will focus on populations likely to impact the animal value chain (wildlife or livestock), including free-ranging wild animals living near areas of intensive livestock farming, wild mammals in ecosystems recently fragmented by expanding human communities, farmed wild mammals and wild mammals sold in live/wet markets.

Domestic animals: Sampling will focus primarily on intensively farmed domestic species that are reservoirs or amplifying hosts for the targeted viral families, characterized in Focus 1-3.

Industrialized farms with poor biosecurity or ecosystem encroachment will be prioritized.

Humans: Sampling will focus on country-specific occupational groups (and controls) at highest risk for spillover already geographically and temporally linked to wildlife described above.

1.3 Country-level Strategic Sampling Approach*

**Specific sampling targets will vary by target country based on in-country context*

Task 1.1: Cross-sectional sampling of wild animals (priority species): We will implement cross-sectional sampling of populations of free ranging wild animals likely to host unknown species of known virus families and target physiologically and immunologically stressed populations (migratory populations/ those living in areas of intense land use change). The highest proportion of samples collected will be fecal matter (e.g., under-roost excreta) to optimize efficiency and sensitivity for viral surveillance and discovery, particularly for henipaviruses and coronaviruses. We will also collect and test wildlife meat from markets and traders.

Year 1: Sample teams: 3 per country, sampling for 45 days/year, collecting 40 samples/day;

Aim Per country: 5000 samples; **Target species:** Bats, rodents, small carnivore species, non-human primates (NHP); **Sample type:** Feces, blood, oral/rectal swabs;

Years 2–5: Sample teams: 3 per country, sampling for 21 days / year, collecting 40 samples/day; Prospective sampling informed by Y1 results; **Aim per country:** 2500 total samples/year; **Target species** and **Sample type:** as in Y1

Task 1.2: Cross-sectional sampling of animals and humans living in proximity:

Humans are frequently in contact with large aggregations of wildlife, such as rodents, bats, and small carnivore species. Such synanthropic wildlife species provide opportunities for spillover to amplifying reservoir species that have greater opportunities for pathogen sharing with humans. We will sample wildlife species among or near areas of intensive livestock farming, farmed wild animals, and wild animals sold in live/wet markets. We will also carry out composite sampling of human and livestock species through collection of fecal slurry (livestock) and sewage (human) samples, prioritizing sampling of environments where animals/humans have recently displayed signs of illness and sites characterized by recent disturbances of neighboring ecosystems. We will also sample domestic carnivores (dogs and cats) as these species typically range widely, scavenge, have contact with wildlife, livestock, and humans and are accessible for sampling.

Year 1: Wild animal sample teams: 3 per country, sampling for 45 days/year, collecting 40 samples/day; **Domestic animal sample teams:** 3 per country, sampling for 30 days/year, collecting 40 samples/day; **Human sample teams:** 3 per country, sampling for 45 days/year, collecting 10 samples/day; **Per country aim:** 5000 wildlife, 3600 domestic animal, 1350 human samples; **Target species:** Rodents, bats, domestic and wild carnivore species (e.g. domestic dogs/cats, civet cats), ungulates, poultry, humans; **Sample type:** Wildlife species: feces, blood, oral/rectal swabs; humans, livestock: composite sampling of fecal slurry and sewage

Years 2–5: Prospective sampling informed by Y1 results; **Wild animal sample teams:** 3 per country, sampling for 21 days/year, collecting 40 samples/day; **Domestic animal sample teams:** 3 per country, sampling for 14 days/year, collecting 40 samples/day; **Human sample teams:** 3 per country, sampling for 20 days/year, collecting 10 samples/day; **Per country aim:** 2500 wildlife, 1600 domestic animal, 600 human samples.

Task 1.3: Retrospective analysis of bio-banked samples: We will request access to bio-banked sera collected from wildlife species, including from previous USAID-funded projects such as PREDICT, in areas determined by our risk analysis activities to be hot-spot zones. Broad multiplex assays will allow identification of all ‘known knowns’ and refinement of subsequent sampling strategies (in Y2-5) to increase the probability of detecting ‘known unknown’ viruses. Additionally, novel peptides generated from recently discovered focus family viruses will allow contemporary viruses to be detected.

Year 1: Per country aim: Collection of up to 10,000 wildlife serum samples from in-country biobanks; **Target species:** Bats, rodents, small carnivore species, NHP

Task 1.4: Prospective cohort studies of humans, livestock, and farmed wildlife

Per country aim: **i) animal workers (human):** 200 blood samples twice/year; 200 risk factor questionnaires monthly; 10 semi-structured interviews monthly; 200 nasal wash samples monthly; **ii) controls (human):** 50 blood samples twice/year; 50 questionnaire surveys monthly; 50 nasal wash samples monthly; **iii) farmed animals:** 200 composite samples monthly; **iv) environmental samples:** 20 samples monthly (1 per farm/month), for example, composited waste water sample or barn air; **v) workplace:** 20 (1 per farm/month) x Animal Workplace Enrolment and Animal Workplace Follow-up Questionnaire; **Target species:** Humans, ungulates, poultry, farmed wildlife

Task 1.5: Responsive sampling in the face of an outbreak: In the face of emerging epidemics, opportunities to understand the epidemiology of an outbreak are lost because of delays

mobilizing sample collecting activities. SOPs and sampling teams will be prepared to undertake rapid collection of samples from wildlife and domestic animals in the immediate geographic area around an index case. We will remain in close communication with public and animal health disease reporting agencies so that disease outbreaks can trigger localized investigations.

1.4 Sample Size and Detection of Known Viruses

The more samples collected and tested, the higher the likelihood of detecting a previously unknown member of the target viral families. Collecting 300 samples from a given target species provides a 95% probability of detecting a virus present in at least 1% of individuals; Therefore, a risk-based approach to selecting animal species is critically important to optimize project resources. We will tether our collected data to baseline detection of known viruses in the PREDICT and VIRION databases and a beta-coronavirus specific database (<https://www.viralemergence.org/betacov>). This will allow estimation of expected prevalence and diversity for comparison with observed values for each viral family and host species. Following Y1 collection, detection, and viral characterization activities, we will use cluster detection algorithms to identify hotspots of prevalence or diversity of known viruses, triggering further focused sampling. Detection of known viruses in the three families provides a positive control.

1.5 Contingency Plans

Although the sampling plan is ambitious in scope we are confident that we can collect the numbers of samples listed. Key reasons for this are that we will a) focus sampling efforts on the collection of fecal matter, including composite slurry/sewage samples, which is an excellent sample type for viral discovery and relatively easy to collect; b) exploit sampling synergies within and between sampling targets, for example, sampling of humans, domestic animals, environments, and farmed wildlife will be carried out by single teams that focus on multiple sampling targets. This will make sample collection more efficient; and c) increase the number of sampling teams and / or sampling days if targets are not met. Finally, the plan will allow sampling targets to be exceeded in countries where collection is efficient, which will counterbalance more modest sampling outputs in less productive countries. It is also important to note that, for restrained animals, multiple samples will be collected (fecal, blood, swabs) and as such the estimated total number of samples refers just that and not number of animals sampled.

1.6 Outcomes

The outcomes of Y1 will be used to inform the strategic planning of the sampling activities in Y2 – 5. This site selection review will be an iterative process to determine whether to add new sampling sites. If outcomes from Y1 activities are inconclusive, sampling activities in Y2 – 5 will be informed through iterative refinement of the epidemiological and QMRA models and detailed, in-country participatory workshops and interviews targeting workers in the human, animal and environmental health sectors. Samples collected will be studied with an array of molecular assays for previously identified as well as novel corona-, filo-, and paramyxoviruses. Where data show a prevalent emergent animal virus, we will identify the location and specific animal hosts of origin and collect data on supply chains and contact networks to target additional specimen collections and molecular studies along the chain of transmission.

1.7 Capacity Building and Sustainability

To facilitate sustainability, we will promote in-country stewardship of all Objective 1 activities, including risk-based analytical approaches, design of sampling strategies and collection of samples. Rapid assessment of in-country capabilities will be conducted to identify gaps in personnel, training and equipment. Training will be provided for each activity (utilizing virtual

methods and translation to local language), and location-appropriate equipment provided in order to allow activities to be performed within, and beyond, the lifetime of the program.

OBJECTIVE 2: Strengthen Detection for Novel Viruses from Priority Viral Families

Our sampling strategy is designed to collect as many specimens as possible. Using a strategically designed, risk-based approach to sampling, we will roll out serial cross-sectional and prospective cohort studies at nodes of potential transmission of novel viruses to collect and screen **~800,000 specimens, with >60% from wildlife**. We will build a detection and characterization program utilizing in-country labs to provide near-real time screening and genome sequencing and finishing. Assuming 1-1.5% yield, based on the yield in the PREDICT program in the 3 viral families targeted for DEEP VZN (DV), this approach is likely to **detect and characterize 8000 – 12,000 novel virus genomes** over the DV program. We estimate these genomes to comprise a total of 1,000 novel viral species, based on the number of novel sequence submissions from the PREDICT project (~2100 novel sequences from 3 highlighted viral families for DV, constituting ~250 novel viral species, or ~8 specimens/sequences per novel virus species).

2.1 Capacity Building and Sustainability

Our capacity building approach for in-country laboratories is summarized in **Fig 3**. *The goal is to ensure that each country independently conducts full virus screening (basic detection to whole-genome sequencing) and basic characterization that includes evaluation of spillover (serology) and later glycoprotein and receptor-binding assays.* We will ensure sustainable, in-country capacity to safely detect and characterize unknown novel viruses by providing high-throughput automated nucleic extraction, multiplex qRT-PCR screening instruments, and *NextSeq* Illumina next-generation sequencing (NGS) platform in each country. All 18 partner institutions we have identified in the 12 target countries have existing serology capacity, while 60% and 25% have qRT-PCR, and NGS capacities, respectively. Building on our consortium's >25 years of experience working in sub-Saharan Africa, Asia, and Latin America, including during the COVID-19 pandemic, we will address the recurrent problem of high cost and delayed delivery by establishing direct-buy credit accounts and service contracts with the manufacturers of equipment involved in the DV program. As illustrated in **Fig 3**, in Year 1 we will conduct rapid assessment of in-country labs to determine needs, followed by provision and installation of

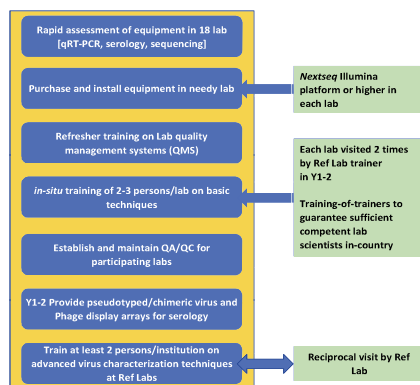


Fig 3. Flow chart of stepwise capacity-building for in-country labs

equipment to ensure they can conduct qRT-PCR, serology (ELISA and pseudotype viral neutralization test (pVNT)), and viral WGS.

Reference Labs: We will establish and fund two Reference Labs in the US, tasked with building in-country lab capacity, and validate advanced virus characterization (*in-silico* glycoprotein and receptor, *in vitro* and *ex vivo* virus-cell studies). The D. Wang (WUSTL) and A. Greninger (UW) labs, supported by other virology, immunology, and protein chemistry labs at these institutions, will in the early phase of the program (Years 1-2) (i) Develop and supply novel virus detection and

characterization standard operating procedures (SOPs), (ii) Conduct *in situ* training to in-country labs on qRT-PCR, whole-genome sequencing (WGS), and serology technologies, including annual refresher trainings, (iii) Develop and supply qRT-PCR controls and standards, (iv) Develop and supply serology screening kits (phage display peptide libraries, pseudotyped and/or chimeric viruses, monoclonal antibodies), (v) Roll out and manage a QA/QC system to ensure

reproducible and comparable data (including proficiency panels and re-testing 10% of positive specimens from each country), (vi) Conduct advanced characterization (*in-silico* glycoprotein and receptor, *in vivo* and *ex vivo* studies with live virus), and (vii) travel and train at least two persons from each participating institution in their US reference labs on development of pseudotyped/chimeric virus and antibodies for serology, and advanced virus characterization. Based on our successful experience with lab capacity strengthening, it is essential that this will be accompanied by reciprocal training visits by reference laboratory trainers to in-country labs, with the goal of ensuring that in-country labs can independently conduct detection and significant advanced virus characterization (except virus culture, or *in vitro* and *ex vivo* studies with live virus that may require high biosecurity laboratories). We recognize that in-country laboratories will not acquire competency at the same rate because of factors such as additional needs to improve infrastructure, biosafety and biosecurity capacity, sub-contracting and procurement challenges, and staff turnover. We also anticipate that early in the DV program in-country labs will identify suspected novel virus samples that require urgent characterization methodologies not yet fully established and transitioned to the country. To address this, the project will expand U.S. based reference lab personnel who will be dedicated to implementing all aspects of in-country virus detection and characterization (as described). These personnel will transition for several month-long periods each year through the in-country laboratories to provide both structured and ad hoc in-country analysis support, including complete bioinformatic analysis of NGS data to identify novel viruses, basic *in-silico* viral glycoprotein and receptor-binding analyses, and serological analysis to determine novel virus spillover. Additionally, this response team may be deployed to work alongside in-country scientists in a country with suspected novel viruses until characterization is completed to the satisfaction of the consortium executive council and USAID. The Reference Laboratories will also validate in-country results by repeating a limited number of the characterization tests conducted on novel viruses. This validation will be achieved by shipping aliquots of not more than ~0.1% of collected samples (negative and positive) as shown in the textbox below.

ESTIMATED NUMBER OF SAMPLES SHIPPED TO REFERENCES LABS IN UNITED STATES

From ~800,000 specimens collected; we estimate at least 8,000 (1,600/year) will have suspected novel viruses. Of these, we expect to ship no more than 10 qRT-PCR positive and 10 negative specimens from each country in Years 1-2 (480 specimens) for validation, and 5 qRT-PCR positive and 5 negative specimens In Years 3-5 (360 specimens), bringing the total specimens shipped to 840 (0.1% of collected specimens) over the 5 years for the DEEP VZN program.

For purposes of virus culture, virus isolation, *in-vitro* and *ex-vivo* studies, we have established access to the Rocky Mountain BSL-4 laboratory (letter of commitment available).

2.2 Overall Detection Strategy

We will use both molecular and serological approaches to detect novel viruses. For maximum sensitivity and efficiency, our primary virus detection strategy will use broad-range qRT-PCR assays that specifically target the 3 virus families for initial screening of specimens. We will utilize consensus RT-PCR followed by sequencing of amplicons and interrogate positive specimens further to obtain complete genomes. Broad serology will be used to adjust the sampling strategy (Objective 1), and also to investigate spillover of novel viruses across the wildlife-livestock-human spectrum (Objective 3). Focusing primarily on sera collected from bats, rodents, NHP, and humans, we will screen for known and newly detected coronaviruses, paramyxoviruses and filoviruses using phage display serology. Evidence of high prevalence of diverse species of target virus families will indicate an ecosystem favourable to maintenance and

transmission of these viruses. *Serologic detection of* antibodies to a novel virus may also provide information on duration of exposure and affected animal species, with high seroprevalence in humans pointing to higher frequency of spillover events.

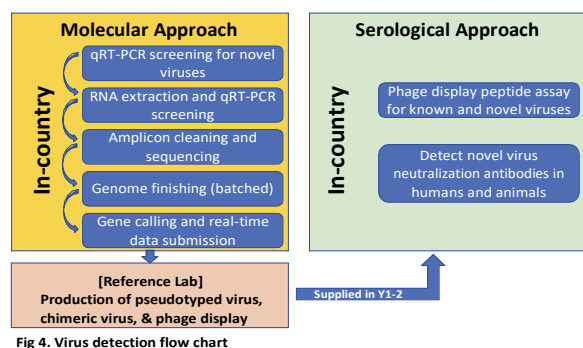


Fig 4. Virus detection flow chart

How our approach enhances efficiency to detect novel viruses: Our molecular screening strategy (Fig. 4) optimizes sensitivity, keeping the most expensive aspects (deep meta-genomic sequencing) to a minimum. All 3 viral families targeted for detection in the DV program are shed and detectable in stool reducing the need for animal trapping and handling. We have also integrated viral load measurement to our screening to improve chances of genome

finishing. During genome recovery from positive specimens, we will be able to infer hosts from environmental metadata and non-viral metagenomic sequencing data, which will be fed back to sampling teams to focus on particular animal species and areas where positives have been detected. The phage display approach is more cost-effective and efficient to serologically screen for known and novel viruses from target families than alternative multiplex serology approaches, such as peptide microarrays. Primarily because the phages self-replicate and thus are a renewable resource. Broad serology is costlier than qRT-PCR and this will limit its use.

2.3 Molecular Screening

Task 2.1: RNA extraction and broad-range qRT-PCR: RNA extraction methods will be standardized across all sites. Ideally, automated extraction instrumentation will be installed at each site. In addition, an alternative manual extraction method will be established as back-up. Our team has validated a family-specific, broad-range, single-well RT-PCR assay for *Orthocoronavirinae*, which enabled discovery of a novel coronavirus from a hospitalized patient in Malaysia. We will also make use of a published two-well pan-paramyxovirus and a one-well pan-filovirus qRT-PCRs to screen specimens. These family-specific primers amplify conserved portions of the RNA-dependent RNA-polymerase and allow for species determination after amplicon sequencing. We will integrate SYBR-Green into family-based RT-PCRs to allow for viral load quantitation at the same time we are detecting novel viruses along with melting curves to ensure appropriate-sized amplicons are generated without gel electrophoresis. As a backup strategy to the quantitative readout, a standard operating protocol for gel electrophoresis-based readout will be established. We will ensure in-country labs have instruments that can perform these assays with a throughput of 20-22 specimens per 96-well plate or 80-84 specimens per 384-well plate. We anticipate a throughput of at least 80 specimens per day per laboratory. Amplicons from qRT-PCR will be cleaned of PCR primers and sequenced on *Nextseq* biweekly, with up to 96 amplicons multiplexed. For further cost efficiency, we will explore the feasibility of multiplexing up to 384 amplicons. To identify novel viruses from the amplicons, all sequences will be aligned to a reference database composed of all target viruses from GenBank. Amplicon sequences that diverge significantly from all known viruses will be prioritized for whole genome sequencing. To standardize assays, the Reference Labs will provide positive and negative control standards for RT-PCR. Qualitative controls will be run through extraction and qRT-PCR on every plate, while quantitative controls will be run monthly. Quantitative controls will consist of a set of serial dilutions (10^7 - 10^0 copies/ul) of *in-vitro* transcribed RNA targets (2 different viruses in the family).

Task 2.2: Genome recovery and finishing: For maximal cost efficiency and timeliness, genome finishing will be performed in batches using *NextSeq* or *NovaSeq* equipment in each country. After identification of amplicons derived from novel viruses, we will ensure that complete genomes are recovered and finished to enable further screening and characterization. Complete genomes are also necessary for development of diagnostics, molecular epidemiology, vaccinology, and therapeutic development. Specimens will be prioritized for whole genome sequencing based on sequence divergence from known viruses and viral load estimates. We will use a variety of NGS methods as needed, including metatranscriptomics with rRNA depletion and/or poly-A enrichment approaches. Based on the identity of the virus, we can also use spike primers that bind the sequences recovered in the family-specific qRT-PCR or other highly conserved regions in that viral family into the cDNA synthesis prior to sequencing to increase coverage of viruses. New rRNA depletion reagents that cross-hybridize across metazoans will ensure fewer reads are spent on rRNA in rodents, bats, NHP, and humans, allowing for 8-150-fold enrichment of on-target reads. All targeted viral families poly-adenylate their transcripts, allowing classical RNA-Seq approaches to help in viral genome recovery. As a default, specimens will be targeted for 25 million reads to ensure genome recovery using high-throughput Illumina sequencers, which can allow recovery of near-complete genomes from specimens with Ct < 27. If needed, we will perform additional deeper sequencing, manually design PCR primers to close gaps, and perform 5' and 3' RACE to recover the viral genome termini. Our team has expertise sequencing whole genomes of novel RNA viruses. In Year 1, we endeavour to obtain and sequence specimens that have novel target virus from prior PREDICT projects. Small 400-500bp fragments of >150 novel paramyxoviruses and more than 60 novel coronaviruses were detected in PREDICT projects, but full genome sequences are not available. **Task 2.3: Genome calling and real-time data deposition:** Genome calling will be performed using a variety of automated and bespoke pipelines, including cloud based IDSeq for comprehensive assessment of viruses present in a specimen. As a complementary approach, we will also use well-described locally installed bioinformatic approaches, such as IRMA (an assembler specifically optimized for RNA virus genomes) and SURPI (pipeline optimized for unbiased metagenomic detection of all pathogens). Reads will be remapped to all draft genomes to ensure accuracy and manually reviewed in Geneious, especially if manual gap filling or 5' and 3' RACE is required. Importantly, our bioinformatics strategy also takes advantage of the global bioinformatics community and the wisdom of crowds by including real-time FASTQ and FASTA sequencing data deposition into NCBI Sequence Read Archive (SRA) and GenBank with **zero embargo time**. Our team has previously published software to facilitate rapid deposition of viral genomes into GenBank. SRA and GenBank accessions and brief initial analyses of sequencing data will be automatically communicated in real-time via our project-specific Twitter, so they are accessible to the global scientific community.

2.4. Broad Serology Screening

Zoonotic spillover is not considered a one-off event, and multiple small spillover events can potentially be detected by serological studies. For SARS-CoV, human serosurveys in south-eastern China found evidence of repeated spillover, with antibodies shown to persist for at least 2 years. To identify the animals or humans that had prior exposure to target viruses, our Reference Labs will generate phage display libraries covering 100,000 of the most conserved 60-mer peptides across all known filovirus, paramyxovirus, and coronavirus genomes following the VirScan protocol. The phage library will be amplified and validated using well-characterized positive control sera obtained from PREDICT labs, NIH-CREID network, in-country and CDC,

and Institute Pasteur labs. Reference Labs will develop kits consisting of phages that can be incubated with sera and protein A/G beads in in-country labs, with library preparation. Following incubation, the beads can be washed and library generation performed. The resultant DNA library is stable and can be sequenced at in-country laboratories. The phage library will be updated with novel viruses detected globally. The library will be used to screen high priority sera collected from bats, rodents, NHP, and humans sampled from nodes of potential transmission, serial cross-sectional samplings, and possibly archived sera. *Broad serology testing will be applied selectively and as a secondary approach, in part because of cost and the broader utility of genome recovery to enable further viral characterization work.* However, we envision that:

- (i) evidence of infection by novel viruses can be obtained from the serological profiles;
- (ii) unique signatures of epitopes distinct from those derived from known infections may suggest prior infection with a novel virus;
- (iii) high prevalence of diverse species of the target virus families may indicate an ecosystem favourable to maintenance and transmission of novel viruses of interest, and therefore point to a preferred sampling location;
- (iv) serologic detection of antibodies to a novel virus could inform the duration of exposure and affected animal species, with high prevalence in humans pointing to increased risk of spillover to humans.

We should point out that low or undetectable antibodies in humans may not indicate that a novel virus poses low risk to humans because other factors such as its recent introduction or potential for acquiring transmissibility to humans through minor mutations still exists.

As an orthogonal method to the broad serological screening, we will also perform binding ELISA serological assays against novel virus glycoproteins. Upon sequencing of a new virus, we will undertake codon-optimized gene synthesis to generate constructs for recombinant protein expression and pseudovirus generation. We expect to purify recombinant spike ectodomain trimers and/or receptor binding domain proteins for coronaviruses, GP trimers for filoviruses, and both fusion (F) trimers and G/H/HN tetramers for novel paramyxoviruses. We will use an antigen prediction pipeline to predict sensitive and specific viral protein antigens. Viral proteins and fragments predicted by this algorithm will be expressed for ELISA serodiagnosis. Negative-stain electron microscopy will be used to ensure the viral proteins are folded correctly after purification. Once viral protein antigens are purified, we will contract with GenScript for rapid generation of custom monoclonal antibody controls. We will then determine the specificity of the ELISA binding assay against a bank of >2,000 historical human serum specimens from UW Virology, including testing for cross-reactivity specifically against sera positive for IgGs to measles/mumps virus for paramyxoviruses, SARS-CoV-2 and all four endemic coronaviruses, and Ebola/Marburg viruses for filoviruses. Pending results from those specificity tests, we can iterate design of antigens for specific serological testing, including use of specific viral peptides, as required. Sensitivity will be tested against convalescent host animal sera as well as any human sera available from individuals known to be infected. This ELISA kit will then be provided to in-country labs with positive and negative controls, as well as host control proteins for testing for vaccine preventable illnesses (SARS-CoV-2 spike protein for coronaviruses; measles H for paramyxoviruses) and will be compatible with commonly available plate readers. Early in the COVID-19 pandemic, our UW Reference Lab provided recombinant SARS-CoV-2 nucleocapsid along with controls for binding ELISAs to laboratory partners in Senegal, Pakistan, Brazil, South Africa, Nigeria, Kenya, and other countries as part of the NIH CREID consortium. In addition to the binding assays described above, we will use pseudotyped lentivirus and chimeric vesicular

stomatitis virus (VSV) neutralization assays with the novel virus glycoproteins to functionally profile sera for neutralizing antibodies. These assays will benefit from the expertise of Dr. Whelan (WUSTL) and Dr. Veessler (UW) and allow for greater rigor and reproducibility of seropositivity identified by binding ELISA by providing an orthogonal and functional readout. Our primary approach will involve generating chimeric VSV reporter viruses (below). As these assays require cell lines permissive for viral entry, these efforts will create synergy between virus detection (Section 2.2) and characterization (Section 3.3) components.

Task 2.4: Generation of chimeric reporter viruses: We have extensive experience generating chimeric VSV reporter viruses where native viral glycoprotein (spike S, attachment glycoprotein G, fusion F, and hemagglutinin H) is replaced by those of heterologous viruses. Our experience with the coronaviruses indicates that either mutation of the endoplasmic reticulum retention sequence in the cytoplasmic tail of the spike, or truncation of the tail by approximately 20 residues can allow effective integration of the respective Spike gene into VSV, yielding viruses

that grow to titers of 10^8 pfu/ml. For filoviruses, we have not found it necessary to manipulate the cytoplasmic tail of the glycoprotein, although we have mutated the transcriptional editing sequence that is used for synthesis of soluble glycoproteins. Once an infectious clone of VSV-chimeras is assembled, we confirm sequences of the recovered virus, and characterize the growth of the respective viruses to establish the optimal conditions for the generation of seed stocks.

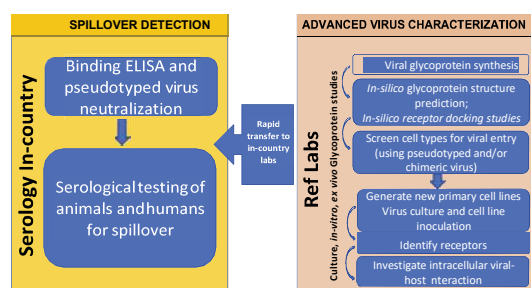


Fig 5. Flow chart for novel virus characterization

Task 2.5: Detection of neutralizing antibodies: We will use VSV-chimeric viruses to monitor levels of neutralizing antibodies in humans and sometimes animals. We are mindful of reports that bats inoculated with some filoviruses do not generate neutralizing antibodies that are detectable in neutralization assays. Accordingly, we will also use the VSV-chimeras to detect antibodies that recognize the respective envelope proteins displayed on the surface of virions. To do this, we will use purified virions that contain the respective envelope proteins on their surface and sera containing antibodies that bind to the virion identified by isolating the bound complexes. As an alternative approach to VSV chimeric viruses, we will use lentivirus-based pseudotyped neutralization assays. Pseudovirus neutralization assays against novel viruses will be optimized for expression and intracellular termini truncations as well as with monoclonal controls. The constructs, controls, and pseudotyped viruses will be made available to in-country partners once the assay is validated by Reference Labs. *These approaches will permit us to determine whether a given animal species has mounted an immune response to the envelope proteins of any novel virus and whether such immune responses include neutralizing antibodies.* The prevalence of such antibody responses may indicate potential risk for spillover into humans, even though low or undetectable antibodies may not mean that a virus is at low risk for human infection. These assays are compatible with BSL-2 settings widely available in in-country labs.

OBJECTIVE 3: Strengthen Characterization of Novel Viruses from Priority Viral Families

3.1. Overall Characterization Strategy

Guided by the understanding that, with timely and complete genome sequencing in Objective 2, >80% of novel virus characterization can be performed in the absence of virus isolation. We will start by characterizing selected novel viruses detected under the PREDICT program and identified as potentially important. Subsequently, we will use sequence data from novel viruses

we detected (Objective 2) to construct qRT-PCR screening kits and recombinantly express and purify viral proteins for reagents development (e.g., monoclonal antibodies) for serological assays and structural studies. We will use these sequences to create pseudotyped and chimeric viruses for serological assays and profiling viral entry. Pseudotyped and chimeric viruses can also be used to identify and screen for receptor usage and identify cell lines that support viral entry. These cell lines can be used to identify other determinants of tropism and to characterize viral entry mechanisms. We will attempt to isolate novel viruses and identify known or novel host genes that enable viral entry. Finally, we will determine the affinity of novel viral glycoproteins for human receptors and mechanisms of innate immunity antagonization to determine zoonotic/ pandemic potential (Fig. 5).

3.2 Profiling Viral Glycoproteins/Receptors to Assess Pandemic Risk of Novel Viruses

Task 3. 1: *In-silico* characterization of novel viruses. Our *in-silico* approach for profiling human transmission risk follows directly from the hypothesis that *affinity for human receptors of a novel viral glycoprotein indicates pandemic potential*. As soon as a novel virus genome is recovered, our UW Reference Lab will perform *in-silico structure prediction* of viral glycoproteins with Rosetta and trRosetta, as well as docking with known receptors for a given viral family to approximate affinity for human receptors. To support this effort, we will model the structures of the extracellular domains of all human proteins and compare these to structures of known host cell viral receptors to determine how closely they match as a way of generating hypotheses **for candidate** human host cell viral entry points. We will interrogate these predicted structures for specific changes in protease site activation. Our ability to determine high- resolution structures of viral glycoprotein-receptor complexes using world-class cryo-EM will be fed back to *in-silico* models to enhance protein structure prediction and viral-host protein-protein interactions. It is worth noting that to-date, no model has successfully predicted viral zoonoses and spread in humans. Therefore, our bias will be to perform as much wet laboratory characterization of novel virus glycoproteins. We will synthesize all viral glycoproteins recovered from novel viral genomes and screen in viral entry, biochemical, and biophysical assays because *in-silico* modelling is insufficient to capture risk.

Task 3.2: Biophysics and structures of viral glycoproteins. Divergent paramyxovirus, filovirus, and coronavirus genomes will be used to carry out structural studies of the corresponding glycoproteins in isolation and bound to target receptors to understand the mechanisms of viral entry into host cells. Our UW Reference Lab is world-renowned for expertise in viral glycoproteins and has developed a streamlined, high-resolution cryo-EM pipeline enabling high-throughput structural studies of viral glycoproteins bound to host receptors and neutralizing antibodies. It will be leveraged to provide atomic-level information of the infection machinery of discovered viral pathogens before they emerge. Novel viral glycoproteins and animal and human receptors will also be expressed and tested directly for binding kinetics and affinity using biolayer interferometry. These affinity measurements will provide biophysical confirmation of receptor interactions and direct biochemical evidence of the degree of pandemic risk of a novel virus. We will correlate binding affinity measurements and functional biochemical measurements of fusogenicity using cell-cell fusion assays.

Task 3.3: Viral isolation-independent viral entry characterization and receptor discovery. The VSV chimeras and pseudoviruses generated above will also be used to perform viral receptor discovery at a BSL-2 level. Previously, our WUSTL Reference Lab has used both VSV

SECURING MTAs FOR SHIPPING SPECIMENS: Our approach is to reduce the number and scope of MTAs. Each in-country lab will only sign one MTA with either UW or WUSTL reference laboratory

and pseudoviruses and a series of cell lines expressing canonical coronavirus receptors to rapidly screen for coronavirus receptor usage and to discover the human receptor of SARS-CoV-2. To establish neutralization assays, VSV chimeras and pseudoviruses will already be tested against a broad array of human, non-human primate, bat, and rodent cell lines that support paramyxovirus, filovirus, and coronavirus growth, including an initial screen of VeroE6, RHMK, CV-1, HAE, HuH-7.5, HEK293, HepG2, CaCo2, BHK (hamster), MEF (mouse), Aji (bat), RhiNi (bat) cell lines. This screen will be performed in the presence and absence of trypsin to determine if host restriction for viral entry exists at the level of proteolytic activation, as previously described for several bat coronaviruses. Canonical receptor usage (e.g., ACE2/DPP4/APN for coronaviruses, NPC1 for filoviruses, or SLAM/EphrinB2/3 for paramyxoviruses) will be confirmed at the protein-level using soluble receptor blocking and/or blocking monoclonal antibodies. If viral entry into one of the above cell lines is not found to be caused by a known or canonical receptor, we will perform genome-wide CRISPRko screens to discover viral receptors. Using this and related genome-wide approaches, we have identified the receptors for multiple coronaviruses, paramyxoviruses and filoviruses validating this approach. We will carry out such screens to identify host genes that are potential determinants of infection and, armed with that information, we can determine the step of viral infection at which any given host gene functions as described in the rest of the proposal. This will allow us to compare the genomic sequence of entry factors between susceptible and non-susceptible host cells.

3.3 Viral Inhibition of Innate Immunity

Viral antagonization of innate immunity is an important component of viral pathogenesis in humans. Like glycoproteins, viral immuno-evasion proteins are often tailored specifically to the host they infect, and thus the zoonotic and pandemic potential of a new virus will be determined in part by how these genes affect human innate immunity pathways. West Nile and Zika virus spread in humans is in part determined by the degree of inhibition of the JAK/STAT pathway.

Infection in animal host species reservoirs can contribute to viral evolution strategies that facilitate evasion of host innate immunity. Bats have specifically downregulated inflammatory pathways while maintaining type I interferon pathways, leading to a unique evolutionary selection for viral antagonization of type I interferons.

Task 3.4: Testing for the degree of innate immune inhibition: The UW Lab will perform tests by all open reading frames from a novel virus in a host innate immune evasion screening platform. If throughput is limited, at a minimum we will characterize the major immuno-evasion genes from the different viral families. Here, the specific viral protein open reading frame is cloned and expressed ectopically in relevant host cell lines, 24 hours later cells are treated with exogenous interferon (IFN) and harvested over a time course to evaluate for possible reduction in innate immune signalling pathway activation compared to control cells treated with IFN but without ectopic expression of viral genes. Loss of innate immune activation will be evaluated by reduced IFIT1 and IFITM1 gene expression measured by RT-qPCR. We recognize that these approaches are limited to evaluating viral evasion from IFN responses and do not evaluate innate immune signalling components that occur prior to (upstream of) IFN induction. To address this, we will assess the ability of viral protein expression constructs to suppress the activation of interferon regulatory factor (IRF)3 activation induced by Sendai virus infection, a control virus that potently induces innate immune activation in infected cells. We will transfect cells with each viral protein expression construct, followed by infection with Sendai virus, and assess total and phospho/active IRF3 abundance. For a broader analysis of innate immune pathway regulation, we will infect relevant host cell lines with the virus panel of interest and evaluate innate immune

response pathways activated by each specific virus using assays (immunoblot and mRNA analyses) to measure the activation state of specific innate immune pathway markers as well as expression of downstream genes linked to each pathway.

3.4 Virus Isolation for Receptor and Intracellular Viral-Host Interaction Studies

Task 3.5: Viral isolation and receptor identification. As illustrated in **Fig. 5**, we may require virus isolation to conduct *in vitro* and *ex vivo* studies. Such studies will be conducted in BSL-3 and BSL-4 labs under proper biosafety protocols. Isolation of novel coronaviruses or paramyxoviruses (determined using sequencing data) when there is no concern of severe human disease can be attempted in certified BSL-3 labs located in-country, regionally, or at Reference Labs. Isolation of viruses of great concern of severe disease, such as filoviruses, will only be attempted in Rocky Mountain Laboratories BSL-4 lab (letter of commitment available on request). Positive specimens will be prioritized based on viral load, with a focus on specimens with >1 million copies per mL or gram. We will inoculate virus onto cells shown to be permissive to pseudovirus entry from above. Viral isolates will be expanded and deposited into central repositories with CDC, BEI, and/or WRCEVA, according to the appropriate biosecurity and national data sharing guidelines. Receptor usage determined in the pseudovirus screen will be confirmed using the viral isolate. For isolated novel viruses that do not show canonical receptor usage but cytopathic effect, we will screen for novel human receptors using genome wide CRISPRko libraries in cell lines that support viral growth as described above. Where possible, we will prefer viral isolate CRISPRko screens over pseudotype screens to identify potential intracellular viral-host interactions at the same time as identifying potential receptors.

Task 3.6: Host cell characterization and cell line generation for viral characterization.

Inoculating existing cell lines and primary cells with virus-positive specimens may not result in viral growth. The cell lines chosen may not contain the correct receptors, proteases, or other intracellular factors to support viral entry and/or growth. To support viral isolation and characterization for such viruses, we will generate primary cells from bat, rodent, and NHP tissues that are specifically sampled in DV and identified by host deep sequencing reads in Objective 2. Over the past decade, several new primary bat cell lines have been established that support growth of many viruses of high zoonotic potential *in vitro*, and yet bat species are so diverse that it is likely that no specific cell lines might be available for the bats sampled here. Should the approaches outlined above fail to support viral isolation, we will use scRNA-Seq sequencing of virus-positive primary specimens to help identify candidate host cells and host receptors to be targeted for cell line generation. scRNA-Seq is a powerful approach to link virus transcription and replication on a single cell level with candidate host cells and receptors should existing cell lines prove insufficient. If we are unable to specifically isolate the relevant host cell lines based on scRNA-Seq data, we will ectopically express candidate viral receptors identified by scRNA-Seq data into candidate host cell lines to determine viral receptor usage.

3.5 Algorithm for Ranking Viruses with Pandemic Potential

A proposed algorithm for ranking emerging viruses for potential spillover to humans was recently published by the PREDICT team (<https://spillover.global/ranking-comparison/doi.org/10.1073/pnas.2002324118>). We will improve on this by applying the findings of our innovative and thorough stepwise virus characterization methodologies described in **Section 3**, and by rating each novel virus based on the following three questions:

- (i) Does the virus have potential for human transmission? This will be investigated using the glycoprotein modeling and functional viral entry studies described above.

- (ii) Is there evidence of its spillover to humans or a broad range of potential animal reservoirs? This will be addressed through serologic testing.
- (iii) Does the virus have capacity to inhibit host innate immunity? Evidence of immunoevasion is consistent with the potential for significant morbidity and/or mortality in humans and should trigger a higher level of public health concern, particularly if the virus rates high on criteria i & ii above.

We will summarize the results in prioritized lists that will be publicly accessible to both in-country partners and international stakeholders. Importantly, our findings, which will be disseminated in scientific publications, presentations, communication with USAID and other stakeholders, will add key metrics to evaluate the zoonotic and pandemic potential of novel viruses.

OBJECTIVE 4: Strengthen Focus Country Capacities for Data Management and the Viral Characterization Process

The proposed project will develop and implement improved data systems at the country and international level, building on learnings from the EIDITH system developed for PREDICT 2, and increasing interoperability and access for partners and stakeholders alike. We will also aim to enhance in-country data collection and use to accelerate detection and response to future public health threats. This will begin with an assessment of the data structure of the EIDITH system, defining a core set of standard variables to be collected across sampling locations for use in describing the distribution of pathogens/exposures. The importance of national-level data autonomy must be balanced with the need for widespread dissemination of data to aid in the prediction and prevention of emerging epidemics. We will work with countries to build on existing systems using an “Adopt-Adapt-Develop” approach while defining protocols for data sharing between the DV and local systems so that project data enhances existing systems while observing local policies and SOPs. The consortium will also draw on previous experience with local and global datasets to advance global surveillance of zoonotic threats. To allow rapid sharing of data across the consortium and with international databases such as NCBI, we will put in place MOUs and data use agreements using a “staged ring” approach, wherein data access can be conceptualized as a series of interlocking rings within which data ownership is retained by in-country stakeholders whilst standardized review, approval, and validation processes allow data to be rapidly shared to key stakeholders at national and international levels. This will ensure that, rather than creating parallel systems, the project builds upon (and integrates into) existing structures and data systems, while ensuring rapid release of validated data to project team, national, and international partners. Pending national approvals, aligned to standardized data sharing agreements supported by DV, and the removal of any sensitive information, data will matriculate across the data management structure, representing gradually more release of data (e.g., USAID staff, external partners, cross-border sharing and full public accessibility). This progression will represent not only increased access but also improved data quality: data sets made available to the public would represent those with well-documented dictionaries and curated metadata, while more incomplete data would remain with project and national stakeholders. In these endeavors, we will build on PREDICT, which has uploaded hundreds of sequences from newly discovered animal pathogens to the NCBI’s Short Read Archive (SRA) and GenBank. With USAID and local stakeholders, we will review and update the data use agreements where PREDICT has been active and use them as models.

4.1 Project Data Collection and Management

Task 4.1: Develop a project-wide data management plan. The consortium will use a data system based on principles of the EIDITH system to collect and manage data among the partners while respecting the need for data safety and ensuring in-country data ownership. This management system has the capability to import data for linkage with surveillance data systems in the host countries, USAID, and global systems such as healthmap, ProMED, NCBI.

Task 4.2 Monitor project implementation. PATH, leading Objective 4 and as a global leader in project monitoring and evaluation, will develop indicators and track project progress via systematic data analysis and review meetings, data quality assessments, technical working groups, and training of data managers at the facility, subnational, and national level.

Task 4.3 Data storage. Following national approvals described in section 4.2, data will be stored within the DV database with data security and access conforming to the FAIR Principles, as well as the Nagoya protocol for genomic data sharing.

4.2 Country Data Management

Task 4.4: Map the data management and policy landscape of each country. In Year 1 an early assessment of existing systems in use at the country and regional levels will be conducted in order to help support and define the architecture, connectivity, flow and human resource capacity to achieve rapid access to quality data at the country level. This assessment will identify gaps and areas that must be strengthened across the continuum from data collection, cleaning, and storage to analysis and presentation to key stakeholders and users and across relevant data sources including laboratory, human and animal clinical, and environmental data sets. This will also entail an extensive evaluation of the enabling environment, including existing health data privacy policies, data use regulations, digital workforce capacity, and information technology infrastructure. The goal is to develop a baseline for each country in terms of existing data agreements, identify adaptations that would enhance data sharing, and understand the policy environment for data sharing and use. Using these assessments, we will develop a roadmap for developing an integrated country-level data architecture with our country partners, including reporting from our DV data system and site- and laboratory-level data collection, as well as ensuring local data sharing through secure, interoperable data exchange.

Task 4.5: Evaluate lab information systems of DV lab and field data collection teams in focus countries. Our consortium will identify the capacity of partner labs in focus countries to support data capture for the project. Similarly, we will ensure that the field data collection teams are trained in data collection according to the data standards that we will extend based on EIDITH/PREDICT. We will build on the existing data structure from in-country data management systems and PREDICT/EIDITH, including sample tagging protocols, geolocation, and survey-based questionnaires.

Task 4.6: Incorporate knowledge and learnings from previous projects. We will use publicly available data, such as PREDICT data available through <https://data.usaid.gov> including readily available country-specific data sets from EIDITH (event animal production, event crop production, animals sampled, event dwellings, event value chain, PCR tests, and site/event characterization) and genomic information available through GenBank in national-level data use and analysis. This will ensure that our project database builds on successes and lessons learned from the EPT project to date. Our data management plan will be able to rapidly incorporate the metadata and genomic data of these samples when they become available.

Task 4.7: Establish data standards and governance. With our in-country partners, we will establish global data standards and assist with establishment of a data warehouse that includes

different collection and management aspects for analyzing, sharing, and storing data. The consortium has previous experience creating similar architecture (the POLIS system for polio eradication and analysis) which has been in use for over eight years. Technical working groups (TWG) will be developed to establish data governance and reporting plans for each target country. These TWG's will conduct regular monitoring of implementation and the assessment of whether goals are being met, while adhering to country needs to try to be more proactive, transparent, to share data rapidly, and be adaptable to addressing issues. We will engage existing standards bodies to ensure that data sharing formats leverage existing works and/or contribute to these standards. This will also address (and ensure) country/regional and local stakeholders' access to genomic/sequencing data from GenBank and other global repositories to build and strengthen research capabilities. We will work with country governments to ensure the timely sharing of information as described, while also recognizing sensitivities around data to avoid stigmatization that could lead to reluctance because of economic and societal pressures.

Task 4.8: Implement data collection using updated data system for focus countries. We will adapt existing technology for the DV digital tool to collect field-based data, including geolocation, animal or plant species, samples collected, unique sample identification, and so on. The tool will be based on an existing technological base, such as CommCare, RedCap or similar, with interfaces for data import, exchange, and interfacing with lab systems. The DV data system will collect necessary data, including accession information for genomic data, connected with sample and location data collected by the DV digital tool.

Task 4.9: Strengthen capacity of in-country partners to store, analyze, and share data. We will train in country partners on use of the DV data system and its linkages with existing in-country data system architecture, work with host governments and data users to identify the key questions they would like to answer with the data, as well intended purposes and requirements, and support implementation of solutions to improve country-level electronic data sharing capacities. Uploading viral sequences to NCBI will also facilitate data exchange between in-country labs and reference labs. We will work to establish harmonized bioinformatics techniques and pipelines across the DV project to ensure comparability of genomic data. User-friendly dashboards including GIS maps to show location of possible priority infectious agents or exposure will be developed to visualize and support interpretation of the data. The consortium will identify "local champions" at the different levels to accelerate this activity. We will work with our in-country partners to publish, supporting their capacity to act as lead authors in internationally recognized journals, and provide training and mentorship in scientific writing.

Task 4.10: Strengthen in-country data management processes for the viral detection and characterization processes. Our consortium will support in-country labs in the focus countries in training the necessary staff on laboratory data management, including genomic data, and to support staff in bioinformatics, monitoring, and maintaining data repositories and architecture.

Task 4.11: Develop an early warning system with country-level dashboards. Learning from tools such as Tableau, DHIS2 dashboards, and other existing AI platforms, by the end of Year 2 we will develop country-level dashboards of DV data to visualize data and identify potential emerging threats based on expert opinion. This will leverage work done under PREDICT 1 and 2 as well as the Spillover data tool (<https://spillover.global>).

4.3 Global Data Sharing

The consortium has identified key data sets to be collected across countries that may require augmentation to in-country systems. Sequencing data will be communicated in as close to real-time as feasible to make this information accessible to the global scientific community, while

also adhering to data governance requirements negotiated with local stakeholders. Sequencing data and correlation with other findings including advanced characterization will also be regularly shared with in-country partners and global stakeholders via published lists of prioritized novel viruses ranked on their pandemic potential. This release of high priority and high-risk pathogens will feed into other risk assessment activities at national and global levels such as STOP Spillover and the proposed WHO Berlin Hub for Pandemic and Epidemic Intelligence. The consortium is already engaging with these stakeholders to cultivate a new model of data solidarity and collaborative intelligence for risk assessment. Another emerging initiative supported by WHO - the International Pathogen Surveillance Network (IPSN) - will also work to support global exchange of genomic information. The consortium will ensure a close integration with and support for IPSN, leveraging this global structure and pathway for R&D. These examples demonstrate opportunities for improved and rapid data sharing in a quickly evolving landscape. The consortium, in collaboration with USAID, will continue to track and engage with these initiatives as appropriate. Wherever possible, the linkages between the consortium data and these international data sharing mechanisms will be built into the project system architecture and part of agreements with national stakeholders.

Task 4.13: Convene multisectoral networks at country and international level. We will build on existing data standards for PREDICT 2 and provide trainings across the consortium and with in-country stakeholders to ensure adherence to data standards.

Task 4.14: Develop improved data sharing processes across data systems at country and international levels and across stakeholders. The project will develop the DV digital tool “esign” – a data-sharing process that supports differing levels of staging and access – with the capability to move data from an internal-only level to internal plus USAID, external partners, and fully public, international levels. While aligning with host country requirements and global guidelines (e.g., WHO’s code of conduct for sharing of pathogen genetic sequence data), our consortium will also ensure appropriate data is made available in a rapid and responsible manner to benefit the global community. In keeping with our “Adopt-Adapt-Develop” approach, we propose a data storage structure that will include three related databases – one for raw sequencing reads, one for assembled data and one for sample metadata. This segregated structure will facilitate real-time reporting of raw sequence data (FASTQ and FASTA) accompanied by limited deidentified metadata to global repositories (NCBI SRA, etc.) while also ensuring that access to sensitive metadata remains restricted until validated and approved for release. This structure will support more routine release of raw sequencing data throughout the duration of the DV project, while enabling local investigators adequate time to complete genome assembly and perform data cleaning and validation prior to submission of finished genome sequences to public domain (NCBI, EMBL-EBI, DDBJ) or public access (e.g. GISAID) repositories, and/or alternative global platforms (e.g., GitHub). Finally, project results and analyses will be regularly communicated via scientific publications, presentations, and direct communication with USAID and other stakeholders. As appropriate, and in accordance with in-country data sharing agreements, outlets will be explored for more rapid dissemination of findings, particularly when novel viruses with high pandemic risk are identified. This includes sharing manuscripts within preprint servers, such as medRxiv or bioRxiv, prior to publication.

5 Capacity Strengthening

A key goal of our DV program is for every activity and outcome to be predicated on a foundation of sustainable capacity strengthening within focus countries. To achieve this, in-country partner organizations will play leading and participatory roles in the development and implementation of

all activities. Further, in-country nationals will coordinate and implement all planned activities, from sample collecting through to laboratory analyses, with language-specific training programs being provided where necessary. Moreover, when planning for the improvements in technical capacity through provision of equipment, care will be taken to ensure the utility of any equipment extends beyond the duration of the program by selecting location-appropriate equipment that can readily be maintained, resourced, and used. This will ensure that during and after the program maximal use is made of the virus detection and characterization capacity that the project will develop. Finally, it is critical that in-country stakeholders understand the value of the knowledge and resources generated. We plan to achieve this in two ways: (1) in-country partners will take leading roles in all aspects of data analysis and the preparation of peer-reviewed publications and (2) the DV project will engage a wide range of in-country stakeholders at project inception to begin the process of raising awareness about the potential value of the generated resources. This process will include multiple fora being hosted within focus countries with a variety of stakeholders to raise awareness of resources that will be generated by the program, and their use (Table 1).

Resource Generated	Resource Uses	Stakeholders
Data from wildlife sampling: species and abundance	Inform conservation efforts	National and international wildlife organizations
Viruses detected in wildlife and domestic animals	Prepare for animal health events	Animal health agencies
Spillover events detected in human populations	Determine risk to humans, control efforts	Human health clinicians, public health
Improved laboratory capacity for qRT-PCR	Improve detection of other infectious diseases	Human health, public health
Improved capacity for ELISA	Improve detection of other infectious diseases	Human health, public health
Improved sequencing and bioinformatics capacity	Application of whole genome sequencing to other pathogens	Laboratories, public health, surveillance

Table 1: Resources generated by the program, their utility, and the stakeholders who will benefit

6 Sample Monitoring and Learning Plan

The WSU-led consortium partners will work with USAID within the first 90 days of the grant to develop a comprehensive Monitoring Evaluation and Learning Plan inclusive of a Learning Agenda and Data Management plan that will describe the processes for monitoring project activities and progress towards achieving the desired results. A comprehensive indicator matrix with output, outcome, and impact indicators, annual and life of project targets, and baseline measures will be at the center of the MEL plan. Table 2 presents illustrative indicators for a subset of intended results and activities under each of the project's 4 objectives, with additional illustrative indicators in Annex 2. Quarterly team check-ins will be used as a venue for Objective Leads to review MEL data with the team to identify areas that are not achieving desired results and flag areas where implementation strategies might need to be adjusted. The team will use MEL data to inform project management and will report semi-annually and annually on progress towards achieving results under the agreed upon indicators in the MEL plan and explain any significant deviations from expected targets. The MEL plan will be reviewed for relevance semi-annually and the WSU-led consortium will work with USAID to revise if and when necessary. The team will collect and analyze data on gender to inform the project's gender action planning to identify opportunities for the project to reduce opportunity gaps between men and women or address power differentials to promote gender equity.

Table 2: Selected illustrative indicators linked to intended results and project activities

Objective 1: Conduct Sampling In Focus Countries For Unknown Viruses From Priority Viral Families		
Intended results	Project Activities/Tasks	Indicators/Milestones
In-country institutional and staff capacity to conduct risk modeling to identify and inform sampling efforts strengthened .	1.7 Capacity Building and Sustainability (cross cutting all Objective 1 activities and tasks)	#/% representatives from in-country wildlife, human, livestock, and environmental health sectors, trained and engaged in risk modeling, sample site and species selection, and sample target setting processes
Key species sampled at research sites.	1.3 Country-level Strategic Sampling	# of wildlife samples collected in each country % of archived wildlife samples of interest screened
Objective 2: Strengthen Detection In Focus Countries For Novel Viruses From The Priority Viral Families		
Detection and genomic sequencing of novel viruses from prospective samples safely conducted .	2.2 Overall Detection Strategy 2.3 Molecular Screening 2.4. Broad Serology Screening	# of in-country labs with instruments that can perform assays with a throughput of 20-22 specimens per 96- well plate or 80-84 specimens per 384-well plate # of genome finishing batches performed using NextSeqor NovaSequequipment in each country
Ability of select in-country laboratories to provide technical assistance and/or detection capabilities for viral discovery in- country and in the region improved .	2.1 Capacity Building and Sustainability	# of labs & # people trained by project on qRT-PCR, serology, next gen sequencing methods, bioinformatics platforms and methods for analysis; % of those trained demonstrating improved competency in new methods; % of laboratory capacity gaps identified in each country that are showing improvement as demonstrated by: % of labs with screening & sequencing instruments
Objective 3: Strengthen Characterization In Focus Countries Of Novel Viruses From Priority Viral Families		
Lab and bioinformatics capacity for characterizing unknown viruses in select in- country institutions strengthened .	3.1. Overall Characterization Strategy	# countries with improved characterization capacity as demonstrated by increased number of novel viruses characterized and fully sequenced by in-country laboratories that have staff who have participated in at least one of the project's capacity building activities.
Objective 4: Strengthen In-Country Capacities For Data Management And Viral Characterization Process		
Newly validated methodologies and protocols, data and analyses associated with viral detection and characterization shared .	4.2 Country Data Management Task 4.9: Strengthen capacity of in-country partners to store, analyze, and share data	# countries with validated protocols for data sharing, MOUs in place; # DV datasets, methodologies, and/or publications made publicly available; # of data managers providing data sets with reliability, accuracy, completeness, consistency and timeliness.

Learning Agenda: Our consortium is committed to utilizing a Collaborating, Learning and Adapting approach to implementing the DV project. The Learning Agenda (LA) will be developed in the first 90 days in collaboration with USAID and in-country technical experts and will be the primary tool for ensuring critical questions that can guide implementation are collaboratively agreed upon and used to inform project implementation. The LA will serve to contextualize project achievements and test assumptions regarding how implemented activities yield intended results. We will review and discuss LA assessments quarterly to ensure learning from identified failures and successes and to improve future implementation. Illustrative LA questions are provided in Table 3. The final LA will include learning activities, timelines, methods and a dissemination plan that will describe key audiences benefitting from the learning

produced by the project and products targeted at those audiences to ensure relevant information is shared back quickly to the right stakeholders in a useful format.

Table 3. Illustrative Learning Agenda questions:

1	To what extent is the project successfully supporting the timely detection and complete characterization of known and un-known pathogens among the prioritized viral families within the in-country reference laboratories? Which approaches are leading to the most robust implementation in countries and greatest effects on timely detection and complete characterization? And what characteristics, differences or similarities do we see across successful vs. less successful reference laboratories or countries where DV is implemented?
2	What data have the project successfully made available for use by local, regional and global audiences, and how have the data generated by the project supported local, regional and global preparedness and response activities to the targeted viral families? Are the appropriate audiences receiving useful data more rapidly? What barriers are still delaying the processes of sharing data and findings as quickly as possible? And what differences or similarities do we see across countries where DV is implemented vs. Countries where DV is not implemented?
3	<p>a. In which areas of capacity building (a-d below), and with which cadres of the workforce, has the project been successful in strengthening in-country capacity? What capacity building strategies are showing greatest / least impact? What remain the biggest barriers to successfully unlocking in-country capacity? Are project activities leading to unexpected capacity improvements? Laboratory capacity in viral detection and characterization of unknown viruses</p> <p>b. Data management capacity, including data collection, quality, analysis, sharing and storage</p> <p>c. Timely dissemination of actionable data and research findings</p> <p>d. In-country capacity to use data and research findings</p>
4	What existing in-country and global data systems are most successfully being leveraged for sharing DV data to increase likelihood of sustainability and interoperability among sectors? How successful is the project with getting virus sequencing data into those data sources? What facilitators can be leveraged and barriers do we still need to overcome to integrate DV data into sustainable systems?

Mixed methods will be used to answer these learning questions. Desk reviews will compile existing evidence; project monitoring and evaluation data will be used to track progress towards achievement of results within the learning agenda topic areas and incorporate project M&E within the learning. Additional methods for collecting data to answer these learning questions will include surveys, checklists, observations, key informant interviews and review of secondary data extracted from existing databases. Data from these sources will be analyzed to answer these questions, help the project understand what is working, where immediate pivots are needed in current implementation strategies and what learning should be shared more broadly. Data collection tools will be stored in a central repository for re-use and continuous learning during the project and beyond. The plan to disseminate and use findings will differ depending on the learning question. In many cases the first audience will be internal team and management to inform activity planning and work planning. Learning exchange sessions, webinars or workshops will be planned to discuss findings with local experts and decision makers to explore the local context and use of the findings. On a global scale, we will develop white papers, blogs, conference presentations, global learning exchange webinars, or publications for peer review.

[END OF ATTACHMENT B]

ATTACHMENT C – STANDARD PROVISIONS

MANDATORY STANDARD PROVISIONS FOR U.S. NONGOVERNMENTAL ORGANIZATIONS

M1. APPLICABILITY OF 2 CFR 200 and 2 CFR 700 (NOVEMBER 2020)

- a. All provisions of 2 CFR 200 and 2 CFR 700 in effect on the date of this award, and all Standard Provisions attached to this agreement are applicable to the recipient and to subrecipients that meet the definition of “Non-Federal Entity” in part 2 CFR 200.1, unless a section specifically excludes a subrecipient from coverage. The recipient must assure that subrecipients have copies of all the attached standard provisions.
- b. For any subawards made with Non-U.S. subrecipients the recipient must include the applicable “Standard Provisions for Non-US Nongovernmental Organizations.” Recipients are required to ensure compliance with monitoring procedures in accordance with 2 CFR 200 and 2 CFR 700.

[END OF PROVISION]

M2. INELIGIBLE COUNTRIES (MAY 1986)

Unless otherwise approved by the USAID Agreement Officer, funds will only be expended for assistance to countries eligible for assistance under the Foreign Assistance Act of 1961, as amended, or under acts appropriating funds for foreign assistance.

[END OF PROVISION]

M3. NONDISCRIMINATION (JUNE 2012)

No U.S. citizen or legal resident shall be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination on the basis of race, color, national origin, age, disability, or sex under any program or activity funded by this award when work under the grant is performed in the U.S. or when employees are recruited from the U.S.

Additionally, USAID is committed to achieving and maintaining a diverse and representative workforce and a workplace free of discrimination. Based on law, Executive Order, and Agency policy, USAID prohibits discrimination, including harassment, in its own workplace on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, disability, age, veteran’s status, sexual orientation, genetic information, marital status, parental status, political affiliation, and any other conduct that does not adversely affect the performance of the employee.

In addition, the Agency strongly encourages its recipients and their subrecipients and vendors (at all tiers), performing both in the U.S. and overseas, to develop and enforce comprehensive nondiscrimination policies for their workplaces that include protection for all their employees on these expanded bases, subject to applicable law.

[END OF PROVISION]

M4. AMENDMENT OF AWARD (JUNE 2012)

This award may only be amended in writing, by formal amendment or letter, signed by the Agreement Officer (AO), and in the case of a bilateral amendment, by the AO and an authorized official of the recipient.

[END OF PROVISION]

M5. NOTICES (JUNE 2012)

Any notice given by USAID or the recipient is sufficient only if in writing and delivered in person, mailed or e-mailed as follows:

- (1) To the USAID Agreement Officer, at the address specified in this award; or
- (2) To the recipient, at the recipient's address shown in this award, or to such other address specified in this award.

[END OF PROVISION]

M6. SUBAWARDS AND CONTRACTS (DECEMBER 2014)

- a. Subawardees and contractors have no relationship with USAID under the terms of this award. All required USAID approvals must be directed through the recipient to USAID.
- b. Notwithstanding any other term of this award, subawardees and contractors have no right to submit claims directly to USAID and USAID assumes no liability for any third party claims against the recipient.

[END OF PROVISION]

M7. OMB APPROVAL UNDER THE PAPERWORK REDUCTION ACT (DECEMBER 2014)

Information collection requirements imposed by this award are covered by OMB approval number 0412-0510; the current expiration date is 04/30/2005. The Standard Provisions containing the requirement and an estimate of the public reporting burden (including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information) are

<u>Standard Provision</u>	<u>Burden Estimate</u>
Air Travel and Transportation	1 (hour)
Ocean Shipment of Goods	.5
Patent Rights	.5
Publications	.5
Negotiated Indirect Cost Rates - (Predetermined and Provisional)	1
Voluntary Population Planning	.5

Protection of the Individual as a Research Subject 1

<u>22 CFR 200</u>	<u>Burden Estimate</u>
2 CFR 200.318-326, Procurement Standards	1
2 CFR 200.310-315, Property Standards	1.5

Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, may be sent to the Bureau for Management, Office of Acquisition and Assistance, Policy Division (M/OAA/P), U.S. Agency for International Development, Washington, DC 20523 and to the Office of Management and Budget, Paperwork Reduction Project (0412-0510), Washington, DC 20503.

[END OF PROVISION]

M8. USAID ELIGIBILITY RULES FOR GOODS AND SERVICES (MAY 2020)

This provision is not applicable to commodities or services that the recipient provides with private funds as part of a cost-sharing requirement, or with Program Income generated under this award.

- a. Ineligible and Restricted Commodities and Services:
- (1) Ineligible Commodities and Services. The recipient must not, under any circumstances, procure any of the following under this award:
 - (i) Military equipment,
 - (ii) Surveillance equipment,
 - (iii) Commodities and services for support of police or other law enforcement activities,
 - (iv) Abortion equipment and services,
 - (v) Luxury goods and gambling equipment, or
 - (vi) Weather modification equipment.
 - (2) Ineligible Suppliers. Any firms or individuals that do not comply with the requirements in Standard Provision, “Debarment, Suspension and Other Responsibility Matters” and Standard Provision, “Preventing Transactions with, or the Provision of Resources or Support to, Sanctioned Groups and Individuals” must not be used to provide any commodities or services funded under this award.
 - (3) Restricted Commodities. The recipient must obtain prior written approval of the Agreement Officer (AO) or comply with required procedures under an applicable waiver, as provided by the AO when procuring any of the following commodities:
 - (i) Agricultural commodities,
 - (ii) Motor vehicles,

- (iii) Pharmaceuticals,
 - (iv) Pesticides,
 - (v) Used equipment,
 - (vi) U.S. Government-owned excess property, or
 - (vii) Fertilizer.
- b. Source and Nationality:
 Except as may be specifically approved in advance by the AO, all commodities and services that will be reimbursed by USAID under this award must be from the authorized geographic code specified in this award and must meet the source and nationality requirements set forth in 22 CFR 228. If the geographic code is not specified, the authorized geographic code is 937. When the total value of procurement for commodities and services during the life of this award is valued at \$250,000 or less, the authorized geographic code for procurement of all goods and services to be reimbursed under this award is code 935. For a current list of countries within each geographic code, see: <http://www.usaid.gov/ads/policy/300/310>.
- c. Guidance on the eligibility of specific commodities and services may be obtained from the AO. If USAID determines that the recipient has procured any commodities or services under this award contrary to the requirements of this provision, and has received payment for such purposes, the AO may require the recipient to refund the entire amount of the purchase.
- d. This provision must be included in all subawards and contracts which include procurement of commodities or services.

[END OF PROVISION]

M9. DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS (JUNE 2012)

- a. The recipient agrees to notify the Agreement Officer (AO) immediately upon learning that it or any of its principals:
 - (1) Are presently excluded or disqualified from covered transactions by any Federal department or agency;
 - (2) Have been convicted within the preceding three-year period preceding this proposal; been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, receiving stolen property, making false claims, or obstruction of justice; commission of any other offense indicating a lack of business integrity or business honesty that seriously and directly affects your present responsibility;
 - (3) Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph a.(2); and
 - (4) Have had one or more public transactions (Federal, State, or local) terminated for cause

or default within the preceding three years.

- b. The recipient agrees that, unless authorized by the AO, it will not knowingly enter into any subawards or contracts under this award with a person or entity that has an active exclusion on the System for Award Management (SAM) (www.sam.gov). The recipient further agrees to include the following provision in any subawards or contracts entered into under this award:

.DEBARMENT, SUSPENSION, INELIGIBILITY, AND VOLUNTARY EXCLUSION
(JUNE 2012)

The recipient/contractor certifies that neither it nor its principals is presently excluded or disqualified from participation in this transaction by any Federal department or agency.

- c. The policies and procedures applicable to debarment, suspension, and ineligibility under USAID-financed transactions are set forth in Subpart C of 2 CFR Section 180, as supplemented by 2 CFR 780.

[END OF PROVISION]

M10. DRUG-FREE WORKPLACE (JUNE 2012)

The recipient must comply with drug-free workplace requirements in subpart B (or subpart C, if the recipient is an individual) of 2 CFR 782, which adopts the Government-wide implementation (2 CFR part 182) of sec. 5152–5158 of the Drug-Free Workplace Act of 1988 (Pub. L. 100–690, Title V, Subtitle D; 41 U.S.C. 701–707).

[END OF PROVISION]

M11. EQUAL PARTICIPATION BY FAITH-BASED ORGANIZATIONS (JUNE 2016)

a. Faith-Based Organizations Encouraged

Faith-based organizations are eligible, on the same basis as any other organization, to participate in any USAID program for which they are otherwise eligible. Neither USAID nor entities that make and administer subawards of USAID funds shall discriminate for or against an organization on the basis of the organization's religious character or affiliation. Additionally, religious organizations shall not be disqualified from participating in USAID programs because such organizations are motivated or influenced by religious faith to provide social services, or because of their religious character or affiliation.

Decisions about awards of USAID financial assistance must be free from political interference or even the appearance of such interference. Awards must be made on the basis of merit, not the basis of the religious affiliation of an applicant, or lack thereof. A faith-based organization may continue to carry out its mission, including the definition, development, practice, and expression of its religious beliefs, within the limits contained in this provision. For more information, see the [USAID Faith-Based and Community Initiatives Web site](#) and [22 CFR 205.1](#).

b. Explicitly Religious Activities Prohibited.

- (1)** Explicitly religious activities include activities that involve overt religious content such as worship, religious instruction, prayer, or proselytization.
 - (2)** The recipient must not engage in explicitly religious activities as part of the programs or services directly funded with financial assistance from USAID. If the recipient engages in explicitly religious activities, the activities must be offered separately, in time or location, from any programs or services directly funded by this award, and participation must be voluntary for beneficiaries of the programs or services funded with USAID assistance.
 - (3)** These restrictions apply equally to religious and secular organizations. All organizations that participate in USAID programs, as recipients or subawardees, including religious ones, must carry out eligible activities in accordance with all program requirements and other applicable requirements governing USAID-funded activities.
 - (4)** Notwithstanding the restrictions of b.(1) and (2), a religious organization that participates in USAID-funded programs or services:
 - (i)** May retain its independence and may continue to carry out its mission, including the definition, development, practice, and expression of its religious beliefs, provided that it does not use direct financial assistance from USAID to support or engage in any explicitly religious activities or in any other manner prohibited by law;
 - (ii)** May use space in its facilities, without removing religious art, icons, scriptures, or other religious symbols; and
 - (iii)** May retain its authority over its internal governance, and may retain religious terms in its organization's name, select its board members on a religious basis, and include religious references in its organization's mission statements and other governing documents.
- c.** Implementation in accordance with the Establishment Clause: Nothing in this provision shall be construed as authorizing the use of USAID funds for activities that are not permitted by Establishment Clause jurisprudence or otherwise by law.
- d.** Discrimination Based on Religion Prohibited: The recipient must not, in providing services, discriminate against a program beneficiary or potential program beneficiary on the basis of religion or religious belief, refusal to hold a religious belief, or a refusal to attend or participate in a religious practice.
- e.** A religious organization's exemption from the Federal prohibition on employment discrimination on the basis of religion, set forth in Sec. 702(a) of the Civil Rights Act of

1964, 42 U.S.C. 2000e–1 is not forfeited when the organization receives financial assistance from USAID.

- f. The Secretary of State may waive the requirements of this section in whole or in part, on a case-by-case basis, where the Secretary determines that such waiver is necessary to further the national security or foreign policy interests of the United States.
- g. This provision must be included in all subawards under this award.

[END OF PROVISION]

M12. PREVENTING TRANSACTIONS WITH, OR THE PROVISION OF RESOURCES OR SUPPORT TO, SANCTIONED GROUPS AND INDIVIDUALS (MAY 2020)

- a. In carrying out activities under this award, except as authorized by a license issued by the Office of Foreign Assets Control (OFAC) of the U.S. Department of Treasury, the recipient will not engage in transactions with, or provide resources or support to, any individual or entity that is subject to sanctions administered by OFAC or the United Nations (UN), including any individual or entity that is included on the Specially Designated Nationals and Blocked Persons List maintained by OFAC (<https://www.treasury.gov/resource-center/sanctions/SDNList/Pages/default.aspx>) or on the UN Security Council consolidated list (<https://www.un.org/securitycouncil/content/un-sc-consolidated-list>).
- b. Any violation of the above will be grounds for unilateral termination of the agreement by USAID.
- c. The Recipient must include this provision in all subawards and contracts issued under this award.

