Exhibit A

USAID
FROM THE AMERICAN PEOPLE

September 29, 2014

Jonna AK Mazet, DVM, MPVM, PhD
Professor and Executive Director
School of Veterinary Medicine
University of California
One Health Institute
Davis, California 95616

Subject: Cooperative Agreement No. AID-OAA-A-14-00102 for PREDICT-2

Dear Dr. Mazet:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, the U.S. Agency for International Development (USAID) awards to University of California, School of Veterinary Medicine, Davis, CA, hereinafter referred to as the "Recipient", the sum of $100,000,000 to provide support to the PREDICT-2 project as described in the Schedule of this award and in Attachment B, entitled "Program Description."

This Cooperative Agreement is effective October 1, 2014 and the obligation shall apply to expenditures made by the Recipient in furtherance of program objectives during the period of performance, beginning with the effective date 10/01/2014 and ending 09/30/2019. USAID will not be liable for reimbursing the Recipient for any costs in excess of the obligated amount or outside of the period of performance.

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

Please sign this letter, where indicated on the second page, to acknowledge your receipt of the Cooperative Agreement, and return to the Agreement Officer at your earliest convenience.

Sincerely yours,

Patricia Bradley

Patricia Bradley
Agreement Officer
USAID

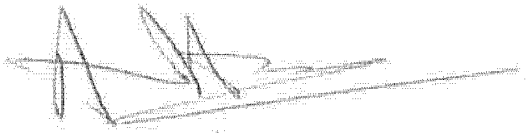
U.S. Agency for International Development
1300 Pennsylvania Avenue, NW
Washington, DC 20523
www.usaid.ov

Attachments:

A. Schedule
B. Program Description
C. Branding Strategy and Marking Plan
D. Standard Provisions
E. Initial Environmental Examination
F. Table of Acronyms

ACKNOWLEDGED:

BY: Ahmad Hakim-Elahi, Ph.D., J.D.
TITLE: Executive Director, Research Administration
DATE: September 30, 2014



9/30/2014

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Executive Director, Research Administration
Office of Research, Sponsored Programs
University of California, Davis
1850 Research Park Drive, Suite 300
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(530) 754-7700, FAX (530) 754-8229

Exhibit A

A. GENERAL

1. Amount Obligated this Action: $13,600,000.00
2. Total Estimated USAID Amount: $100,000,000.00
3. Total Obligated USAID Amount: $13,600,000.00
4. Cost-Sharing Amount (Non-Federal): $3,697,810.00
5. Activity Title: PREDICT-2
6. USAID Technical Office: GH/HIDN/PIOET
7. Tax I.D. Number: 94-6036494
8. DUNS No.: 04-712-0084
9. LOC Number: 29B8P

B. SPECIFIC

Account ID	1
Account Template	GH-HN Program Funds
BBFY	2014
EBFY	2015
Fund	GH-C-AI
OP	GH/HIDN
Program Area	A11
Dist Code	936-4002
Program Elem	A050
BGA	997
SOC	4100201
Obligated Amount	$13,600,000
Fund Type	Appropriated
Treasury Account Symbol	19-1031-000
Payment Office	M/CFO/CMP
Requisition Number	REQ-GH-14-000122

C. PAYMENT OFFICE

The USAID M/FM office prefers to receive invoices via email. When submitting invoices to USAID FM, in addition to the required submission to the Agreement Officer Representative (AOR), please send to:

Vendor invoices: loc@usaid.gov
Point of Contact: LOC Team Leader
Phone: (202) 567-5141
FAX: (202) 567-5264

TABLE OF CONTENTS

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 Cooperative Agreement is October 1, 2014. The estimated completion date of this Cooperative Agreement is September 30, 2019.

2. Funds obligated hereunder are available for program expenditures for the estimated period beginning the effective date of the Agreement through completion date as shown in the Agreement budget below.

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 $100,000,000 not including required cost share of $3,697,810.

2. USAID hereby obligates the amount of $13,600,000 for program expenditures during the period set forth in A.2 above. The Recipient will be given written notice by the Agreement Officer if additional funds will be added. USAID is not obligated to reimburse the Grantee for the expenditure of amounts in excess of the total obligated amount.

3. Payment will be made to the Recipient by Letter of Credit in accordance with procedures set forth in 22 CFR 226

4. Additional funds up to the total amount of the Cooperative Agreement stated in A.3.1, above may be obligated by USAID subject to the availability of funds, satisfactory progress of the project, and continued relevance to USAID programs.

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 22 CFR 226.

Categories	USAID funding
Total Direct Costs	$ 93,513,570
Indirect Costs	$ 6,486,430
Total Federal Share	**$100,000,000**
Cost Share	$3,697,810
Total Program Amount	**$103,697,810**

Exhibit A

A.5 INDIRECT COST RATE

Pending establishment of revised provisional or final indirect cost rates, allowable indirect costs shall be reimbursed on the basis of the following negotiated provisional rates and the appropriate base:

Type	From:	To:	Rate %	Location	Application
Pred.	7/1/2014	6/30/2015	55.50	On campus	Organized Res.
Pred.	7/1/2015	6/30/2016	56.50	On campus	Organized Res.
Pred.	7/1/2016	6/30/2018	57.00	On campus	Organized Res.
Pred.	7/1/2013	6/30/2018	26.00	Off campus	Organized Res.
Pred.	7/1/2014	6/30/2015	38.00	On campus	Other Spans Act
Pred.	7/1/2014	6/30/2015	24.50	Off campus	Other Spans Act
Pred.	7/1/2015	6/30/2016	38.50	On campus	Other Spans Act
Pred.	7/1/2015	6/30/2016	24.50	Off campus	Other Spans Act
Pred.	7/1/2016	6/30/2018	39.00	On campus	Other Spans Act
Pred.	7/1/2016	6/30/2018	25.00	Off campus	Other Spans Act
Pred.	7/1/2013	6/30/2018	50.00	On campus	Instruction
Pred.	7/1/2013	6/30/2018	26.00	Off campus	Instruction
Pred.	7/1/2013	6/30/2018	22.70	Primate Ctr	Core Grant (1)
Pred.	7/1/2013	6/30/2018	54.40	Primate Ctr	Non-Core Fed (1)
Pred.	7/1/2013	6/30/2018	8.00	Off campus	IPA (2)
Prov.	7/1/2018	until amended		(3)	

Base of Application

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 coats 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.

(1) Primate Center - The California National Primate Research Center (CNPRC) Non-Core Federal rate (54.4%) is applied only to the direct research costs of Federally sponsored awards excluding the National Center for Research Resources (NCRR) Core Grant. All recoveries from application of this rate represent university F&A expenditures allocated to the CNPRC (22.7%) and CNPRC-specific F&A expenditures (31.7).

(2) Intergovernmental Personnel Act Agreements.

(3) Use the same rates and conditions as those cited for fiscal year ending June 30, 2018.

A.6 TITLE TO PROPERTY

Property Title will be vested with the Recipient.

A.7 AUTHORIZED GEOGRAPHIC CODE

The authorized geographic code for the procurement of services and commodities for the cooperative agreement is 937.

A.8 COST SHARING

The Recipient agrees to expend cost share in an amount not less than $3,697,810 under this agreement. All cost sharing contributions shall be in accordance with 22 CFR.226.23 and Standard Provisions on Cost Sharing or Matching and are subject to audit.

A.9 PROGRAM INCOME

The Recipient shall account for Program Income in accordance with 22 CFR 226.24 (or the Standard Provision entitled Program Income for non-U.S. organizations). Program Income earned under this award shall be added to the total estimated amount of the program.

A.10 SUBTANTIAL INVOLVEMENT

Substantial involvement during the implementation of this Agreement must be limited to approval of the elements listed below:

1. Approval of all annual implementation plans, budgets, and all modifications which describe the specific activities to be carried out under the Agreement, subawards, and progress reports;

2. Approval of key personnel to include the following positions:
    a. Project Director
    b. Operations Manager
    c. Senior Biological and Ecological Surveillance Coordinator
    d. Senior Behavioral Surveillance Coordinator
    e. EPT-2 Liaison

3. Approval of Monitoring and Evaluation Plans - USAID involvement in monitoring progress toward achievement of the Objective and Expected Results during the course of the Agreements and in monitoring financial expenditures;

4. Collaboration or joint participation of USAID with the Recipient in accomplishing specific elements in the program description; where there are specific elements in the Program Description for which USAID's technical knowledge would benefit the Recipient's successful accomplishment of stated program objectives, to include:

a. Concurrence on the substantive provisions of sub-awards, including work plans, monitoring and evaluation plans, budgets, timelines, personnel, reporting (programmatic and financial), and any modifications.

b. Collaborative involvement in the selection of sub-awardees, grantees, and other partners.

c. USAID will be involved in the substantive direction/re-direction of inter-relationships with other projects as described in section D.3., USAID Management.

5. As appropriate, other monitoring as described in 22 CFR 226.

A.11 REPORTING REQUIREMENTS

a. Initial Work Plan to be submitted within 60 days of signing the cooperative agreement and Annual Work Plans for subsequent years to be submitted 30 days prior to the start of the new year.

b. Semi-annual reports shall be due 30 days after the reporting period. Annual Reports shall be submitted 90 calendar days after the award year in accordance with 22 CFR 226.51(b).

c. Final Evaluation Report: to be submitted 90 calendar days after the expiration or termination of the award which is in accordance with 22 CFR 226.51(b).

d. Financial Reporting: in accordance with 22 CFR 226.52, the SF 425 and SF 272 will be required on a quarterly basis.

A.12 SPECIAL PROVISIONS

A.12.1 SUBAWARD BUDGET APPROVAL

The subaward budget for Metabiota, Inc. is not pre-approved and AO approval post award is required. While the subaward to Metabiota doesn't need to be competed, the detailed budget, and budget notes have to be submitted to the Administrative AO within 60 days from the award date of this agreement. This budget approval will not be delegated to the AOR.

A.12.2 COUNTRY-BY-COUNTRY BREAKDOWN OF EXPENDITURES

The quarterly expenditure reports shall be sent to the AOR, no later than 45 calendar days after the end of each quarter. The quarterly expenditure report shall include, at minimum, obligations to date, the approved budget, expenditures to date, accruals to date, and the balance remaining. The report shall be broken down by country and core funds. Both field support and core funds must be tracked by program directive. In some cases, there will be multiple sources of funding for an activity, but the implementer must be able to demonstrate in the budget, expenditures and balances the flow of the money from multiple sources. The budget line items should include the major categories.

The recipient should 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 "Federal

Financial Report" forms SF 425 or SF 425a, or on a separate sheet of paper with the "Request for Advance or reimbursement" SF270.

A.12.3 ENVIRONMENTAL COMPLIANCE

An Initial Environmental Examination (IEE) has been approved for the PREDICT-2 Project (see Attachment E). The IEE covers activities to be implemented under this cooperative agreement. USAID has determined that a **Negative Determination with conditions** applies to one or more of the proposed activities. This indicates that if these activities are implemented subject to the specified conditions, they are expected to have no significant adverse effect on the environment. The recipient shall be responsible for implementing all IEE conditions pertaining to activities performed under this award.

1. As part of its initial Work Plan, and all Annual Work Plans thereafter, the recipient, in collaboration with the USAID Agreement Officer's Representative (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.
2. 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.
3. 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.

Unless the approved Regulation 216 documentation contains a complete environmental mitigation and monitoring plan (EMMP) or a project mitigation and monitoring (M&M) plan, the recipient shall prepare an EMMP or M&M Plan describing how the recipient will, in specific terms, implement all IEE and/or EA conditions that apply to proposed project activities within the scope of the award. The EMMP or M&M Plan shall include monitoring the implementation of the conditions and their effectiveness.

When the approved Regulation 216 documentation is (1) an IEE that contains one or more Negative Determinations with conditions and/or (2) an EA, the recipient shall integrate a completed EMMP or M&M Plan into the Initial Work Plan or the subsequent Annual Work Plans, making any necessary adjustments to activity implementation in order to minimize adverse impacts to the environment.

End of Attachment A

ATTACHMENT B – PROGRAM DESCRIPTION
PREDICT-2

Technical Approach

In recognition of the realized and forecasted costs of emerging infectious diseases in both lives lost and dollars spent on response, treatment, and control, our consortium proposes to partner with USAID to continue to shift the prevention and surveillance paradigm upstream to: identify and better characterize pathogens of known epidemic and unknown pandemic potential; recognize animal reservoirs and amplification hosts of human-infectious viruses; and efficiently target intervention action at human behaviors which amplify disease transmission at critical animal-animal and animal-human interfaces in hotspots of viral evolution, spillover, amplification, and spread. To achieve these objectives, we will operationalize effective One Health platforms by increasing knowledge and functional technological capacity in local, national, and regional contexts. Critical capacity improvements will be attained in cross-sectoral communications and engagements for surveillance system design, field sampling, laboratory techniques, behavioral risk characterization, information management, public data dissemination, and data analytics and forecasting (e.g. viral ecology, geospatial analysis, pathogen and behavioral risk assessment, integrated pandemic risk analyses, risk communication). Instead of the broad approach needed in EPT-1, we propose to focus efforts on the highest risk locations and interfaces, where animals and people share changing landscapes, and diseases of unknown origin continue to take a significant toll.

Building on the surveillance activities and data made publically available in PREDICT-1, high-risk animal-to-animal and animal-to-human disease transmission interfaces have been integrated here into three major pandemic risk pathways: land conversion for commercialization, intensification of animal production systems, and animal value chains (see figure at right depicting the three major pathways that drive viral emergence in EPT-2 countries that we propose to target in PREDICT-2 and the associated hypothetical change in zoonotic emergence risk). We will use an epizonal approach to target these disease emergence and transmission pathways, characterizing the whole geographic, ecological, and sociological space, from pre-spillover conditions that drive viral evolution, through transmission of zoonoses, to circumstances of pathogen amplification and spread. This approach will facilitate the shaping and optimization of policies and practices that can reduce disease transmission risk through sound, science-based risk mitigation interventions at the community and industrial scale.

Objective 1: Biological and ecological risk characterization

Our consortium is well positioned to enhance the in-country and regional operational platforms, partnerships, and knowledge of best practices in field sampling and data collection recently gained from advances in zoonotic pathogen surveillance at high-risk animal-human disease transmission interfaces. For PREDICT-2, we propose a strategic, highly focused approach to identify the biological and ecological drivers and host-pathogen dynamics at high-risk interfaces within **three**

critical pathways of disease emergence and spread in Asia and Africa.

1.1. Targeted monitoring of zoonotic viruses with pandemic potential at specific high-risk interfaces Surveillance for zoonotic viruses, implemented together with in-country and EPT-2 partners, such as CDC, WHO, and FAO, will be prioritized at field sites most reflective of the processes underlying pathways for viral evolution, spillover, amplification, and spread.

1.1.a. Biological surveillance: to the extent feasible, data sets collected at all field sites will include:

i) Standardized, concurrent, and selectively longitudinal sampling of wildlife, livestock, and at-risk human populations with high levels of contact with animals, with special focus on influenza-like illness (ILI), severe acute respiratory infection (SARI), and fever of unknown origin (FUO) patients.

ii) Standardized collection of data on human movements, behaviors, and practices and the ecological conditions governing these aspects of human ecology (see Obj. 2).

iii) Detection and characterization of pathogens and evidence of infectivity and transmissibility among animal hosts and people.

iv) Analyses of key viral characteristics in combination with data collected on hosts, ecological drivers, human behaviors and practices, exposure rates, and ecological conditions for more precise ranking of high-risk interfaces and identification of key processes influencing the evolution, spillover, amplification, and spread of viral threats.

v) Establishment of collaborative platforms and national partnerships for longitudinal monitoring of viral threats at high-risk interfaces in conjunction with EPT partners and projects. Our intention is to facilitate wildlife, livestock, and human biological surveillance at all targeted high-risk disease emergence pathways (see 1.1.b. below). An initial scoping effort will be necessary on a country-by-country basis to identify sites for sampling activities based on potential to inform on disease emergence pathways and location within an epidemiological zone. Once locations are selected, we will assess feasibility for using existing in-country platforms and collaborating with in- country government partners, CDC, FAO, etc. on sampling activities.

vi) Simultaneous collection of human, livestock, and wildlife samples, as well as environmental and behavioral data, across the pathways described below (1.1.b.) in all intensive countries and most, if not all, less intensive countries. We will partner with in-country ministries, universities, and NGOs to achieve this goal in addition to fully coordinating sampling with FAO, CDC, and WHO in countries where they are actively collecting data for EPT-2. In some countries, the PREDICT-2 team will likely lead sample collection for people and all animals, while in others one or more of our partners may lead a section of the collection. In either scenario, we intend to collect human and animal samples aligned in time and space. In addition, we plan to test samples from livestock and humans using the successfully designed and employed platform used on wildlife samples in PREDICT-1.

1.1.b. High-risk pathways for disease emergence and spread:

i)**Land conversion for commercialization:** We propose focused, standardized biological surveillance for pathogens in rapid and dramatically changing landscapes under circumstances that bring potentially immunologically stressed or naïve individuals into contact with potential spillover organisms.

- New settlements and vulnerable human populations due to extractive industry growth,

conflict, economic hardship, and developing tourism: We will sample in temporary settlement communities in high biodiversity areas that constitute hotspots for disease emergence, as well as in the source communities of workers and their food animals. Sudden incursion into previously pristine areas and settlements with poor infrastructure are frequently associated with new exposure to animal reservoirs, subsequent introduction of infectious diseases, and movement of infected people through local and long-range travel.

- Sampling activities and viral characterization will target wild and domestic animals and people in new settlements with ongoing land-use change (such as mining/oil extraction camps, refugee/migrant worker camps, urban slums, and high-risk ecotourism sites) and vulnerable and highly mobile human populations at these sites within transboundary epizones connected by migration and human travel.
- Key pandemic risk factors identified through previous work will be further characterized by quantifying viral sharing among hosts and determining whether viral diversity and number of new viruses in animals and humans (disaggregated by gender) are higher at sites with new settlements, as well as evaluation of whether geographic distribution of viruses is associated with measures of animal and human mobility, resulting in high-risk epizones and heightened potential for global spread.

- Agricultural conversion in biodiversity hotspots: Cultivated systems cover one quarter of the earth's land surface, and conversion to cropland has been identified as one major driver of emerging infectious disease (EID) events. Agricultural intensification and subsistence farming is a high-risk interface common to all EPT-2 target countries. Crops are commonly raided by wildlife; peri-domestic animal populations (e.g. rodents) often exploit these niches; workers and consumers (including livestock) are exposed to zoonotic diseases in contaminated crops; and amplification and point source spread of disease occurs through shared food sources.
  - In coordination with EPT partners, standardized animal and human sampling activities and viral characterization will target agricultural land adjacent to highly biodiverse regions, such as palm oil plantations, and sentinels for likely routes of spread through transport and trade of agricultural products.
  - Surveillance results will be compared with baseline data from a small number of pristine and light-use sites to identify how rapidly this pathway increases EID risk.

ii) **Intensification of animal production systems:** We propose expanded biological surveillance along a continuum from rural pastoral settings to large-scale animal production systems with varying biosecurity, which facilitate frequent direct human-livestock contact and intermingling with wildlife species.

- Sampling activities and viral characterization will target wild and domestic animals and at-risk people (disaggregated by gender) in a range of production systems that are regionally connected by animal transport within epizones.
- Key pandemic mechanisms identified through previous work will be further characterized in this pathway, including the use of viral traceback and genetic approaches to determine whether co-mingling of wild and domestic animals in low biosecurity systems across the epizone leads to broader viral sharing and expanded host ranges, higher probability of human-to-human transmissibility, and geographic spread.

iii) **Animal value chains:** Collaborative work with FAO, CDC, and others has examined the routes and magnitude of the $350B wildlife trade which provides opportunities for pathogen transmission among domestic animals and co-mingling wild animals transported for consumption, medicinal uses, or to be kept as pets. We propose to focus our biological

surveillance activities along the wildlife and domestic animal value chains from remote naturally biodiverse regions to densely populated urban areas actively trading in varied animal species and products.

- We will characterize known and novel animal and human viruses and high-risk communities, describe animal and human mobility, identify high-risk nodes in the value chain using network analyses, and combine ecological and behavioral risk data (disaggregated by age, culture, and gender) to identify risk factors associated with viral evolution, spillover, amplification, and spread.
- We will also map out local and global trade routes to predict the spread of pathogens and, combined with our knowledge of pathogen diversity in wildlife hosts globally, predict the likelihood of a new pathogen spreading through value chains within an epizone and globally.

1.2. Characterization of climate and ecological factors

We propose the collection of standardized data at regular intervals on climatic and ecological factors identified as important drivers of pandemic risk via their effects on viral evolution, spillover, amplification or spread, including common measures of weather (temperature, precipitation), climatic envelopes, specific land cover, and anthropogenic land-use change activities at field sites prioritized for surveillance as above.

1.2.a. Climate, land use change, and niche modeling: We will integrate host and viral ecological niche model projections with viral and host phylogeographic analyses and current and future land use change scenarios to identify sites of future epizones where reservoir hosts will potentially co-exist based on climate and land conversion projections, flagging areas of concern for virus emergence.

1.2.b. Characterizing ecological risk and predicting spillover: We will continue to advance knowledge of ecological changes, including conversion of land from forest to crops and changes in human population density, that are recognized drivers for disease emergence. Employing geospatial analytical tools we will map and quantify high- risk ecological and behavioral data along our primary pathways of emergence. We will then integrate this spatial risk information with our host and pathogen databases and the phylogenetic and life-history predictors of zoonotic risk, creating a spatially-explicit, macroecological and behavioral framework to model the drivers of viral evolution, spillover risk, amplification, and spread, enabling us to compare pandemic risk within and between specific epizones. Here, life- history refers to the specific characteristics of different host species that affect their demographics and can influence their ability to harbor zoonotic agents. For example, some animal host species have higher reproductive rates, and this can lead to rapid population growth, heightened transmission of viruses, and increased risk of spillover to people. In PREDICT-1, we gathered information on these characteristics, as well as information about the viral diversity in different wildlife species. In PREDICT-2, we propose to analyze how host life history and viral diversity, as well as environmental change and human risk behavior, influence the likelihood of heightened viral evolution, spillover, amplification, and spread.

