Dr. Lauer:

Please see the attached letter from Andrew N. Krinsky on behalf of EcoHealth Alliance, Inc., pursuant to NIH Grants Policy Statement Section 8.7, regarding the decision by NIAID to terminate NIH Research Grant R01 AI 110964 on or about April 24, 2020.

Thank you.

Best,
Matthew R. Torsiello
This email is an informal communication that is not meant to be legally binding upon the sender unless expressly noted to the contrary.

TarterKinsky & Drogin LLP, Attorneys-at-Law.
May 22, 2020

Via Email, Certified Mail, & FedEx

Michael S. Lauer, MD
NIH Deputy Director for Extramural Research
National Institutes of Health
National Institute of Allergy and Infectious Diseases
1 Center Drive, Building 1, Room 144
Bethesda, Maryland 20892

Re: Termination of NIH Grant 2R01 AI 110964-6

Dear Dr. Lauer:

This firm represents EcoHealth Alliance, Inc. ("EcoHealth Alliance") with regard to the post-award decision by the National Institute of Allergy and Infectious Diseases ("NIAID"), an Institute within the National Institute of Health ("NIH"), under the Department of Health and Human Services ("HHS"), to terminate the project Understanding the Risk of Bat Coronavirus Emergence, funded under grant R01 AI 110964, on April 24, 2020 (the "Termination").

This letter, pursuant to NIH Grants Policy Statement Section 8.7 and 42 CFR 50, Subpart D, constitutes EcoHealth Alliance’s first-level appeal of the Termination, which was "for convenience." As set forth in more detail below, the Termination is not authorized under the NIH Grants Policy Statement, arbitrary and capricious and an indefensible attack on public health and welfare given that it undermines a pivotal 10-year research project involving the origins, spread and threat of emerging bat coronaviruses during the peak of an unprecedented worldwide coronavirus pandemic. Accordingly, EcoHealth Alliance hereby demands that grant 2R01 AI 110964-6 be reinstated immediately.

BACKGROUND

A. EcoHealth Alliance

EcoHealth Alliance is a prominent New York-based nonprofit institution dedicated to protecting the health of people, animals, and the environment from emerging zoonotic diseases. For more than a decade, EcoHealth Alliance has been conducting cutting edge scientific research to identify hundreds of new coronaviruses ("CoVs") in bats and to study the capacity of these viruses to infect human cells. The purpose of this research is to identify high risk populations so international actors can leverage their resources to address potential pandemics. In cooperation with a global network of over seventy partners, including academic institutions, intergovernmental
and governmental agencies, infectious disease surveillance laboratories, and other international and national organizations in over thirty countries, EcoHealth Alliance’s work has led to numerous scientific papers published in high impact journals. These publications have been critical in raising awareness of the threat that CoVs pose to global health, the global economy, and U.S. National Security.

EcoHealth Alliance has a long history of successful cooperation with NIH including multiple Research Project Grant R01 awards. In particular, Peter Daszak, EcoHealth Alliance’s President and Chief Scientist, has been the Principal Investigator on five multidisciplinary R01s. All of these projects used modeling, epidemiology, laboratory, and field science to test hypotheses on the emergence of wildlife-origin viral zoonoses, including SARS-CoV, the Nipah and Hendra viruses, Avian influenza, and other bat-origin viruses. EcoHealth Alliance, a 501(c)(3) organization, is unique in that it goes one step further by leveraging its research goals to create an alliance of international collaborators that can advocate for real-world changes to protect high risk populations.

Notably, in collaboration with virologists in China, EcoHealth Alliance isolated and characterized SARSr-CoVs from bats that use the same human host cell receptor (ACE2) as SARS-CoV. This work provided critical reagents and resources that have advanced scientific understanding of virus-host binding and contributed to vaccine development. For example, the genetic sequences of the bat viruses that EcoHealth Alliance discovered under its NIH research funding, which were published online (Genbank & GISAID), have been used to test the effectiveness of the drug Remdesivir against not only SARS-CoV, but also MERS, and other potentially zoonotic or pre-pandemic bat CoVs. Significantly, this type of testing can be performed without the need for viral cultures or shipping viruses internationally.

**B. NIH Awards And Extends EcoHealth Alliance Research Grant R01 AI 110964**

In 2014, NIH issued EcoHealth Alliance a five-year research award for the project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AI 110964 (the “Project”). EcoHealth Alliance received additional awards for the Project each year between 2015 and 2018. Between 2015 and 2019, the Project resulted in the publication of more than twenty papers.