[END OF PROVISION]

M13. MARKING AND PUBLIC COMMUNICATIONS UNDER USAID-FUNDED ASSISTANCE (DECEMBER 2014)

- a. The USAID Identity is the official marking for USAID, comprised of the USAID logo and landmark with the tagline “from the American people,” unless amended by USAID to include additional or substitute use of a logo or seal and tagline representing a presidential initiative or other high level interagency initiative. The USAID Identity (including any required presidential initiative or related identity) is on the USAID Web site at www.usaid.gov/branding. Recipients must use the USAID Identity, of a size and prominence equivalent to or greater than any other identity or logo displayed, to mark the following:
 - (1) Programs, projects, activities, public communications, and commodities partially or fully funded by USAID;
 - (2) Program, project, or activity sites funded by USAID, including visible infrastructure projects or other physical sites;

- (3) Technical assistance, studies, reports, papers, publications, audio-visual productions, public service announcements, Web sites/Internet activities, promotional, informational, media, or communications products funded by USAID;
 - (4) Commodities, equipment, supplies, and other materials funded by USAID, including commodities or equipment provided under humanitarian assistance or disaster relief programs; and
 - (5) Events financed by USAID, such as training courses, conferences, seminars, exhibitions, fairs, workshops, press conferences and other public activities. If the USAID Identity cannot be displayed, the recipient is encouraged to otherwise acknowledge USAID and the support of the American people.
- b. The recipient must implement the requirements of this provision following the approved Marking Plan in the award.
 - c. The AO may require a preproduction review of program materials and “public communications” (documents and messages intended for external distribution, including but not limited to correspondence; publications; studies; reports; audio visual productions; applications; forms; press; and promotional materials) used in connection with USAID-funded programs, projects or activities, for compliance with an approved Marking Plan.
 - d. The recipient is encouraged to give public notice of the receipt of this award and announce progress and accomplishments. The recipient must provide copies of notices or announcements to the Agreement Officer’s Representative (AOR) and to USAID’s Office of Legislative and Public Affairs in advance of release, as practicable. Press releases or other public notices must include a statement substantially as follows:

“The U.S. Agency for International Development administers the U.S. foreign assistance program providing economic and humanitarian assistance in more than 80 countries worldwide.”
 - e. Any “public communication” in which the content has not been approved by USAID must contain the following disclaimer:

“This study/report/audio/visual/other information/media product (specify) is made possible by the generous support of the American people through the United States Agency for International Development (USAID). The contents are the responsibility of [insert recipient name] and do not necessarily reflect the views of USAID or the United States Government.”
 - f. The recipient must provide the USAID AOR with two copies of all program and communications materials produced under this award.
 - g. The recipient may request an exception from USAID marking requirements when USAID

marking requirements would:

- (1) Compromise the intrinsic independence or neutrality of a program or materials where independence or neutrality is an inherent aspect of the program and materials;
 - (2) Diminish the credibility of audits, reports, analyses, studies, or policy recommendations whose data or findings must be seen as independent;
 - (3) Undercut host-country government “ownership” of constitutions, laws, regulations, policies, studies, assessments, reports, publications, surveys or audits, public service announcements, or other communications;
 - (4) Impair the functionality of an item;
 - (5) Incur substantial costs or be impractical;
 - (6) Offend local cultural or social norms, or be considered inappropriate; or
 - (7) Conflict with international law.
- h. The recipient may submit a waiver request of the marking requirements of this provision or the Marking Plan, through the AOR, when USAID-required marking would pose compelling political, safety, or security concerns, or have an adverse impact in the cooperating country.
- (1) Approved waivers “flow down” to subawards and contracts unless specified otherwise. The waiver may also include the removal of USAID markings already affixed, if circumstances warrant.
 - (2) USAID determinations regarding waiver requests are subject to appeal by the recipient, by submitting a written request to reconsider the determination to the cognizant Assistant Administrator.
- i. The recipient must include the following marking provision in any subawards entered into under this award:

“As a condition of receipt of this subaward, marking with the USAID Identity of a size and prominence equivalent to or greater than the recipient’s, subrecipient’s, other donor’s, or third party’s is required. In the event the recipient chooses not to require marking with its own identity or logo by the subrecipient, USAID may, at its discretion, require marking by the subrecipient with the USAID Identity.”

[END OF PROVISION]

M14. REGULATIONS GOVERNING EMPLOYEES (JUNE 2018)

- a. While working overseas, the recipient's employees who are not citizens of the cooperating

Washington State University
Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)
Cooperative Agreement 7200AA21CA00033

country must maintain private status, and may not rely on local U.S. Government offices or facilities for support while under this award.

- b. The sale of personal property or automobiles by the recipient's non-cooperating country citizen employees and their dependents in the foreign country to which they are assigned, are subject to the same limitations and prohibitions that apply to direct-hire USAID personnel employed by the Mission, including the rules contained in 22 CFR 136, except as this may conflict with host government regulations.
- c. Other than work to be performed under this award for which an employee is assigned by the recipient, employees of the recipient who are not citizens of the cooperating country must not engage directly or indirectly, either in the individual's own name or in the name or through an agency of another person, in any business, profession, or occupation in the foreign countries to which the individual is assigned. In addition, the individual must not make loans or investments to or in any business, profession, or occupation in the foreign countries to which the individual is assigned.
- d. The recipient's employees who are not citizens of the cooperating country, while in a foreign country, are expected to show respect for its conventions, customs, and institutions, to abide by its applicable laws and regulations, and not to interfere in its internal political affairs.
- e. In accordance with the internal control requirements in 2 CFR 200.303, which require the recipient to establish standards of conduct for its employees, the recipient must ensure that all its employees adhere to these standards of conduct in a manner consistent with the standards for United Nations (UN) employees in Section 3 of the UN Secretary-General's Bulletin - Special Measures for Protection from Sexual Exploitation and Sexual Abuse (ST/SGB/2003/13).
- f. If the recipient determines that the conduct of any recipient employee is not in accordance with the preceding paragraphs, the recipient's Chief of Party must consult with the Agreement Officer and the USAID Mission Director, and the employee involved, and must recommend to the recipient a course of action with regard to such employee.
- g. The parties recognize the rights of the U.S. Ambassador to direct the removal from a country of any U.S. citizen, or the discharge from this award of any individual (U.S., third-country, or cooperating-country national) when, in the discretion of the Ambassador, the interests of the United States so require.
- h. If it is determined, under paragraph (f) or (g) above, that the services of such employee should be terminated, the recipient must use its best efforts to cause the return of such employee to the United States, or third-country point of origin, as appropriate, and replace the employee with an acceptable substitute at no cost to USAID.
- i. Any matters relating to subrecipients, including the employees of subrecipients, must be coordinated through the recipient's Chief of Party.

[END OF PROVISION]

**M15. CONVERSION OF UNITED STATES DOLLARS TO LOCAL CURRENCY
(NOVEMBER 1985)**

(This provision applies when activities are undertaken outside the United States.)

Upon arrival in the cooperating country, and from time to time as appropriate, the recipient's chief of party must consult with the Mission Director who must provide, in writing, the procedure the recipient and its employees must follow in the conversion of United States dollars to local currency. This may include, but is not limited to, the conversion of currency through the cognizant United States Disbursing Officer or Mission Controller, as appropriate.

[END OF PROVISION]

M16. USE OF POUCH FACILITIES (AUGUST 1992)

(This provision applies when activities are undertaken outside the United States.)

- a. Use of diplomatic pouch is controlled by the Department of State. The Department of State has authorized the use of pouch facilities for USAID recipients and their employees as a general policy, as detailed in items (1) through (6) below. However, the final decision regarding use of pouch facilities rest with the Embassy or USAID Mission. In consideration of the use of pouch facilities, the recipient and its employees agree to indemnify and hold harmless, the Department of State and USAID for loss or damage occurring in pouch transmission:
 - (1) Recipients and their employees are authorized use of the pouch for transmission and receipt of up to a maximum of .9 kgs per shipment of correspondence and documents needed in the administration of assistance programs.
 - (2) U.S. citizen employees are authorized use of the pouch for personal mail up to a maximum of .45 kgs per shipment (but see a.(3) below).
 - (3) Merchandise, parcels, magazines, or newspapers are not considered to be personal mail for purposes of this standard provision and are not authorized to be sent or received by pouch.
 - (4) Official and personal mail pursuant to a.(1) and (2) above sent by pouch should be addressed as follows:

Name of individual or organization (followed by
letter symbol "G")
City Name of post (USAID/_____)
Agency for International Development
Washington, DC 20523-0001
 - (5) Mail sent via the diplomatic pouch may not be in violation of U.S. Postal laws and may

not contain material ineligible for pouch transmission.

(6) Recipient personnel are NOT authorized use of military postal facilities (APO/FPO). This is an Adjutant General's decision based on existing laws and regulations governing military postal facilities and is being enforced worldwide.

- b. The recipient is responsible for advising its employees of this authorization, these guidelines, and limitations on use of pouch facilities.
- c. Specific additional guidance on grantee use of pouch facilities in accordance with this standard provision is available from the Post Communication Center at the Embassy or USAID Mission.

[END OF PROVISION]

M17. TRAVEL AND INTERNATIONAL AIR TRANSPORTATION (DECEMBER 2014)

a. TRAVEL COSTS

All travel costs must comply with the applicable cost principles and must be consistent with those normally allowed in like circumstances in the recipient's non-USAID-funded activities. Costs incurred by employees and officers for travel, including air fare, costs of lodging, other subsistence, and incidental expenses, may be considered reasonable and allowable only to the extent such costs do not exceed reasonable charges normally allowed by the recipient in its regular operations as the result of the recipient organization's written travel policy and are within the limits established by the applicable cost principles.

In the absence of a reasonable written policy regarding international travel costs, the standard for determining the reasonableness of reimbursement for international travel costs will be the Standardized Regulations (Government Civilians, Foreign Areas), published by the U.S. Department of State, as from time to time amended. The most current Standardized Regulations on international travel costs may be obtained from the AO. In the event that the cost for air fare exceeds the customary standard commercial airfare (coach or equivalent) or the lowest commercial discount airfare, the recipient must document one of the allowable exceptions from the applicable cost principles.

b. FLY AMERICA ACT RESTRICTIONS

- (1) The recipient must use U.S. Flag Air Carriers for all international air transportation (including personal effects) funded by this award pursuant to the Fly America Act and its implementing regulations to the extent service by such carriers is available.
- (2) In the event that the recipient selects a carrier other than a U.S. Flag Air Carrier for international air transportation, in order for the costs of such international air transportation to be allowable, the recipient must document such transportation in accordance with this provision and maintain such documentation pursuant to the

Standard Provision, “Accounting, Audit and Records.” The documentation must use one of the following reasons or other exception under the Fly America Act:

- (i) The recipient uses a European Union (EU) flag air carrier, which is an airline operating from an EU country that has signed the US-EU “Open Skies” agreement (<http://www.state.gov/e/eb/rls/othr/ata/i/ic/170684.htm>).
- (ii) Travel to or from one of the following countries on an airline of that country when no city pair fare is in effect for that leg (see <http://apps.fas.gsa.gov/citypairs/search/>):
 - a. Australia on an Australian airline,
 - b. Switzerland on a Swiss airline, or
 - c. Japan on a Japanese airline;
- (iii) Only for a particular leg of a route on which no US Flag Air Carrier provides service on that route;
- (iv) For a trip of 3 hours or less, the use of a US Flag Air Carrier at least doubles the travel time;
- (v) If the US Flag Air Carrier offers direct service, use of the US Flag Air Carrier would increase the travel time by more than 24 hours; or
- (vi) If the US Flag Air Carrier does not offer direct service,
 - a. Use of the US Flag Air Carrier increases the number of aircraft changes by 2 or more,
 - b. Use of the US Flag Air Carrier extends travel time by 6 hours or more, or
 - c. Use of the US Flag Air Carrier requires a layover at an overseas interchange of 4 hours or more.

c. DEFINITIONS

The terms used in this provision have the following meanings:

- (1) “Travel costs” means expenses for transportation, lodging, subsistence (meals and incidentals), and related expenses incurred by employees who are on travel status on official business of the recipient for any travel outside the country in which the organization is located. “Travel costs” do not include expenses incurred by employees who are not on official business of the recipient, such as rest and recuperation (R&R) travel offered as part of an employee’s benefits package that are consistent with the recipient’s personnel and travel policies and procedures.

- (2) "International air transportation" means international air travel by individuals (and their personal effects) or transportation of cargo by air between a place in the United States and a place outside thereof, or between two places both of which are outside the United States.
- (3) "U.S. Flag Air Carrier" means an air carrier on the list issued by the U.S. Department of Transportation at <http://ostpxweb.dot.gov/aviation/certific/certlist.htm>. U.S. Flag Air Carrier service also includes service provided under a code share agreement with another air carrier when the ticket, or documentation for an electronic ticket, identifies the U.S. flag air carrier's designator code and flight number.
- (4) For this provision, the term "United States" includes the fifty states, Commonwealth of Puerto Rico, possessions of the United States, and the District of Columbia.

d. SUBAWARDS AND CONTRACTS

This provision must be included in all subawards and contracts under which this award will finance international air transportation.

[END OF PROVISION]

M18. OCEAN SHIPMENT OF GOODS (JUNE 2012)

- a. Prior to contracting for ocean transportation to ship goods purchased or financed with USAID funds under this award, the recipient must contact the office below to determine the flag and class of vessel to be used for shipment:

U.S. Agency for International Development,
Bureau for Management
Office of Acquisition and Assistance, Transportation Division
1300 Pennsylvania Avenue, NW
Washington, DC 20523
Email: oceantransportation@usaid.gov

- b. This provision must be included in all subawards and contracts.

[END OF PROVISION]

M19. VOLUNTARY POPULATION PLANNING ACTIVITIES – MANDATORY REQUIREMENTS (MAY 2006)

Requirements for Voluntary Sterilization Programs

- (1) Funds made available under this award must not be used to pay for the performance of involuntary sterilization as a method of family planning or to coerce or provide any financial incentive to any individual to practice sterilization.

Prohibition on Abortion-Related Activities:

- (1) No funds made available under this award will be used to finance, support, or be attributed to the following activities: (i) procurement or distribution of equipment intended to be used for the purpose of inducing abortions as a method of family planning; (ii) special fees or incentives to any person to coerce or motivate them to have abortions; (iii) payments to persons to perform abortions or to solicit persons to undergo abortions; (iv) information, education, training, or communication programs that seek to promote abortion as a method of family planning; and (v) lobbying for or against abortion. The term “motivate,” as it relates to family planning assistance, must not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options.
- (2) No funds made available under this award will be used to pay for any biomedical research which relates, in whole or in part, to methods of, or the performance of, abortions or involuntary sterilizations as a means of family planning. Epidemiologic or descriptive research to assess the incidence, extent or consequences of abortions is not precluded.

[END OF PROVISION]

M20. TRAFFICKING IN PERSONS (April 2016)

- a. The recipient, subawardee, or contractor, at any tier, or their employees, labor recruiters, brokers or other agents, must not engage in:
 - (1) Trafficking in persons (as defined in the Protocol to Prevent, Suppress, and Punish Trafficking in Persons, especially Women and Children, supplementing the UN Convention against Transnational Organized Crime) during the period of this award;
 - (2) Procurement of a commercial sex act during the period of this award;
 - (3) Use of forced labor in the performance of this award;
 - (4) Acts that directly support or advance trafficking in persons, including the following acts:
 - i. Destroying, concealing, confiscating, or otherwise denying an employee access to that employee's identity or immigration documents;
 - ii. Failing to provide return transportation or pay for return transportation costs to an employee from a country outside the United States to the country from which the employee was recruited upon the end of employment if requested by the employee, unless:
 - a) exempted from the requirement to provide or pay for such return transportation by USAID under this award; or

- b) the employee is a victim of human trafficking seeking victim services or legal redress in the country of employment or a witness in a human trafficking enforcement action;
 - iii. Soliciting a person for the purpose of employment, or offering employment, by means of materially false or fraudulent pretenses, representations, or promises regarding that employment;
 - iv. Charging employees recruitment fees; or
 - v. Providing or arranging housing that fails to meet the host country housing and safety standards.
- b. In the event of a violation of section (a) of this provision, USAID is authorized to terminate this award, without penalty, and is also authorized to pursue any other remedial actions authorized as stated in section 1704(c) of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112-239, enacted January 2, 2013).
- c. If the estimated value of services required to be performed under the award outside the United States exceeds \$500,000, the recipient must submit to the Agreement Officer, the annual “Certification regarding Trafficking in Persons, Implementing Title XVII of the National Defense Authorization Act for Fiscal Year 2013” as required prior to this award, and must implement a compliance plan to prevent the activities described above in section (a) of this provision. The recipient must provide a copy of the compliance plan to the Agreement Officer upon request and must post the useful and relevant contents of the plan or related materials on its website (if one is maintained) and at the workplace.
- d. The recipient’s compliance plan must be appropriate to the size and complexity of the award and to the nature and scope of the activities, including the number of non-United States citizens expected to be employed. The plan must include, at a minimum, the following:
 - (1) An awareness program to inform employees about the trafficking related prohibitions included in this provision, the activities prohibited and the action that will be taken against the employee for violations.
 - (2) A reporting process for employees to report, without fear of retaliation, activity inconsistent with the policy prohibiting trafficking, including a means to make available to all employees the Global Human Trafficking Hotline at 1-844-888-FREE and its e-mail address at help@befree.org.
 - (3) A recruitment and wage plan that only permits the use of recruitment companies with trained employees, prohibits charging of recruitment fees to the employee, and ensures that wages meet applicable host-country legal requirements or explains any variance.

- (4) A housing plan, if the recipient or any subawardee intends to provide or arrange housing. The housing plan is required to meet any host-country housing and safety standards.
 - (5) Procedures for the recipient to prevent any agents or subawardee at any tier and at any dollar value from engaging in trafficking in persons activities described in section a of this provision. The recipient must also have procedures to monitor, detect, and terminate any agents or subawardee or subawardee employees that have engaged in such activities.
- e. If the Recipient receives any credible information regarding a violation listed in section a(1)-(4) of this provision, the recipient must immediately notify the cognizant Agreement Officer and the USAID Office of the Inspector General; and must fully cooperate with any Federal agencies responsible for audits, investigations, or corrective actions relating to trafficking in persons.
 - f. The Agreement Officer may direct the Recipient to take specific steps to abate an alleged violation or enforce the requirements of a compliance plan.
 - g. For purposes of this provision, “employee” means an individual who is engaged in the performance of this award as a direct employee, consultant, or volunteer of the recipient or any subrecipient.
 - h. The recipient must include in all subawards and contracts a provision prohibiting the conduct described in section a(1)-(4) by the subrecipient, contractor, or any of their employees, or any agents. The recipient must also include a provision authorizing the recipient to terminate the award as described in section b of this provision.

[END OF PROVISION]

M21. SUBMISSIONS TO THE DEVELOPMENT EXPERIENCE CLEARINGHOUSE AND PUBLICATIONS (JUNE 2012)

- a. Submissions to the Development Experience Clearinghouse (DEC).
 - 1) The recipient must provide the Agreement Officer’s Representative one copy of any Intellectual Work that is published, and a list of any Intellectual Work that is not published.
 - 2) In addition, the recipient must submit Intellectual Work, whether published or not, to the DEC, either on-line (preferred) or by mail. The recipient must review the DEC Web site for submission instructions, including document formatting and the types of documents to submit. Submission instructions can be found at: <http://dec.usaid.gov>.

- 3) For purposes of submissions to the DEC, Intellectual Work includes all works that document the implementation, evaluation, and results of international development assistance activities developed or acquired under this award, which may include program and communications materials, evaluations and assessments, information products, research and technical reports, progress and performance reports required under this award (excluding administrative financial information), and other reports, articles and papers prepared by the recipient under the award, whether published or not. The term does not include the recipient's information that is incidental to award administration, such as financial, administrative, cost or pricing, or management information.
 - 4) Each document submitted should contain essential bibliographic information, such as 1) descriptive title; 2) author(s) name; 3) award number; 4) sponsoring USAID office; 5) development objective; and 6) date of publication.
 - 5) The recipient must not submit to the DEC any financially sensitive information or personally identifiable information, such as social security numbers, home addresses and dates of birth. Such information must be removed prior to submission. The recipient must not submit classified documents to the DEC.
- b. In the event award funds are used to underwrite the cost of publishing, in lieu of the publisher assuming this cost as is the normal practice, any profits or royalties up to the amount of such cost must be credited to the award unless the schedule of the award has identified the profits or royalties as program income.

[END OF PROVISION]

M22. LIMITING CONSTRUCTION ACTIVITIES (AUGUST 2013)

- a) Construction is not eligible for reimbursement under this award unless specifically identified in paragraph d) below.
- b) Construction means —construction, alteration, or repair (including dredging and excavation) of buildings, structures, or other real property and includes, without limitation, improvements, renovation, alteration and refurbishment. The term includes, without limitation, roads, power plants, buildings, bridges, water treatment facilities, and vertical structures.
- c) Agreement Officers will not approve any subawards or procurements by recipients for construction activities that are not listed in paragraph d) below. USAID will reimburse allowable costs for only the construction activities listed in this provision not to exceed the amount specified in the construction line item of the award budget. The recipient must receive prior written approval from the AO to transfer funds allotted for construction activities to other cost categories, or vice versa.
- d) Description

Construction is not eligible for reimbursement under this award.

- e) The recipient must include this provision in all subawards and procurements and make vendors providing services under this award and subrecipients aware of the restrictions of this provision.

[END OF PROVISION]

M23. USAID IMPLEMENTING PARTNER NOTICES (IPN) PORTAL FOR ASSISTANCE (JULY 2014)

(a) Definitions

“USAID Implementing Partner Notices (IPN) Portal for Assistance (“IPN Portal)” means the single point where USAID posts proposed universal bilateral amendments for USAID awards, which can be accessed electronically by registered USAID recipients. The IPN Portal is located at <https://sites.google.com/site/usaaidipnforassistance/>. Universal amendments are those which affect all assistance awards or a designated class of awards as specified in each amendment by the IPN Portal Administrator.

“IPN Portal Administrator” means the USAID official designated by the Director, M/OAA, who has overall responsibility for managing the USAID Implementing Partner Notices Portal for Assistance.

“Universal bilateral amendment” means those amendments with revisions or new requirements or provisions that affect all awards or a designated class of awards, as specified in the Agency notification of such revisions or new requirements.

- (b)** By submission of an application and execution of an award, the Applicant/Recipient acknowledges the requirement to:

- (1)** Register with the IPN Portal if awarded an assistance award resulting from this solicitation, and
 - (2)** Receive universal bilateral amendments to this award and general notices via the IPN Portal.

- (c)** Procedure to register for notifications.

Go to <https://sites.google.com/site/usaaidipnforassistance/> and click the “Register” button at the top of the page. Recipient representatives must use their official organization email address when subscribing, not personal email addresses.

- (d)** Processing of IPN Portal Amendments

The Recipient may access the IPN Portal at any time to review all IPN Portal amendments; however, the system will also notify the Recipient by email when the USAID IPN Portal Administrator posts a universal bilateral amendment for Recipient's review and signature. Proposed USAID IPN Portal amendments distributed via the IPN Portal are applicable to all awards, unless otherwise noted in the proposed amendment.

Within 15 calendar days from receipt of the notification email from the IPN Portal, the Recipient must do one of the following:

- (1) (a) verify applicability of the proposed amendment for their award(s) per the instructions provided with each amendment; (b) download the amendment and incorporate the following information on the amendment form: award number, organization name, and organization mailing address as it appears in the basic award; (c) sign the hardcopy version; and (d) send the signed amendment (by email or hardcopy) to the AO for signature. The Recipient must not incorporate any other changes to the IPN Portal amendment. Bilateral amendments provided through the IPN Portal are not effective until the both the Recipient and the AO sign the amendment;
- (2) Notify the AO in writing if the amendment requires negotiation of additional changes to terms and conditions of the award; or
- (3) Notify the AO that the Recipient declines to sign the amendment.

Within 30 calendar days of receipt of a signed amendment from the Recipient, the AO must provide the fully executed amendment to the Recipient or initiate discussions with the Recipient.

[END OF PROVISION]

M24. PILOT PROGRAM FOR ENHANCEMENT OF GRANTEE EMPLOYEE WHISTLEBLOWER PROTECTIONS (SEPTEMBER 2014)

The requirement to comply with and inform all employees of the "Pilot Program for Enhancement of Contractor Employee Whistleblower Protections" is retroactively effective for all assistance awards and subawards (including subcontracts) issued beginning July 1, 2013.

The Grantee must:

1. Inform its employees working under this award in the predominant native language of the workforce that they are afforded the employee whistleblower rights and protections provided under 41 U.S.C. § 4712; and
2. Include such requirement in any subaward or subcontract made under this award.

41 U.S.C. § 4712 states that an employee of a Grantee may not be discharged, demoted, or otherwise discriminated against as a reprisal for "whistleblowing." In addition, whistleblower protections cannot be waived by any agreement, policy, form, or condition of employment.

Whistleblowing is defined as making a disclosure "that the employee reasonably believes" is evidence of any of the following:

- Gross mismanagement of a Federal contract or grant;
- A gross waste of Federal funds;
- An abuse of authority relating to a Federal contract or grant;
- A substantial and specific danger to public health or safety; or
- A violation of law, rule, or regulation related to a Federal contract or grant (including the competition for, or negotiation of, a contract or grant).

To qualify under the statute, the employee's disclosure must be made to:

- A Member of the U.S. Congress, or a representative of a U.S. Congressional Committee;
- A cognizant U.S. Inspector General;
- The U.S. Government Accountability Office;
- A Federal employee responsible for contract or grant oversight or management at the relevant agency;
- A U.S. court or grand jury; or,
- A management official or other employee of the Grantee who has the responsibility to investigate, discover, or address misconduct.

[END OF PROVISION]

M25. SUBMISSION OF DATASETS TO THE DEVELOPMENT DATA LIBRARY (OCTOBER 2014)

a. Definitions. For the purpose of submissions to the DDL:

- (1) "Dataset" is an organized collection of structured data, including data contained in spreadsheets, whether presented in tabular or non-tabular form. For example, a Dataset may represent a single spreadsheet, an extensible mark-up language (XML) file, a geospatial data file, or an organized collection of these. This requirement does not apply to aggregated performance reporting data that the recipient submits directly to a USAID portfolio management system or to unstructured data, such as email messages, PDF files, PowerPoint presentations, word processing documents, photos and graphic images, audio files, collaboration software, and instant messages. Neither does the requirement apply to the recipient's information that is incidental to award administration, such as financial, administrative, cost or pricing, or management information. Datasets submitted to the DDL will generally be those generated with USAID resources and created in support of Intellectual Work that is uploaded to the Development Experience Clearinghouse (DEC) (See M21. SUBMISSIONS TO THE DEVELOPMENT EXPERIENCE CLEARINGHOUSE AND PUBLICATIONS (JUNE 2012)).

- (2) “Intellectual Work” includes all works that document the implementation, monitoring, evaluation, and results of international development assistance activities developed or acquired under this award, which may include program and communications materials, evaluations and assessments, information products, research and technical reports, progress and performance reports required under this award (excluding administrative financial information), and other reports, articles and papers prepared by the recipient under the award, whether published or not. The term does not include the recipient’s information that is incidental to award administration, such as financial, administrative, cost or pricing, or management information.

b. Submissions to the Development Data Library (DDL)

- (1) The recipient must submit to the Development Data Library (DDL) at www.usaid.gov/data, in a machine-readable, non-proprietary format, a copy of any Dataset created or obtained in performance of this award, including Datasets produced by a subawardee or a contractor at any tier. The submission must include supporting documentation describing the Dataset, such as code books, data dictionaries, data gathering tools, notes on data quality, and explanations of redactions.
- (2) Unless otherwise directed by the Agreement Officer (AO) or the Agreement Officer Representative (AOR), the recipient must submit the Dataset and supporting documentation to the DDL within thirty (30) calendar days after the Dataset is first used to produce an Intellectual Work or is of sufficient quality to produce an Intellectual Work. Within thirty (30) calendar days after award completion, the recipient must submit to the DDL any Datasets and supporting documentation that have not previously been submitted to the DDL, along with an index of all Datasets and Intellectual Work created or obtained under the award. The recipient must also provide to the AOR an itemized list of any and all DDL submissions.

The recipient is not required to submit the data to the DDL, when, in accordance with the terms and conditions of this award, Datasets containing results of federally funded scientific research are submitted to a publicly accessible research database. However, the recipient must submit a notice to the DDL by following the instructions at www.usaid.gov/data, with a copy to the agreement officer representative, providing details on where and how to access the data. The direct results of federally funded scientific research must be reported no later than when the data are ready to be submitted to a peer-reviewed journal for publication, or no later than five calendar days prior to the conclusion of the award, whichever occurs earlier.

- (3) The recipient must submit the Datasets following the submission instructions and acceptable formats found at www.usaid.gov/data.
- (4) The recipient must ensure that any Dataset submitted to the DDL does not contain any proprietary or personally identifiable information, such as social security numbers, home

addresses, and dates of birth. Such information must be removed prior to submission.

(5) The recipient must not submit classified data to the DDL.

[END OF PROVISION]

M26. PROHIBITION ON REQUIRING CERTAIN INTERNAL CONFIDENTIALITY AGREEMENTS OR STATEMENTS (MAY 2017)

(a) Definitions.

“Contract” has the meaning given in 2 CFR Part 200.

“Contractor” means an entity that receives a contract as defined in 2 CFR Part 200.

“Internal confidentiality agreement or statement” means a confidentiality agreement or any other written statement that the recipient requires any of its employees or subrecipients to sign regarding nondisclosure of recipient information, except that it does not include confidentiality agreements arising out of civil litigation or confidentiality agreements that recipient employees or subrecipients sign at the behest of a Federal agency.

“Subaward” has the meaning given in 2 CFR Part 200.

“Subrecipient” has the meaning given in 2 CFR Part 200.

(b) The recipient must not require its employees, subrecipients, or contractors to sign or comply with internal confidentiality agreements or statements that prohibit or otherwise restrict employees, subrecipients, or contractors from lawfully reporting waste, fraud, or abuse related to the performance of a Federal award to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (for example, the Agency Office of the Inspector General).

(c) The recipient must notify current employees and subrecipients that prohibitions and restrictions of any preexisting internal confidentiality agreements or statements covered by this provision, to the extent that such prohibitions and restrictions are inconsistent with the prohibitions of this provision, are no longer in effect.

(d) The prohibition in paragraph (b) of this provision does not contravene the requirements applicable to Standard Form 312 (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

(e) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further

Continuing Appropriations Act, 2015, (Pub. L. 113-235), and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions) use of funds appropriated (or otherwise made available) is prohibited, if the Government determines that the recipient is not in compliance with the requirements of this provision.

- (f) The recipient must include the substance of this provision, including this paragraph (f), in subawards and contracts under such awards.

[END OF PROVISION]

M27. CHILD SAFEGUARDING (JUNE 2015)

- (a) Because the activities to be funded under this award may involve children, or personnel engaged in the implementation of the award may come into contact with children, these activities could raise the risk of child abuse, exploitation, or neglect within USAID-funded programs. The organization agrees to abide by the following child safeguarding core principles:
- (1) Ensure compliance with host country and local child welfare and protection legislation or international standards, whichever gives greater protection, and with U.S. law where applicable;
 - (2) Prohibit all personnel from engaging in child abuse, exploitation, or neglect;
 - (3) Consider child safeguarding in project planning and implementation to determine potential risks to children that are associated with project activities and operations;
 - (4) Apply measures to reduce the risk of child abuse, exploitation, or neglect, including, but not limited to, limiting unsupervised interactions with children; prohibiting exposure to pornography; and complying with applicable laws, regulations, or customs regarding the photographing, filming, or other image-generating activities of children;
 - (5) Promote child-safe screening procedures for personnel, particularly personnel whose work brings them in direct contact with children; and
 - (6) Have a procedure for ensuring that personnel and others recognize child abuse, exploitation, or neglect; mandating that personnel and others report allegations; investigating and managing allegations; and taking appropriate action in response to such allegations, including, but not limited to, dismissal of personnel.
- (b) The organization must also include in their code of conduct for all personnel implementing USAID-funded activities the child safeguarding principles in (a) (1) through (6).
- (c) The following definitions apply for purposes of this provision:

- (1) Child: A child or children are defined as persons who have not attained 18 years of age.
 - (2) Child abuse, exploitation, or neglect: Constitutes any form of physical abuse; emotional ill-treatment; sexual abuse; neglect or insufficient supervision; trafficking; or commercial, transactional, labor, or other exploitation resulting in actual or potential harm to the child's health, well-being, survival, development, or dignity. It includes, but is not limited to: any act or failure to act which results in death, serious physical or emotional harm to a child, or an act or failure to act which presents an imminent risk of serious harm to a child.
 - (3) Physical abuse: Constitutes acts or failures to act resulting in injury (not necessarily visible), unnecessary or unjustified pain or suffering without causing injury, harm or risk of harm to a child's health or welfare, or death. Such acts may include, but are not limited to: punching, beating, kicking, biting, shaking, throwing, stabbing, choking, or hitting (regardless of object used), or burning. These acts are considered abuse regardless of whether they were intended to hurt the child.
 - (4) Sexual Abuse: Constitutes fondling a child's genitals, penetration, incest, rape, sodomy, indecent exposure, and exploitation through prostitution or the production of pornographic materials.
 - (5) Emotional abuse or ill treatment: Constitutes injury to the psychological capacity or emotional stability of the child caused by acts, threats of acts, or coercive tactics. Emotional abuse may include, but is not limited to: humiliation, control, isolation, withholding of information, or any other deliberate activity that makes the child feel diminished or embarrassed.
 - (6) Exploitation: Constitutes the abuse of a child where some form of remuneration is involved or whereby the perpetrators benefit in some manner. Exploitation represents a form of coercion and violence that is detrimental to the child's physical or mental health, development, education, or well-being.
 - (7) Neglect: Constitutes failure to provide for a child's basic needs within USAID-funded activities that are responsible for the care of a child in the absence of the child's parent or guardian.
- (d) The recipient must insert the provisions in (a) and (b) in all sub-awards under this award.

[END OF PROVISION]

M28. MANDATORY DISCLOSURES (JULY 2015)

Consistent with 2 CFR §200.113, applicants and recipients must disclose, in a timely manner, in writing to the USAID Office of the Inspector General, with a copy to the cognizant Agreement Officer, all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. Subrecipients must disclose, in a timely manner, in

writing to the USAID Office of the Inspector General and to the prime recipient (pass through entity) all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award.

Disclosures must be sent to:

U.S. Agency for International Development
Office of the Inspector General
P.O. Box 657
Washington, DC 20044-0657

Phone: 1-800-230-6539 or 202-712-1023

Email: ig.hotline@usaid.gov

URL: <https://oig.usaid.gov/content/usaid-contractor-reporting-form>.

Failure to make required disclosures can result in any of the remedies described in 2 CFR §200.338 Remedies for noncompliance, including suspension or debarment (See 2 CFR 180, 2 CFR 780 and 31 U.S.C. 3321).

The recipient must include this mandatory disclosure requirement in all subawards and contracts under this award.

[END OF PROVISION]

M29. NONDISCRIMINATION AGAINST BENEFICIARIES (NOVEMBER 2016)

- (a) USAID policy requires that the recipient not discriminate against any beneficiaries in implementation of this award, such as, but not limited to, by withholding, adversely impacting, or denying equitable access to the benefits provided through this award on the basis of any factor not expressly stated in the award. This includes, for example, race, color, religion, sex (including gender identity, sexual orientation, and pregnancy), national origin, disability, age, genetic information, marital status, parental status, political affiliation, or veteran's status. Nothing in this provision is intended to limit the ability of the recipient to target activities toward the assistance needs of certain populations as defined in the award.
- (b) The recipient must insert this provision, including this paragraph, in all subawards and contracts under this award.

[END OF PROVISION]

M30. CONFLICT OF INTEREST (AUGUST 2018)

- a. A conflict of interest in the award, administration, or monitoring of subawards arises when an employee, officer, or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of these parties, has a

financial or other interest in, or a tangible personal benefit from, a subrecipient considered for a subaward. The officers, employees, and agents of the recipient may neither solicit nor accept gratuities, favors, or anything of monetary value from subrecipients or parties to subawards. However, recipients may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value.

- b. The recipient must maintain written standards of conduct covering conflicts of interest and governing the actions of its employees engaged in the selection, award, and administration of subawards. The standards must prohibit employees from using their positions for a purpose that constitutes or presents the appearance of a conflict of interest. The standards of conduct must provide for disciplinary actions to be applied for violations of such standards by officers, employees, or agents of the recipient.
- c. The recipient must also maintain written standards of conduct covering organizational conflicts of interest. Organizational conflicts of interest means a situation in which the recipient is unable or appears to be unable to be impartial in conducting a subaward action involving a related organization because of relationships with a parent company, affiliate, or subsidiary organization.
- d. The recipient must have a system or systems in place to identify, address, resolve, and disclose to USAID any conflicts of interest as described in this provision that affect any subaward, regardless of the amount of funding.
- e. The recipient must disclose any conflict of interest, including organizational conflicts of interest, and the recipient's approach for resolving the conflict of interest to the cognizant Agreement Officer for the award within ten (10) calendar days of the discovery of the conflict of interest.
- f. Upon notice from the recipient of a potential conflict of interest and the approach for resolving it, the Agreement Officer will make a determination regarding the effectiveness of the recipient's actions to resolve the conflict of interest within thirty (30) calendar days of receipt of the recipient's notice, unless the Agreement Officer advises the recipient that a longer period is necessary.
- g. The recipient must not request payment from USAID for costs for transactions subject to the conflict of interest pending notification of USAID's determination. The recipient's failure to disclose a conflict of interest may result in cost disallowances by USAID.
- h. For conflicts of interest, including organizational conflicts of interest, involving contracts, the recipient must follow 2 CFR 200.318, general procurement standards.
- i. The recipient must insert the substance of this provision, including paragraph (i), in all subawards under this award, at any subaward tier.

[END OF PROVISION]

Washington State University
Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)
Cooperative Agreement 7200AA21CA00033

**REQUIRED AS APPLICABLE STANDARD PROVISIONS FOR U.S.
NONGOVERNMENTAL ORGANIZATIONS**

RAA1. NEGOTIATED INDIRECT COST RATES – PREDETERMINED (NOVEMBER 2020)

- a. The allowable indirect costs must be determined by applying the predetermined indirect cost rates to the bases specified in the schedule of this award.
- b. Except as otherwise provided in 2 CFR 200.414 Indirect (F&A) costs paragraph (e) and (f), a nonprofit organization which has not previously established an indirect cost rate with a Federal agency must submit its initial indirect cost proposal immediately after the organization is advised that a Federal award will be made and, in no event, later than three months after the effective date of the Federal award.

Organizations that have previously established indirect cost rates must submit a new indirect cost proposal to the cognizant agency for indirect costs within six months after the close of each fiscal year.

If USAID is the cognizant agency or no cognizant agency has been designated, the recipient must submit four copies of the audit report, the proposed predetermined indirect cost rates, and supporting cost data to the Overhead, Special Costs, and Closeout Branch, Management Bureau, Office of Acquisition and Assistance, USAID, Washington, DC 20523-7802. The proposed rates must be based on the recipient's actual cost experience during that fiscal year. Negotiations of predetermined indirect cost rates must begin soon after receipt of the recipient's proposal.

- c. Allowability of costs and acceptability of cost allocation methods must be determined in accordance with the applicable cost principles.
- d. The results of each negotiation must be set forth in an indirect cost rate agreement signed by both parties. Such agreement is automatically incorporated into this award and must specify (1) the agreed upon predetermined rates, (2) the bases to which the rates apply, and (3) the fiscal year for which the rates apply. The indirect cost rate agreement must not change any monetary ceiling, award obligation, or specific cost allowance or disallowance provided for in this award.
- e. Predetermined rate means an indirect cost rate, applicable to a specified current or future period, usually the organization's fiscal year. The rate is based on an estimate of the costs to be incurred during the period. A predetermined rate is not subject to adjustment.
- f. If a dispute arises in a negotiation of an indirect cost rate between the cognizant agency for indirect costs and the nonprofit organization, the dispute must be resolved in accordance with the appeals procedures of the cognizant agency for indirect costs.

[END OF PROVISION]

RAA5. EXCHANGE VISITORS AND PARTICIPANT TRAINING (JUNE 2012)

For any Exchange Visitor, Participant Training or Invitational Travel activities, the recipient must comply with this provision.

a. Definitions:

- (1) An **Exchange Visitor** is any host-country or third-country national traveling to the U.S., for any purpose, including Participant Training and Invitational Travel, funded by USAID in whole or in part, directly or indirectly.
- (2) A **Participant** is a host-country or third-country national sponsored by USAID for a Participant Training activity taking place in the U.S., a third country, or in the host country.
- (3) **Participant Training** is a learning activity conducted within the U.S., a third country, or in the host country for the purpose of furthering USAID development objectives. A learning activity takes place in a setting in which an individual (the Participant) interacts with a knowledgeable professional, predominantly for the purpose of acquiring knowledge or skills for the professional or technical enhancement of the individual. Learning activities may be formally structured, such as an academic program or a technical course, or they may be more informal, such as an observational study tour.
- (4) **Invitational Travel** is a type of travel that USAID funds for non-U.S. Government employees. This type of travel may be approved for both U.S. and foreign citizens who are not employed by the U.S. Government (USG), not receiving any type of compensation from the USG for such travel, and only when it is determined that the functions to be performed are essential to the interests of USAID.

b. Program Monitoring and Data Reporting: The recipient must monitor Exchange Visitors' and Participants' progress during their program and ensure that problems are identified and resolved quickly.

- (1) For U.S.-based activities, the recipient must use USAID's official Exchange Visitor and Participant Training information system, currently called "Training Results and Information Network – TraiNet" (see <http://trainethelp.usaid.gov/>), to report and manage Exchange Visitor and Participant Training data. The recipient must also use the USAID Visa Compliance System – VCS (see <http://trainethelp.usaid.gov/>) to transfer required data for USAID Exchange Visitors to the Department of Homeland Security's Student and Exchange Visitor Information System (SEVIS).
- (2) For all third-country activities, and for host-country activities of two consecutive days or 16 contact hours or more in duration, the recipient must use USAID's official

Exchange Visitor and Participant Training information system, currently called “Training Results and Information Network – TraiNet” (see <http://trainethelp.usaid.gov/>), to report and manage Participant Training data.

c. Health and Accident Insurance:

- (1) For Exchange Visitors traveling to the United States, the recipient must enroll Exchange Visitors in health and accident insurance coverage that meets or exceeds Department of State and USAID minimum coverage requirements as set forth in 22 CFR 62.14 and ADS 253.3.6.2. The requirements may be obtained from the Agreement Officer’s Representative.
- (2) For Participants traveling to a third country, the recipient must obtain health and accident insurance coverage for all Participants.
- (3) For Participants traveling within the host country, the recipient must determine whether specific in-country participant training activities subject them to any risk of health and accident liability for medical costs. Participants may incur, and if so, take appropriate steps according to the local situation, including obtaining health and accident insurance coverage for Participants.

d. Immigration Requirements:

- (1) For Exchange Visitors traveling to the United States, the recipient must ensure that all USAID-sponsored Exchange Visitors obtain, use, and comply with the terms of the J-1 visa, issued in conjunction with a USAID-issued Certificate of Eligibility for J-1 Visa Status (DS-2019).
- (2) For Participants traveling to a third country or within the host country, the recipient must ensure that all Participants obtain, use, and comply with the terms of all applicable immigration, visa and other similar requirements.

e. Language Proficiency: The recipient must verify language proficiency. Exchange Visitors must possess sufficient English language proficiency to participate in a U.S.-based activity. Participants of third-country or host-country training must be proficient in the language of training at a sufficient level for participation, unless an interpreter has been arranged. Language competency can be verified through a variety of means including proficiency assessments of interviews, publications, presentations, education conducted in English, and formal testing.

f. Pre-departure Orientation: The recipient must conduct pre-departure orientation for U.S.-bound Exchange Visitors and Participants of third-country training programs. Pre-departure orientation covers: program objectives; administrative and policy review; cultural aspects; and training/learning methods.

- g. **Conditions of Sponsorship:** The recipient must ensure that all Exchange Visitors read and sign the Conditions of Sponsorship for U.S.-Based Activities form (AID 1381-6). The recipient must also ensure that all Participants of long-term (six months or longer) third-country training read and sign the form Conditions of Sponsorship for Third-Country Training form (AID 1381-7). The recipient must report to the Agreement Officer any known violations by Exchange Visitors of visa or other immigration requirements or conditions.
- h. **Exchange Visitor Security Risk and Fraud Inquiry:** Each USAID Mission has an established process for conducting a Security Risk and Fraud Inquiry (SRFI) for Exchange Visitors. The recipient must be prepared to assist Missions in conducting the SRFI, if requested. However, the recipient's role is contributive, and the Mission is ultimately responsible for conducting the SRFI.
- i. **Fly America:** To the extent that participants travel by international air travel, the recipient must comply with the Standard Provision, "International Air Travel and Air Transportation of Property."
- j. **Use of Minority Serving Institutions:** For U.S.-based Participant Training, the recipient must, to the maximum extent possible, maintain their use of Historically Black Colleges and Universities (HBCUs) and other Minority Serving Institutions (MSIs), including Hispanic Serving Institutions and Tribal Colleges and Universities, as training or education providers.

[END OF PROVISION]

RAA7. PROTECTION OF THE INDIVIDUAL AS A RESEARCH SUBJECT (APRIL 1998)

- a. Safeguarding the rights and welfare of human subjects involved in research supported by USAID is the responsibility of the organization to which support is awarded. USAID has adopted the Common Federal Policy for the Protection of Human Subjects, Part 225 of Title 22 of the Code of Federal Regulations (the "Policy"). Additional interpretation, procedures, and implementation guidance of the Policy are found in USAID General Notice entitled "Procedures for the Protection of Human Subjects in Research Supported by USAID," issued April 19, 1995, as amended. USAID's Cognizant Human Subjects Officer (CHSO) in USAID/W has oversight, guidance, and interpretation responsibility for the Policy.
- b. Recipient organizations must comply with USAID policy when humans are the subject of research, as defined in 22 CFR 225.102(d), funded by the grant and recipients must provide "assurance," as required by 22 CFR 225.103, that they follow and abide by the procedures in the Policy. See also Section 5 of the April 19, 1995, USAID General Notice which sets forth activities to which the Policy is applicable. The existence of a bona fide, applicable assurance approved by the Department of Health and Human Services (HHS) such as the "multiple project assurance" (MPA) will satisfy this requirement. Alternatively, organizations can provide an acceptable written assurance to USAID as described in 22 CFR 225.103.

Such assurances must be determined by the CHSO to be acceptable prior to any applicable research being initiated or conducted under the award. In some limited instances outside the U.S., alternative systems for the protection of human subjects may be used provided they are deemed “at least equivalent” to those outlined in Part 225 (See 22 CFR 225.101[h]). Criteria and procedures for making this determination are described in the General Notice cited in the preceding paragraph.

- c. Since the welfare of the research subject is a matter of concern to USAID as well as to the organization, USAID staff consultants and advisory groups may independently review and inspect research and research processes and procedures involving human subjects, and based on such findings, the CHSO may prohibit research which presents unacceptable hazards or otherwise fails to comply with USAID procedures. Informed consent documents must include the stipulation that the subject's records may be subject to such review.

[END OF PROVISION]

RAA8. CARE OF LABORATORY ANIMALS (MARCH 2004)

CARE OF LABORATORY ANIMALS (MARCH 2004)

- a. Before undertaking performance of any grant involving the use of laboratory animals, the recipient must register with the Secretary of Agriculture of the United States in accordance with Section 6, Public Law 89-544, Laboratory Animal Welfare Act, August 24, 1966, as amended by Public Law 91-579, Animal Welfare Act of 1970, December 24, 1970. The recipient must furnish evidence of such registration to the Agreement Officer.
- b. The recipient must acquire animals used in research under this award only from dealers licensed by the Secretary of Agriculture, or from exempted sources in accordance with the Public Laws enumerated in a. above.
- c. In the care of any live animals used or intended for use in the performance of this grant, the recipient must adhere to the principles enunciated in the Guide for Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences - National Research Council (NAS-NRC), and in the United States Department of Agriculture's (USDA) regulations and standards issued under the Public Laws enumerated in a. above. In case of conflict between standards, the higher standard must be used. The recipient's reports on portions of the award in which animals were used must contain a certificate stating that the animals were cared for in accordance with the principles enunciated in the Guide for Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, NAS-NRC, and/or in the regulations and standards as promulgated by the Agricultural Research Service, USDA, pursuant to the Laboratory Animal Welfare Act of 24 August 1966, as amended (P.L. 89-544 and P.L. 91-579). NOTE: The recipient may request registration of the recipient's facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which the recipient's research facility is located. The location of the appropriate APHIS Regional Office as well as information concerning this program may be obtained by contacting the Senior Staff

Office, Animal Care Staff, USDA/APHIS, 4700 River Road, Unit 84, Riverdale, MD 20737-1234 and at www.aphis.usda.gov/animal_welfare/index.shtml.

[END OF PROVISION]

RAA10. COST SHARING (MATCHING) (FEBRUARY 2012)

COST SHARING (MATCHING) (FEBRUARY 2012)

- a. If at the end of any funding period, the recipient has expended an amount of non-Federal funds less than the agreed upon amount or percentage of total expenditures, the Agreement Officer may apply the difference to reduce the amount of USAID incremental funding in the following funding period. If the award has expired or has been terminated, the Agreement Officer may require the recipient to refund the difference to USAID.
- b. The source and nationality requirements and the restricted goods provision established in the Standard Provision entitled "USAID Eligibility Rules for Goods and Services" do not apply to cost sharing (matching) expenditures.

[END OF PROVISION]

RAA11. PROHIBITION OF ASSISTANCE TO DRUG TRAFFICKERS (JUNE 1999)

- a. USAID reserves the right to terminate assistance to, or take other appropriate measures with respect to, any participant approved by USAID who is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR 140.
- b.
 - (1) For any loan over \$1,000 made under this agreement, the recipient must insert a clause in the loan agreement stating that the loan is subject to immediate cancellation, acceleration, recall, or refund by the recipient if the borrower or a key individual of a borrower is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR 140.
 - (2) Upon notice by USAID of a determination under section (1) and at USAID's option, the recipient agrees to immediately cancel, accelerate, or recall the loan, including refund in full of the outstanding balance. USAID reserves the right to have the loan refund returned to USAID.
- c.
 - (1) The recipient agrees not to disburse, or sign documents committing the recipient to disburse, funds to a subrecipient designated by USAID ("Designated Subrecipient") until advised by USAID that: (i) any United States Government review of the Designated Subrecipient and its key individuals has been completed; (ii) any related certifications have been obtained; and (iii) the assistance to the Designated Subrecipient has been

approved. Designation means that the subrecipient has been unilaterally selected by USAID as the subrecipient. USAID approval of a subrecipient, selected by another party, or joint selection by USAID and another party is not designation.

- (2) The recipient must insert the following clause, or its substance, in its agreement with the Designated Subrecipient:

“The recipient reserves the right to terminate this [Agreement/Contract] or take other appropriate measures if the [Subrecipient] or a key individual of the [Subrecipient] is found to have been convicted of a narcotic offense or to have been engaged in drug trafficking as defined in 22 CFR 140.”

[END OF PROVISION]

RAA13. REPORTING HOST GOVERNMENT TAXES (DECEMBER 2014)

- a. By April 16 of each year, the recipient must submit a report containing:
- (1) Contractor/recipient name.
 - (2) Contact name with phone, fax and e-mail.
 - (3) Agreement number(s).
 - (4) The total amount of value-added taxes and customs duties (but not sales taxes) assessed by the host government (or any entity thereof) on purchases in excess of \$500 per transaction of supplies, materials, goods or equipment, during the 12 months ending on the preceding September 30, using funds provided under this contract/agreement.
 - (5) Any reimbursements received by April 1 of the current year on value-added taxes and customs duties reported in (iv).
 - (6) Reports are required even if the recipient did not pay any taxes or receive any reimbursements during the reporting period.
 - (7) Cumulative reports may be provided if the recipient is implementing more than one program in a foreign country.
- b. Submit the reports to: Agreement’s Officer Representative.
- a. Host government taxes are not allowable where the Agreement Officer provides the necessary means to the recipient to obtain an exemption or refund of such taxes, and the recipient fails to take reasonable steps to obtain such exemption or refund. Otherwise, taxes

are allowable in accordance with the Standard Provision, “Allowable Costs,” and must be reported as required in this provision.

- b. The recipient must include this reporting requirement in all applicable subawards and contracts.

[END OF PROVISION]

RAA14. FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)

FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)

- a. U.S. Government funds under this award must not be used to finance the travel, per diem, hotel expenses, meals, conference fees or other conference costs for any member of a foreign government’s delegation to an international conference sponsored by a multilateral organization, as defined below, unless approved by the Agreement Officer in writing.
- b. Definitions:
 - (1) A foreign government delegation is appointed by the national government (including ministries and agencies but excluding local, state and provincial entities) to act on behalf of the appointing authority at the international conference. A conference participant is a delegate for the purposes of this provision, only when there is an appointment or designation that the individual is authorized to officially represent the government or agency. A delegate may be a private citizen.
 - (2) An international conference is a meeting where there is an agenda, an organizational structure, and delegations from countries other than the conference location, in which country delegations participate through discussion, votes, etc.
 - (3) A multilateral organization is an organization established by international agreement and whose governing body is composed principally of foreign governments or other multilateral organizations.

[END OF PROVISION]

RAA18. USAID DISABILITY POLICY - ASSISTANCE (DECEMBER 2004)

- a. The objectives of the USAID Disability Policy are (1) to enhance the attainment of United States foreign assistance program goals by promoting the participation and equalization of opportunities of individuals with disabilities in USAID policy, country and sector strategies, activity designs and implementation; (2) to increase awareness of issues of people with disabilities both within USAID programs and in host countries; (3) to engage other U.S. Government agencies, host country counterparts, governments, implementing organizations

and other donors in fostering a climate of nondiscrimination against people with disabilities; and (4) to support international advocacy for people with disabilities.

- b. USAID therefore requires that the recipient not discriminate against people with disabilities in the implementation of USAID funded programs and that it make every effort to comply with the objectives of the USAID Disability Policy in performing the program under this grant or cooperative agreement. To that end and to the extent it can accomplish this goal within the scope of the program objectives, the recipient should demonstrate a comprehensive and consistent approach for including men, women, and children with disabilities.

[END OF PROVISION]

RAA23. UNIVERSAL IDENTIFIER AND SYSTEM OF AWARD MANAGEMENT (NOVEMBER 2020)

- a. **Requirement for System of Award Management (SAM).** Unless you are exempted from this requirement under 2 CFR 25.110, you as the recipient must maintain current information in the SAM. This includes information on your immediate and highest level owner and subsidiaries, as well as on all of your predecessors that have been awarded a Federal contract or Federal financial assistance within the last three years, if applicable, until you submit the final financial report required under this Federal award or receive the final payment, whichever is later. This requires that you review and update the information at least annually after the initial registration, and more frequently, if required by changes in your information or another Federal award term.
- b. **Requirement for Unique Entity Identifier.** If you are authorized to make subawards under this Federal award, you:
 - (1) Must notify potential subrecipients that no entity (see definition in paragraph c. of this award term) may receive a subaward from you until the entity has provided its Unique Entity Identifier to you.
 - (2) May not make a subaward to an entity unless the entity has provided its Unique Entity Identifier to you. Subrecipients are not required to obtain an active SAM registration but must obtain a Unique Entity Identifier.
- c. **Definitions.** For purposes of this award term:
 - (1) System of Award Management (SAM) means the Federal repository into which a recipient must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM Internet site (currently at <https://www.sam.gov>).

- (2) Unique Entity Identifier means the identifier assigned by SAM to uniquely identify business entities.
- (3) Entity includes non-Federal entities as defined in 2 CFR 200.1 and also includes all of the following, for purposes of this part:
 - a. A foreign organization;
 - b. A foreign public entity;
 - c. A domestic for-profit organization; and
 - d. A Federal agency.
- (4) Subaward has the meaning given in 2 CFR 200.1.
- (5) Subrecipient has the meaning given in 2 CFR 200.1.

ADDENDUM (NOVEMBER 2020):

- d. **Exceptions.** The requirements of this provision to obtain a Unique Entity Identifier and maintain a current registration in the SAM do not apply, at the prime award or subaward level, to:
 - (1) Awards to individuals
 - (2) Awards less than \$25,000 to foreign recipients to be performed outside the United States (based on a USAID determination)
 - (3) Awards where the Agreement Officer determines, in writing, that the Agency must protect entity information from disclosure due to national security or foreign policy interests of the United States or that these requirements would cause personal safety concerns.
- e. This provision does not need to be included in subawards.

[END OF PROVISION]

**RAA24. REPORTING SUBAWARDS AND EXECUTIVE COMPENSATION
(NOVEMBER 2020)**

- a. **Reporting of first-tier subawards.**
 - (1) Applicability. Unless you are exempt as provided in paragraph d. of this award term, you must report each action that equals or exceeds \$30,000 in Federal funds for a subaward to a non-Federal entity or Federal agency (see definitions in paragraph e. of this award term).

(2) Where and when to report.

- (i) The non-Federal entity or Federal agency must report each obligating action described in paragraph a.(1) of this award term to www.fsrs.gov.
- (ii) For subaward information, report no later than the end of the month following the month in which the obligation was made. (For example, if the obligation was made on November 7, 2010, the obligation must be reported by no later than December 31, 2010.)

(3) What to report. You must report the information about each obligating action that the submission instructions posted at www.fsrs.gov specify.

b. Reporting Total Compensation of Recipient Executives.

(1) Applicability and what to report. You must report total compensation for each of your five most highly compensated executives for the preceding completed fiscal year, if –

- (i) The total Federal funding authorized to date under this Federal award equals or exceeds \$30,000 as defined in 2 CFR 170.320;
- (ii) In the preceding fiscal year, you received—
 - (A) 80 percent or more of your annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
 - (B) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
- (iii) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at www.sec.gov/answers/excomp.htm.)

(2) Where and when to report. You must report executive total compensation described in paragraph b.(1) of this award term:

- (i) As part of your registration profile at www.sam.gov.
- (ii) By the end of the month following the month in which this award is made, and annually thereafter.

c. Reporting of Total Compensation of Subrecipient Executives.

- (1) Applicability and what to report. Unless you are exempt as provided in paragraph d. of this award term, for each first-tier subrecipient under this award, you must report the names and total compensation of each of the subrecipient's five most highly compensated executives for the subrecipient's preceding completed fiscal year, if—
 - (i) In the subrecipient's preceding fiscal year, the subrecipient received—
 - (A) 80 percent or more of its annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
 - (B) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts), and Federal financial assistance subject to the Transparency Act (and subawards); and
 - (ii) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at www.sec.gov/answers/execomp.htm.)
- (2) Where and when to report. You must report subrecipient executive total compensation described in paragraph c.(1) of this award term:
 - (i) To the recipient.
 - (ii) By the end of the month following the month during which you make the subaward. For example, if a subaward is obligated on any date during the month of October of a given year (for example, between October 1 and 31), you must report any required compensation information of the subrecipient by November 30 of that year.

d. Exemptions.

If, in the previous tax year, you had gross income, from all sources, under \$300,000, you are exempt from the requirements to report:

- (1) Subawards, and
- (2) The total compensation of the five most highly compensated executives of any subrecipient.

e. Definitions.

For purposes of this award term:

- (1) Federal Agency means a Federal agency as defined at 5 U.S.C. 551(1) and further clarified by 5 U.S.C. 552(f).
- (2) Entity means all of the following, as defined in 2 CFR 25:
 - (i) A governmental organization, which is a State, local government, or Indian tribe;
 - (ii) A foreign public entity;
 - (iii) A domestic or foreign nonprofit organization; and
 - (iv) A domestic or foreign for-profit organization.
- (3) Executive means officers, managing partners, or any other employees in management positions.
- (4) Subaward:
 - (i) This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.
 - (ii) The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see 2 CFR 200.331).
 - (iii) A subaward may be provided through any legal agreement, including an agreement that you or a subrecipient considers a contract.
- (5) Subrecipient means a non-Federal entity or Federal agency that:
 - (i) Receives a subaward from you (the recipient) under this award; and
 - (ii) Is accountable to you for the use of the Federal funds provided by the subaward.
- (6) Total compensation means the cash and noncash dollar value earned by the executive during the recipient's or subrecipient's preceding fiscal year and includes the following (for more information see 17 CFR 229.402(c)(2)):
 - (i) Salary and bonus.

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- (ii) Awards of stock, stock options, and stock appreciation rights. Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Statement of Financial Accounting Standards No. 123 (Revised 2004) (FAS 123R), Shared Based Payments.
- (iii) Earnings for services under nonequity incentive plans. This does not include group life, health, hospitalization, or medical reimbursement plans that do not discriminate in favor of executives, and are available generally to all salaried employees.
- (iv) Change in pension value. This is the change in present value of defined benefit and actuarial pension plans.
- (v) Above-market earnings on deferred compensation which is not tax-qualified.
- (vi) Other compensation, if the aggregate value of all such other compensation (for example, severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property) for the executive exceeds \$10,000.

[END OF PROVISION]

RAA25. PATENT REPORTING PROCEDURES (NOVEMBER 2020)

As incorporated by 2 CFR 200.315 and the standard provision “APPLICABILITY OF 2 CFR 200 and 2 CFR 700,” the clause at 37 CFR 401.14 (“Standard Patent Rights”) is incorporated by reference into this award as if set forth in full text. The recipient must use the National Institutes of Health EDISON Patent Reporting and Tracking system (<http://www.iedison.gov>) to fulfill its disclosure obligations under 37 CFR 401.14(c)(1). The recipient must also submit reports on utilization of subject inventions annually to the Agreement Officer’s Representative under 37 CFR 401.14(h), and the last report must be provided within 90 days of the expiration of the agreement.

[END OF PROVISION]

RAA26. ACCESS TO USAID FACILITIES AND USAID’S INFORMATION SYSTEMS (AUGUST 2013)

- a. A U.S. citizen or resident alien engaged in the performance of this award as an employee, consultant, or volunteer of a U.S organization may obtain access to USAID facilities or logical access to USAID’s information systems only when and to the extent necessary to carry out this award and in accordance with this provision. The recipient’s employees, consultants, or volunteers who are not U.S. citizen as well as employees, consultants, or volunteers of non-U.S.

- b. organizations, irrespective of their citizenship, will not be granted logical access to U.S. Government information technology systems (such as Phoenix, GLAAS, etc.) and must be escorted to use U.S. Government facilities (such as office space).
- c. Before a U.S. citizen or resident alien engaged in the performance of this award as an employee, consultant, or volunteer of the recipient, subrecipient or contractor at any tier may obtain a USAID ID (new or replacement) authorizing the individual routine access to USAID facilities in the United States, or logical access to USAID's information systems, the individual must provide two forms of identity source documents in original form. One identity source document must be a valid Federal or State government-issued picture ID. The recipient must contact the USAID Office of Security to obtain the list of acceptable forms of documentation. Submission of these documents, and related background checks, are mandatory in order for the individual to receive a building access ID, and before access will be granted to any of USAID's information systems. All such individuals must physically present these two source documents for identity proofing at their Security Briefing. All individuals provided access under this provision must return any issued building access ID and remote authentication token to USAID custody upon termination of the individual's employment with the recipient or completion of the award, whichever occurs first.
- d. Individuals engaged in the performance of this award as an employee, consultant, or volunteer of the recipient must comply with all applicable Homeland Security Policy Directive-12 (HSPD-12) and Personal Identity Verification (PIV) procedures, as described above, as well as any subsequent USAID or government-wide HSPD-12 and PIV procedures/policies, including any
- e. HSPD-12 procedures established by the Office of Security in USAID/Washington.
- f. The recipient is required to include this provision in all subawards and contracts at any tier made to a U.S. organization/company, that require employees or consultants engaged in the performance of this award to have routine physical access to USAID facilities or logical access to USAID's information systems in order to perform this award.

[END OF PROVISION]

RAA27. CONTRACT PROVISION FOR DBA INSURANCE UNDER RECIPIENT PROCUREMENTS (DECEMBER 2014)

All contracts made by the recipient under this award for services to be performed overseas must contain the following provision, as applicable.

Workers' Compensation Insurance (Defense Base Act)

(a) The Contractor must--

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Cooperative Agreement 7200AA21CA00033

- (1) Before commencing performance under this contract, establish provisions to provide for the payment of disability compensation and medical benefits to covered employees and death benefits to their eligible survivors, by purchasing Defense Base Act (DBA) insurance pursuant to the terms of the contract between USAID and USAID's DBA insurance carrier unless the Contractor qualifies as a self-insurer under the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 932) as extended by the Defense Base Act (42 U.S.C. 1651, et seq.), or has an approved retrospective rating agreement for DBA. The Contractor must continue to maintain these provisions to provide such Defense Base Act benefits until contract performance is completed.
- (2) If USAID or the Contractor has secured a waiver of DBA coverage in accordance with AIDAR 728.305-70(a) for contractor's employees who are not citizens of, residents of, or hired in the United States, the contractor agrees to provide such employees with worker's compensation benefits as required by the laws of the country in which the employees are working, or by the laws of the employee's native country, whichever offers greater benefits. The Department of Labor has granted partial blanket waivers of DBA coverage applicable to USAID-financed contracts performed in countries listed in the DEFENSE BASE ACT (DBA) WAIVER LIST.
- (3) Within ten days of an employee's injury or death or from the date the Contractor has knowledge of the injury or death, submit Form LS-202 (Employee's First Report of Injury or Occupational Illness) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 930(a), 20 CFR 702.201 to 702.203).
- (4) Pay all compensation due for disability or death within the timeframes required by the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914, 20 CFR 702.231 and 703.232).
- (5) Provide for medical care as required by the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 907, 20 CFR 702.402 and 702.419).
- (6) If controverting the right to compensation, submit Form LS-207 (Notice of Controversion of Right to Compensation) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914(d), 20 CFR 702.251).
- (7) Immediately upon making the first payment of compensation in any case, submit Form LS-206 (Payment of Compensation Without Award) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914(c), 20 CFR 702.234).
- (8) When payments are suspended or when making the final payment, submit Form LS-208 (Notice of Final Payment or Suspension of Compensation Payments) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914 (c) and (g), 20 CFR 702.234 and 702.235).

- (9) Adhere to all other provisions of the Longshore and Harbor Workers' Compensation Act as extended by the Defense Base Act, and Department of Labor regulations at 20 CFR Parts 701 to 704.

For additional information on the Longshore and Harbor Workers' Compensation Act requirements see <http://www.dol.gov/owcp/dlhwc/lbdba.htm>.

The Contractor must insert the substance of this clause including this paragraph (c), in all subcontracts to which the Defense Base Act applies.

[END OF PROVISION]

RAA28. AWARD TERM AND CONDITION FOR RECIPIENT INTEGRITY AND PERFORMANCE MATTERS (APRIL 2016)

A. Reporting of Matters Related to Recipient Integrity and Performance

1. General Reporting Requirement

If the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds \$10,000,000 for any period of time during the period of performance of this Federal award, then you as the recipient during that period of time must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) about civil, criminal, or administrative proceedings described in paragraph 2 of this award term and condition. This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available.

2. Proceedings About Which You Must Report

Submit the information required about each proceeding that:

- a. Is in connection with the award or performance of a grant, cooperative agreement, or procurement contract from the Federal Government;
- b. Reached its final disposition during the most recent five year period; and
- c. Is one of the following:
 - (1) A criminal proceeding that resulted in a conviction, as defined in paragraph 5 of this award term and condition;

- (2) A civil proceeding that resulted in a finding of fault and liability and payment of a monetary fine, penalty, reimbursement, restitution, or damages of \$5,000 or more;
- (3) An administrative proceeding, as defined in paragraph 5. of this award term and condition, that resulted in a finding of fault and liability and your payment of either a monetary fine or penalty of \$5,000 or more or reimbursement, restitution, or damages in excess of \$100,000; or
- (4) Any other criminal, civil, or administrative proceeding if:
 - (i) It could have led to an outcome described in paragraph 2.c.(1), (2), or (3) of this award term and condition;
 - (ii) It had a different disposition arrived at by consent or compromise with an acknowledgment of fault on your part; and
 - (iii) The requirement in this award term and condition to disclose information about the proceeding does not conflict with applicable laws and regulations.

3. Reporting Procedures

Enter in the SAM Entity Management area the information that SAM requires about each proceeding described in paragraph 2 of this award term and condition. You do not need to submit the information a second time under assistance awards that you received if you already provided the information through SAM because you were required to do so under Federal procurement contracts that you were awarded.

4. Reporting Frequency

During any period of time when you are subject to the requirement in paragraph 1 of this award term and condition, you must report proceedings information through SAM for the most recent five year period, either to report new information about any proceeding(s) that you have not reported previously or affirm that there is no new information to report. Recipients that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 must disclose semiannually any information about the criminal, civil, and administrative proceedings.

5. Definitions

For purposes of this award term and condition:

- a. Administrative proceeding means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative proceedings, Civilian Board of Contract Appeals

proceedings, and Armed Services Board of Contract Appeals proceedings). This includes proceedings at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include audits, site visits, corrective plans, or inspection of deliverables.

- b. Conviction, for purposes of this award term and condition, means a judgment or conviction of a criminal offense by any court of competent jurisdiction, whether entered upon a verdict or a plea, and includes a conviction entered upon a plea of nolo contendere.
- c. Total value of currently active grants, cooperative agreements, and procurement contracts includes—
 - (1) Only the Federal share of the funding under any Federal award with a recipient cost share or match; and
 - (2) The value of all expected funding increments under a Federal award and options, even if not yet exercised.

B. [Reserved]

[END OF PROVISION]

[END OF PROVISION]

RAA30. PROGRAM INCOME (AUGUST 2020)

PROGRAM INCOME (August 2020)

- a. Program income is gross income earned by the recipient that is directly generated by a supported activity or earned as a result of the Federal award during the period of performance. Program income includes, but is not limited to: income from fees for services performed; the use or rental of real or personal property acquired under Federal awards; the sale of commodities or items fabricated under a Federal award; license fees and royalties on patents and copyrights; and principal and interest on loans made with Federal award funds. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, or interest earned on any of them.
- b. Program income must be used for the purposes, and under the conditions, of the award, to further project objectives, program objectives, or award activities. Program income must be used only for allowable program costs. Interest earned on program income is subject to the same conditions as program income.
- c. The recipient must apply the approach for use of program income as specified in the schedule of the award. This may include one of the three approaches listed below (see also [2 CFR](#)

200.307). The recipient must also follow the standards in this provision to account for gross income earned from Federally-supported activities under this award.

1) If the deduction approach is used, the recipient must use the program income for current costs, prior to drawdown of USAID funds under the award.

2) If the addition approach is used, the total award amount is increased by the amount of program income. If the award anticipates a specific program income amount, any program income in excess of such amount must be deducted from expenditures.

3) If the cost sharing approach is used, the amount of the award remains the same. If the award anticipates a specific program income amount, any program income in excess of such amount must be deducted from expenditures.

d. Costs subject to generating program income under this award may be deducted from gross income to calculate program income, provided these costs have not been charged to this award and comply with the standard provision, “Allowable Costs.”

e. The recipient must report program income using the **Federal Financial Report, SF-425**. Program income must be accounted for in the same ratio as USAID’s participation in the program. For example, if USAID funded 75 percent of a recipient’s program, then the recipient must report 75 percent of any program income earned under the award as “Federal program income earned” on the SF-425.

f. The recipient should continue to use program income earned after the period of the award to further award objectives, but is not subject to Federal requirements governing the disposition of program income earned after the end of the period of performance for the award.

[END OF PROVISION]

[END OF STANDARD PROVISIONS]

Washington State University
Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)
Cooperative Agreement 7200AA21CA00033

ATTACHMENT D – BRANDING AND MARKING PLAN

Institutional Certification Detail

The institution below has certified on the FDP Clearinghouse that they are compliant with PHS FCOI Regulations.

Institution Name	Washington University in St. Louis
Authorized Representative	Jeneane Braden
Authorized Representative Title	Manager, Research Ethics and Compliance Office
Authorized Representative Email Address	bradenj@wustl.edu
Primary DUNS Number Optional	18



Attachment 7
Standard Invoice

Sub-Recipient:
Name _____
Address _____
Telephone _____
Fax _____
Email _____

Invoice Number: _____	Subaward (G00) Number: _____
Invoice Date: _____	Award Number: _____
Invoice Amount: <u>\$0.00</u>	Subaward PI Name: _____
Cost Share Amount: <u>\$0.00</u>	Subrecipient email address: _____
In Account with:	Subrecipient phone number: _____
Sponsored Programs Services Washington State University PO Box 641025 240 French Administration Building Pullman, WA 99164-1025 (509)-335-2058, sps@wsu.edu	Invoice Period: _____ to _____ <input type="checkbox"/> Check if Final Invoice

Expense Categories	Expenditures for Invoice Period	Cumulative Expenditures	Cost Share Expenditures for Invoice Period	Cost Share Cumulative Expenditures
Project Costs				
Personnel Salaries				
Personnel Wages				
Fringe Benefits				
Supplies & Materials				
Domestic Travel				
International Travel				
Equipment*				
Contractual Services				
Tuition				
Stipends				
Other Direct Costs				
Total Direct Costs	\$0.00	\$0.00	\$0.00	\$0.00
F&A Costs: Rate _____				
Total Costs	\$0.00	\$0.00	\$0.00	\$0.00

*Equipment definition: refer to PART 200—UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR FEDERAL AWARDS, Subpart A, §200.33 Equipment.

http://www.ecfr.gov/cgi-bin/text-idx?SID=421d3e3a239e70bdcef843df7113da50&mc=true&node=se2.1.200_133&rgn=div8

By signing this report, I certify to the best of my knowledge and belief that the report is true, complete, and accurate, and the expenditures, disbursements and cash receipts are for the purposes and objectives set forth in the terms and conditions of the Federal award. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims or otherwise. (U.S. Code Title 18, Section 1001 and Title 31, Sections 3729-3730 and 3801-3812).