1.3. Longitudinal monitoring of viruses to track changes in geographic and host distribution, genetic sequences, transmissibility, infectivity, and viral evolution

1.3.a. Viral detection and discovery: Virus detection across high-risk interfaces within the specified pathways for emergence will be performed using a combination of consensus PCR (cPCR) and high through-put sequencing (HTS), a strategic approach to combine high

sensitivity with broad reactivity to discover novel viruses from many different hosts and sample types. Consensus PCR permits the "universal" amplification of viruses within a given viral family or genus, and the subsequent discernment of strains (both known and new). To guard against the potential of cPCR to miss viruses that are divergent or not among the initial targeted viral families, the application of the more inclusive but less sensitive HTS allows for the capture of a very broad diversity of viruses because it amplifies all viral nucleic acids present in the sample. We plan to use cPCR as our main discovery tool in all countries for biological surveillance (humans, wildlife, and domestic animals) on selected sample types based on interface and contact (i.e. potential for exposure) between animals and people and apply HTS to a subset of these samples for more detailed characterization. Serological assays will also be developed for targeted screening of prior exposure to selected, key pathogens and pathogen clades and will be used to identify previous and potentially ongoing spillover in animal and human populations at high-risk interfaces and amplification zones (see 1.3.c.).

1.3.b. Target viral families: In PREDICT-1 the list of target families/genera was necessarily broad and included families that, despite their (perceived) lower pandemic risk, had sufficient abundance and diversity in wildlife to act as useful targets for laboratory capacity building and successful training using the PREDICT protocols. If the successful bidder for PREDICT-2, we propose to focus our activities on viral families of potential pandemic (Tier 1) or epidemic (Tier 2) significance, as well as those with previous association with ILI, SARI, FUO, and hemorrhagic disease. Tier 1 will include viral families, such as corona-, paramyxo- and influenza viruses, and testing for these families will be conducted on selected, longitudinally-collected samples based on interface and type of contact with humans, wildlife, and domestic animals (performed in coordination with local partners, CDC, WHO, and FAO) in all target epizones. Tier 2 will include viral families, such as retro-, arena-, filo-, flavi-, bunya-, reo-, rhabdo-, picorna-, alpha-, adeno-, and pox- viruses, and will be conducted along with Tier 1 families in intensive-engagement regions; however, not all of these families will be applied equally to all samples. Selection of families from this list (for Tier 2 testing) and additions to Tier 1 testing will be adaptive in both high and low intensive countries and will depend on several criteria, including:
(1) the need to have consistent data across pathways for emergence; (2) high-risk interface; (3) need for knowledge on a particular viral family in a given region/epizone; (4) presence of undiagnosed human disease for which a given family might reasonably include an etiologic agent; and (5) resource availability after formal priority setting.

1.3.c. Serology to characterize exposure in human and animal populations and detect spillover: Because viral infections are often self-limiting in a host, PCR tests directed at detecting viral shedding and the potential for active transmission usually reveal lower numbers of positives than serological tests which may identify up to 100% of individuals previously exposed to a virus. Once key pathogens are identified in a particular epizone, we will, on a selective basis, develop serological assays to screen populations of people and animals (both livestock and wildlife) at high-risk interfaces to determine whether pathogen sharing has occurred. Serological assays may also be used to trace novel pathogens found in acutely ill human subjects back to potential animal reservoirs and amplification hosts. Serology may be used to characterize the frequency of host jumping within specific amplification zones, such as on farms and in markets, by screening animal populations that are in close contact at high density. We will develop in- country capacity to utilize serological assays developed under this

project, focusing on platforms that are readily available and practical to use in partner countries (e.g. ELISA assays).

1.3.d. Mapping viral diversity and evolution: We will integrate host-pathogen evolutionary and ecological data and viral phylogenies into analyses of global viral diversity and viral phylogeography using publically available data from PREDICT-1, longitudinal and other data collected during PREDICT-2, and the published literature. This activity will allow us to better understand how viruses evolve within the three emergence pathways and which viral clades are more likely to spillover in which host species assemblages (e.g. in wildlife/livestock markets) to answer key questions on the rules governing pandemic viral risk.

1.4. Expanded characterization of viruses to better understand pandemic potential, geographic and host distribution, and genetic diversity

Viruses detected from Tier 1 families that have a wider range of hosts, are related to known pathogens, are detected in new or unusual host species, or cluster with known pathogens found in other host taxa will be targeted for further characterization. Full genome sequencing and virus isolation will allow for accurate taxonomic placement, characterization of virus-host cell receptor interactions, improved understanding of host diversity and the evolutionary processes that shape viral diversity (e.g. reassortment/recombination), and the design of assays to investigate human exposure to these agents. Viruses from Tier 2 families may be similarly characterized if they have high host plasticity, are novel or related to a known pathogen, found at high frequencies at high-risk interfaces, and/or detected in species with known exposure to people with clinical disease.

1.5. Characterization of pathogens for Influenza-Like Illnesses (ILI), Severe Acute Respiratory Infections (SARI), and Fevers of Unknown Origin (FUO)

The study of diseases of unknown origin (DUO) provides an important tool for the identification of new and previously undetected pathogens that have the capacity to infect and potentially spread in human populations. Laboratory examination of syndromic surveillance samples are needed to identify novel agents in association with ILI, SARI, FUO, as well as other syndromes, such as hemorrhagic fever and encephalitis. In addition to the viral detection approaches described above, cPCR targeting conserved genes (e.g. 16s) will be used when appropriate to identify the full range of bacterial pathogens in specimens from DUO patients. As with our viral testing, we will adopt a tiered approach (described below) that will utilize the equivalent of viral family-level PCR with follow up characterization to identify new bacterial agents in the DUO specimens.

Consensus PCR for 16s rRNA: Unlike viruses, all bacteria share a conserved RNA called 16s rRNA. The presence of 16s in all bacteria means they can all be readily detected using PCR primers that target this gene. This removes the need to test for many different families or genera one after the other (as we do with viruses), or in the event of resource constraints, to have to choose which families to include/exclude from our testing strategy. This approach saves on resources and time and also prevents sample exhaustion because all bacteria are considered in one assay (important if we are also considering viral agents). That said, this 'universal amplification' also makes the 16s approach extremely vulnerable to false positives because of frequent sample contamination. Bacteria commonly found in the environment, on skin, in lab reagents (buffers, enzymes), or equipment are all known to contaminate diagnostic samples readily and often lead to false positives. Very careful sample collection and laboratory processing protocols must be followed in order to reduce the number of false positive results. We have already established laboratory procedures for handling samples for bacterial diagnostics (including sterile handling

practices, UV sterilization of equipment and tubes, filtration of buffers, and the inclusion of numerous extraction and PCR controls), and part of our resource allocation in PREDICT-2 will include training and implementation of these protocols in PREDICT-2 labs.

Follow-up of 16s rRNA positives: While the 16s approach will identify the presence of bacteria in a given sample and identify the family to which that bacteria belongs, the sequence obtained is rarely sufficient to distinguish down to the species or strain level. The ability to resolve the taxonomy of bacteria is particularly important because several families contain some species/strains that are common in the environment and others that are capable of causing human disease. Distinguishing between an innocuous environmental/commensal bacteria and a potential pathogen will (often) therefore require additional targeted testing. We have already designed assays capable of rapidly identifying all of the major human bacterial pathogens and plan to implement these assays in the event of a 16s positive sample to confirm the specific species present. In the event that these species-specific assays are all negative (suggesting a novel pathogen), we will move to deep-sequencing and possible culture to further characterize the bacteria present.

Characterization and association with disease: Understanding the role of bacteria in the disease state observed is also an important consideration; however, demonstrating causation for bacterial agents can be problematic. Bacterial infections can often occur as a secondary response to a primary viral infection (e.g. *Steptococus pneumoniae* associated with influenza infections), so combining bacterial testing on DUOs with our viral testing strategy will be important in our interpretations. Equally, many of the approaches we would use to demonstrate causation for viruses (such as immunohistochemistry, in-situ hybridization, copy number analyses) are not appropriate for bacteria because of their (mostly) extracellular biology and their potential for rapid overgrowth in the event of poor sample collection. In the event that additional work to demonstrate causation is required, we will use serology and (where possible) pathology and epidemiologic tools to establish this link.

We will also collaborate with established surveillance networks, such as the CDC, Department of Defense (DOD/DTRA), and the WHO/GISRS, to assist with etiological identification of new agents that may pose epidemic threats in the targeted disease emergence pathways, as well as other identified hotspots of human disease. Along with EPT partners, we will identify clinical settings for new studies where prospective samples can be collected in parallel with animal samples (domestic and wild) to detect novel viruses associated with these syndromes. These data will be analyzed in conjunction with behavioral questionnaires and extensive travel histories to assist in understanding human behaviors and practices that underlie the risk of emergence and spread. This work will align pathogen presence across the human-animal interface to better characterize pathogen sharing in time and space. We will compare novel agents detected in people with diseases of unknown origin to novel animal agents to assess animal hosts and regions of heightened risk for potential spread, which will also feed into identifying behaviors and practices (disaggregated by sex, age, social/ethnic group, livelihood strategy) that have the potential to mitigate disease emergence.

The PREDICT consortium has approval for human subjects research (including human biological sampling) in China, Malaysia, Rwanda, Uganda, Cameroon, and DRC. We also have a US exemption (from UCD) for IRB review that allows our team to: 1) perform diagnostic testing on archived human samples in DRC, Cameroon, Gabon, Malaysia, and Indonesia; 2) interview human subjects regarding their occupational and recreational contact with animals in Uganda, Tanzania, Nepal, and Malaysia; and 3) interview human subjects during outbreak response activities to obtain

data on health and contact with animals that may inform on the outbreak in all EPT-1 countries.

Once study design and field logistics are finalized for PREDICT-2, we anticipate 2-6 weeks start-up time may be needed for additional UCD IRB approvals and 2-12 months time for in-country approvals for biological and behavioral sampling of human subjects, with the latter varying substantially from country-to-country. As mentioned above, we will rely on existing in-country platforms that match our biological surveillance design whenever feasible. As necessary, we will implement surveillance platforms and lead field activities to ensure that sampling of wildlife, domestic animals, and humans is aligned in space and time along targeted disease emergence pathways. Regardless of which partner leads surveillance efforts, we will ensure the activities are collaborative and conducted with the appropriate global and in-country ethical clearances, in addition to guaranteeing that data and key findings are shared across in-country and international partners in a timely manner.

1.6. Mainstreaming PREDICT testing protocols and comparing speed and cost-effectiveness of viral screening approaches with standard methods

To ensure that our discovery strategy is both economically and scientifically robust, we will continue to evaluate the ability of our assays to detect diverse viruses by partnering with the CDC, WHO, FAO, and OIE reference labs around the world to compare the performance of our approach to commonly-used assays, including those for detecting specific influenza subtypes, as was performed in China during the H7N9 outbreak. For example, we already have commitments from FAO to partner on pilot projects in National Veterinary laboratories (e.g. beginning in Vietnam, Indonesia, Cameroon, and Malaysia) to test livestock samples with PREDICT viral screening protocols. Results obtained will enable assessments of the ability of these protocols to detect known and new viral pathogens in livestock samples in high-throughput labs (through PREDICT-1 we have shown the utility of these protocols in samples collected from wildlife and people) and will be compared with results found in other surveillance groups (animals and people) in the same areas. We anticipate conducting similar activities in National Public Health Laboratories in collaboration with the appropriate ministries, the WHO, and CDC.

As mentioned above, in PREDICT-1 we performed a small pilot project in China with the Guangdong Centers for Disease Control and Prevention and Guangdong Provincial Institute of Public Health to compare the cost and effectiveness of analysis between the WHO H7N9 real time assay and influenza diagnostic platforms with PREDICT pan-influenza A PCR protocols during the H7N9 outbreak. In PREDICT-2, we expect to expand this comparison by partnering with national laboratories to perform follow-up testing with PREDICT pan-influenza A PCR protocols on samples that tested negative using traditional influenza diagnostic platforms (i.e. only H1N1 and H5N1 screening that occurs routinely in most countries) to detect additional subtypes that may be circulating and assess the utility of a broader approach for screening. Pilot projects such as these are planned in National Veterinary Laboratories, such as at the National Animal Health Centre in Laos. Diagnostic protocols will also be shared with all EPT-2 partners or other agencies/organizations as requested and approved by USAID, and facilitated discussions will help to bring in new ideas and lessons learned from all partners to develop and optimize strategies. The proposed Pathogen Detections Leads (T. Goldstein, S. Anthony) will be responsible for ensuring these projects are piloted and will work closely with the proposed Director (J. Mazet), laboratory teams, and proposed EPT Liaison (W. Karesh).

We will also work with national and international partners to establish new approaches to

coordinated sampling and investigations for zoonotic diseases of pandemic potential by developing strategies which combine simultaneous sampling of humans (both biological and behavioral data), livestock, and wildlife at key interfaces or points of potential contact along the value/production chains outlined above. Both the ongoing and optimized sampling/investigation protocols and diagnostic approaches will be shared with the OHW and P&R projects for integration into pre-service and in-service training and hence, will facilitate adoption into standard practices by in-country professionals and curricula for future public health and animal health professionals. Data will also contribute to One Health analyses described in Obj. 4.

1.7. Technical support for viral surveillance and laboratory testing

Technical support will build on platforms and partnerships developed under EPT-1, with emphasis on further increasing capacities in collaborating laboratories and expanding collaborations with national laboratories and those testing livestock and human samples in coordination with FAO, OIE, CDC, and WHO. We have an established system of regional and global multidisciplinary communications and supply chains and will continually optimize feasible and cost effective strategies for procurement of field and laboratory supplies, as well as best practices in areas such as personal safety and ethical treatment of animals and humans involved in field investigations. These same communication lines enable regular and highly effective two-way transfer of knowledge between local and world-renowned experts in medicine, epidemiology, animal health, virology, ecology, comparative pathology, and social science, which can contribute to the efforts of the EPT PREPAREDNESS AND RESPONSE project (P&R) and ONE HEALTH WORKFORCE project (OHW). Together, we will continue to advance technology and improve local efficiencies and capabilities by harnessing our collective procurement, communication, and training strengths in support of the surveillance, laboratory, and outbreak activities proposed here.

1.8. Assistance to host country partners in outbreaks

Outbreaks in people and animals (domestic and wild) are real-world, real-time viral events that present unique opportunities for assisting collaborating country governments and applying animal sampling, pathogen discovery, hazard mitigation, and risk communication strategies under realistic scenarios and timelines. Furthermore, they are excellent scenarios under which the strengths and strategies of PREDICT-2, as well as P&R and OHW, can be demonstrated and tested. We will build upon previous outbreak experience to better understand the biological and ecological drivers, as well as the human behaviors and practices that contribute to virus evolution, spillover, amplification, and spread. Our teams will be trained, equipped, and supplied in a constant state of preparedness for contributing technically and substantively to focused outbreak response, including employing human-animal contact survey activities. Outbreak response synergies will result from strong ministerial linkages and institutional collaborations already in place (or built as needed), positioning PREDICT-2 teams for invitation by in-country governments from the outset, and allowing for close coordination with FAO, CDC, DOD/DTRA, and WHO partners. Data gained in conducting targeted surveillance during and between disease outbreaks will inform on new or modified policies and practices for outbreak preparedness and response, which will form the basis for coordinating with EPT P&R and OHW partners on recommendations to national task forces, One Health platforms, and the plans and activities of the Global Health Security Agenda (GHSA) partners and others.

Objective 2: Behavioral risk characterization

Human behaviors and practices are key risk components for pathogen spillover, amplification, and

spread. High-risk behaviors of people living and working in close contact with domestic and wild animals directly influence their zoonotic disease risk. We will characterize the type and frequency of contact among people, domestic animals, and potential wildlife reservoirs and investigate the correlation of specific human behaviors and zoonotic disease risk across sites, combining qualitative and quantitative methodologies to more deeply understand the behavioral mechanisms of high-risk pathways for disease emergence and spread. We will identify potential control points and behavior change options, field-piloting strategies to gauge individual and community willingness and uptake potential in order to determine which behavioral change interventions might be taken to scale. We will also focus on high-risk behaviors outside these pathways when and where there is specific evidence for pandemic risk identified through biological surveillance and qualitative research.

Activities characterizing behavioral risk will be disaggregated by age, sex, social/ethnic group, and livelihood strategy, and paired with wildlife, domestic animal, and human viral surveillance in each high-priority epizone. These investigations will fill a global need for more data and analyses on the diversity of high-risk activities, occupational risks, and age- and gender-specific hazards that will inform realistic and practical intervention strategies to support EPT and GHSA goals.

2.1. Standardized approach to study human behavioral risk

We will combine quantitative and qualitative research methods to identify and monitor behaviors, attitudes, practices, and socio-cultural norms and conditions that facilitate animal-human and animal-animal contact and influence the spillover, amplification, and spread of zoonotic pathogens. Risky behaviors and practices will be characterized through standardized surveys and observation of contact events (defined by direct and indirect transmission modalities). We will use extensively field-piloted surveys to initially characterize behavioral risk. A combination of quantitative household surveys, human- animal contact questionnaires, direct participant observation (focal follows), qualitative structured interviews, ethnographic observation, and participatory focus groups with people living or working in sites within defined high-risk pathogen emergence and transmission pathways will be conducted.

2.1.a. Overall approach: We have brought together a talented team with extensive experience in behavioral studies. In addition to the advantage realized by the training and expertise of the new members, the whole team will benefit from the experience gained during PREDICT-1, in which behavioral studies were designed directly in concert with the novel work of zoonotic viral detection and the identification and characterization of spillover and further transmission risk from wildlife. Our approach is designed to be iterative and begins with targeted ethnographic assessments and observations conducted in natural settings at biological and ecological surveillance sites. These provide a framework to gain rapid understanding of human-animal interactions and the actions/meanings surrounding these interactions, as well as for the exploration of unanticipated knowledge, such as the presence and rationale for taboos on certain human-animal interactions. These data in combination with the knowledge base already developed by in-country teams during PREDICT-1, will directly inform the development of detailed surveys with a consistent and systematic approach across countries for all three pathways but with specifics tailored for successful administration in each country and culture.

Alignment of the behavioral studies will coincide with the biological surveillance to maximize the understanding of risk and reconcile information gathered on transmission risk with the actual presence of potentially zoonotic pathogens. Timing will roughly coincide across countries, so that training and initial work is completed in the first 18 months, full surveys will

begin in year 2, analyses will be conducted in year 3, and in-depth potential intervention point surveys will continue in years 3, 4, and 5. Triangulated analyses that incorporate ethnographic, observational, and behavioral and biological survey data will be used to identify very high-risk potential intervention points. This process will be used to garner a greater understanding of the potential intervention points, as well as to inform directions for activities and evaluations of pilot interventions.

Country Coordinators will oversee the work. However, they will not be completely responsible for the design and supervision of the activities. Work will be undertaken by local teams, which may include small subawards to local experts, such as anthropologists and social scientists at local universities. We do anticipate hiring at least one employee under the Country Coordinator to be the local Point of Contact (PoC) for the behavioral studies in each country who ideally has some training in this area. These PREDICT-2 behavioral risk PoCs will be recommended by local partners, vetted by the Country Coordinators, and jointly interviewed and hired by the Country Coordinator and the Senior and/or Deputy Behavioral Risk Coordinators. Just as was done in PREDICT-1 for biological surveillance, training modules will be developed by the globally-based Behavioral Risk Team in conjunction with local partners to ensure quality and consistency across countries and to facilitate training of all local teams. Also similar to PREDICT-1, global personnel from the Behavioral Risk Team will travel to each country to deliver tailored training on the developed protocols specific to the needs of the in-country personnel and partners.

2.1.b. Building upon previous behavioral studies: In PREDICT-1, we systematically conducted behavioral risk characterization in three countries for the Deep Forest project, only two of which are within the geographic focus of PREDICT-2: Malaysia and Uganda. These household surveys were conducted along only one of the pathways (land conversion) proposed for PREDICT-2, not along animal production or trade pathways. We will therefore build upon these two studies by: 1) adding the other proposed approaches (e.g. ethnography and qualitative work described below); 2) conducting larger, deeper surveys (e.g. including children because their behavior is likely to be different and important for zoonotic risk); and 3) conducting surveys along the two other pathways for emergence. While these activities are resource-intensive, we will balance the resource needs by being more focused in our locations and scope of questions and having a better estimate of required sample sizes (based on our Deep Forest experience). This effort will validate the data generated from the surveys as well as account for recall error and biases. For instance, from preliminary Deep Forest data on human-animal contact, we know that self-reported data on hunting can be less reliable in countries where it is explicitly illegal and laws are enforced. In PREDICT-2, the focal follows, ethnographic, and observational studies described below will allow us to collect data on the frequency of contact with different animals and specific behaviors that may be associated with both increased risk and avoidance of detection by authorities.

2.1.c. Structured surveys and ethnographic data collection: Standardized surveys, open-ended interviews, focus groups, and focal follows will be conducted to characterize behavioral risk in all intensive countries. Data collection will involve quantifying the frequency, type, and duration of observed or reported contact events with wildlife and domestic animals. Data will be collected on zoonotic risk behavior and risk perception pertinent to regional beliefs and practices, for example behaviors associated with bushmeat hunting, butchering, and market visitation in the Congo Basin and wet market practices in Southeast Asia. A standardized subset of questions will be included in all surveys administered across pathways and epizones to generate comparative data on

behavioral risk. Special attention will be given to contact with animals identified through biological surveillance as potential zoonotic pathogen reservoirs (i.e. wildlife) or intermediate or amplifying hosts (e.g. pigs, poultry, cattle, camels). Data will be disaggregated by age, sex, social/ethnic group, and livelihood strategy. Sub-populations identified as having high rates of contact will be targeted for viral surveillance if not already included in the biological surveillance strategy. For example, because many animal handling practices (raising, butchering, selling in markets) are socially and culturally circumscribed to women, women will be considered a particularly important sub-population, and gender roles will be explored in-depth to gauge relative zoonotic risk within communities. Comparative data that will emerge from these surveys include: (1) types of animals contacted; (2) the frequency, duration, and type of encounter with key animals and potentially infective fomites; (3) characterization of indirect contact (i.e. contaminated food or environment); (4) how contact may vary by ethnicity, gender, livelihood strategies, and other socio-economic factors; (5) activities associated with high levels of contact with key animals; (6) livestock abundance and interactions with wildlife and people; (7) economic incentives that drive high-risk activities; (8) perceptions and awareness of disease transmission; and (9) economically-viable alternatives to high-risk activities. Findings will be informative for training in EPT OHW and for providing technical and operational assistance during outbreak investigations. In addition, to assess the mobility of populations within emergence and transmission pathways and across epizones, we will use a standardized occupancy survey to spatialize human occupancy and further characterize contact risk.