In 2019, EcoHealth Alliance submitted a renewal application to NIH through NIAID to extend the Project period for an additional five years. Upon filing of its renewal application, the Project was ranked as an “extremely high priority” (in the top 3%) by NIAID during its external review process. In light of its success and the importance of EcoHealth Alliance’s work, on July 24, 2019, NIH reauthorized grant R01 AI 110964 and increased EcoHealth Alliance’s funding. EcoHealth Alliance was issued a notice of award in the amount of $733,750.00 (the “2019 Award”). The notice of award also extended the Project period for an additional five years to 2024. A copy of the notice of award is attached hereto as Exhibit A.

**C. EcoHealth Alliance Agrees Not To Fund The Wuhan Institute Of Virology**

During the pendency of the Project, in December of 2019, China reported a cluster of cases of pneumonia in Wuhan, Hubei Province. It was later determined that the cause of this pneumonia
was a novel CoV, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), causing coronavirus disease (COVID-19). Thereafter, SARS-CoV-2 spread to nearly every country throughout the world. In response, EcoHealth Alliance has prioritized its efforts in conducting research that will be integral to developing an effective strategy to combat SARS-CoV-2.

On April 19, 2020, Michael S. Lauer, MD, NIH Deputy Director for Extramural Research, sent a letter to EcoHealth Alliance on behalf of NIH regarding a laboratory in China, the Wuhan Institute of Virology (“WIV”). WIV was a prior sub-recipient of a small portion of the R01 AI 110964 grant funds. The letter stated that, given allegations that COVID-19 “was precipitated by the release from WIV of the coronavirus responsible for COVID-19”, NIH was pursuing suspension of WIV from participating in Federal programs. However, Mr. Lauer assured EcoHealth Alliance that “[t]his suspension of the sub-recipient does not affect the remainder of [EcoHealth Alliance’s] grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension.” A copy of the letter is attached hereto as Exhibit B.

On April 21, 2020, Dr. Dassak of EcoHealth Alliance responded by email to Dr. Lauer stating that he could “categorically state that no funds from [sic] 2R01 AI 110964-6 have been sent to Wuhan Institute of Virology, nor has any contract been signed.” Dr. Dassak further represented that EcoHealth Alliance would comply with all NIAID requirements. Dr. Lauer acknowledged (1) that no monies from grant 2R01 AI 110964-6 had gone to WIV and no contract between EcoHealth Alliance and WIV had been signed and (2) EcoHealth Alliance’s agreement that it would not provide any funds to WIV until and unless directed otherwise by NIH. A copy of the email correspondence between NIH and EcoHealth Alliance is attached hereto as Exhibit C.

D. **NIH Abruptly Terminates Research Grant 2R01 AI 110964-6 “For Convenience”**

Notwithstanding NIH’s representation that suspension of WIV would not affect the remainder of EcoHealth Alliance’s 2019 Award, on April 24, 2020, NIH notified EcoHealth Alliance by letter that, effective immediately, the 2019 Award had been terminated by NIAID. The stated grounds for the Termination were: (1) convenience; (2) NIH’s discretion not to award a grant, or to award a grant at a particular funding level; and (3) NIH’s belief that the Project outcomes did not align with the program goals and agency priorities. A copy of the Termination is attached hereto as Exhibit D.

**ARGUMENT**

**A. NIH Research Grants Are Not Subject To Termination For Convenience**

“Termination for convenience” refers to the exercise of the government’s right to bring to an end the performance of all or part of the work provided for under a contract prior to the expiration of the contract “when it is in the Government’s interest” to do so. Federal agencies typically incorporate clauses in their procurement contracts which give them the right to terminate for convenience. Here, there is no clause in the terms and conditions applicable to the 2019 Award, or in the NIH Grants Policy Statement, that permits NIAID or NIH to issue a post-award decision to terminate a NIH research grant award “for convenience.”
Moreover, the unprecedented assertion by NIH that active research grants can be terminated “for convenience” during the subject budget period renders Section 8.5.2 of the NIH Grants Policy Statement meaningless. See, e.g., Li v. Eddy, 324 F.3d 1109, 1110 (9th Cir. 2003) (rejecting suggested statutory interpretation on the grounds that the interpretation ran squarely against the canon of construction that courts interpret statutes so as not to render any section meaningless). Section 8.5.2 of the NIH Grants Policy Statement governs, inter alia, modification or termination of an award for misconduct. If NIH grants were terminable for convenience, NIH could always choose to terminate for convenience to avoid (1) the “for cause” restriction on grant terminations and (2) the labor intensive task of enforcing compliance through disallowing costs, withholding further awards, or wholly suspending the grant, pending corrective action.