Subrecipient authorized representative name and title _____

Phone Number _____

Email Address: _____

Subrecipient authorized representative signature _____

Date _____

Voucher # _____
PR: _____

Date Invoice received: _____
Date paid: _____

Attachment 7
Standard Invoice
REPORT OF MATCHING FUNDS EXPENDED

Subcontractor Name: _____

Invoice #: _____

Vendor's Certificate: I hereby certify under penalty of perjury the items and totals listed herein are proper charges for materials, merchandise or services furnished and/or services rendered and reported as match.

Prepared by: _____

Date: _____

Expenses for period: _____ to _____

Salaries/Wages (examples below:)	CASH	IN-KIND	WAIVED F&A	PLEDGED
_____	\$ -	\$ -	\$ -	\$ -
_____	\$ -	\$ -	\$ -	\$ -
_____	\$ -	\$ -	\$ -	\$ -
Total	\$ -	\$ -	\$ -	\$ -
Fringe Benefits				
_____	\$ -	\$ -	\$ -	\$ -
_____	\$ -	\$ -	\$ -	\$ -
_____	\$ -	\$ -	\$ -	\$ -
Total	\$ -	\$ -	\$ -	\$ -
Travel				
Domestic	\$ -	\$ -	\$ -	\$ -
International	\$ -	\$ -	\$ -	\$ -
Total	\$ -	\$ -	\$ -	\$ -
Goods & Services (examples below:)				
_____	\$ -	\$ -	\$ -	\$ -
_____	\$ -	\$ -	\$ -	\$ -
_____	\$ -	\$ -	\$ -	\$ -
Equipment (over \$5,000)				
_____	\$ -	\$ -	\$ -	\$ -
_____	\$ -	\$ -	\$ -	\$ -
_____	\$ -	\$ -	\$ -	\$ -
_____	\$ -	\$ -	\$ -	\$ -
Contractual/Consultants				
_____	\$ -	\$ -	\$ -	\$ -
_____	\$ -	\$ -	\$ -	\$ -
_____	\$ -	\$ -	\$ -	\$ -
F&A @	\$ -	\$ -	\$ -	\$ -
TOTAL - THIS REPORT	\$ -	\$ -	\$ -	\$ -
Previously Reported	\$ -	\$ -	\$ -	\$ -
CUMULATIVE-TO-DATE	\$ -	\$ -	\$ -	\$ -
TOTAL AMOUNT PLEDGED:	\$ -			
BALANCE OF COST SHARE	\$ -			
PERCENT of COST SHARE MET	#DIV/0!			

This report shows the cash and in-kind match by the subcontractor.

Match must be met from non-federal funds and must not be used as match on any other grant.

The time frame of match, whether purchase or work, must be within the time frame of the grant.

Any item submitted as match must also be considered an "allowable" cost on the grant.

From: ORSO <ORSO@wsu.edu>
Sent: Thursday, May 26, 2022 9:55 AM
To: Guzman, Maria; Wang, David
Cc: Yager, Amanda L; Howard, Tyler J; Boni, Troy; Moore, Anke Marga-Christa
Subject: Fully executed SPC003545A
Attachments: 141061 SPC003545A AM DB.pdf

Hello,

Attached is the fully executed agreement.

Thank you,



KATE MARTINSON

e-RESEARCH ADMINISTRATION COORDINATOR
Office of Research Support and Operations
Office of Research
Washington State University
Office: 509-335-9661
Work email: orso@wsu.edu
Personal email: katharine.martinson@wsu.edu
orso.wsu.edu
Pronouns: She/Her/Hers

FDP Subaward Amendment			
Amendment No 1		Subaward No 141061 SPC003545	
Pass-Through Entity (PTE)		Subrecipient	
Washington State University		Entity Name The Washington University	
orso@wsu.edu		Contact Email researchcontracts@wusm.wustl.edu	
Felix Lankester		Principal Investigator David Wang	
Project Title Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)			
PTE/Prime Award No. 7200AA21CA00033		Awarding Agency US Agency for International Development	
Cumulative Budget Period(s) <small>(Agreement Start Date) (End Date of Latest Budget Period)</small> Start Date: 10/01/2021 End Date: 09/30/2022		Amount Funded This Action \$ 748,949.00	
		Total Amount of Funds Obligated to Date \$ 840,000.00	
Subrecipient Cost Share <input type="checkbox"/>	Subject to FFATA <input type="checkbox"/>	Subrecipient UEI <small>(Unique Entity Identifier - May leave blank if unchanged from prior Agreement)</small>	18
Amendment(s) to Original Terms and Conditions This Amendment revises the above-referenced Subaward Agreement as follows:			
<input type="checkbox"/> Additional Budget Period <input type="checkbox"/> No Cost Extension <input checked="" type="checkbox"/> Additional Funding Additional funding in the amount of \$ 748,949.00 is hereby obligated to this Subaward. <input type="checkbox"/> Deobligation Carryover is Automatic Carryover is allowed across all budget periods. <input type="checkbox"/> Carryover Authorized <input checked="" type="checkbox"/> Detailed Budget/Scope of Work/Notice of Award Attached <small>(Specify if the Budget and Scope of Work are "New", "Revised", or "Supplemental" in dropdown or "Other")</small> A Detailed Budget is incorporated by attachment to this Amendment. <input checked="" type="checkbox"/> Other (See Below)			
<small>Additional cost share of \$37,672, is incorporated.</small> <small>Monthly technical/progress reports will be submitted to the PTE's Administrator contact Chana Rabiner.</small> <small>Approval for subawards issued under this award are no longer subject to additional USAID approval.</small> <small>If applicable, Subrecipient certifies that its Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), and Institutional Review Board (IRB) are in full compliance with applicable state and federal laws and regulations. Subrecipient agrees that any non-exempt research involving animals, recombinant or synthetic nucleic acid molecules or select agents, and human subjects conducted under this agreement shall be reviewed and approved by its IACUC/IBC/IRB, as applicable. In Addition, Subrecipient will maintain current and duly approved research protocols for all periods of the Agreement involving animals, recombinant or synthetic nucleic acid molecules or select agents, and human subjects. The Subrecipient certifies that any submitted animal protocol, recombinant or synthetic nucleic acid molecules or select agents protocol, and human subjects protocol approval represents a valid, approved protocol that is entirely consistent with project associated with this subaward. In no event shall subrecipient invoice or be reimbursed for any research involving animals, recombinant or synthetic nucleic acid molecules or select agents, or human subject related expense incurred in a period where any applicable approval is not properly in place. In addition to other applicable provisions in the NOA, the mandatory standard provisions for U.S. Nongovernmental organizations found in the NOA are incorporated by reference into this subaward.</small> <small>Washington State University is an educational institution of the state of Washington, WSU is subject to Washington State laws and regulations including the Washington Public Records Act, RCW 42.56 et seq.</small>			
<i>For clarity: all amounts stated in this amendment are in United States Dollars.</i>			
All other terms and conditions of this Subaward Agreement remain in full force and effect.			
By an Authorized Official of PTE:		By an Authorized Official of Subrecipient:	
Date 		Date 5/25/2022 11:08 AM	
Name 		Name Megan White	
Title 		Title Director, Research Contracts	

PI Name(s): Lankester, Felix	YR1
	Allotment 2

Agency Name: USAID

Cognizant Agency

Approved By: Troy Boni
Date: 15Mar22

Category/Object	Year 1
Salaries - 00	205,798
Wages - 01	
Personal Svc Contract - 02	
Goods/Services - 03	200,995
Travel - 04	12,000
Computer Services - 05	
Equipment - 06	
Benefits - 07	56,730
Tuition (QTR) - 07QT	
Stipends/Subsides - 08	
SBCTs/Restricted - 14	
Small/Attractive Items - 16	
Total Direct Costs	475,523
F&A - 13	49
Total Costs	748,949
Cost Share	37,672

Washington University in St. Louis

Budget Item ID	Esc Factor	Unit Cost, \$	Unit	YR 1 Units	Year 1 Total Budget \$	YR 1 1st Allotment \$	YR 1 2nd Allotment \$
a. Personnel							
Essential Personnel							
David Wang	0	\$ 204,795	LOE	0.20	40,959.00	7,201.00	33,758.00
Co-Investigator							
Sean Whelan	0	\$ 199,300	LOE	0.20	39,860.00	7,193.00	32,667.00
Co-Investigator							
Scott Handley	0	\$ 139,394	LOE	0.08	10,455.00	1,887.00	8,568.00
Postdoc Research Associate							
Tianyu Gan	0	\$ 53,760	LOE	0.25	13,440.00	2,425.00	11,015.00
Research Lab Manager							
Lindsay Droit	0	\$ 78,045	LOE	0.25	19,511.00	3,521.00	15,990.00
Research Assistant							
Susan Vernon	0	\$ 48,299	LOE	0.25	12,075.00	2,179.00	9,896.00
Grant/Finance Administrator							
Maria Guzman	0	\$ 90,885	LOE	0.10	9,089.00	1,640.00	7,449.00
Bioinformatics Research Analyst							
Binita Febles	0	\$ 60,000	LOE	0.25	15,000.00	2,707.00	12,293.00
Staff Scientist							
Zhuoming Liu	0	\$ 72,000	LOE	0.50	36,000.00	6,497.00	29,503.00
Research Lab Manager							
Brynn Alford	0	\$ 54,843	LOE	0.50	27,422.00	4,949.00	22,473.00
Postdoc Research Associate							
Marjorie Pontelli	0	\$ 54,144	LOE	0.50	27,072.00	4,886.00	22,186.00
Total Personnel					250,883.00	45,085.00	205,798.00
b. Fringe Benefits							
Essential Personnel		28.23%	percent		11,561.00	2,032.00	9,529.00
Co-Investigator		28.90%	percent		11,520.00	2,030.00	9,490.00
Co-Investigator		28.90%	percent		3,021.00	533.00	2,488.00
Postdoc Research Associate		22.05%	percent		2,964.00	684.00	2,280.00
Research Lab Manager		28.90%	percent		5,639.00	994.00	4,645.00
Research Assistant		28.90%	percent		3,490.00	615.00	2,875.00
Grant/Finance Administrator		28.90%	percent		2,627.00	463.00	2,164.00
Bioinformatics Research Analyst		28.90%	percent		4,335.00	764.00	3,571.00
Staff Scientist		28.90%	percent		10,404.00	1,834.00	8,570.00
Research Lab Manager		28.90%	percent		7,925.00	1,397.00	6,528.00
Postdoc Research Associate		22.05%	percent		5,969.00	1,379.00	4,590.00
Total Fringe Benefits					69,455.00	12,725.00	56,730.00
c. Travel							
Wang - Travel to attend 3 meetings per year		\$ 2,000	trip	3	6,000.00	-	6,000.00
Whelan - Travel to attend 3 meetings per year		\$ 2,000	trip	3	6,000.00	-	6,000.00
Total Travel					12,000.00	-	12,000.00
d. Equipment							
Equipment 1	0		each		-	-	-
Total Equipment					-	-	-
e. Materials and Supplies							
Molecular Biology Reagents (Cloning, in vitro transcrip)		\$ 29,696	lot	1	29,696.00	-	29,696.00
Oligonucleotide synthesis for VirScan		\$ 20,848	lot	1	20,848.00	-	20,848.00
qRT-PCR reagents		\$ 20,848	lot	1	20,848.00	-	20,848.00
General Lab Supplies (gloves, ips, plas icware, etc.)		\$ 14,781	lot	1	14,781.00	-	14,781.00
Cell culture supplies (including medium, serum, etc.)		\$ 4,659	lot	1	4,659.00	-	4,659.00
Plates for viral plaque supplies		\$ 2,554	lot	1	2,554.00	-	2,554.00
Viral purification supplies		\$ 4,659	lot	1	4,659.00	-	4,659.00
Molecular Biology supplies		\$ 4,659	lot	1	4,659.00	-	4,659.00
Competent cells, media and plates for growth of bac.		\$ 4,477	lot	1	4,477.00	-	4,477.00
Gels, chemicals and general lab supplies		\$ 4,477	lot	1	4,477.00	-	4,477.00
CRISPR library		\$ 4,659	lot	1	4,659.00	-	4,659.00
Total Supplies					116,317.00	-	116,317.00
f. Contractual Services							
			lot		-	-	-
Total Contractual Services					-	-	-
g. US subawards							

Washington University in St. Louis

Budget Item ID	Esc Factor	Unit Cost, \$	Unit	YR 1 Units	Year 1 Total Budget \$	YR 1 1st Allotment \$	YR 1 2nd Allotment \$
Sub 1		\$ -			-	-	-
Total US Subawards					-	-	-
h. Tuition							
Tuition 1	0		lot		-	-	-
Total Tuition					-	-	-
i. Other Direct Costs							
Dept. fees for glasswashing, etc.	0	\$ 7,330	lot	1	7,330.00	-	7,330 00
Next generation Sequencing Library const & sequenc	0	\$ 39,495	lot	1	39,495.00	-	39,495.00
Computer cluster usage costs and data storage costs	0	\$ 990	lot	1	990.00	-	990 00
World courier dry ice shipments (1/yr x 6 countries)	0	\$ 8,909	lot	1	8,909.00	-	8,909 00
WUCCI fees	0	\$ 3,106	lot	1	3,106.00	-	3,106 00
Sequence validation of viral stocks	0	\$ 4,659	lot	1	4,659.00	-	4,659 00
Construction of infec ious cDNA clones of chimeric vir	0	\$ 4,659	lot	1	4,659.00	-	4,659 00
Gene block synthesis of heterologous envelope protein	0	\$ 4,659	lot	1	4,659.00	-	4,659 00
Sequence validation of plasmids	0	\$ 4,659	lot	1	4,659.00	-	4,659 00
Sequencing and bioinforma ics analysis of CRISPIR	0	\$ 6,212	lot	1	6,212.00	-	6,212 00
Total Other Direct Costs					84,678.00	-	84,678.00
j. Total Direct Cost					533,333.00	57,810.00	475,523.00
k.1 Indirect Cost (MTDC base)							
					49 %	49	49
					0% Percent	-	-
k. Total Indirect Cost					49	49	49
l. Total					840,000.00	91,051.00	748,949.00

From: ORSO <ORSO@wsu.edu>
Sent: Tuesday, January 18, 2022 5:00 PM
To: Awards@path.org; mdiehl@path.org; Amy Strang; Ashima Tandan; Linda Venczel
Cc: Yager, Amanda L; Manning, Rebecca Ann; Moore, Anke Marga-Christa
Subject: Fully executed SPC003572
Attachments: 141061 SPC003572 AM DN.pdf

Hello,

Attached is the fully executed agreement for your records.

Thank you,



KATE MARTINSON

e-RESEARCH ADMINISTRATION COORDINATOR

Office of Research Support and Operations

Office of Research

Washington State University

Office: 509-335-9661

Email: katharine.martinson@wsu.edu

orso.wsu.edu


Pronouns: She/Her/Hers

FDP Cost Reimbursement Subaward

Federal Awarding Agency: Other [Type in Agency]		US Agency for International Development
Pass-Through Entity (PTE):		Subrecipient:
Washington State University		PATH
PTE PI: Felix Lankester	Sub PI: Linda Venczel	
PTE Federal Award No: 7200AA21CA00033	Subaward No: 141061-SPC003572	
Project Title: Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)		
Subaward Budget Period:		Amount Funded This Action (USD): \$ 195,866.00
Start: 10/01/2021	End: 09/30/2022	
Estimated Period of Performance:		Incrementally Estimated Total (USD): \$ 24,922,805.00
Start: 10/01/2021	End: 09/30/2026	

Terms and Conditions

1. PTE hereby awards a cost reimbursable subaward, (as determined by 2 CFR 200.331), to Subrecipient. The Statement of Work and budget for this Subaward are as shown in Attachment 5. In its performance of Subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.
2. Subrecipient shall submit invoices not more often than monthly and not less frequently than quarterly for allowable costs incurred. Upon the receipt of proper invoices, the PTE agrees to process payments in accordance with this Subaward and 2 CFR 200.305. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), breakdown by major cost category, Subaward number, and certification, as required in 2 CFR 200.415(a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments shall be directed to the party's Financial Contact, shown in Attachment 3A.
3. A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Financial Contact, as shown in Attachment 3A, not later than 60 days after the final Budget Period end date. The final statement of costs shall constitute Subrecipient's final financial report.
4. All payments shall be considered provisional and are subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Subrecipient.
5. Matters concerning the technical performance of this Subaward shall be directed to the appropriate party's Principal Investigator as shown in Attachments 3A and 3B. Technical reports are required as shown in Attachment 4.
6. Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this Subaward, and any changes requiring prior approval, shall be directed to the PTE's Authorized Official Contact and the Subrecipient's Authorized Official Contact shown in Attachments 3A and 3B. Any such change made to this Subaward requires the written approval of each party's Authorized Official as shown in Attachments 3A and 3B.
7. The PTE may issue non-substantive changes to the Budget Period(s) and Budget Bilaterally. Unilateral modification shall be considered valid 14 days after receipt unless otherwise indicated by Subrecipient when sent to Subrecipient's Authorized Official Contact, as shown in Attachment 3B.
8. Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.
9. Either party may terminate this Subaward with 30 days written notice. Notwithstanding, if the Awarding Agency terminates the Federal Award, PTE will terminate in accordance with Awarding Agency requirements. PTE notice shall be directed to the Authorized Official Contact, and Subrecipient notice shall be directed to the Authorized Official Contact as shown in Attachments 3A and 3B. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix IX, as applicable.
10. By signing this Subaward, including the attachments hereto which are hereby incorporated by reference, Subrecipient certifies that it will perform the Statement of Work in accordance with the terms and conditions of this Subaward and the applicable terms of the Federal Award, including the appropriate Research Terms and Conditions ("RTCs") of the Federal Awarding Agency, as referenced in Attachment 2. The parties further agree that they intend this subaward to comply with all applicable laws, regulations, and requirements.

By an Authorized Official of the PTE:		By an Authorized Official of the Subrecipient:	
<div style="display: flex; justify-content: space-between;"> <div>Name: _____</div> <div>Date: _____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Title: _____</div> <div></div> </div>		<div style="display: flex; justify-content: space-between;"> <div> <small>DocuSigned by:</small>  <small>D68EAF4F4E034471</small> Nikolaj Gilbert </div> <div>January 14, 2022</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Name: _____</div> <div>Date: _____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Title: CEO & President</div> <div></div> </div>	

Attachment 1

Certifications and Assurances

Subaward Number:

141061-SPC003572

Certification Regarding Lobbying (2 CFR 200.450)

By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief, that no Federal appropriated funds have been paid or will be paid, by or on behalf of the Subrecipient, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement in accordance with 2 CFR 200.450.

If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or intending to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the Subrecipient shall complete and submit Standard Form -LLL, "Disclosure Form to Report Lobbying," to the PTE.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by 31 U.S.C. 1352. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

Debarment, Suspension, and Other Responsibility Matters (2 CFR 200.214 and 2 CFR 180)

By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief that neither the Subrecipient nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this transaction by any federal department or agency, in accordance with 2 CFR 200.213 and 2 CFR 180.

Audit and Access to Records

Subrecipient certifies that it will provide PTE with notice of any adverse findings which impact this Subaward. Subrecipient certifies compliance with applicable provisions of 2 CFR 200.501-200.521. If Subrecipient is not required to have a Single Audit as defined by 200.501, Awarding Agency requirements, or the Single Audit Act, then Subrecipient will provide notice of the completion of any required audits and will provide access to such audits upon request. Subrecipient will provide access to records as required by parts 2 CFR 200.337 and 200.338 as applicable.

Program for Enhancement of Contractor Employee Protections (41 U.S.C 4712)

Subrecipient is hereby notified that they are required to: inform their employees working on any federal award that they are subject to the whistleblower rights and remedies of the program; inform their employees in writing of employee whistleblower protections under 41 U.S.C §4712 in the predominant native language of the workforce; and include such requirements in any agreement made with a subcontractor or subgrantee.

The Subrecipient shall require that the language of the certifications above in this Attachment 1 be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

Use of Name

Neither party shall use the other party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may use factual information regarding the existence and purpose of the relationship that is the subject of this Subaward for legitimate business purposes, to satisfy any reporting and funding obligations, or as required by applicable law or regulation without written permission from the other party. In any such statement, the relationship of the parties shall be accurately and appropriately described.

Prohibition on Certain Telecommunication and Video Surveillance Services or Equipment

Pursuant to 2 CFR 200.216, Subrecipient will not obligate or expend funds received under this Subaward to: (1) procure or obtain; (2) extend or renew a contract to procure or obtain; or (3) enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that uses covered telecommunications equipment or services (as described in Public Law 115-232, section 889) as a substantial or essential component of any system, or as a critical technology as part of any system.

Attachment 2

Federal Award Terms and Conditions

Subaward Number

141061-SPC003572

Required Data Elements

The data elements required by Uniform
Guidance are incorporated in the attached Federal Award.

Awarding Agency Institute (If Applicable)

USAID

Federal Award Issue Date FAIN Assistance Listing No.

09/22/21

7200AA21CA00033

98.001

Assistance Listing Program Title (ALPT)

USAID Foreign Assistance for Programs Overseas

Key Personnel Per NOA

Ch. Rabiner; B.T. Leader

This Subaward Is:

Research & Development



Subject to FFATA

General Terms and Conditions

By signing this Subaward, Subrecipient agrees to the following:

1. To abide by the conditions on activities and restrictions on expenditure of federal funds in appropriations acts that are applicable to this Subaward to the extent those restrictions are pertinent. This includes any recent legislation noted on the Federal Awarding Agency's website:

<https://www.usaid.gov/who-we-are/agency-policy>

2. 2 CFR 200

3. The Federal Awarding Agency's grants policy guidance, including addenda in effect as of the beginning date of the period of performance or as amended found at:

<https://www.usaid.gov/ads/policy/300/303>

4. Research Terms and Conditions, including any Federal Awarding Agency's Specific Requirements found at:

see attachment #6

except for the following :

- a. No-cost extensions require the written approval of the PTE. Any requests for a no-cost extension shall be directed to the Authorized Official Contact shown in Attachment 3A, not less than 30 days prior to the desired effective date of the requested change.
- b. Any payment mechanisms and financial reporting requirements described in the applicable Federal Awarding Agency Terms and Conditions and Agency-Specific Requirements are replaced with Terms and Conditions (1) through (4) of this Subaward; and
- c. Any prior approvals are to be sought from the PTE and not the Federal Awarding Agency.
- d. Title to equipment as defined in 2 CFR 200.1 that is purchased or fabricated with research funds or Subrecipient cost sharing funds, as direct costs of the project or program, shall vest in the Subrecipient subject to the conditions specified in 2 CFR 200.313.
- e. Prior approval must be sought for a change in Subrecipient PI or change in Key Personnel (defined as listed on the NOA).

5. Treatment of program income: Additive

Special Terms and Conditions:**Data Sharing and Access:**

Subrecipient agrees to comply with the Federal Awarding Agency's data sharing and/or access requirements as reflected in the NOA or the Federal Awarding Agency's standard terms and conditions as referenced in General Terms and Conditions 1-4 above.

Provided upon request

is a Data Management and/or Sharing Plan that incorporates additional requirements as submitted to the Federal Awarding Agency.

Data Rights:

Subrecipient grants to PTE the right to use data created in the performance of this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Copyrights:

Subrecipient Shall Grant to PTE an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted material (including any computer software and its documentation and/or databases) first developed and delivered under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Subrecipient grants to PTE the right to use any written progress reports and deliverables created under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its Federal Award.

Promoting Objectivity in Research (COI):

Subrecipient must designate herein which entity's Financial Conflicts of Interest policy (COI) will apply: Subrecipient

If applying its own COI policy, by execution of this Subaward, Subrecipient certifies that its policy complies with the requirements of the relevant Federal Awarding Agency as identified herein: US Agency for International Development

Subrecipient shall report any financial conflict of interest to PTE's Administrative Representative or COI contact, as designated on Attachment 3A. Any financial conflicts of interest identified shall, when applicable, subsequently be reported to Federal Awarding Agency. Such report shall be made before expenditure of funds authorized in this Subaward and within 45 days of any subsequently identified COI.

Work Involving Human or Vertebrate Animals (Select Applicable Options)☐ No Human or Vertebrate Animals

IRB

Upon Request

☒ Human Subjects

IACUC

Upon Request

☒ Vertebrate Animals*The PTE requires verification of IRB and/or IACUC approval be sent to the **Administrative Contact** as required above:*

Subrecipient agrees that any non-exempt human and/or vertebrate animal research protocol conducted under this Subaward shall be reviewed and approved by the appropriate Institutional Review Board (IRB) and/or its Institutional Animal Care and Use Committee (IACUC), as applicable and that it will maintain current and duly approved research protocols for all periods of the Subaward involving human and/or vertebrate animal research. Subrecipient certifies that the appropriate IRB and/or IACUC are in full compliance with applicable state and federal laws and regulations. The Subrecipient certifies that any submitted IRB / IACUC approval represents a valid, approved protocol that is entirely consistent with the Project associated with this Subaward. In no event shall Subrecipient invoice or be reimbursed for any human or vertebrate animals related expenses incurred in a period where any applicable IRB / IACUC approval is not properly in place.

Human Subjects Data (Select One)

Applicable

Human Subjects Data will be exchanged under this Subaward (check all that apply):

The PTE will set forth the terms of the exchange of Human Subjects Data (Select One):

☒ From Subrecipient to PTE☒ From PTE to Subrecipient

Via a separate Data Use Agreement

This section left intentionally blank

Additional Terms

Subawards issued under this award are subject to additional USAID approval.

If applicable, Subrecipient certifies that its Institutional Biosafety committee is in full compliance with applicable state and federal laws and regulations. Subrecipient agrees that any non-exempt research involving recombinant or synthetic nucleic acid molecules or select agents conducted under this agreement shall be reviewed and approved by its Institutional Biosafety Committee, as applicable. In Addition, Subrecipient will maintain current and duly approved research protocols for all periods of the Agreement involving recombinant or synthetic nucleic acid molecules or select agents.

The Subrecipient certifies that any submitted recombinant or synthetic nucleic acid molecules or select agents approval represents a valid, approved protocol that is entirely consistent with project associated with this subaward. In no event shall subrecipient invoice or be reimbursed for any recombinant or synthetic nucleic acid molecules or select agents related expense incurred in a period where any applicable IRB/IACUC approval is not properly in place.

In addition to other applicable provisions in the NOA, the mandatory provisions for U.S. Nongovernmental organizations found in the NOA as part of Attachment 6 (Pages 40-65 of this subaward) are incorporated by reference into this subaward.

Attachment 3A
Pass-Through Entity (PTE) Contacts

Subaward Number:

141061-SPC003572

PTE Information

Entity Name: Washington State University

Legal Address: Office of Research Support and Operations
280 Lighty
PO Box 641060
Pullman, WA 99164-1060Website: <https://orso.wsu.edu/>**PTE Contacts**

Central Email: orso@wsu.edu

Principal Investigator Name: Felix Lankester

Email: felix.lankester@wsu.edu

Telephone Number:

Administrative Contact Name: Chana Rabiner

Email: chana.rabiner@wsu.edu

Telephone Number:

COI Contact email (if different to above): orso@wsu.edu

Financial Contact Name: Casey St. Clair, Director, Sponsored Programs

Email: sps@wsu.edu

Telephone Number: (509) 335-2058

Email invoices? ☒ Yes ☐ No Invoice email (if different): ayager@wsu.edu

Authorized Official Name: Dan Nordquist, AVP ORSO

Email: orso@wsu.edu

Telephone Number: (509) 335-9661

PI Address:Washington State University
Paul G. Allen School for Global Animal Health
PO Box 647090
Pullman WA 99164-7090**Administrative Address:**Washington State University
Office of Research Support and Operations
PO Box 641060
Pullman, WA 99164-1060**Invoice Address:**Washington State University
Sponsored Programs Services
PO Box 641025
Pullman, WA 99164-1025

Attachment 3B**Research Subaward Agreement
Subrecipient Contacts**

Subaward Number:

141061-SPC003572

Subrecipient Information for [FFATA](#)

reporting Entity's UEI/DUNS Name: PATH

EIN No.:

40

Institution Type:

Nonprofit with 501c3 Status (other than Inst. of Higher Ed.)

UEI / DUNS:

DUNS: 18

UEI: 18

Currently registered in SAM.gov: ☒ Yes ☐ NoExempt from reporting executive compensation: ☒ Yes ☐ No (if no, complete 3Bpg2)

Parent UEI / DUNS: N/A

This section for U.S. Entities:

Zip Code [Look-up](#)

Congressional District: WA-007

Zip Code+4: 98121-2778

Place of Performance Address2201 Westlake Avenue, Suite 200
Seattle, WA 98121-2778
United States**Subrecipient Contacts**

Central Email:

awards@path.org

Website:

www.path.org

Principal Investigator Name:

Linda Venczel

Email:

lvenczel@path.org

Telephone Number:

206-830-0250

Administrative Contact Name:

Ashima Tandan

Email:

atandan@path.org

Telephone Number:

206-285-3500

Financial Contact Name:

Rosa Joncich

Email:

rjoncich@path.org

Telephone Number:

206-285-3500

Invoice Email:

accountspayable@path.org

Authorized Official Name:

Nikolaj Gilbert

Email:

awards@path.org

Telephone Number:

206-285-3500

Legal Address:2201 Westlake Avenue, Suite 200
Seattle, WA 98121-2778
United States**Administrative Address:**2201 Westlake Avenue, Suite 200
Seattle, WA 98121-2778
United States**Payment Address:**2201 Westlake Avenue, Suite 200
Seattle, WA 98121-2778
United States

Attachment 3B Page 2
Research Subaward Agreement
Highest Compensated Officers

Subaward Number:

141061-SPC003572

Subrecipient

Entity Name: PATH

PI Name: Linda Venczel

Highest Compensated Officers

The names and total compensation of the five most highly compensated officers of the entity(ies) must be listed if the entity in the preceding fiscal year received 80 percent or more of its annual gross revenues in Federal awards; and \$25,000,000 or more in annual gross revenues from Federal awards; and the public does not have access to this information about the compensation of the senior executives of the entity through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. See FFATA § 2(b)(1) Internal Revenue Code of 1986.

Officer 1 Name:

Officer 1 Compensation:

Officer 2 Name:

Officer 2 Compensation:

Officer 3 Name:

Officer 3 Compensation:

Officer 4 Name:

Officer 4 Compensation:

Officer 5 Name:

Officer 5 Compensation:

Attachment 4

Reporting and Prior Approval Terms

Subaward Number:

141061-SPC003572

Subrecipient agrees to submit the following reports (PTE contacts are identified in Attachment 3A):

Technical Reports:

- ☐ Monthly technical/progress reports will be submitted to the PTE's Administrative Contact within 15 days of the end of the month.
- ☐ Quarterly technical/progress reports will be submitted within 30 days after the end of each project quarter to the PTE's Administrative Contact.
- ☒ Annual technical / progress reports will be submitted within 60 days prior to the end of each budget period to the PTE's Administrative Contact. Such report shall also include a detailed budget for the next Budget Period, updated other support for key personnel, certification of appropriate education in the conduct of human subject research of any new key personnel, and annual IRB or IACUC approval, if applicable.
- ☒ A Final technical/progress report will be submitted to the PTE's Administrative Contact within 45 days of the end of the Project Period or after termination of this award, whichever comes first.
- ☒ Technical/progress reports on the project as may be required by PTE's Administrative Contact in order for the PTE to satisfy its reporting obligations to the Federal Awarding Agency.

Prior Approvals:

Carryover:

Carryover is automatic

Other Reports:

- ☒ In accordance with 37 CFR 401.14, Subrecipient agrees to notify both the Federal Awarding Agency via iEdison and PTE's Financial Contact within 60 days after Subrecipient's inventor discloses invention(s) in writing to Subrecipient's personnel responsible for patent matters. The Subrecipient will submit a final invention report using Federal Awarding Agency specific forms to the PTE's Financial Contact within 60 days of the end of the Project Period to be included as part of the PTE's final invention report to the Federal Awarding Agency.

A negative report is required: Yes

- ☒ Property Inventory Report (only when required by Federal Awarding Agency), specific requirements below.

Additional cost sharing requirements included below:

Additional Technical and Reporting Requirements:

Subrecipients shall list each country included in the program and the total amount expended for each country when submitting financial reports. These will be noted to each partner as countries are onboarded.

Kenya 615-GH-W	141061-SPC003573
Senegal 685-GH-W	141061-SPC003574
Peru 527-GH-W	141061-SPC003575
Vietnam 440-GH-W	141061-SPC003576
Thailand 493-GH-W	141061-SPC003577

There may be additional reporting requirements and ad hoc information requests including, but not limited to, those associated with Mission buy-ins or additional sources of funding provided to DEEP VZN. Ad hoc refers to an unscheduled report for immediate, specific use. These requests will need to be approved by USAID.

Title of property financed under this award shall vest with the recipient subject to the requirements of 2 CFR 200.311-200.316, until such time as USAID issues disposition instructions. Please see A.7 in prime award.

Subaward Number:

141061-SPC003572

Attachment 5

Statement of Work, Cost Sharing, Indirects & Budget

Statement of Work

☐ Below ☒ Attached, pages

If award is FFATA eligible and SOW exceeds 4000 characters, include a *Subrecipient Federal Award Project Description*

PATH will leverage its strong country offices and national and local relationships to lead activities in Senegal, Vietnam, and India. PATH will also provide expertise and technical assistance throughout the four project objectives.

Objective 1: Provide technical input at global level and lead implementation of activities in PATH-led countries. PATH will design and implement One Health sampling strategies and activities, including along the value chain.

Objective 2: Contribute to defining stakeholder requirements for candidate detection technologies, identifying, and selecting appropriate technologies to best meet these needs, and providing technical assistance to laboratory sites during implementation and use of new methods for viral detection.

Objective 3: Contribute to the consortium's understanding of risk, which is essential for efficient use of resources for precision targeted surveillance, prevention, and preparedness through novel virus characterization. PATH will assist with method selection and facilitating an enabling environment to share samples and data among local, regional, and international partners.

Objective 4: Lead the objective, providing thought leadership for data management, system integration and interoperability, data analysis and sharing. This includes data, findings, and analyses from objectives 1, 2, and 3, using country data systems to avoid duplication, and sharing information across sectors to support a One Health approach.

Budget Information

Indirect Information Indirect Cost Rate (IDC) Applied

%

Cost Sharing

Rate Type:

If Yes, include Amount: \$

Budget Details

☒ Below ☐ Attached, pages

Salaries - \$110,672

Benefits - \$31,368

F&A - \$

Total - \$195,866

Only partial budget at this time is being submitted until USAID approves the project workplan and budget detail.

Budget Totals

Direct Costs \$

Indirect Costs \$

Total Costs \$

All amounts are in United States Dollars

Attachment 6

Notice of Award (NOA) and any additional documents



The following pages include the NOA and if applicable any additional documentation referenced throughout this Subaward.



Not incorporating the NOA or any additional documentation to this Subaward.



September 22, 2021

Dan Nordquist
Associate Vice President for Research
Washington State University
P.O. Box 641060
Pullman, WA 99164-1060
orso@wsu.edu

Reference: Award No. Titled "Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)" Cooperative Agreement 7200AA21CA00033

Dear Dan Nordquist:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, the U.S. Agency for International Development (USAID) hereby awards to Washington State University, hereinafter referred to as the "Recipient", the sum of \$124,679,896 to provide support for a program titled "Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)", as described in the Schedule of this award and in Attachment B, entitled "Program Description."

This Cooperative Agreement will be effective October 1, 2021. Obligation will be made upon receipt of the Recipient's acknowledgement and shall apply to expenditures made by the Recipient in furtherance of program objectives during the period beginning with the effective date October 1, 2021 and ending September 30, 2026. USAID will not be liable for reimbursing the Recipient for any costs in excess of the obligated amount.

This Cooperative Agreement is made to Washington State University, on condition that the funds will be administered in accordance with the terms and conditions as set forth in Attachment A (the Schedule), Attachment B (the Program Description), Attachment C (the Standard Provisions), and Attachment D (the Branding & Marking Plan) all of which have been agreed to by your organization.

Please sign the second page of this cover letter to acknowledge your receipt of this award and e-mail a copy of only the signed page to Anna Nelson at annelson@usaid.gov with a cc: to Patricia Bradley at pbradley@usaid.gov.

Sincerely,

Patricia Elena Bradley
(affiliate)
Patricia Bradley
Agreement Officer

Digitally signed by Patricia Elena
Bradley (affiliate)
Date: 2021.09.22 10:24:23 -04'00'

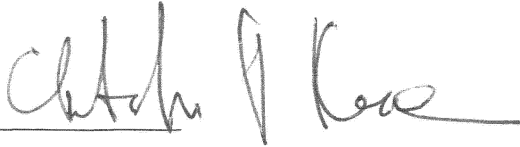
Washington State University
Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)
Cooperative Agreement 7200AA21CA00033

Attachments:

- A. Schedule
- B. Program Description
- C. Standard Provisions
- D. Branding & Marking Plan

ACKNOWLEDGED BY:

NAME: Christopher J. Keane



TITLE: Vice President for Research, WSU and Vice Chancellor for Research, WSU Pullman

DATE: 9/23/2021

Washington State University
Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)
Cooperative Agreement 7200AA21CA00033

ACCOUNTING AND APPROPRIATION DATA

A. GENERAL

1. Amount Obligated this Action: \$ 10,000,000
 2. Total Estimated USAID Amount: \$124,679,896
 3. Total Obligated USAID Amount: \$ 10,000,000
 4. Cost-Sharing Amount (Non-Federal): \$ 6,607,682
 5. Activity Title: “Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)”
 6. USAID Technical Office: GH/ID/ETD
 7. Tax I.D. Number: 40
 8. DUNS No.: 18
 9. LOC Number: 42A5P

B. SPECIFIC

GLAAS Requisition: REQ-GH-21-000020

Account ID	Accounting Template	BBFY	EBFY	Fund	Operating Unit	Prog Area	Program Name	Dist Code	BGA	SOC	Funded Amount
1-1	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	615-GH-W	615	4100201	\$2,000,000
1-2	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	685-GH-W	685	4100201	\$2,000,000
1-3	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	440-GH-W	440	4100201	\$2,000,000
1-4	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	527-GH-W	527	4100201	\$2,000,000
1-5	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	493-GH-W	493	4100201	\$2,000,000

C. PAYMENT OFFICE

M/CFO/CMP Letter of Credit Office
USAID/Washington

USAID Office of Financial Management (M/CFO/CMP) prefers the submittal of invoices to be electronic. In addition to the required submission to the Agreement Officer’s Representative (AOR), please submit a copy of the invoices to loc@usaid.gov.

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ATTACHMENT A - SCHEDULE

A.1 PURPOSE OF AWARD

The purpose of this Cooperative Agreement is to provide support for the program described in Attachment B to this Cooperative Agreement entitled "Program Description."

A.2 PERIOD OF AWARD

1. The effective date of this Award is **October 1, 2021**. The estimated completion date of this Award is **September 30, 2026**.

A.3 AMOUNT OF AWARD AND PAYMENT

1. The total estimated amount of this Award for the period shown in A.2.1 above is \$124,679,897, not including cost share.
2. USAID hereby obligates the amount of \$10,000,000 for program expenditures during the period set forth in A.2.1 above and as encompassed in the Budget below. The recipient must use funds obligated under this award and any subsequent amendments from the specific Operating Units (OU) and Program Areas (PA) for activities approved in the award and detailed in the work plan, as applicable. Program disbursements for each OU/PA must not exceed the amounts specified in the Accounting and Appropriates data for each Operating Unit (OU) and Program Area (PA). The Recipient will be given written notice by the Agreement Officer if additional funds will be added.
3. As the obligated amount for the program shall equal the total USAID estimated amount of this Agreement, additional increments of funds may be obligated by USAID under this Agreement (by a unilateral modification to this Agreement), subject to availability of funds, successful performance by the Recipient, possible evaluation of the program, program priorities at the time, and the requirements of the 2 CFR 200.308.
4. Payment will be made to the Recipient by Letter of Credit in accordance with procedures set forth in 2 CFR 200 and 2 CFR 700.

A.4 AWARD BUDGET

The following is the Award Budget, including local cost financing items, if authorized. Revisions to this budget shall be made in accordance with 2 CFR 200 and 2 CFR 700.

TOTAL BUDGET

Cost Element	USD
Direct Costs	\$116,474,256
Indirect Costs	\$ 49
Total Federal Contribution	\$124,679,897
Cost Share	\$6,607,682
Total Program Cost	\$131,287,579

Washington State University is responsible for managing available funds. This agreement includes a ceiling amount and obligated amount that the recipient exceeds at its own risk.

A.5 PLANNING, REPORTING, AND EVALUATION

1. Financial Reporting:

The recipient must submit the Federal Financial Form (SF-425) on a quarterly basis via electronic format to the U.S. Department of Health and Human Services. The recipient also must submit a copy of the SF-425 to the Agreement Officer (AO) and the Agreement Officer's Representative (AOR). These financial reports are due no later than 30 calendar days at the end of each quarter based on the federal fiscal calendar. The recipient must submit final financial reports to USAID/Washington, M/CFO/CMP-LOC Unit, the AO, and the AOR. The recipient must also submit an electronic version of the final financial report to the U.S. Department of Health and Human Services in accordance with the paragraph above.

2. Performance Planning:

Implementation Plans

Annual implementation plans serve as a guide to activity implementation and detail how the recipient will use the implementation year to achieve the objectives of DEEP VZN. The implementation plan is intended to be an annual roadmap for USAID and the recipient. With approval from the AOR, reasonable and justifiable modifications can be made to improve the chances of achieving the medium- and long-term results of the award. The recipient must submit the following implementation and reporting documents in English. The AOR and recipient will agree on the appropriate format and length.

Implementation plans include, but are not limited to, the following:

- Annual work plans, including planned activities for the following year and any subsequent revisions
- International travel plans
- Planned expenditures
- Event planning/management
- International meeting preparation
- Material Transfer Agreement (MTA) risk mitigation plan
- Country-level Level of Effort (LOE) chart, to include any oversight provided by headquarters
- Protocol Development and Review Plan
- Biosecurity and Biosafety (BSBS) Plan

USAID requires the AOR approval of implementation plans annually to ensure alignment with stated goals, milestones and outputs. The implementation plan communicates how and when the recipient will complete project activities and is drafted annually to describe new activities. The AOR will ensure that the implementation plans fit within the scope, terms and conditions of the agreement.

First Year Work Plan and Budget

The recipient will submit a draft work plan for the first year within the first 90 calendar days of executing the award. Depending on the start date of the agreement, the first-year work plan may be less than a full year or more than a full year. The first-year work plan must include a detailed budget and budget narrative for the first year. As part of the First Year Work Plan submission, the recipient will include a supplementary annual work plan describing planned contributions to the GHSA on a template designated by the AOR. All work plans and budgets, including

significant revisions thereto, must be approved by the AOR.

Annual Work Plan and Budget

Starting with the second year of the award and for each subsequent year of performance thereafter, the recipient will submit annual work plans, budgets, and budget narratives to the AOR for the next federal fiscal year within 30 calendar days prior to the end of the current federal fiscal year in a format agreed upon by the AOR and the recipient. The recipient also will submit supplementary annual work plans describing planned contributions to the Global Health Security Agenda (GHSa) within a timeframe and on a template designated by the AOR.

Monitoring, Evaluation and Learning (MEL) Plan

The recipient will finalize a MEL plan for the life of DEEP VZN that derives from the activities outlined in the Program Description and submit it to the AOR within 90 calendar days of the award for approval. The MEL plan will outline key program interventions, indicators of achievement, associated annual and life-of-Activity targets and a learning agenda. The learning agenda will outline key questions to be addressed, a plan for addressing these questions, and a process for incorporating findings into program implementation and the detection and characterization of unknown viruses. Where appropriate, the MEL plan must track gender equality issues in implementing activities. The recipient will update the MEL plan annually and submit it as an attachment to the annual report.

Biosecurity and Biosafety (BSBS) Plan

The recipient will finalize a BSBS plan for the life of DEEP VZN and submit it to the AOR within 90 calendar days of the award for approval. The BSBS will outline all program interventions that have biosafety/biosecurity implications and steps (e.g. protocols, training) that will be taken to minimize risk.

Gender Action Plan

The recipient will conduct a gender analysis that assesses context and gender needs, including time constraints and participation limitations. This analysis will inform a subsequent gender action plan, which will be developed in collaboration with the USAID management team and finalized within 90 calendar days of the award and updated annually. The gender action plan will inform the Activity's technical approach as it relates to gender throughout the life of the Activity. It also will be used to inform the design of activities that seek to reduce opportunity gaps between men and women or address power differentials to promote gender equity. The gender action plans should be developed in conjunction with the Activity's monitoring, evaluation and learning plan, and progress should be reflected in annual work plans and performance reports.

Data Management Plan

A Data Management Plan (DMP) is a document that describes how the recipient will manage data during the project and what happens to the data after the project ends. The initial DMP, which will be developed in collaboration with the USAID management team, will be finalized within 90 calendar days of the award and updated semi-annually and annually.

A comprehensive DMP will discuss the following aspects of the data life cycle:

- Collect - How the data is collected and processed by the researcher.
- Assure - How to make sure the data is high quality and free of errors.
- Describe - How the data will be documented so that other researchers can use it.
- Preserve - How and where the data will be stored so that researchers can access it forever.

The data management plan will inform the Activity's technical approach as it relates to data throughout the life of the Activity. The data management plan should be developed in conjunction with the Activity's monitoring, evaluation and learning plan, and progress should be reflected in annual work plans and performance reports.

Closeout Plan

No later than six (6) months prior to the completion date of the agreement, the recipient will submit a demobilization plan for Agreement Officer's approval. The demobilization plan shall include: 1) a draft property disposition plan, 2) a plan for the phase-out of in-country operations, 3) a staffing discharge plan, 4) a delivery schedule for all reports or other deliverables required under the agreement, and 5) a timetable for completing all required actions in the demobilization plan, including the submission date of the final property disposition plan to the Agreement Officer.

3. Performance Reporting:

The recipient must submit via email a copy of semi-annual, annual, and final performance reports, in English, to the AOR in accordance with 2 CFR 200.328.

Semi-Annual and Annual Reports

The recipient will submit semi-annual and annual progress reports based on the federal fiscal calendar. The semi-annual report will be due within 30 days after the end of the reporting period and will cover the first six months of the year (October 1 - March 31). The annual report will cover the entire fiscal year (October 1 - September 30) and will be due within 90 days of the end of the federal fiscal year.

At a minimum, both semi-annual and annual reports will contain:

- Narrative description of activities completed and major accomplishments achieved during the reporting period in all countries supported by DEEP VZN, presented by objective
- Qualitative and quantitative data on program achievements and results
- Progress on standard and agreed upon indicators, as outlined in the MEL plan, including status towards achieving targets and explanations for significant deviations
- An updated MEL plan, including progress on the learning agenda (annually)
- An updated BSBS plan
- An updated Data Management plan
- Problems encountered and whether they were solved or are still outstanding
- Proposed solutions to ongoing or new problems
- Success stories, blogs, articles, publications, press releases, and photographs, if available
- Update on expenditures for the reporting period against the pipeline
- Analysis and explanation of cost overruns or high unit costs, when applicable
- Planned activities for the next performance period

Global Health Security Agenda (GHSA) reports

The Recipient will submit semi-annual GHSA performance reports within a timeframe and on a template designated by the AOR. The Recipient will submit the GHSA semi-annual reports to the AOR via email.

Ad Hoc Reports

There may be additional reporting requirements and ad hoc information requests including, but not limited to, those associated with Mission buy-ins or additional sources of funding provided to DEEP VZN. Ad hoc refers to an unscheduled report for immediate, specific use. USAID will define the purpose, content, and specific use for any ad hoc report.

Final Report

Within ninety (90) calendar days after the period performance date, the recipient will submit one (1) original and two (2) copies of the Final Report to the AOR and one (1) copy to the Agreement Officer. In addition, one (1) copy will be submitted to the Development Experience Clearinghouse:

- 1) Electronically: <http://www.usaid.gov/results-and-data/informationresources/developmentexperience-clearinghouse-dec>
or
- 2) By U.S. Postal Service delivery to:
U.S. Agency for International Development
Development Experience Clearinghouse
M/CIO/ITSD/KM
Ronald Reagan Building M. 01-010
Washington, DC 20523-6100

The Final Report must include a narrative report and summary table of results, a comparison of actual accomplishments to the objectives established for the period of performance, and a gender analysis that describes how gender equality issues were tracked and addressed. It should highlight accomplishments against implementation plans; outline progress of benchmarks against targets; describe results; and document lessons learned during implementation. The Final Report also must contain a three-page executive summary, an index of all reports and information products produced under the agreement, and a summary of the program's finances. More details on the format of the final report will be provided after the award.

A.6 INDIRECT COST RATE

Allowable indirect costs shall be reimbursed on the basis of the following negotiated Colleges and Universities Rate Agreement, dated August 20, 2019.

INDIRECT COST RATES:

TYPE	FROM	TO	LOCATION	RATE%	APPLICABLE TO
Predetermined	7/1/2019	6/30/2023	On-Campus	49	Organized Research
			Off-Campus	49	Organized Research
			On-Campus	49	Instruction
			Off-Campus	49	Instruction
			On-Campus	49	Other Sponsored Activities
			Off-Campus	49	Other Sponsored Activities
Provisional	7/1/2023	Until Amended	Use same rates and conditions as those cited for fiscal year ending June 30, 2023.		

Base

Modified total direct costs, consisting of all salaries and wages, fringe benefits, materials, supplies, services, travel and subgrants and subcontracts up to the first \$25,000 of each

subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). Modified total direct costs shall exclude equipment, capital expenditures, charges for patient care, student tuition remission, rental costs of off-site facilities, scholarships, and fellowships as well as the portion of each subgrant and subcontract in excess of \$25,000.

A.7 TITLE TO PROPERTY

Title of property financed under this award shall vest with the recipient subject to the requirements of 2 CFR 200.311-200.316, until such time as USAID issues disposition instructions.

Furthermore, the following requirements apply regarding the use, care, accountability, maintenance, and disposition thereof:

(a) Tangible Property

(1) Equipment: “Equipment” means an article of tangible nonexpendable personal property having a useful life of one year or more and a per-unit acquisition cost (purchase price) of \$5,000 or more. Equipment is subject to the requirements set forth in 2 CFR 200.313.

(2) Supplies and Other Expendable Equipment: “Supplies and other expendable equipment” means items of tangible personal property that do not meet the definition of “equipment” in paragraph (a)(1) above. Supplies and other expendable equipment are subject to the requirements set forth in 2 CFR 200.314.

(3) Real Property: “Real property” means land, land improvements, structures, and appurtenances thereto. Real property is subject to the requirements set forth in 2 CFR 200.311.

(b) Intangible (Intellectual) Property

“Intangible property” means, but is not limited to, copyrights, inventions and patents, and data first produced under this Agreement. Intangible property is subject to the requirements set forth in 2 CFR 200.315.

A.8 AUTHORIZED GEOGRAPHIC CODE

The authorized geographic code for procurement of goods and services under this award is 935.

A.9 COST SHARING

The Recipient will contribute 5.03% percent of the total obligated amount of the award, excluding the sub-awards to the networks, as cost share throughout the life of the project. The cost share contribution shall be listed per cost category and presented in the work plan budgets.

Description	USD
Federal Amount Subject to Cost Share	\$124,679,897
Proposed Cost Share Amount	\$6,607,682
Cost Share Percentage	5.03%
Total Project Amount	\$131,287,579

A.10 SUBSTANTIAL INVOLVEMENT

a. Approval of the Recipient’s Annual Implementation Plans:

Implementation plans include, but are not limited to, annual work plans, budget and budget narrative, including planned activities for the following year and any subsequent revisions, international travel plans, planned expenditures, event planning/management, international meeting preparation, MTA risk mitigation plan, country-level LOE chart, to include any oversight provided by headquarters, and protocol development and review plan.

USAID requires AOR approval of implementation plans annually to ensure alignment with stated goals, milestones and outputs. Each implementation plan communicates how and when the recipient will complete project activities and is drafted annually to describe new activities. This plan will be developed in partnership between the recipient and the AOR team. The AOR will ensure that each implementation plan fits within the scope, terms and conditions of the agreement.

b. Approval of Specified Key Personnel:

Designation of key personnel positions, approval of key personnel and any changes for the positions listed below:

- Project Director
- Deputy Project Director/Operational Lead

All individuals proposed as Key Personnel in the Recipient’s application are hereby approved. Any future approval of key personnel will be authorized by the Agreement Officer in a separate administrative letter. The Recipient must submit to the AOR, reasonably in advance, any proposed replacement (including proposed substitutions) along with written justification in sufficient detail to permit evaluation of the impact on the program. Any proposed replacement Key Personnel must meet the minimum requirements stated in the Notice of Funding Opportunity (NOFO) number 7200AA21RFA00005, Section D.5.g). No replacement shall be made by the Recipient without the written consent of the Agreement Officer.

c. Agency and Recipient Collaboration or Joint Participation:

- Collaborative involvement in the selection of advisory committee members, if the recipient establishes an advisory committee that provides advice to the recipient. The AOR may participate as a member of this committee. Advisory committees must only deal with programmatic or technical issues and not routine administrative matters.
- Collaborative involvement in the selection of countries, viruses, and interfaces.
- USAID review and approval of monitoring, evaluation, and learning plans.
- USAID review and approval of data management plans.
- USAID involvement in the substantive direction/re-direction of interrelationships with other projects.
- USAID involvement in monitoring progress toward achievement of the Objectives and Expected Achievements during the course of the Agreement(s) and in monitoring of financial expenditures.

d. Direction and Redirection:

USAID will be involved in the substantive direction/re-direction of inter-relationships with other projects.

A.11 PROGRAM INCOME

The Recipient shall account for Program Income in accordance with 2 CFR 200.307 (or the Standard Provision entitled Program Income for non-U.S. organizations). Program Income earned under this award shall be added to the project.

A.12 AGREEMENT OFFICER'S REPRESENTATIVE

The Agreement Officer's Representative (AOR) for this Agreement will be designated in a separate memorandum from the Agreement Officer to the AOR with copy to the Recipient and the payment office.

A.13 SPECIAL PROVISIONS

A.13.1 SUBAWARD APPROVAL

Pursuant to the approved budget of this cooperative agreement, the following sub-awards are approved. All other sub-awards are subject to additional USAID approval.

Sub-awardee

University of Washington – UW
Family Health International 360 – FHI 360
PATH
Washington University at Saint Louis – WUSTL
Duke University

A.13.2 COUNTRY-BY-COUNTRY BREAKDOWN OF EXPENDITURES

The Recipient shall list each country included in the program and the total amount expended for each country under the award for the reporting period in the "Remarks" block on the "Financial Status Report" SF 425, or on a separate sheet of paper with the "Request for Advance or Reimbursement" SF 270.

A.13.3 BRANDING STRATEGY & MARKING PLAN

The Recipient shall submit within 30 calendar days of award, a Branding Strategy and Marking Plan. Upon the approval of the AO and AOR, the plan shall be incorporated as Attachment D.

A.13.4 ENVIRONMENTAL COMPLIANCE

The Foreign Assistance Act of 1961, as amended, Section 117 requires that the impact of USAID's activities on the environment be considered and that USAID include environmental sustainability as a central consideration in designing and carrying out its development programs. This mandate is codified in Federal Regulations (22 CFR 216) and in USAID's Automated Directives System (ADS) Parts 201.5.10g and 204 (<http://www.usaid.gov/policy/ADS/200/>), which, in part, require that the potential environmental impacts of USAID-financed activities are

identified prior to a final decision to proceed and that appropriate environmental safeguards are adopted for all activities. The recipient's environmental compliance obligations under these regulations and procedures are specified in the following paragraphs of this cooperative agreement.

In addition, the recipient must comply with host country environmental regulations unless otherwise directed in writing by USAID. In case of conflict between host country and USAID regulations, the latter shall govern.

No activity funded under this cooperative agreement will be implemented unless an environmental threshold determination, as defined by 22 CFR 216, has been reached for that activity, as documented in a Request for Categorical Exclusion (RCE), Initial Environmental Examination (IEE), or Environmental Assessment (EA) duly signed by the Bureau Environmental Officer (BEO). (Hereinafter, such documents are described as "approved Regulation 216 environmental documentation.")

As part of its initial Work Plan, and all Annual Work Plans thereafter, the Recipient, in collaboration with the USAID AOR and Mission Environmental Officer or Bureau Environmental Officer, as appropriate, shall review all ongoing and planned activities under this cooperative agreement to determine if they are within the scope of the approved Regulation 216 environmental documentation.

If the Recipient plans any new activities outside the scope of the approved Regulation 216 environmental documentation, it shall prepare an amendment to the documentation for USAID review and approval. No such new activities shall be undertaken prior to receiving written USAID approval of environmental documentation amendments.

Any ongoing activities found to be outside the scope of the approved Regulation 216 environmental documentation shall be halted until an amendment to the documentation is submitted and written approval is received from USAID.

A.13.5 OPEN DATA AND DATA SHARING

The recipient will be expected to comply with the Office of Management and Budget's Open Data Policy, as well as any USAID open data policy. Relevant MEL related data, knowledge and specifically lessons learned from sampling, discovery, characterization, and data analysis and use will be documented. All final data sets that USAID and the recipient deem as valuable to its stakeholders shall be submitted to USAID in a reliable media prior to the award end date and will be available for dissemination as appropriate. During the term of the agreement, preliminary data and analysis will be submitted to USAID on a periodic basis, but no less than annually, as agreed upon by USAID and recipient during work planning.

A.13.6 ORGANIZATIONAL CONFLICT OF INTEREST

Recipient must adhere to conflict of interest regulations found in 2 CFR 200.112 and 2 CFR 200.318(c)(1).

A.13.7 COORDINATION, COMMUNICATION, AND COLLABORATION

Coordination, communication and collaboration among stakeholders facilitate trust and mutual understanding; reduce redundancy; increase synergy, scalability, and impact; and promote learning and mutual accountability. DEEP VZN is expected to build and enhance constructive

partnerships, as appropriate. DEEP VZN will collaborate and coordinate with a wide variety of stakeholders, including country National NTD Programs, Ministries of Health and other relevant government entities; USAID Missions and Country Offices, USG partners, bilateral and multilateral agencies; academic and research institutions; private sector and philanthropic organizations; and civil society organizations.

A.14 SPECIAL REQUIREMENTS

A.14.1 FOR U.S. ORGANIZATIONS -- SPECIAL AWARD REQUIREMENT RELATING TO THE PROHIBITION ON CERTAIN TELECOMMUNICATION AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUGUST 2020)

- a. 2 CFR 200.216, “Prohibition on certain telecommunications and video surveillance services or equipment” implements Pub. L. 115-232, Section 889.
- b. USAID has been granted a temporary, limited waiver under Section 889(d)(2) that will allow the recipient to use award funds for the duration of this award to procure internet, cellular and landline services from communication service-providers who use covered telecommunications. All other costs incurred for covered telecommunications and video surveillance services or equipment, such as phones, video surveillance, and cloud servers specified in 2 CFR 200.216 remain unallowable in accordance with 2 CFR 200.471.

[End of Special Award Requirement]

A.14.2 FOR NON-U.S. ORGANIZATIONS -- SPECIAL AWARD REQUIREMENT RELATING TO THE PROHIBITION ON CERTAIN TELECOMMUNICATION AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUGUST 2020)

- a. The mandatory standard provision “Prohibition on Certain Telecommunication and Video Surveillance Services or Equipment (AUGUST 2020)” implements Pub. L. 115-232, Section 889.
- b. USAID has been granted a temporary, limited waiver under Section 889(d)(2) that will allow the recipient to use award funds for the duration of this award to procure internet, cellular and landline services from communication service-providers who use covered telecommunications. All other costs incurred for covered telecommunications and video surveillance services or equipment, such as phones, video surveillance, and cloud servers specified in the standard provision in paragraph a. above remain unallowable in accordance with the mandatory standard provision “Allowable Costs” and 2 CFR 200.471.

[End of Special Award Requirement]

[END OF ATTACHMENT A]

ATTACHMENT B – PROGRAM DESCRIPTION

EXECUTIVE SUMMARY

With an overarching goal of detecting ‘known unknown’ viruses that might pose a pre-pandemic threat, we will carry out an innovative, sustainable, and responsive surveillance program for detection and characterization of novel animal viruses with zoonotic potential. Our consortium, which includes University of Washington (UW), PATH, FHI360, and Washington University in St. Louis (WUSTL) is led by Washington State University’s (WSU) Allen School for Global Health, whose approach of placing full-time faculty in global regions has seen it lead innovative emerging infectious disease studies in East and Central Africa that target landscapes inhabited by humans, their livestock and diverse wildlife populations in ecosystems ideal for the maintenance and transmission of emerging zoonotic pathogens. The consortium features strong in-country partners supported by world class virology reference laboratories at UW and WUSTL involved in novel virus discovery and characterization, unparalleled experience in laboratory strengthening, One Health epidemiology and social science, and global reach. Apart from collective presence and institutional links in countries located in the six DEEP VZN global regions, our consortium partners bring complementary expertise, including global field studies and sampling by WSU and UW, laboratory capacity by WUSTL and UW, and data management and in-country stewardship by PATH, FHI360 and WSU. We will build on the achievements of the USAID EPT programs, and our collective prominence in the global NIH-supported Centers for Research in Infectious Diseases (NIH-CREID), to enable partner labs in focus countries to fully sequence and characterize novel viruses in unprecedented breadth and depth. We will leverage scientific breakthroughs with SARS CoV2 and other emerging viruses to apply cutting edge technologies to prioritize potential for viral spillover and pandemics. In focus countries, we will target high-risk locations and subpopulations at the human-animal interface using a risk-based analytical approach to guide sample collection where there is evidence of previous spillover or high prevalence of zoonotic viruses. Additionally, we will establish an efficient sample collection and transportation system and align capacities at in-country laboratories to identify viruses of zoonotic potential in a timely manner, thus triggering additional targeted sampling focused up- and downstream of the transmission chain.

We plan to collect over 800,000 samples, of which approximately 60% will come from wildlife. Assuming a 1-1.5% yield, our in-country labs will provide near-real time screening and genome sequencing to detect and characterize between 8,000 and 12,000 novel viruses from the target families over the five years of the DEEP VZN program. To effectively characterize viruses of zoonotic potential from the detected pool, we will use a combination of innovative molecular, protein structure and receptor analyses, and serological techniques to generate evidence of spillover to humans, and potential for human-to-human transmission. This consortium will also strengthen capacity within focus countries for continued assessment of viruses of zoonotic potential and enhance response to future outbreaks. To enhance sustainability, we will build in-country stewardship of all surveillance, diagnostic and data management activities through the development of meaningful partnerships with focus country stakeholders. Through engagement and integration with other USAID EPT efforts, NIH CREID networks and other professionals across human, animal, and environmental health sectors, we will promote meaningful sharing of resources and data in an inclusive and cost-effective One Health-approach. The overall outcomes of this program will be the detection of an unprecedented number of unknown viruses of pandemic potential that can be monitored by public health institutions worldwide, and significant

advances in our collective ability to characterize zoonotic and pandemic potential of emerging viruses.

OBJECTIVE 1: Conduct Sampling for Unknown Viruses from the Priority Viral Families

We have designed an efficient, responsive, and sustainable program that uses existing data and models on spillover risk to guide initial sampling and interim data to refine sampling targets.

Building on baseline detection of known viruses in the PREDICT, VIRION and EIDITH databases, our strategies will lead to the detection of previously unknown wildlife-origin viruses from the target families and identify a subset that pose a significant pandemic threat. Our

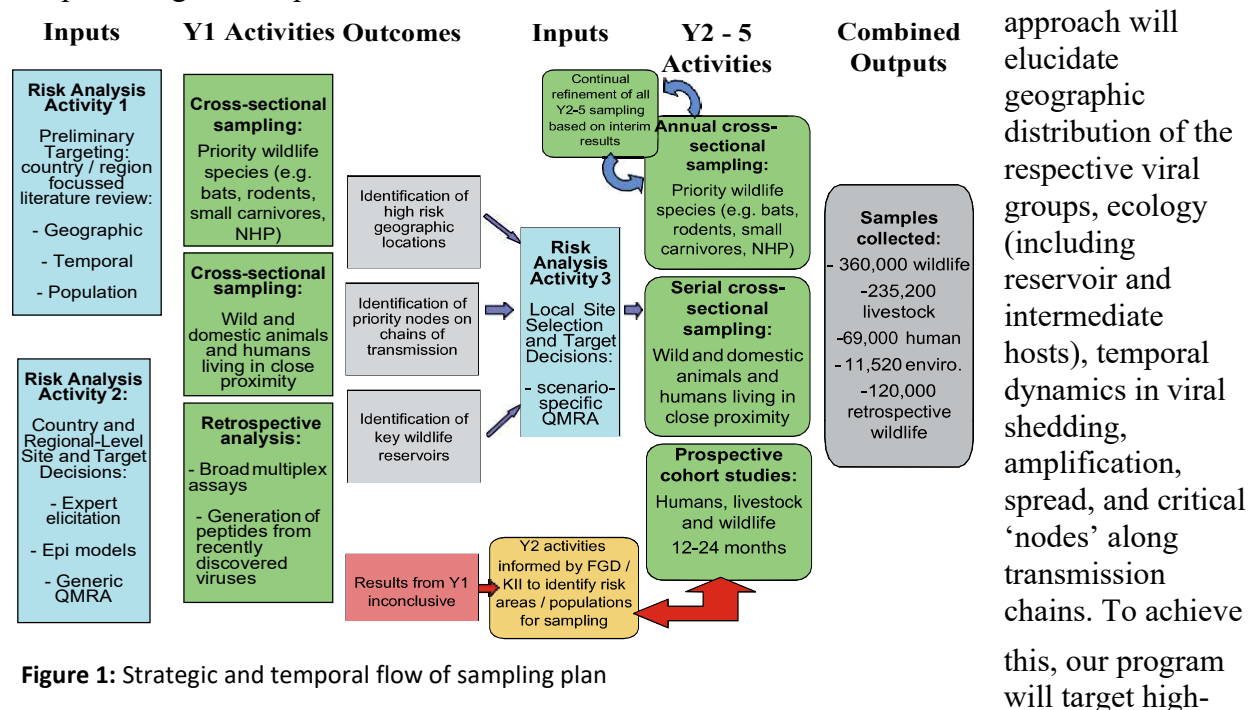


Figure 1: Strategic and temporal flow of sampling plan

risk locations and subpopulations at the human-animal interface, optimizing yield and resources (Fig. 1). This targeting will be adaptive, with locations identified through an iterative process informed by ongoing data collection. We will establish a pipeline of sample collection and transportation, aligned with capacities at existing in-country laboratories (utilizing a hub and spoke approach). Identification of a virus of zoonotic potential will trigger additional sampling focused up- and downstream on the transmission chain. Sampling will be guided by a risk-based analytical approach informed by evidence of a previous spillover event, a high prevalence of zoonotic viruses, or close contact between humans and reservoir hosts. Finally, we will employ a One Health-approach through engagement of human, animal, and environmental health sectors.

1.1 Sample Site and Species Selection

Focus 1: Preliminary Targeting - country/region focused literature review

To inform initial geographic, temporal, and species sampling plans and further risk-based targeting, we will carry out a rapid and comprehensive literature review (including grey literature and proceedings from meetings and One Health platforms) in Y1 to identify where prevalence and diversity of the target viral families are high, where critical nodes on chains of transmission are located, and key wildlife species are abundant (Focus 2 and Fig. 2).

Geographic Selection: We will use literature review, remote-sensed data, and existing risk maps of zoonotic disease emergence risk and its drivers to make a primary selection of geographic

areas of interest. Priority drivers of disease emergence will include human population density, land use change, density and diversity of wildlife species (focusing on mammalian species),

intensive farming of domestic and wild species, and live/wet wildlife markets. We will also leverage maps and data from PREDICT sampling data.

Temporal Selection: Viral (and host) seasonality and multiannual trends impact viral load and thus detection rates and will be critical determinants of sampling timeframes, particularly for wild animal sampling. The literature review will leverage existing knowledge of targeted viral families and host dynamics to inform our risk-based sampling strategies.

Population Selection: Country-specific literature review will identify wildlife and livestock species, human occupational groups, and value chains to consider for sampling.

Focus 2: Country and Regional-Level Site and Target Decisions - risk-based analysis Using a hybrid risk-based approach, we will refine geographic, temporal, and population targets defined by Focus 1 to plan the location and the timing of each sampling activity, with emphasis on identifying populations of wildlife, domestic animals, and humans on transmission chains. This approach will build upon existing knowledge from previous USAID-funded research projects, tailored to country-specific contexts. We will use available data and models and in-country stakeholder engagement, ensuring rapid site selection and start-up of project activities.

Epidemiological Models: In collaboration with key partners, such as the USAID-funded STOP Spillover project, in-country research institutions, and relevant government ministries, the team will review existing epidemiologic models (spatial and mathematical) of spillover risk parameterized to the geographic areas and populations identified in Focus 1. This work will both

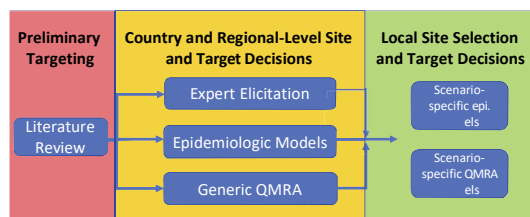


Fig. 2: Risk-based analytical approach to sample site selection

inform the structure of the epidemiologic models developed in Focus 3 and collate data for these later models. Existing models of viral and host seasonality, host dynamics in targeted wildlife populations, and seasonal trends in wild meat hunting will be used to plan sample timing. **Expert Elicitation:** In the absence of context- and site-specific data or relevant

epidemiologic models preclude the use of modeling to refine sampling plans, we will use an expert elicitation-based risk ranking approach to scope initial rounds of sampling.

QMRA: As part of a multimodal strategy, the team will develop prospective probabilistic models utilizing a quantitative microbial risk assessment (QMRA) approach to identify populations and areas of greatest risk and uncertainty. Such approaches have been used to estimate environmental risk of zoonoses transmission and provide a way to include viral load data into our risk prioritization process. As the magnitude of risk will likely be driven by scenario-specific exposures, updated models will be developed at the onset of the project following literature review and subsequently tailored to specific exposure scenarios (Fig. 2).

Focus 3: Local Site Selection and Target Decisions

Based on site- and context-specific information and models generated in Focus 2, detailed exposure modules will be incorporated into location-specific QMRA models, the findings of which will be triangulated with spatial epidemiologic models. These models will be informed by geolocated data indicating prior spillover events, presence of immunocompromised wildlife species, disturbances that increase physiological stress, human activities that facilitate wildlife contact, and high population density. We will develop an initial set of location specific QMRA models based on the sampling sites and data from PREDICT 1 & 2 and evaluate these models to identify sites with the greatest estimated risks and/or uncertainty. In concert with our QMRA models, we will use the computationally efficient stochastic partial differential equations approach to Gaussian process modelling to generate high-resolution maps of spillover risk in the

target geographies identified in Focus 1 - 3. Both models will be continually iterated as new data become available, and sampling sites/targets will be adjusted.

1.2 Sampling Targets

To reduce delay, as soon as each of Focus 1-3 is completed decisions on site identification and timing for initial rounds of sample collection can begin. We will use pre-existing models and computational frameworks to complete these models while sampling approvals are pending. Targeted sampling locations, timelines, and species will be refined through participatory workshops, including representatives from wildlife, human, livestock, and environmental health sectors, and supply chain mapping integrated with network data. Retail outlets for wildlife products will be the terminus of this mapping, with focus on the movement of animals or their products from their points of origin to consumers. Eco-centric network data and value chain data will be collected at each node to identify priority nodes for viral transmission.