2.1.d. High-risk Pathways for disease emergence and spread:

i)**Land conversion for commercialization:** Particularly intense land use change in tropical regions supports behavioral drivers that may directly facilitate contact between potentially susceptible hosts and novel pathogenic microbial communities, especially where primary forest is opened up for mining, logging, plantation development, oil and gas extraction, encampments, and developing tourism.

- Focal follows: This method has previously been used by social scientists interested in assessing foraging patterns and human-animal interactions, including pathogen transmission between humans and non-human primates. Focal subject follows involve observing a particular individual for up to 24 hours and recording the specific activities in which the individual is engaged. Since self-reported data on hunting and other particularly high-risk activities can be unreliable, we will supplement data by following high-risk focal individuals during daily activities, using trained observers from within the local communities.
- Ecotourism/recreation surveys and global travel: Within this pathway and in many countries where wildlife populations are diverse and charismatic, ecotourism and other recreational activities bring an added risk for pandemic emergence, bringing travelers into contact with wildlife and people who contact animals frequently. We will target travelers and the workers that support them to examine their contact with wildlife and their health at the time of exposure to evaluate the overall epizonal risk and likelihood of global spread. In addition, broader surveys of travelers will assess willingness of individuals to travel in different health states to PREDICT-2 countries and will be used in combination with publically available travel data to continue to refine the risk of global spread of EIDs.
- Occupancy survey for human migration/mobility: Additional survey effort will be employed at high priority sites using a randomized point or transect survey design to get an unbiased estimate of the number of people occupying and moving through landscapes with varying characteristics. We will use geographic information systems (GIS) to develop spatial models

from these surveys that will use environmental and geographic covariates to produce an overall human occupancy map for each appropriate epizone. These data will complement currently available human population density maps that are frequently used in associative analyses of disease emergence, providing a more accurate picture of human occupancy by accounting for human population movement, rather than relying on the usual method of fixed household data censuses. Results will support EPT P&R efforts and local WHO programs.

ii) **Intensification of animal production systems:** To characterize behavioral risk in domestic animal farming systems and build upon the work conducted to date by FAO, we propose to implement a targeted occupational health study to identify specific behaviors and practices that could increase risk of cross-species transmission, viral amplification, and spread. We will also use observational studies (as described above) to characterize livestock production systems across an intensity gradient (rural systems, intermediate/peri-urban systems, large intensive farms) following FAO frameworks. We expect that zoonotic virus amplification in livestock production systems will increase with the degree of intensification primarily due to increased host animal density (as reported for H5N1 influenza) and also by facilitating novel interactions among species that may have had no prior contact (as reported for Nipah virus in Malaysia). In conjunction with FAO, we will support work examining how intensification also encourages greater frequency of movement of people and vehicles on and off farms for animal exchange and export to market, which may further increase the risk of pathogen spread.

- Occupational Health Study: In cooperation with our in-country teams, local health and agricultural agencies, FAO, and other agencies where appropriate, we will implement a standardized survey to identify people with exposure to domestic animals (and farmed wildlife). We will recruit participants for biological sample donation to correlate viral infection with specific behaviors and practices that may increase risk of exposure, including collaboration with local hospitals receiving individuals when presenting with symptoms. In conjunction with our biological surveillance in intensive countries, we will implement longitudinal cohort surveys with highly exposed farmers, transporters, and market workers. We will use serological tests for viral exposure in the longitudinal cohorts, as well as viral-family PCR screening for people when they are ill. We will thus be able to monitor past exposure and circulating viruses and potentially identify spillover in cohabiting human/animal populations, as well as identify emerging diseases of unknown origin.
- Observational studies: In conjunction with FAO and using existing data to target study sites, we will characterize the three levels of intensification in domestic animal farming systems including measures of animal abundance; type of enclosure; number of enclosures on the farm; approximate size; and general observations on farm structure, conditions, and hygiene (fecal matter in enclosure, mixed species, number of animals, open/ventilated, etc.). We will also assess other risky practices such as slaughtering, butchering, close contact with animals in high-density production (closed spaces), and other biosecurity risks.

iii) **Animal value chains:** Identified by some as the highest risk setting for the emergence of pandemic threats, animal value chains may present the best targets for pandemic prevention and strategic intervention. Therefore, we will investigate human behaviors that contribute to risk in this pathway.

- Systematic behavioral studies will employ standardized survey and observational methodologies described above to assess risk in animal value chains in selected countries at key locations within identified epizones. Specific data to be collected include species composition in markets, origins and types of products, volume, length of time in market, condition of animal meat, market size, market structure, proximity of live animals to one another, sanitary conditions, and human-animal contact type and frequency.
- Consumer surveys and market observations: In collaboration with FAO where feasible, we will determine which factors drive food preference, purchase, and consumption. Data from market and consumer surveys will be used to inform policy by evaluating and communicating the relative contribution to market disease risk by: variety and volume of taxa sold in markets, rate of animals turnover, sources of animals sold, location and method of slaughter, ethnocultural and socioeconomic influences on consumption decisions, and the revenue generated from live or butchered animals at each stage of the value chain.
- Wildlife farm surveys: We will conduct behavioral contact surveys and in-depth structured interviews of wildlife farmers and workers and economic analyses of wildlife farming to assess the risks and viability of alternatives to wild-origin trade in parallel with in-depth viral characterization of animals and people on farms.

2.2 Incorporating behavioral data into predictive models

We will measure key indicators of high-risk contact (e.g. frequency of contact, type of contact) among demographic groups (gender, ethnicity, age, location, religion, etc.) in order to identify subpopulations at high risk. We will use multivariate analyses to determine the relationship between high-risk contact indicators and land development index (for pathway 1), farming system change data (for pathway 2), and animal product demand data (for pathway 3), as well as metrics of ethnicity, gender, age, religion, socioeconomic status, knowledge, and attitudes, to understand the factors that influence different types and frequencies of contact. Specific high-risk contact behaviors commonly reported and associated with increased risk based on biological surveillance data will be targeted for further in-depth study to advise on suitable intervention approaches.

Quantitative data on human-animal contact generated from the surveys will be combined with biological and ecological surveillance data and used to predict spillover risk across targeted landscapes. Data from the behavioral surveys will inform on two components of our spillover risk model: 1) the probability of contact and 2) the probability of transmission. These data will be integrated with the biological and ecological surveillance data to evaluate risk among the three different disease emergence pathways (land conversion, animal production systems, and animal value chains) to identify key targets for disease control and behavior change. Contact rates will be extrapolated by combining survey population data on particular behaviors (consuming wildlife, butchering animals, working in markets, etc.) with demographic-specific population density data to arrive at population level behavior and exposure estimates.

2.3. Identification of potential intervention points

We will integrate data from biological surveillance, behavioral risk characterization, and economic and anthropologic studies using a dynamic analytical framework to identify potential targets for intervention to reduce the risk of viral amplification and spread. The framework builds on analytical approaches described elsewhere in this proposal, including extrapolating risk to the landscape and comparing the relative risk of similar systems in different countries. The framework is dynamic

because it can be used in combination with data on sampling and testing, as detailed above, to assess rapidly- evolving situations (e.g. a new wildlife farming system or a newly reported wildlife trade market chain) in a timely manner. We will use micro and macro-level behavioral and socioeconomic analyses for each pathway to identify the incentives for high and low-risk behaviors and the likely acceptability and cost-effectiveness of potential alternatives. This activity will be conducted with governments, experts in the field, and other EPT-2 partners to help identify and pilot evidence-based intervention points at the population level and determine topic areas where zoonotic risk-reduction interventions might be taken to scale at a regional level to support EPT P&R and OHW and for consideration by in-country governments and USAID for additional uses.

Objective 3: Global surveillance networks and analysis

Access to accurate, comprehensive, and timely biological surveillance and behavioral risk data is critical to predicting and responding to emerging diseases. Efficient data sharing and exchange is maximized through the use of user-friendly and standardized data organization platforms and ensures that information collected by disparate parties can be seamlessly integrated for detection of early warning signals, as well as for multi-national analyses across epizones. Our integrated consortium will use an internal data storage and sharing platform that will improve the ease of collection, synthesis, storage, access, and dissemination of relevant animal and human (age- and sex-disaggregated), spatially-explicit epidemiological, and ecological data that will help countries comply with IHR and OIE reporting obligations.

3.1. Standardized data collection

3.1.a. Standardized human and animal data management:

We have created an internal information networking system that has facilitated data collection in over 20 countries across disparate ecological, cultural, and linguistic situations and facilitated sharing of those data with country governments, international organizations, and the general public. Together with our partners at HealthMap, who implemented field data collection tools in the aftermath of the 2010 Haiti earthquake (OutbreakMD) and the 2010 Deepwater Horizon oil spill (GulfMedic), we will further refine our system to develop and deploy new field data collection tools to improve the data entry interface. Specifically, we will adapt these tools to optimize collection of standardized data on human and animal hosts and pathogens; behaviors and risks of disease emergence; and drivers, ecological conditions, and transmission interfaces (as well as other critical epidemiological information) during standard surveillance and outbreak situations. Deployment of improved data collection tools will reduce the time associated with data collection and curation, as improved point-of-entry validation tools will reduce the need for labor- intensive data cleaning and verification. We will improve our current data entry temporal standards (e.g. within 2 weeks of data collection) by using tools that reduce the need for recording data on paper and subsequent transcription (i.e. allowing electronic entry of data at time of sample collection). We propose to align standardized data collection approaches for both known and novel viral detection and influenza monitoring activities, across the three pathways, so as to construct longitudinal datasets and allow insight into ILI, SARI, FUO, and their underlying etiologies. We will work to develop the capacity for these databases to be hosted and managed locally, yet enable controlled sharing globally.

3.1.b. Biosurveillance data collection:

To further add to the world's understanding of novel disease emergence events (beyond EPT-2 activities) and help target PREDICT-2 surveillance strategies, publicly available information

(ProMED and HealthMap) on emerging diseases will be collected, filtered, geo-referenced, and integrated with human and animal field surveillance data.

i)HealthMap alerts are reports of disease outbreaks, collected by HealthMap's automated process. Updating 24/7/365, the system monitors, organizes, integrates, filters, visualizes, and disseminates publicly available information about these priority diseases. PREDICT-2 surveillance data will be provided to host-country governments as test results are finalized and interpreted and, combined with HealthMap alerts, will deliver near real-time intelligence on a range of emerging pathogens to governments for near real-time intelligence to inform on disease surveillance and mitigation actions, before public release authorization is given by the government. The process of internal (government) circulation of data is at the discretion of our ministry partners and does not preclude eventual public release of data. We will work with our government partners to reduce the time it takes for public release of data, with a goal of eventual "near real-time" public release of data, with the caveat that this release is always at the discretion of our government partners. Because the HealthMap alerts are derived from publicly available information (e.g. news stories, blogs, press releases etc.), they do not require data sharing authorization. As in PREDICT-1, we will continue to work with ProMED and HealthMap to optimize the digital searches to report improved public data on the HealthMap PREDICT interface.

ii) In addition to tracking disease events reported digitally, we have developed a low-cost local media surveillance program and tools for tracking rumors (e.g. the Vaccine Sentimeter, http://www.healthmap.org/viss/) that we propose to adapt to track and distinguish between "good" (reliable) and "bad" (unreliable) outbreak rumors. Our process for distinguishing "good" and "bad" rumors (i.e. distinguishing signal from noise in remotely sensed, digital media) involves a multi-stage process wherein reports are evaluated based on source reliability, report redundancy, or repetition (e.g. are there multiple sources for the report?), language on certainty in the report (e.g. suspected versus confirmed), as well as likelihood of the report given our epidemiological understanding. Validated reports will then be integrated into the PREDICT public data site (www.healthmap.org/predict) and used along with other data sources to provide information to host-country governments, USAID, EPT partners, and other partners on developing epidemiological situations as they arise. For example, during the Ebola outbreak in Uganda in 2011, daily summaries of validated media reports were provided to USAID and PREDICT staff who participated in the Zoonotic Disease National Task Force.

iii) We also plan to employ biosurveillance platforms to move beyond the reporting of events to increase pre-event awareness. Building on the success of the wildlife trade surveillance tool (healthmap.org/wildlifetrade), we propose to develop an experimental "outbreak sensitization" tool that maps real-time alerts on known disease drivers and integrates them with hotspot data to provide information to local health stakeholders and EPT OHW and P&R in order to sensitize them to the potential for disease events. EPT partner staff in PREDICT-2 countries will be trained in the use and management of these data, linking to better response and contributing to countries meeting IHR standards.

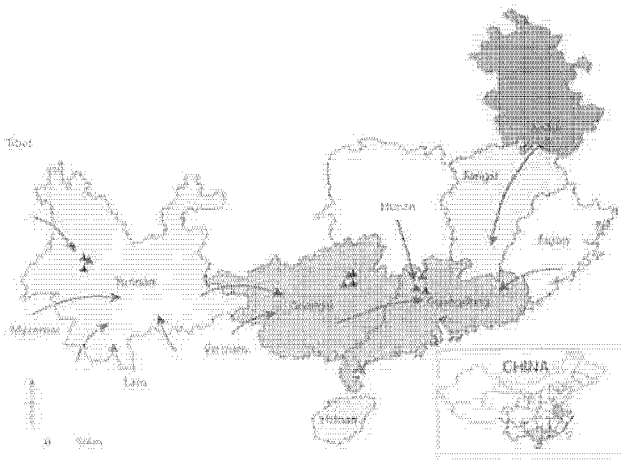
3.2. Global data synthesis

We will build on and extend the Global Animal Information System (GAINS) to create a new secured and internal globally accessible database to house aggregated (anonymized) human behavioral risk, biological surveillance, and outbreak information. Once approved for release by participating country governments, data will be made freely available through the public facing side

of PREDICT-2's dissemination tools (see 3.3 below), along with novel analytic and visualization tools.

3.2.a. PREDICT-2 database: In order to meet national and international privacy regulations and local country government requirements for data collection and release, we will use an internal database for the consortium that will provide the access and integration capabilities necessary for biological, ecological, and behavioral risk characterization, as well as tracking for progress on project deliverables and for annual data reviews (Obj. 6). Linkages will be created to allow national governments to link local databases to the PREDICT-2 database for integration of PREDICT-2 data collected in their country into national systems. Specifically, we will expand the current internal PREDICT database, the Global Animal Information System (GAINS), which currently includes data on animal hosts and associated diagnostic testing, to house additional data to enable examination of broader epidemiological dimensions of disease emergence. Thus as we move forward, for all sampling sites and events we will be able to include data on the animal hosts sampled, anthropogenic drivers and interfaces, and human behavior risk factors for analysis in the context of the pathogens present. This enhanced system will allow us to combine and examine data as needed for presentation by PREDICT staff to host-country governments, USAID, and EPT and other partners in a manner that provides a comprehensive view of the processes of disease spillover and amplification.

3.2.b. Development of an open access database on global respiratory pathogens: Publicly releasable data collected during PREDICT-2 will be integrated with influenza monitoring databases (e.g. EpiFlu). In addition, a specimen-information repository will be developed to allow researchers and public health officials to deposit and exchange metadata on respiratory illnesses to facilitate specimen exchange, matching those with specimens to those with the diagnostic capabilities to determine etiologies. Measures to protect data sharing agreements between providers and diagnostic laboratories will be implemented. These data will be integrated with formal and informal data on respiratory cases obtained via web-mining of HealthMap and curation by ProMED.



3.2.c. Identifying and characterizing changing epizones for viruses with known pandemic potential: As described above, we will employ an epizonal approach that encompasses geographic, ecological, and sociological space, from pre-spillover conditions through transmission of zoonoses to circumstances of pathogen amplification and spread. Thus, data collection, organization, and integration tools will be critical for ongoing identification and characterization of active epizones. For example, the epizone for SARS-CoV includes the wildlife markets of Guangdong where it amplified and spread, but also the whole wildlife trade along Southern China back to Yunnan Province, where we identified an unusually diverse cluster of bat SARS-like CoVs capable of infecting

human cells (see figure at left). We will use global data extractable from our platforms to conduct combined phylogeographic, ecological, and epidemiological analyses to better define and recognize epizones for known and novel viruses and identify regions within these epizones where viral evolution is enhanced and pandemic potential increased.

3.2.d. Actionable surveillance improvements and risk mitigation strategies will be developed throughout the PREDICT-2 project. We will use modeling and other analytics to evaluate optimal surveillance strategies for biological and behavioral data collection. As the results of PREDICT-1 are being analyzed now, we anticipate honing our surveillance strategies even further than proposed here based on the most productive data sources in PREDICT-1 (interfaces, locations, prioritized viral families, etc.), just as we have done with sample size estimates and sample type and host selection throughout PREDICT-1. Modeling platforms are constructed as concepts of pathogen risk develop within and outside of the EPT team, and modeling outputs are generated regularly (weekly to monthly), as the platforms are optimized and new data become available. There was a disconnect in this process during PREDICT-1 because of the necessary time lag needed to build sampling and laboratory capacity. The capacity building in those areas now being successful, we anticipate more real-time adaptive management of the surveillance arm of the project using modeling and analytics. That said, these adaptive changes have always occurred and will continue – what will primarily be different is the communication with USAID on how we are using the data and models in order to base internal decisions. We do not anticipate a dramatic change in the pace at which modeling activities are generating information for a broader, public audience. The most appropriate use of PREDICT-2 models will be to improve surveillance strategies and generate further hypotheses regarding pathogen emergence, amplification, and spread. We do, however, anticipate testing those hypotheses and validating the generated models with PREDICT-1 and -2 data on an on-going basis throughout PREDICT-2. We will also generate intervention and control scenarios and analytically evaluate probabilities for best investments using mathematical models. These will be run on an on-going basis, first based on likely assumptions and then refined as appropriate data are generated by PREDICT-2 and the collaborating EPT partners.

3.3. Global data dissemination

Ultimately, data are of use in disease forecasting, prevention, response, and mitigation strategies only if available to the stakeholders that require them for decision-making. Local authorities will be provided with PREDICT-2 results for policy use, response, and meeting IHR and OIE reporting obligations either via PREDICT-2 country coordinator communications or directly via linkages between the PREDICT-2 database and national systems. PREDICT-2 data released for public access by governments will be distributed using a globally accessible public portal www.healthmap.org/predict. We will also incorporate processed risk-characterization data, coupled with clearly documented cross-cutting forecasting of risk resulting from the characterization process.

3.3.a. Specific types of data and information that we will make accessible through this portal or that our website will include:

i)**PREDICT-2 standardized biological surveillance data**, including potential pathogens

detected.

ii) **Database on influenzas and other respiratory pathogens**, including a repository of metadata on available human respiratory illnesses of unknown origin and PREDICT-2 surveillance data on zoonotic viruses of known and unknown pandemic potential. This database will include analytic, forecasting, and visualization tools. Role- based security will be implemented so as to allow health officials access to surveillance data collected in their countries before data are approved for general public release, as necessary.

iii) **Digital disease alerting data** from systems such as HealthMap and ProMED. We will also provide push alerts so that stakeholders can be immediately notified of disease alerts and new samples collected.

iv) **Baseline risk information** developed through ongoing analyses, such as hotspot forecasting.

v) **Training materials and tools for real-time data collection and management during outbreaks** (e.g. the PREDICT data collection tool described above, Epi Info, NovaModeler etc.) shared with EPT partners.

vi) **Protocols and guides** for conducting biological surveillance and behavioral risk characterization (made available in multiple languages upon request) and shared with EPT OHW, P&R, and other EPT partners.

3.3.b. Global data dissemination goal: Facilitate sharing and integration of PREDICT-2 and other host country data on behaviors related to disease risk and surveillance and test results into global data streams to support IHR, OIE, and GHSA goals of data sharing. Training on how to access and utilize the data and project findings will be conducted in several ways. First, as a readily available online resource, written guides and protocols developed in PREDICT-1 and -2 will be shared to provide detail to in-country teams for working with the data sets and platforms. Additionally, webinars and workshops for interactive training will be offered to introduce end-users to key aspects of the data sets and platforms while providing a forum for them to also ask questions. Specific training sessions may be provided to focus on the basic skills needed to manage and analyze data such as bioinformatics, epidemiologic analyses, and risk mapping. The goal is to build intellectual capacity and enhance the abilities of stakeholders to appropriately interpret and analyze data. As the training gaps and most useful platforms are identified across EPT partners over time (see above), our training materials and workshops will be updated to address the current needs of end-users in an effort to facilitate science-based management. We anticipate that even more useful to many decision makers than the data themselves will be the syntheses and interpretations that our expert in-country project teams will produce in the form of regular project updates, reports, and publications. These products will be shared with stakeholders and ministries as they become available, and meetings will be held to discuss the findings, train on interpretation and implications, and foster dialogue to move towards science-based policy development that enhances cross-sectoral collaborations and helps to prevent disease emergence.

Objective 4: Validation of One Health approaches

Our team assisted in developing the World Bank's report "People, pathogens, and our planet: the economics of one health", which explored country investments in One Health infrastructure and the potentially realized cost efficiencies. It documented continued keen interest from country governments and international organizations for implementation of One Health strategies but highlighted that a concerted, coordinated, and comprehensive valuation of the benefits of and best

practices for adopting a One Health approach has not been formally conducted. Building on the One Health practices operationalized in EPT-1 countries and at global levels, we propose to undertake a systematic and dedicated effort for validating One Health approaches by gathering and evaluating data and presenting One Health case studies. EPT lessons learned will be utilized along with comparative data available from other national and regional activities to evaluate the utility of One Health approaches using all available evidence.