Once sampling targets have been identified, we will use sampling methods selected based on population sampled, risk characterization, and country-context, including serial cross-sectional sampling and prospective cohort sampling. Where possible, serial cross-sectional sampling will be repeated in the same population to determine which viruses are adapting to humans (pre-pandemic viruses) and to allow development of interventions to mitigate transmission. In addition, we will use composite sampling to screen samples, with follow-up testing of discrete samples from positive composites to decrease cost and increase throughput. We will also collect socio-anthropological data at these high-risk locations to better understand human-animal-ecosystem interactions relevant to viral transmission. Sampling targets will include:

Wildlife: Focus 1-3 will identify sites for initial sampling and priority mammalian species.

Supplementing risk characterization, trait-based statistical modelling will be used to prioritize bat species for each viral taxon, which will be iteratively improved as more host-virus data become available. Within these sites and species, sampling will focus on populations likely to impact the animal value chain (wildlife or livestock), including free-ranging wild animals living near areas of intensive livestock farming, wild mammals in ecosystems recently fragmented by expanding human communities, farmed wild mammals and wild mammals sold in live/wet markets.

Domestic animals: Sampling will focus primarily on intensively farmed domestic species that are reservoirs or amplifying hosts for the targeted viral families, characterized in Focus 1-3.

Industrialized farms with poor biosecurity or ecosystem encroachment will be prioritized.

Humans: Sampling will focus on country-specific occupational groups (and controls) at highest risk for spillover already geographically and temporally linked to wildlife described above.

1.3 Country-level Strategic Sampling Approach*

**Specific sampling targets will vary by target country based on in-country context*

Task 1.1: Cross-sectional sampling of wild animals (priority species): We will implement cross-sectional sampling of populations of free ranging wild animals likely to host unknown species of known virus families and target physiologically and immunologically stressed populations (migratory populations/ those living in areas of intense land use change). The highest proportion of samples collected will be fecal matter (e.g., under-roost excreta) to optimize efficiency and sensitivity for viral surveillance and discovery, particularly for henipaviruses and coronaviruses. We will also collect and test wildlife meat from markets and traders.

Year 1: Sample teams: 3 per country, sampling for 45 days/year, collecting 40 samples/day;

Aim Per country: 5000 samples; **Target species:** Bats, rodents, small carnivore species, non-human primates (NHP); **Sample type:** Feces, blood, oral/rectal swabs;

Years 2–5: Sample teams: 3 per country, sampling for 21 days / year, collecting 40 samples/day; Prospective sampling informed by Y1 results; **Aim per country:** 2500 total samples/year; **Target species** and **Sample type:** as in Y1

Task 1.2: Cross-sectional sampling of animals and humans living in proximity:

Humans are frequently in contact with large aggregations of wildlife, such as rodents, bats, and small carnivore species. Such synanthropic wildlife species provide opportunities for spillover to amplifying reservoir species that have greater opportunities for pathogen sharing with humans. We will sample wildlife species among or near areas of intensive livestock farming, farmed wild animals, and wild animals sold in live/wet markets. We will also carry out composite sampling of human and livestock species through collection of fecal slurry (livestock) and sewage (human) samples, prioritizing sampling of environments where animals/humans have recently displayed signs of illness and sites characterized by recent disturbances of neighboring ecosystems. We will also sample domestic carnivores (dogs and cats) as these species typically range widely, scavenge, have contact with wildlife, livestock, and humans and are accessible for sampling.

Year 1: Wild animal sample teams: 3 per country, sampling for 45 days/year, collecting 40 samples/day; **Domestic animal sample teams:** 3 per country, sampling for 30 days/year, collecting 40 samples/day; **Human sample teams:** 3 per country, sampling for 45 days/year, collecting 10 samples/day; **Per country aim:** 5000 wildlife, 3600 domestic animal, 1350 human samples; **Target species:** Rodents, bats, domestic and wild carnivore species (e.g. domestic dogs/cats, civet cats), ungulates, poultry, humans; **Sample type:** Wildlife species: feces, blood, oral/rectal swabs; humans, livestock: composite sampling of fecal slurry and sewage

Years 2–5: Prospective sampling informed by Y1 results; **Wild animal sample teams:** 3 per country, sampling for 21 days/year, collecting 40 samples/day; **Domestic animal sample teams:** 3 per country, sampling for 14 days/year, collecting 40 samples/day; **Human sample teams:** 3 per country, sampling for 20 days/year, collecting 10 samples/day; **Per country aim:** 2500 wildlife, 1600 domestic animal, 600 human samples.

Task 1.3: Retrospective analysis of bio-banked samples: We will request access to bio-banked sera collected from wildlife species, including from previous USAID-funded projects such as PREDICT, in areas determined by our risk analysis activities to be hot-spot zones. Broad multiplex assays will allow identification of all ‘known knowns’ and refinement of subsequent sampling strategies (in Y2-5) to increase the probability of detecting ‘known unknown’ viruses. Additionally, novel peptides generated from recently discovered focus family viruses will allow contemporary viruses to be detected.

Year 1: Per country aim: Collection of up to 10,000 wildlife serum samples from in-country biobanks; **Target species:** Bats, rodents, small carnivore species, NHP

Task 1.4: Prospective cohort studies of humans, livestock, and farmed wildlife

Per country aim: **i) animal workers (human):** 200 blood samples twice/year; 200 risk factor questionnaires monthly; 10 semi-structured interviews monthly; 200 nasal wash samples monthly; **ii) controls (human):** 50 blood samples twice/year; 50 questionnaire surveys monthly; 50 nasal wash samples monthly; **iii) farmed animals:** 200 composite samples monthly; **iv) environmental samples:** 20 samples monthly (1 per farm/month), for example, composited waste water sample or barn air; **v) workplace:** 20 (1 per farm/month) x Animal Workplace Enrolment and Animal Workplace Follow-up Questionnaire; **Target species:** Humans, ungulates, poultry, farmed wildlife

Task 1.5: Responsive sampling in the face of an outbreak: In the face of emerging epidemics, opportunities to understand the epidemiology of an outbreak are lost because of delays

mobilizing sample collecting activities. SOPs and sampling teams will be prepared to undertake rapid collection of samples from wildlife and domestic animals in the immediate geographic area around an index case. We will remain in close communication with public and animal health disease reporting agencies so that disease outbreaks can trigger localized investigations.

1.4 Sample Size and Detection of Known Viruses

The more samples collected and tested, the higher the likelihood of detecting a previously unknown member of the target viral families. Collecting 300 samples from a given target species provides a 95% probability of detecting a virus present in at least 1% of individuals; Therefore, a risk-based approach to selecting animal species is critically important to optimize project resources. We will tether our collected data to baseline detection of known viruses in the PREDICT and VIRION databases and a beta-coronavirus specific database (<https://www.viralemergence.org/betacov>). This will allow estimation of expected prevalence and diversity for comparison with observed values for each viral family and host species. Following Y1 collection, detection, and viral characterization activities, we will use cluster detection algorithms to identify hotspots of prevalence or diversity of known viruses, triggering further focused sampling. Detection of known viruses in the three families provides a positive control.

1.5 Contingency Plans

Although the sampling plan is ambitious in scope we are confident that we can collect the numbers of samples listed. Key reasons for this are that we will a) focus sampling efforts on the collection of fecal matter, including composite slurry/sewage samples, which is an excellent sample type for viral discovery and relatively easy to collect; b) exploit sampling synergies within and between sampling targets, for example, sampling of humans, domestic animals, environments, and farmed wildlife will be carried out by single teams that focus on multiple sampling targets. This will make sample collection more efficient; and c) increase the number of sampling teams and / or sampling days if targets are not met. Finally, the plan will allow sampling targets to be exceeded in countries where collection is efficient, which will counterbalance more modest sampling outputs in less productive countries. It is also important to note that, for restrained animals, multiple samples will be collected (fecal, blood, swabs) and as such the estimated total number of samples refers just that and not number of animals sampled.

1.6 Outcomes

The outcomes of Y1 will be used to inform the strategic planning of the sampling activities in Y2 – 5. This site selection review will be an iterative process to determine whether to add new sampling sites. If outcomes from Y1 activities are inconclusive, sampling activities in Y2 – 5 will be informed through iterative refinement of the epidemiological and QMRA models and detailed, in-country participatory workshops and interviews targeting workers in the human, animal and environmental health sectors. Samples collected will be studied with an array of molecular assays for previously identified as well as novel corona-, filo-, and paramyxoviruses. Where data show a prevalent emergent animal virus, we will identify the location and specific animal hosts of origin and collect data on supply chains and contact networks to target additional specimen collections and molecular studies along the chain of transmission.

1.7 Capacity Building and Sustainability

To facilitate sustainability, we will promote in-country stewardship of all Objective 1 activities, including risk-based analytical approaches, design of sampling strategies and collection of samples. Rapid assessment of in-country capabilities will be conducted to identify gaps in personnel, training and equipment. Training will be provided for each activity (utilizing virtual

methods and translation to local language), and location-appropriate equipment provided in order to allow activities to be performed within, and beyond, the lifetime of the program.

OBJECTIVE 2: Strengthen Detection for Novel Viruses from Priority Viral Families

Our sampling strategy is designed to collect as many specimens as possible. Using a strategically designed, risk-based approach to sampling, we will roll out serial cross-sectional and prospective cohort studies at nodes of potential transmission of novel viruses to collect and screen **~800,000 specimens, with >60% from wildlife**. We will build a detection and characterization program utilizing in-country labs to provide near-real time screening and genome sequencing and finishing. Assuming 1-1.5% yield, based on the yield in the PREDICT program in the 3 viral families targeted for DEEP VZN (DV), this approach is likely to **detect and characterize 8000 – 12,000 novel virus genomes** over the DV program. We estimate these genomes to comprise a total of 1,000 novel viral species, based on the number of novel sequence submissions from the PREDICT project (~2100 novel sequences from 3 highlighted viral families for DV, constituting ~250 novel viral species, or ~8 specimens/sequences per novel virus species).

2.1 Capacity Building and Sustainability

Our capacity building approach for in-country laboratories is summarized in **Fig 3**. *The goal is to ensure that each country independently conducts full virus screening (basic detection to whole-genome sequencing) and basic characterization that includes evaluation of spillover (serology) and later glycoprotein and receptor-binding assays.* We will ensure sustainable, in-country capacity to safely detect and characterize unknown novel viruses by providing high-throughput automated nucleic extraction, multiplex qRT-PCR screening instruments, and *NextSeq* Illumina next-generation sequencing (NGS) platform in each country. All 18 partner institutions we have identified in the 12 target countries have existing serology capacity, while 60% and 25% have qRT-PCR, and NGS capacities, respectively. Building on our consortium's >25 years of experience working in sub-Saharan Africa, Asia, and Latin America, including during the COVID-19 pandemic, we will address the recurrent problem of high cost and delayed delivery by establishing direct-buy credit accounts and service contracts with the manufacturers of equipment involved in the DV program. As illustrated in **Fig 3**, in Year 1 we will conduct rapid assessment of in-country labs to determine needs, followed by provision and installation of

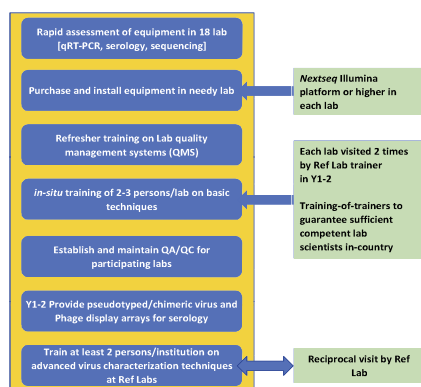


Fig 3. Flow chart of stepwise capacity-building for in-country labs

equipment to ensure they can conduct qRT-PCR, serology (ELISA and pseudotype viral neutralization test (pVNT)), and viral WGS.

Reference Labs: We will establish and fund two Reference Labs in the US, tasked with building in-country lab capacity, and validate advanced virus characterization (*in-silico* glycoprotein and receptor, *in vitro* and *ex vivo* virus-cell studies). The D. Wang (WUSTL) and A. Greninger (UW) labs, supported by other virology, immunology, and protein chemistry labs at these institutions, will in the early phase of the program (Years 1-2) (i) Develop and supply novel virus detection and

characterization standard operating procedures (SOPs), (ii) Conduct *in situ* training to in-country labs on qRT-PCR, whole-genome sequencing (WGS), and serology technologies, including annual refresher trainings, (iii) Develop and supply qRT-PCR controls and standards, (iv) Develop and supply serology screening kits (phage display peptide libraries, pseudotyped and/or chimeric viruses, monoclonal antibodies), (v) Roll out and manage a QA/QC system to ensure

reproducible and comparable data (including proficiency panels and re-testing 10% of positive specimens from each country), (vi) Conduct advanced characterization (*in-silico* glycoprotein and receptor, *in vivo* and *ex vivo* studies with live virus), and (vii) travel and train at least two persons from each participating institution in their US reference labs on development of pseudotyped/chimeric virus and antibodies for serology, and advanced virus characterization. Based on our successful experience with lab capacity strengthening, it is essential that this will be accompanied by reciprocal training visits by reference laboratory trainers to in-country labs, with the goal of ensuring that in-country labs can independently conduct detection and significant advanced virus characterization (except virus culture, or *in vitro* and *ex vivo* studies with live virus that may require high biosecurity laboratories). We recognize that in-country laboratories will not acquire competency at the same rate because of factors such as additional needs to improve infrastructure, biosafety and biosecurity capacity, sub-contracting and procurement challenges, and staff turnover. We also anticipate that early in the DV program in-country labs will identify suspected novel virus samples that require urgent characterization methodologies not yet fully established and transitioned to the country. To address this, the project will expand U.S. based reference lab personnel who will be dedicated to implementing all aspects of in-country virus detection and characterization (as described). These personnel will transition for several month-long periods each year through the in-country laboratories to provide both structured and ad hoc in-country analysis support, including complete bioinformatic analysis of NGS data to identify novel viruses, basic *in-silico* viral glycoprotein and receptor-binding analyses, and serological analysis to determine novel virus spillover. Additionally, this response team may be deployed to work alongside in-country scientists in a country with suspected novel viruses until characterization is completed to the satisfaction of the consortium executive council and USAID. The Reference Laboratories will also validate in-country results by repeating a limited number of the characterization tests conducted on novel viruses. This validation will be achieved by shipping aliquots of not more than ~0.1% of collected samples (negative and positive) as shown in the textbox below.

ESTIMATED NUMBER OF SAMPLES SHIPPED TO REFERENCES LABS IN UNITED STATES

From ~800,000 specimens collected; we estimate at least 8,000 (1,600/year) will have suspected novel viruses. Of these, we expect to ship no more than 10 qRT-PCR positive and 10 negative specimens from each country in Years 1-2 (480 specimens) for validation, and 5 qRT-PCR positive and 5 negative specimens In Years 3-5 (360 specimens), bringing the total specimens shipped to 840 (0.1% of collected specimens) over the 5 years for the DEEP VZN program.

For purposes of virus culture, virus isolation, *in-vitro* and *ex-vivo* studies, we have established access to the Rocky Mountain BSL-4 laboratory (letter of commitment available).

2.2 Overall Detection Strategy

We will use both molecular and serological approaches to detect novel viruses. For maximum sensitivity and efficiency, our primary virus detection strategy will use broad-range qRT-PCR assays that specifically target the 3 virus families for initial screening of specimens. We will utilize consensus RT-PCR followed by sequencing of amplicons and interrogate positive specimens further to obtain complete genomes. Broad serology will be used to adjust the sampling strategy (Objective 1), and also to investigate spillover of novel viruses across the wildlife-livestock-human spectrum (Objective 3). Focusing primarily on sera collected from bats, rodents, NHP, and humans, we will screen for known and newly detected coronaviruses, paramyxoviruses and filoviruses using phage display serology. Evidence of high prevalence of diverse species of target virus families will indicate an ecosystem favourable to maintenance and

transmission of these viruses. *Serologic detection of* antibodies to a novel virus may also provide information on duration of exposure and affected animal species, with high seroprevalence in humans pointing to higher frequency of spillover events.

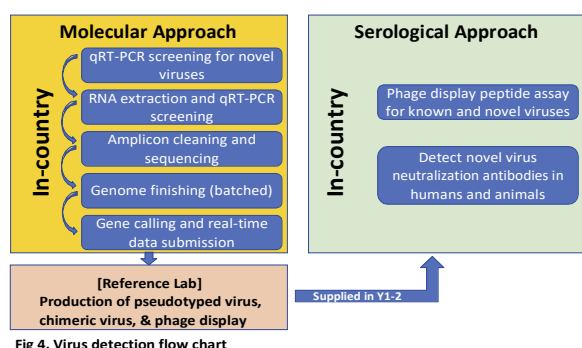


Fig 4. Virus detection flow chart

How our approach enhances efficiency to detect novel viruses: Our molecular screening strategy (Fig. 4) optimizes sensitivity, keeping the most expensive aspects (deep meta-genomic sequencing) to a minimum. All 3 viral families targeted for detection in the DV program are shed and detectable in stool reducing the need for animal trapping and handling. We have also integrated viral load measurement to our screening to improve chances of genome

finishing. During genome recovery from positive specimens, we will be able to infer hosts from environmental metadata and non-viral metagenomic sequencing data, which will be fed back to sampling teams to focus on particular animal species and areas where positives have been detected. The phage display approach is more cost-effective and efficient to serologically screen for known and novel viruses from target families than alternative multiplex serology approaches, such as peptide microarrays. Primarily because the phages self-replicate and thus are a renewable resource. Broad serology is costlier than qRT-PCR and this will limit its use.

2.3 Molecular Screening

Task 2.1: RNA extraction and broad-range qRT-PCR: RNA extraction methods will be standardized across all sites. Ideally, automated extraction instrumentation will be installed at each site. In addition, an alternative manual extraction method will be established as back-up. Our team has validated a family-specific, broad-range, single-well RT-PCR assay for *Orthocoronavirinae*, which enabled discovery of a novel coronavirus from a hospitalized patient in Malaysia. We will also make use of a published two-well pan-paramyxovirus and a one-well pan-filovirus qRT-PCRs to screen specimens. These family-specific primers amplify conserved portions of the RNA-dependent RNA-polymerase and allow for species determination after amplicon sequencing. We will integrate SYBR-Green into family-based RT-PCRs to allow for viral load quantitation at the same time we are detecting novel viruses along with melting curves to ensure appropriate-sized amplicons are generated without gel electrophoresis. As a backup strategy to the quantitative readout, a standard operating protocol for gel electrophoresis-based readout will be established. We will ensure in-country labs have instruments that can perform these assays with a throughput of 20-22 specimens per 96-well plate or 80-84 specimens per 384-well plate. We anticipate a throughput of at least 80 specimens per day per laboratory. Amplicons from qRT-PCR will be cleaned of PCR primers and sequenced on *Nextseq* biweekly, with up to 96 amplicons multiplexed. For further cost efficiency, we will explore the feasibility of multiplexing up to 384 amplicons. To identify novel viruses from the amplicons, all sequences will be aligned to a reference database composed of all target viruses from GenBank. Amplicon sequences that diverge significantly from all known viruses will be prioritized for whole genome sequencing. To standardize assays, the Reference Labs will provide positive and negative control standards for RT-PCR. Qualitative controls will be run through extraction and qRT-PCR on every plate, while quantitative controls will be run monthly. Quantitative controls will consist of a set of serial dilutions (10^7 - 10^0 copies/ul) of *in-vitro* transcribed RNA targets (2 different viruses in the family).

Task 2.2: Genome recovery and finishing: For maximal cost efficiency and timeliness, genome finishing will be performed in batches using *NextSeq* or *NovaSeq* equipment in each country. After identification of amplicons derived from novel viruses, we will ensure that complete genomes are recovered and finished to enable further screening and characterization. Complete genomes are also necessary for development of diagnostics, molecular epidemiology, vaccinology, and therapeutic development. Specimens will be prioritized for whole genome sequencing based on sequence divergence from known viruses and viral load estimates. We will use a variety of NGS methods as needed, including metatranscriptomics with rRNA depletion and/or poly-A enrichment approaches. Based on the identity of the virus, we can also use spike primers that bind the sequences recovered in the family-specific qRT-PCR or other highly conserved regions in that viral family into the cDNA synthesis prior to sequencing to increase coverage of viruses. New rRNA depletion reagents that cross-hybridize across metazoans will ensure fewer reads are spent on rRNA in rodents, bats, NHP, and humans, allowing for 8-150-fold enrichment of on-target reads. All targeted viral families poly-adenylate their transcripts, allowing classical RNA-Seq approaches to help in viral genome recovery. As a default, specimens will be targeted for 25 million reads to ensure genome recovery using high-throughput Illumina sequencers, which can allow recovery of near-complete genomes from specimens with Ct < 27. If needed, we will perform additional deeper sequencing, manually design PCR primers to close gaps, and perform 5' and 3' RACE to recover the viral genome termini. Our team has expertise sequencing whole genomes of novel RNA viruses. In Year 1, we endeavour to obtain and sequence specimens that have novel target virus from prior PREDICT projects. Small 400-500bp fragments of >150 novel paramyxoviruses and more than 60 novel coronaviruses were detected in PREDICT projects, but full genome sequences are not available. **Task 2.3: Genome calling and real-time data deposition:** Genome calling will be performed using a variety of automated and bespoke pipelines, including cloud based IDSeq for comprehensive assessment of viruses present in a specimen. As a complementary approach, we will also use well-described locally installed bioinformatic approaches, such as IRMA (an assembler specifically optimized for RNA virus genomes) and SURPI (pipeline optimized for unbiased metagenomic detection of all pathogens). Reads will be remapped to all draft genomes to ensure accuracy and manually reviewed in Geneious, especially if manual gap filling or 5' and 3' RACE is required. Importantly, our bioinformatics strategy also takes advantage of the global bioinformatics community and the wisdom of crowds by including real-time FASTQ and FASTA sequencing data deposition into NCBI Sequence Read Archive (SRA) and GenBank with **zero embargo time**. Our team has previously published software to facilitate rapid deposition of viral genomes into GenBank. SRA and GenBank accessions and brief initial analyses of sequencing data will be automatically communicated in real-time via our project-specific Twitter, so they are accessible to the global scientific community.

2.4. Broad Serology Screening

Zoonotic spillover is not considered a one-off event, and multiple small spillover events can potentially be detected by serological studies. For SARS-CoV, human serosurveys in south-eastern China found evidence of repeated spillover, with antibodies shown to persist for at least 2 years. To identify the animals or humans that had prior exposure to target viruses, our Reference Labs will generate phage display libraries covering 100,000 of the most conserved 60-mer peptides across all known filovirus, paramyxovirus, and coronavirus genomes following the VirScan protocol. The phage library will be amplified and validated using well-characterized positive control sera obtained from PREDICT labs, NIH-CREID network, in-country and CDC,

and Institute Pasteur labs. Reference Labs will develop kits consisting of phages that can be incubated with sera and protein A/G beads in in-country labs, with library preparation. Following incubation, the beads can be washed and library generation performed. The resultant DNA library is stable and can be sequenced at in-country laboratories. The phage library will be updated with novel viruses detected globally. The library will be used to screen high priority sera collected from bats, rodents, NHP, and humans sampled from nodes of potential transmission, serial cross-sectional samplings, and possibly archived sera. *Broad serology testing will be applied selectively and as a secondary approach, in part because of cost and the broader utility of genome recovery to enable further viral characterization work.* However, we envision that:

- (i) evidence of infection by novel viruses can be obtained from the serological profiles;
- (ii) unique signatures of epitopes distinct from those derived from known infections may suggest prior infection with a novel virus;
- (iii) high prevalence of diverse species of the target virus families may indicate an ecosystem favourable to maintenance and transmission of novel viruses of interest, and therefore point to a preferred sampling location;
- (iv) serologic detection of antibodies to a novel virus could inform the duration of exposure and affected animal species, with high prevalence in humans pointing to increased risk of spillover to humans.

We should point out that low or undetectable antibodies in humans may not indicate that a novel virus poses low risk to humans because other factors such as its recent introduction or potential for acquiring transmissibility to humans through minor mutations still exists.

As an orthogonal method to the broad serological screening, we will also perform binding ELISA serological assays against novel virus glycoproteins. Upon sequencing of a new virus, we will undertake codon-optimized gene synthesis to generate constructs for recombinant protein expression and pseudovirus generation. We expect to purify recombinant spike ectodomain trimers and/or receptor binding domain proteins for coronaviruses, GP trimers for filoviruses, and both fusion (F) trimers and G/H/HN tetramers for novel paramyxoviruses. We will use an antigen prediction pipeline to predict sensitive and specific viral protein antigens. Viral proteins and fragments predicted by this algorithm will be expressed for ELISA serodiagnosis. Negative-stain electron microscopy will be used to ensure the viral proteins are folded correctly after purification. Once viral protein antigens are purified, we will contract with GenScript for rapid generation of custom monoclonal antibody controls. We will then determine the specificity of the ELISA binding assay against a bank of >2,000 historical human serum specimens from UW Virology, including testing for cross-reactivity specifically against sera positive for IgGs to measles/mumps virus for paramyxoviruses, SARS-CoV-2 and all four endemic coronaviruses, and Ebola/Marburg viruses for filoviruses. Pending results from those specificity tests, we can iterate design of antigens for specific serological testing, including use of specific viral peptides, as required. Sensitivity will be tested against convalescent host animal sera as well as any human sera available from individuals known to be infected. This ELISA kit will then be provided to in-country labs with positive and negative controls, as well as host control proteins for testing for vaccine preventable illnesses (SARS-CoV-2 spike protein for coronaviruses; measles H for paramyxoviruses) and will be compatible with commonly available plate readers. Early in the COVID-19 pandemic, our UW Reference Lab provided recombinant SARS-CoV-2 nucleocapsid along with controls for binding ELISAs to laboratory partners in Senegal, Pakistan, Brazil, South Africa, Nigeria, Kenya, and other countries as part of the NIH CREID consortium. In addition to the binding assays described above, we will use pseudotyped lentivirus and chimeric vesicular

stomatitis virus (VSV) neutralization assays with the novel virus glycoproteins to functionally profile sera for neutralizing antibodies. These assays will benefit from the expertise of Dr. Whelan (WUSTL) and Dr. Veessler (UW) and allow for greater rigor and reproducibility of seropositivity identified by binding ELISA by providing an orthogonal and functional readout. Our primary approach will involve generating chimeric VSV reporter viruses (below). As these assays require cell lines permissive for viral entry, these efforts will create synergy between virus detection (Section 2.2) and characterization (Section 3.3) components.

Task 2.4: Generation of chimeric reporter viruses: We have extensive experience generating chimeric VSV reporter viruses where native viral glycoprotein (spike S, attachment glycoprotein G, fusion F, and hemagglutinin H) is replaced by those of heterologous viruses. Our experience with the coronaviruses indicates that either mutation of the endoplasmic reticulum retention sequence in the cytoplasmic tail of the spike, or truncation of the tail by approximately 20 residues can allow effective integration of the respective Spike gene into VSV, yielding viruses

that grow to titers of 10^8 pfu/ml. For filoviruses, we have not found it necessary to manipulate the cytoplasmic tail of the glycoprotein, although we have mutated the transcriptional editing sequence that is used for synthesis of soluble glycoproteins. Once an infectious clone of VSV-chimeras is assembled, we confirm sequences of the recovered virus, and characterize the growth of the respective viruses to establish the optimal conditions for the generation of seed stocks.

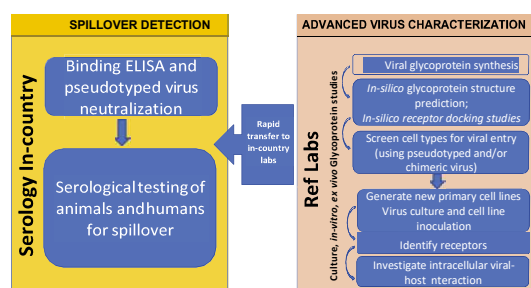


Fig 5. Flow chart for novel virus characterization

Task 2.5: Detection of neutralizing antibodies: We will use VSV-chimeric viruses to monitor levels of neutralizing antibodies in humans and sometimes animals. We are mindful of reports that bats inoculated with some filoviruses do not generate neutralizing antibodies that are detectable in neutralization assays. Accordingly, we will also use the VSV-chimeras to detect antibodies that recognize the respective envelope proteins displayed on the surface of virions. To do this, we will use purified virions that contain the respective envelope proteins on their surface and sera containing antibodies that bind to the virion identified by isolating the bound complexes. As an alternative approach to VSV chimeric viruses, we will use lentivirus-based pseudotyped neutralization assays. Pseudovirus neutralization assays against novel viruses will be optimized for expression and intracellular termini truncations as well as with monoclonal controls. The constructs, controls, and pseudotyped viruses will be made available to in-country partners once the assay is validated by Reference Labs. *These approaches will permit us to determine whether a given animal species has mounted an immune response to the envelope proteins of any novel virus and whether such immune responses include neutralizing antibodies.* The prevalence of such antibody responses may indicate potential risk for spillover into humans, even though low or undetectable antibodies may not mean that a virus is at low risk for human infection. These assays are compatible with BSL-2 settings widely available in in-country labs.

OBJECTIVE 3: Strengthen Characterization of Novel Viruses from Priority Viral Families

3.1. Overall Characterization Strategy

Guided by the understanding that, with timely and complete genome sequencing in Objective 2, >80% of novel virus characterization can be performed in the absence of virus isolation. We will start by characterizing selected novel viruses detected under the PREDICT program and identified as potentially important. Subsequently, we will use sequence data from novel viruses

we detected (Objective 2) to construct qRT-PCR screening kits and recombinantly express and purify viral proteins for reagents development (e.g., monoclonal antibodies) for serological assays and structural studies. We will use these sequences to create pseudotyped and chimeric viruses for serological assays and profiling viral entry. Pseudotyped and chimeric viruses can also be used to identify and screen for receptor usage and identify cell lines that support viral entry. These cell lines can be used to identify other determinants of tropism and to characterize viral entry mechanisms. We will attempt to isolate novel viruses and identify known or novel host genes that enable viral entry. Finally, we will determine the affinity of novel viral glycoproteins for human receptors and mechanisms of innate immunity antagonization to determine zoonotic/ pandemic potential (Fig. 5).

3.2 Profiling Viral Glycoproteins/Receptors to Assess Pandemic Risk of Novel Viruses

Task 3. 1: *In-silico* characterization of novel viruses. Our *in-silico* approach for profiling human transmission risk follows directly from the hypothesis that *affinity for human receptors of a novel viral glycoprotein indicates pandemic potential*. As soon as a novel virus genome is recovered, our UW Reference Lab will perform *in-silico structure prediction* of viral glycoproteins with Rosetta and trRosetta, as well as docking with known receptors for a given viral family to approximate affinity for human receptors. To support this effort, we will model the structures of the extracellular domains of all human proteins and compare these to structures of known host cell viral receptors to determine how closely they match as a way of generating hypotheses **for candidate** human host cell viral entry points. We will interrogate these predicted structures for specific changes in protease site activation. Our ability to determine high- resolution structures of viral glycoprotein-receptor complexes using world-class cryo-EM will be fed back to *in-silico* models to enhance protein structure prediction and viral-host protein-protein interactions. It is worth noting that to-date, no model has successfully predicted viral zoonoses and spread in humans. Therefore, our bias will be to perform as much wet laboratory characterization of novel virus glycoproteins. We will synthesize all viral glycoproteins recovered from novel viral genomes and screen in viral entry, biochemical, and biophysical assays because *in-silico* modelling is insufficient to capture risk.

Task 3.2: Biophysics and structures of viral glycoproteins. Divergent paramyxovirus, filovirus, and coronavirus genomes will be used to carry out structural studies of the corresponding glycoproteins in isolation and bound to target receptors to understand the mechanisms of viral entry into host cells. Our UW Reference Lab is world-renowned for expertise in viral glycoproteins and has developed a streamlined, high-resolution cryo-EM pipeline enabling high-throughput structural studies of viral glycoproteins bound to host receptors and neutralizing antibodies. It will be leveraged to provide atomic-level information of the infection machinery of discovered viral pathogens before they emerge. Novel viral glycoproteins and animal and human receptors will also be expressed and tested directly for binding kinetics and affinity using biolayer interferometry. These affinity measurements will provide biophysical confirmation of receptor interactions and direct biochemical evidence of the degree of pandemic risk of a novel virus. We will correlate binding affinity measurements and functional biochemical measurements of fusogenicity using cell-cell fusion assays.

Task 3.3: Viral isolation-independent viral entry characterization and receptor discovery. The VSV chimeras and pseudoviruses generated above will also be used to perform viral receptor discovery at a BSL-2 level. Previously, our WUSTL Reference Lab has used both VSV

SECURING MTAs FOR SHIPPING SPECIMENS: Our approach is to reduce the number and scope of MTAs. Each in-country lab will only sign one MTA with either UW or WUSTL reference laboratory

and pseudoviruses and a series of cell lines expressing canonical coronavirus receptors to rapidly screen for coronavirus receptor usage and to discover the human receptor of SARS-CoV-2. To establish neutralization assays, VSV chimeras and pseudoviruses will already be tested against a broad array of human, non-human primate, bat, and rodent cell lines that support paramyxovirus, filovirus, and coronavirus growth, including an initial screen of VeroE6, RHMK, CV-1, HAE, HuH-7.5, HEK293, HepG2, CaCo2, BHK (hamster), MEF (mouse), Aji (bat), RhiNi (bat) cell lines. This screen will be performed in the presence and absence of trypsin to determine if host restriction for viral entry exists at the level of proteolytic activation, as previously described for several bat coronaviruses. Canonical receptor usage (e.g., ACE2/DPP4/APN for coronaviruses, NPC1 for filoviruses, or SLAM/EphrinB2/3 for paramyxoviruses) will be confirmed at the protein-level using soluble receptor blocking and/or blocking monoclonal antibodies. If viral entry into one of the above cell lines is not found to be caused by a known or canonical receptor, we will perform genome-wide CRISPRko screens to discover viral receptors. Using this and related genome-wide approaches, we have identified the receptors for multiple coronaviruses, paramyxoviruses and filoviruses validating this approach. We will carry out such screens to identify host genes that are potential determinants of infection and, armed with that information, we can determine the step of viral infection at which any given host gene functions as described in the rest of the proposal. This will allow us to compare the genomic sequence of entry factors between susceptible and non-susceptible host cells.

3.3 Viral Inhibition of Innate Immunity

Viral antagonization of innate immunity is an important component of viral pathogenesis in humans. Like glycoproteins, viral immuno-evasion proteins are often tailored specifically to the host they infect, and thus the zoonotic and pandemic potential of a new virus will be determined in part by how these genes affect human innate immunity pathways. West Nile and Zika virus spread in humans is in part determined by the degree of inhibition of the JAK/STAT pathway. Infection in animal host species reservoirs can contribute to viral evolution strategies that facilitate evasion of host innate immunity. Bats have specifically downregulated inflammatory pathways while maintaining type I interferon pathways, leading to a unique evolutionary selection for viral antagonization of type I interferons.

Task 3.4: Testing for the degree of innate immune inhibition: The UW Lab will perform tests by all open reading frames from a novel virus in a host innate immune evasion screening platform. If throughput is limited, at a minimum we will characterize the major immuno-evasion genes from the different viral families. Here, the specific viral protein open reading frame is cloned and expressed ectopically in relevant host cell lines, 24 hours later cells are treated with exogenous interferon (IFN) and harvested over a time course to evaluate for possible reduction in innate immune signalling pathway activation compared to control cells treated with IFN but without ectopic expression of viral genes. Loss of innate immune activation will be evaluated by reduced IFIT1 and IFITM1 gene expression measured by RT-qPCR. We recognize that these approaches are limited to evaluating viral evasion from IFN responses and do not evaluate innate immune signalling components that occur prior to (upstream of) IFN induction. To address this, we will assess the ability of viral protein expression constructs to suppress the activation of interferon regulatory factor (IRF)3 activation induced by Sendai virus infection, a control virus that potently induces innate immune activation in infected cells. We will transfect cells with each viral protein expression construct, followed by infection with Sendai virus, and assess total and phospho/active IRF3 abundance. For a broader analysis of innate immune pathway regulation, we will infect relevant host cell lines with the virus panel of interest and evaluate innate immune

response pathways activated by each specific virus using assays (immunoblot and mRNA analyses) to measure the activation state of specific innate immune pathway markers as well as expression of downstream genes linked to each pathway.

3.4 Virus Isolation for Receptor and Intracellular Viral-Host Interaction Studies

Task 3.5: Viral isolation and receptor identification. As illustrated in **Fig. 5**, we may require virus isolation to conduct *in vitro* and *ex vivo* studies. Such studies will be conducted in BSL-3 and BSL-4 labs under proper biosafety protocols. Isolation of novel coronaviruses or paramyxoviruses (determined using sequencing data) when there is no concern of severe human disease can be attempted in certified BSL-3 labs located in-country, regionally, or at Reference Labs. Isolation of viruses of great concern of severe disease, such as filoviruses, will only be attempted in Rocky Mountain Laboratories BSL-4 lab (letter of commitment available on request). Positive specimens will be prioritized based on viral load, with a focus on specimens with >1 million copies per mL or gram. We will inoculate virus onto cells shown to be permissive to pseudovirus entry from above. Viral isolates will be expanded and deposited into central repositories with CDC, BEI, and/or WRCEVA, according to the appropriate biosecurity and national data sharing guidelines. Receptor usage determined in the pseudovirus screen will be confirmed using the viral isolate. For isolated novel viruses that do not show canonical receptor usage but cytopathic effect, we will screen for novel human receptors using genome wide CRISPRko libraries in cell lines that support viral growth as described above. Where possible, we will prefer viral isolate CRISPRko screens over pseudotype screens to identify potential intracellular viral-host interactions at the same time as identifying potential receptors.

Task 3.6: Host cell characterization and cell line generation for viral characterization.

Inoculating existing cell lines and primary cells with virus-positive specimens may not result in viral growth. The cell lines chosen may not contain the correct receptors, proteases, or other intracellular factors to support viral entry and/or growth. To support viral isolation and characterization for such viruses, we will generate primary cells from bat, rodent, and NHP tissues that are specifically sampled in DV and identified by host deep sequencing reads in Objective 2. Over the past decade, several new primary bat cell lines have been established that support growth of many viruses of high zoonotic potential *in vitro*, and yet bat species are so diverse that it is likely that no specific cell lines might be available for the bats sampled here. Should the approaches outlined above fail to support viral isolation, we will use scRNA-Seq sequencing of virus-positive primary specimens to help identify candidate host cells and host receptors to be targeted for cell line generation. scRNA-Seq is a powerful approach to link virus transcription and replication on a single cell level with candidate host cells and receptors should existing cell lines prove insufficient. If we are unable to specifically isolate the relevant host cell lines based on scRNA-Seq data, we will ectopically express candidate viral receptors identified by scRNA-Seq data into candidate host cell lines to determine viral receptor usage.

3.5 Algorithm for Ranking Viruses with Pandemic Potential

A proposed algorithm for ranking emerging viruses for potential spillover to humans was recently published by the PREDICT team (<https://spillover.global/ranking-comparison/doi.org/10.1073/pnas.2002324118>). We will improve on this by applying the findings of our innovative and thorough stepwise virus characterization methodologies described in **Section 3**, and by rating each novel virus based on the following three questions:

- (i) Does the virus have potential for human transmission? This will be investigated using the glycoprotein modeling and functional viral entry studies described above.

- (ii) Is there evidence of its spillover to humans or a broad range of potential animal reservoirs? This will be addressed through serologic testing.
- (iii) Does the virus have capacity to inhibit host innate immunity? Evidence of immunoevasion is consistent with the potential for significant morbidity and/or mortality in humans and should trigger a higher level of public health concern, particularly if the virus rates high on criteria i & ii above.

We will summarize the results in prioritized lists that will be publicly accessible to both in-country partners and international stakeholders. Importantly, our findings, which will be disseminated in scientific publications, presentations, communication with USAID and other stakeholders, will add key metrics to evaluate the zoonotic and pandemic potential of novel viruses.

OBJECTIVE 4: Strengthen Focus Country Capacities for Data Management and the Viral Characterization Process

The proposed project will develop and implement improved data systems at the country and international level, building on learnings from the EIDITH system developed for PREDICT 2, and increasing interoperability and access for partners and stakeholders alike. We will also aim to enhance in-country data collection and use to accelerate detection and response to future public health threats. This will begin with an assessment of the data structure of the EIDITH system, defining a core set of standard variables to be collected across sampling locations for use in describing the distribution of pathogens/exposures. The importance of national-level data autonomy must be balanced with the need for widespread dissemination of data to aid in the prediction and prevention of emerging epidemics. We will work with countries to build on existing systems using an “Adopt-Adapt-Develop” approach while defining protocols for data sharing between the DV and local systems so that project data enhances existing systems while observing local policies and SOPs. The consortium will also draw on previous experience with local and global datasets to advance global surveillance of zoonotic threats. To allow rapid sharing of data across the consortium and with international databases such as NCBI, we will put in place MOUs and data use agreements using a “staged ring” approach, wherein data access can be conceptualized as a series of interlocking rings within which data ownership is retained by in-country stakeholders whilst standardized review, approval, and validation processes allow data to be rapidly shared to key stakeholders at national and international levels. This will ensure that, rather than creating parallel systems, the project builds upon (and integrates into) existing structures and data systems, while ensuring rapid release of validated data to project team, national, and international partners. Pending national approvals, aligned to standardized data sharing agreements supported by DV, and the removal of any sensitive information, data will matriculate across the data management structure, representing gradually more release of data (e.g., USAID staff, external partners, cross-border sharing and full public accessibility). This progression will represent not only increased access but also improved data quality: data sets made available to the public would represent those with well-documented dictionaries and curated metadata, while more incomplete data would remain with project and national stakeholders. In these endeavors, we will build on PREDICT, which has uploaded hundreds of sequences from newly discovered animal pathogens to the NCBI’s Short Read Archive (SRA) and GenBank. With USAID and local stakeholders, we will review and update the data use agreements where PREDICT has been active and use them as models.

4.1 Project Data Collection and Management

Task 4.1: Develop a project-wide data management plan. The consortium will use a data system based on principles of the EIDITH system to collect and manage data among the partners while respecting the need for data safety and ensuring in-country data ownership. This management system has the capability to import data for linkage with surveillance data systems in the host countries, USAID, and global systems such as healthmap, ProMED, NCBI.

Task 4.2 Monitor project implementation. PATH, leading Objective 4 and as a global leader in project monitoring and evaluation, will develop indicators and track project progress via systematic data analysis and review meetings, data quality assessments, technical working groups, and training of data managers at the facility, subnational, and national level.

Task 4.3 Data storage. Following national approvals described in section 4.2, data will be stored within the DV database with data security and access conforming to the FAIR Principles, as well as the Nagoya protocol for genomic data sharing.

4.2 Country Data Management

Task 4.4: Map the data management and policy landscape of each country. In Year 1 an early assessment of existing systems in use at the country and regional levels will be conducted in order to help support and define the architecture, connectivity, flow and human resource capacity to achieve rapid access to quality data at the country level. This assessment will identify gaps and areas that must be strengthened across the continuum from data collection, cleaning, and storage to analysis and presentation to key stakeholders and users and across relevant data sources including laboratory, human and animal clinical, and environmental data sets. This will also entail an extensive evaluation of the enabling environment, including existing health data privacy policies, data use regulations, digital workforce capacity, and information technology infrastructure. The goal is to develop a baseline for each country in terms of existing data agreements, identify adaptations that would enhance data sharing, and understand the policy environment for data sharing and use. Using these assessments, we will develop a roadmap for developing an integrated country-level data architecture with our country partners, including reporting from our DV data system and site- and laboratory-level data collection, as well as ensuring local data sharing through secure, interoperable data exchange.

Task 4.5: Evaluate lab information systems of DV lab and field data collection teams in focus countries. Our consortium will identify the capacity of partner labs in focus countries to support data capture for the project. Similarly, we will ensure that the field data collection teams are trained in data collection according to the data standards that we will extend based on EIDITH/PREDICT. We will build on the existing data structure from in-country data management systems and PREDICT/EIDITH, including sample tagging protocols, geolocation, and survey-based questionnaires.

Task 4.6: Incorporate knowledge and learnings from previous projects. We will use publicly available data, such as PREDICT data available through <https://data.usaid.gov> including readily available country-specific data sets from EIDITH (event animal production, event crop production, animals sampled, event dwellings, event value chain, PCR tests, and site/event characterization) and genomic information available through GenBank in national-level data use and analysis. This will ensure that our project database builds on successes and lessons learned from the EPT project to date. Our data management plan will be able to rapidly incorporate the metadata and genomic data of these samples when they become available.

Task 4.7: Establish data standards and governance. With our in-country partners, we will establish global data standards and assist with establishment of a data warehouse that includes

different collection and management aspects for analyzing, sharing, and storing data. The consortium has previous experience creating similar architecture (the POLIS system for polio eradication and analysis) which has been in use for over eight years. Technical working groups (TWG) will be developed to establish data governance and reporting plans for each target country. These TWG's will conduct regular monitoring of implementation and the assessment of whether goals are being met, while adhering to country needs to try to be more proactive, transparent, to share data rapidly, and be adaptable to addressing issues. We will engage existing standards bodies to ensure that data sharing formats leverage existing works and/or contribute to these standards. This will also address (and ensure) country/regional and local stakeholders' access to genomic/sequencing data from GenBank and other global repositories to build and strengthen research capabilities. We will work with country governments to ensure the timely sharing of information as described, while also recognizing sensitivities around data to avoid stigmatization that could lead to reluctance because of economic and societal pressures.

Task 4.8: Implement data collection using updated data system for focus countries. We will adapt existing technology for the DV digital tool to collect field-based data, including geolocation, animal or plant species, samples collected, unique sample identification, and so on. The tool will be based on an existing technological base, such as CommCare, RedCap or similar, with interfaces for data import, exchange, and interfacing with lab systems. The DV data system will collect necessary data, including accession information for genomic data, connected with sample and location data collected by the DV digital tool.

Task 4.9: Strengthen capacity of in-country partners to store, analyze, and share data. We will train in country partners on use of the DV data system and its linkages with existing in-country data system architecture, work with host governments and data users to identify the key questions they would like to answer with the data, as well intended purposes and requirements, and support implementation of solutions to improve country-level electronic data sharing capacities. Uploading viral sequences to NCBI will also facilitate data exchange between in-country labs and reference labs. We will work to establish harmonized bioinformatics techniques and pipelines across the DV project to ensure comparability of genomic data. User-friendly dashboards including GIS maps to show location of possible priority infectious agents or exposure will be developed to visualize and support interpretation of the data. The consortium will identify "local champions" at the different levels to accelerate this activity. We will work with our in-country partners to publish, supporting their capacity to act as lead authors in internationally recognized journals, and provide training and mentorship in scientific writing.

Task 4.10: Strengthen in-country data management processes for the viral detection and characterization processes. Our consortium will support in-country labs in the focus countries in training the necessary staff on laboratory data management, including genomic data, and to support staff in bioinformatics, monitoring, and maintaining data repositories and architecture.

Task 4.11: Develop an early warning system with country-level dashboards. Learning from tools such as Tableau, DHIS2 dashboards, and other existing AI platforms, by the end of Year 2 we will develop country-level dashboards of DV data to visualize data and identify potential emerging threats based on expert opinion. This will leverage work done under PREDICT 1 and 2 as well as the Spillover data tool (<https://spillover.global>).

4.3 Global Data Sharing

The consortium has identified key data sets to be collected across countries that may require augmentation to in-country systems. Sequencing data will be communicated in as close to real-time as feasible to make this information accessible to the global scientific community, while

also adhering to data governance requirements negotiated with local stakeholders. Sequencing data and correlation with other findings including advanced characterization will also be regularly shared with in-country partners and global stakeholders via published lists of prioritized novel viruses ranked on their pandemic potential. This release of high priority and high-risk pathogens will feed into other risk assessment activities at national and global levels such as STOP Spillover and the proposed WHO Berlin Hub for Pandemic and Epidemic Intelligence. The consortium is already engaging with these stakeholders to cultivate a new model of data solidarity and collaborative intelligence for risk assessment. Another emerging initiative supported by WHO - the International Pathogen Surveillance Network (IPSN) - will also work to support global exchange of genomic information. The consortium will ensure a close integration with and support for IPSN, leveraging this global structure and pathway for R&D. These examples demonstrate opportunities for improved and rapid data sharing in a quickly evolving landscape. The consortium, in collaboration with USAID, will continue to track and engage with these initiatives as appropriate. Wherever possible, the linkages between the consortium data and these international data sharing mechanisms will be built into the project system architecture and part of agreements with national stakeholders.

Task 4.13: Convene multisectoral networks at country and international level. We will build on existing data standards for PREDICT 2 and provide trainings across the consortium and with in-country stakeholders to ensure adherence to data standards.

Task 4.14: Develop improved data sharing processes across data systems at country and international levels and across stakeholders. The project will develop the DV digital tool “esign” – a data-sharing process that supports differing levels of staging and access – with the capability to move data from an internal-only level to internal plus USAID, external partners, and fully public, international levels. While aligning with host country requirements and global guidelines (e.g., WHO’s code of conduct for sharing of pathogen genetic sequence data), our consortium will also ensure appropriate data is made available in a rapid and responsible manner to benefit the global community. In keeping with our “Adopt-Adapt-Develop” approach, we propose a data storage structure that will include three related databases – one for raw sequencing reads, one for assembled data and one for sample metadata. This segregated structure will facilitate real-time reporting of raw sequence data (FASTQ and FASTA) accompanied by limited deidentified metadata to global repositories (NCBI SRA, etc.) while also ensuring that access to sensitive metadata remains restricted until validated and approved for release. This structure will support more routine release of raw sequencing data throughout the duration of the DV project, while enabling local investigators adequate time to complete genome assembly and perform data cleaning and validation prior to submission of finished genome sequences to public domain (NCBI, EMBL-EBI, DDBJ) or public access (e.g. GISAID) repositories, and/or alternative global platforms (e.g., GitHub). Finally, project results and analyses will be regularly communicated via scientific publications, presentations, and direct communication with USAID and other stakeholders. As appropriate, and in accordance with in-country data sharing agreements, outlets will be explored for more rapid dissemination of findings, particularly when novel viruses with high pandemic risk are identified. This includes sharing manuscripts within preprint servers, such as medRxiv or bioRxiv, prior to publication.

5 Capacity Strengthening

A key goal of our DV program is for every activity and outcome to be predicated on a foundation of sustainable capacity strengthening within focus countries. To achieve this, in-country partner organizations will play leading and participatory roles in the development and implementation of

all activities. Further, in-country nationals will coordinate and implement all planned activities, from sample collecting through to laboratory analyses, with language-specific training programs being provided where necessary. Moreover, when planning for the improvements in technical capacity through provision of equipment, care will be taken to ensure the utility of any equipment extends beyond the duration of the program by selecting location-appropriate equipment that can readily be maintained, resourced, and used. This will ensure that during and after the program maximal use is made of the virus detection and characterization capacity that the project will develop. Finally, it is critical that in-country stakeholders understand the value of the knowledge and resources generated. We plan to achieve this in two ways: (1) in-country partners will take leading roles in all aspects of data analysis and the preparation of peer-reviewed publications and (2) the DV project will engage a wide range of in-country stakeholders at project inception to begin the process of raising awareness about the potential value of the generated resources. This process will include multiple fora being hosted within focus countries with a variety of stakeholders to raise awareness of resources that will be generated by the program, and their use (Table 1).

Resource Generated	Resource Uses	Stakeholders
Data from wildlife sampling: species and abundance	Inform conservation efforts	National and international wildlife organizations
Viruses detected in wildlife and domestic animals	Prepare for animal health events	Animal health agencies
Spillover events detected in human populations	Determine risk to humans, control efforts	Human health clinicians, public health
Improved laboratory capacity for qRT-PCR	Improve detection of other infectious diseases	Human health, public health
Improved capacity for ELISA	Improve detection of other infectious diseases	Human health, public health
Improved sequencing and bioinformatics capacity	Application of whole genome sequencing to other pathogens	Laboratories, public health, surveillance

Table 1: Resources generated by the program, their utility, and the stakeholders who will benefit

6 Sample Monitoring and Learning Plan

The WSU-led consortium partners will work with USAID within the first 90 days of the grant to develop a comprehensive Monitoring Evaluation and Learning Plan inclusive of a Learning Agenda and Data Management plan that will describe the processes for monitoring project activities and progress towards achieving the desired results. A comprehensive indicator matrix with output, outcome, and impact indicators, annual and life of project targets, and baseline measures will be at the center of the MEL plan. Table 2 presents illustrative indicators for a subset of intended results and activities under each of the project's 4 objectives, with additional illustrative indicators in Annex 2. Quarterly team check-ins will be used as a venue for Objective Leads to review MEL data with the team to identify areas that are not achieving desired results and flag areas where implementation strategies might need to be adjusted. The team will use MEL data to inform project management and will report semi-annually and annually on progress towards achieving results under the agreed upon indicators in the MEL plan and explain any significant deviations from expected targets. The MEL plan will be reviewed for relevance semi-annually and the WSU-led consortium will work with USAID to revise if and when necessary. The team will collect and analyze data on gender to inform the project's gender action planning to identify opportunities for the project to reduce opportunity gaps between men and women or address power differentials to promote gender equity.

Table 2: Selected illustrative indicators linked to intended results and project activities

Objective 1: Conduct Sampling In Focus Countries For Unknown Viruses From Priority Viral Families		
Intended results	Project Activities/Tasks	Indicators/Milestones
In-country institutional and staff capacity to conduct risk modeling to identify and inform sampling efforts strengthened .	1.7 Capacity Building and Sustainability (cross cutting all Objective 1 activities and tasks)	#/% representatives from in-country wildlife, human, livestock, and environmental health sectors, trained and engaged in risk modeling, sample site and species selection, and sample target setting processes
Key species sampled at research sites.	1.3 Country-level Strategic Sampling	# of wildlife samples collected in each country % of archived wildlife samples of interest screened
Objective 2: Strengthen Detection In Focus Countries For Novel Viruses From The Priority Viral Families		
Detection and genomic sequencing of novel viruses from prospective samples safely conducted .	2.2 Overall Detection Strategy 2.3 Molecular Screening 2.4. Broad Serology Screening	# of in-country labs with instruments that can perform assays with a throughput of 20-22 specimens per 96- well plate or 80-84 specimens per 384-well plate # of genome finishing batches performed using NextSeqor NovaSequequipment in each country
Ability of select in-country laboratories to provide technical assistance and/or detection capabilities for viral discovery in- country and in the region improved .	2.1 Capacity Building and Sustainability	# of labs & # people trained by project on qRT-PCR, serology, next gen sequencing methods, bioinformatics platforms and methods for analysis; % of those trained demonstrating improved competency in new methods; % of laboratory capacity gaps identified in each country that are showing improvement as demonstrated by: % of labs with screening & sequencing instruments
Objective 3: Strengthen Characterization In Focus Countries Of Novel Viruses From Priority Viral Families		
Lab and bioinformatics capacity for characterizing unknown viruses in select in- country institutions strengthened .	3.1. Overall Characterization Strategy	# countries with improved characterization capacity as demonstrated by increased number of novel viruses characterized and fully sequenced by in-country laboratories that have staff who have participated in at least one of the project's capacity building activities.
Objective 4: Strengthen In-Country Capacities For Data Management And Viral Characterization Process		
Newly validated methodologies and protocols, data and analyses associated with viral detection and characterization shared .	4.2 Country Data Management Task 4.9: Strengthen capacity of in-country partners to store, analyze, and share data	# countries with validated protocols for data sharing, MOUs in place; # DV datasets, methodologies, and/or publications made publicly available; # of data managers providing data sets with reliability, accuracy, completeness, consistency and timeliness.

Learning Agenda: Our consortium is committed to utilizing a Collaborating, Learning and Adapting approach to implementing the DV project. The Learning Agenda (LA) will be developed in the first 90 days in collaboration with USAID and in-country technical experts and will be the primary tool for ensuring critical questions that can guide implementation are collaboratively agreed upon and used to inform project implementation. The LA will serve to contextualize project achievements and test assumptions regarding how implemented activities yield intended results. We will review and discuss LA assessments quarterly to ensure learning from identified failures and successes and to improve future implementation. Illustrative LA questions are provided in Table 3. The final LA will include learning activities, timelines, methods and a dissemination plan that will describe key audiences benefitting from the learning

produced by the project and products targeted at those audiences to ensure relevant information is shared back quickly to the right stakeholders in a useful format.

Table 3. Illustrative Learning Agenda questions:

1	To what extent is the project successfully supporting the timely detection and complete characterization of known and un-known pathogens among the prioritized viral families within the in-country reference laboratories? Which approaches are leading to the most robust implementation in countries and greatest effects on timely detection and complete characterization? And what characteristics, differences or similarities do we see across successful vs. less successful reference laboratories or countries where DV is implemented?
2	What data have the project successfully made available for use by local, regional and global audiences, and how have the data generated by the project supported local, regional and global preparedness and response activities to the targeted viral families? Are the appropriate audiences receiving useful data more rapidly? What barriers are still delaying the processes of sharing data and findings as quickly as possible? And what differences or similarities do we see across countries where DV is implemented vs. Countries where DV is not implemented?
3	<p>a. In which areas of capacity building (a-d below), and with which cadres of the workforce, has the project been successful in strengthening in-country capacity? What capacity building strategies are showing greatest / least impact? What remain the biggest barriers to successfully unlocking in-country capacity? Are project activities leading to unexpected capacity improvements? Laboratory capacity in viral detection and characterization of unknown viruses</p> <p>b. Data management capacity, including data collection, quality, analysis, sharing and storage</p> <p>c. Timely dissemination of actionable data and research findings</p> <p>d. In-country capacity to use data and research findings</p>
4	What existing in-country and global data systems are most successfully being leveraged for sharing DV data to increase likelihood of sustainability and interoperability among sectors? How successful is the project with getting virus sequencing data into those data sources? What facilitators can be leveraged and barriers do we still need to overcome to integrate DV data into sustainable systems?

Mixed methods will be used to answer these learning questions. Desk reviews will compile existing evidence; project monitoring and evaluation data will be used to track progress towards achievement of results within the learning agenda topic areas and incorporate project M&E within the learning. Additional methods for collecting data to answer these learning questions will include surveys, checklists, observations, key informant interviews and review of secondary data extracted from existing databases. Data from these sources will be analyzed to answer these questions, help the project understand what is working, where immediate pivots are needed in current implementation strategies and what learning should be shared more broadly. Data collection tools will be stored in a central repository for re-use and continuous learning during the project and beyond. The plan to disseminate and use findings will differ depending on the learning question. In many cases the first audience will be internal team and management to inform activity planning and work planning. Learning exchange sessions, webinars or workshops will be planned to discuss findings with local experts and decision makers to explore the local context and use of the findings. On a global scale, we will develop white papers, blogs, conference presentations, global learning exchange webinars, or publications for peer review.

[END OF ATTACHMENT B]

ATTACHMENT C – STANDARD PROVISIONS

MANDATORY STANDARD PROVISIONS FOR U.S. NONGOVERNMENTAL ORGANIZATIONS

M1. APPLICABILITY OF 2 CFR 200 and 2 CFR 700 (NOVEMBER 2020)

- a. All provisions of 2 CFR 200 and 2 CFR 700 in effect on the date of this award, and all Standard Provisions attached to this agreement are applicable to the recipient and to subrecipients that meet the definition of “Non-Federal Entity” in part 2 CFR 200.1, unless a section specifically excludes a subrecipient from coverage. The recipient must assure that subrecipients have copies of all the attached standard provisions.
- b. For any subawards made with Non-U.S. subrecipients the recipient must include the applicable “Standard Provisions for Non-US Nongovernmental Organizations.” Recipients are required to ensure compliance with monitoring procedures in accordance with 2 CFR 200 and 2 CFR 700.

[END OF PROVISION]

M2. INELIGIBLE COUNTRIES (MAY 1986)

Unless otherwise approved by the USAID Agreement Officer, funds will only be expended for assistance to countries eligible for assistance under the Foreign Assistance Act of 1961, as amended, or under acts appropriating funds for foreign assistance.

[END OF PROVISION]

M3. NONDISCRIMINATION (JUNE 2012)

No U.S. citizen or legal resident shall be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination on the basis of race, color, national origin, age, disability, or sex under any program or activity funded by this award when work under the grant is performed in the U.S. or when employees are recruited from the U.S.

Additionally, USAID is committed to achieving and maintaining a diverse and representative workforce and a workplace free of discrimination. Based on law, Executive Order, and Agency policy, USAID prohibits discrimination, including harassment, in its own workplace on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, disability, age, veteran’s status, sexual orientation, genetic information, marital status, parental status, political affiliation, and any other conduct that does not adversely affect the performance of the employee.

In addition, the Agency strongly encourages its recipients and their subrecipients and vendors (at all tiers), performing both in the U.S. and overseas, to develop and enforce comprehensive nondiscrimination policies for their workplaces that include protection for all their employees on these expanded bases, subject to applicable law.

[END OF PROVISION]

M4. AMENDMENT OF AWARD (JUNE 2012)

This award may only be amended in writing, by formal amendment or letter, signed by the Agreement Officer (AO), and in the case of a bilateral amendment, by the AO and an authorized official of the recipient.

[END OF PROVISION]

M5. NOTICES (JUNE 2012)

Any notice given by USAID or the recipient is sufficient only if in writing and delivered in person, mailed or e-mailed as follows:

- (1) To the USAID Agreement Officer, at the address specified in this award; or
- (2) To the recipient, at the recipient's address shown in this award, or to such other address specified in this award.

[END OF PROVISION]

M6. SUBAWARDS AND CONTRACTS (DECEMBER 2014)

- a. Subawardees and contractors have no relationship with USAID under the terms of this award. All required USAID approvals must be directed through the recipient to USAID.
- b. Notwithstanding any other term of this award, subawardees and contractors have no right to submit claims directly to USAID and USAID assumes no liability for any third party claims against the recipient.

[END OF PROVISION]

M7. OMB APPROVAL UNDER THE PAPERWORK REDUCTION ACT (DECEMBER 2014)

Information collection requirements imposed by this award are covered by OMB approval number 0412-0510; the current expiration date is 04/30/2005. The Standard Provisions containing the requirement and an estimate of the public reporting burden (including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information) are

<u>Standard Provision</u>	<u>Burden Estimate</u>
Air Travel and Transportation	1 (hour)
Ocean Shipment of Goods	.5
Patent Rights	.5
Publications	.5
Negotiated Indirect Cost Rates - (Predetermined and Provisional)	1
Voluntary Population Planning	.5

Protection of the Individual as a Research Subject 1

<u>22 CFR 200</u>	<u>Burden Estimate</u>
2 CFR 200.318-326, Procurement Standards	1
2 CFR 200.310-315, Property Standards	1.5

Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, may be sent to the Bureau for Management, Office of Acquisition and Assistance, Policy Division (M/OAA/P), U.S. Agency for International Development, Washington, DC 20523 and to the Office of Management and Budget, Paperwork Reduction Project (0412-0510), Washington, DC 20503.

[END OF PROVISION]

M8. USAID ELIGIBILITY RULES FOR GOODS AND SERVICES (MAY 2020)

This provision is not applicable to commodities or services that the recipient provides with private funds as part of a cost-sharing requirement, or with Program Income generated under this award.

- a. Ineligible and Restricted Commodities and Services:
- (1) Ineligible Commodities and Services. The recipient must not, under any circumstances, procure any of the following under this award:
 - (i) Military equipment,
 - (ii) Surveillance equipment,
 - (iii) Commodities and services for support of police or other law enforcement activities,
 - (iv) Abortion equipment and services,
 - (v) Luxury goods and gambling equipment, or
 - (vi) Weather modification equipment.
 - (2) Ineligible Suppliers. Any firms or individuals that do not comply with the requirements in Standard Provision, “Debarment, Suspension and Other Responsibility Matters” and Standard Provision, “Preventing Transactions with, or the Provision of Resources or Support to, Sanctioned Groups and Individuals” must not be used to provide any commodities or services funded under this award.
 - (3) Restricted Commodities. The recipient must obtain prior written approval of the Agreement Officer (AO) or comply with required procedures under an applicable waiver, as provided by the AO when procuring any of the following commodities:
 - (i) Agricultural commodities,
 - (ii) Motor vehicles,

- (iii) Pharmaceuticals,
 - (iv) Pesticides,
 - (v) Used equipment,
 - (vi) U.S. Government-owned excess property, or
 - (vii) Fertilizer.
- b. Source and Nationality:
 Except as may be specifically approved in advance by the AO, all commodities and services that will be reimbursed by USAID under this award must be from the authorized geographic code specified in this award and must meet the source and nationality requirements set forth in 22 CFR 228. If the geographic code is not specified, the authorized geographic code is 937. When the total value of procurement for commodities and services during the life of this award is valued at \$250,000 or less, the authorized geographic code for procurement of all goods and services to be reimbursed under this award is code 935. For a current list of countries within each geographic code, see: <http://www.usaid.gov/ads/policy/300/310>.
- c. Guidance on the eligibility of specific commodities and services may be obtained from the AO. If USAID determines that the recipient has procured any commodities or services under this award contrary to the requirements of this provision, and has received payment for such purposes, the AO may require the recipient to refund the entire amount of the purchase.
- d. This provision must be included in all subawards and contracts which include procurement of commodities or services.

[END OF PROVISION]

M9. DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS (JUNE 2012)

- a. The recipient agrees to notify the Agreement Officer (AO) immediately upon learning that it or any of its principals:
 - (1) Are presently excluded or disqualified from covered transactions by any Federal department or agency;
 - (2) Have been convicted within the preceding three-year period preceding this proposal; been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, receiving stolen property, making false claims, or obstruction of justice; commission of any other offense indicating a lack of business integrity or business honesty that seriously and directly affects your present responsibility;
 - (3) Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph a.(2); and
 - (4) Have had one or more public transactions (Federal, State, or local) terminated for cause

or default within the preceding three years.

- b. The recipient agrees that, unless authorized by the AO, it will not knowingly enter into any subawards or contracts under this award with a person or entity that has an active exclusion on the System for Award Management (SAM) (www.sam.gov). The recipient further agrees to include the following provision in any subawards or contracts entered into under this award:

.DEBARMENT, SUSPENSION, INELIGIBILITY, AND VOLUNTARY EXCLUSION
(JUNE 2012)

The recipient/contractor certifies that neither it nor its principals is presently excluded or disqualified from participation in this transaction by any Federal department or agency.

- c. The policies and procedures applicable to debarment, suspension, and ineligibility under USAID-financed transactions are set forth in Subpart C of 2 CFR Section 180, as supplemented by 2 CFR 780.

[END OF PROVISION]

M10. DRUG-FREE WORKPLACE (JUNE 2012)

The recipient must comply with drug-free workplace requirements in subpart B (or subpart C, if the recipient is an individual) of 2 CFR 782, which adopts the Government-wide implementation (2 CFR part 182) of sec. 5152–5158 of the Drug-Free Workplace Act of 1988 (Pub. L. 100–690, Title V, Subtitle D; 41 U.S.C. 701–707).

[END OF PROVISION]

M11. EQUAL PARTICIPATION BY FAITH-BASED ORGANIZATIONS (JUNE 2016)

a. Faith-Based Organizations Encouraged

Faith-based organizations are eligible, on the same basis as any other organization, to participate in any USAID program for which they are otherwise eligible. Neither USAID nor entities that make and administer subawards of USAID funds shall discriminate for or against an organization on the basis of the organization's religious character or affiliation. Additionally, religious organizations shall not be disqualified from participating in USAID programs because such organizations are motivated or influenced by religious faith to provide social services, or because of their religious character or affiliation.

Decisions about awards of USAID financial assistance must be free from political interference or even the appearance of such interference. Awards must be made on the basis of merit, not the basis of the religious affiliation of an applicant, or lack thereof. A faith-based organization may continue to carry out its mission, including the definition, development, practice, and expression of its religious beliefs, within the limits contained in this provision. For more information, see the [USAID Faith-Based and Community Initiatives Web site](#) and [22 CFR 205.1](#).

b. Explicitly Religious Activities Prohibited.

- (1)** Explicitly religious activities include activities that involve overt religious content such as worship, religious instruction, prayer, or proselytization.
 - (2)** The recipient must not engage in explicitly religious activities as part of the programs or services directly funded with financial assistance from USAID. If the recipient engages in explicitly religious activities, the activities must be offered separately, in time or location, from any programs or services directly funded by this award, and participation must be voluntary for beneficiaries of the programs or services funded with USAID assistance.
 - (3)** These restrictions apply equally to religious and secular organizations. All organizations that participate in USAID programs, as recipients or subawardees, including religious ones, must carry out eligible activities in accordance with all program requirements and other applicable requirements governing USAID-funded activities.
 - (4)** Notwithstanding the restrictions of b.(1) and (2), a religious organization that participates in USAID-funded programs or services:
 - (i)** May retain its independence and may continue to carry out its mission, including the definition, development, practice, and expression of its religious beliefs, provided that it does not use direct financial assistance from USAID to support or engage in any explicitly religious activities or in any other manner prohibited by law;
 - (ii)** May use space in its facilities, without removing religious art, icons, scriptures, or other religious symbols; and
 - (iii)** May retain its authority over its internal governance, and may retain religious terms in its organization's name, select its board members on a religious basis, and include religious references in its organization's mission statements and other governing documents.
- c.** Implementation in accordance with the Establishment Clause: Nothing in this provision shall be construed as authorizing the use of USAID funds for activities that are not permitted by Establishment Clause jurisprudence or otherwise by law.
- d.** Discrimination Based on Religion Prohibited: The recipient must not, in providing services, discriminate against a program beneficiary or potential program beneficiary on the basis of religion or religious belief, refusal to hold a religious belief, or a refusal to attend or participate in a religious practice.
- e.** A religious organization's exemption from the Federal prohibition on employment discrimination on the basis of religion, set forth in Sec. 702(a) of the Civil Rights Act of

1964, 42 U.S.C. 2000e–1 is not forfeited when the organization receives financial assistance from USAID.

- f. The Secretary of State may waive the requirements of this section in whole or in part, on a case-by-case basis, where the Secretary determines that such waiver is necessary to further the national security or foreign policy interests of the United States.
- g. This provision must be included in all subawards under this award.

[END OF PROVISION]

M12. PREVENTING TRANSACTIONS WITH, OR THE PROVISION OF RESOURCES OR SUPPORT TO, SANCTIONED GROUPS AND INDIVIDUALS (MAY 2020)

- a. In carrying out activities under this award, except as authorized by a license issued by the Office of Foreign Assets Control (OFAC) of the U.S. Department of Treasury, the recipient will not engage in transactions with, or provide resources or support to, any individual or entity that is subject to sanctions administered by OFAC or the United Nations (UN), including any individual or entity that is included on the Specially Designated Nationals and Blocked Persons List maintained by OFAC (<https://www.treasury.gov/resource-center/sanctions/SDNList/Pages/default.aspx>) or on the UN Security Council consolidated list (<https://www.un.org/securitycouncil/content/un-sc-consolidated-list>).
- b. Any violation of the above will be grounds for unilateral termination of the agreement by USAID.
- c. The Recipient must include this provision in all subawards and contracts issued under this award.

[END OF PROVISION]

M13. MARKING AND PUBLIC COMMUNICATIONS UNDER USAID-FUNDED ASSISTANCE (DECEMBER 2014)

- a. The USAID Identity is the official marking for USAID, comprised of the USAID logo and brandmark with the tagline “from the American people,” unless amended by USAID to include additional or substitute use of a logo or seal and tagline representing a presidential initiative or other high level interagency initiative. The USAID Identity (including any required presidential initiative or related identity) is on the USAID Web site at www.usaid.gov/branding. Recipients must use the USAID Identity, of a size and prominence equivalent to or greater than any other identity or logo displayed, to mark the following:
 - (1) Programs, projects, activities, public communications, and commodities partially or fully funded by USAID;
 - (2) Program, project, or activity sites funded by USAID, including visible infrastructure projects or other physical sites;

- (3) Technical assistance, studies, reports, papers, publications, audio-visual productions, public service announcements, Web sites/Internet activities, promotional, informational, media, or communications products funded by USAID;
 - (4) Commodities, equipment, supplies, and other materials funded by USAID, including commodities or equipment provided under humanitarian assistance or disaster relief programs; and
 - (5) Events financed by USAID, such as training courses, conferences, seminars, exhibitions, fairs, workshops, press conferences and other public activities. If the USAID Identity cannot be displayed, the recipient is encouraged to otherwise acknowledge USAID and the support of the American people.
- b. The recipient must implement the requirements of this provision following the approved Marking Plan in the award.
 - c. The AO may require a preproduction review of program materials and “public communications” (documents and messages intended for external distribution, including but not limited to correspondence; publications; studies; reports; audio visual productions; applications; forms; press; and promotional materials) used in connection with USAID-funded programs, projects or activities, for compliance with an approved Marking Plan.
 - d. The recipient is encouraged to give public notice of the receipt of this award and announce progress and accomplishments. The recipient must provide copies of notices or announcements to the Agreement Officer’s Representative (AOR) and to USAID’s Office of Legislative and Public Affairs in advance of release, as practicable. Press releases or other public notices must include a statement substantially as follows:

“The U.S. Agency for International Development administers the U.S. foreign assistance program providing economic and humanitarian assistance in more than 80 countries worldwide.”
 - e. Any “public communication” in which the content has not been approved by USAID must contain the following disclaimer:

“This study/report/audio/visual/other information/media product (specify) is made possible by the generous support of the American people through the United States Agency for International Development (USAID). The contents are the responsibility of [insert recipient name] and do not necessarily reflect the views of USAID or the United States Government.”
 - f. The recipient must provide the USAID AOR with two copies of all program and communications materials produced under this award.
 - g. The recipient may request an exception from USAID marking requirements when USAID

marking requirements would:

- (1) Compromise the intrinsic independence or neutrality of a program or materials where independence or neutrality is an inherent aspect of the program and materials;
 - (2) Diminish the credibility of audits, reports, analyses, studies, or policy recommendations whose data or findings must be seen as independent;
 - (3) Undercut host-country government “ownership” of constitutions, laws, regulations, policies, studies, assessments, reports, publications, surveys or audits, public service announcements, or other communications;
 - (4) Impair the functionality of an item;
 - (5) Incur substantial costs or be impractical;
 - (6) Offend local cultural or social norms, or be considered inappropriate; or
 - (7) Conflict with international law.
- h. The recipient may submit a waiver request of the marking requirements of this provision or the Marking Plan, through the AOR, when USAID-required marking would pose compelling political, safety, or security concerns, or have an adverse impact in the cooperating country.
- (1) Approved waivers “flow down” to subawards and contracts unless specified otherwise. The waiver may also include the removal of USAID markings already affixed, if circumstances warrant.
 - (2) USAID determinations regarding waiver requests are subject to appeal by the recipient, by submitting a written request to reconsider the determination to the cognizant Assistant Administrator.
- i. The recipient must include the following marking provision in any subawards entered into under this award:

“As a condition of receipt of this subaward, marking with the USAID Identity of a size and prominence equivalent to or greater than the recipient’s, subrecipient’s, other donor’s, or third party’s is required. In the event the recipient chooses not to require marking with its own identity or logo by the subrecipient, USAID may, at its discretion, require marking by the subrecipient with the USAID Identity.”

[END OF PROVISION]

M14. REGULATIONS GOVERNING EMPLOYEES (JUNE 2018)

- a. While working overseas, the recipient's employees who are not citizens of the cooperating

Washington State University
Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)
Cooperative Agreement 7200AA21CA00033

country must maintain private status, and may not rely on local U.S. Government offices or facilities for support while under this award.

- b. The sale of personal property or automobiles by the recipient's non-cooperating country citizen employees and their dependents in the foreign country to which they are assigned, are subject to the same limitations and prohibitions that apply to direct-hire USAID personnel employed by the Mission, including the rules contained in 22 CFR 136, except as this may conflict with host government regulations.
- c. Other than work to be performed under this award for which an employee is assigned by the recipient, employees of the recipient who are not citizens of the cooperating country must not engage directly or indirectly, either in the individual's own name or in the name or through an agency of another person, in any business, profession, or occupation in the foreign countries to which the individual is assigned. In addition, the individual must not make loans or investments to or in any business, profession, or occupation in the foreign countries to which the individual is assigned.
- d. The recipient's employees who are not citizens of the cooperating country, while in a foreign country, are expected to show respect for its conventions, customs, and institutions, to abide by its applicable laws and regulations, and not to interfere in its internal political affairs.
- e. In accordance with the internal control requirements in 2 CFR 200.303, which require the recipient to establish standards of conduct for its employees, the recipient must ensure that all its employees adhere to these standards of conduct in a manner consistent with the standards for United Nations (UN) employees in Section 3 of the UN Secretary-General's Bulletin - Special Measures for Protection from Sexual Exploitation and Sexual Abuse (ST/SGB/2003/13).
- f. If the recipient determines that the conduct of any recipient employee is not in accordance with the preceding paragraphs, the recipient's Chief of Party must consult with the Agreement Officer and the USAID Mission Director, and the employee involved, and must recommend to the recipient a course of action with regard to such employee.
- g. The parties recognize the rights of the U.S. Ambassador to direct the removal from a country of any U.S. citizen, or the discharge from this award of any individual (U.S., third-country, or cooperating-country national) when, in the discretion of the Ambassador, the interests of the United States so require.
- h. If it is determined, under paragraph (f) or (g) above, that the services of such employee should be terminated, the recipient must use its best efforts to cause the return of such employee to the United States, or third-country point of origin, as appropriate, and replace the employee with an acceptable substitute at no cost to USAID.
- i. Any matters relating to subrecipients, including the employees of subrecipients, must be coordinated through the recipient's Chief of Party.

[END OF PROVISION]

**M15. CONVERSION OF UNITED STATES DOLLARS TO LOCAL CURRENCY
(NOVEMBER 1985)**

(This provision applies when activities are undertaken outside the United States.)

Upon arrival in the cooperating country, and from time to time as appropriate, the recipient's chief of party must consult with the Mission Director who must provide, in writing, the procedure the recipient and its employees must follow in the conversion of United States dollars to local currency. This may include, but is not limited to, the conversion of currency through the cognizant United States Disbursing Officer or Mission Controller, as appropriate.

[END OF PROVISION]

M16. USE OF POUCH FACILITIES (AUGUST 1992)

(This provision applies when activities are undertaken outside the United States.)

- a. Use of diplomatic pouch is controlled by the Department of State. The Department of State has authorized the use of pouch facilities for USAID recipients and their employees as a general policy, as detailed in items (1) through (6) below. However, the final decision regarding use of pouch facilities rest with the Embassy or USAID Mission. In consideration of the use of pouch facilities, the recipient and its employees agree to indemnify and hold harmless, the Department of State and USAID for loss or damage occurring in pouch transmission:

- (1) Recipients and their employees are authorized use of the pouch for transmission and receipt of up to a maximum of .9 kgs per shipment of correspondence and documents needed in the administration of assistance programs.
- (2) U.S. citizen employees are authorized use of the pouch for personal mail up to a maximum of .45 kgs per shipment (but see a.(3) below).
- (3) Merchandise, parcels, magazines, or newspapers are not considered to be personal mail for purposes of this standard provision and are not authorized to be sent or received by pouch.
- (4) Official and personal mail pursuant to a.(1) and (2) above sent by pouch should be addressed as follows:
 Name of individual or organization (followed by
 letter symbol "G")
 City Name of post (USAID/_____)
 Agency for International Development
 Washington, DC 20523-0001

- (5) Mail sent via the diplomatic pouch may not be in violation of U.S. Postal laws and may

not contain material ineligible for pouch transmission.

(6) Recipient personnel are NOT authorized use of military postal facilities (APO/FPO). This is an Adjutant General's decision based on existing laws and regulations governing military postal facilities and is being enforced worldwide.

- b. The recipient is responsible for advising its employees of this authorization, these guidelines, and limitations on use of pouch facilities.
- c. Specific additional guidance on grantee use of pouch facilities in accordance with this standard provision is available from the Post Communication Center at the Embassy or USAID Mission.

[END OF PROVISION]

M17. TRAVEL AND INTERNATIONAL AIR TRANSPORTATION (DECEMBER 2014)

a. TRAVEL COSTS

All travel costs must comply with the applicable cost principles and must be consistent with those normally allowed in like circumstances in the recipient's non-USAID-funded activities. Costs incurred by employees and officers for travel, including air fare, costs of lodging, other subsistence, and incidental expenses, may be considered reasonable and allowable only to the extent such costs do not exceed reasonable charges normally allowed by the recipient in its regular operations as the result of the recipient organization's written travel policy and are within the limits established by the applicable cost principles.

In the absence of a reasonable written policy regarding international travel costs, the standard for determining the reasonableness of reimbursement for international travel costs will be the Standardized Regulations (Government Civilians, Foreign Areas), published by the U.S. Department of State, as from time to time amended. The most current Standardized Regulations on international travel costs may be obtained from the AO. In the event that the cost for air fare exceeds the customary standard commercial airfare (coach or equivalent) or the lowest commercial discount airfare, the recipient must document one of the allowable exceptions from the applicable cost principles.

b. FLY AMERICA ACT RESTRICTIONS

- (1) The recipient must use U.S. Flag Air Carriers for all international air transportation (including personal effects) funded by this award pursuant to the Fly America Act and its implementing regulations to the extent service by such carriers is available.
- (2) In the event that the recipient selects a carrier other than a U.S. Flag Air Carrier for international air transportation, in order for the costs of such international air transportation to be allowable, the recipient must document such transportation in accordance with this provision and maintain such documentation pursuant to the

Standard Provision, “Accounting, Audit and Records.” The documentation must use one of the following reasons or other exception under the Fly America Act:

- (i) The recipient uses a European Union (EU) flag air carrier, which is an airline operating from an EU country that has signed the US-EU “Open Skies” agreement (<http://www.state.gov/e/eb/rls/othr/ata/i/ic/170684.htm>).
- (ii) Travel to or from one of the following countries on an airline of that country when no city pair fare is in effect for that leg (see <http://apps.fas.gsa.gov/citypairs/search/>):
 - a. Australia on an Australian airline,
 - b. Switzerland on a Swiss airline, or
 - c. Japan on a Japanese airline;
- (iii) Only for a particular leg of a route on which no US Flag Air Carrier provides service on that route;
- (iv) For a trip of 3 hours or less, the use of a US Flag Air Carrier at least doubles the travel time;
- (v) If the US Flag Air Carrier offers direct service, use of the US Flag Air Carrier would increase the travel time by more than 24 hours; or
- (vi) If the US Flag Air Carrier does not offer direct service,
 - a. Use of the US Flag Air Carrier increases the number of aircraft changes by 2 or more,
 - b. Use of the US Flag Air Carrier extends travel time by 6 hours or more, or
 - c. Use of the US Flag Air Carrier requires a layover at an overseas interchange of 4 hours or more.

c. DEFINITIONS

The terms used in this provision have the following meanings:

- (1) “Travel costs” means expenses for transportation, lodging, subsistence (meals and incidentals), and related expenses incurred by employees who are on travel status on official business of the recipient for any travel outside the country in which the organization is located. “Travel costs” do not include expenses incurred by employees who are not on official business of the recipient, such as rest and recuperation (R&R) travel offered as part of an employee’s benefits package that are consistent with the recipient’s personnel and travel policies and procedures.

- (2) "International air transportation" means international air travel by individuals (and their personal effects) or transportation of cargo by air between a place in the United States and a place outside thereof, or between two places both of which are outside the United States.
- (3) "U.S. Flag Air Carrier" means an air carrier on the list issued by the U.S. Department of Transportation at <http://ostpxweb.dot.gov/aviation/certific/certlist.htm>. U.S. Flag Air Carrier service also includes service provided under a code share agreement with another air carrier when the ticket, or documentation for an electronic ticket, identifies the U.S. flag air carrier's designator code and flight number.
- (4) For this provision, the term "United States" includes the fifty states, Commonwealth of Puerto Rico, possessions of the United States, and the District of Columbia.

d. SUBAWARDS AND CONTRACTS

This provision must be included in all subawards and contracts under which this award will finance international air transportation.

[END OF PROVISION]

M18. OCEAN SHIPMENT OF GOODS (JUNE 2012)

- a. Prior to contracting for ocean transportation to ship goods purchased or financed with USAID funds under this award, the recipient must contact the office below to determine the flag and class of vessel to be used for shipment:

U.S. Agency for International Development,
Bureau for Management
Office of Acquisition and Assistance, Transportation Division
1300 Pennsylvania Avenue, NW
Washington, DC 20523
Email: oceantransportation@usaid.gov

- b. This provision must be included in all subawards and contracts.

[END OF PROVISION]

M19. VOLUNTARY POPULATION PLANNING ACTIVITIES – MANDATORY REQUIREMENTS (MAY 2006)

Requirements for Voluntary Sterilization Programs

- (1) Funds made available under this award must not be used to pay for the performance of involuntary sterilization as a method of family planning or to coerce or provide any financial incentive to any individual to practice sterilization.

Prohibition on Abortion-Related Activities:

- (1) No funds made available under this award will be used to finance, support, or be attributed to the following activities: (i) procurement or distribution of equipment intended to be used for the purpose of inducing abortions as a method of family planning; (ii) special fees or incentives to any person to coerce or motivate them to have abortions; (iii) payments to persons to perform abortions or to solicit persons to undergo abortions; (iv) information, education, training, or communication programs that seek to promote abortion as a method of family planning; and (v) lobbying for or against abortion. The term “motivate,” as it relates to family planning assistance, must not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options.
- (2) No funds made available under this award will be used to pay for any biomedical research which relates, in whole or in part, to methods of, or the performance of, abortions or involuntary sterilizations as a means of family planning. Epidemiologic or descriptive research to assess the incidence, extent or consequences of abortions is not precluded.

[END OF PROVISION]

M20. TRAFFICKING IN PERSONS (April 2016)

- a. The recipient, subawardee, or contractor, at any tier, or their employees, labor recruiters, brokers or other agents, must not engage in:
 - (1) Trafficking in persons (as defined in the Protocol to Prevent, Suppress, and Punish Trafficking in Persons, especially Women and Children, supplementing the UN Convention against Transnational Organized Crime) during the period of this award;
 - (2) Procurement of a commercial sex act during the period of this award;
 - (3) Use of forced labor in the performance of this award;
 - (4) Acts that directly support or advance trafficking in persons, including the following acts:
 - i. Destroying, concealing, confiscating, or otherwise denying an employee access to that employee's identity or immigration documents;
 - ii. Failing to provide return transportation or pay for return transportation costs to an employee from a country outside the United States to the country from which the employee was recruited upon the end of employment if requested by the employee, unless:
 - a) exempted from the requirement to provide or pay for such return transportation by USAID under this award; or

- b) the employee is a victim of human trafficking seeking victim services or legal redress in the country of employment or a witness in a human trafficking enforcement action;
 - iii. Soliciting a person for the purpose of employment, or offering employment, by means of materially false or fraudulent pretenses, representations, or promises regarding that employment;
 - iv. Charging employees recruitment fees; or
 - v. Providing or arranging housing that fails to meet the host country housing and safety standards.
- b. In the event of a violation of section (a) of this provision, USAID is authorized to terminate this award, without penalty, and is also authorized to pursue any other remedial actions authorized as stated in section 1704(c) of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112-239, enacted January 2, 2013).
- c. If the estimated value of services required to be performed under the award outside the United States exceeds \$500,000, the recipient must submit to the Agreement Officer, the annual “Certification regarding Trafficking in Persons, Implementing Title XVII of the National Defense Authorization Act for Fiscal Year 2013” as required prior to this award, and must implement a compliance plan to prevent the activities described above in section (a) of this provision. The recipient must provide a copy of the compliance plan to the Agreement Officer upon request and must post the useful and relevant contents of the plan or related materials on its website (if one is maintained) and at the workplace.
- d. The recipient’s compliance plan must be appropriate to the size and complexity of the award and to the nature and scope of the activities, including the number of non-United States citizens expected to be employed. The plan must include, at a minimum, the following:
 - (1) An awareness program to inform employees about the trafficking related prohibitions included in this provision, the activities prohibited and the action that will be taken against the employee for violations.
 - (2) A reporting process for employees to report, without fear of retaliation, activity inconsistent with the policy prohibiting trafficking, including a means to make available to all employees the Global Human Trafficking Hotline at 1-844-888-FREE and its e-mail address at help@befree.org.
 - (3) A recruitment and wage plan that only permits the use of recruitment companies with trained employees, prohibits charging of recruitment fees to the employee, and ensures that wages meet applicable host-country legal requirements or explains any variance.

- (4) A housing plan, if the recipient or any subawardee intends to provide or arrange housing. The housing plan is required to meet any host-country housing and safety standards.
- (5) Procedures for the recipient to prevent any agents or subawardee at any tier and at any dollar value from engaging in trafficking in persons activities described in section a of this provision. The recipient must also have procedures to monitor, detect, and terminate any agents or subawardee or subawardee employees that have engaged in such activities.
- e. If the Recipient receives any credible information regarding a violation listed in section a(1)-(4) of this provision, the recipient must immediately notify the cognizant Agreement Officer and the USAID Office of the Inspector General; and must fully cooperate with any Federal agencies responsible for audits, investigations, or corrective actions relating to trafficking in persons.
- f. The Agreement Officer may direct the Recipient to take specific steps to abate an alleged violation or enforce the requirements of a compliance plan.
- g. For purposes of this provision, “employee” means an individual who is engaged in the performance of this award as a direct employee, consultant, or volunteer of the recipient or any subrecipient.
- h. The recipient must include in all subawards and contracts a provision prohibiting the conduct described in section a(1)-(4) by the subrecipient, contractor, or any of their employees, or any agents. The recipient must also include a provision authorizing the recipient to terminate the award as described in section b of this provision.

[END OF PROVISION]

M21. SUBMISSIONS TO THE DEVELOPMENT EXPERIENCE CLEARINGHOUSE AND PUBLICATIONS (JUNE 2012)

- a. Submissions to the Development Experience Clearinghouse (DEC).
 - 1) The recipient must provide the Agreement Officer’s Representative one copy of any Intellectual Work that is published, and a list of any Intellectual Work that is not published.
 - 2) In addition, the recipient must submit Intellectual Work, whether published or not, to the DEC, either on-line (preferred) or by mail. The recipient must review the DEC Web site for submission instructions, including document formatting and the types of documents to submit. Submission instructions can be found at: <http://dec.usaid.gov>.

- 3) For purposes of submissions to the DEC, Intellectual Work includes all works that document the implementation, evaluation, and results of international development assistance activities developed or acquired under this award, which may include program and communications materials, evaluations and assessments, information products, research and technical reports, progress and performance reports required under this award (excluding administrative financial information), and other reports, articles and papers prepared by the recipient under the award, whether published or not. The term does not include the recipient's information that is incidental to award administration, such as financial, administrative, cost or pricing, or management information.
 - 4) Each document submitted should contain essential bibliographic information, such as 1) descriptive title; 2) author(s) name; 3) award number; 4) sponsoring USAID office; 5) development objective; and 6) date of publication.
 - 5) The recipient must not submit to the DEC any financially sensitive information or personally identifiable information, such as social security numbers, home addresses and dates of birth. Such information must be removed prior to submission. The recipient must not submit classified documents to the DEC.
- b. In the event award funds are used to underwrite the cost of publishing, in lieu of the publisher assuming this cost as is the normal practice, any profits or royalties up to the amount of such cost must be credited to the award unless the schedule of the award has identified the profits or royalties as program income.

[END OF PROVISION]

M22. LIMITING CONSTRUCTION ACTIVITIES (AUGUST 2013)

- a) Construction is not eligible for reimbursement under this award unless specifically identified in paragraph d) below.
- b) Construction means —construction, alteration, or repair (including dredging and excavation) of buildings, structures, or other real property and includes, without limitation, improvements, renovation, alteration and refurbishment. The term includes, without limitation, roads, power plants, buildings, bridges, water treatment facilities, and vertical structures.
- c) Agreement Officers will not approve any subawards or procurements by recipients for construction activities that are not listed in paragraph d) below. USAID will reimburse allowable costs for only the construction activities listed in this provision not to exceed the amount specified in the construction line item of the award budget. The recipient must receive prior written approval from the AO to transfer funds allotted for construction activities to other cost categories, or vice versa.
- d) Description

Construction is not eligible for reimbursement under this award.

- e) The recipient must include this provision in all subawards and procurements and make vendors providing services under this award and subrecipients aware of the restrictions of this provision.

[END OF PROVISION]

M23. USAID IMPLEMENTING PARTNER NOTICES (IPN) PORTAL FOR ASSISTANCE (JULY 2014)

(a) Definitions

“USAID Implementing Partner Notices (IPN) Portal for Assistance (“IPN Portal)” means the single point where USAID posts proposed universal bilateral amendments for USAID awards, which can be accessed electronically by registered USAID recipients. The IPN Portal is located at <https://sites.google.com/site/usaaidipnforassistance/>. Universal amendments are those which affect all assistance awards or a designated class of awards as specified in each amendment by the IPN Portal Administrator.

“IPN Portal Administrator” means the USAID official designated by the Director, M/OAA, who has overall responsibility for managing the USAID Implementing Partner Notices Portal for Assistance.

“Universal bilateral amendment” means those amendments with revisions or new requirements or provisions that affect all awards or a designated class of awards, as specified in the Agency notification of such revisions or new requirements.

- (b)** By submission of an application and execution of an award, the Applicant/Recipient acknowledges the requirement to:

- (1)** Register with the IPN Portal if awarded an assistance award resulting from this solicitation, and
- (2)** Receive universal bilateral amendments to this award and general notices via the IPN Portal.

- (c)** Procedure to register for notifications.

Go to <https://sites.google.com/site/usaaidipnforassistance/> and click the “Register” button at the top of the page. Recipient representatives must use their official organization email address when subscribing, not personal email addresses.

- (d)** Processing of IPN Portal Amendments

The Recipient may access the IPN Portal at any time to review all IPN Portal amendments; however, the system will also notify the Recipient by email when the USAID IPN Portal Administrator posts a universal bilateral amendment for Recipient's review and signature. Proposed USAID IPN Portal amendments distributed via the IPN Portal are applicable to all awards, unless otherwise noted in the proposed amendment.

Within 15 calendar days from receipt of the notification email from the IPN Portal, the Recipient must do one of the following:

- (1) (a) verify applicability of the proposed amendment for their award(s) per the instructions provided with each amendment; (b) download the amendment and incorporate the following information on the amendment form: award number, organization name, and organization mailing address as it appears in the basic award; (c) sign the hardcopy version; and (d) send the signed amendment (by email or hardcopy) to the AO for signature. The Recipient must not incorporate any other changes to the IPN Portal amendment. Bilateral amendments provided through the IPN Portal are not effective until the both the Recipient and the AO sign the amendment;
- (2) Notify the AO in writing if the amendment requires negotiation of additional changes to terms and conditions of the award; or
- (3) Notify the AO that the Recipient declines to sign the amendment.

Within 30 calendar days of receipt of a signed amendment from the Recipient, the AO must provide the fully executed amendment to the Recipient or initiate discussions with the Recipient.

[END OF PROVISION]

M24. PILOT PROGRAM FOR ENHANCEMENT OF GRANTEE EMPLOYEE WHISTLEBLOWER PROTECTIONS (SEPTEMBER 2014)

The requirement to comply with and inform all employees of the "Pilot Program for Enhancement of Contractor Employee Whistleblower Protections" is retroactively effective for all assistance awards and subawards (including subcontracts) issued beginning July 1, 2013.

The Grantee must:

1. Inform its employees working under this award in the predominant native language of the workforce that they are afforded the employee whistleblower rights and protections provided under 41 U.S.C. § 4712; and
2. Include such requirement in any subaward or subcontract made under this award.

41 U.S.C. § 4712 states that an employee of a Grantee may not be discharged, demoted, or otherwise discriminated against as a reprisal for "whistleblowing." In addition, whistleblower protections cannot be waived by any agreement, policy, form, or condition of employment.

Whistleblowing is defined as making a disclosure "that the employee reasonably believes" is evidence of any of the following:

- Gross mismanagement of a Federal contract or grant;
- A gross waste of Federal funds;
- An abuse of authority relating to a Federal contract or grant;
- A substantial and specific danger to public health or safety; or
- A violation of law, rule, or regulation related to a Federal contract or grant (including the competition for, or negotiation of, a contract or grant).

To qualify under the statute, the employee's disclosure must be made to:

- A Member of the U.S. Congress, or a representative of a U.S. Congressional Committee;
- A cognizant U.S. Inspector General;
- The U.S. Government Accountability Office;
- A Federal employee responsible for contract or grant oversight or management at the relevant agency;
- A U.S. court or grand jury; or,
- A management official or other employee of the Grantee who has the responsibility to investigate, discover, or address misconduct.

[END OF PROVISION]

M25. SUBMISSION OF DATASETS TO THE DEVELOPMENT DATA LIBRARY (OCTOBER 2014)

a. Definitions. For the purpose of submissions to the DDL:

- (1) "Dataset" is an organized collection of structured data, including data contained in spreadsheets, whether presented in tabular or non-tabular form. For example, a Dataset may represent a single spreadsheet, an extensible mark-up language (XML) file, a geospatial data file, or an organized collection of these. This requirement does not apply to aggregated performance reporting data that the recipient submits directly to a USAID portfolio management system or to unstructured data, such as email messages, PDF files, PowerPoint presentations, word processing documents, photos and graphic images, audio files, collaboration software, and instant messages. Neither does the requirement apply to the recipient's information that is incidental to award administration, such as financial, administrative, cost or pricing, or management information. Datasets submitted to the DDL will generally be those generated with USAID resources and created in support of Intellectual Work that is uploaded to the Development Experience Clearinghouse (DEC) (See M21. SUBMISSIONS TO THE DEVELOPMENT EXPERIENCE CLEARINGHOUSE AND PUBLICATIONS (JUNE 2012)).

- (2) “Intellectual Work” includes all works that document the implementation, monitoring, evaluation, and results of international development assistance activities developed or acquired under this award, which may include program and communications materials, evaluations and assessments, information products, research and technical reports, progress and performance reports required under this award (excluding administrative financial information), and other reports, articles and papers prepared by the recipient under the award, whether published or not. The term does not include the recipient’s information that is incidental to award administration, such as financial, administrative, cost or pricing, or management information.
- b. Submissions to the Development Data Library (DDL)
- (1) The recipient must submit to the Development Data Library (DDL) at www.usaid.gov/data, in a machine-readable, non-proprietary format, a copy of any Dataset created or obtained in performance of this award, including Datasets produced by a subawardee or a contractor at any tier. The submission must include supporting documentation describing the Dataset, such as code books, data dictionaries, data gathering tools, notes on data quality, and explanations of redactions.
- (2) Unless otherwise directed by the Agreement Officer (AO) or the Agreement Officer Representative (AOR), the recipient must submit the Dataset and supporting documentation to the DDL within thirty (30) calendar days after the Dataset is first used to produce an Intellectual Work or is of sufficient quality to produce an Intellectual Work. Within thirty (30) calendar days after award completion, the recipient must submit to the DDL any Datasets and supporting documentation that have not previously been submitted to the DDL, along with an index of all Datasets and Intellectual Work created or obtained under the award. The recipient must also provide to the AOR an itemized list of any and all DDL submissions.
- The recipient is not required to submit the data to the DDL, when, in accordance with the terms and conditions of this award, Datasets containing results of federally funded scientific research are submitted to a publicly accessible research database. However, the recipient must submit a notice to the DDL by following the instructions at www.usaid.gov/data, with a copy to the agreement officer representative, providing details on where and how to access the data. The direct results of federally funded scientific research must be reported no later than when the data are ready to be submitted to a peer-reviewed journal for publication, or no later than five calendar days prior to the conclusion of the award, whichever occurs earlier.
- (3) The recipient must submit the Datasets following the submission instructions and acceptable formats found at www.usaid.gov/data.
- (4) The recipient must ensure that any Dataset submitted to the DDL does not contain any proprietary or personally identifiable information, such as social security numbers, home

addresses, and dates of birth. Such information must be removed prior to submission.

- (5) The recipient must not submit classified data to the DDL.

[END OF PROVISION]

M26. PROHIBITION ON REQUIRING CERTAIN INTERNAL CONFIDENTIALITY AGREEMENTS OR STATEMENTS (MAY 2017)

- (a) Definitions.

“Contract” has the meaning given in 2 CFR Part 200.

“Contractor” means an entity that receives a contract as defined in 2 CFR Part 200.

“Internal confidentiality agreement or statement” means a confidentiality agreement or any other written statement that the recipient requires any of its employees or subrecipients to sign regarding nondisclosure of recipient information, except that it does not include confidentiality agreements arising out of civil litigation or confidentiality agreements that recipient employees or subrecipients sign at the behest of a Federal agency.

“Subaward” has the meaning given in 2 CFR Part 200.

“Subrecipient” has the meaning given in 2 CFR Part 200.

- (b) The recipient must not require its employees, subrecipients, or contractors to sign or comply with internal confidentiality agreements or statements that prohibit or otherwise restrict employees, subrecipients, or contractors from lawfully reporting waste, fraud, or abuse related to the performance of a Federal award to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (for example, the Agency Office of the Inspector General).
- (c) The recipient must notify current employees and subrecipients that prohibitions and restrictions of any preexisting internal confidentiality agreements or statements covered by this provision, to the extent that such prohibitions and restrictions are inconsistent with the prohibitions of this provision, are no longer in effect.
- (d) The prohibition in paragraph (b) of this provision does not contravene the requirements applicable to Standard Form 312 (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.
- (e) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further

Continuing Appropriations Act, 2015, (Pub. L. 113-235), and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions) use of funds appropriated (or otherwise made available) is prohibited, if the Government determines that the recipient is not in compliance with the requirements of this provision.

- (f) The recipient must include the substance of this provision, including this paragraph (f), in subawards and contracts under such awards.

[END OF PROVISION]

M27. CHILD SAFEGUARDING (JUNE 2015)

- (a) Because the activities to be funded under this award may involve children, or personnel engaged in the implementation of the award may come into contact with children, these activities could raise the risk of child abuse, exploitation, or neglect within USAID-funded programs. The organization agrees to abide by the following child safeguarding core principles:
- (1) Ensure compliance with host country and local child welfare and protection legislation or international standards, whichever gives greater protection, and with U.S. law where applicable;
 - (2) Prohibit all personnel from engaging in child abuse, exploitation, or neglect;
 - (3) Consider child safeguarding in project planning and implementation to determine potential risks to children that are associated with project activities and operations;
 - (4) Apply measures to reduce the risk of child abuse, exploitation, or neglect, including, but not limited to, limiting unsupervised interactions with children; prohibiting exposure to pornography; and complying with applicable laws, regulations, or customs regarding the photographing, filming, or other image-generating activities of children;
 - (5) Promote child-safe screening procedures for personnel, particularly personnel whose work brings them in direct contact with children; and
 - (6) Have a procedure for ensuring that personnel and others recognize child abuse, exploitation, or neglect; mandating that personnel and others report allegations; investigating and managing allegations; and taking appropriate action in response to such allegations, including, but not limited to, dismissal of personnel.
- (b) The organization must also include in their code of conduct for all personnel implementing USAID-funded activities the child safeguarding principles in (a) (1) through (6).
- (c) The following definitions apply for purposes of this provision:

- (1) Child: A child or children are defined as persons who have not attained 18 years of age.
 - (2) Child abuse, exploitation, or neglect: Constitutes any form of physical abuse; emotional ill-treatment; sexual abuse; neglect or insufficient supervision; trafficking; or commercial, transactional, labor, or other exploitation resulting in actual or potential harm to the child's health, well-being, survival, development, or dignity. It includes, but is not limited to: any act or failure to act which results in death, serious physical or emotional harm to a child, or an act or failure to act which presents an imminent risk of serious harm to a child.
 - (3) Physical abuse: Constitutes acts or failures to act resulting in injury (not necessarily visible), unnecessary or unjustified pain or suffering without causing injury, harm or risk of harm to a child's health or welfare, or death. Such acts may include, but are not limited to: punching, beating, kicking, biting, shaking, throwing, stabbing, choking, or hitting (regardless of object used), or burning. These acts are considered abuse regardless of whether they were intended to hurt the child.
 - (4) Sexual Abuse: Constitutes fondling a child's genitals, penetration, incest, rape, sodomy, indecent exposure, and exploitation through prostitution or the production of pornographic materials.
 - (5) Emotional abuse or ill treatment: Constitutes injury to the psychological capacity or emotional stability of the child caused by acts, threats of acts, or coercive tactics. Emotional abuse may include, but is not limited to: humiliation, control, isolation, withholding of information, or any other deliberate activity that makes the child feel diminished or embarrassed.
 - (6) Exploitation: Constitutes the abuse of a child where some form of remuneration is involved or whereby the perpetrators benefit in some manner. Exploitation represents a form of coercion and violence that is detrimental to the child's physical or mental health, development, education, or well-being.
 - (7) Neglect: Constitutes failure to provide for a child's basic needs within USAID-funded activities that are responsible for the care of a child in the absence of the child's parent or guardian.
- (d) The recipient must insert the provisions in (a) and (b) in all sub-awards under this award.

[END OF PROVISION]

M28. MANDATORY DISCLOSURES (JULY 2015)

Consistent with 2 CFR §200.113, applicants and recipients must disclose, in a timely manner, in writing to the USAID Office of the Inspector General, with a copy to the cognizant Agreement Officer, all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. Subrecipients must disclose, in a timely manner, in

writing to the USAID Office of the Inspector General and to the prime recipient (pass through entity) all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award.

Disclosures must be sent to:

U.S. Agency for International Development
Office of the Inspector General
P.O. Box 657
Washington, DC 20044-0657

Phone: 1-800-230-6539 or 202-712-1023

Email: ig.hotline@usaid.gov

URL: <https://oig.usaid.gov/content/usaid-contractor-reporting-form>.

Failure to make required disclosures can result in any of the remedies described in 2 CFR §200.338 Remedies for noncompliance, including suspension or debarment (See 2 CFR 180, 2 CFR 780 and 31 U.S.C. 3321).

The recipient must include this mandatory disclosure requirement in all subawards and contracts under this award.

[END OF PROVISION]

M29. NONDISCRIMINATION AGAINST BENEFICIARIES (NOVEMBER 2016)

- (a) USAID policy requires that the recipient not discriminate against any beneficiaries in implementation of this award, such as, but not limited to, by withholding, adversely impacting, or denying equitable access to the benefits provided through this award on the basis of any factor not expressly stated in the award. This includes, for example, race, color, religion, sex (including gender identity, sexual orientation, and pregnancy), national origin, disability, age, genetic information, marital status, parental status, political affiliation, or veteran's status. Nothing in this provision is intended to limit the ability of the recipient to target activities toward the assistance needs of certain populations as defined in the award.
- (b) The recipient must insert this provision, including this paragraph, in all subawards and contracts under this award.

[END OF PROVISION]

M30. CONFLICT OF INTEREST (AUGUST 2018)

- a. A conflict of interest in the award, administration, or monitoring of subawards arises when an employee, officer, or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of these parties, has a

financial or other interest in, or a tangible personal benefit from, a subrecipient considered for a subaward. The officers, employees, and agents of the recipient may neither solicit nor accept gratuities, favors, or anything of monetary value from subrecipients or parties to subawards. However, recipients may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value.

- b. The recipient must maintain written standards of conduct covering conflicts of interest and governing the actions of its employees engaged in the selection, award, and administration of subawards. The standards must prohibit employees from using their positions for a purpose that constitutes or presents the appearance of a conflict of interest. The standards of conduct must provide for disciplinary actions to be applied for violations of such standards by officers, employees, or agents of the recipient.
- c. The recipient must also maintain written standards of conduct covering organizational conflicts of interest. Organizational conflicts of interest means a situation in which the recipient is unable or appears to be unable to be impartial in conducting a subaward action involving a related organization because of relationships with a parent company, affiliate, or subsidiary organization.
- d. The recipient must have a system or systems in place to identify, address, resolve, and disclose to USAID any conflicts of interest as described in this provision that affect any subaward, regardless of the amount of funding.
- e. The recipient must disclose any conflict of interest, including organizational conflicts of interest, and the recipient's approach for resolving the conflict of interest to the cognizant Agreement Officer for the award within ten (10) calendar days of the discovery of the conflict of interest.
- f. Upon notice from the recipient of a potential conflict of interest and the approach for resolving it, the Agreement Officer will make a determination regarding the effectiveness of the recipient's actions to resolve the conflict of interest within thirty (30) calendar days of receipt of the recipient's notice, unless the Agreement Officer advises the recipient that a longer period is necessary.
- g. The recipient must not request payment from USAID for costs for transactions subject to the conflict of interest pending notification of USAID's determination. The recipient's failure to disclose a conflict of interest may result in cost disallowances by USAID.
- h. For conflicts of interest, including organizational conflicts of interest, involving contracts, the recipient must follow 2 CFR 200.318, general procurement standards.
- i. The recipient must insert the substance of this provision, including paragraph (i), in all subawards under this award, at any subaward tier.

[END OF PROVISION]

Washington State University
Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)
Cooperative Agreement 7200AA21CA00033

**REQUIRED AS APPLICABLE STANDARD PROVISIONS FOR U.S.
NONGOVERNMENTAL ORGANIZATIONS**

RAA1. NEGOTIATED INDIRECT COST RATES – PREDETERMINED (NOVEMBER 2020)

- a. The allowable indirect costs must be determined by applying the predetermined indirect cost rates to the bases specified in the schedule of this award.
- b. Except as otherwise provided in 2 CFR 200.414 Indirect (F&A) costs paragraph (e) and (f), a nonprofit organization which has not previously established an indirect cost rate with a Federal agency must submit its initial indirect cost proposal immediately after the organization is advised that a Federal award will be made and, in no event, later than three months after the effective date of the Federal award.

Organizations that have previously established indirect cost rates must submit a new indirect cost proposal to the cognizant agency for indirect costs within six months after the close of each fiscal year.

If USAID is the cognizant agency or no cognizant agency has been designated, the recipient must submit four copies of the audit report, the proposed predetermined indirect cost rates, and supporting cost data to the Overhead, Special Costs, and Closeout Branch, Management Bureau, Office of Acquisition and Assistance, USAID, Washington, DC 20523-7802. The proposed rates must be based on the recipient's actual cost experience during that fiscal year. Negotiations of predetermined indirect cost rates must begin soon after receipt of the recipient's proposal.

- c. Allowability of costs and acceptability of cost allocation methods must be determined in accordance with the applicable cost principles.
- d. The results of each negotiation must be set forth in an indirect cost rate agreement signed by both parties. Such agreement is automatically incorporated into this award and must specify (1) the agreed upon predetermined rates, (2) the bases to which the rates apply, and (3) the fiscal year for which the rates apply. The indirect cost rate agreement must not change any monetary ceiling, award obligation, or specific cost allowance or disallowance provided for in this award.
- e. Predetermined rate means an indirect cost rate, applicable to a specified current or future period, usually the organization's fiscal year. The rate is based on an estimate of the costs to be incurred during the period. A predetermined rate is not subject to adjustment.
- f. If a dispute arises in a negotiation of an indirect cost rate between the cognizant agency for indirect costs and the nonprofit organization, the dispute must be resolved in accordance with the appeals procedures of the cognizant agency for indirect costs.

[END OF PROVISION]

RAA5. EXCHANGE VISITORS AND PARTICIPANT TRAINING (JUNE 2012)

For any Exchange Visitor, Participant Training or Invitational Travel activities, the recipient must comply with this provision.

a. Definitions:

- (1) An **Exchange Visitor** is any host-country or third-country national traveling to the U.S., for any purpose, including Participant Training and Invitational Travel, funded by USAID in whole or in part, directly or indirectly.
- (2) A **Participant** is a host-country or third-country national sponsored by USAID for a Participant Training activity taking place in the U.S., a third country, or in the host country.
- (3) **Participant Training** is a learning activity conducted within the U.S., a third country, or in the host country for the purpose of furthering USAID development objectives. A learning activity takes place in a setting in which an individual (the Participant) interacts with a knowledgeable professional, predominantly for the purpose of acquiring knowledge or skills for the professional or technical enhancement of the individual. Learning activities may be formally structured, such as an academic program or a technical course, or they may be more informal, such as an observational study tour.
- (4) **Invitational Travel** is a type of travel that USAID funds for non-U.S. Government employees. This type of travel may be approved for both U.S. and foreign citizens who are not employed by the U.S. Government (USG), not receiving any type of compensation from the USG for such travel, and only when it is determined that the functions to be performed are essential to the interests of USAID.

b. Program Monitoring and Data Reporting: The recipient must monitor Exchange Visitors' and Participants' progress during their program and ensure that problems are identified and resolved quickly.

- (1) For U.S.-based activities, the recipient must use USAID's official Exchange Visitor and Participant Training information system, currently called "Training Results and Information Network – TraiNet" (see <http://trainethelp.usaid.gov/>), to report and manage Exchange Visitor and Participant Training data. The recipient must also use the USAID Visa Compliance System – VCS (see <http://trainethelp.usaid.gov/>) to transfer required data for USAID Exchange Visitors to the Department of Homeland Security's Student and Exchange Visitor Information System (SEVIS).
- (2) For all third-country activities, and for host-country activities of two consecutive days or 16 contact hours or more in duration, the recipient must use USAID's official

Exchange Visitor and Participant Training information system, currently called “Training Results and Information Network – TraiNet” (see <http://trainethelp.usaid.gov/>), to report and manage Participant Training data.

c. Health and Accident Insurance:

- (1) For Exchange Visitors traveling to the United States, the recipient must enroll Exchange Visitors in health and accident insurance coverage that meets or exceeds Department of State and USAID minimum coverage requirements as set forth in 22 CFR 62.14 and ADS 253.3.6.2. The requirements may be obtained from the Agreement Officer’s Representative.
- (2) For Participants traveling to a third country, the recipient must obtain health and accident insurance coverage for all Participants.
- (3) For Participants traveling within the host country, the recipient must determine whether specific in-country participant training activities subject them to any risk of health and accident liability for medical costs. Participants may incur, and if so, take appropriate steps according to the local situation, including obtaining health and accident insurance coverage for Participants.

d. Immigration Requirements:

- (1) For Exchange Visitors traveling to the United States, the recipient must ensure that all USAID-sponsored Exchange Visitors obtain, use, and comply with the terms of the J-1 visa, issued in conjunction with a USAID-issued Certificate of Eligibility for J-1 Visa Status (DS-2019).
- (2) For Participants traveling to a third country or within the host country, the recipient must ensure that all Participants obtain, use, and comply with the terms of all applicable immigration, visa and other similar requirements.

e. Language Proficiency: The recipient must verify language proficiency. Exchange Visitors must possess sufficient English language proficiency to participate in a U.S.-based activity. Participants of third-country or host-country training must be proficient in the language of training at a sufficient level for participation, unless an interpreter has been arranged. Language competency can be verified through a variety of means including proficiency assessments of interviews, publications, presentations, education conducted in English, and formal testing.

f. Pre-departure Orientation: The recipient must conduct pre-departure orientation for U.S.-bound Exchange Visitors and Participants of third-country training programs. Pre-departure orientation covers: program objectives; administrative and policy review; cultural aspects; and training/learning methods.

- g. **Conditions of Sponsorship:** The recipient must ensure that all Exchange Visitors read and sign the Conditions of Sponsorship for U.S.-Based Activities form (AID 1381-6). The recipient must also ensure that all Participants of long-term (six months or longer) third-country training read and sign the form Conditions of Sponsorship for Third-Country Training form (AID 1381-7). The recipient must report to the Agreement Officer any known violations by Exchange Visitors of visa or other immigration requirements or conditions.
- h. **Exchange Visitor Security Risk and Fraud Inquiry:** Each USAID Mission has an established process for conducting a Security Risk and Fraud Inquiry (SRFI) for Exchange Visitors. The recipient must be prepared to assist Missions in conducting the SRFI, if requested. However, the recipient's role is contributive, and the Mission is ultimately responsible for conducting the SRFI.
- i. **Fly America:** To the extent that participants travel by international air travel, the recipient must comply with the Standard Provision, "International Air Travel and Air Transportation of Property."
- j. **Use of Minority Serving Institutions:** For U.S.-based Participant Training, the recipient must, to the maximum extent possible, maintain their use of Historically Black Colleges and Universities (HBCUs) and other Minority Serving Institutions (MSIs), including Hispanic Serving Institutions and Tribal Colleges and Universities, as training or education providers.

[END OF PROVISION]

RAA7. PROTECTION OF THE INDIVIDUAL AS A RESEARCH SUBJECT (APRIL 1998)

- a. Safeguarding the rights and welfare of human subjects involved in research supported by USAID is the responsibility of the organization to which support is awarded. USAID has adopted the Common Federal Policy for the Protection of Human Subjects, Part 225 of Title 22 of the Code of Federal Regulations (the "Policy"). Additional interpretation, procedures, and implementation guidance of the Policy are found in USAID General Notice entitled "Procedures for the Protection of Human Subjects in Research Supported by USAID," issued April 19, 1995, as amended. USAID's Cognizant Human Subjects Officer (CHSO) in USAID/W has oversight, guidance, and interpretation responsibility for the Policy.
- b. Recipient organizations must comply with USAID policy when humans are the subject of research, as defined in 22 CFR 225.102(d), funded by the grant and recipients must provide "assurance," as required by 22 CFR 225.103, that they follow and abide by the procedures in the Policy. See also Section 5 of the April 19, 1995, USAID General Notice which sets forth activities to which the Policy is applicable. The existence of a bona fide, applicable assurance approved by the Department of Health and Human Services (HHS) such as the "multiple project assurance" (MPA) will satisfy this requirement. Alternatively, organizations can provide an acceptable written assurance to USAID as described in 22 CFR 225.103.

Such assurances must be determined by the CHSO to be acceptable prior to any applicable research being initiated or conducted under the award. In some limited instances outside the U.S., alternative systems for the protection of human subjects may be used provided they are deemed “at least equivalent” to those outlined in Part 225 (See 22 CFR 225.101[h]). Criteria and procedures for making this determination are described in the General Notice cited in the preceding paragraph.

- c. Since the welfare of the research subject is a matter of concern to USAID as well as to the organization, USAID staff consultants and advisory groups may independently review and inspect research and research processes and procedures involving human subjects, and based on such findings, the CHSO may prohibit research which presents unacceptable hazards or otherwise fails to comply with USAID procedures. Informed consent documents must include the stipulation that the subject's records may be subject to such review.

[END OF PROVISION]

RAA8. CARE OF LABORATORY ANIMALS (MARCH 2004)

CARE OF LABORATORY ANIMALS (MARCH 2004)

- a. Before undertaking performance of any grant involving the use of laboratory animals, the recipient must register with the Secretary of Agriculture of the United States in accordance with Section 6, Public Law 89-544, Laboratory Animal Welfare Act, August 24, 1966, as amended by Public Law 91-579, Animal Welfare Act of 1970, December 24, 1970. The recipient must furnish evidence of such registration to the Agreement Officer.
- b. The recipient must acquire animals used in research under this award only from dealers licensed by the Secretary of Agriculture, or from exempted sources in accordance with the Public Laws enumerated in a. above.
- c. In the care of any live animals used or intended for use in the performance of this grant, the recipient must adhere to the principles enunciated in the Guide for Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences - National Research Council (NAS-NRC), and in the United States Department of Agriculture's (USDA) regulations and standards issued under the Public Laws enumerated in a. above. In case of conflict between standards, the higher standard must be used. The recipient's reports on portions of the award in which animals were used must contain a certificate stating that the animals were cared for in accordance with the principles enunciated in the Guide for Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, NAS-NRC, and/or in the regulations and standards as promulgated by the Agricultural Research Service, USDA, pursuant to the Laboratory Animal Welfare Act of 24 August 1966, as amended (P.L. 89-544 and P.L. 91-579). NOTE: The recipient may request registration of the recipient's facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which the recipient's research facility is located. The location of the appropriate APHIS Regional Office as well as information concerning this program may be obtained by contacting the Senior Staff

Office, Animal Care Staff, USDA/APHIS, 4700 River Road, Unit 84, Riverdale, MD 20737-1234 and at www.aphis.usda.gov/animal_welfare/index.shtml.

[END OF PROVISION]

RAA10. COST SHARING (MATCHING) (FEBRUARY 2012)

COST SHARING (MATCHING) (FEBRUARY 2012)

- a. If at the end of any funding period, the recipient has expended an amount of non-Federal funds less than the agreed upon amount or percentage of total expenditures, the Agreement Officer may apply the difference to reduce the amount of USAID incremental funding in the following funding period. If the award has expired or has been terminated, the Agreement Officer may require the recipient to refund the difference to USAID.
- b. The source and nationality requirements and the restricted goods provision established in the Standard Provision entitled "USAID Eligibility Rules for Goods and Services" do not apply to cost sharing (matching) expenditures.

[END OF PROVISION]

RAA11. PROHIBITION OF ASSISTANCE TO DRUG TRAFFICKERS (JUNE 1999)

- a. USAID reserves the right to terminate assistance to, or take other appropriate measures with respect to, any participant approved by USAID who is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR 140.
- b.
 - (1) For any loan over \$1,000 made under this agreement, the recipient must insert a clause in the loan agreement stating that the loan is subject to immediate cancellation, acceleration, recall, or refund by the recipient if the borrower or a key individual of a borrower is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR 140.
 - (2) Upon notice by USAID of a determination under section (1) and at USAID's option, the recipient agrees to immediately cancel, accelerate, or recall the loan, including refund in full of the outstanding balance. USAID reserves the right to have the loan refund returned to USAID.
- c.
 - (1) The recipient agrees not to disburse, or sign documents committing the recipient to disburse, funds to a subrecipient designated by USAID ("Designated Subrecipient") until advised by USAID that: (i) any United States Government review of the Designated Subrecipient and its key individuals has been completed; (ii) any related certifications have been obtained; and (iii) the assistance to the Designated Subrecipient has been

approved. Designation means that the subrecipient has been unilaterally selected by USAID as the subrecipient. USAID approval of a subrecipient, selected by another party, or joint selection by USAID and another party is not designation.

- (2) The recipient must insert the following clause, or its substance, in its agreement with the Designated Subrecipient:

“The recipient reserves the right to terminate this [Agreement/Contract] or take other appropriate measures if the [Subrecipient] or a key individual of the [Subrecipient] is found to have been convicted of a narcotic offense or to have been engaged in drug trafficking as defined in 22 CFR 140.”

[END OF PROVISION]

RAA13. REPORTING HOST GOVERNMENT TAXES (DECEMBER 2014)

- a. By April 16 of each year, the recipient must submit a report containing:
- (1) Contractor/recipient name.
 - (2) Contact name with phone, fax and e-mail.
 - (3) Agreement number(s).
 - (4) The total amount of value-added taxes and customs duties (but not sales taxes) assessed by the host government (or any entity thereof) on purchases in excess of \$500 per transaction of supplies, materials, goods or equipment, during the 12 months ending on the preceding September 30, using funds provided under this contract/agreement.
 - (5) Any reimbursements received by April 1 of the current year on value-added taxes and customs duties reported in (iv).
 - (6) Reports are required even if the recipient did not pay any taxes or receive any reimbursements during the reporting period.
 - (7) Cumulative reports may be provided if the recipient is implementing more than one program in a foreign country.
- b. Submit the reports to: Agreement’s Officer Representative.
- a. Host government taxes are not allowable where the Agreement Officer provides the necessary means to the recipient to obtain an exemption or refund of such taxes, and the recipient fails to take reasonable steps to obtain such exemption or refund. Otherwise, taxes

are allowable in accordance with the Standard Provision, “Allowable Costs,” and must be reported as required in this provision.

- b. The recipient must include this reporting requirement in all applicable subawards and contracts.

[END OF PROVISION]

RAA14. FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)

FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)

- a. U.S. Government funds under this award must not be used to finance the travel, per diem, hotel expenses, meals, conference fees or other conference costs for any member of a foreign government’s delegation to an international conference sponsored by a multilateral organization, as defined below, unless approved by the Agreement Officer in writing.
- b. Definitions:
 - (1) A foreign government delegation is appointed by the national government (including ministries and agencies but excluding local, state and provincial entities) to act on behalf of the appointing authority at the international conference. A conference participant is a delegate for the purposes of this provision, only when there is an appointment or designation that the individual is authorized to officially represent the government or agency. A delegate may be a private citizen.
 - (2) An international conference is a meeting where there is an agenda, an organizational structure, and delegations from countries other than the conference location, in which country delegations participate through discussion, votes, etc.
 - (3) A multilateral organization is an organization established by international agreement and whose governing body is composed principally of foreign governments or other multilateral organizations.

[END OF PROVISION]

RAA18. USAID DISABILITY POLICY - ASSISTANCE (DECEMBER 2004)

- a. The objectives of the USAID Disability Policy are (1) to enhance the attainment of United States foreign assistance program goals by promoting the participation and equalization of opportunities of individuals with disabilities in USAID policy, country and sector strategies, activity designs and implementation; (2) to increase awareness of issues of people with disabilities both within USAID programs and in host countries; (3) to engage other U.S. Government agencies, host country counterparts, governments, implementing organizations

and other donors in fostering a climate of nondiscrimination against people with disabilities; and (4) to support international advocacy for people with disabilities.

- b. USAID therefore requires that the recipient not discriminate against people with disabilities in the implementation of USAID funded programs and that it make every effort to comply with the objectives of the USAID Disability Policy in performing the program under this grant or cooperative agreement. To that end and to the extent it can accomplish this goal within the scope of the program objectives, the recipient should demonstrate a comprehensive and consistent approach for including men, women, and children with disabilities.

[END OF PROVISION]

RAA23. UNIVERSAL IDENTIFIER AND SYSTEM OF AWARD MANAGEMENT (NOVEMBER 2020)

- a. **Requirement for System of Award Management (SAM).** Unless you are exempted from this requirement under 2 CFR 25.110, you as the recipient must maintain current information in the SAM. This includes information on your immediate and highest level owner and subsidiaries, as well as on all of your predecessors that have been awarded a Federal contract or Federal financial assistance within the last three years, if applicable, until you submit the final financial report required under this Federal award or receive the final payment, whichever is later. This requires that you review and update the information at least annually after the initial registration, and more frequently, if required by changes in your information or another Federal award term.
- b. **Requirement for Unique Entity Identifier.** If you are authorized to make subawards under this Federal award, you:
 - (1) Must notify potential subrecipients that no entity (see definition in paragraph c. of this award term) may receive a subaward from you until the entity has provided its Unique Entity Identifier to you.
 - (2) May not make a subaward to an entity unless the entity has provided its Unique Entity Identifier to you. Subrecipients are not required to obtain an active SAM registration but must obtain a Unique Entity Identifier.
- c. **Definitions.** For purposes of this award term:
 - (1) System of Award Management (SAM) means the Federal repository into which a recipient must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM Internet site (currently at <https://www.sam.gov>).

- (2) Unique Entity Identifier means the identifier assigned by SAM to uniquely identify business entities.
- (3) Entity includes non-Federal entities as defined in 2 CFR 200.1 and also includes all of the following, for purposes of this part:
 - a. A foreign organization;
 - b. A foreign public entity;
 - c. A domestic for-profit organization; and
 - d. A Federal agency.
- (4) Subaward has the meaning given in 2 CFR 200.1.
- (5) Subrecipient has the meaning given in 2 CFR 200.1.

ADDENDUM (NOVEMBER 2020):

- d. **Exceptions.** The requirements of this provision to obtain a Unique Entity Identifier and maintain a current registration in the SAM do not apply, at the prime award or subaward level, to:
 - (1) Awards to individuals
 - (2) Awards less than \$25,000 to foreign recipients to be performed outside the United States (based on a USAID determination)
 - (3) Awards where the Agreement Officer determines, in writing, that the Agency must protect entity information from disclosure due to national security or foreign policy interests of the United States or that these requirements would cause personal safety concerns.
- e. This provision does not need to be included in subawards.

[END OF PROVISION]

**RAA24. REPORTING SUBAWARDS AND EXECUTIVE COMPENSATION
(NOVEMBER 2020)**

- a. **Reporting of first-tier subawards.**
 - (1) Applicability. Unless you are exempt as provided in paragraph d. of this award term, you must report each action that equals or exceeds \$30,000 in Federal funds for a subaward to a non-Federal entity or Federal agency (see definitions in paragraph e. of this award term).

(2) Where and when to report.

- (i) The non-Federal entity or Federal agency must report each obligating action described in paragraph a.(1) of this award term to www.fsrs.gov.
- (ii) For subaward information, report no later than the end of the month following the month in which the obligation was made. (For example, if the obligation was made on November 7, 2010, the obligation must be reported by no later than December 31, 2010.)

(3) What to report. You must report the information about each obligating action that the submission instructions posted at www.fsrs.gov specify.

b. Reporting Total Compensation of Recipient Executives.

(1) Applicability and what to report. You must report total compensation for each of your five most highly compensated executives for the preceding completed fiscal year, if –

- (i) The total Federal funding authorized to date under this Federal award equals or exceeds \$30,000 as defined in 2 CFR 170.320;
- (ii) In the preceding fiscal year, you received—
 - (A) 80 percent or more of your annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
 - (B) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
- (iii) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at www.sec.gov/answers/execomp.htm.)

(2) Where and when to report. You must report executive total compensation described in paragraph b.(1) of this award term:

- (i) As part of your registration profile at www.sam.gov.
- (ii) By the end of the month following the month in which this award is made, and annually thereafter.

c. Reporting of Total Compensation of Subrecipient Executives.

- (1) Applicability and what to report. Unless you are exempt as provided in paragraph d. of this award term, for each first-tier subrecipient under this award, you must report the names and total compensation of each of the subrecipient's five most highly compensated executives for the subrecipient's preceding completed fiscal year, if–
 - (i) In the subrecipient's preceding fiscal year, the subrecipient received—
 - (A) 80 percent or more of its annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
 - (B) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts), and Federal financial assistance subject to the Transparency Act (and subawards); and
 - (ii) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at www.sec.gov/answers/execomp.htm.)
- (2) Where and when to report. You must report subrecipient executive total compensation described in paragraph c.(1) of this award term:
 - (i) To the recipient.
 - (ii) By the end of the month following the month during which you make the subaward. For example, if a subaward is obligated on any date during the month of October of a given year (for example, between October 1 and 31), you must report any required compensation information of the subrecipient by November 30 of that year.

d. Exemptions.

If, in the previous tax year, you had gross income, from all sources, under \$300,000, you are exempt from the requirements to report:

- (1) Subawards, and
- (2) The total compensation of the five most highly compensated executives of any subrecipient.

e. Definitions.

For purposes of this award term:

- (1) Federal Agency means a Federal agency as defined at 5 U.S.C. 551(1) and further clarified by 5 U.S.C. 552(f).
- (2) Entity means all of the following, as defined in 2 CFR 25:
 - (i) A governmental organization, which is a State, local government, or Indian tribe;
 - (ii) A foreign public entity;
 - (iii) A domestic or foreign nonprofit organization; and
 - (iv) A domestic or foreign for-profit organization.
- (3) Executive means officers, managing partners, or any other employees in management positions.
- (4) Subaward:
 - (i) This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.
 - (ii) The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see 2 CFR 200.331).
 - (iii) A subaward may be provided through any legal agreement, including an agreement that you or a subrecipient considers a contract.
- (5) Subrecipient means a non-Federal entity or Federal agency that:
 - (i) Receives a subaward from you (the recipient) under this award; and
 - (ii) Is accountable to you for the use of the Federal funds provided by the subaward.
- (6) Total compensation means the cash and noncash dollar value earned by the executive during the recipient's or subrecipient's preceding fiscal year and includes the following (for more information see 17 CFR 229.402(c)(2)):
 - (i) Salary and bonus.

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- (ii) Awards of stock, stock options, and stock appreciation rights. Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Statement of Financial Accounting Standards No. 123 (Revised 2004) (FAS 123R), Shared Based Payments.
- (iii) Earnings for services under nonequity incentive plans. This does not include group life, health, hospitalization, or medical reimbursement plans that do not discriminate in favor of executives, and are available generally to all salaried employees.
- (iv) Change in pension value. This is the change in present value of defined benefit and actuarial pension plans.
- (v) Above-market earnings on deferred compensation which is not tax-qualified.
- (vi) Other compensation, if the aggregate value of all such other compensation (for example, severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property) for the executive exceeds \$10,000.

[END OF PROVISION]

RAA25. PATENT REPORTING PROCEDURES (NOVEMBER 2020)

As incorporated by 2 CFR 200.315 and the standard provision “APPLICABILITY OF 2 CFR 200 and 2 CFR 700,” the clause at 37 CFR 401.14 (“Standard Patent Rights”) is incorporated by reference into this award as if set forth in full text. The recipient must use the National Institutes of Health EDISON Patent Reporting and Tracking system (<http://www.iedison.gov>) to fulfill its disclosure obligations under 37 CFR 401.14(c)(1). The recipient must also submit reports on utilization of subject inventions annually to the Agreement Officer’s Representative under 37 CFR 401.14(h), and the last report must be provided within 90 days of the expiration of the agreement.

[END OF PROVISION]

RAA26. ACCESS TO USAID FACILITIES AND USAID’S INFORMATION SYSTEMS (AUGUST 2013)

- a. A U.S. citizen or resident alien engaged in the performance of this award as an employee, consultant, or volunteer of a U.S organization may obtain access to USAID facilities or logical access to USAID’s information systems only when and to the extent necessary to carry out this award and in accordance with this provision. The recipient’s employees, consultants, or volunteers who are not U.S. citizen as well as employees, consultants, or volunteers of non-U.S.

- b. organizations, irrespective of their citizenship, will not be granted logical access to U.S. Government information technology systems (such as Phoenix, GLAAS, etc.) and must be escorted to use U.S. Government facilities (such as office space).
- c. Before a U.S. citizen or resident alien engaged in the performance of this award as an employee, consultant, or volunteer of the recipient, subrecipient or contractor at any tier may obtain a USAID ID (new or replacement) authorizing the individual routine access to USAID facilities in the United States, or logical access to USAID's information systems, the individual must provide two forms of identity source documents in original form. One identity source document must be a valid Federal or State government-issued picture ID. The recipient must contact the USAID Office of Security to obtain the list of acceptable forms of documentation. Submission of these documents, and related background checks, are mandatory in order for the individual to receive a building access ID, and before access will be granted to any of USAID's information systems. All such individuals must physically present these two source documents for identity proofing at their Security Briefing. All individuals provided access under this provision must return any issued building access ID and remote authentication token to USAID custody upon termination of the individual's employment with the recipient or completion of the award, whichever occurs first.
- d. Individuals engaged in the performance of this award as an employee, consultant, or volunteer of the recipient must comply with all applicable Homeland Security Policy Directive-12 (HSPD-12) and Personal Identity Verification (PIV) procedures, as described above, as well as any subsequent USAID or government-wide HSPD-12 and PIV procedures/policies, including any
- e. HSPD-12 procedures established by the Office of Security in USAID/Washington.
- f. The recipient is required to include this provision in all subawards and contracts at any tier made to a U.S. organization/company, that require employees or consultants engaged in the performance of this award to have routine physical access to USAID facilities or logical access to USAID's information systems in order to perform this award.

[END OF PROVISION]

RAA27. CONTRACT PROVISION FOR DBA INSURANCE UNDER RECIPIENT PROCUREMENTS (DECEMBER 2014)

All contracts made by the recipient under this award for services to be performed overseas must contain the following provision, as applicable.

Workers' Compensation Insurance (Defense Base Act)

- (a) The Contractor must--

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- (1) Before commencing performance under this contract, establish provisions to provide for the payment of disability compensation and medical benefits to covered employees and death benefits to their eligible survivors, by purchasing Defense Base Act (DBA) insurance pursuant to the terms of the contract between USAID and USAID's DBA insurance carrier unless the Contractor qualifies as a self-insurer under the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 932) as extended by the Defense Base Act (42 U.S.C. 1651, et seq.), or has an approved retrospective rating agreement for DBA. The Contractor must continue to maintain these provisions to provide such Defense Base Act benefits until contract performance is completed.
- (2) If USAID or the Contractor has secured a waiver of DBA coverage in accordance with AIDAR 728.305-70(a) for contractor's employees who are not citizens of, residents of, or hired in the United States, the contractor agrees to provide such employees with worker's compensation benefits as required by the laws of the country in which the employees are working, or by the laws of the employee's native country, whichever offers greater benefits. The Department of Labor has granted partial blanket waivers of DBA coverage applicable to USAID-financed contracts performed in countries listed in the DEFENSE BASE ACT (DBA) WAIVER LIST.
- (3) Within ten days of an employee's injury or death or from the date the Contractor has knowledge of the injury or death, submit Form LS-202 (Employee's First Report of Injury or Occupational Illness) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 930(a), 20 CFR 702.201 to 702.203).
- (4) Pay all compensation due for disability or death within the timeframes required by the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914, 20 CFR 702.231 and 703.232).
- (5) Provide for medical care as required by the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 907, 20 CFR 702.402 and 702.419).
- (6) If controverting the right to compensation, submit Form LS-207 (Notice of Controversion of Right to Compensation) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914(d), 20 CFR 702.251).
- (7) Immediately upon making the first payment of compensation in any case, submit Form LS-206 (Payment of Compensation Without Award) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914(c), 20 CFR 702.234).
- (8) When payments are suspended or when making the final payment, submit Form LS-208 (Notice of Final Payment or Suspension of Compensation Payments) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914 (c) and (g), 20 CFR 702.234 and 702.235).

- (9) Adhere to all other provisions of the Longshore and Harbor Workers' Compensation Act as extended by the Defense Base Act, and Department of Labor regulations at 20 CFR Parts 701 to 704.

For additional information on the Longshore and Harbor Workers' Compensation Act requirements see <http://www.dol.gov/owcp/dlhwc/lbdba.htm>.

The Contractor must insert the substance of this clause including this paragraph (c), in all subcontracts to which the Defense Base Act applies.

[END OF PROVISION]

RAA28. AWARD TERM AND CONDITION FOR RECIPIENT INTEGRITY AND PERFORMANCE MATTERS (APRIL 2016)

A. Reporting of Matters Related to Recipient Integrity and Performance

1. General Reporting Requirement

If the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds \$10,000,000 for any period of time during the period of performance of this Federal award, then you as the recipient during that period of time must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) about civil, criminal, or administrative proceedings described in paragraph 2 of this award term and condition. This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available.

2. Proceedings About Which You Must Report

Submit the information required about each proceeding that:

- a. Is in connection with the award or performance of a grant, cooperative agreement, or procurement contract from the Federal Government;
- b. Reached its final disposition during the most recent five year period; and
- c. Is one of the following:
 - (1) A criminal proceeding that resulted in a conviction, as defined in paragraph 5 of this award term and condition;

- (2) A civil proceeding that resulted in a finding of fault and liability and payment of a monetary fine, penalty, reimbursement, restitution, or damages of \$5,000 or more;
- (3) An administrative proceeding, as defined in paragraph 5. of this award term and condition, that resulted in a finding of fault and liability and your payment of either a monetary fine or penalty of \$5,000 or more or reimbursement, restitution, or damages in excess of \$100,000; or
- (4) Any other criminal, civil, or administrative proceeding if:
 - (i) It could have led to an outcome described in paragraph 2.c.(1), (2), or (3) of this award term and condition;
 - (ii) It had a different disposition arrived at by consent or compromise with an acknowledgment of fault on your part; and
 - (iii) The requirement in this award term and condition to disclose information about the proceeding does not conflict with applicable laws and regulations.

3. Reporting Procedures

Enter in the SAM Entity Management area the information that SAM requires about each proceeding described in paragraph 2 of this award term and condition. You do not need to submit the information a second time under assistance awards that you received if you already provided the information through SAM because you were required to do so under Federal procurement contracts that you were awarded.

4. Reporting Frequency

During any period of time when you are subject to the requirement in paragraph 1 of this award term and condition, you must report proceedings information through SAM for the most recent five year period, either to report new information about any proceeding(s) that you have not reported previously or affirm that there is no new information to report. Recipients that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 must disclose semiannually any information about the criminal, civil, and administrative proceedings.

5. Definitions

For purposes of this award term and condition:

- a. Administrative proceeding means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative proceedings, Civilian Board of Contract Appeals

proceedings, and Armed Services Board of Contract Appeals proceedings). This includes proceedings at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include audits, site visits, corrective plans, or inspection of deliverables.

- b. Conviction, for purposes of this award term and condition, means a judgment or conviction of a criminal offense by any court of competent jurisdiction, whether entered upon a verdict or a plea, and includes a conviction entered upon a plea of nolo contendere.
- c. Total value of currently active grants, cooperative agreements, and procurement contracts includes—
 - (1) Only the Federal share of the funding under any Federal award with a recipient cost share or match; and
 - (2) The value of all expected funding increments under a Federal award and options, even if not yet exercised.

B. [Reserved]

[END OF PROVISION]

[END OF PROVISION]

RAA30. PROGRAM INCOME (AUGUST 2020)

PROGRAM INCOME (August 2020)

- a. Program income is gross income earned by the recipient that is directly generated by a supported activity or earned as a result of the Federal award during the period of performance. Program income includes, but is not limited to: income from fees for services performed; the use or rental of real or personal property acquired under Federal awards; the sale of commodities or items fabricated under a Federal award; license fees and royalties on patents and copyrights; and principal and interest on loans made with Federal award funds. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, or interest earned on any of them.
- b. Program income must be used for the purposes, and under the conditions, of the award, to further project objectives, program objectives, or award activities. Program income must be used only for allowable program costs. Interest earned on program income is subject to the same conditions as program income.
- c. The recipient must apply the approach for use of program income as specified in the schedule of the award. This may include one of the three approaches listed below (see also [2 CFR](#)

200.307). The recipient must also follow the standards in this provision to account for gross income earned from Federally-supported activities under this award.

1) If the deduction approach is used, the recipient must use the program income for current costs, prior to drawdown of USAID funds under the award.

2) If the addition approach is used, the total award amount is increased by the amount of program income. If the award anticipates a specific program income amount, any program income in excess of such amount must be deducted from expenditures.

3) If the cost sharing approach is used, the amount of the award remains the same. If the award anticipates a specific program income amount, any program income in excess of such amount must be deducted from expenditures.

d. Costs subject to generating program income under this award may be deducted from gross income to calculate program income, provided these costs have not been charged to this award and comply with the standard provision, “Allowable Costs.”

e. The recipient must report program income using the **Federal Financial Report, SF-425**. Program income must be accounted for in the same ratio as USAID’s participation in the program. For example, if USAID funded 75 percent of a recipient’s program, then the recipient must report 75 percent of any program income earned under the award as “Federal program income earned” on the SF-425.

f. The recipient should continue to use program income earned after the period of the award to further award objectives, but is not subject to Federal requirements governing the disposition of program income earned after the end of the period of performance for the award.

[END OF PROVISION]

[END OF STANDARD PROVISIONS]

Washington State University
Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)
Cooperative Agreement 7200AA21CA00033

ATTACHMENT D – BRANDING AND MARKING PLAN

From: Yager, Amanda L
Sent: Friday, December 17, 2021 4:55 PM
To: ORSO
Cc: Moore, Anke Marga-Christa
Subject: 141061 WUSTL subaward
Attachments: subaward-initiation-form WUSTL.pdf; 141061 WUSTL.pdf

Attached is the subaward information for The Washington University – St. Louis under 141061. Let me know if you have any questions.



Amanda Yager
Research Services Manager
Paul G. Allen School for Global Health
College of Veterinary Medicine
Washington State University
Email: ayager@wsu.edu

SUBAGREEMENT INITIATION FORM

Washington State University

Hover over each section for additional guidance

ORSO#: 141061

Project Title: PMU: Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)

Financial Overview:

1. Check if your subrecipient is listed as pre-approved, [here](#).
2. If not listed via the link above, please obtain and attach w/this form the subrecipient's most recent [Single Audit](#) for financial review. If unavailable, send recent tax record or certified financial statement.
3. No financial information? Please have subrecipient fill and return this [Subrecipient Questionnaire](#).