4.1. Promoting policies and practices that reduce the risk of virus evolution, spillover, amplification, and spread

4.1.a. Multidisciplinary and inter-ministerial best practices: We believe that One Health approaches can assist in the development of more integrated high-level interventions for the reduction of risk from emerging pathogens. Working with EPT partners (locally and internationally), we will develop the evidence base to support the strategic application of these policy approaches, as well as their institutionalization.

i) Case studies: We will compile and create case studies for situations in which a One Health approach has been used, backed with economic analyses (when available), as well as outcome measures (e.g. DALYs, incidence, mortality, joint multi-departmental, multi-sectoral training or surveillance activities; qualitative data, etc.) to provide evidence-based support for One Health strategies. In-country government partners, as well as partners from other EPT-2 projects, FAO, WHO, CDC, World Bank, and other local, regional, and intergovernmental entities will be engaged in prospective and retrospective assembly of information to validate the use of One Health approaches, complemented by findings from literature and external data that can be applied to EPT-2 contexts.

ii) Gender equality and integration of under-represented populations: We will gather and analyze data on gender equality and integration to elucidate how comprehensive representation contributes to a more successful One Health approach, noting that unique determinants may influence gender-specific risks, as well as the success of risk mitigation and prevention strategies. We will work with P&R to help determine and encourage best practices for overcoming gender bias in One Health efforts, as well as provide information to P&R, OHW, and other EPT partners on populations that could be further integrated into One Health approaches (e.g. economically, culturally, and occupationally).

4.1.b. Support for national One Health platforms and outbreak response: Through assessment and validation of approaches that facilitate broad and sustained engagement, including data sharing, sufficient workforce development, improved technical capacity, and harmonization of disease surveillance systems, we will contribute to overcoming the obstacles of disciplinary silos at local levels that have impeded public health progress. Working with EPT partners at local levels and in the context of meeting IHR and OIE reporting obligations, we will support efforts to more effectively utilize One Health platforms.

4.2. EPT-2 Partner coordination

4.2.a. The EPT Liaison: Because of the scope and complexity of the EPT Program, we propose the inclusion of an EPT Liaison at the Key Personnel level (see Staff section below). The PREDICT-2 EPT Liaison will promote strong communication and data sharing opportunities that support One Health approaches throughout the EPT-2 programs themselves and in partner countries and international forums. Together, we believe our efforts in close

coordination with other EPT-2 partners and stakeholders (especially FAO, CDC, WHO, OHW, and P&R) will demonstrate the value of adopting One Health approaches for biological surveillance, capacity building, and outbreak response, in terms of indicators such as cost, time efficiency, and health outcomes, as well as investments in One Health training and curricula development. The EPT Liaison will manage the processes of disseminating information and best practice guidance (see 4.2.d. below) to policy makers, increasing the likelihood of adoption of One Health-promoting policies and practices for national preparedness and prevention efforts. The impact will be further broadened by engagement with policy processes and policy-making institutions (including private sector) at local, national, regional, and international scales. For example, at country levels, coordination will be promoted with EPT-2 program partners, including local agencies representing health, livestock, and wildlife, and local implementing representatives of USG agencies and global organizations, including FAO and WHO, to jointly share One Health validation findings and best practice recommendations. Concurrently, efforts will also occur at global levels, by collaboratively engaging with leadership of EPT-2 and GHSA partners and intergovernmental organizations to broaden support and resources for One Health approaches.

i)The PREDICT-2 EPT Liaison will promote strong communication and data sharing opportunities that support One Health approaches throughout the EPT-2 programs themselves and in partner countries and international forums. His focus will be on communications with the FAO, CDC, WHO, OHW, and P&R, as well as making sure that the country coordinators are making all efforts to maintain active and productive communications with in- country partners, especially USAID Missions and host-country ministries. The EPT Liaison will manage the processes of disseminating information and best practice guidance, including dissemination of the following through in-person, electronic, and conference call communications:

- Annual Global Key Findings Review meetings with USAID and EPT-2 Partners
- Organized quarterly or semiannual conference calls or webinars on topical areas, such as behavioral studies, surveillance, analytics, gender equity, etc.
- PREDICT-2 quarterly reports (or sections of reports indicated by USAID)
- Quarterly country-level reports or written briefings (similar to bulleted country-specific Quarterly Partner Updates in PREDICT-1)
- Country Coordinator updates on activities and findings at quarterly or monthly country-level meetings as determined by the USAID local Mission
- Monthly or biweekly telephone updates with USAID for key PREDICT-2 staff
- Public posting of results from human, livestock, and wildlife testing on the PREDICT-2 public website (through HealthMap) as soon as approved by government authorities
- Updated protocols and guides for conducting biological surveillance and behavioral risk characterization

ii) In addition, the PREDICT-2 EPT Liaison will examine One Health case studies within the PREDICT-2 countries and begin to amass a case for implementing One Health approaches if the data continue to support the paradigm shift. He will draft messages for policy makers, increasing the likelihood of adoption of One Health-promoting policies and practices for national preparedness and prevention efforts. The impact will be further broadened by engagement with policy processes and policy-making institutions (including private sector) at local, national, regional, and international scales. If possible, the capacity for achieving articulation with the policy process will be developed with the Country Coordinators through

hands-on training and webinars. Concurrently, efforts will also occur at global levels via the EPT Liaison and other PREDICT-2 Key Personnel collaboratively engaging with leadership of EPT-2 and GHSA partners and intergovernmental organizations to broaden support and resources for One Health approaches.

iii) On an *ad hoc* or requested basis, we will also provide to USAID and other EPT Programs (as indicated by USAID):

- Immediate notification of findings of urgent public or animal health significance
- Activities and findings from participation in emergency response activities
- Analyses and graphical interpretations of key findings as agreed upon with USAID and PREDICT-2 staff (similar to quad charts developed at the end of PREDICT-1)
- PowerPoint presentations developed on project findings
- Briefing Sheets on specific topics, findings, or trends
- Updated risk information developed through ongoing analyses, such as interface characterization and hotspot forecasting
- Case studies on One Health approaches, backed with economic analyses and outcome measures (e.g. DALYs, incidence, mortality, etc.) to provide evidence-based support for One Health strategies, as described above
- Meetings with USAID and other EPT program personnel to collaborate on efforts stemming from project findings or trends
- Peer-reviewed publications to increase awareness in the public health community and drive pandemic prevention strategies globally

4.2.b. Surveillance and outbreak response: Through ongoing coordination with partners, we will monitor where One Health approaches are being utilized in surveillance and outbreak response situations for comparison with other contemporary (single-silo) outbreak responses to determine differences in effectiveness, using indicators such as frequency of outbreaks, length of time to outbreak containment, morbidity and mortality, and identification of animal host species involvement. Where identified, the costs of disease outbreak response and control measures will be compared to costs of implementation of One Health strategies to calculate and demonstrate potential savings from prevention obtained through One Health approaches. Given its health and economic impacts, cross-species transmission potential, and viral evolution dynamics, influenza will provide ample opportunity to investigate this objective and will offer common ground for working closely with FAO and WHO in gathering information. Additionally, official reports submitted to the OIE will provide further insight on species and numbers of animals affected by reportable diseases to feed into assessments of impacts of influenza and other diseases as part of the evaluation of One Health approaches.

4.2.c. Advancing socioeconomic arguments: In year three, we propose to organize a workshop with the World Bank in collaboration with USAID and other EPT-2 and World Bank stakeholders. The workshop will conduct an evaluation of new information at the five-year mark of the World Bank's report on One Health investments (published in 2012) and be designed to yield information for the production of a number of audience-targeted documents with evidence-based guidance on where One Health approaches are highly suited to assist in the prevention and control of emerging pandemic threats. We will also conduct global scale analyses of the economics of pandemic mitigation vs. adaptation policies directly applied to the World Bank/FAO One World, One Health capacity building plan.

4.2.d. Sharing of lessons learned among EPT projects: We will use information acquired

and best practices developed in the implementation of biological surveillance and behavioral risk characterization to help identify core competencies that can be proposed for incorporation into curricula for the One Health Workforce (OHW). Specifically, insight gained about the type and structure of cost-effective investments in a One Health workforce, as well as the multidisciplinary sectors represented and associated core competencies, will be shared with the OHW project on an ongoing basis and at the annual data sharing meetings. Additionally, evidence-based strategies will be validated for their use in support of effective One Health platforms and shared accordingly with the P&R program to inform best practices and activities being implemented at national levels. Tools developed by PREDICT-2, including mechanisms for promoting gender equity in risk assessments and population-based interventions, sampling and testing protocols, human-animal contact surveys, and outbreak response planning practices, will be shared with the P&R project and other EPT partners for utilization in national preparedness plans for public health events. Additional support for hands- on training and curriculum development is described below.

Objective 5: Overall capacity strengthening

We plan to add depth and scope to trans-disciplinary One Health platforms using a systems approach to classify and track biological surveillance and behavioral risk characterization advances, thereby strengthening the capacities of the surveillance systems in each PREDICT-2 country and region. An adaptive management style will be utilized to assess progress and set capacity building priorities on an annual basis so that the most current information can be used in response to key opportunities and challenges. Activities will build on and support all strategic areas of focus for EPT-2; however, key areas of emphasis will include increasing technological capacities in collaborating laboratories and expanding to include more human and national laboratories in coordination with FAO, CDC, and WHO, as well as enhancing information management and data analysis through technology transfer and training for in-country collaborators and host country governments.

5.1. Systems approach to capacity building for wildlife, livestock, and human surveillance

We will focus on continued training for field sampling and survey design, advanced laboratory training, information management, and technology transfer to address all areas from managing field data to tracking laboratory samples and results. In addition, introductory sequence analysis and epidemiologic data analysis, risk assessment, and cross-sectoral collaboration strengthening will be introduced. Within each PREDICT-2 country, five core components will be evaluated and tracked over time:

i)Biological Sampling and Behavioral Survey Design: Continued protocol refinements for animal and human sampling and behavioral surveys will be made and distributed in multiple languages. Similarly, we will continue to improve cold chains and transportation infrastructure to increase the quality and quantity of samples being collected and tested from remote field sites. PREDICT-2 activities will supplement currently available resources and training activities, especially in systematic survey design, and as needed in newly added EPT countries. Additional protocols will be developed and standardized for collection of behavioral and risk mitigation data at field sites.

ii) Laboratory Testing: We will continue to strengthen local laboratory capacity in basic cPCR protocols, as well as for use of serological assay protocols using our pathogen detection and discovery framework (see Objective 1 above). Focused areas for additional training for pathogen discovery and characterization include specific training for Tier 1 viral families in all

countries where capacity does not already exist and the additional training for Tier 2 families in countries targeted for intense engagement. It also includes the need to expand our activities (and where required, training) to include human and national laboratories in all countries. More emphasis and training will be provided on appropriate specimen selection based on pathway of emergence and spread among people, wildlife, and domestic animals; biosafety and biosecurity (e.g. appropriate handling of samples during extraction and storage); trouble- shooting viral family PCR protocols; and the interpretation of results. Introductory training in basic pathogen sequence analysis and bioinformatics will also be provided, as well as training in PCR assay design to facilitate rapid local outbreak response where necessary, and to ensure the persistence of skills that protect the long-term viability of this diagnostic platform. Additionally, reference panels will be developed and deployed to all participating laboratories to perform quality control and assessments of laboratory analytical procedures. Training will include opportunities in US- based laboratories when possible, as well as instruction by visiting laboratory technicians. Materials will also be made available to assist with and provide content for developing curricula by OHW programs to train the next generation of laboratory diagnosticians.

iii) Information Management: The use of digital data collection and databases is common practice in developed countries but is not yet a standard approach in many developing countries. In PREDICT-2, we aim to train key personnel from PREDICT teams, laboratories, and ministries in target countries to better manage field data, track laboratory sample and results data, interpret data, and analyze results by providing training resources and common best practices so that countries may enhance their abilities to manage and work with large datasets.

iv) Risk Assessment: An understanding of patterns of risk factors and disease transmission informs risk management and disease control strategies. The ability to describe, map, and model data is therefore imperative for all surveillance activities. PREDICT-2 activities will include providing training on basic data analysis tools, spatial mapping, and disease modeling to key constituents and training programs in the target countries so that they can understand and engage with our global disease modeling and analytics teams to inform new models of refined risk and disease control potential at key interfaces around the world.

v) Cross-sectoral Collaborations: Institutionalizing One Health approaches to disease surveillance, control, behavioral risk characterization, and outbreak response requires horizontal as well as vertical integration into government ministries and stakeholder organizations. We aim to support One Health Platform activities by fostering dialogue and providing data to inform on policy across disciplines and sectors at local and national levels through meetings, workshops, and coordinated field activities.

5.2. Coordinated capacity development across EPT projects

We will coordinate with other EPT-2 projects, such as OHW and P&R, to identify and assist with needs for training the next generation at universities and ministries associated with One Health networks, especially OHCEA and SEAOHUN, to better prepare the future workforce for positions in laboratories, ministries, and other organizations and to successfully maintain surveillance systems. Similarly, Field Epidemiology Training Programs may benefit from interactions with PREDICT-2 personnel and projects as part of developing the next generation of One Health professionals. Coordinated training activities across the EPT program may range from short, intensive workshops to provisional fellowships to long- term on-the-job training or academic degree endeavors, depending on the target audience and competencies.

Opportunities for practical field experiences will be provided for appropriate EPT trainees based on

fit and EPT project alignment.

Our consortium has extensive training experience that ranges from developing new curricula to implementing short- and long-term trainings in classroom, laboratory, and field settings. Depending on the identified needs and gaps in training, we are prepared to contribute to pre-service training in coordination with the One Health Workforce that may involve: 1) developing protocols and curricula, 2) virtual and in-person training sessions on topics related to the PREDICT-2 scope, and 3) field activities that provide real-life experience for trainees to practice skills and enrich competencies. Training topics include surveillance strategies, wildlife management, field veterinary services, laboratory diagnostics, epidemiologic outbreak investigation and response, research methods, information management, risk assessment, medical anthropology, public health, environmental health, and policy development. During PREDICT-1 we tailored our trainings depending on the needs of individuals and organizations, and whereas classes and workshops worked well for some audiences, longer-term internship placements at field and laboratory sites served as the formative experiences for other trainees. In the past, we have also utilized mock scenarios and interactive online case studies to foster real-time and globally networked team thinking that gives trainees virtual experiences as preparation for what they may deal with in their daily activities throughout their careers. We will closely coordinate with the OHW team to identify needs and develop a plan for our participation in pre-service training for the One Health networks. The convening and coordination will be the responsibility of the PREDICT EPT Liaison with finalization of plans and implementation then falling under the responsibility of the Capacity Strengthening Lead.

Objective 6: Assisting in the organizing of annual data review meetings for USAID's PIOET program In close coordination with other EPT-2 projects and partners (including FAO, CDC, WHO, etc.), we will organize annual data reviews to optimize and refine ongoing and future activities. The data review meetings will serve to improve global databases, flow of information, and pace of data sharing, and thus will promote the overall success of the PIOET program. Enabling collaborative, focused and ongoing data sharing and associated communication among EPT-2 program stakeholders will also assist in avoiding duplication and maximizing synergies across projects. This objective is especially important for optimizing EPT-2's potential, given the breadth of data collected across partners and the implications of ongoing information yielded by iterative analyses that build on prior findings, as demonstrated in EPT-1.

6.1. Meeting participants and content

By bringing together EPT-2 projects and partners, the meetings will build on data from EPT-1 and EPT-*plus* to facilitate progress in compiling robust and targeted longitudinal data sets. Collaboration with CDC and FAO will be a key component. The involvement of EPT-2 projects, as well as international organizations and other stakeholders, allows for compilation of a variety of data, including information yielded from on-the-ground efforts, as well as those collected through global reporting systems. The data review meetings will facilitate the examination of available data for population-based analyses and will allow a platform for identifying state of the art practices, sharing of key findings, and strengthening of partnerships that could inform risk-reductive policies and practices. Selected country-level discussions will be used to strengthen One Health platforms and produce recommendations to be utilized by EPT P&R around sustained cross- sectoral collaboration, including data sharing. Review of data collected related to investments in the One Health workforce will be vital to compiling lessons learned and developing and advancing

curricula. Finally, meetings will be key for compiling and improving global data sets of influenza and other respiratory pathogens (benefitting from coordination with FAO, CDC, WHO, and others) and exploring optimized ways to link bio-surveillance data to response through "IT portals" (including crucial input gained from CDC and WHO's well-established systems) that advance global networks for real-time biosurveillance. The meetings will also serve to explore ideas for additional or potential data sets that would help advance EPT-2 projects' and partners' contributions to the goals of the PIOET program.

6.2. Ensuring appropriate representation

To ensure gender equity is promoted in the data review process, including for development and testing of data collection tools, participants themselves will be balanced across sectors and gender and will be requested to bring sex-, age-, and culture-disaggregated data sets to facilitate analyses and sharing of disaggregated data as appropriate. The data reviews will guide recommendations for programmatic adjustments, such as broadening research and intervention focus to more effectively integrate specific high-risk and/or underserved or underrepresented populations (e.g. to overcome gender, age, socio-economic, and other biases).

6.3. Frequency and agenda development

At least one annual global key findings review meeting will be held, with participation from key stakeholders, including representatives from PREDICT-2, P&R, OHW, FAO, WHO, CDC, as well as other in-country participants and external partners identified by USAID. In close consultation with USAID staff and PREDICT-2 Key Personnel, PREDICT-2's EPT Liaison will coordinate and develop the agenda(s), incorporating topics and opportunities identified during ongoing collaborations and communications with EPT-2 partner points of contacts and key stakeholders in order to synthesize input and identify key issues to be addressed. In addition, we will leverage opportunities for using EPT-2 regional and country- level meetings to conduct targeted country and region-specific data review, as well as provide agenda inputs, identify data sharing needs, and prepare data frameworks for the annual global data review meetings. Summaries of key discussions and findings and recommended programmatic adjustments as approved by USAID will be compiled and distributed following each annual meeting.

Monitoring and Evaluation

We will use a robust monitoring and evaluation (M&E) plan to track progress on PREDICT-2's goals of identifying and characterizing pathogens of known epidemic and unknown pandemic potential; classifying animal reservoirs and amplification hosts of human-infectious viruses; and targeting intervention action at human behaviors which amplify disease transmission at critical animal-animal and animal-human interfaces in hotspots of viral evolution, spillover, amplification, and spread. Our project indicators, detailed in the Monitoring and Evaluation Table below, will quantitatively assess how well the proposed PREDICT-2 objectives contribute to the desired goals and end of project results presented by USAID in RFA-OAA-14-000019. This proposed M&E plan will be implemented in conjunction with USAID to track project progress in close coordination with other EPT-2 projects, as well as with in-country and international partners. We believe these indicators will also aid us in effectively managing the project for timely achievement of project targets and provision of results. During the first 30 days of project implementation, PREDICT-2 Key Personnel will work with USAID to further refine the proposed M&E plan. Once finalized, measurable progress towards indicators will be assessed semi- annually with USAID and annually

with external advisers to hone activities and adapt work plans to ensure targeted end- of-project results are met.

To this end and in addition to evaluations prescribed by USAID or in compliance with guidance provided by other US Government agencies/initiatives, we will establish a two-tiered evaluation system consisting of semi-annual assessment of progress on our M&E plan by the key personnel, consortium leads, and USAID and an annual assessment, estimated at three intensive days of effort, by an External Advisory Panel (PREDICT-2 EAP) managed by the PREDICT-2 EPT Liaison. The PREDICT-2 EAP members will be selected based on their experience conducting successful US government projects and their in-depth knowledge of USAID monitoring and evaluation. The initially proposed members provide a range of multidisciplinary experience and knowledge across the entire spectrum of emerging disease issues facing humans, domestic animals, and wildlife. We intend to keep the EAP to a limited number of highly qualified individuals and therefore have chosen to initially invite Dr. Pierre Formenty (WHO), Dr. James Hughes (Emory University and formerly of CDC), Dr. Subhash Morzaria (FAO), and Dr. Ronald Waldman (the George Washington University and formerly of WHO, CDC, and USAID). Qualifications of our proposed PREDICT-2 EAP members are provided in their resumes (Annex A).

In evaluation of progress on each activity, we will assess the scope and quality of partner engagement, especially in- country ministries, FAO, CDC, WHO, OHW, and P&R. Also critical will be the measurement of gender representation in each activity and the provision of capacity building in core competencies and skills in disease surveillance, response, prevention, and control as described above. To the extent applicable, we will use US Centers for Disease Control and Prevention "Updated guidelines for evaluating public health surveillance systems" (MMWR 50 (RR13);1-35) to evaluate the effectiveness and impact of our surveillance activities and capacity building, particularly as they relate to the viruses detected, quality of the data collected, presentation of data and key findings to national and international partners, timeliness of reporting activities, and representativeness of the key interfaces and epizones targeted for surveillance.

We have designed our monitoring and evaluation plan and indicators to target major goals and impacts for each PREDICT-2 objective. These objectives were designed to contribute to each new EPT-2 strategic area of focus by establishing longitudinal datasets for understanding drivers and human behaviors needed to inform on policies to reduce the risk of zoonotic virus emergence and strengthening real-time biosurveillance and preparedness for public health events, while investing in One Health workforce and platforms. In the table below, we show sample indicators of success, their corresponding suggested timeframe, along with key project outcomes and data sources.