Attached with this form are the following:

☒ Statement of Work* ☒ Budget* ☐ Budget* Justification ☐ F&A Rate Agreement ☐ FCOI form ☐ RCR form ☐ Financial Documents
for New Supplier only: ☐ W9* Domestic ☐ W8* BEN/BENE Foreign

*Required attachments

WSU Information

PI: Felix Lankester Admin Contact: Amanda Yager
Phone: Phone:
Email: felix.lankester@wsu.edu Email: ayager@wsu.edu
Address: Paul G. Allen School for Global Animal Health PO Box 647090

☒ Federal Sponsor: USAID Prime Award #: 7200AA21CA00033
☐ Non-Fed Sponsor:

Funds set aside in AWD #: 003704 GR# 00008484 WD Supplier # SCP003545

Subrecipient Information

Legal Name: The Washington University Admin. Contact: Maria Guzman Phone: (314) 362-4829
DUNS/UEI#: 18 EIN#: 40 Email: mguzman@wustl.edu Remittance Address:
PI: David Wang General Address: Washington University in St. Louis
Phone: (314) 286-1123 Campus Box 1054 Sponsored Projects Accounting
Email: davewang@wustl.edu One Brookings Drive Campus Box 1034, 700 Rosedale Avenue
St. Louis, MO 63130-4862 St. Louis, MO 63112-1408

Subagreement Information

Amount Funded this action: \$ 91,051.00 Total Est. Funding: \$ 7,500,000.00
Cost Share this action: \$ 4,580.00 F&A Rate, if applicable: 49 %
Budget Period this action: 10/01/2021 — 09/30/2022 Est. Project Period: 10/01/2021 — 09/30/2026

Human Subjects ☒ Yes ☐ No

Subrecipient IRB not required for the following reason:

- ☐ IRB Exempt
☐ WSU acting as sIRB
☐ Other sIRB designated
☐ Approval will be sought after 1 year

Status of IRB:

- ☐ Approved
☒ Pending

Comments: These will be requested when the use of human subjects is approved by USAID

Animal Subjects ☒ Yes ☐ No

Status of IACUC approval

- ☐ Approved
☒ Pending

Comments: These will be requested when use of animals is approved by USAID

Technical/Progress Reporting requirement		
<input type="checkbox"/> Annual	<input type="checkbox"/> Monthly	
<input checked="" type="checkbox"/> Quarterly	<input checked="" type="checkbox"/> At the discretion of the PI to satisfy reporting REQs	
Other		
<input checked="" type="checkbox"/> Data Management/Sharing Plan	<input type="checkbox"/> Foreign subrecipient	<input type="checkbox"/> Select Agents Name/ Comments below:
<input checked="" type="checkbox"/> Human Subjects Data	<input type="checkbox"/> Carryforward restricted by PI	
<input type="checkbox"/> Fixed Priced Agreement	<input type="checkbox"/> Biohazardous materials	
<p>Please list any special requirements or provide any other information you think might be useful for the person preparing this subagreement:</p> <p>Please work closely with Amanda Yager; Research Services Manager, Paul G. Allen School of Global Health, on any updates. Only partial budget at this time is being submitted until USAID approves the project workplan and budget detail. After approval budget and budget justification will be submitted.</p>		

WSU PI Verification
<p>By signing below, I certify that I have read the following statements and certify that they are accurate and true to the best of my knowledge:</p> <p>The subagency's proposed costs have been reviewed and are reasonable for the technical effort proposed. Funding is available for this subagreement and is an allowable cost under the terms of the prime.</p> <p><input type="checkbox"/> The project and relationship with this subagency present a potential conflict of interest or appearance thereof and a COI plan and explanation are attached.</p> <p>[OR]</p> <p><input checked="" type="checkbox"/> No conflict of interest as defined in <u>Executive Policy #27</u> has been identified as a result of this project and relationship with the subagency.</p>
<p>Unavailable for Signature</p> <p>_____</p> <p>Signature of WSU PI</p>

For accounting purposes, please fill the below subrecipient budget template by WSU object code:

Salaries – 00	\$ 57,810.00
Wages - 01	
Personal Svc Contract – 02	
Goods/Services – 03	
Travel – 04	
Computer Services -05	
Equipment – 06	
Benefits – 07	
Stipends/Subsides - 08	
SBCTs/Restricted – 14	
Small/Attractive Items – 16	
Total Direct Costs	\$ 57,810.00
F&A - 13	\$ 49
Total Costs	\$ 91,051.00

Helpful Links:

Sam.gov:

<https://sam.gov/SAM/>

Federal Audit Clearinghouse:

<https://harvester.census.gov/facweb/>

ORSO Policy & Guidelines:

<https://orso.wsu.edu/wsu-policies-guidelines/>

For questions:

Please contact ORSO at 5-9661 or orso@wsu.edu.

FDP Cost Reimbursement Subaward

Federal Awarding Agency: Other [Type in Agency]		US Agency for International Development
Pass-Through Entity (PTE):		Subrecipient:
Washington State University		The Washington University
PTE PI: Felix Lankester	Sub PI: David Wang	
PTE Federal Award No: 7200AA21CA00033	Subaward No: 141061 - SPC003545	
Project Title: Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)		
Subaward Budget Period:		Amount Funded This Action (USD): \$ 91,051.00
Start: 10/01/2021	End: 09/30/2022	
Estimated Period of Performance:		Incrementally Estimated Total (USD): \$ 7,500,000.00
Start: 10/01/2021	End: 09/30/2026	

Terms and Conditions

1. PTE hereby awards a cost reimbursable subaward, (as determined by 2 CFR 200.331), to Subrecipient. The Statement of Work and budget for this Subaward are as shown in Attachment 5. In its performance of Subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.
2. Subrecipient shall submit invoices not more often than monthly and not less frequently than quarterly for allowable costs incurred. Upon the receipt of proper invoices, the PTE agrees to process payments in accordance with this Subaward and 2 CFR 200.305. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), breakdown by major cost category, Subaward number, and certification, as required in 2 CFR 200.415(a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments shall be directed to the party's Financial Contact, shown in Attachment 3A.
3. A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Financial Contact, as shown in Attachment 3A, not later than 60 days after the final Budget Period end date. The final statement of costs shall constitute Subrecipient's final financial report.
4. All payments shall be considered provisional and are subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Subrecipient.
5. Matters concerning the technical performance of this Subaward shall be directed to the appropriate party's Principal Investigator as shown in Attachments 3A and 3B. Technical reports are required as shown in Attachment 4.
6. Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this Subaward, and any changes requiring prior approval, shall be directed to the PTE's Authorized Official Contact and the Subrecipient's Authorized Official Contact shown in Attachments 3A and 3B. Any such change made to this Subaward requires the written approval of each party's Authorized Official as shown in Attachments 3A and 3B.
7. The PTE may issue non-substantive changes to the Budget Period(s) and Budget Bilaterally. Unilateral modification shall be considered valid 14 days after receipt unless otherwise indicated by Subrecipient when sent to Subrecipient's Authorized Official Contact, as shown in Attachment 3B.
8. Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.
9. Either party may terminate this Subaward with 30 days written notice. Notwithstanding, if the Awarding Agency terminates the Federal Award, PTE will terminate in accordance with Awarding Agency requirements. PTE notice shall be directed to the Authorized Official Contact, and Subrecipient notice shall be directed to the Authorized Official Contact as shown in Attachments 3A and 3B. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix IX, as applicable.
10. By signing this Subaward, including the attachments hereto which are hereby incorporated by reference, Subrecipient certifies that it will perform the Statement of Work in accordance with the terms and conditions of this Subaward and the applicable terms of the Federal Award, including the appropriate Research Terms and Conditions ("RTCs") of the Federal Awarding Agency, as referenced in Attachment 2. The parties further agree that they intend this subaward to comply with all applicable laws, regulations, and requirements.

By an Authorized Official of the PTE:		By an Authorized Official of the Subrecipient:	
<div style="border-bottom: 1px solid black; width: 100%;"></div> <div style="display: flex; justify-content: space-between;"> Name: <div style="border-bottom: 1px solid black; width: 80%;"></div> Date: <div style="border-bottom: 1px solid black; width: 15%;"></div> </div> <div style="display: flex; justify-content: space-between;"> Title: <div style="border-bottom: 1px solid black; width: 80%;"></div> </div>	<div style="border-bottom: 1px solid black; width: 100%;"></div> <div style="display: flex; justify-content: space-between;"> Name: <div style="border-bottom: 1px solid black; width: 80%;"></div> Date: <div style="border-bottom: 1px solid black; width: 15%;"></div> </div> <div style="display: flex; justify-content: space-between;"> Title: <div style="border-bottom: 1px solid black; width: 80%;"></div> </div>		

Attachment 1

Certifications and Assurances

Subaward Number:

141061 - SPC003545

Certification Regarding Lobbying (2 CFR 200.450)

By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief, that no Federal appropriated funds have been paid or will be paid, by or on behalf of the Subrecipient, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement in accordance with 2 CFR 200.450.

If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or intending to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the Subrecipient shall complete and submit Standard Form -LLL, "Disclosure Form to Report Lobbying," to the PTE.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by 31 U.S.C. 1352. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

Debarment, Suspension, and Other Responsibility Matters (2 CFR 200.214 and 2 CFR 180)

By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief that neither the Subrecipient nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this transaction by any federal department or agency, in accordance with 2 CFR 200.213 and 2 CFR 180.

Audit and Access to Records

Subrecipient certifies that it will provide PTE with notice of any adverse findings which impact this Subaward. Subrecipient certifies compliance with applicable provisions of 2 CFR 200.501-200.521. If Subrecipient is not required to have a Single Audit as defined by 200.501, Awarding Agency requirements, or the Single Audit Act, then Subrecipient will provide notice of the completion of any required audits and will provide access to such audits upon request. Subrecipient will provide access to records as required by parts 2 CFR 200.337 and 200.338 as applicable.

Program for Enhancement of Contractor Employee Protections (41 U.S.C 4712)

Subrecipient is hereby notified that they are required to: inform their employees working on any federal award that they are subject to the whistleblower rights and remedies of the program; inform their employees in writing of employee whistleblower protections under 41 U.S.C §4712 in the predominant native language of the workforce; and include such requirements in any agreement made with a subcontractor or subgrantee.

The Subrecipient shall require that the language of the certifications above in this Attachment 1 be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

Use of Name

Neither party shall use the other party's name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may use factual information regarding the existence and purpose of the relationship that is the subject of this Subaward for legitimate business purposes, to satisfy any reporting and funding obligations, or as required by applicable law or regulation without written permission from the other party. In any such statement, the relationship of the parties shall be accurately and appropriately described.

Prohibition on Certain Telecommunication and Video Surveillance Services or Equipment

Pursuant to 2 CFR 200.216, Subrecipient will not obligate or expend funds received under this Subaward to: (1) procure or obtain; (2) extend or renew a contract to procure or obtain; or (3) enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that uses covered telecommunications equipment or services (as described in Public Law 115-232, section 889) as a substantial or essential component of any system, or as a critical technology as part of any system.

Attachment 2

Federal Award Terms and Conditions

Subaward Number

141061 - SPC003545

Required Data Elements

The data elements required by Uniform Guidance are incorporated in the attached Federal Award.

This Subaward Is:

☒ Research & Development ☐ Subject to FFATA

Awarding Agency Institute (If Applicable)

USAID

Federal Award Issue Date FAIN Assistance Listing No.

09/22/21

7200AA21CA00033

98.001

Assistance Listing Program Title (ALPT)

USAID Foreign Assistance for Programs Overseas

Key Personnel Per NOA

Ch. Rabiner; B.T. Leader

General Terms and Conditions

By signing this Subaward, Subrecipient agrees to the following:

- To abide by the conditions on activities and restrictions on expenditure of federal funds in appropriations acts that are applicable to this Subaward to the extent those restrictions are pertinent. This includes any recent legislation noted on the Federal Awarding Agency's website:
<https://www.usaid.gov/who-we-are/agency-policy>
- 2 CFR 200
- The Federal Awarding Agency's grants policy guidance, including addenda in effect as of the beginning date of the period of performance or as amended found at:
<https://www.usaid.gov/ads/policy/300/303>
- Research Terms and Conditions, including any Federal Awarding Agency's Specific Requirements found at:
see attachment #6 except for the following :
 - No-cost extensions require the written approval of the PTE. Any requests for a no-cost extension shall be directed to the Authorized Official Contact shown in Attachment 3A, not less than 30 days prior to the desired effective date of the requested change.
 - Any payment mechanisms and financial reporting requirements described in the applicable Federal Awarding Agency Terms and Conditions and Agency-Specific Requirements are replaced with Terms and Conditions (1) through (4) of this Subaward; and
 - Any prior approvals are to be sought from the PTE and not the Federal Awarding Agency.
 - Title to equipment as defined in 2 CFR 200.1 that is purchased or fabricated with research funds or Subrecipient cost sharing funds, as direct costs of the project or program, shall vest in the Subrecipient subject to the conditions specified in 2 CFR 200.313.
 - Prior approval must be sought for a change in Subrecipient PI or change in Key Personnel (defined as listed on the NOA).
- Treatment of program income: Additive

Special Terms and Conditions:

Data Sharing and Access:

Subrecipient agrees to comply with the Federal Awarding Agency's data sharing and/or access requirements as reflected in the NOA or the Federal Awarding Agency's standard terms and conditions as referenced in General Terms and Conditions 1-4 above.

Provided upon request is a Data Management and/or Sharing Plan that incorporates additional requirements as submitted to the Federal Awarding Agency.

Data Rights:

Subrecipient grants to PTE the right to use data created in the performance of this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Copyrights:

Subrecipient Shall Grant to PTE an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted material (including any computer software and its documentation and/or databases) first developed and delivered under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Subrecipient grants to PTE the right to use any written progress reports and deliverables created under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its Federal Award.

Promoting Objectivity in Research (COI):

Subrecipient must designate herein which entity's Financial Conflicts of Interest policy (COI) will apply: Subrecipient

If applying its own COI policy, by execution of this Subaward, Subrecipient certifies that its policy complies with the requirements of the relevant Federal Awarding Agency as identified herein: US Agency for International Development

Subrecipient shall report any financial conflict of interest to PTE's Administrative Representative or COI contact, as designated on Attachment 3A. Any financial conflicts of interest identified shall, when applicable, subsequently be reported to Federal Awarding Agency. Such report shall be made before expenditure of funds authorized in this Subaward and within 45 days of any subsequently identified COI.

Work Involving Human or Vertebrate Animals (Select Applicable Options)☐ No Human or Vertebrate Animals**IRB**☒ Human Subjects**IACUC**☒ Vertebrate Animals

The PTE requires verification of IRB and/or IACUC approval be sent to the as required above:

Subrecipient agrees that any non-exempt human and/or vertebrate animal research protocol conducted under this Subaward shall be reviewed and approved by the appropriate Institutional Review Board (IRB) and/or its Institutional Animal Care and Use Committee (IACUC), as applicable and that it will maintain current and duly approved research protocols for all periods of the Subaward involving human and/or vertebrate animal research. Subrecipient certifies that the appropriate IRB and/or IACUC are in full compliance with applicable state and federal laws and regulations. The Subrecipient certifies that any submitted IRB / IACUC approval represents a valid, approved protocol that is entirely consistent with the Project associated with this Subaward. In no event shall Subrecipient invoice or be reimbursed for any human or vertebrate animals related expenses incurred in a period where any applicable IRB / IACUC approval is not properly in place.

Human Subjects Data (Select One)

Human Subjects Data will be exchanged under this Subaward (check all that apply):

- ☒ From Subrecipient to PTE
☒ From PTE to Subrecipient

The PTE will set forth the terms of the exchange of Human Subjects Data (Select One):

This section left intentionally blank

Additional Terms

Subawards issued under this award are subject to additional USAID approval.

If applicable, Subrecipient certifies that its Institutional Biosafety committee is in full compliance with applicable state and federal laws and regulations. Subrecipient agrees that any non-exempt research involving recombinant or synthetic nucleic acid molecules or select agents conducted under this agreement shall be reviewed and approved by its Institutional Biosafety Committee, as applicable. In Addition, Subrecipient will maintain current and duly approved research protocols for all periods of the Agreement involving recombinant or synthetic nucleic acid molecules or select agents.

The Subrecipient certifies that any submitted recombinant or synthetic nucleic acid molecules or select agents approval represents a valid, approved protocol that is entirely consistent with project associated with this subaward. In no event shall subrecipient invoice or be reimbursed for any recombinant or synthetic nucleic acid molecules or select agents related expense incurred in a period where any applicable IRB/IACUC approval is not properly in place.

In addition to other applicable provisions in the NOA, the mandatory provisions for U.S. Nongovernmental organizations found in the NOA as part of Attachment 6 (Pages 40-65 of this subaward) are incorporated by reference into this subaward.

Attachment 3A
Pass-Through Entity (PTE) Contacts

Subaward Number:

141061 - SPC003545

PTE Information

Entity Name: Washington State University

Legal Address: Office of Research Support and Operations
280 Lighty
PO Box 641060
Pullman, WA 99164-1060

Website: <https://orso.wsu.edu/>

PTE Contacts

Central Email: orso@wsu.edu

Principal Investigator Name: Felix Lankester

Email: felix.lankester@wsu.edu

Telephone Number:

Administrative Contact Name: Chana Rabiner

Email: chana.rabiner@wsu.edu

Telephone Number:

COI Contact email (if different to above): orso@wsu.edu

Financial Contact Name: Casey St. Clair, Director, Sponsored Programs

Email: sps@wsu.edu

Telephone Number: (509) 335-2058

Email invoices? ☒ Yes ☐ No Invoice email (if different): ayager@wsu.edu

Authorized Official Name: Dan Nordquist, AVP ORSO

Email: orso@wsu.edu

Telephone Number: (509) 335-9661

PI Address:

Washington State University
Paul G. Allen School for Global Animal Health
PO Box 647090
Pullman WA 99164-7090

Administrative Address:

Washington State University
Office of Research Support and Operations
PO Box 641060
Pullman, WA 99164-1060

Invoice Address:

Washington State University
Sponsored Programs Services
PO Box 641025
Pullman, WA 99164-1025

Attachment 3B**Research Subaward Agreement
Subrecipient Contacts**

Subaward Number:

141061 - SPC003545

Subrecipient Information for FFATA

reporting Entity's UEI/DUNS Name: The Washington University

EIN No.: 40 Institution Type: Private Institution of Higher Education

UEI / DUNS: 18 Currently registered in SAM.gov: ☒ Yes ☐ No
Exempt from reporting executive compensation: ☒ Yes ☐ No (if no, complete 3Bpg2)Parent UEI / DUNS: 18 This section for U.S. Entities: Zip Code Look-up
Congressional District: MO-001 Zip Code+4: 63130-4862**Place of Performance Address**Washington University
Campus Box 1054
One Brookings Drive
St. Louis, MO 63130-4862**Subrecipient Contacts**

Central Email: researchcontracts@wusm.wustl.edu

Website:

Principal Investigator Name: David Wang

Email: davewang@wustl.edu

Telephone Number: 314-286-1123

Administrative Contact Name: Maria Guzman

Email: mguzman@wustl.edu

Telephone Number: 314-362-4829

Financial Contact Name: Joseph M. Gindhart, Assoc. VC for Finance & Sponsored Projects

Email: jgindhart@wustl.edu

Telephone Number: 314-935-7089

Invoice Email:

Authorized Official Name: Teri Medley, Director of Grants

Email: researchgrants@wusm.wustl.edu

Telephone Number: 314-747-4134

Legal Address:The Washington University
Campus Box 1054
One Brookings Drive
St. Louis, MO 63130-4862**Administrative Address:**Campus Box 1054
One Brookings Drive
St. Louis, MO 63130-4862**Payment Address:**Washington University in St. Louis
Sponsored Projects Accounting
Campus Box 1034, 700 Rosedale Avenue
St. Louis, MO 63112-1408

Attachment 3B Page 2
Research Subaward Agreement
Highest Compensated Officers

Subaward Number:
141061 - SPC003545

Subrecipient

Entity Name:

PI Name:

Highest Compensated Officers

The names and total compensation of the five most highly compensated officers of the entity(ies) must be listed if the entity in the preceding fiscal year received 80 percent or more of its annual gross revenues in Federal awards; and \$25,000,000 or more in annual gross revenues from Federal awards; and the public does not have access to this information about the compensation of the senior executives of the entity through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. See FFATA § 2(b)(1) Internal Revenue Code of 1986.

Officer 1 Name:

Officer 1 Compensation:

Officer 2 Name:

Officer 2 Compensation:

Officer 3 Name:

Officer 3 Compensation:

Officer 4 Name:

Officer 4 Compensation:

Officer 5 Name:

Officer 5 Compensation:

Attachment 4

Reporting and Prior Approval Terms

Subaward Number:

141061 - SPC003545

Subrecipient agrees to submit the following reports (PTE contacts are identified in Attachment 3A):

Technical Reports:

- ☐ Monthly technical/progress reports will be submitted to the PTE's within days of the end of the month.
- ☐ Quarterly technical/progress reports will be submitted within 30 days after the end of each project quarter to the PTE's .
- ☒ Annual technical / progress reports will be submitted within days prior to the end of each budget period to the PTE's . Such report shall also include a detailed budget for the next Budget Period, updated other support for key personnel, certification of appropriate education in the conduct of human subject research of any new key personnel, and annual IRB or IACUC approval, if applicable.
- ☒ A Final technical/progress report will be submitted to the PTE's within days of the end of the Project Period or after termination of this award, whichever comes first.
- ☒ Technical/progress reports on the project as may be required by PTE's in order for the PTE to satisfy its reporting obligations to the Federal Awarding Agency.

Prior Approvals:

Carryover:

Other Reports:

- ☒ In accordance with 37 CFR 401.14, Subrecipient agrees to notify both the Federal Awarding Agency via iEdison and PTE's within 60 days after Subrecipient's inventor discloses invention(s) in writing to Subrecipient's personnel responsible for patent matters. The Subrecipient will submit a final invention report using Federal Awarding Agency specific forms to the PTE's within 60 days of the end of the Project Period to be included as part of the PTE's final invention report to the Federal Awarding Agency.

A negative report is required:

- ☒ Property Inventory Report (only when required by Federal Awarding Agency), specific requirements below.

Additional cost sharing requirements included below:

Additional Technical and Reporting Requirements:

Subrecipients shall list each country included in the program and the total amount expended for each country when submitting financial reports. These will be noted to each partner as countries are onboarded.

Kenya 615-GH-W 141061-SPC003546

Senegal 685-GH-W 141061-SPC003547

Peru 527-GH-W 141061-SPC003548

Vietnam 440-GH-W 141061-SPC003549

Thailand 493-GH-W 141061-SPC003550

There may be additional reporting requirements and ad hoc information requests including, but not limited to, those associated with Mission buy-ins or additional sources of funding provided to DEEP VZN. Ad hoc refers to an unscheduled report for immediate, specific use. These requests will need to be approved by USAID.

Attachment 5
Statement of Work, Cost Sharing, Indirects & Budget

Subaward Number:

141061 - SPC003545

Statement of Work

☒ Below ☐ Attached, pages

If award is FFATA eligible and SOW exceeds 4000 characters, include a *Subrecipient Federal Award Project Description*

Washington University at Saint Louis will provide laboratory and training services. Specifically, they will develop SOPs for broad RT-PCR screening, amplicon sequencing, genome finishing and highly parallel phage display based viral serology. They will optimize and validate protocols, perform proficiency testing to ensure quality and standardization across the sites, and perform highly specialized characterization of novel viruses that cannot be done in-country. Additionally, they will hire four new personnel to travel to the in-country regional laboratories and provide training for in-country scientists to conduct cross-validation in the latter years of the project. These personnel will work with the in-country teams to troubleshoot challenges as country teams develop or strengthen their laboratory techniques.

Budget Information

Indirect Information Indirect Cost Rate (IDC) Applied

%

Cost Sharing

Rate Type:

If Yes, include Amount: \$

Budget Details

☒ Below ☐ Attached, pages

Salaries and Benefits - \$57,810

Indirect - \$

Total - \$91,051

Only partial budget at this time is being submitted until USAID approves the project workplan and budget detail.

Budget Totals

Direct Costs \$

Indirect Costs \$

Total Costs \$

All amounts are in United States Dollars

Attachment 6

Notice of Award (NOA) and any additional documents



The following pages include the NOA and if applicable any additional documentation referenced throughout this Subaward.



Not incorporating the NOA or any additional documentation to this Subaward.



September 22, 2021

Dan Nordquist
Associate Vice President for Research
Washington State University
P.O. Box 641060
Pullman, WA 99164-1060
orso@wsu.edu

Reference: Award No. Titled "Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)" Cooperative Agreement 7200AA21CA00033

Dear Dan Nordquist:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, the U.S. Agency for International Development (USAID) hereby awards to Washington State University, hereinafter referred to as the "Recipient", the sum of \$124,679,896 to provide support for a program titled "Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)", as described in the Schedule of this award and in Attachment B, entitled "Program Description."

This Cooperative Agreement will be effective October 1, 2021. Obligation will be made upon receipt of the Recipient's acknowledgement and shall apply to expenditures made by the Recipient in furtherance of program objectives during the period beginning with the effective date October 1, 2021 and ending September 30, 2026. USAID will not be liable for reimbursing the Recipient for any costs in excess of the obligated amount.

This Cooperative Agreement is made to Washington State University, on condition that the funds will be administered in accordance with the terms and conditions as set forth in Attachment A (the Schedule), Attachment B (the Program Description), Attachment C (the Standard Provisions), and Attachment D (the Branding & Marking Plan) all of which have been agreed to by your organization.

Please sign the second page of this cover letter to acknowledge your receipt of this award and e-mail a copy of only the signed page to Anna Nelson at annelson@usaid.gov with a cc: to Patricia Bradley at pbradley@usaid.gov.

Sincerely,

Patricia Elena Bradley
(affiliate)
Patricia Bradley
Agreement Officer

Digitally signed by Patricia Elena
Bradley (affiliate)
Date: 2021.09.22 10:24:23 -04'00'

Attachments:

- A. Schedule
- B. Program Description
- C. Standard Provisions
- D. Branding & Marking Plan

ACKNOWLEDGED BY:

NAME: Christopher J. Keane



TITLE: Vice President for Research, WSU and Vice Chancellor for Research, WSU Pullman

DATE: 9/23/2021

ACCOUNTING AND APPROPRIATION DATA

A. GENERAL

1. Amount Obligated this Action: \$ 10,000,000
 2. Total Estimated USAID Amount: \$124,679,896
 3. Total Obligated USAID Amount: \$ 10,000,000
 4. Cost-Sharing Amount (Non-Federal): \$ 6,607,682
 5. Activity Title: “Discovery & Exploration of Emerging Pathogens – Viral Zoonoses (DEEP VZN)”
 6. USAID Technical Office: GH/ID/ETD
 7. Tax I.D. Number: 40
 8. DUNS No.: 18
 9. LOC Number: 42A5P

B. SPECIFIC

GLAAS Requisition: REQ-GH-21-000020

Account ID	Accounting Template	BBFY	EBFY	Fund	Operating Unit	Prog Area	Program Name	Dist Code	BGA	SOC	Funded Amount
1-1	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	615-GH-W	615	4100201	\$2,000,000
1-2	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	685-GH-W	685	4100201	\$2,000,000
1-3	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	440-GH-W	440	4100201	\$2,000,000
1-4	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	527-GH-W	527	4100201	\$2,000,000
1-5	GH-HN Program Funds	2020	2021	GH-C-AI	GH/ID	HL.4	Pandemic Influenza and Other Emerging Threats (PIOET)	493-GH-W	493	4100201	\$2,000,000

C. PAYMENT OFFICE

M/CFO/CMP Letter of Credit Office
USAID/Washington

USAID Office of Financial Management (M/CFO/CMP) prefers the submittal of invoices to be electronic. In addition to the required submission to the Agreement Officer’s Representative (AOR), please submit a copy of the invoices to loc@usaid.gov.

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ATTACHMENT A - SCHEDULE

A.1 PURPOSE OF AWARD

The purpose of this Cooperative Agreement is to provide support for the program described in Attachment B to this Cooperative Agreement entitled "Program Description."

A.2 PERIOD OF AWARD

1. The effective date of this Award is **October 1, 2021**. The estimated completion date of this Award is **September 30, 2026**.

A.3 AMOUNT OF AWARD AND PAYMENT

1. The total estimated amount of this Award for the period shown in A.2.1 above is \$124,679,897, not including cost share.
2. USAID hereby obligates the amount of \$10,000,000 for program expenditures during the period set forth in A.2.1 above and as encompassed in the Budget below. The recipient must use funds obligated under this award and any subsequent amendments from the specific Operating Units (OU) and Program Areas (PA) for activities approved in the award and detailed in the work plan, as applicable. Program disbursements for each OU/PA must not exceed the amounts specified in the Accounting and Appropriates data for each Operating Unit (OU) and Program Area (PA). The Recipient will be given written notice by the Agreement Officer if additional funds will be added.
3. As the obligated amount for the program shall equal the total USAID estimated amount of this Agreement, additional increments of funds may be obligated by USAID under this Agreement (by a unilateral modification to this Agreement), subject to availability of funds, successful performance by the Recipient, possible evaluation of the program, program priorities at the time, and the requirements of the 2 CFR 200.308.
4. Payment will be made to the Recipient by Letter of Credit in accordance with procedures set forth in 2 CFR 200 and 2 CFR 700.

A.4 AWARD BUDGET

The following is the Award Budget, including local cost financing items, if authorized. Revisions to this budget shall be made in accordance with 2 CFR 200 and 2 CFR 700.

TOTAL BUDGET

Cost Element	USD
Direct Costs	\$116,474,256
Indirect Costs	\$ 49
Total Federal Contribution	\$124,679,897
Cost Share	\$6,607,682
Total Program Cost	\$131,287,579

Washington State University is responsible for managing available funds. This agreement includes a ceiling amount and obligated amount that the recipient exceeds at its own risk.

A.5 PLANNING, REPORTING, AND EVALUATION

1. Financial Reporting:

The recipient must submit the Federal Financial Form (SF-425) on a quarterly basis via electronic format to the U.S. Department of Health and Human Services. The recipient also must submit a copy of the SF-425 to the Agreement Officer (AO) and the Agreement Officer's Representative (AOR). These financial reports are due no later than 30 calendar days at the end of each quarter based on the federal fiscal calendar. The recipient must submit final financial reports to USAID/Washington, M/CFO/CMP-LOC Unit, the AO, and the AOR. The recipient must also submit an electronic version of the final financial report to the U.S. Department of Health and Human Services in accordance with the paragraph above.

2. Performance Planning:

Implementation Plans

Annual implementation plans serve as a guide to activity implementation and detail how the recipient will use the implementation year to achieve the objectives of DEEP VZN. The implementation plan is intended to be an annual roadmap for USAID and the recipient. With approval from the AOR, reasonable and justifiable modifications can be made to improve the chances of achieving the medium- and long-term results of the award. The recipient must submit the following implementation and reporting documents in English. The AOR and recipient will agree on the appropriate format and length.

Implementation plans include, but are not limited to, the following:

- Annual work plans, including planned activities for the following year and any subsequent revisions
- International travel plans
- Planned expenditures
- Event planning/management
- International meeting preparation
- Material Transfer Agreement (MTA) risk mitigation plan
- Country-level Level of Effort (LOE) chart, to include any oversight provided by headquarters
- Protocol Development and Review Plan
- Biosecurity and Biosafety (BSBS) Plan

USAID requires the AOR approval of implementation plans annually to ensure alignment with stated goals, milestones and outputs. The implementation plan communicates how and when the recipient will complete project activities and is drafted annually to describe new activities. The AOR will ensure that the implementation plans fit within the scope, terms and conditions of the agreement.

First Year Work Plan and Budget

The recipient will submit a draft work plan for the first year within the first 90 calendar days of executing the award. Depending on the start date of the agreement, the first-year work plan may be less than a full year or more than a full year. The first-year work plan must include a detailed budget and budget narrative for the first year. As part of the First Year Work Plan submission, the recipient will include a supplementary annual work plan describing planned contributions to the GHSA on a template designated by the AOR. All work plans and budgets, including

significant revisions thereto, must be approved by the AOR.

Annual Work Plan and Budget

Starting with the second year of the award and for each subsequent year of performance thereafter, the recipient will submit annual work plans, budgets, and budget narratives to the AOR for the next federal fiscal year within 30 calendar days prior to the end of the current federal fiscal year in a format agreed upon by the AOR and the recipient. The recipient also will submit supplementary annual work plans describing planned contributions to the Global Health Security Agenda (GHSa) within a timeframe and on a template designated by the AOR.

Monitoring, Evaluation and Learning (MEL) Plan

The recipient will finalize a MEL plan for the life of DEEP VZN that derives from the activities outlined in the Program Description and submit it to the AOR within 90 calendar days of the award for approval. The MEL plan will outline key program interventions, indicators of achievement, associated annual and life-of-Activity targets and a learning agenda. The learning agenda will outline key questions to be addressed, a plan for addressing these questions, and a process for incorporating findings into program implementation and the detection and characterization of unknown viruses. Where appropriate, the MEL plan must track gender equality issues in implementing activities. The recipient will update the MEL plan annually and submit it as an attachment to the annual report.

Biosecurity and Biosafety (BSBS) Plan

The recipient will finalize a BSBS plan for the life of DEEP VZN and submit it to the AOR within 90 calendar days of the award for approval. The BSBS will outline all program interventions that have biosafety/biosecurity implications and steps (e.g. protocols, training) that will be taken to minimize risk.

Gender Action Plan

The recipient will conduct a gender analysis that assesses context and gender needs, including time constraints and participation limitations. This analysis will inform a subsequent gender action plan, which will be developed in collaboration with the USAID management team and finalized within 90 calendar days of the award and updated annually. The gender action plan will inform the Activity's technical approach as it relates to gender throughout the life of the Activity. It also will be used to inform the design of activities that seek to reduce opportunity gaps between men and women or address power differentials to promote gender equity. The gender action plans should be developed in conjunction with the Activity's monitoring, evaluation and learning plan, and progress should be reflected in annual work plans and performance reports.

Data Management Plan

A Data Management Plan (DMP) is a document that describes how the recipient will manage data during the project and what happens to the data after the project ends. The initial DMP, which will be developed in collaboration with the USAID management team, will be finalized within 90 calendar days of the award and updated semi-annually and annually.

A comprehensive DMP will discuss the following aspects of the data life cycle:

- Collect - How the data is collected and processed by the researcher.
- Assure - How to make sure the data is high quality and free of errors.
- Describe - How the data will be documented so that other researchers can use it.
- Preserve - How and where the data will be stored so that researchers can access it forever.

The data management plan will inform the Activity's technical approach as it relates to data throughout the life of the Activity. The data management plan should be developed in conjunction with the Activity's monitoring, evaluation and learning plan, and progress should be reflected in annual work plans and performance reports.

Closeout Plan

No later than six (6) months prior to the completion date of the agreement, the recipient will submit a demobilization plan for Agreement Officer's approval. The demobilization plan shall include: 1) a draft property disposition plan, 2) a plan for the phase-out of in-country operations, 3) a staffing discharge plan, 4) a delivery schedule for all reports or other deliverables required under the agreement, and 5) a timetable for completing all required actions in the demobilization plan, including the submission date of the final property disposition plan to the Agreement Officer.

3. Performance Reporting:

The recipient must submit via email a copy of semi-annual, annual, and final performance reports, in English, to the AOR in accordance with 2 CFR 200.328.

Semi-Annual and Annual Reports

The recipient will submit semi-annual and annual progress reports based on the federal fiscal calendar. The semi-annual report will be due within 30 days after the end of the reporting period and will cover the first six months of the year (October 1 - March 31). The annual report will cover the entire fiscal year (October 1 - September 30) and will be due within 90 days of the end of the federal fiscal year.

At a minimum, both semi-annual and annual reports will contain:

- Narrative description of activities completed and major accomplishments achieved during the reporting period in all countries supported by DEEP VZN, presented by objective
- Qualitative and quantitative data on program achievements and results
- Progress on standard and agreed upon indicators, as outlined in the MEL plan, including status towards achieving targets and explanations for significant deviations
- An updated MEL plan, including progress on the learning agenda (annually)
- An updated BSBS plan
- An updated Data Management plan
- Problems encountered and whether they were solved or are still outstanding
- Proposed solutions to ongoing or new problems
- Success stories, blogs, articles, publications, press releases, and photographs, if available
- Update on expenditures for the reporting period against the pipeline
- Analysis and explanation of cost overruns or high unit costs, when applicable
- Planned activities for the next performance period

Global Health Security Agenda (GHS) reports

The Recipient will submit semi-annual GHS performance reports within a timeframe and on a template designated by the AOR. The Recipient will submit the GHS semi-annual reports to the AOR via email.

Ad Hoc Reports

There may be additional reporting requirements and ad hoc information requests including, but not limited to, those associated with Mission buy-ins or additional sources of funding provided to DEEP VZN. Ad hoc refers to an unscheduled report for immediate, specific use. USAID will define the purpose, content, and specific use for any ad hoc report.

Final Report

Within ninety (90) calendar days after the period performance date, the recipient will submit one (1) original and two (2) copies of the Final Report to the AOR and one (1) copy to the Agreement Officer. In addition, one (1) copy will be submitted to the Development Experience Clearinghouse:

- 1) Electronically: <http://www.usaid.gov/results-and-data/informationresources/developmentexperience-clearinghouse-dec>
or
- 2) By U.S. Postal Service delivery to:
U.S. Agency for International Development
Development Experience Clearinghouse
M/CIO/ITSD/KM
Ronald Reagan Building M. 01-010
Washington, DC 20523-6100

The Final Report must include a narrative report and summary table of results, a comparison of actual accomplishments to the objectives established for the period of performance, and a gender analysis that describes how gender equality issues were tracked and addressed. It should highlight accomplishments against implementation plans; outline progress of benchmarks against targets; describe results; and document lessons learned during implementation. The Final Report also must contain a three-page executive summary, an index of all reports and information products produced under the agreement, and a summary of the program's finances. More details on the format of the final report will be provided after the award.

A.6 INDIRECT COST RATE

Allowable indirect costs shall be reimbursed on the basis of the following negotiated Colleges and Universities Rate Agreement, dated August 20, 2019.

INDIRECT COST RATES:

TYPE	FROM	TO	LOCATION	RATE%	APPLICABLE TO
Predetermined	7/1/2019	6/30/2023	On-Campus	49	Organized Research
			Off-Campus	49	Organized Research
			On-Campus	49	Instruction
			Off-Campus	49	Instruction
			On-Campus	49	Other Sponsored Activities
			Off-Campus	49	Other Sponsored Activities
Provisional	7/1/2023	Until Amended	Use same rates and conditions as those cited for fiscal year ending June 30, 2023.		

Base

Modified total direct costs, consisting of all salaries and wages, fringe benefits, materials, supplies, services, travel and subgrants and subcontracts up to the first \$25,000 of each

subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). Modified total direct costs shall exclude equipment, capital expenditures, charges for patient care, student tuition remission, rental costs of off-site facilities, scholarships, and fellowships as well as the portion of each subgrant and subcontract in excess of \$25,000.

A.7 TITLE TO PROPERTY

Title of property financed under this award shall vest with the recipient subject to the requirements of 2 CFR 200.311-200.316, until such time as USAID issues disposition instructions.

Furthermore, the following requirements apply regarding the use, care, accountability, maintenance, and disposition thereof:

(a) Tangible Property

(1) Equipment: “Equipment” means an article of tangible nonexpendable personal property having a useful life of one year or more and a per-unit acquisition cost (purchase price) of \$5,000 or more. Equipment is subject to the requirements set forth in 2 CFR 200.313.

(2) Supplies and Other Expendable Equipment: “Supplies and other expendable equipment” means items of tangible personal property that do not meet the definition of “equipment” in paragraph (a)(1) above. Supplies and other expendable equipment are subject to the requirements set forth in 2 CFR 200.314.

(3) Real Property: “Real property” means land, land improvements, structures, and appurtenances thereto. Real property is subject to the requirements set forth in 2 CFR 200.311.

(b) Intangible (Intellectual) Property

“Intangible property” means, but is not limited to, copyrights, inventions and patents, and data first produced under this Agreement. Intangible property is subject to the requirements set forth in 2 CFR 200.315.

A.8 AUTHORIZED GEOGRAPHIC CODE

The authorized geographic code for procurement of goods and services under this award is 935.

A.9 COST SHARING

The Recipient will contribute 5.03% percent of the total obligated amount of the award, excluding the sub-awards to the networks, as cost share throughout the life of the project. The cost share contribution shall be listed per cost category and presented in the work plan budgets.

Description	USD
Federal Amount Subject to Cost Share	\$124,679,897
Proposed Cost Share Amount	\$6,607,682
Cost Share Percentage	5.03%
Total Project Amount	\$131,287,579

A.10 SUBSTANTIAL INVOLVEMENT

a. Approval of the Recipient's Annual Implementation Plans:

Implementation plans include, but are not limited to, annual work plans, budget and budget narrative, including planned activities for the following year and any subsequent revisions, international travel plans, planned expenditures, event planning/management, international meeting preparation, MTA risk mitigation plan, country-level LOE chart, to include any oversight provided by headquarters, and protocol development and review plan.

USAID requires AOR approval of implementation plans annually to ensure alignment with stated goals, milestones and outputs. Each implementation plan communicates how and when the recipient will complete project activities and is drafted annually to describe new activities. This plan will be developed in partnership between the recipient and the AOR team. The AOR will ensure that each implementation plan fits within the scope, terms and conditions of the agreement.

b. Approval of Specified Key Personnel:

Designation of key personnel positions, approval of key personnel and any changes for the positions listed below:

- Project Director
- Deputy Project Director/Operational Lead

All individuals proposed as Key Personnel in the Recipient's application are hereby approved. Any future approval of key personnel will be authorized by the Agreement Officer in a separate administrative letter. The Recipient must submit to the AOR, reasonably in advance, any proposed replacement (including proposed substitutions) along with written justification in sufficient detail to permit evaluation of the impact on the program. Any proposed replacement Key Personnel must meet the minimum requirements stated in the Notice of Funding Opportunity (NOFO) number 7200AA21RFA00005, Section D.5.g). No replacement shall be made by the Recipient without the written consent of the Agreement Officer.

c. Agency and Recipient Collaboration or Joint Participation:

- Collaborative involvement in the selection of advisory committee members, if the recipient establishes an advisory committee that provides advice to the recipient. The AOR may participate as a member of this committee. Advisory committees must only deal with programmatic or technical issues and not routine administrative matters.
- Collaborative involvement in the selection of countries, viruses, and interfaces.
- USAID review and approval of monitoring, evaluation, and learning plans.
- USAID review and approval of data management plans.
- USAID involvement in the substantive direction/re-direction of interrelationships with other projects.
- USAID involvement in monitoring progress toward achievement of the Objectives and Expected Achievements during the course of the Agreement(s) and in monitoring of financial expenditures.

d. Direction and Redirection:

USAID will be involved in the substantive direction/re-direction of inter-relationships with other projects.

A.11 PROGRAM INCOME

The Recipient shall account for Program Income in accordance with 2 CFR 200.307 (or the Standard Provision entitled Program Income for non-U.S. organizations). Program Income earned under this award shall be added to the project.

A.12 AGREEMENT OFFICER'S REPRESENTATIVE

The Agreement Officer's Representative (AOR) for this Agreement will be designated in a separate memorandum from the Agreement Officer to the AOR with copy to the Recipient and the payment office.

A.13 SPECIAL PROVISIONS

A.13.1 SUBAWARD APPROVAL

Pursuant to the approved budget of this cooperative agreement, the following sub-awards are approved. All other sub-awards are subject to additional USAID approval.

Sub-awardee

University of Washington – UW
Family Health International 360 – FHI 360
PATH
Washington University at Saint Louis – WUSTL
Duke University

A.13.2 COUNTRY-BY-COUNTRY BREAKDOWN OF EXPENDITURES

The Recipient shall list each country included in the program and the total amount expended for each country under the award for the reporting period in the "Remarks" block on the "Financial Status Report" SF 425, or on a separate sheet of paper with the "Request for Advance or Reimbursement" SF 270.

A.13.3 BRANDING STRATEGY & MARKING PLAN

The Recipient shall submit within 30 calendar days of award, a Branding Strategy and Marking Plan. Upon the approval of the AO and AOR, the plan shall be incorporated as Attachment D.

A.13.4 ENVIRONMENTAL COMPLIANCE

The Foreign Assistance Act of 1961, as amended, Section 117 requires that the impact of USAID's activities on the environment be considered and that USAID include environmental sustainability as a central consideration in designing and carrying out its development programs. This mandate is codified in Federal Regulations (22 CFR 216) and in USAID's Automated Directives System (ADS) Parts 201.5.10g and 204 (<http://www.usaid.gov/policy/ADS/200/>), which, in part, require that the potential environmental impacts of USAID-financed activities are

identified prior to a final decision to proceed and that appropriate environmental safeguards are adopted for all activities. The recipient's environmental compliance obligations under these regulations and procedures are specified in the following paragraphs of this cooperative agreement.

In addition, the recipient must comply with host country environmental regulations unless otherwise directed in writing by USAID. In case of conflict between host country and USAID regulations, the latter shall govern.

No activity funded under this cooperative agreement will be implemented unless an environmental threshold determination, as defined by 22 CFR 216, has been reached for that activity, as documented in a Request for Categorical Exclusion (RCE), Initial Environmental Examination (IEE), or Environmental Assessment (EA) duly signed by the Bureau Environmental Officer (BEO). (Hereinafter, such documents are described as "approved Regulation 216 environmental documentation.")

As part of its initial Work Plan, and all Annual Work Plans thereafter, the Recipient, in collaboration with the USAID AOR and Mission Environmental Officer or Bureau Environmental Officer, as appropriate, shall review all ongoing and planned activities under this cooperative agreement to determine if they are within the scope of the approved Regulation 216 environmental documentation.

If the Recipient plans any new activities outside the scope of the approved Regulation 216 environmental documentation, it shall prepare an amendment to the documentation for USAID review and approval. No such new activities shall be undertaken prior to receiving written USAID approval of environmental documentation amendments.

Any ongoing activities found to be outside the scope of the approved Regulation 216 environmental documentation shall be halted until an amendment to the documentation is submitted and written approval is received from USAID.

A.13.5 OPEN DATA AND DATA SHARING

The recipient will be expected to comply with the Office of Management and Budget's Open Data Policy, as well as any USAID open data policy. Relevant MEL related data, knowledge and specifically lessons learned from sampling, discovery, characterization, and data analysis and use will be documented. All final data sets that USAID and the recipient deem as valuable to its stakeholders shall be submitted to USAID in a reliable media prior to the award end date and will be available for dissemination as appropriate. During the term of the agreement, preliminary data and analysis will be submitted to USAID on a periodic basis, but no less than annually, as agreed upon by USAID and recipient during work planning.

A.13.6 ORGANIZATIONAL CONFLICT OF INTEREST

Recipient must adhere to conflict of interest regulations found in 2 CFR 200.112 and 2 CFR 200.318(c)(1).

A.13.7 COORDINATION, COMMUNICATION, AND COLLABORATION

Coordination, communication and collaboration among stakeholders facilitate trust and mutual understanding; reduce redundancy; increase synergy, scalability, and impact; and promote learning and mutual accountability. DEEP VZN is expected to build and enhance constructive

partnerships, as appropriate. DEEP VZN will collaborate and coordinate with a wide variety of stakeholders, including country National NTD Programs, Ministries of Health and other relevant government entities; USAID Missions and Country Offices, USG partners, bilateral and multilateral agencies; academic and research institutions; private sector and philanthropic organizations; and civil society organizations.

A.14 SPECIAL REQUIREMENTS

A.14.1 FOR U.S. ORGANIZATIONS -- SPECIAL AWARD REQUIREMENT RELATING TO THE PROHIBITION ON CERTAIN TELECOMMUNICATION AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUGUST 2020)

- a. 2 CFR 200.216, “Prohibition on certain telecommunications and video surveillance services or equipment” implements Pub. L. 115-232, Section 889.
- b. USAID has been granted a temporary, limited waiver under Section 889(d)(2) that will allow the recipient to use award funds for the duration of this award to procure internet, cellular and landline services from communication service-providers who use covered telecommunications. All other costs incurred for covered telecommunications and video surveillance services or equipment, such as phones, video surveillance, and cloud servers specified in 2 CFR 200.216 remain unallowable in accordance with 2 CFR 200.471.

[End of Special Award Requirement]

A.14.2 FOR NON-U.S. ORGANIZATIONS -- SPECIAL AWARD REQUIREMENT RELATING TO THE PROHIBITION ON CERTAIN TELECOMMUNICATION AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUGUST 2020)

- a. The mandatory standard provision “Prohibition on Certain Telecommunication and Video Surveillance Services or Equipment (AUGUST 2020)” implements Pub. L. 115-232, Section 889.
- b. USAID has been granted a temporary, limited waiver under Section 889(d)(2) that will allow the recipient to use award funds for the duration of this award to procure internet, cellular and landline services from communication service-providers who use covered telecommunications. All other costs incurred for covered telecommunications and video surveillance services or equipment, such as phones, video surveillance, and cloud servers specified in the standard provision in paragraph a. above remain unallowable in accordance with the mandatory standard provision “Allowable Costs” and 2 CFR 200.471.

[End of Special Award Requirement]

[END OF ATTACHMENT A]

ATTACHMENT B – PROGRAM DESCRIPTION

EXECUTIVE SUMMARY

With an overarching goal of detecting ‘known unknown’ viruses that might pose a pre-pandemic threat, we will carry out an innovative, sustainable, and responsive surveillance program for detection and characterization of novel animal viruses with zoonotic potential. Our consortium, which includes University of Washington (UW), PATH, FHI360, and Washington University in St. Louis (WUSTL) is led by Washington State University’s (WSU) Allen School for Global Health, whose approach of placing full-time faculty in global regions has seen it lead innovative emerging infectious disease studies in East and Central Africa that target landscapes inhabited by humans, their livestock and diverse wildlife populations in ecosystems ideal for the maintenance and transmission of emerging zoonotic pathogens. The consortium features strong in-country partners supported by world class virology reference laboratories at UW and WUSTL involved in novel virus discovery and characterization, unparalleled experience in laboratory strengthening, One Health epidemiology and social science, and global reach. Apart from collective presence and institutional links in countries located in the six DEEP VZN global regions, our consortium partners bring complementary expertise, including global field studies and sampling by WSU and UW, laboratory capacity by WUSTL and UW, and data management and in-country stewardship by PATH, FHI360 and WSU. We will build on the achievements of the USAID EPT programs, and our collective prominence in the global NIH-supported Centers for Research in Infectious Diseases (NIH-CREID), to enable partner labs in focus countries to fully sequence and characterize novel viruses in unprecedented breadth and depth. We will leverage scientific breakthroughs with SARS CoV2 and other emerging viruses to apply cutting edge technologies to prioritize potential for viral spillover and pandemics. In focus countries, we will target high-risk locations and subpopulations at the human-animal interface using a risk-based analytical approach to guide sample collection where there is evidence of previous spillover or high prevalence of zoonotic viruses. Additionally, we will establish an efficient sample collection and transportation system and align capacities at in-country laboratories to identify viruses of zoonotic potential in a timely manner, thus triggering additional targeted sampling focused up- and downstream of the transmission chain.

We plan to collect over 800,000 samples, of which approximately 60% will come from wildlife. Assuming a 1-1.5% yield, our in-country labs will provide near-real time screening and genome sequencing to detect and characterize between 8,000 and 12,000 novel viruses from the target families over the five years of the DEEP VZN program. To effectively characterize viruses of zoonotic potential from the detected pool, we will use a combination of innovative molecular, protein structure and receptor analyses, and serological techniques to generate evidence of spillover to humans, and potential for human-to-human transmission. This consortium will also strengthen capacity within focus countries for continued assessment of viruses of zoonotic potential and enhance response to future outbreaks. To enhance sustainability, we will build in-country stewardship of all surveillance, diagnostic and data management activities through the development of meaningful partnerships with focus country stakeholders. Through engagement and integration with other USAID EPT efforts, NIH CREID networks and other professionals across human, animal, and environmental health sectors, we will promote meaningful sharing of resources and data in an inclusive and cost-effective One Health-approach. The overall outcomes of this program will be the detection of an unprecedented number of unknown viruses of pandemic potential that can be monitored by public health institutions worldwide, and significant

advances in our collective ability to characterize zoonotic and pandemic potential of emerging viruses.

OBJECTIVE 1: Conduct Sampling for Unknown Viruses from the Priority Viral Families **We have designed an efficient, responsive, and sustainable program that uses existing data and models on spillover risk to guide initial sampling and interim data to refine sampling targets.**

Building on baseline detection of known viruses in the PREDICT, VIRION and EIDITH databases, our strategies will lead to the detection of previously unknown wildlife-origin viruses from the target families and identify a subset that pose a significant pandemic threat. Our

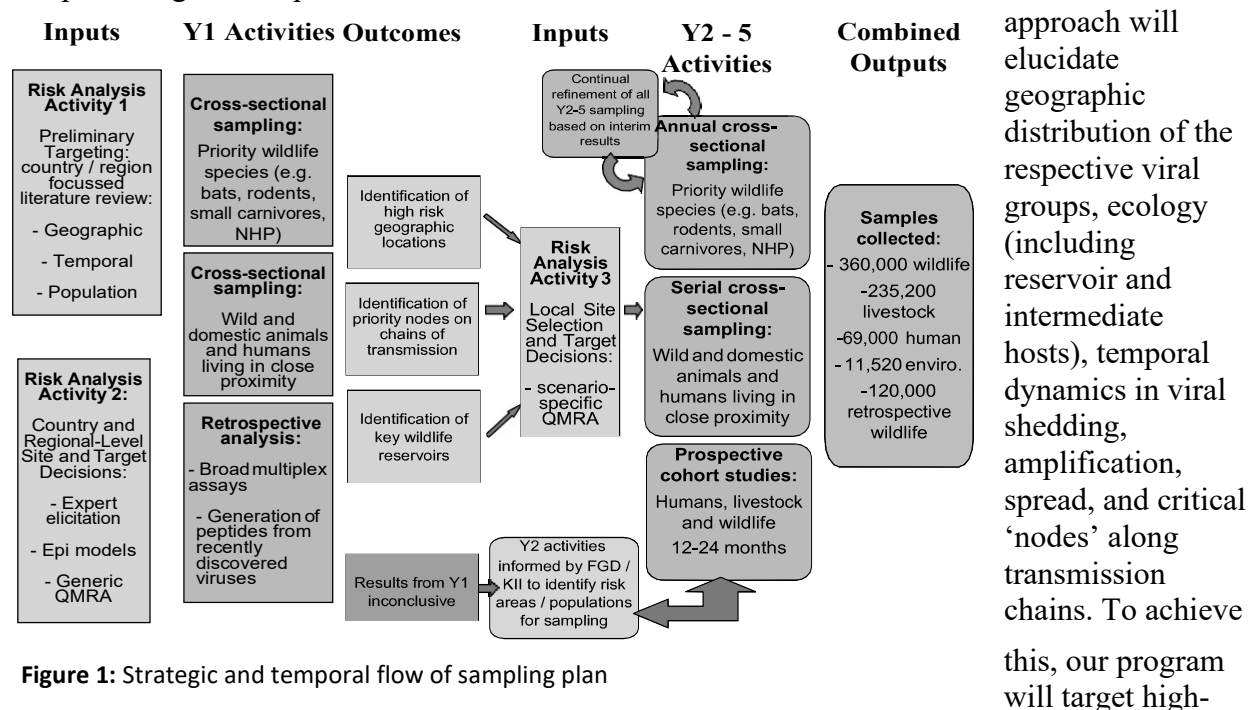


Figure 1: Strategic and temporal flow of sampling plan

risk locations and subpopulations at the human-animal interface, optimizing yield and resources (Fig. 1). This targeting will be adaptive, with locations identified through an iterative process informed by ongoing data collection. We will establish a pipeline of sample collection and transportation, aligned with capacities at existing in-country laboratories (utilizing a hub and spoke approach). Identification of a virus of zoonotic potential will trigger additional sampling focused up- and downstream on the transmission chain. Sampling will be guided by a risk-based analytical approach informed by evidence of a previous spillover event, a high prevalence of zoonotic viruses, or close contact between humans and reservoir hosts. Finally, we will employ a One Health-approach through engagement of human, animal, and environmental health sectors.

1.1 Sample Site and Species Selection

Focus 1: Preliminary Targeting - country/region focused literature review

To inform initial geographic, temporal, and species sampling plans and further risk-based targeting, we will carry out a rapid and comprehensive literature review (including grey literature and proceedings from meetings and One Health platforms) in Y1 to identify where prevalence and diversity of the target viral families are high, where critical nodes on chains of transmission are located, and key wildlife species are abundant (Focus 2 and Fig. 2).

Geographic Selection: We will use literature review, remote-sensed data, and existing risk maps of zoonotic disease emergence risk and its drivers to make a primary selection of geographic

areas of interest. Priority drivers of disease emergence will include human population density, land use change, density and diversity of wildlife species (focusing on mammalian species),

intensive farming of domestic and wild species, and live/wet wildlife markets. We will also leverage maps and data from PREDICT sampling data.

Temporal Selection: Viral (and host) seasonality and multiannual trends impact viral load and thus detection rates and will be critical determinants of sampling timeframes, particularly for wild animal sampling. The literature review will leverage existing knowledge of targeted viral families and host dynamics to inform our risk-based sampling strategies.

Population Selection: Country-specific literature review will identify wildlife and livestock species, human occupational groups, and value chains to consider for sampling.

Focus 2: Country and Regional-Level Site and Target Decisions - risk-based analysis Using a hybrid risk-based approach, we will refine geographic, temporal, and population targets defined by Focus 1 to plan the location and the timing of each sampling activity, with emphasis on identifying populations of wildlife, domestic animals, and humans on transmission chains. This approach will build upon existing knowledge from previous USAID-funded research projects, tailored to country-specific contexts. We will use available data and models and in-country stakeholder engagement, ensuring rapid site selection and start-up of project activities.

Epidemiological Models: In collaboration with key partners, such as the USAID-funded STOP Spillover project, in-country research institutions, and relevant government ministries, the team will review existing epidemiologic models (spatial and mathematical) of spillover risk parameterized to the geographic areas and populations identified in Focus 1. This work will both

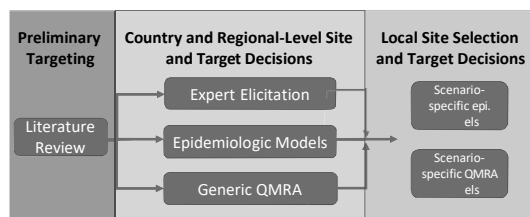


Fig. 2: Risk-based analytical approach to sample site selection

inform the structure of the epidemiologic models developed in Focus 3 and collate data for these later models. Existing models of viral and host seasonality, host dynamics in targeted wildlife populations, and seasonal trends in wild meat hunting will be used to plan sample timing. **Expert Elicitation:** If the absence of context- and site-specific data or relevant

epidemiologic models preclude the use of modeling to refine sampling plans, we will use an expert elicitation-based risk ranking approach to scope initial rounds of sampling.

QMRA: As part of a multimodal strategy, the team will develop prospective probabilistic models utilizing a quantitative microbial risk assessment (QMRA) approach to identify populations and areas of greatest risk and uncertainty. Such approaches have been used to estimate environmental risk of zoonoses transmission and provide a way to include viral load data into our risk prioritization process. As the magnitude of risk will likely be driven by scenario-specific exposures, updated models will be developed at the onset of the project following literature review and subsequently tailored to specific exposure scenarios (Fig. 2).

Focus 3: Local Site Selection and Target Decisions

Based on site- and context-specific information and models generated in Focus 2, detailed exposure modules will be incorporated into location-specific QMRA models, the findings of which will be triangulated with spatial epidemiologic models. These models will be informed by geolocated data indicating prior spillover events, presence of immunocompromised wildlife species, disturbances that increase physiological stress, human activities that facilitate wildlife contact, and high population density. We will develop an initial set of location specific QMRA models based on the sampling sites and data from PREDICT 1 & 2 and evaluate these models to identify sites with the greatest estimated risks and/or uncertainty. In concert with our QMRA models, we will use the computationally efficient stochastic partial differential equations approach to Gaussian process modelling to generate high-resolution maps of spillover risk in the

target geographies identified in Focus 1 - 3. Both models will be continually iterated as new data become available, and sampling sites/targets will be adjusted.

1.2 Sampling Targets

To reduce delay, as soon as each of Focus 1-3 is completed decisions on site identification and timing for initial rounds of sample collection can begin. We will use pre-existing models and computational frameworks to complete these models while sampling approvals are pending. Targeted sampling locations, timelines, and species will be refined through participatory workshops, including representatives from wildlife, human, livestock, and environmental health sectors, and supply chain mapping integrated with network data. Retail outlets for wildlife products will be the terminus of this mapping, with focus on the movement of animals or their products from their points of origin to consumers. Eco-centric network data and value chain data will be collected at each node to identify priority nodes for viral transmission.

Once sampling targets have been identified, we will use sampling methods selected based on population sampled, risk characterization, and country-context, including serial cross-sectional sampling and prospective cohort sampling. Where possible, serial cross-sectional sampling will be repeated in the same population to determine which viruses are adapting to humans (pre-pandemic viruses) and to allow development of interventions to mitigate transmission. In addition, we will use composite sampling to screen samples, with follow-up testing of discrete samples from positive composites to decrease cost and increase throughput. We will also collect socio-anthropological data at these high-risk locations to better understand human-animal-ecosystem interactions relevant to viral transmission. Sampling targets will include:

Wildlife: Focus 1-3 will identify sites for initial sampling and priority mammalian species.

Supplementing risk characterization, trait-based statistical modelling will be used to prioritize bat species for each viral taxon, which will be iteratively improved as more host-virus data become available. Within these sites and species, sampling will focus on populations likely to impact the animal value chain (wildlife or livestock), including free-ranging wild animals living near areas of intensive livestock farming, wild mammals in ecosystems recently fragmented by expanding human communities, farmed wild mammals and wild mammals sold in live/wet markets.

Domestic animals: Sampling will focus primarily on intensively farmed domestic species that are reservoirs or amplifying hosts for the targeted viral families, characterized in Focus 1-3.

Industrialized farms with poor biosecurity or ecosystem encroachment will be prioritized.

Humans: Sampling will focus on country-specific occupational groups (and controls) at highest risk for spillover already geographically and temporally linked to wildlife described above.

1.3 Country-level Strategic Sampling Approach*

**Specific sampling targets will vary by target country based on in-country context*

Task 1.1: Cross-sectional sampling of wild animals (priority species): We will implement cross-sectional sampling of populations of free ranging wild animals likely to host unknown species of known virus families and target physiologically and immunologically stressed populations (migratory populations/ those living in areas of intense land use change). The highest proportion of samples collected will be fecal matter (e.g., under-roost excreta) to optimize efficiency and sensitivity for viral surveillance and discovery, particularly for henipaviruses and coronaviruses. We will also collect and test wildlife meat from markets and traders.

Year 1: Sample teams: 3 per country, sampling for 45 days/year, collecting 40 samples/day;

Aim Per country: 5000 samples; **Target species:** Bats, rodents, small carnivore species, non-human primates (NHP); **Sample type:** Feces, blood, oral/rectal swabs;

Years 2–5: Sample teams: 3 per country, sampling for 21 days / year, collecting 40 samples/day; Prospective sampling informed by Y1 results; **Aim per country:** 2500 total samples/year; **Target species** and **Sample type:** as in Y1

Task 1.2: Cross-sectional sampling of animals and humans living in proximity:

Humans are frequently in contact with large aggregations of wildlife, such as rodents, bats, and small carnivore species. Such synanthropic wildlife species provide opportunities for spillover to amplifying reservoir species that have greater opportunities for pathogen sharing with humans. We will sample wildlife species among or near areas of intensive livestock farming, farmed wild animals, and wild animals sold in live/wet markets. We will also carry out composite sampling of human and livestock species through collection of fecal slurry (livestock) and sewage (human) samples, prioritizing sampling of environments where animals/humans have recently displayed signs of illness and sites characterized by recent disturbances of neighboring ecosystems. We will also sample domestic carnivores (dogs and cats) as these species typically range widely, scavenge, have contact with wildlife, livestock, and humans and are accessible for sampling.

Year 1: Wild animal sample teams: 3 per country, sampling for 45 days/year, collecting 40 samples/day; **Domestic animal sample teams:** 3 per country, sampling for 30 days/year, collecting 40 samples/day; **Human sample teams:** 3 per country, sampling for 45 days/year, collecting 10 samples/day; **Per country aim:** 5000 wildlife, 3600 domestic animal, 1350 human samples; **Target species:** Rodents, bats, domestic and wild carnivore species (e.g. domestic dogs/cats, civet cats), ungulates, poultry, humans; **Sample type:** Wildlife species: feces, blood, oral/rectal swabs; humans, livestock: composite sampling of fecal slurry and sewage

Years 2–5: Prospective sampling informed by Y1 results; **Wild animal sample teams:** 3 per country, sampling for 21 days/year, collecting 40 samples/day; **Domestic animal sample teams:** 3 per country, sampling for 14 days/year, collecting 40 samples/day; **Human sample teams:** 3 per country, sampling for 20 days/year, collecting 10 samples/day; **Per country aim:** 2500 wildlife, 1600 domestic animal, 600 human samples.

Task 1.3: Retrospective analysis of bio-banked samples: We will request access to bio-banked sera collected from wildlife species, including from previous USAID-funded projects such as PREDICT, in areas determined by our risk analysis activities to be hot-spot zones. Broad multiplex assays will allow identification of all ‘known knowns’ and refinement of subsequent sampling strategies (in Y2-5) to increase the probability of detecting ‘known unknown’ viruses. Additionally, novel peptides generated from recently discovered focus family viruses will allow contemporary viruses to be detected.

Year 1: Per country aim: Collection of up to 10,000 wildlife serum samples from in-country biobanks; **Target species:** Bats, rodents, small carnivore species, NHP

Task 1.4: Prospective cohort studies of humans, livestock, and farmed wildlife

Per country aim: i) **animal workers (human):** 200 blood samples twice/year; 200 risk factor questionnaires monthly; 10 semi-structured interviews monthly; 200 nasal wash samples monthly; ii) **controls (human):** 50 blood samples twice/year; 50 questionnaire surveys monthly; 50 nasal wash samples monthly; iii) **farmed animals:** 200 composite samples monthly; iv) **environmental samples:** 20 samples monthly (1 per farm/month), for example, composited waste water sample or barn air; v) **workplace:** 20 (1 per farm/month) x Animal Workplace Enrolment and Animal Workplace Follow-up Questionnaire; **Target species:** Humans, ungulates, poultry, farmed wildlife

Task 1.5: Responsive sampling in the face of an outbreak: In the face of emerging epidemics, opportunities to understand the epidemiology of an outbreak are lost because of delays

mobilizing sample collecting activities. SOPs and sampling teams will be prepared to undertake rapid collection of samples from wildlife and domestic animals in the immediate geographic area around an index case. We will remain in close communication with public and animal health disease reporting agencies so that disease outbreaks can trigger localized investigations.

1.4 Sample Size and Detection of Known Viruses

The more samples collected and tested, the higher the likelihood of detecting a previously unknown member of the target viral families. Collecting 300 samples from a given target species provides a 95% probability of detecting a virus present in at least 1% of individuals; Therefore, a risk-based approach to selecting animal species is critically important to optimize project resources. We will tether our collected data to baseline detection of known viruses in the PREDICT and VIRION databases and a beta-coronavirus specific database (<https://www.viralemergence.org/betacov>). This will allow estimation of expected prevalence and diversity for comparison with observed values for each viral family and host species. Following Y1 collection, detection, and viral characterization activities, we will use cluster detection algorithms to identify hotspots of prevalence or diversity of known viruses, triggering further focused sampling. Detection of known viruses in the three families provides a positive control.

1.5 Contingency Plans

Although the sampling plan is ambitious in scope we are confident that we can collect the numbers of samples listed. Key reasons for this are that we will a) focus sampling efforts on the collection of fecal matter, including composite slurry/sewage samples, which is an excellent sample type for viral discovery and relatively easy to collect; b) exploit sampling synergies within and between sampling targets, for example, sampling of humans, domestic animals, environments, and farmed wildlife will be carried out by single teams that focus on multiple sampling targets. This will make sample collection more efficient; and c) increase the number of sampling teams and / or sampling days if targets are not met. Finally, the plan will allow sampling targets to be exceeded in countries where collection is efficient, which will counterbalance more modest sampling outputs in less productive countries. It is also important to note that, for restrained animals, multiple samples will be collected (fecal, blood, swabs) and as such the estimated total number of samples refers just that and not number of animals sampled.

1.6 Outcomes

The outcomes of Y1 will be used to inform the strategic planning of the sampling activities in Y2 – 5. This site selection review will be an iterative process to determine whether to add new sampling sites. If outcomes from Y1 activities are inconclusive, sampling activities in Y2 – 5 will be informed through iterative refinement of the epidemiological and QMRA models and detailed, in-country participatory workshops and interviews targeting workers in the human, animal and environmental health sectors. Samples collected will be studied with an array of molecular assays for previously identified as well as novel corona-, filo-, and paramyxoviruses. Where data show a prevalent emergent animal virus, we will identify the location and specific animal hosts of origin and collect data on supply chains and contact networks to target additional specimen collections and molecular studies along the chain of transmission.

1.7 Capacity Building and Sustainability

To facilitate sustainability, we will promote in-country stewardship of all Objective 1 activities, including risk-based analytical approaches, design of sampling strategies and collection of samples. Rapid assessment of in-country capabilities will be conducted to identify gaps in personnel, training and equipment. Training will be provided for each activity (utilizing virtual

methods and translation to local language), and location-appropriate equipment provided in order to allow activities to be performed within, and beyond, the lifetime of the program.

OBJECTIVE 2: Strengthen Detection for Novel Viruses from Priority Viral Families

Our sampling strategy is designed to collect as many specimens as possible. Using a strategically designed, risk-based approach to sampling, we will roll out serial cross-sectional and prospective cohort studies at nodes of potential transmission of novel viruses to collect and screen **~800,000 specimens, with >60% from wildlife**. We will build a detection and characterization program utilizing in-country labs to provide near-real time screening and genome sequencing and finishing. Assuming 1-1.5% yield, based on the yield in the PREDICT program in the 3 viral families targeted for DEEP VZN (DV), this approach is likely to **detect and characterize 8000 – 12,000 novel virus genomes** over the DV program. We estimate these genomes to comprise a total of 1,000 novel viral species, based on the number of novel sequence submissions from the PREDICT project (~2100 novel sequences from 3 highlighted viral families for DV, constituting ~250 novel viral species, or ~8 specimens/sequences per novel virus species).

2.1 Capacity Building and Sustainability

Our capacity building approach for in-country laboratories is summarized in **Fig 3**. *The goal is to ensure that each country independently conducts full virus screening (basic detection to whole-genome sequencing) and basic characterization that includes evaluation of spillover (serology) and later glycoprotein and receptor-binding assays.* We will ensure sustainable, in-country capacity to safely detect and characterize unknown novel viruses by providing high-throughput automated nucleic extraction, multiplex qRT-PCR screening instruments, and *NextSeq* Illumina next-generation sequencing (NGS) platform in each country. All 18 partner institutions we have identified in the 12 target countries have existing serology capacity, while 60% and 25% have qRT-PCR, and NGS capacities, respectively. Building on our consortium's >25 years of experience working in sub-Saharan Africa, Asia, and Latin America, including during the COVID-19 pandemic, we will address the recurrent problem of high cost and delayed delivery by establishing direct-buy credit accounts and service contracts with the manufacturers of equipment involved in the DV program. As illustrated in **Fig 3**, in Year 1 we will conduct rapid assessment of in-country labs to determine needs, followed by provision and installation of equipment to ensure they can conduct qRT-PCR, serology (ELISA and pseudotype viral neutralization test (pVNT)), and viral WGS.

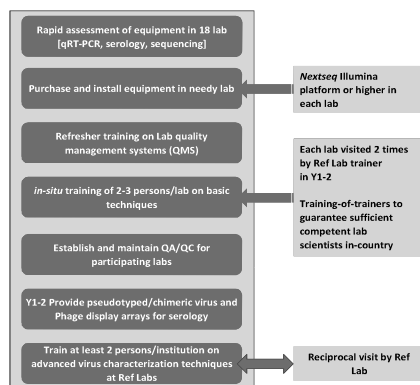


Fig 3. Flow chart of stepwise capacity-building for in-country labs

Reference Labs: We will establish and fund two Reference Labs in the US, tasked with building in-country lab capacity, and validate advanced virus characterization (*in-silico* glycoprotein and receptor, *in vitro* and *ex vivo* virus-cell studies). The D. Wang (WUSTL) and A. Greninger (UW) labs, supported by other virology, immunology, and protein chemistry labs at these institutions, will in the early phase of the program (Years 1-2) (i) Develop and supply novel virus detection and

characterization standard operating procedures (SOPs), (ii) Conduct *in situ* training to in-country labs on qRT-PCR, whole-genome sequencing (WGS), and serology technologies, including annual refresher trainings, (iii) Develop and supply qRT-PCR controls and standards, (iv) Develop and supply serology screening kits (phage display peptide libraries, pseudotyped and/or chimeric viruses, monoclonal antibodies), (v) Roll out and manage a QA/QC system to ensure

reproducible and comparable data (including proficiency panels and re-testing 10% of positive specimens from each country), (vi) Conduct advanced characterization (*in-silico* glycoprotein and receptor, *in vivo* and *ex vivo* studies with live virus), and (vii) travel and train at least two persons from each participating institution in their US reference labs on development of pseudotyped/chimeric virus and antibodies for serology, and advanced virus characterization. Based on our successful experience with lab capacity strengthening, it is essential that this will be accompanied by reciprocal training visits by reference laboratory trainers to in-country labs, with the goal of ensuring that in-country labs can independently conduct detection and significant advanced virus characterization (except virus culture, or *in vitro* and *ex vivo* studies with live virus that may require high biosecurity laboratories). We recognize that in-country laboratories will not acquire competency at the same rate because of factors such as additional needs to improve infrastructure, biosafety and biosecurity capacity, sub-contracting and procurement challenges, and staff turnover. We also anticipate that early in the DV program in-country labs will identify suspected novel virus samples that require urgent characterization methodologies not yet fully established and transitioned to the country. To address this, the project will expand U.S. based reference lab personnel who will be dedicated to implementing all aspects of in-country virus detection and characterization (as described). These personnel will transition for several month-long periods each year through the in-country laboratories to provide both structured and ad hoc in-country analysis support, including complete bioinformatic analysis of NGS data to identify novel viruses, basic *in-silico* viral glycoprotein and receptor-binding analyses, and serological analysis to determine novel virus spillover. Additionally, this response team may be deployed to work alongside in-country scientists in a country with suspected novel viruses until characterization is completed to the satisfaction of the consortium executive council and USAID. The Reference Laboratories will also validate in-country results by repeating a limited number of the characterization tests conducted on novel viruses. This validation will be achieved by shipping aliquots of not more than ~0.1% of collected samples (negative and positive) as shown in the textbox below.

ESTIMATED NUMBER OF SAMPLES SHIPPED TO REFERENCES LABS IN UNITED STATES

From ~800,000 specimens collected; we estimate at least 8,000 (1,600/year) will have suspected novel viruses. Of these, we expect to ship no more than 10 qRT-PCR positive and 10 negative specimens from each country in Years 1-2 (480 specimens) for validation, and 5 qRT-PCR positive and 5 negative specimens In Years 3-5 (360 specimens), bringing the total specimens shipped to 840 (0.1% of collected specimens) over the 5 years for the DEEP VZN program.

For purposes of virus culture, virus isolation, *in-vitro* and *ex-vivo* studies, we have established access to the Rocky Mountain BSL-4 laboratory (letter of commitment available).

2.2 Overall Detection Strategy

We will use both molecular and serological approaches to detect novel viruses. For maximum sensitivity and efficiency, our primary virus detection strategy will use broad-range qRT-PCR assays that specifically target the 3 virus families for initial screening of specimens. We will utilize consensus RT-PCR followed by sequencing of amplicons and interrogate positive specimens further to obtain complete genomes. Broad serology will be used to adjust the sampling strategy (Objective 1), and also to investigate spillover of novel viruses across the wildlife-livestock-human spectrum (Objective 3). Focusing primarily on sera collected from bats, rodents, NHP, and humans, we will screen for known and newly detected coronaviruses, paramyxoviruses and filoviruses using phage display serology. Evidence of high prevalence of diverse species of target virus families will indicate an ecosystem favourable to maintenance and

transmission of these viruses. *Serologic detection of* antibodies to a novel virus may also provide information on duration of exposure and affected animal species, with high seroprevalence in humans pointing to higher frequency of spillover events.

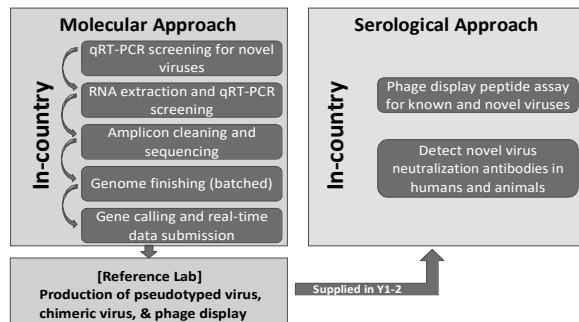


Fig 4. Virus detection flow chart

How our approach enhances efficiency to detect novel viruses: Our molecular screening strategy (Fig. 4) optimizes sensitivity, keeping the most expensive aspects (deep meta-genomic sequencing) to a minimum. All 3 viral families targeted for detection in the DV program are shed and detectable in stool reducing the need for animal trapping and handling. We have also integrated viral load measurement to our screening to improve chances of genome

finishing. During genome recovery from positive specimens, we will be able to infer hosts from environmental metadata and non-viral metagenomic sequencing data, which will be fed back to sampling teams to focus on particular animal species and areas where positives have been detected. The phage display approach is more cost-effective and efficient to serologically screen for known and novel viruses from target families than alternative multiplex serology approaches, such as peptide microarrays. Primarily because the phages self-replicate and thus are a renewable resource. Broad serology is costlier than qRT-PCR and this will limit its use.

2.3 Molecular Screening

Task 2.1: RNA extraction and broad-range qRT-PCR: RNA extraction methods will be standardized across all sites. Ideally, automated extraction instrumentation will be installed at each site. In addition, an alternative manual extraction method will be established as back-up. Our team has validated a family-specific, broad-range, single-well RT-PCR assay for *Orthocoronavirinae*, which enabled discovery of a novel coronavirus from a hospitalized patient in Malaysia. We will also make use of a published two-well pan-paramyxovirus and a one-well pan-filovirus qRT-PCRs to screen specimens. These family-specific primers amplify conserved portions of the RNA-dependent RNA-polymerase and allow for species determination after amplicon sequencing. We will integrate SYBR-Green into family-based RT-PCRs to allow for viral load quantitation at the same time we are detecting novel viruses along with melting curves to ensure appropriate-sized amplicons are generated without gel electrophoresis. As a backup strategy to the quantitative readout, a standard operating protocol for gel electrophoresis-based readout will be established. We will ensure in-country labs have instruments that can perform these assays with a throughput of 20-22 specimens per 96-well plate or 80-84 specimens per 384-well plate. We anticipate a throughput of at least 80 specimens per day per laboratory. Amplicons from qRT-PCR will be cleaned of PCR primers and sequenced on *Nextseq* biweekly, with up to 96 amplicons multiplexed. For further cost efficiency, we will explore the feasibility of multiplexing up to 384 amplicons. To identify novel viruses from the amplicons, all sequences will be aligned to a reference database composed of all target viruses from GenBank. Amplicon sequences that diverge significantly from all known viruses will be prioritized for whole genome sequencing. To standardize assays, the Reference Labs will provide positive and negative control standards for RT-PCR. Qualitative controls will be run through extraction and qRT-PCR on every plate, while quantitative controls will be run monthly. Quantitative controls will consist of a set of serial dilutions (10^7 - 10^0 copies/ul) of *in-vitro* transcribed RNA targets (2 different viruses in the family).

Task 2.2: Genome recovery and finishing: For maximal cost efficiency and timeliness, genome finishing will be performed in batches using *NextSeq* or *NovaSeq* equipment in each country. After identification of amplicons derived from novel viruses, we will ensure that complete genomes are recovered and finished to enable further screening and characterization. Complete genomes are also necessary for development of diagnostics, molecular epidemiology, vaccinology, and therapeutic development. Specimens will be prioritized for whole genome sequencing based on sequence divergence from known viruses and viral load estimates. We will use a variety of NGS methods as needed, including metatranscriptomics with rRNA depletion and/or poly-A enrichment approaches. Based on the identity of the virus, we can also use spike primers that bind the sequences recovered in the family-specific qRT-PCR or other highly conserved regions in that viral family into the cDNA synthesis prior to sequencing to increase coverage of viruses. New rRNA depletion reagents that cross-hybridize across metazoans will ensure fewer reads are spent on rRNA in rodents, bats, NHP, and humans, allowing for 8-150-fold enrichment of on-target reads. All targeted viral families poly-adenylate their transcripts, allowing classical RNA-Seq approaches to help in viral genome recovery. As a default, specimens will be targeted for 25 million reads to ensure genome recovery using high-throughput Illumina sequencers, which can allow recovery of near-complete genomes from specimens with Ct < 27. If needed, we will perform additional deeper sequencing, manually design PCR primers to close gaps, and perform 5' and 3' RACE to recover the viral genome termini. Our team has expertise sequencing whole genomes of novel RNA viruses. In Year 1, we endeavour to obtain and sequence specimens that have novel target virus from prior PREDICT projects. Small 400-500bp fragments of >150 novel paramyxoviruses and more than 60 novel coronaviruses were detected in PREDICT projects, but full genome sequences are not available. **Task 2.3: Genome calling and real-time data deposition:** Genome calling will be performed using a variety of automated and bespoke pipelines, including cloud based IDSeq for comprehensive assessment of viruses present in a specimen. As a complementary approach, we will also use well-described locally installed bioinformatic approaches, such as IRMA (an assembler specifically optimized for RNA virus genomes) and SURPI (pipeline optimized for unbiased metagenomic detection of all pathogens). Reads will be remapped to all draft genomes to ensure accuracy and manually reviewed in Geneious, especially if manual gap filling or 5' and 3' RACE is required. Importantly, our bioinformatics strategy also takes advantage of the global bioinformatics community and the wisdom of crowds by including real-time FASTQ and FASTA sequencing data deposition into NCBI Sequence Read Archive (SRA) and GenBank with **zero embargo time**. Our team has previously published software to facilitate rapid deposition of viral genomes into GenBank. SRA and GenBank accessions and brief initial analyses of sequencing data will be automatically communicated in real-time via our project-specific Twitter, so they are accessible to the global scientific community.

2.4. Broad Serology Screening

Zoonotic spillover is not considered a one-off event, and multiple small spillover events can potentially be detected by serological studies. For SARS-CoV, human serosurveys in south-eastern China found evidence of repeated spillover, with antibodies shown to persist for at least 2 years. To identify the animals or humans that had prior exposure to target viruses, our Reference Labs will generate phage display libraries covering 100,000 of the most conserved 60-mer peptides across all known filovirus, paramyxovirus, and coronavirus genomes following the VirScan protocol. The phage library will be amplified and validated using well-characterized positive control sera obtained from PREDICT labs, NIH-CREID network, in-country and CDC,

and Institute Pasteur labs. Reference Labs will develop kits consisting of phages that can be incubated with sera and protein A/G beads in in-country labs, with library preparation. Following incubation, the beads can be washed and library generation performed. The resultant DNA library is stable and can be sequenced at in-country laboratories. The phage library will be updated with novel viruses detected globally. The library will be used to screen high priority sera collected from bats, rodents, NHP, and humans sampled from nodes of potential transmission, serial cross-sectional samplings, and possibly archived sera. *Broad serology testing will be applied selectively and as a secondary approach, in part because of cost and the broader utility of genome recovery to enable further viral characterization work.* However, we envision that:

- (i) evidence of infection by novel viruses can be obtained from the serological profiles;
- (ii) unique signatures of epitopes distinct from those derived from known infections may suggest prior infection with a novel virus;
- (iii) high prevalence of diverse species of the target virus families may indicate an ecosystem favourable to maintenance and transmission of novel viruses of interest, and therefore point to a preferred sampling location;
- (iv) serologic detection of antibodies to a novel virus could inform the duration of exposure and affected animal species, with high prevalence in humans pointing to increased risk of spillover to humans.

We should point out that low or undetectable antibodies in humans may not indicate that a novel virus poses low risk to humans because other factors such as its recent introduction or potential for acquiring transmissibility to humans through minor mutations still exists.

As an orthogonal method to the broad serological screening, we will also perform binding ELISA serological assays against novel virus glycoproteins. Upon sequencing of a new virus, we will undertake codon-optimized gene synthesis to generate constructs for recombinant protein expression and pseudovirus generation. We expect to purify recombinant spike ectodomain trimers and/or receptor binding domain proteins for coronaviruses, GP trimers for filoviruses, and both fusion (F) trimers and G/H/HN tetramers for novel paramyxoviruses. We will use an antigen prediction pipeline to predict sensitive and specific viral protein antigens. Viral proteins and fragments predicted by this algorithm will be expressed for ELISA serodiagnosis. Negative-stain electron microscopy will be used to ensure the viral proteins are folded correctly after purification. Once viral protein antigens are purified, we will contract with GenScript for rapid generation of custom monoclonal antibody controls. We will then determine the specificity of the ELISA binding assay against a bank of >2,000 historical human serum specimens from UW Virology, including testing for cross-reactivity specifically against sera positive for IgGs to measles/mumps virus for paramyxoviruses, SARS-CoV-2 and all four endemic coronaviruses, and Ebola/Marburg viruses for filoviruses. Pending results from those specificity tests, we can iterate design of antigens for specific serological testing, including use of specific viral peptides, as required. Sensitivity will be tested against convalescent host animal sera as well as any human sera available from individuals known to be infected. This ELISA kit will then be provided to in-country labs with positive and negative controls, as well as host control proteins for testing for vaccine preventable illnesses (SARS-CoV-2 spike protein for coronaviruses; measles H for paramyxoviruses) and will be compatible with commonly available plate readers. Early in the COVID-19 pandemic, our UW Reference Lab provided recombinant SARS-CoV-2 nucleocapsid along with controls for binding ELISAs to laboratory partners in Senegal, Pakistan, Brazil, South Africa, Nigeria, Kenya, and other countries as part of the NIH CREID consortium. In addition to the binding assays described above, we will use pseudotyped lentivirus and chimeric vesicular

stomatitis virus (VSV) neutralization assays with the novel virus glycoproteins to functionally profile sera for neutralizing antibodies. These assays will benefit from the expertise of Dr. Whelan (WUSTL) and Dr. Veessler (UW) and allow for greater rigor and reproducibility of seropositivity identified by binding ELISA by providing an orthogonal and functional readout. Our primary approach will involve generating chimeric VSV reporter viruses (below). As these assays require cell lines permissive for viral entry, these efforts will create synergy between virus detection (Section 2.2) and characterization (Section 3.3) components.

Task 2.4: Generation of chimeric reporter viruses: We have extensive experience generating chimeric VSV reporter viruses where native viral glycoprotein (spike S, attachment glycoprotein G, fusion F, and hemagglutinin H) is replaced by those of heterologous viruses. Our experience with the coronaviruses indicates that either mutation of the endoplasmic reticulum retention sequence in the cytoplasmic tail of the spike, or truncation of the tail by approximately 20 residues can allow effective integration of the respective Spike gene into VSV, yielding viruses

that grow to titers of 10^8 pfu/ml. For filoviruses, we have not found it necessary to manipulate the cytoplasmic tail of the glycoprotein, although we have mutated the transcriptional editing sequence that is used for synthesis of soluble glycoproteins. Once an infectious clone of VSV-chimeras is assembled, we confirm sequences of the recovered virus, and characterize the growth of the respective viruses to establish the optimal conditions for the generation of seed stocks.

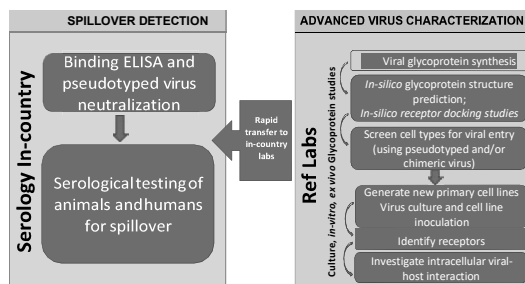


Fig 5. Flow chart for novel virus characterization

Task 2.5: Detection of neutralizing antibodies: We will use VSV-chimeric viruses to monitor levels of neutralizing antibodies in humans and sometimes animals. We are mindful of reports that bats inoculated with some filoviruses do not generate neutralizing antibodies that are detectable in neutralization assays. Accordingly, we will also use the VSV-chimeras to detect antibodies that recognize the respective envelope proteins displayed on the surface of virions. To do this, we will use purified virions that contain the respective envelope proteins on their surface and sera containing antibodies that bind to the virion identified by isolating the bound complexes. As an alternative approach to VSV chimeric viruses, we will use lentivirus-based pseudotyped neutralization assays. Pseudovirus neutralization assays against novel viruses will be optimized for expression and intracellular termini truncations as well as with monoclonal controls. The constructs, controls, and pseudotyped viruses will be made available to in-country partners once the assay is validated by Reference Labs. *These approaches will permit us to determine whether a given animal species has mounted an immune response to the envelope proteins of any novel virus and whether such immune responses include neutralizing antibodies.* The prevalence of such antibody responses may indicate potential risk for spillover into humans, even though low or undetectable antibodies may not mean that a virus is at low risk for human infection. These assays are compatible with BSL-2 settings widely available in in-country labs.

OBJECTIVE 3: Strengthen Characterization of Novel Viruses from Priority Viral Families

3.1. Overall Characterization Strategy

Guided by the understanding that, with timely and complete genome sequencing in Objective 2, >80% of novel virus characterization can be performed in the absence of virus isolation. We will start by characterizing selected novel viruses detected under the PREDICT program and identified as potentially important. Subsequently, we will use sequence data from novel viruses

we detected (Objective 2) to construct qRT-PCR screening kits and recombinantly express and purify viral proteins for reagents development (e.g., monoclonal antibodies) for serological assays and structural studies. We will use these sequences to create pseudotyped and chimeric viruses for serological assays and profiling viral entry. Pseudotyped and chimeric viruses can also be used to identify and screen for receptor usage and identify cell lines that support viral entry. These cell lines can be used to identify other determinants of tropism and to characterize viral entry mechanisms. We will attempt to isolate novel viruses and identify known or novel host genes that enable viral entry. Finally, we will determine the affinity of novel viral glycoproteins for human receptors and mechanisms of innate immunity antagonization to determine zoonotic/ pandemic potential (Fig. 5).

3.2 Profiling Viral Glycoproteins/Receptors to Assess Pandemic Risk of Novel Viruses

Task 3. 1: *In-silico* characterization of novel viruses. Our *in-silico* approach for profiling human transmission risk follows directly from the hypothesis that *affinity for human receptors of a novel viral glycoprotein indicates pandemic potential*. As soon as a novel virus genome is recovered, our UW Reference Lab will perform *in-silico structure prediction* of viral glycoproteins with Rosetta and trRosetta, as well as docking with known receptors for a given viral family to approximate affinity for human receptors. To support this effort, we will model the structures of the extracellular domains of all human proteins and compare these to structures of known host cell viral receptors to determine how closely they match as a way of generating hypotheses **for candidate** human host cell viral entry points. We will interrogate these predicted structures for specific changes in protease site activation. Our ability to determine high- resolution structures of viral glycoprotein-receptor complexes using world-class cryo-EM will be fed back to *in-silico* models to enhance protein structure prediction and viral-host protein-protein interactions. It is worth noting that to-date, no model has successfully predicted viral zoonoses and spread in humans. Therefore, our bias will be to perform as much wet laboratory characterization of novel virus glycoproteins. We will synthesize all viral glycoproteins recovered from novel viral genomes and screen in viral entry, biochemical, and biophysical assays because *in-silico* modelling is insufficient to capture risk.

Task 3.2: Biophysics and structures of viral glycoproteins. Divergent paramyxovirus, filovirus, and coronavirus genomes will be used to carry out structural studies of the corresponding glycoproteins in isolation and bound to target receptors to understand the mechanisms of viral entry into host cells. Our UW Reference Lab is world-renowned for expertise in viral glycoproteins and has developed a streamlined, high-resolution cryo-EM pipeline enabling high-throughput structural studies of viral glycoproteins bound to host receptors and neutralizing antibodies. It will be leveraged to provide atomic-level information of the infection machinery of discovered viral pathogens before they emerge. Novel viral glycoproteins and animal and human receptors will also be expressed and tested directly for binding kinetics and affinity using biolayer interferometry. These affinity measurements will provide biophysical confirmation of receptor interactions and direct biochemical evidence of the degree of pandemic risk of a novel virus. We will correlate binding affinity measurements and functional biochemical measurements of fusogenicity using cell-cell fusion assays.

Task 3.3: Viral isolation-independent viral entry characterization and receptor discovery. The VSV chimeras and pseudoviruses generated above will also be used to perform viral receptor discovery at a BSL-2 level. Previously, our WUSTL Reference Lab has used both VSV

SECURING MTAs FOR SHIPPING SPECIMENS: Our approach is to reduce the number and scope of MTAs. Each in-country lab will only sign one MTA with either UW or WUSTL reference laboratory

and pseudoviruses and a series of cell lines expressing canonical coronavirus receptors to rapidly screen for coronavirus receptor usage and to discover the human receptor of SARS-CoV-2. To establish neutralization assays, VSV chimeras and pseudoviruses will already be tested against a broad array of human, non-human primate, bat, and rodent cell lines that support paramyxovirus, filovirus, and coronavirus growth, including an initial screen of VeroE6, RHEK, CV-1, HAE, HuH-7.5, HEK293, HepG2, CaCo2, BHK (hamster), MEF (mouse), A549 (bat), RHEK (bat) cell lines. This screen will be performed in the presence and absence of trypsin to determine if host restriction for viral entry exists at the level of proteolytic activation, as previously described for several bat coronaviruses. Canonical receptor usage (e.g., ACE2/DPP4/APN for coronaviruses, NPC1 for filoviruses, or SLAMF6/EphrinB2/3 for paramyxoviruses) will be confirmed at the protein-level using soluble receptor blocking and/or blocking monoclonal antibodies.

If viral entry into one of the above cell lines is not found to be caused by a known or canonical receptor, we will perform genome-wide CRISPRko screens to discover viral receptors. Using this and related genome-wide approaches, we have identified the receptors for multiple coronaviruses, paramyxoviruses and filoviruses validating this approach. We will carry out such screens to identify host genes that are potential determinants of infection and, armed with that information, we can determine the step of viral infection at which any given host gene functions as described in the rest of the proposal. This will allow us to compare the genomic sequence of entry factors between susceptible and non-susceptible host cells.

3.3 Viral Inhibition of Innate Immunity

Viral antagonization of innate immunity is an important component of viral pathogenesis in humans. Like glycoproteins, viral immuno-evasion proteins are often tailored specifically to the host they infect, and thus the zoonotic and pandemic potential of a new virus will be determined in part by how these genes affect human innate immunity pathways. West Nile and Zika virus spread in humans is in part determined by the degree of inhibition of the JAK/STAT pathway.

Infection in animal host species reservoirs can contribute to viral evolution strategies that facilitate evasion of host innate immunity. Bats have specifically downregulated inflammatory pathways while maintaining type I interferon pathways, leading to a unique evolutionary selection for viral antagonization of type I interferons.

Task 3.4: Testing for the degree of innate immune inhibition: The UW Lab will perform tests by all open reading frames from a novel virus in a host innate immune evasion screening platform. If throughput is limited, at a minimum we will characterize the major immuno-evasion genes from the different viral families. Here, the specific viral protein open reading frame is cloned and expressed ectopically in relevant host cell lines, 24 hours later cells are treated with exogenous interferon (IFN) and harvested over a time course to evaluate for possible reduction in innate immune signalling pathway activation compared to control cells treated with IFN but without ectopic expression of viral genes. Loss of innate immune activation will be evaluated by reduced IFIT1 and IFITM1 gene expression measured by RT-qPCR. We recognize that these approaches are limited to evaluating viral evasion from IFN responses and do not evaluate innate immune signalling components that occur prior to (upstream of) IFN induction. To address this, we will assess the ability of viral protein expression constructs to suppress the activation of interferon regulatory factor (IRF)3 activation induced by Sendai virus infection, a control virus that potently induces innate immune activation in infected cells. We will transfect cells with each viral protein expression construct, followed by infection with Sendai virus, and assess total and phospho/active IRF3 abundance. For a broader analysis of innate immune pathway regulation, we will infect relevant host cell lines with the virus panel of interest and evaluate innate immune

response pathways activated by each specific virus using assays (immunoblot and mRNA analyses) to measure the activation state of specific innate immune pathway markers as well as expression of downstream genes linked to each pathway.

3.4 Virus Isolation for Receptor and Intracellular Viral-Host Interaction Studies

Task 3.5: Viral isolation and receptor identification. As illustrated in Fig. 5, we may require virus isolation to conduct *in vitro* and *ex vivo* studies. Such studies will be conducted in BSL-3 and BSL-4 labs under proper biosafety protocols. Isolation of novel coronaviruses or paramyxoviruses (determined using sequencing data) when there is no concern of severe human disease can be attempted in certified BSL-3 labs located in-country, regionally, or at Reference Labs. Isolation of viruses of great concern of severe disease, such as filoviruses, will only be attempted in Rocky Mountain Laboratories BSL-4 lab (letter of commitment available on request). Positive specimens will be prioritized based on viral load, with a focus on specimens with >1 million copies per mL or gram. We will inoculate virus onto cells shown to be permissive to pseudovirus entry from above. Viral isolates will be expanded and deposited into central repositories with CDC, BEI, and/or WRCEVA, according to the appropriate biosecurity and national data sharing guidelines. Receptor usage determined in the pseudovirus screen will be confirmed using the viral isolate. For isolated novel viruses that do not show canonical receptor usage but cytopathic effect, we will screen for novel human receptors using genome wide CRISPRko libraries in cell lines that support viral growth as described above. Where possible, we will prefer viral isolate CRISPRko screens over pseudotype screens to identify potential intracellular viral-host interactions at the same time as identifying potential receptors.

Task 3.6: Host cell characterization and cell line generation for viral characterization.

Inoculating existing cell lines and primary cells with virus-positive specimens may not result in viral growth. The cell lines chosen may not contain the correct receptors, proteases, or other intracellular factors to support viral entry and/or growth. To support viral isolation and characterization for such viruses, we will generate primary cells from bat, rodent, and NHP tissues that are specifically sampled in DV and identified by host deep sequencing reads in Objective 2. Over the past decade, several new primary bat cell lines have been established that support growth of many viruses of high zoonotic potential *in vitro*, and yet bat species are so diverse that it is likely that no specific cell lines might be available for the bats sampled here. Should the approaches outlined above fail to support viral isolation, we will use scRNA-Seq sequencing of virus-positive primary specimens to help identify candidate host cells and host receptors to be targeted for cell line generation. scRNA-Seq is a powerful approach to link virus transcription and replication on a single cell level with candidate host cells and receptors should existing cell lines prove insufficient. If we are unable to specifically isolate the relevant host cell lines based on scRNA-Seq data, we will ectopically express candidate viral receptors identified by scRNA-Seq data into candidate host cell lines to determine viral receptor usage.

3.5 Algorithm for Ranking Viruses with Pandemic Potential

A proposed algorithm for ranking emerging viruses for potential spillover to humans was recently published by the PREDICT team (<https://spillover.global/ranking-comparison/>;doi.org/10.1073/pnas.2002324118). We will improve on this by applying the findings of our innovative and thorough stepwise virus characterization methodologies described in Section 3, and by rating each novel virus based on the following three questions:

- (i) Does the virus have potential for human transmission? This will be investigated using the glycoprotein modeling and functional viral entry studies described above.

- (ii) Is there evidence of its spillover to humans or a broad range of potential animal reservoirs? This will be addressed through serologic testing.
- (iii) Does the virus have capacity to inhibit host innate immunity? Evidence of immunoevasion is consistent with the potential for significant morbidity and/or mortality in humans and should trigger a higher level of public health concern, particularly if the virus rates high on criteria i & ii above.

We will summarize the results in prioritized lists that will be publicly accessible to both in-country partners and international stakeholders. Importantly, our findings, which will be disseminated in scientific publications, presentations, communication with USAID and other stakeholders, will add key metrics to evaluate the zoonotic and pandemic potential of novel viruses.

OBJECTIVE 4: Strengthen Focus Country Capacities for Data Management and the Viral Characterization Process

The proposed project will develop and implement improved data systems at the country and international level, building on learnings from the EIDITH system developed for PREDICT 2, and increasing interoperability and access for partners and stakeholders alike. We will also aim to enhance in-country data collection and use to accelerate detection and response to future public health threats. This will begin with an assessment of the data structure of the EIDITH system, defining a core set of standard variables to be collected across sampling locations for use in describing the distribution of pathogens/exposures. The importance of national-level data autonomy must be balanced with the need for widespread dissemination of data to aid in the prediction and prevention of emerging epidemics. We will work with countries to build on existing systems using an “Adopt-Adapt-Develop” approach while defining protocols for data sharing between the DV and local systems so that project data enhances existing systems while observing local policies and SOPs. The consortium will also draw on previous experience with local and global datasets to advance global surveillance of zoonotic threats. To allow rapid sharing of data across the consortium and with international databases such as NCBI, we will put in place MOUs and data use agreements using a “staged ring” approach, wherein data access can be conceptualized as a series of interlocking rings within which data ownership is retained by in-country stakeholders whilst standardized review, approval, and validation processes allow data to be rapidly shared to key stakeholders at national and international levels. This will ensure that, rather than creating parallel systems, the project builds upon (and integrates into) existing structures and data systems, while ensuring rapid release of validated data to project team, national, and international partners. Pending national approvals, aligned to standardized data sharing agreements supported by DV, and the removal of any sensitive information, data will matriculate across the data management structure, representing gradually more release of data (e.g., USAID staff, external partners, cross-border sharing and full public accessibility). This progression will represent not only increased access but also improved data quality: data sets made available to the public would represent those with well-documented dictionaries and curated metadata, while more incomplete data would remain with project and national stakeholders. In these endeavors, we will build on PREDICT, which has uploaded hundreds of sequences from newly discovered animal pathogens to the NCBI’s Short Read Archive (SRA) and GenBank. With USAID and local stakeholders, we will review and update the data use agreements where PREDICT has been active and use them as models.

4.1 Project Data Collection and Management

Task 4.1: Develop a project-wide data management plan. The consortium will use a data system based on principles of the EIDITH system to collect and manage data among the partners while respecting the need for data safety and ensuring in-country data ownership. This management system has the capability to import data for linkage with surveillance data systems in the host countries, USAID, and global systems such as healthmap, ProMED, NCBI.

Task 4.2 Monitor project implementation. PATH, leading Objective 4 and as a global leader in project monitoring and evaluation, will develop indicators and track project progress via systematic data analysis and review meetings, data quality assessments, technical working groups, and training of data managers at the facility, subnational, and national level.

Task 4.3 Data storage. Following national approvals described in section 4.2, data will be stored within the DV database with data security and access conforming to the FAIR Principles, as well as the Nagoya protocol for genomic data sharing.

4.2 Country Data Management

Task 4.4: Map the data management and policy landscape of each country. In Year 1 an early assessment of existing systems in use at the country and regional levels will be conducted in order to help support and define the architecture, connectivity, flow and human resource capacity to achieve rapid access to quality data at the country level. This assessment will identify gaps and areas that must be strengthened across the continuum from data collection, cleaning, and storage to analysis and presentation to key stakeholders and users and across relevant data sources including laboratory, human and animal clinical, and environmental data sets. This will also entail an extensive evaluation of the enabling environment, including existing health data privacy policies, data use regulations, digital workforce capacity, and information technology infrastructure. The goal is to develop a baseline for each country in terms of existing data agreements, identify adaptations that would enhance data sharing, and understand the policy environment for data sharing and use. Using these assessments, we will develop a roadmap for developing an integrated country-level data architecture with our country partners, including reporting from our DV data system and site- and laboratory-level data collection, as well as ensuring local data sharing through secure, interoperable data exchange.

Task 4.5: Evaluate lab information systems of DV lab and field data collection teams in focus countries. Our consortium will identify the capacity of partner labs in focus countries to support data capture for the project. Similarly, we will ensure that the field data collection teams are trained in data collection according to the data standards that we will extend based on EIDITH/PREDICT. We will build on the existing data structure from in-country data management systems and PREDICT/EIDITH, including sample tagging protocols, geolocation, and survey-based questionnaires.

Task 4.6: Incorporate knowledge and learnings from previous projects. We will use publicly available data, such as PREDICT data available through <https://data.usaid.gov> including readily available country-specific data sets from EIDITH (event animal production, event crop production, animals sampled, event dwellings, event value chain, PCR tests, and site/event characterization) and genomic information available through GenBank in national-level data use and analysis. This will ensure that our project database builds on successes and lessons learned from the EPT project to date. Our data management plan will be able to rapidly incorporate the metadata and genomic data of these samples when they become available.

Task 4.7: Establish data standards and governance. With our in-country partners, we will establish global data standards and assist with establishment of a data warehouse that includes

different collection and management aspects for analyzing, sharing, and storing data. The consortium has previous experience creating similar architecture (the POLIS system for polio eradication and analysis) which has been in use for over eight years. Technical working groups (TWG) will be developed to establish data governance and reporting plans for each target country. These TWG's will conduct regular monitoring of implementation and the assessment of whether goals are being met, while adhering to country needs to try to be more proactive, transparent, to share data rapidly, and be adaptable to addressing issues. We will engage existing standards bodies to ensure that data sharing formats leverage existing works and/or contribute to these standards. This will also address (and ensure) country/regional and local stakeholders' access to genomic/sequencing data from GenBank and other global repositories to build and strengthen research capabilities. We will work with country governments to ensure the timely sharing of information as described, while also recognizing sensitivities around data to avoid stigmatization that could lead to reluctance because of economic and societal pressures.

Task 4.8: Implement data collection using updated data system for focus countries. We will adapt existing technology for the DV digital tool to collect field-based data, including geolocation, animal or plant species, samples collected, unique sample identification, and so on. The tool will be based on an existing technological base, such as CommCare, RedCap or similar, with interfaces for data import, exchange, and interfacing with lab systems. The DV data system will collect necessary data, including accession information for genomic data, connected with sample and location data collected by the DV digital tool.

Task 4.9: Strengthen capacity of in-country partners to store, analyze, and share data. We will train in country partners on use of the DV data system and its linkages with existing in-country data system architecture, work with host governments and data users to identify the key questions they would like to answer with the data, as well intended purposes and requirements, and support implementation of solutions to improve country-level electronic data sharing capacities. Uploading viral sequences to NCBI will also facilitate data exchange between in-country labs and reference labs. We will work to establish harmonized bioinformatics techniques and pipelines across the DV project to ensure comparability of genomic data. User-friendly dashboards including GIS maps to show location of possible priority infectious agents or exposure will be developed to visualize and support interpretation of the data. The consortium will identify "local champions" at the different levels to accelerate this activity. We will work with our in-country partners to publish, supporting their capacity to act as lead authors in internationally recognized journals, and provide training and mentorship in scientific writing.

Task 4.10: Strengthen in-country data management processes for the viral detection and characterization processes. Our consortium will support in-country labs in the focus countries in training the necessary staff on laboratory data management, including genomic data, and to support staff in bioinformatics, monitoring, and maintaining data repositories and architecture.

Task 4.11: Develop an early warning system with country-level dashboards. Learning from tools such as Tableau, DHIS2 dashboards, and other existing AI platforms, by the end of Year 2 we will develop country-level dashboards of DV data to visualize data and identify potential emerging threats based on expert opinion. This will leverage work done under PREDICT 1 and 2 as well as the Spillover data tool (<https://spillover.global>).

4.3 Global Data Sharing

The consortium has identified key data sets to be collected across countries that may require augmentation to in-country systems. Sequencing data will be communicated in as close to real-time as feasible to make this information accessible to the global scientific community, while

also adhering to data governance requirements negotiated with local stakeholders. Sequencing data and correlation with other findings including advanced characterization will also be regularly shared with in-country partners and global stakeholders via published lists of prioritized novel viruses ranked on their pandemic potential. This release of high priority and high-risk pathogens will feed into other risk assessment activities at national and global levels such as STOP Spillover and the proposed WHO Berlin Hub for Pandemic and Epidemic Intelligence. The consortium is already engaging with these stakeholders to cultivate a new model of data solidarity and collaborative intelligence for risk assessment. Another emerging initiative supported by WHO - the International Pathogen Surveillance Network (IPSN) - will also work to support global exchange of genomic information. The consortium will ensure a close integration with and support for IPSN, leveraging this global structure and pathway for R&D. These examples demonstrate opportunities for improved and rapid data sharing in a quickly evolving landscape. The consortium, in collaboration with USAID, will continue to track and engage with these initiatives as appropriate. Wherever possible, the linkages between the consortium data and these international data sharing mechanisms will be built into the project system architecture and part of agreements with national stakeholders.

Task 4.13: Convene multisectoral networks at country and international level. We will build on existing data standards for PREDICT 2 and provide trainings across the consortium and with in-country stakeholders to ensure adherence to data standards.

Task 4.14: Develop improved data sharing processes across data systems at country and international levels and across stakeholders. The project will develop the DV digital tool “esign” – a data-sharing process that supports differing levels of staging and access – with the capability to move data from an internal-only level to internal plus USAID, external partners, and fully public, international levels. While aligning with host country requirements and global guidelines (e.g., WHO’s code of conduct for sharing of pathogen genetic sequence data), our consortium will also ensure appropriate data is made available in a rapid and responsible manner to benefit the global community. In keeping with our “Adopt-Adapt-Develop” approach, we propose a data storage structure that will include three related databases – one for raw sequencing reads, one for assembled data and one for sample metadata. This segregated structure will facilitate real-time reporting of raw sequence data (FASTQ and FASTA) accompanied by limited deidentified metadata to global repositories (NCBI SRA, etc.) while also ensuring that access to sensitive metadata remains restricted until validated and approved for release. This structure will support more routine release of raw sequencing data throughout the duration of the DV project, while enabling local investigators adequate time to complete genome assembly and perform data cleaning and validation prior to submission of finished genome sequences to public domain (NCBI, EMBL-EBI, DDBJ) or public access (e.g. GISAID) repositories, and/or alternative global platforms (e.g., GitHub). Finally, project results and analyses will be regularly communicated via scientific publications, presentations, and direct communication with USAID and other stakeholders. As appropriate, and in accordance with in-country data sharing agreements, outlets will be explored for more rapid dissemination of findings, particularly when novel viruses with high pandemic risk are identified. This includes sharing manuscripts within preprint servers, such as medRxiv or bioRxiv, prior to publication.

5 Capacity Strengthening

A key goal of our DV program is for every activity and outcome to be predicated on a foundation of sustainable capacity strengthening within focus countries. To achieve this, in-country partner organizations will play leading and participatory roles in the development and implementation of

all activities. Further, in-country nationals will coordinate and implement all planned activities, from sample collecting through to laboratory analyses, with language-specific training programs being provided where necessary. Moreover, when planning for the improvements in technical capacity through provision of equipment, care will be taken to ensure the utility of any equipment extends beyond the duration of the program by selecting location-appropriate equipment that can readily be maintained, resourced, and used. This will ensure that during and after the program maximal use is made of the virus detection and characterization capacity that the project will develop. Finally, it is critical that in-country stakeholders understand the value of the knowledge and resources generated. We plan to achieve this in two ways: (1) in-country partners will take leading roles in all aspects of data analysis and the preparation of peer-reviewed publications and (2) the DV project will engage a wide range of in-country stakeholders at project inception to begin the process of raising awareness about the potential value of the generated resources. This process will include multiple fora being hosted within focus countries with a variety of stakeholders to raise awareness of resources that will be generated by the program, and their use (Table 1).

Resource Generated	Resource Uses	Stakeholders
Data from wildlife sampling: species and abundance	Inform conservation efforts	National and international wildlife organizations
Viruses detected in wildlife and domestic animals	Prepare for animal health events	Animal health agencies
Spillover events detected in human populations	Determine risk to humans, control efforts	Human health clinicians, public health
Improved laboratory capacity for qRT-PCR	Improve detection of other infectious diseases	Human health, public health
Improved capacity for ELISA	Improve detection of other infectious diseases	Human health, public health
Improved sequencing and bioinformatics capacity	Application of whole genome sequencing to other pathogens	Laboratories, public health, surveillance

Table 1: Resources generated by the program, their utility, and the stakeholders who will benefit

6 Sample Monitoring and Learning Plan

The WSU-led consortium partners will work with USAID within the first 90 days of the grant to develop a comprehensive Monitoring Evaluation and Learning Plan inclusive of a Learning Agenda and Data Management plan that will describe the processes for monitoring project activities and progress towards achieving the desired results. A comprehensive indicator matrix with output, outcome, and impact indicators, annual and life of project targets, and baseline measures will be at the center of the MEL plan. Table 2 presents illustrative indicators for a subset of intended results and activities under each of the project's 4 objectives, with additional illustrative indicators in Annex 2. Quarterly team check-ins will be used as a venue for Objective Leads to review MEL data with the team to identify areas that are not achieving desired results and flag areas where implementation strategies might need to be adjusted. The team will use MEL data to inform project management and will report semi-annually and annually on progress towards achieving results under the agreed upon indicators in the MEL plan and explain any significant deviations from expected targets. The MEL plan will be reviewed for relevance semi-annually and the WSU-led consortium will work with USAID to revise if and when necessary. The team will collect and analyze data on gender to inform the project's gender action planning to identify opportunities for the project to reduce opportunity gaps between men and women or address power differentials to promote gender equity.

Table 2: Selected illustrative indicators linked to intended results and project activities

Objective 1: Conduct Sampling In Focus Countries For Unknown Viruses From Priority Viral Families		
Intended results	Project Activities/Tasks	Indicators/Milestones
In-country institutional and staff capacity to conduct risk modeling to identify and inform sampling efforts strengthened .	1.7 Capacity Building and Sustainability (cross cutting all Objective 1 activities and tasks)	#/% representatives from in-country wildlife, human, livestock, and environmental health sectors, trained and engaged in risk modeling, sample site and species selection, and sample target setting processes
Key species sampled at research sites.	1.3 Country-level Strategic Sampling	# of wildlife samples collected in each country % of archived wildlife samples of interest screened
Objective 2: Strengthen Detection In Focus Countries For Novel Viruses From The Priority Viral Families		
Detection and genomic sequencing of novel viruses from prospective samples safely conducted .	2.2 Overall Detection Strategy 2.3 Molecular Screening 2.4. Broad Serology Screening	# of in-country labs with instruments that can perform assays with a throughput of 20-22 specimens per 96- well plate or 80-84 specimens per 384-well plate # of genome finishing batches performed using NextSeqor NovaSequequipment in each country
Ability of select in-country laboratories to provide technical assistance and/or detection capabilities for viral discovery in- country and in the region improved .	2.1 Capacity Building and Sustainability	# of labs & # people trained by project on qRT-PCR, serology, next gen sequencing methods, bioinformatics platforms and methods for analysis; % of those trained demonstrating improved competency in new methods; % of laboratory capacity gaps identified in each country that are showing improvement as demonstrated by: % of labs with screening & sequencing instruments
Objective 3: Strengthen Characterization In Focus Countries Of Novel Viruses From Priority Viral Families		
Lab and bioinformatics capacity for characterizing unknown viruses in select in- country institutions strengthened .	3.1. Overall Characterization Strategy	# countries with improved characterization capacity as demonstrated by increased number of novel viruses characterized and fully sequenced by in-country laboratories that have staff who have participated in at least one of the project's capacity building activities.
Objective 4: Strengthen In-Country Capacities For Data Management And Viral Characterization Process		
Newly validated methodologies and protocols, data and analyses associated with viral detection and characterization shared .	4.2 Country Data Management Task 4.9: Strengthen capacity of in-country partners to store, analyze, and share data	# countries with validated protocols for data sharing, MOUs in place; # DV datasets, methodologies, and/or publications made publicly available; # of data managers providing data sets with reliability, accuracy, completeness, consistency and timeliness.

Learning Agenda: Our consortium is committed to utilizing a Collaborating, Learning and Adapting approach to implementing the DV project. The Learning Agenda (LA) will be developed in the first 90 days in collaboration with USAID and in-country technical experts and will be the primary tool for ensuring critical questions that can guide implementation are collaboratively agreed upon and used to inform project implementation. The LA will serve to contextualize project achievements and test assumptions regarding how implemented activities yield intended results. We will review and discuss LA assessments quarterly to ensure learning from identified failures and successes and to improve future implementation. Illustrative LA questions are provided in Table 3. The final LA will include learning activities, timelines, methods and a dissemination plan that will describe key audiences benefitting from the learning

produced by the project and products targeted at those audiences to ensure relevant information is shared back quickly to the right stakeholders in a useful format.

Table 3. Illustrative Learning Agenda questions:	
1	To what extent is the project successfully supporting the timely detection and complete characterization of known and un-known pathogens among the prioritized viral families within the in-country reference laboratories? Which approaches are leading to the most robust implementation in countries and greatest effects on timely detection and complete characterization? And what characteristics, differences or similarities do we see across successful vs. less successful reference laboratories or countries where DV is implemented?
2	What data have the project successfully made available for use by local, regional and global audiences, and how have the data generated by the project supported local, regional and global preparedness and response activities to the targeted viral families? Are the appropriate audiences receiving useful data more rapidly? What barriers are still delaying the processes of sharing data and findings as quickly as possible? And what differences or similarities do we see across countries where DV is implemented vs. Countries where DV is not implemented?
3	<p>a. In which areas of capacity building (a-d below), and with which cadres of the workforce, has the project been successful in strengthening in-country capacity? What capacity building strategies are showing greatest / least impact? What remain the biggest barriers to successfully unlocking in-country capacity? Are project activities leading to unexpected capacity improvements? Laboratory capacity in viral detection and characterization of unknown viruses</p> <p>b. Data management capacity, including data collection, quality, analysis, sharing and storage</p> <p>c. Timely dissemination of actionable data and research findings</p> <p>d. In-country capacity to use data and research findings</p>
4	What existing in-country and global data systems are most successfully being leveraged for sharing DV data to increase likelihood of sustainability and interoperability among sectors? How successful is the project with getting virus sequencing data into those data sources? What facilitators can be leveraged and barriers do we still need to overcome to integrate DV data into sustainable systems?

Mixed methods will be used to answer these learning questions. Desk reviews will compile existing evidence; project monitoring and evaluation data will be used to track progress towards achievement of results within the learning agenda topic areas and incorporate project M&E within the learning. Additional methods for collecting data to answer these learning questions will include surveys, checklists, observations, key informant interviews and review of secondary data extracted from existing databases. Data from these sources will be analyzed to answer these questions, help the project understand what is working, where immediate pivots are needed in current implementation strategies and what learning should be shared more broadly. Data collection tools will be stored in a central repository for re-use and continuous learning during the project and beyond. The plan to disseminate and use findings will differ depending on the learning question. In many cases the first audience will be internal team and management to inform activity planning and work planning. Learning exchange sessions, webinars or workshops will be planned to discuss findings with local experts and decision makers to explore the local context and use of the findings. On a global scale, we will develop white papers, blogs, conference presentations, global learning exchange webinars, or publications for peer review.

[END OF ATTACHMENT B]

ATTACHMENT C – STANDARD PROVISIONS

MANDATORY STANDARD PROVISIONS FOR U.S. NONGOVERNMENTAL ORGANIZATIONS

M1. APPLICABILITY OF 2 CFR 200 and 2 CFR 700 (NOVEMBER 2020)

- a. All provisions of 2 CFR 200 and 2 CFR 700 in effect on the date of this award, and all Standard Provisions attached to this agreement are applicable to the recipient and to subrecipients that meet the definition of “Non-Federal Entity” in part 2 CFR 200.1, unless a section specifically excludes a subrecipient from coverage. The recipient must assure that subrecipients have copies of all the attached standard provisions.
- b. For any subawards made with Non-U.S. subrecipients the recipient must include the applicable “Standard Provisions for Non-US Nongovernmental Organizations.” Recipients are required to ensure compliance with monitoring procedures in accordance with 2 CFR 200 and 2 CFR 700.

[END OF PROVISION]

M2. INELIGIBLE COUNTRIES (MAY 1986)

Unless otherwise approved by the USAID Agreement Officer, funds will only be expended for assistance to countries eligible for assistance under the Foreign Assistance Act of 1961, as amended, or under acts appropriating funds for foreign assistance.

[END OF PROVISION]

M3. NONDISCRIMINATION (JUNE 2012)

No U.S. citizen or legal resident shall be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination on the basis of race, color, national origin, age, disability, or sex under any program or activity funded by this award when work under the grant is performed in the U.S. or when employees are recruited from the U.S.

Additionally, USAID is committed to achieving and maintaining a diverse and representative workforce and a workplace free of discrimination. Based on law, Executive Order, and Agency policy, USAID prohibits discrimination, including harassment, in its own workplace on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, disability, age, veteran’s status, sexual orientation, genetic information, marital status, parental status, political affiliation, and any other conduct that does not adversely affect the performance of the employee.

In addition, the Agency strongly encourages its recipients and their subrecipients and vendors (at all tiers), performing both in the U.S. and overseas, to develop and enforce comprehensive nondiscrimination policies for their workplaces that include protection for all their employees on these expanded bases, subject to applicable law.

[END OF PROVISION]

M4. AMENDMENT OF AWARD (JUNE 2012)

This award may only be amended in writing, by formal amendment or letter, signed by the Agreement Officer (AO), and in the case of a bilateral amendment, by the AO and an authorized official of the recipient.

[END OF PROVISION]

M5. NOTICES (JUNE 2012)

Any notice given by USAID or the recipient is sufficient only if in writing and delivered in person, mailed or e-mailed as follows:

- (1) To the USAID Agreement Officer, at the address specified in this award; or
- (2) To the recipient, at the recipient's address shown in this award, or to such other address specified in this award.

[END OF PROVISION]

M6. SUBAWARDS AND CONTRACTS (DECEMBER 2014)

- a. Subawardees and contractors have no relationship with USAID under the terms of this award. All required USAID approvals must be directed through the recipient to USAID.
- b. Notwithstanding any other term of this award, subawardees and contractors have no right to submit claims directly to USAID and USAID assumes no liability for any third party claims against the recipient.

[END OF PROVISION]

M7. OMB APPROVAL UNDER THE PAPERWORK REDUCTION ACT (DECEMBER 2014)

Information collection requirements imposed by this award are covered by OMB approval number 0412-0510; the current expiration date is 04/30/2005. The Standard Provisions containing the requirement and an estimate of the public reporting burden (including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information) are

<u>Standard Provision</u>	<u>Burden Estimate</u>
Air Travel and Transportation	1 (hour)
Ocean Shipment of Goods	.5
Patent Rights	.5
Publications	.5
Negotiated Indirect Cost Rates - (Predetermined and Provisional)	1
Voluntary Population Planning	.5

Protection of the Individual as a Research Subject 1

<u>22 CFR 200</u>	<u>Burden Estimate</u>
2 CFR 200.318-326, Procurement Standards	1
2 CFR 200.310-315, Property Standards	1.5

Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, may be sent to the Bureau for Management, Office of Acquisition and Assistance, Policy Division (M/OAA/P), U.S. Agency for International Development, Washington, DC 20523 and to the Office of Management and Budget, Paperwork Reduction Project (0412-0510), Washington, DC 20503.

[END OF PROVISION]

M8. USAID ELIGIBILITY RULES FOR GOODS AND SERVICES (MAY 2020)

This provision is not applicable to commodities or services that the recipient provides with private funds as part of a cost-sharing requirement, or with Program Income generated under this award.

- a. Ineligible and Restricted Commodities and Services:
- (1) Ineligible Commodities and Services. The recipient must not, under any circumstances, procure any of the following under this award:
 - (i) Military equipment,
 - (ii) Surveillance equipment,
 - (iii) Commodities and services for support of police or other law enforcement activities,
 - (iv) Abortion equipment and services,
 - (v) Luxury goods and gambling equipment, or
 - (vi) Weather modification equipment.
 - (2) Ineligible Suppliers. Any firms or individuals that do not comply with the requirements in Standard Provision, “Debarment, Suspension and Other Responsibility Matters” and Standard Provision, “Preventing Transactions with, or the Provision of Resources or Support to, Sanctioned Groups and Individuals” must not be used to provide any commodities or services funded under this award.
 - (3) Restricted Commodities. The recipient must obtain prior written approval of the Agreement Officer (AO) or comply with required procedures under an applicable waiver, as provided by the AO when procuring any of the following commodities:
 - (i) Agricultural commodities,
 - (ii) Motor vehicles,

- (iii) Pharmaceuticals,
 - (iv) Pesticides,
 - (v) Used equipment,
 - (vi) U.S. Government-owned excess property, or
 - (vii) Fertilizer.
- b. Source and Nationality:
Except as may be specifically approved in advance by the AO, all commodities and services that will be reimbursed by USAID under this award must be from the authorized geographic code specified in this award and must meet the source and nationality requirements set forth in 22 CFR 228. If the geographic code is not specified, the authorized geographic code is 937. When the total value of procurement for commodities and services during the life of this award is valued at \$250,000 or less, the authorized geographic code for procurement of all goods and services to be reimbursed under this award is code 935. For a current list of countries within each geographic code, see: <http://www.usaid.gov/ads/policy/300/310>.
- c. Guidance on the eligibility of specific commodities and services may be obtained from the AO. If USAID determines that the recipient has procured any commodities or services under this award contrary to the requirements of this provision, and has received payment for such purposes, the AO may require the recipient to refund the entire amount of the purchase.
- d. This provision must be included in all subawards and contracts which include procurement of commodities or services.

[END OF PROVISION]

**M9. DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS
(JUNE 2012)**

- a. The recipient agrees to notify the Agreement Officer (AO) immediately upon learning that it or any of its principals:
 - (1) Are presently excluded or disqualified from covered transactions by any Federal department or agency;
 - (2) Have been convicted within the preceding three-year period preceding this proposal; been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, receiving stolen property, making false claims, or obstruction of justice; commission of any other offense indicating a lack of business integrity or business honesty that seriously and directly affects your present responsibility;
 - (3) Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph a.(2); and
 - (4) Have had one or more public transactions (Federal, State, or local) terminated for cause

or default within the preceding three years.

- b. The recipient agrees that, unless authorized by the AO, it will not knowingly enter into any subawards or contracts under this award with a person or entity that has an active exclusion on the System for Award Management (SAM) (www.sam.gov). The recipient further agrees to include the following provision in any subawards or contracts entered into under this award:

.DEBARMENT, SUSPENSION, INELIGIBILITY, AND VOLUNTARY EXCLUSION
(JUNE 2012)

The recipient/contractor certifies that neither it nor its principals is presently excluded or disqualified from participation in this transaction by any Federal department or agency.

- c. The policies and procedures applicable to debarment, suspension, and ineligibility under USAID-financed transactions are set forth in Subpart C of 2 CFR Section 180, as supplemented by 2 CFR 780.

[END OF PROVISION]

M10. DRUG-FREE WORKPLACE (JUNE 2012)

The recipient must comply with drug-free workplace requirements in subpart B (or subpart C, if the recipient is an individual) of 2 CFR 782, which adopts the Government-wide implementation (2 CFR part 182) of sec. 5152–5158 of the Drug-Free Workplace Act of 1988 (Pub. L. 100–690, Title V, Subtitle D; 41 U.S.C. 701–707).

[END OF PROVISION]

M11. EQUAL PARTICIPATION BY FAITH-BASED ORGANIZATIONS (JUNE 2016)

a. Faith-Based Organizations Encouraged

Faith-based organizations are eligible, on the same basis as any other organization, to participate in any USAID program for which they are otherwise eligible. Neither USAID nor entities that make and administer subawards of USAID funds shall discriminate for or against an organization on the basis of the organization's religious character or affiliation. Additionally, religious organizations shall not be disqualified from participating in USAID programs because such organizations are motivated or influenced by religious faith to provide social services, or because of their religious character or affiliation.

Decisions about awards of USAID financial assistance must be free from political interference or even the appearance of such interference. Awards must be made on the basis of merit, not the basis of the religious affiliation of an applicant, or lack thereof. A faith-based organization may continue to carry out its mission, including the definition, development, practice, and expression of its religious beliefs, within the limits contained in this provision. For more information, see the **USAID Faith-Based and Community Initiatives Web site** and **22 CFR 205.1**.

b. Explicitly Religious Activities Prohibited.

- (1)** Explicitly religious activities include activities that involve overt religious content such as worship, religious instruction, prayer, or proselytization.
 - (2)** The recipient must not engage in explicitly religious activities as part of the programs or services directly funded with financial assistance from USAID. If the recipient engages in explicitly religious activities, the activities must be offered separately, in time or location, from any programs or services directly funded by this award, and participation must be voluntary for beneficiaries of the programs or services funded with USAID assistance.
 - (3)** These restrictions apply equally to religious and secular organizations. All organizations that participate in USAID programs, as recipients or subawardees, including religious ones, must carry out eligible activities in accordance with all program requirements and other applicable requirements governing USAID-funded activities.
 - (4)** Notwithstanding the restrictions of b.(1) and (2), a religious organization that participates in USAID-funded programs or services:
 - (i)** May retain its independence and may continue to carry out its mission, including the definition, development, practice, and expression of its religious beliefs, provided that it does not use direct financial assistance from USAID to support or engage in any explicitly religious activities or in any other manner prohibited by law;
 - (ii)** May use space in its facilities, without removing religious art, icons, scriptures, or other religious symbols; and
 - (iii)** May retain its authority over its internal governance, and may retain religious terms in its organization's name, select its board members on a religious basis, and include religious references in its organization's mission statements and other governing documents.
- c.** Implementation in accordance with the Establishment Clause: Nothing in this provision shall be construed as authorizing the use of USAID funds for activities that are not permitted by Establishment Clause jurisprudence or otherwise by law.
- d.** Discrimination Based on Religion Prohibited: The recipient must not, in providing services, discriminate against a program beneficiary or potential program beneficiary on the basis of religion or religious belief, refusal to hold a religious belief, or a refusal to attend or participate in a religious practice.
- e.** A religious organization's exemption from the Federal prohibition on employment discrimination on the basis of religion, set forth in Sec. 702(a) of the Civil Rights Act of

1964, 42 U.S.C. 2000e–1 is not forfeited when the organization receives financial assistance from USAID.

- f. The Secretary of State may waive the requirements of this section in whole or in part, on a case-by-case basis, where the Secretary determines that such waiver is necessary to further the national security or foreign policy interests of the United States.
- g. This provision must be included in all subawards under this award.

[END OF PROVISION]

M12. PREVENTING TRANSACTIONS WITH, OR THE PROVISION OF RESOURCES OR SUPPORT TO, SANCTIONED GROUPS AND INDIVIDUALS (MAY 2020)

- a. In carrying out activities under this award, except as authorized by a license issued by the Office of Foreign Assets Control (OFAC) of the U.S. Department of Treasury, the recipient will not engage in transactions with, or provide resources or support to, any individual or entity that is subject to sanctions administered by OFAC or the United Nations (UN), including any individual or entity that is included on the Specially Designated Nationals and Blocked Persons List maintained by OFAC (<https://www.treasury.gov/resource-center/sanctions/SDNList/Pages/default.aspx>) or on the UN Security Council consolidated list (<https://www.un.org/securitycouncil/content/un-sc-consolidated-list>).
- b. Any violation of the above will be grounds for unilateral termination of the agreement by USAID.
- c. The Recipient must include this provision in all subawards and contracts issued under this award.

[END OF PROVISION]

M13. MARKING AND PUBLIC COMMUNICATIONS UNDER USAID-FUNDED ASSISTANCE (DECEMBER 2014)

- a. The USAID Identity is the official marking for USAID, comprised of the USAID logo and landmark with the tagline “from the American people,” unless amended by USAID to include additional or substitute use of a logo or seal and tagline representing a presidential initiative or other high level interagency initiative. The USAID Identity (including any required presidential initiative or related identity) is on the USAID Web site at www.usaid.gov/branding. Recipients must use the USAID Identity, of a size and prominence equivalent to or greater than any other identity or logo displayed, to mark the following:
 - (1) Programs, projects, activities, public communications, and commodities partially or fully funded by USAID;
 - (2) Program, project, or activity sites funded by USAID, including visible infrastructure projects or other physical sites;

- (3) Technical assistance, studies, reports, papers, publications, audio-visual productions, public service announcements, Web sites/Internet activities, promotional, informational, media, or communications products funded by USAID;
 - (4) Commodities, equipment, supplies, and other materials funded by USAID, including commodities or equipment provided under humanitarian assistance or disaster relief programs; and
 - (5) Events financed by USAID, such as training courses, conferences, seminars, exhibitions, fairs, workshops, press conferences and other public activities. If the USAID Identity cannot be displayed, the recipient is encouraged to otherwise acknowledge USAID and the support of the American people.
- b. The recipient must implement the requirements of this provision following the approved Marking Plan in the award.
 - c. The AO may require a preproduction review of program materials and “public communications” (documents and messages intended for external distribution, including but not limited to correspondence; publications; studies; reports; audio visual productions; applications; forms; press; and promotional materials) used in connection with USAID-funded programs, projects or activities, for compliance with an approved Marking Plan.
 - d. The recipient is encouraged to give public notice of the receipt of this award and announce progress and accomplishments. The recipient must provide copies of notices or announcements to the Agreement Officer’s Representative (AOR) and to USAID’s Office of Legislative and Public Affairs in advance of release, as practicable. Press releases or other public notices must include a statement substantially as follows:

“The U.S. Agency for International Development administers the U.S. foreign assistance program providing economic and humanitarian assistance in more than 80 countries worldwide.”
 - e. Any “public communication” in which the content has not been approved by USAID must contain the following disclaimer:

“This study/report/audio/visual/other information/media product (specify) is made possible by the generous support of the American people through the United States Agency for International Development (USAID). The contents are the responsibility of [insert recipient name] and do not necessarily reflect the views of USAID or the United States Government.”
 - f. The recipient must provide the USAID AOR with two copies of all program and communications materials produced under this award.
 - g. The recipient may request an exception from USAID marking requirements when USAID

marking requirements would:

- (1) Compromise the intrinsic independence or neutrality of a program or materials where independence or neutrality is an inherent aspect of the program and materials;
 - (2) Diminish the credibility of audits, reports, analyses, studies, or policy recommendations whose data or findings must be seen as independent;
 - (3) Undercut host-country government “ownership” of constitutions, laws, regulations, policies, studies, assessments, reports, publications, surveys or audits, public service announcements, or other communications;
 - (4) Impair the functionality of an item;
 - (5) Incur substantial costs or be impractical;
 - (6) Offend local cultural or social norms, or be considered inappropriate; or
 - (7) Conflict with international law.
- h. The recipient may submit a waiver request of the marking requirements of this provision or the Marking Plan, through the AOR, when USAID-required marking would pose compelling political, safety, or security concerns, or have an adverse impact in the cooperating country.
- (1) Approved waivers “flow down” to subawards and contracts unless specified otherwise. The waiver may also include the removal of USAID markings already affixed, if circumstances warrant.
 - (2) USAID determinations regarding waiver requests are subject to appeal by the recipient, by submitting a written request to reconsider the determination to the cognizant Assistant Administrator.
- i. The recipient must include the following marking provision in any subawards entered into under this award:

“As a condition of receipt of this subaward, marking with the USAID Identity of a size and prominence equivalent to or greater than the recipient’s, subrecipient’s, other donor’s, or third party’s is required. In the event the recipient chooses not to require marking with its own identity or logo by the subrecipient, USAID may, at its discretion, require marking by the subrecipient with the USAID Identity.”

[END OF PROVISION]

M14. REGULATIONS GOVERNING EMPLOYEES (JUNE 2018)

- a. While working overseas, the recipient's employees who are not citizens of the cooperating

country must maintain private status, and may not rely on local U.S. Government offices or facilities for support while under this award.

- b. The sale of personal property or automobiles by the recipient's non-cooperating country citizen employees and their dependents in the foreign country to which they are assigned, are subject to the same limitations and prohibitions that apply to direct-hire USAID personnel employed by the Mission, including the rules contained in 22 CFR 136, except as this may conflict with host government regulations.
- c. Other than work to be performed under this award for which an employee is assigned by the recipient, employees of the recipient who are not citizens of the cooperating country must not engage directly or indirectly, either in the individual's own name or in the name or through an agency of another person, in any business, profession, or occupation in the foreign countries to which the individual is assigned. In addition, the individual must not make loans or investments to or in any business, profession, or occupation in the foreign countries to which the individual is assigned.
- d. The recipient's employees who are not citizens of the cooperating country, while in a foreign country, are expected to show respect for its conventions, customs, and institutions, to abide by its applicable laws and regulations, and not to interfere in its internal political affairs.
- e. In accordance with the internal control requirements in 2 CFR 200.303, which require the recipient to establish standards of conduct for its employees, the recipient must ensure that all its employees adhere to these standards of conduct in a manner consistent with the standards for United Nations (UN) employees in Section 3 of the UN Secretary-General's Bulletin - Special Measures for Protection from Sexual Exploitation and Sexual Abuse (ST/SGB/2003/13).
- f. If the recipient determines that the conduct of any recipient employee is not in accordance with the preceding paragraphs, the recipient's Chief of Party must consult with the Agreement Officer and the USAID Mission Director, and the employee involved, and must recommend to the recipient a course of action with regard to such employee.
- g. The parties recognize the rights of the U.S. Ambassador to direct the removal from a country of any U.S. citizen, or the discharge from this award of any individual (U.S., third-country, or cooperating-country national) when, in the discretion of the Ambassador, the interests of the United States so require.
- h. If it is determined, under paragraph (f) or (g) above, that the services of such employee should be terminated, the recipient must use its best efforts to cause the return of such employee to the United States, or third-country point of origin, as appropriate, and replace the employee with an acceptable substitute at no cost to USAID.
- i. Any matters relating to subrecipients, including the employees of subrecipients, must be coordinated through the recipient's Chief of Party.

[END OF PROVISION]

**M15. CONVERSION OF UNITED STATES DOLLARS TO LOCAL CURRENCY
(NOVEMBER 1985)**

(This provision applies when activities are undertaken outside the United States.)

Upon arrival in the cooperating country, and from time to time as appropriate, the recipient's chief of party must consult with the Mission Director who must provide, in writing, the procedure the recipient and its employees must follow in the conversion of United States dollars to local currency. This may include, but is not limited to, the conversion of currency through the cognizant United States Disbursing Officer or Mission Controller, as appropriate.

[END OF PROVISION]

M16. USE OF POUCH FACILITIES (AUGUST 1992)

(This provision applies when activities are undertaken outside the United States.)

- a. Use of diplomatic pouch is controlled by the Department of State. The Department of State has authorized the use of pouch facilities for USAID recipients and their employees as a general policy, as detailed in items (1) through (6) below. However, the final decision regarding use of pouch facilities rest with the Embassy or USAID Mission. In consideration of the use of pouch facilities, the recipient and its employees agree to indemnify and hold harmless, the Department of State and USAID for loss or damage occurring in pouch transmission:
 - (1) Recipients and their employees are authorized use of the pouch for transmission and receipt of up to a maximum of .9 kgs per shipment of correspondence and documents needed in the administration of assistance programs.
 - (2) U.S. citizen employees are authorized use of the pouch for personal mail up to a maximum of .45 kgs per shipment (but see a.(3) below).
 - (3) Merchandise, parcels, magazines, or newspapers are not considered to be personal mail for purposes of this standard provision and are not authorized to be sent or received by pouch.
 - (4) Official and personal mail pursuant to a.(1) and (2) above sent by pouch should be addressed as follows:

Name of individual or organization (followed by
letter symbol "G")
City Name of post (USAID/_____)
Agency for International Development
Washington, DC 20523-0001
 - (5) Mail sent via the diplomatic pouch may not be in violation of U.S. Postal laws and may

not contain material ineligible for pouch transmission.

(6) Recipient personnel are NOT authorized use of military postal facilities (APO/FPO).

This is an Adjutant General's decision based on existing laws and regulations governing military postal facilities and is being enforced worldwide.

- b. The recipient is responsible for advising its employees of this authorization, these guidelines, and limitations on use of pouch facilities.
- c. Specific additional guidance on grantee use of pouch facilities in accordance with this standard provision is available from the Post Communication Center at the Embassy or USAID Mission.

[END OF PROVISION]

M17. TRAVEL AND INTERNATIONAL AIR TRANSPORTATION (DECEMBER 2014)

a. TRAVEL COSTS

All travel costs must comply with the applicable cost principles and must be consistent with those normally allowed in like circumstances in the recipient's non-USAID-funded activities. Costs incurred by employees and officers for travel, including air fare, costs of lodging, other subsistence, and incidental expenses, may be considered reasonable and allowable only to the extent such costs do not exceed reasonable charges normally allowed by the recipient in its regular operations as the result of the recipient organization's written travel policy and are within the limits established by the applicable cost principles.

In the absence of a reasonable written policy regarding international travel costs, the standard for determining the reasonableness of reimbursement for international travel costs will be the Standardized Regulations (Government Civilians, Foreign Areas), published by the U.S. Department of State, as from time to time amended. The most current Standardized Regulations on international travel costs may be obtained from the AO. In the event that the cost for air fare exceeds the customary standard commercial airfare (coach or equivalent) or the lowest commercial discount airfare, the recipient must document one of the allowable exceptions from the applicable cost principles.

b. FLY AMERICA ACT RESTRICTIONS

- (1) The recipient must use U.S. Flag Air Carriers for all international air transportation (including personal effects) funded by this award pursuant to the Fly America Act and its implementing regulations to the extent service by such carriers is available.
- (2) In the event that the recipient selects a carrier other than a U.S. Flag Air Carrier for international air transportation, in order for the costs of such international air transportation to be allowable, the recipient must document such transportation in accordance with this provision and maintain such documentation pursuant to the

Standard Provision, “Accounting, Audit and Records.” The documentation must use one of the following reasons or other exception under the Fly America Act:

- (i) The recipient uses a European Union (EU) flag air carrier, which is an airline operating from an EU country that has signed the US-EU “Open Skies” agreement (<http://www.state.gov/e/eb/rls/othr/ata/i/ic/170684.htm>).
- (ii) Travel to or from one of the following countries on an airline of that country when no city pair fare is in effect for that leg (see <http://apps.fas.gsa.gov/citypairs/search/>):
 - a. Australia on an Australian airline,
 - b. Switzerland on a Swiss airline, or
 - c. Japan on a Japanese airline;
- (iii) Only for a particular leg of a route on which no US Flag Air Carrier provides service on that route;
- (iv) For a trip of 3 hours or less, the use of a US Flag Air Carrier at least doubles the travel time;
- (v) If the US Flag Air Carrier offers direct service, use of the US Flag Air Carrier would increase the travel time by more than 24 hours; or
- (vi) If the US Flag Air Carrier does not offer direct service,
 - a. Use of the US Flag Air Carrier increases the number of aircraft changes by 2 or more,
 - b. Use of the US Flag Air Carrier extends travel time by 6 hours or more, or
 - c. Use of the US Flag Air Carrier requires a layover at an overseas interchange of 4 hours or more.

c. DEFINITIONS

The terms used in this provision have the following meanings:

- (1) “Travel costs” means expenses for transportation, lodging, subsistence (meals and incidentals), and related expenses incurred by employees who are on travel status on official business of the recipient for any travel outside the country in which the organization is located. “Travel costs” do not include expenses incurred by employees who are not on official business of the recipient, such as rest and recuperation (R&R) travel offered as part of an employee’s benefits package that are consistent with the recipient’s personnel and travel policies and procedures.

- (2) "International air transportation" means international air travel by individuals (and their personal effects) or transportation of cargo by air between a place in the United States and a place outside thereof, or between two places both of which are outside the United States.
- (3) "U.S. Flag Air Carrier" means an air carrier on the list issued by the U.S. Department of Transportation at <http://ostpxweb.dot.gov/aviation/certific/certlist.htm>. U.S. Flag Air Carrier service also includes service provided under a code share agreement with another air carrier when the ticket, or documentation for an electronic ticket, identifies the U.S. flag air carrier's designator code and flight number.
- (4) For this provision, the term "United States" includes the fifty states, Commonwealth of Puerto Rico, possessions of the United States, and the District of Columbia.

d. SUBAWARDS AND CONTRACTS

This provision must be included in all subawards and contracts under which this award will finance international air transportation.