Exhibit A

PREDICT-2 Monitoring and Evaluation Table

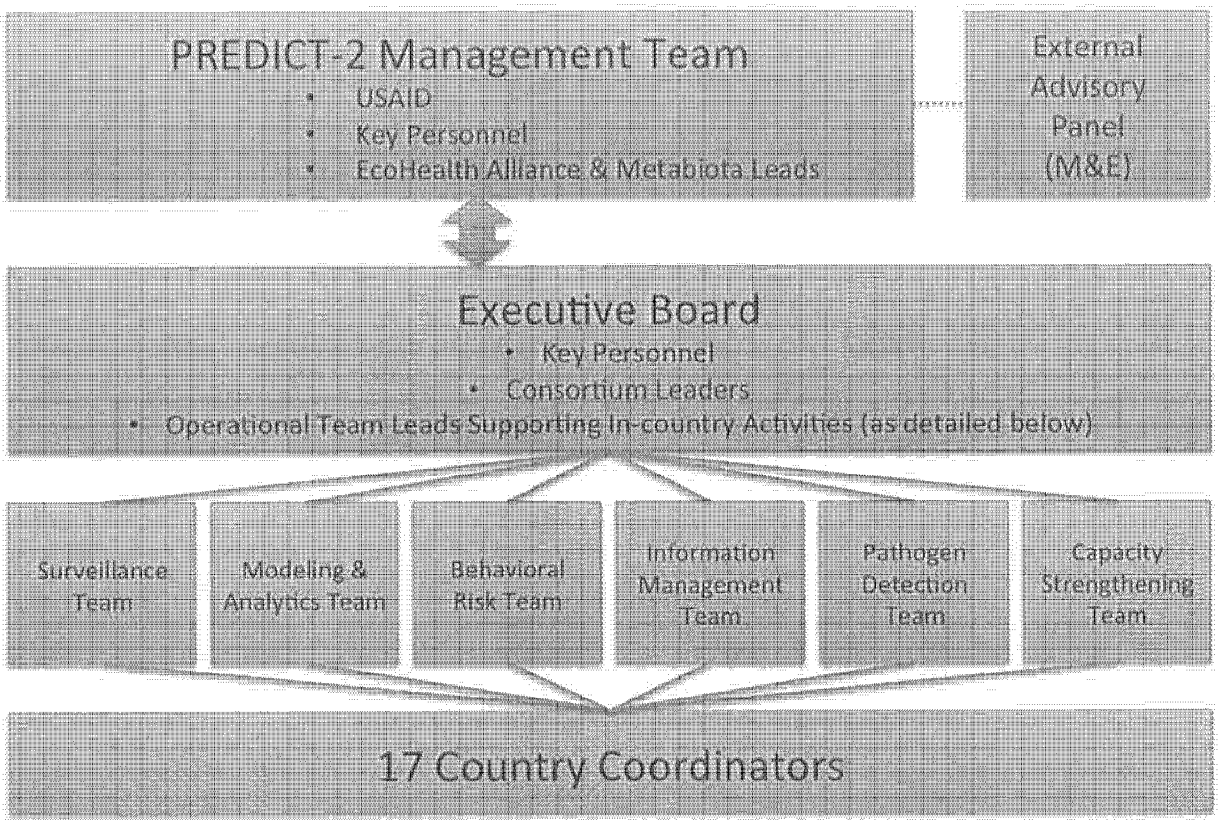
Objectives & Activity	Indicators with Timeframe	Outcomes and End-of-Project Results with Data sources
Objective 1: Biological and ecological risk characterization		
Identify epizones and collect longitudinal data for at least one priority family of zoonotic viruses with known pandemic potential	Percent of PREDICT-2 countries conducting surveillance in epizone(s) and collecting longitudinal data on at least one pathogen of known pandemic capacity Timeframe: initiate epizone surveillance in all intensive countries by end of Year 1 and all less countries by middle of Year 2; semi-annual/annual assessment of country progress	Enhanced in-country disease surveillance, laboratory and data synthesis capability for detection and response to zoonotic diseases, biological strengthening of transdisciplinary teams skilled in One Health approaches to disease surveillance, and identification and more precise ranking of high-risk interfaces and key epidemiologic zones involved in disease amplification and spread Data sources: wildlife, domestic animal, and human pathogen detection data; ecological data; risk characterization for animal-to-animal and intensive animal-to-human transmission; results from phylogeographic and ecological analyses; and key findings from longitudinal monitoring
Identify high-risk interfaces and ecological and climatic conditions facilitating transmission of viruses from animals to people	Percent of PREDICT-2 countries conducting analysis of risk factors associated with virus evolution, spillover, amplification, and spread Timeframe: initiate in all intensive countries by end and all less intensive countries by middle of Year 2; semi-annual/annual assessment of country progress	Enhanced in-country capacity to synthesize biological, ecological, and behavioral data to evaluate risk factors influencing virus evolution, spillover, amplification, and spread; strengthening of transdisciplinary teams skilled in One Health approaches to disease surveillance, identification and more precise ranking of high-risk interfaces and key epidemiologic zones involved in disease amplification and spread Data sources: biological surveillance data, niche models, and host-virus ecologic analyses, and of Year 1 characterization of viruses for zoonotic and pandemic potential in wildlife, domestic animals, and people, including high-risk human cohorts and ILI, SARI, FUO patients with measured animal contact data
Objective 2: Behavioral risk characterization		
Identify behaviors and practices facilitating animal-animal and animal-human contact	Percent of PREDICT-2 countries conducting surveys of animal-animal and animal-contact Timeframe: initiate in all intensive countries by end Year 1 and all less intensive countries by middle Year 2; semi-annually/annual assessment of progress	Enhanced in-country behavioral risk monitoring and data synthesis capability for identification of behaviors, practices, and conditions that facilitate animal-animal and animal-human contact, standardized dissemination of information on risk of zoonotic human diseases, ranking of key intervention points, and validation of interventions to reduce risk of zoonotic disease evolution, spillover, amplification, and spread Data sources: standardized structured household of surveys, occupational surveys, consumer surveys, of and focal follows data across the range of risk country settings to generate comparative data on human-animal and animal-animal contact
Objective 3: Global surveillance networks and analysis		

Exhibit A

Utilize data management systems for collection and dissemination of standardized biological and behavioral surveillance and outbreak data	Percent of PREDICT-2 countries contributing biological and behavioral data to PREDICT-2 data management systems Timeframe: targeting all countries by end of Year 1; semi-annual/annual assessment of country progress	Improved global disease datasets, information networking and data sharing, enhanced rapid dissemination and integration of biological surveillance, behavioral, and outbreak data, to inform pandemic preparedness Data sources: PREDICT-2 database for animal and human biological, ecological, and behavioral data; data collection tools for surveillance and outbreak response; outbreak monitoring systems in coordination with Global Health Security Initiative Early Alerting and Reporting Project
Objective 4: Validation of One Health approaches		
Gather data and conduct analyses to evaluate One Health approaches	Percent of PREDICT-2 countries quantitatively evaluating One Health Approaches Timeframe: initiate in all intensive countries by end of Year 2 and all less intensive countries by middle of Year 3; semi-annual/annual assessment of country progress	Evidence generated for policy makers and partners on effectiveness and economic benefits of One Health approaches and workforce Data sources: One Health case studies; measures of stakeholder and organizational participation; integration of animal, human, and ecological surveillance and risk characterization; gender equity in One Health workforce; costs savings and cost mitigation; DALYs in outbreaks; time to detection, response, control of outbreaks; dissemination of information and tools generated by PREDICT-2; sustained One Health programs; and global One Health policies
Objective 5: Overall capacity strengthening		
Strengthen training of in-country staff	Percent of PREDICT-2 countries with government personnel participating in training in field sampling, information management, laboratory techniques and assay development, and risk characterization Timeframe: targeting all intensive countries by end of Year 2 and all less intensive countries by middle of Year 3; semi-annual/annual assessment of country progress	Enhanced in country trans-disciplinary skills, competencies, and knowledge in One Health approach to biological surveillance and risk characterization Data sources: semi-annual reports characterizing and summarizing number of individuals cross trained in One Health trans-disciplinary approaches in biological surveillance, laboratory testing, information management, data analysis, and risk characterization; quality control and assessment of laboratory analytical procedures and assay development in collaborating laboratories
Objective 6: Assisting in the organizing of annual data review meetings for USAID's PIOET program		
Coordinate effective data review meeting(s) with other EPT partners and USAID and engage EPT partners in data sharing and data review	Number of annual data review meetings engaging key national and international organizations and EPT partners in data sharing and data review Timeframe: at least one annual meeting initiated at end of Year 1; consider needs for additional or regional meetings annually	Evidence shared among EPT partners and national and international partners for key findings from biological, ecological, and behavioral risk characterization, training of in-country staff, and benefits of One Health approaches Data sources: PREDICT-2 semi-annual reports, meeting agendas, and key findings shared

Organization and Management

1. PREDICT-2 ORGANIZATIONAL CHART



2. MANAGEMENT PLAN

Our consortium is a functionally collaborative and fully integrated working team that benefits from the experience of world leaders in zoonotic disease surveillance, epidemiology, disease ecology, and behavioral risk characterization. Building upon existing personnel resources from UC Davis (UCD), EcoHealth Alliance (EHA), Metabiota (MB), the Smithsonian Institution (SI), Wildlife Conservation Society (WCS), and other global health leaders, the *Director* will facilitate the efficient accomplishment of all PREDICT-2 objectives, as well as careful monitoring, evaluation, and adaptive project management, through the organizational structure (Organizational Chart) depicted above. The implementation of previous and ongoing, collaborative and complex zoonotic pathogen projects has allowed the consortium to test the function and feasibility of this working group and optimize the productivity of the team using this structure. The Management Team, made up of USAID representatives, the Key Personnel (detailed above, pending approval by USAID), and the EHA and MB organizational leads, will meet by teleconference twice per month to track the progress of PREDICT-2 activities and make operational adjustments to assure management functionality and achievement of project goals and end-of-project deliverables. To guarantee fiscal responsibility and responsiveness to the needs of the program, the Director will review and approve budgets to ensure they are appropriate to the work proposed, consistent with applicable rules and guidelines, and are committing sufficient resources to achieve in-country objectives. The Director will conduct periodic reviews with the Operations Manager to assess ongoing budgetary needs and will include the

Management Team in financial decisions needed to adaptively manage the project successfully.

As discussed in the Monitoring and Evaluation section above, external guidance will be provided to the Management Team by an External Advisory Panel (EAP). In addition to assessing PREDICT-2 progress according to USAID-approved M&E, this group of distinguished scientists will review activities and plans and advise on priorities, strategic focus, and broader partner collaboration. All have extensive experience in leadership and management of large agencies and projects or programs with operations in developing countries. We will also benefit from the EAP's knowledge, experience, and extensive contacts, which will facilitate achieving the objectives of the project.

An Executive Board, consisting of the Key Personnel, the most senior representative of the core consortium (EHA, MB, WCS, SI), and the Operational Team Leads will shape the management of all activities and ensure that all 17 countries are receiving the support needed to achieve the in-country objectives according to their approved work plans. The Executive Board will meet at least monthly to review country activities, identify programmatic gaps, determine progress toward objectives, and coordinate capacity-building and training plans. To respond to emergencies or unforeseen needs, additional conference calls will be convened by the Director or at the request of any of the Executive Board members. In addition to regular conference calls, there will be at least two face-to-face meetings annually of the Executive Board, as well as an approximately annual meeting of the Executive Board with the Country Coordinators and leaders of the PREDICT-2 laboratories for the purpose of information exchange, lessons learned-sharing, and coordination.

All consortium partners will have representatives on each of the operational teams illustrated in the organizational chart above. For example, the Behavioral Risk Team will be led by Dr. Maureen Miller from EcoHealth Alliance, and she will be supported by a deputy – Dr. Karen Saylors of Metabiota, Dr. Alex Nading of UCD, Dr. Suzan Murray of the Smithsonian, and Dr. Sarah Olson of the Wildlife Conservation Society. Others involved in the behavioral risk work and in the team as needed and appropriate include: the Country Coordinators (n = 17); Country Behavioral Risk leads, including Jusuf D. Kalengkongan (Indonesia), Lanesh Thanda and Alice Mathew (Malaysia), Mwokozi Mwanzalila (Tanzania), Ditum (Uganda), and other PoCs (sometimes contracted to local universities as in the focused work during PREDICT-1, approx. 17); Elizabeth Loh (EHA); Toph Allen (EHA); Emily Hagan (EHA); David Wolking (UCD); Kirsten Gilardi (UCD); Paulina Zielinska (UCD); Corina Monagin (MB); and Molly Voss Fannon (SI). In addition, the PREDICT-2 Operational Teams (in conjunction with PREDICT-2 and USAID leadership) will reach out to and contract with appropriate in-country and global teams as needed to complete the work most excellently and expeditiously. For this behavioral risk example, our consortium has been offered partnership by the teams led by Steve Luby of Stanford, Susan Zimicki of FHI 360, Dee Bennett of Another Option, and Andreas Salomonsen currently consulting for the World Bank, among others. We will enthusiastically engage partners, such as these and others as appropriate, in targeted implementation of the project and in other activities, like the evaluation of behavioral interventions.

Day-to-day management of the project and implementation of activities to achieve objectives will be the responsibility of each of the 17 Country Coordinators with the support of the personnel and structure described above. Country Coordinators will be in almost constant (electronic) contact with the Operational Team Leads to ensure consistent work plan implementation. Almost all Country Coordinators are citizens of the PREDICT-2 countries with extensive experience in project management and implementation of surveillance (see Resumes in Annex E). In many cases, they are embedded in local organizations (ministries, universities, or NGOs), as those organizations have aligned missions with PREDICT-2 activities and are likely to help build the support for continuing country activities at the end of PREDICT-2. The duties of the Country Coordinators include:

- Plan and coordinate local biological surveillance and behavioral risk characterization activities and ensure that written standardized protocols are implemented;
- Coordinate field teams and supervise data collection, handling, and tracking from collection to the laboratory or centralized database;
- Coordinate and organize in-country capacity assessment, trainings, and meetings with ministry officials, local partners, and trainees to disseminate information and improve interpretation of surveillance data;
- Facilitate equipment and supply acquisition and distribution;
- Coordinate diagnostics with laboratory personnel including sample processing, testing, and tracking and delivery of data into the PREDICT-2 database;
- Manage data entry, including quality assurance;
- Identify, recruit, and track in-country trainees, including OHW pre-service and P&R in-service candidates;
- Produce and disseminate reports, as required, that document country activities and findings;
- Assess development of local capacity for sustainable surveillance, risk characterization, intervention acceptance, and outbreak response;
- Liaise with local governments and stakeholders to improve information sharing and facilitate approval of data release to the general public; and
- Liaise with local OHW, P&R, CDC, WHO, and FAO personnel to ensure cross-cutting activities.

Because of the complexity of a project that involves many partners working in over 17 countries, and a budget of $100 million, some specialized staff will be required for implementation, especially to ensure cost-effective administration of activities. Our staffing plan is based on previous experience administering international programs and our knowledge that excellent surveillance and behavioral risk characterization through a distributed management structure requires adequate staffing and diligent supervision to guarantee success. We will adaptively manage the PREDICT-2 project to ensure that staffing and staff placement is appropriately matched to the level of project activities.

End of Attachment B

Exhibit A

ATTACHMENT C – BRANDING STRATEGY AND MARKING PLAN
PREDICT-2

I. BRANDING STRATEGY

Estimated Costs

All estimated costs associated with branding and marking the PREDICT program are included in the Budget Table below. Items such as stickers were procured in PREDICT 1 and the program maintains some inventory; items to be used at USAID funded meetings such as banners (when necessary) are budgeted at an estimated $9,000 per year across the program's countries' supplies line items in the estimated PREDICT 2 budget. Communications materials (see item 4 below) are primarily developed at UC Davis by our program staff and Content Manager, as described in the estimated budget; those costs are included in salary line items.

Budget Table

Item and use	Cost
Banners and signs: USAID, UC Davis, and sub-grantees branded banners with graphic identities to be displayed prominently at all USAID funded meetings, gatherings and presentations.	$9,000, budgeted within supply costs in countries anticipating meetings
Stickers: Branded as described below to be used for marking of equipment.	No additional cost – procured in PREDICT 1
Reports and Training Materials: USAID branding incorporated as specified below.	No additional cost
Website and UC Davis promotional publications: Inclusion as a Partner and acknowledgement as donor (at no cost).	No additional cost – budgeted in communication salaries

Intended Name of the Program

Name of Program: PREDICT

Where appropriate, the name is accompanied by USAID Graphic Identity, UC Davis Logo, Sub-grantee logos. See attached proposed logo and letterhead to be used as necessary and appropriate.

Audiences

Primary Audience: Members of the national, state, and local governments; community-based leaders; local community members; and civil society organizations where the PREDICT project is active. Focus will be on stakeholders, involving both genders, ranging from local individuals to highest levels of government.
Communication materials for these target groups will range from posters to reports and media such as TV, radio, and press presentations. In addition, regular correspondence with multiple units of USAID (including mission offices in countries of operation), appropriate US Government offices (as recommended and approved by the USAID AOTR), and international health organizations with which PREDICT will operate collaboratively (e.g. WHO, OIE, FAO).

Secondary Audience: International community, governments, bi-lateral and multi-laterals donors, international NGOs, and others working on emerging infectious diseases from wildlife sources.

Planned Communication

Main Program Message: *Building capacity to detect zoonotic pathogens; identifying drivers of transmission; and reducing the risk for spillover, amplification and spread, thereby protecting human health and minimizing threats from pandemic disease.*

Training materials, pamphlets, etc.: Similar to our communications efforts in PREDICT-1, we will make training manuals available to the public and keep and maintain both a website with program information and pamphlets or handouts for individual country activities and impacts. Examples of these works can be found at http://www.vetmed.ucdavis.edu/ohi/predict/index.cfm

Press and Promotional Activities: In all USAID-funded and related activities, the PREDICT Program, our collaborators, and sub-grantees will consistently undertake the following steps to highlight USAID's collaboration and support:

TEXTUALLY: UC Davis and sub-grantees and their partners will include references to USAID support in press releases, websites, and fact sheets relating to PREDICT Program Activities.

VERBALLY: UC Davis and sub-grantees and their partners will ensure that USAID is publicly credited in speeches, public presentations, training workshops, and community meetings when referencing project activities.

VISUALLY: The USAID identity will be prominently displayed on all written reports and training and program materials regarding PREDICT activities. The USAID graphic identity will always be equal to or more prominent than the logos of UC Davis, its sub-grantees or implementing partners. UC Davis will provide graphical templates to be used for PREDICT letterhead and for graphic identity blocks on UC Davis and sub-grantee communications and materials in the implementation of PREDICT. These graphical templates will be reviewed and approved by the USAID AOTR and Communications Officer prior to use. In PREDICT regions and countries, activities may be implemented by UC Davis and one or more sub- grantees. Approved graphical templates will be provided to the individual sub-grantees in the instances where using the general template with all sub-grantees represented may be inappropriate. USAID, UC Davis, and sub-grantees will be included as follows: the USAID graphic identity will be prominently displayed, and UC Davis and sub-grantee logos will be displayed to the right or below the USAID graphic identity. English versions of the USAID graphic identity will be used on reports, publications, and materials. Materials produced will be pre-reviewed by the USAID Communications Officer as required. If pre-review is not possible, the communications disclaimer will be placed clearly as outlined in the USAID Branding policy.

IN MEDIA: USAID will be notified of all public events, workshops, and activities. USAID will be acknowledged at all media events and reporting on the activities of the project. Media coverage of the work may include local radio, local TV, international TV, film, webcasts and reporting, magazines, and radio.

PHOTOS and STORIES: USAID and UC Davis jointly-approved press releases and captioned digital photos will be provided at each official media event. Noteworthy or especially interesting stories and photos will be sent to the USAID punctually. Materials produced will be pre-reviewed by USAID, as required. If pre-review is not possible, the communications disclaimer will be placed clearly as outlined in the USAID Branding policy.

Governments and/or Ministries

UC Davis and sub-grantees will acknowledge USAID on all publications. UC Davis and sub-grantees will also acknowledge local governments and their ministries as appropriate (i.e. ministries of environment, health, agriculture, wildlife conservation, tourism, etc.) as they collaborate in implementation of the various project activities.

Other Groups

UC Davis and sub-grantees will acknowledge local partners, that may include universities and public or private research institutions, that are instrumental in the local or regional implementation of the PREDICT program. UC Davis and sub-grantees will co-brand jointly-produced materials and activities where appropriate and consistent with USAID and local government requirements. UC Davis will acknowledge other donors for jointly funded activities and materials.

UC Davis will acknowledge other institutions for jointly-implemented, -funded, and -produced materials as appropriate. Other organizations with whom we have been engaged in selected activities will be acknowledged.

USAID will always receive prominence on materials and activities.

II. MARKING PLAN

Program Deliverables To Be Marked

Consistent with the detail provided above, UC Davis and its sub-grantees will mark all of the following with the USAID Graphic Identity as described:

Public Communications
- Reports
- Public Service announcements
- Promotional Materials
- Information Products

Events
- Training workshop materials
- Events supported by USAID and PREDICT-supported personnel, such as conferences, seminars, etc...

Commodities

Equipment (non-administrative), Program Materials (non-administrative)

Program Deliverables

Description of communications, commodities, and program materials	How Marked	When and Where Marked	Exceptions to Labeling
Equipment	USAID identity, UC Davis or sub-grantees identity and inventory number	Upon receipt, USAID prominently displayed and UC Davis or sub-grantees to the right or below the USAID graphic identity.	none

Selected Infrastructure	Signs with USAID identity, UC Davis or sub-grantees identities and local government	As appropriate, USAID, UC Davis, and sub-grantees prominently and together.	none
Final programmatic report	USAID identity, UC Davis, and sub-grantees identities	At publication, USAID upper or lower left and UC Davis and partner graphic identities displayed to the right or below the USAID graphic identity.	none
Specific activity reports	USAID, UC Davis, and sub-grantees	At publication, USAID upper or lower left and partner logos displayed to the right or below the USAID graphic identity.	none
Training materials	USAID, UC Davis, and sub-grantees	At publication, USAID upper or lower left, and partner logos displayed to the right or below the USAID graphic identity.	none
Project website	USAID identity, UC Davis, and sub-grantees	At publication, USAID listed with other partners and donors (i.e. UC Davis and sub-grantees) same size text	none
Program Deliverables not planned to mark with the USAID Identity	N/A – there are no deliverables that fit this category; however, the instructions required inclusion in the table	N/A – there are no deliverables that fit this category; however, the instructions required inclusion in the table	N/A

Presumptive Exception Requests

No exceptions are currently requested; however, we reserve the right to request such exceptions should extraordinary circumstances warrant them.

Proposed Logo and Letterhead Examples

USAID FROM THE AMERICAN PEOPLE | PREDICT

USAID FROM THE AMERICAN PEOPLE · UCDAVIS VETERINARY MEDICINE One Health Institute · Wildlife Conservation Society · EcoHealth Alliance · METABIOTA · Smithsonian Institution

End of Attachment C

ATTACHMENT D – STANDARD PROVISIONS FOR U.S. NONGOVERNMENTAL ORGANIZATIONS

I. MANDATORY STANDARD PROVISIONS FOR U.S. NONGOVERNMENTAL ORGANIZATIONS

M1. APPLICABILITY OF 22 CFR PART 226 (MAY 2005)

a. All provisions of 22 CFR 226 and all Standard Provisions attached to this agreement are applicable to the recipient and to subrecipients which meet the definition of "Recipient" in part 226, 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 OMB Circular A-133.

[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. SUBAGREEMENTS (JUNE 2012)

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 2003)

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

Standard Provision	Burden Estimate
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

22 CFR 226	Burden Estimate
22 CFR 226.40-.49, Procurement of Goods and Services	1
22 CFR 226.30 -.36, 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 Office of Acquisition and Assistance, Policy Division (M/OAA/P), U.S. Agency for International Development, Washington, DC 20523-7801 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 (JUNE 2012)

a. 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.

b. 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 Terrorist Financing" 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.

c. 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.

d. 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.

e. This provision must be included in all subagreements, including 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 subagreements 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 subagreements 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)

a. 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 2012)

a. Faith-Based Organizations Encouraged.

Faith-based organizations are eligible to compete on an equal basis as any other organization to participate in USAID programs. Neither USAID nor entities that make and administer subawards of USAID funds will discriminate for or against an organization on the basis of the organization's religious character or affiliation. A faith-based organization may continue to carry out its mission, including the definition, practice, and expression of its religious beliefs, within the limits contained in this provision. More information can be found at the USAID Faith-Based and Community Initiatives Web site: http://www.usaid.gov and 22 CFR 205.1.

b. Inherently Religious Activities Prohibited.

(1) Inherently religious activities include, among other things, worship, religious instruction, prayer, or proselytization.

(2) The recipient must not engage in inherently religious activities as part of the programs or services directly funded with financial assistance from USAID. If the recipient engages in inherently religious activities, it must offer those services at a different time or location from any programs or services directly funded by this award, and participation by beneficiaries in any such inherently religious activities must be voluntary.

(3) These restrictions apply equally to religious and secular organizations. All organizations that participate in USAID programs, including religious ones, must carry out eligible activities in accordance with all program requirements and other applicable requirements governing USAID-funded activities.

(4) These restrictions do not apply to USAID-funded programs where chaplains work with inmates in prisons, detention facilities, or community correction centers, or where USAID funds are provided to religious or other organizations for programs

in prisons, detention facilities, or community correction centers, in which such organizations assist chaplains in carrying out their duties.

(5) Notwithstanding the restrictions of b.(1) and (2), a religious organization that participates in USAID-funded programs or services

(i) Retains its independence and may continue to carry out its mission, including the definition, practice, and expression of its religious beliefs, provided that it does not use direct financial assistance from USAID to support any inherently religious activities,

(ii) May use space in its facilities, without removing religious art, icons, scriptures, or other religious symbols, and

(iii) Retains its authority over its internal governance, and it 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. Construction of Structures Used for Inherently Religious Activities Prohibited. The recipient must not use USAID funds for the acquisition, construction, or rehabilitation of structures to the extent that those structures are used for inherently religious activities, such as sanctuaries, chapels, or other rooms that the recipient uses as its principal place of worship. Except for a structure used as its principal place of worship, where a structure is used for both eligible and inherently religious activities, USAID funds may not exceed the cost of those portions of the acquisition, construction, or rehabilitation that are attributable to eligible activities.

d. Discrimination Based on Religion Prohibited. The recipient must not discriminate against any beneficiary or potential beneficiary on the basis of religion or religious belief as part of the programs or services directly funded with financial assistance from USAID.

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.

[END OF PROVISION]

M12. PREVENTING TERRORIST FINANCING -- IMPLEMENTATION OF E.O. 13224 (AUGUST 2013)

a. The recipient must not engage in transactions with, or provide resources or support to, individuals and organizations associated with terrorism, including those individuals or entities that appear on the Specially Designated Nationals and Blocked Persons List maintained by the U.S. Treasury (online at: **http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx**) or the United Nations Security designation list (online at: **http://www.un.org/sc/committees/1267/aq_sanctions_list.shtml**).

b. This provision must be included in all subagreements, including subawards and contracts issued under this award.

[END OF PROVISION]

M13. MARKING AND PUBLIC COMMUNICATIONS UNDER USAID-FUNDED ASSISTANCE (AUGUST 2013)

a. The USAID Identity is the official marking for USAID, comprised of the USAID logo and brandmark with the tagline "from the American people." The USAID 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 subagreements, including 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 subagreements 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 (AUGUST 1992)

(The following applies to the recipient's employees working in the cooperating country under the agreement who are not citizens of the cooperating country.)

a. The recipient's employees must maintain private status and may not rely on local U.S. Government offices or facilities for support while under this grant.

b. The sale of personal property or automobiles by recipient employees and their dependents in the foreign country to which they are assigned are subject to the same limitations and prohibitions which 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 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, 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 the event the conduct of any recipient employee is not in accordance with the preceding paragraphs, the recipient's chief of party must consult with the USAID Mission Director and the employee involved, and must recommend to the recipient a course of action with regard to such employee.

f. 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 grant award of any third country national when, in the discretion of the Ambassador, the interests of the United States so require.

g. If it is determined, either under e. or f. 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 point of origin, as appropriate.

[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 (AUGUST 2013)

a. PRIOR BUDGET APPROVAL

Direct charges for travel costs for international air travel by individuals are allowable only when each international trip has received prior budget approval. Such approval is met when all of the following are met:

(1) The trip is identified by providing the following information: the number of trips, the number of individuals per trip, and the origin and destination countries or regions;

(2) All of the information noted at a.(1) above is incorporated in the Schedule of this award or amendments to this award; and

(3) The costs related to the travel are incorporated in the budget of this award.

The Agreement Officer (AO) may approve, in writing, international travel costs that have not been incorporated in this award. To obtain AO approval, the recipient must request approval at least three weeks before the international travel, or as far in advance as possible. The recipient must keep a copy of the AO's approval in its files. No other clearance (including country clearance) is required for employees of the recipient, its subrecipients or contractors. International travel 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, must be consistent with the recipient's personnel and travel policies and procedures and does not require approval.

b. 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.

c. **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.

d. 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.

e. SUBAGREEMENTS

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

[END OF PROVISION]

M18. OCEAN SHIPMENT OF GOODS (JUNE 2012)

APPLICABILITY: *This provision is applicable for awards and subawards for which the recipient contracts for ocean transportation for goods purchased or financed with USAID funds. In accordance with 22 CFR 228.21, ocean transportation shipments are subject to the provisions of 46 CFR Part 381.*

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,
Office of Acquisition and Assistance, Transportation Division
1300 Pennsylvania Avenue, NW
Washington, DC 20523-7900
Email: **oceantransportation@usaid.gov**

b. This provision must be included in all subagreements, including subwards 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 (JUNE 2012)

a. USAID is authorized to terminate this award, without penalty, if the recipient or its employees, or any subrecipient or its employees, engage in any of the following conduct:

(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; or

(3) Use of forced labor in the performance of this award.

b. 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.

c. The recipient must include in all subagreements, including subawards and contracts, a provision prohibiting the conduct described in a(1)-(3) by the subrecipient, contractor or any of their employees.

[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]

M. 22 LIMITING CONSTRUCTION ACTIVITIES (AUGUST 2013)

APPLICABILITY: *In accordance with the policy at ADS 303.3.30, AOs must include this provision in all solicitations and awards. When no construction activities are contemplated under the award, the AO must insert* "Construction is not eligible for reimbursement under this award" *in section d) of this provision. If the award permits construction activities based on the policy above (or as authorized by waiver), the AO must insert the description and location(s) of the specific construction activities in section d) of this provision. The AO must not make a general reference to the Program Description. The AO must also ensure that there is a specific line item for construction activities in the award budget.*

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
[*Type of construction and location(s)*]

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]

M. 23 USAID Implementing Partner Notices (IPN) Portal for Assistance (July 2014)

USAID IMPLEMENTING PARTNER NOTICES (IPN) PORTAL FOR ASSISTANCE

For use in all solicitations and resulting awards. Please refer to **ADS 303, Section 303.3.31, "USAID Implementing Partner Notices (IPN) Portal For Assistance"** for additional guidance.

(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/usaidipnforassistance/**. 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/usaidipnforassistance/** 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]

[END OF MANDATORY PROVISIONS]

II. REQUIRED AS APPLICABLE STANDARD PROVISIONS FOR U.S. NONGOVERNMENTALORGANIZATIONS

RAA1. NEGOTIATED INDIRECT COST RATES - PREDETERMINED (APRIL 1998)

APPLICABILITY: *This provision is applicable to educational or nonprofit institutions whose indirect cost rates under this award are on a predetermined basis.*

NEGOTIATED INDIRECT COST RATES - PREDETERMINED (APRIL 1998)

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. Within the earlier of 30 days after receipt of the A-133 audit report or nine months after the end of the audit period, the recipient must submit to the cognizant agency for audit the required OMB Circular A-133 audit report, proposed predetermined indirect cost rates, and supporting cost data. 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, 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, (3) the fiscal year for which the rates apply, and (4) the specific items treated as direct costs. 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. Pending establishment of predetermined indirect costs rates for any fiscal year, the recipient must be reimbursed either at the rates fixed for the previous fiscal year or at billing rates acceptable to the USAID Agreement Officer, subject to appropriate adjustment when the final rates for the fiscal year or other period are established.

[END OF PROVISION]

RAA2. NEGOTIATED INDIRECT COST RATES - PROVISIONAL (Nonprofit) (APRIL 1998)

APPLICABILITY: This provision is applicable to any nonprofit organizations whose indirect cost rates under this award are on a provisional basis.

NEGOTIATED INDIRECT COST RATES - PROVISIONAL (Nonprofit) (APRIL 1998)

a. Provisional indirect cost rates must be established for each of the recipient's accounting periods during the term of this award. Pending establishment of revised provisional or final rates, allowable indirect costs must be reimbursed at the rates, on the bases, and for the periods shown in the schedule of the award.

b. Within the earlier of 30 days after receipt of the A-133 audit report or nine months after the end of the audit period, the recipient must submit to the cognizant agency for audit the required OMB Circular A-133 audit report, proposed final indirect cost rates, and supporting cost data. If USAID is the cognizant agency or no cognizant agency has been designated, the recipient must submit four copies of the audit report, along with the proposed final indirect cost rates and supporting cost data, to the Overhead, Special Costs, and Closeout Branch, 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 final 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 a written indirect cost rate agreement signed by both parties. Such agreement is automatically incorporated into this award and must specify (1) the agreed upon final rates, (2) the bases to which the rates apply, (3) the fiscal year for which the rates apply, and (4) the items treated as direct costs. The agreement must not change any monetary ceiling, award obligation, or specific cost allowance or disallowance provided for in this award.

e. Pending establishment of final indirect cost rate(s) for any fiscal year, the recipient must be reimbursed either at negotiated provisional rates or at billing rates acceptable to the Agreement Officer, subject to appropriate adjustment when the final rates for the fiscal year are established. To prevent substantial overpayment or underpayment, the provisional or billing rates may be prospectively or retroactively revised by mutual agreement.

f. Failure by the parties to agree on final rates is a 22 CFR 226.90 dispute.

[END OF PROVISION]

RAA4. EXCHANGE VISITORS AND PARTICIPANT TRAINING (JUNE 2012)

APPLICABILITY: This provision applies to awards that contain funding for any exchange visitor activities or participant training, as defined in ADS 252 and 253, respectively, conducted or paid for by the recipient with USAID funds under this award.

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 (see **http://pdf.usaid.gov/pdf_docs/PNADT444.pdf**).

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]

RAA6. PROTECTION OF THE INDIVIDUAL AS A RESEARCH SUBJECT (APRIL 1998)

APPLICABILITY: This provision is applicable when human subjects are involved in research financed by the award.

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]

RAA7. CARE OF LABORATORY ANIMALS (MARCH 2004)

APPLICABILITY: This provision is applicable when laboratory animals are involved in research performed in the U.S. and financed by the award.

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 Animals 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]

RAA9. COST SHARING (MATCHING) (FEBRUARY 2012)

APPLICABILITY: *This provision, along with 22 CFR 226, is applicable when the recipient has agreed or is required to cost share or provide a matching share.*

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]

RAA10. PROHIBITION OF ASSISTANCE TO DRUG TRAFFICKERS (JUNE 1999)

APPLICABILITY: This provision is applicable where performance of the award will take place in "Covered" Countries, as described in ADS 206.

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]

RAA11. INVESTMENT PROMOTION (NOVEMBER 2003)

APPLICABILITY: The following clause is required for grants and cooperative agreements when the program includes gray-area activities or investment-related activities where specific activities are not identified at the time of obligation but could be for investment-related activities, as described in ADS 225 (see 225.3.1.8).

INVESTMENT PROMOTION (NOVEMBER 2003)

a. Except as specifically set forth in this award or otherwise authorized by USAID in writing, no funds or other support provided hereunder may be used for any activity that involves investment promotion in a foreign country.

b. In the event the recipient is requested or wishes to provide assistance in the above area or requires clarification from USAID as to whether the activity would be consistent with the limitation set forth above, the recipient must notify the Agreement Officer and provide a detailed description of the proposed activity. The recipient must not proceed with the activity until advised by USAID that it may do so.

c. The recipient must ensure that its employees and subrecipients and contractors providing investment promotion services hereunder are made aware of the restrictions set forth in this clause and must include this clause in all contracts and other subagreements entered into hereunder.

[END OF PROVISION]

RAA12. REPORTING HOST GOVERNMENT TAXES (JUNE 2012)

APPLICABILITY: This provision is applicable to all USAID agreements that obligate or subobligate FY 2003 or later funds except for agreements funded with Operating Expense, Pub. L. 480 funds, or trust funds, or agreements where there will be no commodity transactions in a foreign country over the amount of $500. Please insert address and point of contact at the Embassy, Mission, or M/CFO/CMP as appropriate under section (b) of this provision.

REPORTING HOST GOVERNMENT TAXES (JUNE 2012)

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: [insert address and point of contact at the Embassy, Mission, or M/CFO/CMP as appropriate, may include an optional "with a copy to"].

c. 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.

d. The recipient must include this reporting requirement in all applicable subagreements, including subawards and contracts.

[END OF PROVISION]

RAA13. FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JUNE 2012)

APPLICABILITY: Include this provision in agreements funded from the following accounts:

- *Development Assistance, including assistance for sub-Saharan Africa,*
- *Global Health Programs, and*
- *Micro and Small Enterprise Development Program Account.*

Further information found in the Mandatory Reference for ADS 303, "Guidance on Funding Foreign Government Delegations to International Conferences," (http://www.usaid.gov/ads/policy/300/350maa).

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]

RAA17. STANDARDS FOR ACCESSIBILITY FOR THE DISABLED IN USAID ASSISTANCE AWARDS INVOLVING CONSTRUCTION (SEPTEMBER 2004)

APPLICABILITY: *This provision must be included in solicitations (e.g., Requests for Applications (RFAs) or Annual Program Statements), and in awards involving construction.*

STANDARDS FOR ACCESSIBILITY FOR THE DISABLED IN USAID ASSISTANCE AWARDS INVOLVING CONSTRUCTION (SEPTEMBER 2004)

a. One of the objectives of the USAID Disability Policy is 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. As part of this policy USAID has established standards for any new or renovation construction project funded by USAID to allow access by people with disabilities (PWDs). The full text of the policy paper can be found at the following Web site: pdf.usaid.gov/pdf_docs/PDABQ631.pdf.

b. USAID requires the recipient to comply with standards of accessibility for people with disabilities in all structures, buildings or facilities resulting from new or renovation construction or alterations of an existing structure.

c. The recipient will comply with the host country or regional standards for accessibility in

construction when such standards result in at least substantially equivalent accessibility and usability as the standard provided in the Americans with Disabilities Act (ADA) of 1990 and the Architectural Barriers Act (ABA) Accessibility Guidelines of July 2004. Where there are no host country or regional standards for universal access or where the host country or regional standards fail to meet the ADA/ABA threshold, the standard prescribed in the ADA and the ABA will be used.

d. New Construction. All new construction will comply with the above standards for accessibility.

e. Alterations. Changes to an existing structure that affect, the usability of the structure will comply with the above standards for accessibility unless the recipient obtains the Agreement Officer's advance approval that compliance is technically infeasible or constitutes an undue burden or both. Compliance is technically infeasible where structural conditions would require removing or altering a load-bearing member that is an essential part of the structural frame or because other existing physical or site constraints prohibit modification or addition of elements, spaces, or features that are in full and strict compliance with the minimum requirements of the standard. Compliance is an undue burden where it entails either a significant difficulty or expense or both.

f. Exceptions. The following construction related activities are excepted from the requirements of paragraphs a. through d. above:

(1) Normal maintenance, reroofing, painting or wall papering, or changes to mechanical or electrical systems are not alterations and the above standards do not apply unless they affect the accessibility of the building or facility; and

(2) Emergency construction (which may entail the provision of plastic sheeting or tents, minor repair and upgrading of existing structures, rebuilding of part of existing structures, or provision of temporary structures) intended to be temporary in nature. A portion of emergency construction assistance may be provided to people with disabilities as part of the process of identifying disaster- and crisis-affected people as "most vulnerable."

[END OF PROVISION]

RAA21. CENTRAL CONTRACTOR REGISTRATION AND UNIVERSAL IDENTIFIER (OCTOBER 2010)

APPLICABILITY: *This provision is required in accordance with 2 CFR 25, Award Term for Central Contractor Registration and Universal Identifier. Agreement Officers (AOs) must include this provision in all assistance solicitations and all awards, unless the AO exempts an organization from compliance with the provision under one of the following exceptions, from paragraph d. below:*

Exceptions. The requirements of this provision to obtain a Data Universal Numbering System (DUNS) number and maintain a current registration in the Central Contractor Registration (CCR) 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 AO determines, in writing, that these requirements would cause personal safety concerns.

CENTRAL CONTRACTOR REGISTRATION AND UNIVERSAL IDENTIFIER (OCTOBER 2010)

a. **Requirement for Central Contractor Registration (CCR).** Unless you are exempted from this requirement under 2 CFR 25.110, you as the recipient must maintain the currency of your information in the CCR until you submit the final financial report required under this 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 award term.

b. **Requirement for Data Universal Numbering System (DUNS) numbers.** If you are authorized to make subawards under this 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 unless the entity has provided its DUNS number to you.

(2) May not make a subaward to an entity unless the entity has provided its DUNS number to you.

c. **Definitions.** For purposes of this award term:

(1) Central Contractor Registration (CCR) means the Federal repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the CCR Internet site (currently at www.ccr.gov).

(2) Data Universal Numbering System (DUNS) number means the nine-digit number established and assigned by Dun and Bradstreet, Inc. (D&B) to uniquely identify business entities. A DUNS number may be obtained from D&B by telephone (currently 866-705-5711) or the Internet (currently at fedgov.dnb.com/webform).

(3) Entity, as it is used in this award term, means all of the following, as defined at 2 CFR 25, subpart C:

(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;

(iv) A domestic or foreign for-profit organization; and

(v) A Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity.

(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 Sec. --.210 of the attachment to OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations").

(iii) A subaward may be provided through any legal agreement, including an agreement that you consider a contract.

(5) Subrecipient means an entity that:

(i) Receives a subaward from you under this award; and

(ii) Is accountable to you for the use of the Federal funds provided by the subaward.

ADDENDUM (JUNE 2012):

a. **Exceptions.** The requirements of this provision to obtain a Data Universal Numbering System (DUNS) number and maintain a current registration in the Central Contractor Registration (CCR) 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 these requirements would cause personal safety concerns.

b. This provision does not need to be included in subawards.

[END OF PROVISION]

RAA22. REPORTING SUBAWARDS AND EXECUTIVE COMPENSATION (OCTOBER 2010)

APPLICABILITY: *This provision is required in accordance with 2 CFR 170, Award Term for Reporting Subawards and Executive Compensation. AOs must include this provision in all assistance solicitations and all awards expected to exceed $25,000, unless an exemption applies under paragraph d. of the provision or the exemptions listed below in this applicability statement. If the AO determines that an exemption applies, the AO must provide guidance to the recipient on reporting with generic information.*

Exemptions.

(1) The requirements to report under this provision do not apply to:

(i) Awards to individuals

(ii) Awards less than $25,000

(2) When the AO determines, in writing, that these requirements would cause personal safety concerns, reporting under this provision can be accomplished using generic information.

REPORTING SUBAWARDS AND EXECUTIVE COMPENSATION (OCTOBER 2010)

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 obligates $25,000 or more in Federal funds that does not include Recovery funds (as defined in section 1512(a)(2) of the American Recovery and Reinvestment Act of 2009, Pub. L. 111-5) for a subaward to an entity (see definitions in paragraph e. of this award term).

(2) Where and when to report.

(i) You 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 award is $25,000 or more;

(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.bpn.gov/ccr.

(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) 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;

(iv) A domestic or foreign for-profit organization; and

(v) A Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity.

(2) Executive means officers, managing partners, or any other employees in management positions.

(3) 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 Sec. __.210 of the attachment to OMB Circular A-133, "Audits of States, Local Governments, and Non- Profit Organizations").

(iii) A subaward may be provided through any legal agreement, including an agreement that you or a subrecipient considers a contract.

(4) Subrecipient means an entity 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.

(5) 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]

RAA23. PATENT REPORTING PROCEDURES (JULY 2012)

APPLICABILITY: *This provision is applicable whenever the agreement finances research activities, or patentable processes or practices.)*

PATENT REPORTING PROCEDURES (JULY 2012)

As incorporated by 22 CFR 226.36 and the standard provision "APPLICABILITY OF 22 CFR PART 226," the clause at 37 CFR 401.14 ("Patent Rights (Small Business Firms and Nonprofit Organizations)") 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]

[END OF STANDARD PROVISIONS]

End of Attachment D

ATTACHMENT E – INITIAL ENVIRONMENTAL EXAMINATION
SUMMARY OF PROGRAMMATIC INITIAL ENVIRONMENTAL EXAMINATION (PIEE)
PREDICT - 2

PROGRAM/ACTIVITY DATA

IEE Number:	XXX GH-13-39
Program/Project Number:	AAD 936-4002
Country:	Global
Functional Objective:	Investing in People
Program Area:	Health
Program Elements:	Pandemic Influenza and Other Emerging Threats
Funding Period:	FY14 - FY18
Life of Activity Funding:	September 2014 through September 2019
Life of PIEE:	Five years from date of signing or at the time of any change/amendment to the Program.