[END OF PROVISION]

M18. OCEAN SHIPMENT OF GOODS (JUNE 2012)

- a. Prior to contracting for ocean transportation to ship goods purchased or financed with USAID funds under this award, the recipient must contact the office below to determine the flag and class of vessel to be used for shipment:

U.S. Agency for International Development,
Bureau for Management
Office of Acquisition and Assistance, Transportation Division
1300 Pennsylvania Avenue, NW
Washington, DC 20523
Email: oceantransportation@usaid.gov

- b. This provision must be included in all subawards and contracts.

[END OF PROVISION]

M19. VOLUNTARY POPULATION PLANNING ACTIVITIES – MANDATORY REQUIREMENTS (MAY 2006)

Requirements for Voluntary Sterilization Programs

- (1) Funds made available under this award must not be used to pay for the performance of involuntary sterilization as a method of family planning or to coerce or provide any financial incentive to any individual to practice sterilization.

Prohibition on Abortion-Related Activities:

- (1) No funds made available under this award will be used to finance, support, or be attributed to the following activities: (i) procurement or distribution of equipment intended to be used for the purpose of inducing abortions as a method of family planning; (ii) special fees or incentives to any person to coerce or motivate them to have abortions; (iii) payments to persons to perform abortions or to solicit persons to undergo abortions; (iv) information, education, training, or communication programs that seek to promote abortion as a method of family planning; and (v) lobbying for or against abortion. The term “motivate,” as it relates to family planning assistance, must not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options.
- (2) No funds made available under this award will be used to pay for any biomedical research which relates, in whole or in part, to methods of, or the performance of, abortions or involuntary sterilizations as a means of family planning. Epidemiologic or descriptive research to assess the incidence, extent or consequences of abortions is not precluded.

[END OF PROVISION]

M20. TRAFFICKING IN PERSONS (April 2016)

- a. The recipient, subawardee, or contractor, at any tier, or their employees, labor recruiters, brokers or other agents, must not engage in:
 - (1) Trafficking in persons (as defined in the Protocol to Prevent, Suppress, and Punish Trafficking in Persons, especially Women and Children, supplementing the UN Convention against Transnational Organized Crime) during the period of this award;
 - (2) Procurement of a commercial sex act during the period of this award;
 - (3) Use of forced labor in the performance of this award;
 - (4) Acts that directly support or advance trafficking in persons, including the following acts:
 - i. Destroying, concealing, confiscating, or otherwise denying an employee access to that employee's identity or immigration documents;
 - ii. Failing to provide return transportation or pay for return transportation costs to an employee from a country outside the United States to the country from which the employee was recruited upon the end of employment if requested by the employee, unless:
 - a) exempted from the requirement to provide or pay for such return transportation by USAID under this award; or

- b) the employee is a victim of human trafficking seeking victim services or legal redress in the country of employment or a witness in a human trafficking enforcement action;
 - iii. Soliciting a person for the purpose of employment, or offering employment, by means of materially false or fraudulent pretenses, representations, or promises regarding that employment;
 - iv. Charging employees recruitment fees; or
 - v. Providing or arranging housing that fails to meet the host country housing and safety standards.
- b. In the event of a violation of section (a) of this provision, USAID is authorized to terminate this award, without penalty, and is also authorized to pursue any other remedial actions authorized as stated in section 1704(c) of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112-239, enacted January 2, 2013).
- c. If the estimated value of services required to be performed under the award outside the United States exceeds \$500,000, the recipient must submit to the Agreement Officer, the annual “Certification regarding Trafficking in Persons, Implementing Title XVII of the National Defense Authorization Act for Fiscal Year 2013” as required prior to this award, and must implement a compliance plan to prevent the activities described above in section (a) of this provision. The recipient must provide a copy of the compliance plan to the Agreement Officer upon request and must post the useful and relevant contents of the plan or related materials on its website (if one is maintained) and at the workplace.
- d. The recipient’s compliance plan must be appropriate to the size and complexity of the award and to the nature and scope of the activities, including the number of non-United States citizens expected to be employed. The plan must include, at a minimum, the following:
 - (1) An awareness program to inform employees about the trafficking related prohibitions included in this provision, the activities prohibited and the action that will be taken against the employee for violations.
 - (2) A reporting process for employees to report, without fear of retaliation, activity inconsistent with the policy prohibiting trafficking, including a means to make available to all employees the Global Human Trafficking Hotline at 1-844-888-FREE and its e-mail address at help@befree.org.
 - (3) A recruitment and wage plan that only permits the use of recruitment companies with trained employees, prohibits charging of recruitment fees to the employee, and ensures that wages meet applicable host-country legal requirements or explains any variance.

- (4) A housing plan, if the recipient or any subawardee intends to provide or arrange housing. The housing plan is required to meet any host-country housing and safety standards.
 - (5) Procedures for the recipient to prevent any agents or subawardee at any tier and at any dollar value from engaging in trafficking in persons activities described in section a of this provision. The recipient must also have procedures to monitor, detect, and terminate any agents or subawardee or subawardee employees that have engaged in such activities.
- e. If the Recipient receives any credible information regarding a violation listed in section a(1)-(4) of this provision, the recipient must immediately notify the cognizant Agreement Officer and the USAID Office of the Inspector General; and must fully cooperate with any Federal agencies responsible for audits, investigations, or corrective actions relating to trafficking in persons.
 - f. The Agreement Officer may direct the Recipient to take specific steps to abate an alleged violation or enforce the requirements of a compliance plan.
 - g. For purposes of this provision, “employee” means an individual who is engaged in the performance of this award as a direct employee, consultant, or volunteer of the recipient or any subrecipient.
 - h. The recipient must include in all subawards and contracts a provision prohibiting the conduct described in section a(1)-(4) by the subrecipient, contractor, or any of their employees, or any agents. The recipient must also include a provision authorizing the recipient to terminate the award as described in section b of this provision.

[END OF PROVISION]

M21. SUBMISSIONS TO THE DEVELOPMENT EXPERIENCE CLEARINGHOUSE AND PUBLICATIONS (JUNE 2012)

- a. Submissions to the Development Experience Clearinghouse (DEC).
 - 1) The recipient must provide the Agreement Officer’s Representative one copy of any Intellectual Work that is published, and a list of any Intellectual Work that is not published.
 - 2) In addition, the recipient must submit Intellectual Work, whether published or not, to the DEC, either on-line (preferred) or by mail. The recipient must review the DEC Web site for submission instructions, including document formatting and the types of documents to submit. Submission instructions can be found at: <http://dec.usaid.gov>.

- 3) For purposes of submissions to the DEC, Intellectual Work includes all works that document the implementation, evaluation, and results of international development assistance activities developed or acquired under this award, which may include program and communications materials, evaluations and assessments, information products, research and technical reports, progress and performance reports required under this award (excluding administrative financial information), and other reports, articles and papers prepared by the recipient under the award, whether published or not. The term does not include the recipient's information that is incidental to award administration, such as financial, administrative, cost or pricing, or management information.
 - 4) Each document submitted should contain essential bibliographic information, such as 1) descriptive title; 2) author(s) name; 3) award number; 4) sponsoring USAID office; 5) development objective; and 6) date of publication.
 - 5) The recipient must not submit to the DEC any financially sensitive information or personally identifiable information, such as social security numbers, home addresses and dates of birth. Such information must be removed prior to submission. The recipient must not submit classified documents to the DEC.
- b. In the event award funds are used to underwrite the cost of publishing, in lieu of the publisher assuming this cost as is the normal practice, any profits or royalties up to the amount of such cost must be credited to the award unless the schedule of the award has identified the profits or royalties as program income.

[END OF PROVISION]

M22. LIMITING CONSTRUCTION ACTIVITIES (AUGUST 2013)

- a) Construction is not eligible for reimbursement under this award unless specifically identified in paragraph d) below.
- b) Construction means —construction, alteration, or repair (including dredging and excavation) of buildings, structures, or other real property and includes, without limitation, improvements, renovation, alteration and refurbishment. The term includes, without limitation, roads, power plants, buildings, bridges, water treatment facilities, and vertical structures.
- c) Agreement Officers will not approve any subawards or procurements by recipients for construction activities that are not listed in paragraph d) below. USAID will reimburse allowable costs for only the construction activities listed in this provision not to exceed the amount specified in the construction line item of the award budget. The recipient must receive prior written approval from the AO to transfer funds allotted for construction activities to other cost categories, or vice versa.
- d) Description

Construction is not eligible for reimbursement under this award.

- e) The recipient must include this provision in all subawards and procurements and make vendors providing services under this award and subrecipients aware of the restrictions of this provision.

[END OF PROVISION]

M23. USAID IMPLEMENTING PARTNER NOTICES (IPN) PORTAL FOR ASSISTANCE (JULY 2014)

(a) Definitions

“USAID Implementing Partner Notices (IPN) Portal for Assistance (“IPN Portal)” means the single point where USAID posts proposed universal bilateral amendments for USAID awards, which can be accessed electronically by registered USAID recipients. The IPN Portal is located at <https://sites.google.com/site/usaaidipnforassistance/>. Universal amendments are those which affect all assistance awards or a designated class of awards as specified in each amendment by the IPN Portal Administrator.

“IPN Portal Administrator” means the USAID official designated by the Director, M/OAA, who has overall responsibility for managing the USAID Implementing Partner Notices Portal for Assistance.

“Universal bilateral amendment” means those amendments with revisions or new requirements or provisions that affect all awards or a designated class of awards, as specified in the Agency notification of such revisions or new requirements.

- (b)** By submission of an application and execution of an award, the Applicant/Recipient acknowledges the requirement to:

- (1)** Register with the IPN Portal if awarded an assistance award resulting from this solicitation, and
 - (2)** Receive universal bilateral amendments to this award and general notices via the IPN Portal.

- (c)** Procedure to register for notifications.

Go to <https://sites.google.com/site/usaaidipnforassistance/> and click the “Register” button at the top of the page. Recipient representatives must use their official organization email address when subscribing, not personal email addresses.

- (d)** Processing of IPN Portal Amendments

The Recipient may access the IPN Portal at any time to review all IPN Portal amendments; however, the system will also notify the Recipient by email when the USAID IPN Portal Administrator posts a universal bilateral amendment for Recipient's review and signature. Proposed USAID IPN Portal amendments distributed via the IPN Portal are applicable to all awards, unless otherwise noted in the proposed amendment.

Within 15 calendar days from receipt of the notification email from the IPN Portal, the Recipient must do one of the following:

- (1) (a) verify applicability of the proposed amendment for their award(s) per the instructions provided with each amendment; (b) download the amendment and incorporate the following information on the amendment form: award number, organization name, and organization mailing address as it appears in the basic award; (c) sign the hardcopy version; and (d) send the signed amendment (by email or hardcopy) to the AO for signature. The Recipient must not incorporate any other changes to the IPN Portal amendment. Bilateral amendments provided through the IPN Portal are not effective until the both the Recipient and the AO sign the amendment;
- (2) Notify the AO in writing if the amendment requires negotiation of additional changes to terms and conditions of the award; or
- (3) Notify the AO that the Recipient declines to sign the amendment.

Within 30 calendar days of receipt of a signed amendment from the Recipient, the AO must provide the fully executed amendment to the Recipient or initiate discussions with the Recipient.

[END OF PROVISION]

M24. PILOT PROGRAM FOR ENHANCEMENT OF GRANTEE EMPLOYEE WHISTLEBLOWER PROTECTIONS (SEPTEMBER 2014)

The requirement to comply with and inform all employees of the "Pilot Program for Enhancement of Contractor Employee Whistleblower Protections" is retroactively effective for all assistance awards and subawards (including subcontracts) issued beginning July 1, 2013.

The Grantee must:

1. Inform its employees working under this award in the predominant native language of the workforce that they are afforded the employee whistleblower rights and protections provided under 41 U.S.C. § 4712; and
2. Include such requirement in any subaward or subcontract made under this award.

41 U.S.C. § 4712 states that an employee of a Grantee may not be discharged, demoted, or otherwise discriminated against as a reprisal for "whistleblowing." In addition, whistleblower protections cannot be waived by any agreement, policy, form, or condition of employment.

Whistleblowing is defined as making a disclosure "that the employee reasonably believes" is evidence of any of the following:

- Gross mismanagement of a Federal contract or grant;
- A gross waste of Federal funds;
- An abuse of authority relating to a Federal contract or grant;
- A substantial and specific danger to public health or safety; or
- A violation of law, rule, or regulation related to a Federal contract or grant (including the competition for, or negotiation of, a contract or grant).

To qualify under the statute, the employee's disclosure must be made to:

- A Member of the U.S. Congress, or a representative of a U.S. Congressional Committee;
- A cognizant U.S. Inspector General;
- The U.S. Government Accountability Office;
- A Federal employee responsible for contract or grant oversight or management at the relevant agency;
- A U.S. court or grand jury; or,
- A management official or other employee of the Grantee who has the responsibility to investigate, discover, or address misconduct.

[END OF PROVISION]

M25. SUBMISSION OF DATASETS TO THE DEVELOPMENT DATA LIBRARY (OCTOBER 2014)

a. Definitions. For the purpose of submissions to the DDL:

- (1) "Dataset" is an organized collection of structured data, including data contained in spreadsheets, whether presented in tabular or non-tabular form. For example, a Dataset may represent a single spreadsheet, an extensible mark-up language (XML) file, a geospatial data file, or an organized collection of these. This requirement does not apply to aggregated performance reporting data that the recipient submits directly to a USAID portfolio management system or to unstructured data, such as email messages, PDF files, PowerPoint presentations, word processing documents, photos and graphic images, audio files, collaboration software, and instant messages. Neither does the requirement apply to the recipient's information that is incidental to award administration, such as financial, administrative, cost or pricing, or management information. Datasets submitted to the DDL will generally be those generated with USAID resources and created in support of Intellectual Work that is uploaded to the Development Experience Clearinghouse (DEC) (See M21. SUBMISSIONS TO THE DEVELOPMENT EXPERIENCE CLEARINGHOUSE AND PUBLICATIONS (JUNE 2012)).

- (2) “Intellectual Work” includes all works that document the implementation, monitoring, evaluation, and results of international development assistance activities developed or acquired under this award, which may include program and communications materials, evaluations and assessments, information products, research and technical reports, progress and performance reports required under this award (excluding administrative financial information), and other reports, articles and papers prepared by the recipient under the award, whether published or not. The term does not include the recipient’s information that is incidental to award administration, such as financial, administrative, cost or pricing, or management information.

b. Submissions to the Development Data Library (DDL)

- (1) The recipient must submit to the Development Data Library (DDL) at www.usaid.gov/data, in a machine-readable, non-proprietary format, a copy of any Dataset created or obtained in performance of this award, including Datasets produced by a subawardee or a contractor at any tier. The submission must include supporting documentation describing the Dataset, such as code books, data dictionaries, data gathering tools, notes on data quality, and explanations of redactions.
- (2) Unless otherwise directed by the Agreement Officer (AO) or the Agreement Officer Representative (AOR), the recipient must submit the Dataset and supporting documentation to the DDL within thirty (30) calendar days after the Dataset is first used to produce an Intellectual Work or is of sufficient quality to produce an Intellectual Work. Within thirty (30) calendar days after award completion, the recipient must submit to the DDL any Datasets and supporting documentation that have not previously been submitted to the DDL, along with an index of all Datasets and Intellectual Work created or obtained under the award. The recipient must also provide to the AOR an itemized list of any and all DDL submissions.

The recipient is not required to submit the data to the DDL, when, in accordance with the terms and conditions of this award, Datasets containing results of federally funded scientific research are submitted to a publicly accessible research database. However, the recipient must submit a notice to the DDL by following the instructions at www.usaid.gov/data, with a copy to the agreement officer representative, providing details on where and how to access the data. The direct results of federally funded scientific research must be reported no later than when the data are ready to be submitted to a peer-reviewed journal for publication, or no later than five calendar days prior to the conclusion of the award, whichever occurs earlier.

- (3) The recipient must submit the Datasets following the submission instructions and acceptable formats found at www.usaid.gov/data.
- (4) The recipient must ensure that any Dataset submitted to the DDL does not contain any proprietary or personally identifiable information, such as social security numbers, home

addresses, and dates of birth. Such information must be removed prior to submission.

- (5) The recipient must not submit classified data to the DDL.

[END OF PROVISION]

M26. PROHIBITION ON REQUIRING CERTAIN INTERNAL CONFIDENTIALITY AGREEMENTS OR STATEMENTS (MAY 2017)

- (a) Definitions.

“Contract” has the meaning given in 2 CFR Part 200.

“Contractor” means an entity that receives a contract as defined in 2 CFR Part 200.

“Internal confidentiality agreement or statement” means a confidentiality agreement or any other written statement that the recipient requires any of its employees or subrecipients to sign regarding nondisclosure of recipient information, except that it does not include confidentiality agreements arising out of civil litigation or confidentiality agreements that recipient employees or subrecipients sign at the behest of a Federal agency.

“Subaward” has the meaning given in 2 CFR Part 200.

“Subrecipient” has the meaning given in 2 CFR Part 200.

- (b) The recipient must not require its employees, subrecipients, or contractors to sign or comply with internal confidentiality agreements or statements that prohibit or otherwise restrict employees, subrecipients, or contractors from lawfully reporting waste, fraud, or abuse related to the performance of a Federal award to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (for example, the Agency Office of the Inspector General).
- (c) The recipient must notify current employees and subrecipients that prohibitions and restrictions of any preexisting internal confidentiality agreements or statements covered by this provision, to the extent that such prohibitions and restrictions are inconsistent with the prohibitions of this provision, are no longer in effect.
- (d) The prohibition in paragraph (b) of this provision does not contravene the requirements applicable to Standard Form 312 (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.
- (e) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further

Continuing Appropriations Act, 2015, (Pub. L. 113-235), and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions) use of funds appropriated (or otherwise made available) is prohibited, if the Government determines that the recipient is not in compliance with the requirements of this provision.

- (f) The recipient must include the substance of this provision, including this paragraph (f), in subawards and contracts under such awards.

[END OF PROVISION]

M27. CHILD SAFEGUARDING (JUNE 2015)

- (a) Because the activities to be funded under this award may involve children, or personnel engaged in the implementation of the award may come into contact with children, these activities could raise the risk of child abuse, exploitation, or neglect within USAID-funded programs. The organization agrees to abide by the following child safeguarding core principles:
- (1) Ensure compliance with host country and local child welfare and protection legislation or international standards, whichever gives greater protection, and with U.S. law where applicable;
 - (2) Prohibit all personnel from engaging in child abuse, exploitation, or neglect;
 - (3) Consider child safeguarding in project planning and implementation to determine potential risks to children that are associated with project activities and operations;
 - (4) Apply measures to reduce the risk of child abuse, exploitation, or neglect, including, but not limited to, limiting unsupervised interactions with children; prohibiting exposure to pornography; and complying with applicable laws, regulations, or customs regarding the photographing, filming, or other image-generating activities of children;
 - (5) Promote child-safe screening procedures for personnel, particularly personnel whose work brings them in direct contact with children; and
 - (6) Have a procedure for ensuring that personnel and others recognize child abuse, exploitation, or neglect; mandating that personnel and others report allegations; investigating and managing allegations; and taking appropriate action in response to such allegations, including, but not limited to, dismissal of personnel.
- (b) The organization must also include in their code of conduct for all personnel implementing USAID-funded activities the child safeguarding principles in (a) (1) through (6).
- (c) The following definitions apply for purposes of this provision:

- (1) Child: A child or children are defined as persons who have not attained 18 years of age.
 - (2) Child abuse, exploitation, or neglect: Constitutes any form of physical abuse; emotional ill-treatment; sexual abuse; neglect or insufficient supervision; trafficking; or commercial, transactional, labor, or other exploitation resulting in actual or potential harm to the child's health, well-being, survival, development, or dignity. It includes, but is not limited to: any act or failure to act which results in death, serious physical or emotional harm to a child, or an act or failure to act which presents an imminent risk of serious harm to a child.
 - (3) Physical abuse: Constitutes acts or failures to act resulting in injury (not necessarily visible), unnecessary or unjustified pain or suffering without causing injury, harm or risk of harm to a child's health or welfare, or death. Such acts may include, but are not limited to: punching, beating, kicking, biting, shaking, throwing, stabbing, choking, or hitting (regardless of object used), or burning. These acts are considered abuse regardless of whether they were intended to hurt the child.
 - (4) Sexual Abuse: Constitutes fondling a child's genitals, penetration, incest, rape, sodomy, indecent exposure, and exploitation through prostitution or the production of pornographic materials.
 - (5) Emotional abuse or ill treatment: Constitutes injury to the psychological capacity or emotional stability of the child caused by acts, threats of acts, or coercive tactics. Emotional abuse may include, but is not limited to: humiliation, control, isolation, withholding of information, or any other deliberate activity that makes the child feel diminished or embarrassed.
 - (6) Exploitation: Constitutes the abuse of a child where some form of remuneration is involved or whereby the perpetrators benefit in some manner. Exploitation represents a form of coercion and violence that is detrimental to the child's physical or mental health, development, education, or well-being.
 - (7) Neglect: Constitutes failure to provide for a child's basic needs within USAID-funded activities that are responsible for the care of a child in the absence of the child's parent or guardian.
- (d) The recipient must insert the provisions in (a) and (b) in all sub-awards under this award.

[END OF PROVISION]

M28. MANDATORY DISCLOSURES (JULY 2015)

Consistent with 2 CFR §200.113, applicants and recipients must disclose, in a timely manner, in writing to the USAID Office of the Inspector General, with a copy to the cognizant Agreement Officer, all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. Subrecipients must disclose, in a timely manner, in

writing to the USAID Office of the Inspector General and to the prime recipient (pass through entity) all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award.

Disclosures must be sent to:

U.S. Agency for International Development
Office of the Inspector General
P.O. Box 657
Washington, DC 20044-0657

Phone: 1-800-230-6539 or 202-712-1023

Email: ig.hotline@usaid.gov

URL: <https://oig.usaid.gov/content/usaid-contractor-reporting-form>.

Failure to make required disclosures can result in any of the remedies described in 2 CFR §200.338 Remedies for noncompliance, including suspension or debarment (See 2 CFR 180, 2 CFR 780 and 31 U.S.C. 3321).

The recipient must include this mandatory disclosure requirement in all subawards and contracts under this award.

[END OF PROVISION]

M29. NONDISCRIMINATION AGAINST BENEFICIARIES (NOVEMBER 2016)

- (a) USAID policy requires that the recipient not discriminate against any beneficiaries in implementation of this award, such as, but not limited to, by withholding, adversely impacting, or denying equitable access to the benefits provided through this award on the basis of any factor not expressly stated in the award. This includes, for example, race, color, religion, sex (including gender identity, sexual orientation, and pregnancy), national origin, disability, age, genetic information, marital status, parental status, political affiliation, or veteran's status. Nothing in this provision is intended to limit the ability of the recipient to target activities toward the assistance needs of certain populations as defined in the award.
- (b) The recipient must insert this provision, including this paragraph, in all subawards and contracts under this award.

[END OF PROVISION]

M30. CONFLICT OF INTEREST (AUGUST 2018)

- a. A conflict of interest in the award, administration, or monitoring of subawards arises when an employee, officer, or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of these parties, has a

financial or other interest in, or a tangible personal benefit from, a subrecipient considered for a subaward. The officers, employees, and agents of the recipient may neither solicit nor accept gratuities, favors, or anything of monetary value from subrecipients or parties to subawards. However, recipients may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value.

- b. The recipient must maintain written standards of conduct covering conflicts of interest and governing the actions of its employees engaged in the selection, award, and administration of subawards. The standards must prohibit employees from using their positions for a purpose that constitutes or presents the appearance of a conflict of interest. The standards of conduct must provide for disciplinary actions to be applied for violations of such standards by officers, employees, or agents of the recipient.
- c. The recipient must also maintain written standards of conduct covering organizational conflicts of interest. Organizational conflicts of interest means a situation in which the recipient is unable or appears to be unable to be impartial in conducting a subaward action involving a related organization because of relationships with a parent company, affiliate, or subsidiary organization.
- d. The recipient must have a system or systems in place to identify, address, resolve, and disclose to USAID any conflicts of interest as described in this provision that affect any subaward, regardless of the amount of funding.
- e. The recipient must disclose any conflict of interest, including organizational conflicts of interest, and the recipient's approach for resolving the conflict of interest to the cognizant Agreement Officer for the award within ten (10) calendar days of the discovery of the conflict of interest.
- f. Upon notice from the recipient of a potential conflict of interest and the approach for resolving it, the Agreement Officer will make a determination regarding the effectiveness of the recipient's actions to resolve the conflict of interest within thirty (30) calendar days of receipt of the recipient's notice, unless the Agreement Officer advises the recipient that a longer period is necessary.
- g. The recipient must not request payment from USAID for costs for transactions subject to the conflict of interest pending notification of USAID's determination. The recipient's failure to disclose a conflict of interest may result in cost disallowances by USAID.
- h. For conflicts of interest, including organizational conflicts of interest, involving contracts, the recipient must follow 2 CFR 200.318, general procurement standards.
- i. The recipient must insert the substance of this provision, including paragraph (i), in all subawards under this award, at any subaward tier.

[END OF PROVISION]

**REQUIRED AS APPLICABLE STANDARD PROVISIONS FOR U.S.
NONGOVERNMENTAL ORGANIZATIONS**

RAA1. NEGOTIATED INDIRECT COST RATES – PREDETERMINED (NOVEMBER 2020)

- a. The allowable indirect costs must be determined by applying the predetermined indirect cost rates to the bases specified in the schedule of this award.
- b. Except as otherwise provided in 2 CFR 200.414 Indirect (F&A) costs paragraph (e) and (f), a nonprofit organization which has not previously established an indirect cost rate with a Federal agency must submit its initial indirect cost proposal immediately after the organization is advised that a Federal award will be made and, in no event, later than three months after the effective date of the Federal award.

Organizations that have previously established indirect cost rates must submit a new indirect cost proposal to the cognizant agency for indirect costs within six months after the close of each fiscal year.

If USAID is the cognizant agency or no cognizant agency has been designated, the recipient must submit four copies of the audit report, the proposed predetermined indirect cost rates, and supporting cost data to the Overhead, Special Costs, and Closeout Branch, Management Bureau, Office of Acquisition and Assistance, USAID, Washington, DC 20523-7802. The proposed rates must be based on the recipient's actual cost experience during that fiscal year. Negotiations of predetermined indirect cost rates must begin soon after receipt of the recipient's proposal.

- c. Allowability of costs and acceptability of cost allocation methods must be determined in accordance with the applicable cost principles.
- d. The results of each negotiation must be set forth in an indirect cost rate agreement signed by both parties. Such agreement is automatically incorporated into this award and must specify (1) the agreed upon predetermined rates, (2) the bases to which the rates apply, and (3) the fiscal year for which the rates apply. The indirect cost rate agreement must not change any monetary ceiling, award obligation, or specific cost allowance or disallowance provided for in this award.
- e. Predetermined rate means an indirect cost rate, applicable to a specified current or future period, usually the organization's fiscal year. The rate is based on an estimate of the costs to be incurred during the period. A predetermined rate is not subject to adjustment.
- f. If a dispute arises in a negotiation of an indirect cost rate between the cognizant agency for indirect costs and the nonprofit organization, the dispute must be resolved in accordance with the appeals procedures of the cognizant agency for indirect costs.

[END OF PROVISION]

RAA5. EXCHANGE VISITORS AND PARTICIPANT TRAINING (JUNE 2012)

For any Exchange Visitor, Participant Training or Invitational Travel activities, the recipient must comply with this provision.

a. Definitions:

- (1) An **Exchange Visitor** is any host-country or third-country national traveling to the U.S., for any purpose, including Participant Training and Invitational Travel, funded by USAID in whole or in part, directly or indirectly.
- (2) A **Participant** is a host-country or third-country national sponsored by USAID for a Participant Training activity taking place in the U.S., a third country, or in the host country.
- (3) **Participant Training** is a learning activity conducted within the U.S., a third country, or in the host country for the purpose of furthering USAID development objectives. A learning activity takes place in a setting in which an individual (the Participant) interacts with a knowledgeable professional, predominantly for the purpose of acquiring knowledge or skills for the professional or technical enhancement of the individual. Learning activities may be formally structured, such as an academic program or a technical course, or they may be more informal, such as an observational study tour.
- (4) **Invitational Travel** is a type of travel that USAID funds for non-U.S. Government employees. This type of travel may be approved for both U.S. and foreign citizens who are not employed by the U.S. Government (USG), not receiving any type of compensation from the USG for such travel, and only when it is determined that the functions to be performed are essential to the interests of USAID.

b. Program Monitoring and Data Reporting: The recipient must monitor Exchange Visitors' and Participants' progress during their program and ensure that problems are identified and resolved quickly.

- (1) For U.S.-based activities, the recipient must use USAID's official Exchange Visitor and Participant Training information system, currently called "Training Results and Information Network – TraiNet" (see <http://trainethelp.usaid.gov/>), to report and manage Exchange Visitor and Participant Training data. The recipient must also use the USAID Visa Compliance System – VCS (see <http://trainethelp.usaid.gov/>) to transfer required data for USAID Exchange Visitors to the Department of Homeland Security's Student and Exchange Visitor Information System (SEVIS).
- (2) For all third-country activities, and for host-country activities of two consecutive days or 16 contact hours or more in duration, the recipient must use USAID's official

Exchange Visitor and Participant Training information system, currently called “Training Results and Information Network – TraiNet” (see <http://trainethelp.usaid.gov/>), to report and manage Participant Training data.

c. Health and Accident Insurance:

- (1) For Exchange Visitors traveling to the United States, the recipient must enroll Exchange Visitors in health and accident insurance coverage that meets or exceeds Department of State and USAID minimum coverage requirements as set forth in 22 CFR 62.14 and ADS 253.3.6.2. The requirements may be obtained from the Agreement Officer’s Representative.
- (2) For Participants traveling to a third country, the recipient must obtain health and accident insurance coverage for all Participants.
- (3) For Participants traveling within the host country, the recipient must determine whether specific in-country participant training activities subject them to any risk of health and accident liability for medical costs. Participants may incur, and if so, take appropriate steps according to the local situation, including obtaining health and accident insurance coverage for Participants.

d. Immigration Requirements:

- (1) For Exchange Visitors traveling to the United States, the recipient must ensure that all USAID-sponsored Exchange Visitors obtain, use, and comply with the terms of the J-1 visa, issued in conjunction with a USAID-issued Certificate of Eligibility for J-1 Visa Status (DS-2019).
- (2) For Participants traveling to a third country or within the host country, the recipient must ensure that all Participants obtain, use, and comply with the terms of all applicable immigration, visa and other similar requirements.

e. Language Proficiency: The recipient must verify language proficiency. Exchange Visitors must possess sufficient English language proficiency to participate in a U.S.-based activity. Participants of third-country or host-country training must be proficient in the language of training at a sufficient level for participation, unless an interpreter has been arranged. Language competency can be verified through a variety of means including proficiency assessments of interviews, publications, presentations, education conducted in English, and formal testing.

f. Pre-departure Orientation: The recipient must conduct pre-departure orientation for U.S.-bound Exchange Visitors and Participants of third-country training programs. Pre-departure orientation covers: program objectives; administrative and policy review; cultural aspects; and training/learning methods.

- g. **Conditions of Sponsorship:** The recipient must ensure that all Exchange Visitors read and sign the Conditions of Sponsorship for U.S.-Based Activities form (AID 1381-6). The recipient must also ensure that all Participants of long-term (six months or longer) third-country training read and sign the form Conditions of Sponsorship for Third-Country Training form (AID 1381-7). The recipient must report to the Agreement Officer any known violations by Exchange Visitors of visa or other immigration requirements or conditions.
- h. **Exchange Visitor Security Risk and Fraud Inquiry:** Each USAID Mission has an established process for conducting a Security Risk and Fraud Inquiry (SRFI) for Exchange Visitors. The recipient must be prepared to assist Missions in conducting the SRFI, if requested. However, the recipient's role is contributive, and the Mission is ultimately responsible for conducting the SRFI.
- i. **Fly America:** To the extent that participants travel by international air travel, the recipient must comply with the Standard Provision, "International Air Travel and Air Transportation of Property."
- j. **Use of Minority Serving Institutions:** For U.S.-based Participant Training, the recipient must, to the maximum extent possible, maintain their use of Historically Black Colleges and Universities (HBCUs) and other Minority Serving Institutions (MSIs), including Hispanic Serving Institutions and Tribal Colleges and Universities, as training or education providers.

[END OF PROVISION]

RAA7. PROTECTION OF THE INDIVIDUAL AS A RESEARCH SUBJECT (APRIL 1998)

- a. Safeguarding the rights and welfare of human subjects involved in research supported by USAID is the responsibility of the organization to which support is awarded. USAID has adopted the Common Federal Policy for the Protection of Human Subjects, Part 225 of Title 22 of the Code of Federal Regulations (the "Policy"). Additional interpretation, procedures, and implementation guidance of the Policy are found in USAID General Notice entitled "Procedures for the Protection of Human Subjects in Research Supported by USAID," issued April 19, 1995, as amended. USAID's Cognizant Human Subjects Officer (CHSO) in USAID/W has oversight, guidance, and interpretation responsibility for the Policy.
- b. Recipient organizations must comply with USAID policy when humans are the subject of research, as defined in 22 CFR 225.102(d), funded by the grant and recipients must provide "assurance," as required by 22 CFR 225.103, that they follow and abide by the procedures in the Policy. See also Section 5 of the April 19, 1995, USAID General Notice which sets forth activities to which the Policy is applicable. The existence of a bona fide, applicable assurance approved by the Department of Health and Human Services (HHS) such as the "multiple project assurance" (MPA) will satisfy this requirement. Alternatively, organizations can provide an acceptable written assurance to USAID as described in 22 CFR 225.103.

Such assurances must be determined by the CHSO to be acceptable prior to any applicable research being initiated or conducted under the award. In some limited instances outside the U.S., alternative systems for the protection of human subjects may be used provided they are deemed “at least equivalent” to those outlined in Part 225 (See 22 CFR 225.101[h]). Criteria and procedures for making this determination are described in the General Notice cited in the preceding paragraph.

- c. Since the welfare of the research subject is a matter of concern to USAID as well as to the organization, USAID staff consultants and advisory groups may independently review and inspect research and research processes and procedures involving human subjects, and based on such findings, the CHSO may prohibit research which presents unacceptable hazards or otherwise fails to comply with USAID procedures. Informed consent documents must include the stipulation that the subject's records may be subject to such review.

[END OF PROVISION]

RAA8. CARE OF LABORATORY ANIMALS (MARCH 2004)

CARE OF LABORATORY ANIMALS (MARCH 2004)

- a. Before undertaking performance of any grant involving the use of laboratory animals, the recipient must register with the Secretary of Agriculture of the United States in accordance with Section 6, Public Law 89-544, Laboratory Animal Welfare Act, August 24, 1966, as amended by Public Law 91-579, Animal Welfare Act of 1970, December 24, 1970. The recipient must furnish evidence of such registration to the Agreement Officer.
- b. The recipient must acquire animals used in research under this award only from dealers licensed by the Secretary of Agriculture, or from exempted sources in accordance with the Public Laws enumerated in a. above.
- c. In the care of any live animals used or intended for use in the performance of this grant, the recipient must adhere to the principles enunciated in the Guide for Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences - National Research Council (NAS-NRC), and in the United States Department of Agriculture's (USDA) regulations and standards issued under the Public Laws enumerated in a. above. In case of conflict between standards, the higher standard must be used. The recipient's reports on portions of the award in which animals were used must contain a certificate stating that the animals were cared for in accordance with the principles enunciated in the Guide for Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, NAS-NRC, and/or in the regulations and standards as promulgated by the Agricultural Research Service, USDA, pursuant to the Laboratory Animal Welfare Act of 24 August 1966, as amended (P.L. 89-544 and P.L. 91-579). NOTE: The recipient may request registration of the recipient's facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which the recipient's research facility is located. The location of the appropriate APHIS Regional Office as well as information concerning this program may be obtained by contacting the Senior Staff

Office, Animal Care Staff, USDA/APHIS, 4700 River Road, Unit 84, Riverdale, MD 20737-1234 and at www.aphis.usda.gov/animal_welfare/index.shtml.

[END OF PROVISION]

RAA10. COST SHARING (MATCHING) (FEBRUARY 2012)

COST SHARING (MATCHING) (FEBRUARY 2012)

- a. If at the end of any funding period, the recipient has expended an amount of non-Federal funds less than the agreed upon amount or percentage of total expenditures, the Agreement Officer may apply the difference to reduce the amount of USAID incremental funding in the following funding period. If the award has expired or has been terminated, the Agreement Officer may require the recipient to refund the difference to USAID.
- b. The source and nationality requirements and the restricted goods provision established in the Standard Provision entitled "USAID Eligibility Rules for Goods and Services" do not apply to cost sharing (matching) expenditures.

[END OF PROVISION]

RAA11. PROHIBITION OF ASSISTANCE TO DRUG TRAFFICKERS (JUNE 1999)

- a. USAID reserves the right to terminate assistance to, or take other appropriate measures with respect to, any participant approved by USAID who is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR 140.
- b.
 - (1) For any loan over \$1,000 made under this agreement, the recipient must insert a clause in the loan agreement stating that the loan is subject to immediate cancellation, acceleration, recall, or refund by the recipient if the borrower or a key individual of a borrower is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR 140.
 - (2) Upon notice by USAID of a determination under section (1) and at USAID's option, the recipient agrees to immediately cancel, accelerate, or recall the loan, including refund in full of the outstanding balance. USAID reserves the right to have the loan refund returned to USAID.
- c.
 - (1) The recipient agrees not to disburse, or sign documents committing the recipient to disburse, funds to a subrecipient designated by USAID ("Designated Subrecipient") until advised by USAID that: (i) any United States Government review of the Designated Subrecipient and its key individuals has been completed; (ii) any related certifications have been obtained; and (iii) the assistance to the Designated Subrecipient has been

approved. Designation means that the subrecipient has been unilaterally selected by USAID as the subrecipient. USAID approval of a subrecipient, selected by another party, or joint selection by USAID and another party is not designation.

- (2) The recipient must insert the following clause, or its substance, in its agreement with the Designated Subrecipient:

“The recipient reserves the right to terminate this [Agreement/Contract] or take other appropriate measures if the [Subrecipient] or a key individual of the [Subrecipient] is found to have been convicted of a narcotic offense or to have been engaged in drug trafficking as defined in 22 CFR 140.”

[END OF PROVISION]

RAA13. REPORTING HOST GOVERNMENT TAXES (DECEMBER 2014)

- a. By April 16 of each year, the recipient must submit a report containing:
- (1) Contractor/recipient name.
 - (2) Contact name with phone, fax and e-mail.
 - (3) Agreement number(s).
 - (4) The total amount of value-added taxes and customs duties (but not sales taxes) assessed by the host government (or any entity thereof) on purchases in excess of \$500 per transaction of supplies, materials, goods or equipment, during the 12 months ending on the preceding September 30, using funds provided under this contract/agreement.
 - (5) Any reimbursements received by April 1 of the current year on value-added taxes and customs duties reported in (iv).
 - (6) Reports are required even if the recipient did not pay any taxes or receive any reimbursements during the reporting period.
 - (7) Cumulative reports may be provided if the recipient is implementing more than one program in a foreign country.
- b. Submit the reports to: Agreement’s Officer Representative.
- a. Host government taxes are not allowable where the Agreement Officer provides the necessary means to the recipient to obtain an exemption or refund of such taxes, and the recipient fails to take reasonable steps to obtain such exemption or refund. Otherwise, taxes

are allowable in accordance with the Standard Provision, “Allowable Costs,” and must be reported as required in this provision.

- b. The recipient must include this reporting requirement in all applicable subawards and contracts.

[END OF PROVISION]

RAA14. FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)

FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)

- a. U.S. Government funds under this award must not be used to finance the travel, per diem, hotel expenses, meals, conference fees or other conference costs for any member of a foreign government’s delegation to an international conference sponsored by a multilateral organization, as defined below, unless approved by the Agreement Officer in writing.
- b. Definitions:
 - (1) A foreign government delegation is appointed by the national government (including ministries and agencies but excluding local, state and provincial entities) to act on behalf of the appointing authority at the international conference. A conference participant is a delegate for the purposes of this provision, only when there is an appointment or designation that the individual is authorized to officially represent the government or agency. A delegate may be a private citizen.
 - (2) An international conference is a meeting where there is an agenda, an organizational structure, and delegations from countries other than the conference location, in which country delegations participate through discussion, votes, etc.
 - (3) A multilateral organization is an organization established by international agreement and whose governing body is composed principally of foreign governments or other multilateral organizations.

[END OF PROVISION]

RAA18. USAID DISABILITY POLICY - ASSISTANCE (DECEMBER 2004)

- a. The objectives of the USAID Disability Policy are (1) to enhance the attainment of United States foreign assistance program goals by promoting the participation and equalization of opportunities of individuals with disabilities in USAID policy, country and sector strategies, activity designs and implementation; (2) to increase awareness of issues of people with disabilities both within USAID programs and in host countries; (3) to engage other U.S. Government agencies, host country counterparts, governments, implementing organizations

and other donors in fostering a climate of nondiscrimination against people with disabilities; and (4) to support international advocacy for people with disabilities.

- b. USAID therefore requires that the recipient not discriminate against people with disabilities in the implementation of USAID funded programs and that it make every effort to comply with the objectives of the USAID Disability Policy in performing the program under this grant or cooperative agreement. To that end and to the extent it can accomplish this goal within the scope of the program objectives, the recipient should demonstrate a comprehensive and consistent approach for including men, women, and children with disabilities.

[END OF PROVISION]

RAA23. UNIVERSAL IDENTIFIER AND SYSTEM OF AWARD MANAGEMENT (NOVEMBER 2020)

- a. **Requirement for System of Award Management (SAM).** Unless you are exempted from this requirement under 2 CFR 25.110, you as the recipient must maintain current information in the SAM. This includes information on your immediate and highest level owner and subsidiaries, as well as on all of your predecessors that have been awarded a Federal contract or Federal financial assistance within the last three years, if applicable, until you submit the final financial report required under this Federal award or receive the final payment, whichever is later. This requires that you review and update the information at least annually after the initial registration, and more frequently, if required by changes in your information or another Federal award term.
- b. **Requirement for Unique Entity Identifier.** If you are authorized to make subawards under this Federal award, you:
 - (1) Must notify potential subrecipients that no entity (see definition in paragraph c. of this award term) may receive a subaward from you until the entity has provided its Unique Entity Identifier to you.
 - (2) May not make a subaward to an entity unless the entity has provided its Unique Entity Identifier to you. Subrecipients are not required to obtain an active SAM registration but must obtain a Unique Entity Identifier.
- c. **Definitions.** For purposes of this award term:
 - (1) System of Award Management (SAM) means the Federal repository into which a recipient must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM Internet site (currently at <https://www.sam.gov>).

- (2) Unique Entity Identifier means the identifier assigned by SAM to uniquely identify business entities.
- (3) Entity includes non-Federal entities as defined in 2 CFR 200.1 and also includes all of the following, for purposes of this part:
 - a. A foreign organization;
 - b. A foreign public entity;
 - c. A domestic for-profit organization; and
 - d. A Federal agency.
- (4) Subaward has the meaning given in 2 CFR 200.1.
- (5) Subrecipient has the meaning given in 2 CFR 200.1.

ADDENDUM (NOVEMBER 2020):

- d. **Exceptions.** The requirements of this provision to obtain a Unique Entity Identifier and maintain a current registration in the SAM do not apply, at the prime award or subaward level, to:
 - (1) Awards to individuals
 - (2) Awards less than \$25,000 to foreign recipients to be performed outside the United States (based on a USAID determination)
 - (3) Awards where the Agreement Officer determines, in writing, that the Agency must protect entity information from disclosure due to national security or foreign policy interests of the United States or that these requirements would cause personal safety concerns.
- e. This provision does not need to be included in subawards.

[END OF PROVISION]

**RAA24. REPORTING SUBAWARDS AND EXECUTIVE COMPENSATION
(NOVEMBER 2020)**

- a. **Reporting of first-tier subawards.**
 - (1) Applicability. Unless you are exempt as provided in paragraph d. of this award term, you must report each action that equals or exceeds \$30,000 in Federal funds for a subaward to a non-Federal entity or Federal agency (see definitions in paragraph e. of this award term).

(2) Where and when to report.

- (i) The non-Federal entity or Federal agency must report each obligating action described in paragraph a.(1) of this award term to www.fsrs.gov.
- (ii) For subaward information, report no later than the end of the month following the month in which the obligation was made. (For example, if the obligation was made on November 7, 2010, the obligation must be reported by no later than December 31, 2010.)

(3) What to report. You must report the information about each obligating action that the submission instructions posted at www.fsrs.gov specify.

b. Reporting Total Compensation of Recipient Executives.

(1) Applicability and what to report. You must report total compensation for each of your five most highly compensated executives for the preceding completed fiscal year, if –

- (i) The total Federal funding authorized to date under this Federal award equals or exceeds \$30,000 as defined in 2 CFR 170.320;
- (ii) In the preceding fiscal year, you received—
 - (A) 80 percent or more of your annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
 - (B) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
- (iii) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at www.sec.gov/answers/execomp.htm.)

(2) Where and when to report. You must report executive total compensation described in paragraph b.(1) of this award term:

- (i) As part of your registration profile at www.sam.gov.
- (ii) By the end of the month following the month in which this award is made, and annually thereafter.

c. Reporting of Total Compensation of Subrecipient Executives.

- (1) Applicability and what to report. Unless you are exempt as provided in paragraph d. of this award term, for each first-tier subrecipient under this award, you must report the names and total compensation of each of the subrecipient's five most highly compensated executives for the subrecipient's preceding completed fiscal year, if—
 - (i) In the subrecipient's preceding fiscal year, the subrecipient received—
 - (A) 80 percent or more of its annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and
 - (B) \$25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts), and Federal financial assistance subject to the Transparency Act (and subawards); and
 - (ii) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at www.sec.gov/answers/execomp.htm.)
- (2) Where and when to report. You must report subrecipient executive total compensation described in paragraph c.(1) of this award term:
 - (i) To the recipient.
 - (ii) By the end of the month following the month during which you make the subaward. For example, if a subaward is obligated on any date during the month of October of a given year (for example, between October 1 and 31), you must report any required compensation information of the subrecipient by November 30 of that year.

d. Exemptions.

If, in the previous tax year, you had gross income, from all sources, under \$300,000, you are exempt from the requirements to report:

- (1) Subawards, and
- (2) The total compensation of the five most highly compensated executives of any subrecipient.

e. Definitions.

For purposes of this award term:

- (1) Federal Agency means a Federal agency as defined at 5 U.S.C. 551(1) and further clarified by 5 U.S.C. 552(f).
- (2) Entity means all of the following, as defined in 2 CFR 25:
 - (i) A governmental organization, which is a State, local government, or Indian tribe;
 - (ii) A foreign public entity;
 - (iii) A domestic or foreign nonprofit organization; and
 - (iv) A domestic or foreign for-profit organization.
- (3) Executive means officers, managing partners, or any other employees in management positions.
- (4) Subaward:
 - (i) This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.
 - (ii) The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see 2 CFR 200.331).
 - (iii) A subaward may be provided through any legal agreement, including an agreement that you or a subrecipient considers a contract.
- (5) Subrecipient means a non-Federal entity or Federal agency that:
 - (i) Receives a subaward from you (the recipient) under this award; and
 - (ii) Is accountable to you for the use of the Federal funds provided by the subaward.
- (6) Total compensation means the cash and noncash dollar value earned by the executive during the recipient's or subrecipient's preceding fiscal year and includes the following (for more information see 17 CFR 229.402(c)(2)):
 - (i) Salary and bonus.

- (ii) Awards of stock, stock options, and stock appreciation rights. Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Statement of Financial Accounting Standards No. 123 (Revised 2004) (FAS 123R), Shared Based Payments.
- (iii) Earnings for services under nonequity incentive plans. This does not include group life, health, hospitalization, or medical reimbursement plans that do not discriminate in favor of executives, and are available generally to all salaried employees.
- (iv) Change in pension value. This is the change in present value of defined benefit and actuarial pension plans.
- (v) Above-market earnings on deferred compensation which is not tax-qualified.
- (vi) Other compensation, if the aggregate value of all such other compensation (for example, severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property) for the executive exceeds \$10,000.

[END OF PROVISION]

RAA25. PATENT REPORTING PROCEDURES (NOVEMBER 2020)

As incorporated by 2 CFR 200.315 and the standard provision “APPLICABILITY OF 2 CFR 200 and 2 CFR 700,” the clause at 37 CFR 401.14 (“Standard Patent Rights”) is incorporated by reference into this award as if set forth in full text. The recipient must use the National Institutes of Health EDISON Patent Reporting and Tracking system (<http://www.iedison.gov>) to fulfill its disclosure obligations under 37 CFR 401.14(c)(1). The recipient must also submit reports on utilization of subject inventions annually to the Agreement Officer’s Representative under 37 CFR 401.14(h), and the last report must be provided within 90 days of the expiration of the agreement.

[END OF PROVISION]

RAA26. ACCESS TO USAID FACILITIES AND USAID’S INFORMATION SYSTEMS (AUGUST 2013)

- a. A U.S. citizen or resident alien engaged in the performance of this award as an employee, consultant, or volunteer of a U.S organization may obtain access to USAID facilities or logical access to USAID’s information systems only when and to the extent necessary to carry out this award and in accordance with this provision. The recipient’s employees, consultants, or volunteers who are not U.S. citizen as well as employees, consultants, or volunteers of non-U.S.

- b. organizations, irrespective of their citizenship, will not be granted logical access to U.S. Government information technology systems (such as Phoenix, GLAAS, etc.) and must be escorted to use U.S. Government facilities (such as office space).
- c. Before a U.S. citizen or resident alien engaged in the performance of this award as an employee, consultant, or volunteer of the recipient, subrecipient or contractor at any tier may obtain a USAID ID (new or replacement) authorizing the individual routine access to USAID facilities in the United States, or logical access to USAID's information systems, the individual must provide two forms of identity source documents in original form. One identity source document must be a valid Federal or State government-issued picture ID. The recipient must contact the USAID Office of Security to obtain the list of acceptable forms of documentation. Submission of these documents, and related background checks, are mandatory in order for the individual to receive a building access ID, and before access will be granted to any of USAID's information systems. All such individuals must physically present these two source documents for identity proofing at their Security Briefing. All individuals provided access under this provision must return any issued building access ID and remote authentication token to USAID custody upon termination of the individual's employment with the recipient or completion of the award, whichever occurs first.
- d. Individuals engaged in the performance of this award as an employee, consultant, or volunteer of the recipient must comply with all applicable Homeland Security Policy Directive-12 (HSPD-12) and Personal Identity Verification (PIV) procedures, as described above, as well as any subsequent USAID or government-wide HSPD-12 and PIV procedures/policies, including any
- e. HSPD-12 procedures established by the Office of Security in USAID/Washington.
- f. The recipient is required to include this provision in all subawards and contracts at any tier made to a U.S. organization/company, that require employees or consultants engaged in the performance of this award to have routine physical access to USAID facilities or logical access to USAID's information systems in order to perform this award.

[END OF PROVISION]

RAA27. CONTRACT PROVISION FOR DBA INSURANCE UNDER RECIPIENT PROCUREMENTS (DECEMBER 2014)

All contracts made by the recipient under this award for services to be performed overseas must contain the following provision, as applicable.

Workers' Compensation Insurance (Defense Base Act)

(a) The Contractor must--

- (1) Before commencing performance under this contract, establish provisions to provide for the payment of disability compensation and medical benefits to covered employees and death benefits to their eligible survivors, by purchasing Defense Base Act (DBA) insurance pursuant to the terms of the contract between USAID and USAID's DBA insurance carrier unless the Contractor qualifies as a self-insurer under the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 932) as extended by the Defense Base Act (42 U.S.C. 1651, et seq.), or has an approved retrospective rating agreement for DBA. The Contractor must continue to maintain these provisions to provide such Defense Base Act benefits until contract performance is completed.
- (2) If USAID or the Contractor has secured a waiver of DBA coverage in accordance with AIDAR 728.305-70(a) for contractor's employees who are not citizens of, residents of, or hired in the United States, the contractor agrees to provide such employees with worker's compensation benefits as required by the laws of the country in which the employees are working, or by the laws of the employee's native country, whichever offers greater benefits. The Department of Labor has granted partial blanket waivers of DBA coverage applicable to USAID-financed contracts performed in countries listed in the DEFENSE BASE ACT (DBA) WAIVER LIST.
- (3) Within ten days of an employee's injury or death or from the date the Contractor has knowledge of the injury or death, submit Form LS-202 (Employee's First Report of Injury or Occupational Illness) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 930(a), 20 CFR 702.201 to 702.203).
- (4) Pay all compensation due for disability or death within the timeframes required by the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914, 20 CFR 702.231 and 703.232).
- (5) Provide for medical care as required by the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 907, 20 CFR 702.402 and 702.419).
- (6) If controverting the right to compensation, submit Form LS-207 (Notice of Controversion of Right to Compensation) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914(d), 20 CFR 702.251).
- (7) Immediately upon making the first payment of compensation in any case, submit Form LS-206 (Payment of Compensation Without Award) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914(c), 20 CFR 702.234).
- (8) When payments are suspended or when making the final payment, submit Form LS-208 (Notice of Final Payment or Suspension of Compensation Payments) to the Department of Labor in accordance with the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 914 (c) and (g), 20 CFR 702.234 and 702.235).

- (9) Adhere to all other provisions of the Longshore and Harbor Workers' Compensation Act as extended by the Defense Base Act, and Department of Labor regulations at 20 CFR Parts 701 to 704.

For additional information on the Longshore and Harbor Workers' Compensation Act requirements see <http://www.dol.gov/owcp/dlhw/lsdba.htm>.

The Contractor must insert the substance of this clause including this paragraph (c), in all subcontracts to which the Defense Base Act applies.

[END OF PROVISION]

RAA28. AWARD TERM AND CONDITION FOR RECIPIENT INTEGRITY AND PERFORMANCE MATTERS (APRIL 2016)

A. Reporting of Matters Related to Recipient Integrity and Performance

1. General Reporting Requirement

If the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds \$10,000,000 for any period of time during the period of performance of this Federal award, then you as the recipient during that period of time must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) about civil, criminal, or administrative proceedings described in paragraph 2 of this award term and condition. This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available.

2. Proceedings About Which You Must Report

Submit the information required about each proceeding that:

- a. Is in connection with the award or performance of a grant, cooperative agreement, or procurement contract from the Federal Government;
- b. Reached its final disposition during the most recent five year period; and
- c. Is one of the following:
 - (1) A criminal proceeding that resulted in a conviction, as defined in paragraph 5 of this award term and condition;

- (2) A civil proceeding that resulted in a finding of fault and liability and payment of a monetary fine, penalty, reimbursement, restitution, or damages of \$5,000 or more;
- (3) An administrative proceeding, as defined in paragraph 5. of this award term and condition, that resulted in a finding of fault and liability and your payment of either a monetary fine or penalty of \$5,000 or more or reimbursement, restitution, or damages in excess of \$100,000; or
- (4) Any other criminal, civil, or administrative proceeding if:
 - (i) It could have led to an outcome described in paragraph 2.c.(1), (2), or (3) of this award term and condition;
 - (ii) It had a different disposition arrived at by consent or compromise with an acknowledgment of fault on your part; and
 - (iii) The requirement in this award term and condition to disclose information about the proceeding does not conflict with applicable laws and regulations.

3. Reporting Procedures

Enter in the SAM Entity Management area the information that SAM requires about each proceeding described in paragraph 2 of this award term and condition. You do not need to submit the information a second time under assistance awards that you received if you already provided the information through SAM because you were required to do so under Federal procurement contracts that you were awarded.

4. Reporting Frequency

During any period of time when you are subject to the requirement in paragraph 1 of this award term and condition, you must report proceedings information through SAM for the most recent five year period, either to report new information about any proceeding(s) that you have not reported previously or affirm that there is no new information to report. Recipients that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 must disclose semiannually any information about the criminal, civil, and administrative proceedings.

5. Definitions

For purposes of this award term and condition:

- a. Administrative proceeding means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative proceedings, Civilian Board of Contract Appeals

proceedings, and Armed Services Board of Contract Appeals proceedings). This includes proceedings at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include audits, site visits, corrective plans, or inspection of deliverables.

- b. Conviction, for purposes of this award term and condition, means a judgment or conviction of a criminal offense by any court of competent jurisdiction, whether entered upon a verdict or a plea, and includes a conviction entered upon a plea of nolo contendere.
- c. Total value of currently active grants, cooperative agreements, and procurement contracts includes—
 - (1) Only the Federal share of the funding under any Federal award with a recipient cost share or match; and
 - (2) The value of all expected funding increments under a Federal award and options, even if not yet exercised.

B. [Reserved]

[END OF PROVISION]

[END OF PROVISION]

RAA30. PROGRAM INCOME (AUGUST 2020)

PROGRAM INCOME (August 2020)

- a. Program income is gross income earned by the recipient that is directly generated by a supported activity or earned as a result of the Federal award during the period of performance. Program income includes, but is not limited to: income from fees for services performed; the use or rental of real or personal property acquired under Federal awards; the sale of commodities or items fabricated under a Federal award; license fees and royalties on patents and copyrights; and principal and interest on loans made with Federal award funds. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, or interest earned on any of them.
- b. Program income must be used for the purposes, and under the conditions, of the award, to further project objectives, program objectives, or award activities. Program income must be used only for allowable program costs. Interest earned on program income is subject to the same conditions as program income.
- c. The recipient must apply the approach for use of program income as specified in the schedule of the award. This may include one of the three approaches listed below (see also **2 CFR**

200.307). The recipient must also follow the standards in this provision to account for gross income earned from Federally-supported activities under this award.

1) If the deduction approach is used, the recipient must use the program income for current costs, prior to drawdown of USAID funds under the award.

2) If the addition approach is used, the total award amount is increased by the amount of program income. If the award anticipates a specific program income amount, any program income in excess of such amount must be deducted from expenditures.

3) If the cost sharing approach is used, the amount of the award remains the same. If the award anticipates a specific program income amount, any program income in excess of such amount must be deducted from expenditures.

d. Costs subject to generating program income under this award may be deducted from gross income to calculate program income, provided these costs have not been charged to this award and comply with the standard provision, “Allowable Costs.”

e. The recipient must report program income using the **Federal Financial Report, SF-425**. Program income must be accounted for in the same ratio as USAID’s participation in the program. For example, if USAID funded 75 percent of a recipient’s program, then the recipient must report 75 percent of any program income earned under the award as “Federal program income earned” on the SF-425.

f. The recipient should continue to use program income earned after the period of the award to further award objectives, but is not subject to Federal requirements governing the disposition of program income earned after the end of the period of performance for the award.

[END OF PROVISION]

[END OF STANDARD PROVISIONS]

ATTACHMENT D – BRANDING AND MARKING PLAN

MODIFICATION OF ASSISTANCE AWARD				Page 1 of 2								
1. MODIFICATION NUMBER: <div style="text-align: center;">P001</div>	2. EFFECTIVE DATE OF MODIFICATION: <div style="text-align: center;">See Block 15</div>	3. AWARD NUMBER: <div style="text-align: center;">7200AA21CA00033</div>	4. EFFECTIVE DATE OF AWARD: <div style="text-align: center;">October 01, 2021</div>									
5. RECIPIENT: Washington State University P.O. Box 641060 Pullman, WA 99164-1060 DUNS No.: 18 TIN No.: 40 <div style="text-align: right; margin-top: 10px;">LOC: 42A5P</div>		6. ADMINISTERED BY: U.S. Agency for International Development Office of Acquisition and Assistance M/OAA/GH/HIDN 1300 Pennsylvania Ave., NW SA-44, 549 Washington, DC 20532-7900										
7. FISCAL DATA: Amount Obligated: \$0.00 Detail: (see continuation page)		8. TECHNICAL OFFICE: USAID/GH/ID 9. PAYMENT OFFICE: U.S. Agency for International Development M/FM/CMP/LOC loc@usaid.gov										
10. FUNDING SUMMARY: Amount Obligated prior to this Modification: Change made by this Modification: New/Current Total:		<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; border-bottom: 1px solid black;"><u>Obligated Amount</u></th> <th style="text-align: right; border-bottom: 1px solid black;"><u>Total Est. Amount</u></th> </tr> </thead> <tbody> <tr> <td style="text-align: right;">\$ 10,000,000 00</td> <td style="text-align: right;">\$ 124,679,896 00</td> </tr> <tr> <td style="text-align: right;">\$ 0 00</td> <td style="text-align: right;">\$ 0 00</td> </tr> <tr> <td style="text-align: right; border-top: 1px solid black;">\$ 10,000,000 00</td> <td style="text-align: right; border-top: 1px solid black;">\$ 124,679,896 00</td> </tr> </tbody> </table>			<u>Obligated Amount</u>	<u>Total Est. Amount</u>	\$ 10,000,000 00	\$ 124,679,896 00	\$ 0 00	\$ 0 00	\$ 10,000,000 00	\$ 124,679,896 00
<u>Obligated Amount</u>	<u>Total Est. Amount</u>											
\$ 10,000,000 00	\$ 124,679,896 00											
\$ 0 00	\$ 0 00											
\$ 10,000,000 00	\$ 124,679,896 00											
11. DESCRIPTION OF MODIFICATION: The purpose of this modification is to: <ol style="list-style-type: none"> 1) Extend Performance Planning due dates; 2) Add Environmental Mitigation and Monitoring Report to Performance Reporting; and 3) Remove Duke University from Subaward Approval. <div style="text-align: center; margin-top: 20px;">Continued...</div>												
12. THIS MODIFICATION IS ENTERED INTO PURSUANT TO THE AUTHORITY OF THE FOREIGN ASSISTANCE ACT OF 1961, AS AMENDED. EXCEPT AS SPECIFICALLY AMENDED HEREIN, ALL TERMS AND CONDITIONS OF THE AWARD REFERENCED ON BLOCK #3 ABOVE, AS IT MAY HAVE HERETOFORE BEEN AMENDED, REMAIN UNCHANGED AND IN FULL FORCE AND EFFECT.												
13. RECIPIENT	<input checked="" type="checkbox"/>	IS	<input type="checkbox"/> IS NOT REQUIRED TO SIGN THIS DOCUMENT TO RECONFIRM ITS AGREEMENT WITH THE CHANGES EFFECTED HEREIN.									
14. RECIPIENT: <div style="margin-top: 20px;">BY</div> <div style="border-bottom: 1px solid black; margin-top: 5px;"></div> <div style="text-align: center; margin-top: 10px;"><i>(Name Typed or Printed)</i></div> <div style="margin-top: 20px;">TITLE</div> <div style="border-bottom: 1px solid black; margin-top: 5px;"></div> <div style="margin-top: 20px;">DATE</div> <div style="border-bottom: 1px solid black; margin-top: 5px;"></div>		15. THE UNITED STATES OF AMERICA U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT <div style="margin-top: 20px;">BY</div> <div style="border-bottom: 1px solid black; margin-top: 5px;"></div> <div style="text-align: center; margin-top: 10px;">Anna Nelson <i>(Name Typed or Printed)</i></div> <div style="margin-top: 20px;">TITLE</div> <div style="border-bottom: 1px solid black; margin-top: 5px;"></div> <div style="text-align: center; margin-top: 10px;">Agreement Officer</div> <div style="margin-top: 20px;">DATE</div> <div style="border-bottom: 1px solid black; margin-top: 5px;"></div>										

MODIFICATION OF ASSISTANCE AWARD
CONTINUATION PAGE

7200AA21CA00033

Modification P001

The Cooperative Agreement is modified as follows:

- 1) In **ATTACHMENT A – SCHEDULE, A.5 PLANNING, REPORTING, AND EVALUATION, 2. Performance Planning:**
 - a. **First Year Work Plan and Budget** DELETE “90 days” and REPLACE with “120 days”
 - b. **Monitoring, Evaluation and Learning (MEL) Plan** DELETE “90 days” and REPLACE with “120 days”
 - c. **Biosecurity and Biosafety (BSBS) Plan** DELETE “90 days” and REPLACE with “120 days”
 - d. **Gender Action Plan** DELETE “90 days” and REPLACE with “150 days”
 - e. **Data Management Plan** DELETE “90 days” and REPLACE with “120 days”
 - f. After Data Management Plan, but before Closeout Plan, INSERT:
Environmental Mitigation and Monitoring Plan
In accordance with A.13.4 Environmental Compliance of this award, an Environmental Monitoring and Mitigation Plan (EMMP) is a document that sets out (i) mitigation actions: actions that will be taken to satisfy the IEE or EA conditions; (ii) monitoring actions: indicators or criteria that will be used to monitor (1) whether the mitigation actions have been implemented, and (2) whether they are effective and sufficient; and (iii) responsibility and schedule for mitigation, monitoring, and reporting: the EMMP specifies the parties responsible for these actions and the schedule for these tasks. The initial EMMP, which will be developed in collaboration with the USAID management team, will be finalized within 120 calendar days of the award and updated semi-annually and annually.
- 2) In **ATTACHMENT A – SCHEDULE, A.5 PLANNING, REPORTING, AND EVALUATION, 3. Performance Reporting, Semi-Annual and Annual Reports**, “At a minimum, both semi-annual and annual reports will contain:” ADD:
 - An updated EMMP
- 3) In **ATTACHMENT A – SCHEDULE, A.13.1 SUBAWARD APPROVAL**, DELETE “Duke University”

All other terms and conditions of this award remain unchanged and in full effect.

--- END OF MODIFICATION P001 ---

MODIFICATION OF ASSISTANCE AWARD				Page 1 of 3											
1. MODIFICATION NUMBER: P004	2. EFFECTIVE DATE OF MODIFICATION: See Block 15	3. AWARD NUMBER: 7200AA21CA00033	4. EFFECTIVE DATE OF AWARD: May 10, 2022												
5. RECIPIENT: Washington State University P.O. Box 641060 Pullman, WA 99164-1060 UEI No.: 40 TIN No.: 18 LOC: 42A5P		6. ADMINISTERED BY: U.S. Agency for International Development Office of Acquisition and Assistance M/OAA/GH/ID 1300 Pennsylvania Ave., NW SA-44, 549 Washington, DC 20532-7900													
7. FISCAL DATA: Amount Obligated: Detail: (see continuation page)		8. TECHNICAL OFFICE: USAID/GH/ID 9. PAYMENT OFFICE: U.S. Agency for International Development M/FM/CMP/LOC loc@usaid.gov													
10. FUNDING SUMMARY:		<table><thead><tr><th></th><th>Obligated Amount</th><th>Total Est. Amount</th></tr></thead><tbody><tr><td>Amount Obligated prior to this Modification:</td><td>\$ 14,000,000 00</td><td>\$ 124,679,896 00</td></tr><tr><td>Change made by this Modification:</td><td>\$ 00 00</td><td>\$ 0 00</td></tr><tr><td>New/Current Total:</td><td><u>\$ 14,000,000 00</u></td><td><u>\$ 124,679,896 00</u></td></tr></tbody></table>			Obligated Amount	Total Est. Amount	Amount Obligated prior to this Modification:	\$ 14,000,000 00	\$ 124,679,896 00	Change made by this Modification:	\$ 00 00	\$ 0 00	New/Current Total:	<u>\$ 14,000,000 00</u>	<u>\$ 124,679,896 00</u>
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11. DESCRIPTION OF MODIFICATION: The purpose of this modification is to: Revise performance requirements in Schedule A.5 and to revise aspects of Schedule B Program Description. Specific changes to the award listed on page 2. Continued...															
12. THIS MODIFICATION IS ENTERED INTO PURSUANT TO THE AUTHORITY OF THE FOREIGN ASSISTANCE ACT OF 1961, AS AMENDED. EXCEPT AS SPECIFICALLY AMENDED HEREIN, ALL TERMS AND CONDITIONS OF THE AWARD REFERENCED ON BLOCK #3 ABOVE, AS IT MAY HAVE HERETOFORE BEEN AMENDED, REMAIN UNCHANGED AND IN FULL FORCE AND EFFECT.															
13. RECIPIENT <input checked="" type="checkbox"/> IS <input type="checkbox"/> IS NOT REQUIRED TO SIGN THIS DOCUMENT TO RECONFIRM ITS AGREEMENT WITH THE CHANGES EFFECTED HEREIN.															
14. RECIPIENT: BY _____ _____ (Name Typed or Printed) TITLE _____ DATE _____		15. THE UNITED STATES OF AMERICA U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT BY _____ _____ Patricia Bradley (Name Typed or Printed) TITLE _____ Agreement Officer DATE _____													

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The Cooperative Agreement is modified as follows:

I. In Attachment A-Schedule, A.5 Planning, Reporting, and Evaluation, Section 3. Performance Reporting:

Remove the following from the semi- and annual report requirement annual work plan submission:

- a. An updated MEL plan
- b. An updated BSBS plan
- c. An updated Data Management plan

and move to A.5 Planning, Reporting, and Evaluation, Section 2 Performance Planning Implementation Plan.

In Attachment A-Schedule, A.13.5 Open Data and Data Sharing DELETE “characterization” and REPLACE with “assessment”.

II. In Attachment B- Program Description:

1. DELETE “characterization” are REPLACE with “assessment” throughout the program description.
2. At the end of Section 1.3 INSERT “All current sampling numbers were illustrative, and that new sampling and other numbered targets will be determined in conjunction with USAID once the project is fully implemented.”
3. At the end of Section 1.3 INSERT “Country-level Strategic Sampling Approach” will be REVISED as follows:
 - a. In order to enhance biosafety and biosecurity, all samples will be inactivated at the sampling site or as soon as safely possible before laboratory detection and assessment activities are initiated-- thus prohibiting the isolation of strains of novel wild type viruses from samples collected under DEEP VZN and the subsequent use of such viruses in prohibited research activities including animal transmission studies.
 - b. Any bio-banked samples that were collected under other projects using funding from sources other than DEEP VZN will require a detailed justification that will be reviewed and approved by USAID.
 - c. Any bio-banked samples (if approved to include under DEEP VZN) and outbreak samples that have not been previously inactivated will be immediately inactivated in the participating DEEP VZN laboratory once the sample is thawed and before viral testing to reduce the biosafety/biosecurity risks associated with subsequent handling and storing these samples.
4. At the end of Task 4.3 INSERT “Virus Isolation for Receptor and Intracellular Viral-Host Interaction Studies” will be REVISED as follows:
 - a. At this time, there will be no isolation of and studies using novel coronaviruses, paramyxoviruses or filoviruses (to include virus rescue).
 - b. Laboratory studies conducted under DEEP VZN will strictly prohibit Dual-Use Research of Concern with a focus on Gain of Function Research, and live animal research.
5. At the end of Section 3.5 INSERT “Algorithm for Ranking Viruses with Pandemic Potential” will be REVISED as follows:
 - a. At this time, novel viruses detected by DEEP VZN will not be ranked by “epidemic/pandemic potential” in order to prevent others from selecting the most dangerous ones and weaponizing them. Instead, viruses may be classified simply as “no current evidence for zoonotic potential”, “possibly zoonotic”, “likely zoonotic”, or “zoonotic” based on phylogenetic comparisons, serological studies, in vitro cell-binding studies using pseudoviruses, and in silico studies of receptor proteins based on genetic sequence.

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6. At the end of Task 4.3 “Data storage” will ADD the following language:
 - a. In addition to submission of datasets to the development data library, data collected by DEEP VZN activities, including information derived from these data, should be uploaded to the GHS/ETD data management system. Datasets may include, but are not limited to, databases related to animal, human, and environmental samples, deidentified human surveys, genomic and sequence data.
 - b. Once the GHS/ETD data management system is operational, datasets should be uploaded once year, along with the annual reports.The rest of the terms and conditions of this award remain unchanged and in full effect.

--- END OF MODIFICATION P004 ---