PIEE Amendment: Yes_____ No__X __ If yes, date of original IEE: _____

PIEE Prepared by: August Pabst, GH/HIDN/PIOET

Current date: May 2013

ENVIRONMENTAL ACTION RECOMMENDED

Categorical Exclusion: _____
Negative Determination: _____
Negative Determination w/ Conditions: ____X____
Positive Determination: _____

SUMMARY OF FINDINGS

The purpose of this document is to review the overall activities and the potential environmental impact that will be undertaken by the recipient organization of the PREDICT 2 cooperative agreement. The PREDICT 2 Programmatic Initial Environmental Examination (PIEE) evaluates the potential impacts of the CBP activities and has determined that a **Negative Determination with Conditions** is appropriate for the actions described in the document. Other actions not described in this paper will require supplemental environmental analysis.

THRESHOLD ENVIRONMENTAL DETERMINATIONS

The overall environmental determination for PREDICT 2 is a **Negative Determination, with conditions**.

Pursuant to 22 CFR216.3(a)(2)(iii), a **Negative Determination with Conditions** is recommended for any PREDICT 2 activities that have potential for negative impact on the environment in the following categories, as presented in Table 3b in this document:

1) Procurement, storage, management and disposal of public health commodities, including laboratory supplies and reagents.
2) Actions that directly or indirectly result in the generation and disposal of hazardous or highly hazardous medical waste (e.g., laboratory diagnosis, wildlife surveillance, etc.)
3) Actions associated with establishing a wildlife surveillance capacity in selected countries and regions that target specific microbial agents.
4) Outbreak response planning and implementation.

SUMMARY OF MONITORING AND REPORTING MEASURES

1. **Agreement Officer Responsibilities**: USAID procurement should include consideration of the implementing partner's ability to perform the mandatory environmental compliance requirements as envisioned under the Program/ Project. The Agreements Officer (AO)/Contraction Officer (CO) shall include required environmental compliance and reporting language into each implementation instrument, and ensure that appropriate resources (budget), qualified staff, equipment, and reporting procedures are dedicated to this portion of the project.

2. **AOR Responsibilities:** The AOR and/or on-site manager or their representative of the Program/Project will undertake field visits, as possible, and consultations with implementing partners to jointly assess the environmental impacts of ongoing activities, and associated mitigation and monitoring conditions
    a. The AOR, in consultation with the mission activity managers and implementing partners, Mission Environmental Officers (MEO), Regional Environmental Officers (REO), and/or Bureau Environmental Officers as appropriate, will actively monitor and evaluate whether environmental consequences unforeseen under activities covered by this PIEE arise during implementation, and modify or end activities as appropriate. If additional activities are added at the primary award level that are not described in this document, an amended PIEE must be prepared.

3. **Supplemental Initial Environmental Examinations**: In the event that any new proposed activity differs substantially from the type or nature of activities described here, or requires different or additional mitigation measures beyond those described, an amendment to this PIEE will be prepared and the SIEE will reference the amended PIEE.

4. **Environmental Mitigation and Monitoring Plans**: It is expected that subsequent funds will either be core or field support funds awarded at the bi-lateral or the core level. For each major core and country activity under this program, an Environmental Mitigation and Monitoring Plan (EMMP) will be completed by the implementing partner and submitted to the AOR, the Global Health Bureau Environmental Officer (BEO), and the Mission Environmental Officer or the Regional Environmental Officer for their approval.
    a. The EMMP must be completed prior to the start of activities.
    b. Implementing partners will provide an Environmental Mitigation and Monitoring Plan (EMMP) for each for the primary award and a country specific EMMP.
    c. This EMMP will be a detailed implementation plan for the conditions prescribed in this document.

d. The EMMP will be reviewed and approved by the GH BEO prior to the commencement of activities. The mitigation measures and monitoring criteria found in the EMMP should be incorporated into pertinent Performance Monitoring Plans and Annual Workplans.
e. The implementing partners' Project Work Plan will identify those activities outlined in this PIEE that have potential impacts to the environment and discuss plans for environmental management, mitigation approaches, and monitoring measures. Implementing partners will be required to include Environmental Compliance Monitoring in their project work plan and monitoring and evaluation plan
f. An evaluation of the implementation of the EMMP must be part of the mid, and end of project evaluations.
g. Operating Units will ensure that implementing partners have sufficient capacity to implement and to complete mitigation and monitoring measures
h. The EMMP must be stored in project files

5. **Environmental Mitigation And Monitoring Report**: Implementing partners under this award will complete an annual environmental mitigation and monitoring report (EMMR) of all activities.
   a. The environmental monitoring report should be submitted to the AOR by November 1 of each year.
   b. The EMMR will record the environmental mitigation and monitoring measures outlined in the EMMP and will indicate the activities used to ensure that those measures were implemented.
   c. Based on the process outlined in the Project Work Plan, the implementing partners' annual reports to USAID will include brief updates on mitigation and monitoring measures being implemented, results of environmental monitoring, and any other major modifications/revisions in the development activities, and mitigation and monitoring procedures. The EMMR will also identify issues and challenges associated with the implementation of the EMMP.
   d. The EMMR must be stored in project files

6. **Sub-Agreements or Funds Transfers**: Any sub-agreements or fund transfers from the implementing partners to other organizations must incorporate provisions stipulating:
   a. Any sub agreement or funds transfer must include provisions that stipulate the implementation of conditions outlined in the SIEE for country level programs or an IEE for non-country level programs.
   b. The completion of an environmental mitigation and monitoring plan (EMMP) and annual report (EMMR), and submission to the implementing partner.
   c. Any activity to be undertaken will be within the scope of the environmental determinations and recommendations of this PIEE. This includes assurance that any mitigating measures required for those activities be followed.

7. Implementation will in all cases adhere to applicable host country environmental laws and policies.

APPROVAL OF ENVIRONMENTAL ACTION RECOMMENDED:

Recommended By: _____ 6/14/13
Elizabeth Fox — Date
Director, Office of Health Infectious Disease and Nutrition

Concurrence: _____ 6/14/13
Teresa Bernhard — Date
Global Health Bureau Environmental Officer

Approved: X
Disapproved: _____

Filename: PREDICT 2 PIEE

PROGRAMMATIC INITIAL ENVIRONMENTAL EXAMINATION (PIEE)

PREDICT 2

TABLE OF CONTENTS

ACRONYM LIST

AIDS	Acquired Immune Deficiency Syndrome
AO	Agreement Officer
AOTR	Agreement Officer's Technical Representative
BEO	Bureau Environmental Officer
CO	Contract/Grants Officer
EMMR	Environmental Mitigation and Monitoring Report
FAR	Federal Acquisition Regulation
FY	Fiscal Year
GH	Bureau for Global Health
HIV	Human Immunodeficiency Virus
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
HMIS	Health Management Information Systems
HRH	Human Resources for Health
LOE	Level of Effort
MCH	Maternal Child Health
M&E	Monitoring and Evaluation
MEO	Mission Environmental Officer
MNCH	Maternal, Newborn, and Child Health
MOH	Ministry of Health
NGO	Non governmental Organization
OP	Operating Plan
OAA	Office of Acquisition and Assistance
PIEE	Programmatic Initial Environmental Examination
PMI	Presidential Malaria Initiative
PR	Program Results
PRH	Population, Reproductive Health
REO	Regional Environmental Officer
RFA	Request for Application
SIEE	Supplemental Initial Environmental Examination
SLMG	Sustainable Leadership, Management, and Governance
TB	Tuberculosis
USAID	United States Agency for International Development
USG	United States Government
WHO	World Health Organization

PROGRAMMATIC INITIAL ENVIRONMENTAL EXAMINATION (PIEE)
PREDICT 2

PROGRAM/ACTIVITY DATA

IEE Number	**XXX**
Program/Project Number:	AAD 936-4002
Country:	Global
Functional Objective:	Investing in People
Program Area:	Health
Program Elements:	Pandemic Influenza and Other Emerging Threats
Funding Period:	FY 14 – FY18
Life of Activity Funding:	September 2014 through September 2019

Purpose and Scope of PIEE

The purpose of this document is to review the overall activities undertaken by the PREDICT 2 and provide threshold determinations of environmental impact and conditions for mitigation.

Section 1 of this document covers the categories of activities undertaken by the program; Section 2 is background information on the geographical coverage; Section 3 provides an evaluation of the potential environmental impacts of the Program activities; and Section 4 provides the threshold environmental determination for the Program activities and describes mitigation measures required for implementation.

SECTION 1: Background and Activity/Program Description

Overview of the PREDICT 2 Cooperative Agreement

Background

Explosive human population growth and environmental changes have resulted in increased numbers of people living in close contact with animals. Unfortunately, the resulting increased contact, together with changes in land use, have altered the inherent ecological balance between pathogens and their human and animal hosts, which increases the likelihood of zoonotic diseases—diseases that jump from animals to humans. In order to predict, respond to, and prevent the emergence of novel zoonotic diseases in humans, pathogens must be identified at their source. The PREDICT 2 Project is a follow-on cooperative agreement to the PREDICT project (ending September 29, 2014) and will continue to use a risk-based approach to focus efforts on activities that will increase a countries chances of locating pathogens that could potential harm human populations. In addition, PREDICT 2 will include a social science component that will research the different human/animal interfaces to add to global models of risk attribution and aid in the development and study of risk mitigation options.

Objectives

Objective I: Assess existing capacity and develop plans for the implementation of wildlife surveillance support.

The PREDICT project will assess the capability of each country/region to conduct wildlife surveillance and develop a plan of action that identifies the inputs needed from this project to achieve the other objectives described in the RFA.

This objective should result in a comprehensive understanding of the existing capacity in the countries and regions targeted through this project. It will describe the existing capabilities, their current utility, and any opportunities to use those capabilities for broader surveillance of diseases in wild animals that are of potential public health impact. Close coordination with the organizations that own, support, and/or operate these assets will help to understand the true potential for use in this wild animal surveillance project. Gaps in systems will be identified and options for solutions will be developed and presented. Barriers to implementation of a wild animal surveillance system will be identified and addressed.

Objective II: Develop models of disease occurrence and spread as well as determining specific areas at high risk.

This objective should produce computational models of disease occurrence and spread that will aid in the development of wild animal surveillance systems and risk-based forecasting for early disease events. Using existing data sets, historical information, scientific publications and other credible, relevant information, these models will identify geographic areas and animal species to target for surveillance activities, identify the factors and conditions most likely to influence the spread of disease from wild animals to domestic animals and/or humans, describe the strengths and weaknesses of differing levels of detection and reporting, and assess the potential impacts (e.g, health, social) of disease and disease control measures.

Objective III: Establish a wildlife surveillance capacity in selected countries and regions that targets specific microbial agents

Routine surveillance of disease occurrence and spread in wild animals, with a focus on rodents, bats and nonhuman primates will be developed and/or improved in pre-determined countries/regions.

Objective IV: Introduce new technologies where they are appropriate and sustainable.

Technological advances have extended the ability to conduct disease surveillance in developing countries. For example, disease reporting can occur through text messaging or SMS. Also, field diagnostic technology can help reduce logistical issues for specimen transport and laboratory backlogs. This project will capitalize on the practical, sustainable application of technology to support and streamline surveillance of targeted microbial agents among wild animals. It will focus on technologies that are proven effective, adaptable to low-resource countries, sustainable and promising for long-term use

Objective V: Improve the flow and handling of information, specimens and samples resulting from the surveillance activities.

This objective will develop the policy considerations around notification of emerging diseases and ensure timely, parallel flows of communication through animal and public health sectors so that timely decisions and actions can occur. It will also develop communication and feedback channels to support and strengthen wild animal surveillance systems.

Objective VI: Characterize and identify high risk human practices and populations that contribute to disease spillover and amplification at the human/animal interface.

Objective VII: Develop, validate and implement behavior change activities among high risk human populations that lower the risk of transmission of novel pathogens from animals to humans and between humans.

SECTION 2: Country and Environmental Information

Locations Affected and Local Environmental Regulations
USAID's PREDICT 2 programs are worldwide and may take place in any of the USAID mission countries or in countries covered by USAID Regional missions. The status of country level policies on environmental reviews varies. Procedures for disposal of waste are often detailed in national policies for injection safety and in Standard Operating Procedures of laboratories, and are typically based on the WHO Manuals "Laboratory Biosafety Manual, 3rd edition, 2004" and the WHO Manual "Safe Management of Wastes from Health Care Settings."

Location conditions: TBD

SECTION 3: Evaluation of Project/Program Issues

The activities under the Program/Project are numerous and complex. Many Program activities do not have direct adverse environmental impacts such as information, education, communication, community mobilization, planning, management, leadership, sustainable, and outreach activities. However, in the course of implementation of these activities, implementing partners should take advantage of opportunities to incorporate and improve means of addressing environmental health issues (like hazardous and infectious waste management) into health service delivery systems.

Certain activities supported by the program will directly or indirectly affect the environment, or have the potential to do so. Based on the analysis conducted by the AOR these activities could affect the environment in four ways:

1) Procurement, storage, management and disposal of public health commodities, including laboratory supplies and reagents.
2) Actions that directly or indirectly result in the generation and disposal of hazardous or highly hazardous medical waste (e.g., laboratory diagnosis and wildlife surveillance, etc.)

3) Actions associated with establishing a wildlife surveillance capacity in selected countries and regions that targets specific microbial agents.
4) Outbreak response planning and implementation.

The potential impact is discussed in detail below, and summarized in Table 3a towards the end of this section.

1) Procurement, Storage, Management and Disposal of Public Health Commodities

This activity includes procurement of laboratory supplies and wildlife surveillance equipment, such as personal protective gear.

Improper management of those public health commodities mentioned above, either during use or disposal, can have adverse effects on the environment by contributing to solid waste and/or contaminating soil and groundwater. Many countries do not have facilities to manage solid wastes other than uncontrolled burns. Plastics and other inorganic materials pose solid waste management issues for some countries. Those commodities that can contribute to hazardous waste will be addressed in the next section.

Information on solid waste management can be found in the Sphere Handbook at: http://www.spherehandbook.org/en/solid-waste-management/

2) Activities that directly or indirectly result in the generation and disposal of hazardous or highly hazardous medical waste or in techniques that have a direct or indirect environmental impact.

Small-Scale "one health" initiatives, such as laboratory and wildlife surveillance training provide important and often critical services to countries that would otherwise have little or no access to such services.

However, improper training, handling, storage and disposal of the waste generated in these facilities or activities can spread disease through several mechanisms. Transmission of disease through infectious waste is the greatest and most immediate threat from healthcare waste. If waste is not treated in a way that destroys the pathogenic organisms, dangerous quantities of microscopic disease-causing agents—viruses, bacteria, parasites or fungi—will be present in the waste. These agents can enter the body through punctures and other breaks in the skin, mucous membranes in the mouth, by being inhaled into the lungs, being swallowed, or being transmitted by a vector organism. Those who come in direct contact with the waste are at greatest risk. Examples include healthcare workers, cleaning staff, patients, visitors, waste collectors, disposal site staff, waste pickers, substance abusers and those who knowingly or unknowingly use "recycled" contaminated syringes and needles. Although sharps pose an inherent physical hazard of cuts and punctures, the much greater threat comes from sharps that are also infectious waste. Healthcare workers, waste handlers, waste-pickers, substance abusers and others who handle sharps have become infected with HIV and/or hepatitis B and C viruses through pricks or reuse of syringes/needles.

Contamination of water supply from untreated healthcare waste can also have devastating effects. If infectious stools or bodily fluids are not treated before being disposed of, they can create and extend epidemics. The absence of proper sterilization procedures is believed to have increased the severity and size of cholera epidemics in Africa during the last decade.

Healthcare wastes generally fall into three categories in terms of public health risk and recommended methods of disposal:

- *General* healthcare waste, similar or identical to domestic waste, including materials such as packaging or unwanted paper. This waste is generally harmless and needs no special handling; 75–90% of waste generated by healthcare facilities falls into this category, and it can be burned or taken to the landfill without any additional treatment.
- *Hazardous* healthcare wastes including infectious waste (except sharps and waste from patients with highly infectious diseases), small quantities of chemicals and pharmaceuticals, and non-recyclable pressurized containers. All blood and body fluids are potentially infectious.
- *Highly hazardous* healthcare wastes, which should be given special attention, includes sharps (especially hypodermic needles), highly infectious non-sharp waste such as laboratory supplies, highly infectious physiological fluids, pathological and anatomical waste, stools from cholera patients, and sputum and blood of patients with highly infectious diseases such as TB and HIV. They also include large quantities of expired or unwanted pharmaceuticals and hazardous chemicals, as well as all radioactive or genotoxic wastes.

If a project's training activities for professional health workers or community health workers involve techniques that would generate and require disposal of hazardous or highly hazardous waste, the Implementing Partners shall be required to include training in or ensure that the training curriculum covers best management practices concerning the proper handling, use, and disposal of medical waste, including blood, sputum, and sharps.

As appropriate, the implementing partners will work with facility, local, regional and/or national officials, to implement and apply appropriate best management practices which incorporate appropriate health and safety measures and environmental safeguards, including proper disposal of medical waste in accordance with international norms as spelled out by the WHO in "WHO's Safe Management of Wastes from Healthcare Activities." National policies and laws should also be considered, though most countries follow WHO Guidelines.

References for this section include:
http://www.who.int/water_sanitation_health/medicalwaste/167to180.pdf
http://www.bchealthguide.org/healthfiles/hfile29.stm
Safe management of wastes from health-care activities, edited by A. Prüss, E. Giroult and P. Rushbrook. Geneva, WHO, 1999,
http://www.who.int/water_sanitation_health/Environmental_sanit/MHCWHanbook.htm. English

EGSSAA Chapter 8, "Healthcare Waste: Generation, Handling, Treatment and Disposal" (http://www.encapafrica.org/EGSSAA/Word_English/medwaste.doc) for additional guidance on proper handling and disposal of medical waste.

3) Actions associated with establishing a wildlife surveillance capacity in selected countries and regions that targets specific microbial agents.

A key objective under the PREDICT 2 project is establishing a wildlife surveillance capacity in select countries were risk of disease spillover is high. In addition to informing global models on disease emergence, the information collected will help determine mitigation approaches and help countries develop policies to control human/animal interfaces in highest risk areas. To accomplish this objective, wildlife sampling is essential. Wildlife sampling includes taking blood, fecal matter, and sputum samples, from a range of species, with a particular focus on rodents, bats and nonhuman primates. Live animal specimens will be sampled and in certain situations, such as interactions with bushmeat hunters, samples will be taken from dead animals. Given that sampling requires direct contact between humans and animals, besides the generation of solid waste, some potential environmental impacts include:

- Removing an animal specimen from its native habitat
- Infecting a healthy animal specimen with a disease
- Harm or death to the animal specimen
- Damaging an ecosystem by impacting the distribution or population of a particular species

Further information can be found in the Guidelines On: The Care and Use of Wildlife by The Canadian Council on Animal Care, at:
http://www.ccac.ca/Documents/Standards/Guidelines/Wildlife.pdf

4) Outbreak response planning and implementation.

Response support and technical assistance should be conducted with consideration to potential impacts to the environment. Simple measures to manage the potential impacts can be built into the design of any response program and can be planned and implemented regardless of the response activity.

Some potential impacts include:

- Spread of infectious agents from persons or properties used during response efforts
- Destruction of sensitive habitats, short and long term impacts to threatened and endangered species due to untimely or invasive response actions
- Contamination of soil, sediment or groundwater due to the presence of infectious agents, chemicals etc at the response site.
- Contamination of persons, property and environment due to inadequate containment planning and implementation.

Table 3a: PREDICT 2 Activities with Potential Negative Environmental Impacts				
Investing in People: Health Program Areas	**Procurement, Storage, Management and Disposal of Public Health Commodities**	**Direct or Indirect generation, and need for disposal of hazardous and highly hazardous medical waste (as defined in Section 3 of this IEE)**	**Actions associated with establishing a wildlife surveillance capacity in selected countries and regions that targets specific microbial agents**	**Outbreak response planning and implementation**
	Laboratory reagents and supplies Wildlife surveillance equipment Personal Protective Gear	Generation of sharps Generation of hazardous and highly hazardous medical waste, including blood Generation of sputum and other waste	Harm or death to animals being sampled Negative impacts to the ecology of the area being sampled	Spread of infectious disease Contamination of soil Destruction of sensitive habitats/species

Table 3b: CONDITIONS FOR IMPLEMENTATION OF CATEGORIES OF PREDICT 2 ACTIVITIES	
Key Elements of Program/Activities	**Mitigation Conditions and/or Proactive Interventions**
PREDICT 2 activities that involve: Procurement, Storage, Management and Disposal of Public Health Commodities	Conditions: Consignees for all public health commodities procured under this funding will be advised to store the product according to the information provided on the manufacturer's Materials Safety Data Sheet (MSDS). These are supplied by the manufacturer, and can also be found on the internet by using the active ingredient and MSDS as search terms. If disposal of any of these commodities is required, due to expiration date or any other reason, the consignee will be advised that the preferred method of disposal is to return to the manufacturer. If this is not possible (for example if the expired or spoiled pharmaceuticals are considered hazardous and as such, if transferred across frontiers, become regulated and subject to the Basel Convention an the transfrontier shipment of hazardous wastes) then follow the guidelines in the WHO document *Guidelines for Safe Disposal of Unwanted Pharmaceuticals During and After Emergencies*, found at www.who.int/water_sanitation_health/medicalwaste/unwantpharm.pdf. At the request of the Mission, subject to available funding, the implementing partner will make all reasonable attempts to facilitate the disposal of expired commodities under this activity to mitigate the impact of medical waste. Implementing partners will work with the host country as appropriate on aspects of essential medicine supply chain management, including estimating demand, distribution, and storage issues of time and temperature. Commodities that, during use, become hazardous or highly hazardous waste are managed under the conditions in the following section "Activities that involve the collection, safe handling and disposal of hazardous and highly hazardous medical waste" Packaging and disposal of all other public health commodities will be treated using the guidelines provided in Environmental Guidelines for Small-Scale Activities in Africa (EGSSAA) 2nd Edition, Chapter 15: Solid Waste (http://www.encapafrica.org/EGSSAA/Word_English/solidwaste.doc) In addition, the following guidelines should be followed where appropriate: • USAID/PREDICT, Biosafety and PPE Use (English, French, Spanish) • USAID/PREDICT, Implementing a Cold Chain for Safe Sample Transport and Storage (English, Spanish)

PREDICT 2 activities that involve: Generation, storage, handling and disposal of hazardous or highly hazardous medical waste (as defined in Section 3 of this PIEE)	Conditions: For activities entailing training of professionals in methods that result in the generation and disposal of hazardous or highly hazardous medical waste, including blood or sputum testing, basic and emergency obstetric care techniques, and laboratory support, the implementing partner will include training in or ensure the training curriculum covers procedures to properly handle, label, treat, store, transport and properly dispose of blood, sharps and other medical waste, as applicable, and follows either WHO guidelines, in Environmental Guidelines for Small Scale Activities in Africa Chapter 8, "Healthcare Waste: Generation, Handling, Treatment and Disposal," and is consistent with national policy and procedure for medical waste. For all USAID-supported activities entailing service delivery, including blood testing and laboratory support, AORs will work with its implementing partners to assure, to the extent possible, that the medical facilities and operations involved have adequate procedures and capacities in place to properly handle, label, treat, store, transport and properly dispose of blood, sharps and other medical waste. This includes **annual completion of the Healthcare Waste Management Minimum Program Checklist and Action Plan (Annex 1)** for all facilities where implementing partners are directly providing services. Completion of this checklist should be included in the annual workplan. Healthcare waste is most appropriately identified by color-coding bags and containers. In addition, the following are well-established practices in the safe handling, storage, and transportation of health-care waste: • Sharps should be collected together (regardless of whether or not they are contaminated), and stored in puncture-proof, impermeable, and tamper-proof containers with fitted covers. If plastic or metal containers are unavailable, then containers made of dense cardboard are recommended. • Highly infectious waste should be immediately sterilized by autoclaving. • On-site collection of waste should be handled at frequent intervals to avoid accumulation, and an adequate supply of fresh collection bags/containers should be available for replacement. • Waste should be stored in an accessible room with adequate space and protection from sunlight. • In any area that produces hazardous waste - hospital wards, treatment rooms, operating theatres, laboratories, etc., three bins plus a separate sharps container will be needed to separate these types of waste. (If hazardous and highly hazardous waste will be disposed of in the same manner, they should not be collected separately.) • For hazardous waste and highly hazardous waste the use of double packaging, e.g. a plastic bag inside a holder or container is recommended for ease of cleaning. • To make separate collection possible, hospital personnel at all levels, especially nurses, support staff, and

	cleaners, should be trained to sort the waste they produce. See EGSSAA Chapter 8, "Healthcare Waste: Generation, Handling, Treatment and Disposal" (http://www.encapafrica.org/EGSSAA/Word_English/medwaste.doc) for additional conditions on proper handling and disposal of medical waste. Other important references to consult are "WHO's Safe Management of Wastes from Healthcare Activities" http://www.who.int/water_sanitation_health/medicalwaste/wastemanag/en/ In addition, the following guidelines should be followed where appropriate: • USAID/PREDICT, Safety Guide: Laboratory Operations (English, French, Spanish)
PREDICT 2 activities that involve: Actions associated with establishing a wildlife surveillance capacity in selected countries and regions that targets specific microbial agents	For activities under PREDICT 2, implementing partners shall conduct wildlife sampling in a humane and ethical manner, including practicing a "no kill policy" when possible. Proper training and management of wildlife sampling activities is essential and implementing partners will follow the ensuing USAID/PREDICT generated protocols and guidelines where appropriate (made available to implementing partner upon award of cooperative agreement): • Guide: For Safe Animal Capture and Sampling (English, French, Spanish) • Protocol: Small Carnivore Sampling Methods (English) • Protocol: Bushmeat Sampling Methods (English, French, Spanish) • Protocol: Bat and Rodent Sampling Methods (English, French, Spanish) • Protocol: Primates Sampling Methods (English) • Guide: Packing and Shipping Biological Samples (English, Spanish) In addition, PREDICT 2 implementing partners will follow all country specific laws and regulations with regards to wildlife capture, handling, and sample acquisition. Further information on wildlife handling can be found in the Guidelines On: The Care and Use of Wildlife by The Canadian Council on Animal Care, at: http://www.ccac.ca/Documents/Standards/Guidelines/Wildlife.pdf
PREDICT 2 activities that involve:	Response support and technical assistance should be conducted with consideration to the potential environment. Simple measures to manage the potential impacts can be built into the design of any response program and can be planned and implemented regardless of the response activity.

Outbreak response planning and implementation	The implementing partner will coordinate with local environmental experts, officials, NGOs and the MEO to understand the sensitive species and habitats in the region and to design procedures that ensure the protection of those habitats and species. The implementing partner will ensure that all USAID employees or USAID contractors or USAID trained personnel can visually identify any important habitat or species from the target species. This may include using identification cards, have a specialist on site or on call during the response etc. Some helpful information about solid waste management in response situations may be found in the Sphere Handbook at: http://www.spherehandbook.org/en/solid-waste-management-standard-1-collection-and-disposal/

SECTION 4: Recommended Determinations and Conditions for Implementation

4a. Determination

Based on the analysis presented in Section 3, this PIEE recommends threshold decisions and conditions for implementation of PREDICT 2 activities. USAID/GH acknowledges that the environmental screening and review procedures described here do not substitute for the recipient country's own environmental laws and policies.

The overall threshold determination for PREDICT 2 is a **Negative Determination, with conditions**. However, various classes of activities have been grouped into two different determinations. The conditions for implementation of the activities follow in Table 4a. If program activities are similar to the activities in Section 3, the conditions established must be implemented as part of the program design and implementation.

Activities presented in Section 4. Table 4 of this document

Pursuant to 22 CFR216.3(a)(2)(iii), a **Negative Determination with Conditions** is recommended for any Program activities that have potential for negative impact on the environment in the following categories, as presented in Table 2 in Section 3 of this document:

1) Procurement, storage, management and disposal of public health commodities, including laboratory supplies and reagents.
2) Actions that directly or indirectly result in the generation and disposal of hazardous or highly hazardous medical waste (e.g., laboratory diagnosis and wildlife surveillance, etc.)
3) Actions associated with establishing a wildlife surveillance capacity in selected countries and regions that targets specific microbial agents.
4) Outbreak response planning and implementation.

Table 4: Determinations for Activities Executed Under This Program

Activities	Recommended Threshold Determination and 22 CFR Part 216 citation
Activities not involving any biophysical interventions : ○ Document and information transfers e.g. dissemination of PREDICT 2 best practices materials ○ Controlled experimentation exclusively for the purpose of research and field evaluation and carefully monitored; ○ Analyses, studies, academic or research workshops and meetings ○ Studies, projects or programs intended to develop the capability of recipient countries and organizations to engage in development planning ○ Develop models of disease occurrence and spread as well as determining specific areas at high risk. ○ Improve the flow and handling of information, specimens and samples resulting from the surveillance activities. ○ Characterize and identify high risk practices and populations that contribute to disease spillover and amplification at the human/animal interface. ○ Develop, validate and implement behavior change activities among high risk populations that lowers the risk of transmission of novel pathogens from animals to humans and between humans.	Categorical Exclusion, per ○ 22 CFR 216.2 (c)(1)(iii), for research activities which may have an effect on the physical and natural environment but will not have a significant effect as a result of limited scope, carefully controlled nature and effective monitoring; ○ 216.2 (c)(2)(i), for all activities consisting of education, technical assistance or training programs, except to the extent such programs include activities directly affecting the environment (such as construction of facilities, etc.); ○ 216.2 (c)(2)(ii), for controlled experimentation exclusively for the purpose of research and field evaluation which are confined to small areas and carefully monitored ○ 216.2 (c)(2)(iii), for analyses, studies, academic or research workshops and meetings; ○ 216.2 (c)(2)(v), for document and information transfers; ○ 216.2(c)(2)(xiv), for studies, projects or programs intended to develop the capability of recipient countries to engage in development planning, expect to the extent designed to result in activities directly affecting the environment (such as construction of facilities, etc.)
Procurement, storage, management and disposal of public health commodities, including pharmaceutical drugs, immunizations and nutritional supplements, laboratory supplies and reagents.	Negative Determination with Conditions, 22 CFR 216.3 (a) (2) (iii) for activities involving procurement, storage, management and disposal of public health commodities
Actions that directly or indirectly result in the generation and	Negative Determination with Conditions, 22 CFR 216.3 (a) (2) (iii) for all

disposal of hazardous or highly hazardous medical waste (e.g., basic and emergency obstetric care techniques, administration of injectables, HIV or TB testing, disease diagnosis and treatment, etc.)	the health activities directly or indirectly result in the generation and disposal of hazardous or highly hazardous medical waste
Actions associated with establishing a wildlife surveillance capacity in selected countries and regions that targets specific microbial agents.	Negative Determination with Conditions, 22 CFR 216.3 (a) (2) (iii) for activities involving direct interaction with wildlife
Outbreak response planning and implementation.	Negative Determination with Conditions, 22 CFR 216.3 (a) (2) (iii) for activities involving outbreak response planning and implementation

4b. Monitoring Conditions

1. **Agreement Officer Responsibilities**: USAID procurement should include consideration of the implementing partner's ability to perform the mandatory environmental compliance requirements as envisioned under the Program/ Project. The Agreements Officer (AO) shall include required environmental compliance and reporting language into each implementation instrument, and ensure that appropriate resources (budget), qualified staff, equipment, and reporting procedures are dedicated to this portion of the project.

2. **AOR Responsibilities:** The AOR and/or on-site manager or their representative of the Program/Project will undertake field visits, as possible, and consultations with implementing partners to jointly assess the environmental impacts of ongoing activities, and associated mitigation and monitoring conditions
    a. The AOR, in consultation with the mission activity managers and implementing partners, Mission Environmental Officers (MEO), Regional Environmental Officers (REO), and/or Bureau Environmental Officers as appropriate, will actively monitor and evaluate whether environmental consequences unforeseen under activities covered by this PIEE arise during implementation, and modify or end activities as appropriate. If additional activities are added at the primary award level that are not described in this document, an amended PIEE must be prepared.

3. **Supplemental Initial Environmental Examinations**: In the event that any new proposed activity differs substantially from the type or nature of activities described here, or requires different or additional mitigation measures beyond those described, an amendment to this PIEE will be prepared and the SIEE will reference the amended PIEE.

4. **Environmental Mitigation and Monitoring Plans**: It is expected that subsequent funds will either be core or field support funds awarded at the bi-lateral or the core level. For each major core and country activity under this program, an Environmental Mitigation and Monitoring Plan (EMMP) will be completed by the implementing partner and submitted to the AOR, the Global Health Bureau Environmental Officer (BEO), and the Mission Environmental Officer or the Regional Environmental Officer for their approval.
    a. The EMMP must be completed prior to the start of activities,
    b. Implementing partners will provide an Environmental Mitigation and Monitoring Plan (EMMP) for each for the primary award and a country specific EMMP.
    c. This EMMP will be a detailed implementation plan for the conditions prescribed in this document.
    d. The EMMP will be reviewed and approved by the GH BEO prior to the commencement of activities. The mitigation measures and monitoring criteria found in the EMMP should be incorporated into pertinent Performance Monitoring Plans and Annual Workplans.
    e. The implementing partners' Project Work Plan will identify those activities outlined in this PIEE that have potential impacts to the environment and discuss plans for environmental management, mitigation approaches, and monitoring measures. Implementing partners will be required to include Environmental

Compliance Monitoring in their project work plan and monitoring and evaluation plan

f. An evaluation of the implementation of the EMMP must be part of the mid, and end of project evaluations.
g. Operating Units will ensure that implementing partners have sufficient capacity to complete to implement mitigation and monitoring measures
h. The EMMP must be stored in project files

5. **Environmental Mitigation And Monitoring Report**: Implementing partners under this award will complete an annual environmental mitigation and monitoring report (EMMR) of all activities.
   a. The environmental monitoring report should be submitted to the AOR by November 1 of each year.
   b. The EMMR will record the environmental mitigation and monitoring measures outlined in the EMMP and will indicate the activities used to ensure that those measures were implemented.
   c. Based on the process outlined in the Project Work Plan, the implementing partners' annual reports to USAID will include brief updates on mitigation and monitoring measures being implemented, results of environmental monitoring, and any other major modifications/revisions in the development activities, and mitigation and monitoring procedures. The EMMR will also identify issues and challenges associated with the implementation of the EMMP.
   d. The EMMR must be stored in project files

6. **Sub-Agreements or Funds Transfers**: Any sub-agreements or fund transfers from the implementing partners to other organizations must incorporate provisions stipulating:
   a. Any sub agreement or funds transfer must include provisions that stipulate the implementation of an EMMP
   b. the completion of an annual environmental monitoring plan and report, and
   c. Any activity to be undertaken will be within the scope of the environmental determinations and recommendations of this PIEE. This includes assurance that any mitigating measures required for those activities be followed.

7. Implementation will in all cases adhere to applicable host country environmental laws and policies.

4c. The Environmental Mitigation And Monitoring Plan And Report (EMMP/R)

Operating Units for Associate Awards will use an annual Environmental Mitigation and Monitoring Plan (EMMP) to ensure programmatic compliance with 22 CFR 216. An EMMR will be completed annually so that the conditions specified and met in this PIEE and subsequent SIEE are shown to have been carried out under OEPA. The EMMPs and EMMRs are reviewed and approved by the mission activity manager and the Mission Environmental Officer.

The EMMP is described in the table below and should be filled out in detail in the prior to the start of activities. The specific mitigation measures identified in the EMMP must be integrated into the annual work-plan for the project and activities.

The Reporting Form, labeled EMMR is below. It should be submitted in the annual performance report.

PREDICT 2 Cooperative Agreement
Environmental Mitigation and Monitoring Plan (EMMP)

Category of Activity from Section 4 of PREDICT 2 IEE	Describe specific environmental threats of your organization's activities (based on analysis in Section 3 of PREDICT 2 IEE)	Description of Specific Mitigation Measures for these activities as required in Section 4 of PREDICT 2 IEE	Who is responsible for monitoring	Monitoring Indicator	Monitoring Method	Frequency of Monitoring
For instance: 1. Education, technical assistance, training etc.	No environmental impacts anticipated as a result of these activities	Education, technical assistance and training about activities that inherently affect the environment include discussion prevention and mitigation of potential negative environmental effects.		Discussion of environmental impact included in education, technical assistance, training and other materials	Review of materials	Annual
2. Public Health Commodities						

PREDICT 2
Environmental Mitigation and Monitoring Report (EMMR)

List each Mitigation Measure from column 3 in the EMMR Mitigation Plan (EMMR Part 1 of 2)	Status of Mitigative Measures	List any outstanding issues relating to required conditions	Remarks

Certification

I certify the completeness and the accuracy of the Environmental Monitoring and Mitigation Report (EMMR) compliance monitoring plan for PREDICT 2 COOPERATIVE AGREEMENT above (and covered by the PREDICT 2 PIEE) for which I am responsible:

_____ _____

Signature Date

_____

Print Name

_____

Organization

_____

BELOW THIS LINE FOR USAID USE ONLY

USAID Mission or Central Bureau Clearance of EMMR:

Agreement Officer's Representative: _____ Date: _____

Mission Environmental Officer: _____ Date: _____

Regional Environmental Advisor: _____ Date: _____

Bureau Environmental Officer: _____ Date: _____

Note: If clearance is denied, comments must be provided to applicant.

Annex 1. Healthcare Waste Management Minimal Program Checklist and Action Plan to be Included in Training Materials/Programs

Elements/Actions	*In Place?*	*Next Steps to be done*		
		What	*By Whom*	*By When*
Written plans and procedures				
1. *A written waste management plan* Describing all the practices for handling, storing, treating, and disposing of hazardous and non-hazardous waste, as well as types of worker training required.				
2. *Internal rules for generation, handling, storage, treatment, and disposal of healthcare waste.*				
3. *Clearly assigned staff responsibilities that cover all steps in the waste management process.*				
4. *Staff waste handling training curricula or a list of topics covered.*				
5. *Waste minimization, reuse, and recycling procedures.*				
Staff Training, Practices, and Protection*				
6. *Staff trained in safe handling, storage, treatment, and disposal.* Does staff exhibit good hygiene, safe sharps handling, proper use of protective clothing, proper packaging and labeling of waste, and safe storage of waste? Does staff know the correct responses for spills, injury, and exposure?				
7. *Protective clothing available for workers who move and treat collected infections waste* such as surgical masks and gloves, aprons, and boots.				
8. *Good hygiene practices.* Are soap and, ideally, warm water readily available workers to				

Exhibit A - Exhibit A Agreement

Exhibit A-1

use and can workers be observed regularly washing.				
9. *Workers vaccinated* for against viral hepatitis B, tetanus infections, and other endemic infections for which vaccines are available.				
Handling and Storage Practices				
10. *Temporary storage containers and designated storage locations.* *11.* Are there labeled, covered, leak-proof, puncture-resistant temporary storage containers for hazardous healthcare wastes?				
12. *Minimization, reuse, and recycling procedures.* • Does the facility have good inventory practices for chemicals and pharmaceuticals, i.e.: ○ use the oldest batch first; ○ open new containers only after the last one is empty; procedures to prevent products from being thrown out during routine cleaning; and				
13. *A waste segregation system.* • Is general waste separated from infectious/hazardous waste? • Is sharp waste (needles, broken glass, etc.) collected in separate puncture-proof containers? • Are other levels of segregation being applied e.g. hazardous liquids, chemicals and pharmaceuticals, PVC plastic, and materials containing heavy metals ((these are valuable, but less essential)?				
14. *Temporary storage containers and designated storage locations.* • Are there labeled, covered, leak-proof, puncture-resistant temporary storage containers for hazardous healthcare wastes? • Is the location distant from patients or food?				
Treatment Practices				
15. Frequent removal and treatment of waste				

• Are wastes collected daily? • Are wastes treated with a frequency appropriate to the climate and season? ○ Warm season in warm climates within **24 hrs** ○ In the cool season in warm climates within **48 hrs** ○ In the warm season in temperate climates within **48 hrs**				
16. *Treatment mechanisms for hazardous and highly hazardous waste*. (The most important function of treatment is disinfection). • Are wastes being burned in the open air, in a drum or brick incinerator, or a single-chamber incinerator? • If not are they being buried safely (in a pit with an impermeable plastic or clay lining)? • Is the final disposal site (usually a pit) surrounded by fencing or other materials and in view of the facility to prevent accidental injury or scavenging of syringes and other medical supplies?				
17. If the waste is transported off-site, are precautions taken to ensure that it is transported and disposed of safely?				

*** Training should be conducted before starting activity implementation**

For more detailed checklists and guidance consult: *Safe management of wastes from health-care activities*, edited by A. Prüss, E. Giroult and P. Rushbrook. Geneva, WHO, 1999, http://www.who.int/water_sanitation_health/Environmental_sanit/MHCWHanbook.htm. English

Annex 2. Disposal and Treatment Methods Suitable for Different Categories of Healthcare Waste to be Included in Training Materials/Programs (EXAMPLE)

Method	Infectious Waste (laboratory cultures, excreta)	Sharps (needles, blades, broken glass)	Pharmaceutical Waste (expired pharmaceuticals, boxes contaminated by pharmaceuticals)	Chemical Waste (laboratory reagents, solvents)	Radioactive Waste (unused liquids from laboratory research)
Rotary kiln	✓	✓	✓	✓	✓[2]
Pyrolytic incinerator	✓	✓	✓[1]	✓[1]	✓[2]
Single-chamber incinerator	✓	✓			✓[2]
Drum or brick incinerator	✓	✓			
Chemical disinfection	✓	✓			
Wet thermal treatment	✓	✓			
Microwave irradiation	✓	✓			
Encapsulation		✓	✓	✓[1]	
Safe burial on hospital premises	✓	✓	✓[1]	✓[1]	
Sanitary landfill	✓		✓[1]		
Discharge to sewer			✓[1]		Low-level liquid waste
Inertization			✓		
Other			Return to supplier	Return to supplier	Decay by storage

1: Small quantities only
2: Low-level infectious waste

Exhibit A - Exhibit A Agreement

Exhibit A-1

ATTACHMENT F – TABLE OF ACRONYMS

BSL	Biohazard Safety Level
CDC	United States Centers for Disease Control and Prevention
cPCR	Consensus Polymerase Chain Reaction
DALYs	Disability Adjusted Life Years
DOD	United States Department of Defense
DTRA	U.S. DOD/Defense Threat Reduction Agency
DUO	Diseases of Unknown Origin
EAP	External Advisory Panel
EHA	EcoHealth Alliance
EID	Emerging Infectious Disease
ELISA	Enzyme-linked Immunosorbent Assay
EPT	Emerging Pandemic Threats Program of
USAID FAO	The Food and Agriculture Organization
FUO	Fever of Unknown Origin
GAINS	Global Animal Information System
GHSA	Global Health Security Agenda
GIS	Geographic Information Systems
GISRS	WHO Global Influenza Surveillance and Response System
HTS	High Through-put Sequencing
IHR	International Health Regulations
ILI	Influenza-like Illness
INSERM	Institut National de la Sánte et de la Recherche Médicale
MB	Metabiota, Inc.
M&E	Monitoring and Evaluation
MERS	Middle Eastern Respiratory Syndrome
OFFLU	OIE-FAO Network of Expertise on Animal Influenza
OHCEA	One Health Central and East Africa University Network
OHI	One Health Institute
OHW	USAID One Health Workforce project
OIE	Organization for Animal Health
PIOET	USAID's Pandemic Influenza and Other Emerging Threats Program
PPE	Personal Protective Equipment
P&R	USAID Preparedness and Response project
SARI	Severe Acute Respiratory Infection
SARS-CoV	Severe Acute Respiratory Syndrome Coronavirus
SEAOHUN	Southeast Asia One Health University Network
SI	Smithsonian Institution
SOP	Standard Operating Procedure
SVM	School of Veterinary Medicine
USAID	United States Agency for International Development
UCD	University of California, Davis
UCG	United States Government
WAHIS	World Animal Health Information System
WCS	Wildlife Conservation Society

WHO	The World Health Organization
ZIPI	Zoonotic Infections Prevention Integration committee

End of Attachment F