B. **NIH’s Discretion Not To Award A Grant, Or To Award a Grant At A Particular Funding Level, Does Not Authorize A Post-Award Decision To Terminate**

NIH’s discretion regarding the “decision not to award a grant, or to award a grant at a particular funding level” does not give NIH the authority to issue a post-award decision terminating a duly awarded grant during the budget period. This purported discretion, which is based on language in the last paragraph of NIH Grants Policy Statement Section 2.4.4, entitled *Disposition of Applications*, concerns NIH’s authority to reject incomplete or otherwise undesirable grant applications in the first instance only. The provisions of Section 2, generally, have no bearing on post-award decisions affecting duly approved grants for which specified funds have already been allocated. As the 2019 Grant in the amount of $733,750.00 was awarded to EcoHealth Alliance on July 24, 2019, NIH’s authority to deny initial grant applications does not allow NIH to terminate the 2019 Grant.

C. **The Research Goals Of EcoHealth Alliance And NIAID Are Virtually Identical**

NIH’s contention that the Project’s outcomes do not align with the agency’s priorities is demonstrably false. First, the Project was ranked as “extremely high priority” on external review by NIAID less than nine months ago, before the discovery of SARS-CoV-2. Since this discovery, NIH has promulgated new grants seeking applicants to conduct research on the same issues covered by the Project and the 2019 Award.

In addition, there is substantial overlap between the four strategic research priorities on page 1 of NIAID’s Strategic Plan for COVID-19 Research, published April 22, 2020, and the three Specific Aims of the Project. Both NIAID and EcoHealth Alliance seek to: (1) improve fundamental knowledge of SARS-CoV-2; (2) develop methods to assess the rate of infection and disease incidence; (3) contribute to the development of an effective vaccine; and (4) increase public health preparedness. Copies of the Project’s Specific Aims and the NIAID Strategic Plan’s four strategic research priorities for COVID-19 research are attached hereto as Exhibit E.

D. **There Is No Rational Basis To Terminate The 2019 Award For Cause**

The grounds and procedures for suspension and termination of awards are specified in NIH Grants Policy Statement Section 8.5.2 and 45 CFR Parts 75.371 through 75.373. Notably, Section
8.5.2 provides, *inter alia*, that NIH will generally suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision. Through this lens, 45 CFR 75.372 provides that NIH may terminate a Federal award, in whole or in part, if: (1) the non-Federal entity fails to comply with the terms and conditions of the award; (2) for cause; (3) by the HHS awarding agency or pass-through entity with the consent of the non-Federal entity; or (4) by the non-Federal entity upon written notice to the HHS awarding agency setting forth the reasons for such termination, and other information. None of the foregoing predicate conditions exist here.

As of the date of the Termination, EcoHealth Alliance had not received any notice from NIH, NIAID, or HHS that it either failed to comply with any of the terms or conditions of the 2019 Award, or committed any misconduct in connection with the award. To the contrary, in email correspondence following EcoHealth Alliance’s representation that it had not and would not give any funds from the 2019 Award to WIV, Aleksei Chmura, EcoHealth Alliance’s Chief of Staff, memorialized the mutual agreement between NIH and EcoHealth Alliance that EcoHealth Alliance was in compliance with all requests. (Ex. C, # 8). To be clear, EcoHealth Alliance clearly and unequivocally stated that it had not and will not distribute any funds from the 2019 Award to WIV.

In sum, there is no statutory, regulatory, or contractual basis for NIAID’s termination of the Project, *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant 2R01 AI 110964-6. However, please note that this letter is not intended to provide an exhaustive list of all possible grounds for reversal of the Termination and may not reflect all arguments and claims that EcoHealth Alliance will assert in the event that a formal second-level appeal of the Termination is required.

Should you wish to present evidence in an effort to refute any of the factual assertions made in this letter and/or to engage in good faith negotiations regarding appropriate terms and conditions for the resumption of funding for grant 2R01 AI 110964-6, we are prepared to review such evidence and to participate in such negotiations.

We await your response to this letter.

Very truly yours,

Andrew B. Krinsky

cc: (by email)

Dr. Erik Stemmy (b)(6)
Ms. Emily Linde (b)(6)
Exhibit A
Grant Number: 2R01AI110964-06
FAIN: R01AI110964

Principal Investigator(s):
PETER DASZAK, PHD

Project Title: Understanding the Risk of Bat Coronavirus Emergence

Dr. Daszak, Peter
PD/PI
480 West 34th Street
Suite 1701
New York, NY 100012320

Award e-mailed to: (b)(6)

Period Of Performance:
Budget Period: 07/24/2019 – 06/30/2020
Project Period: 06/01/2014 – 06/30/2024

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $733,750 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to ECOHEALTH ALLIANCE, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI110964. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator’s Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,
SECTION I – AWARD DATA – 2R01AI110964-06

Approved Budget: $733,750
Total Amount of Federal Funds Obligated (Federal Share): $733,750
TOTAL FEDERAL AWARD AMOUNT: $733,750
AMOUNT OF THIS ACTION (FEDERAL SHARE): $733,750

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Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project.

Fiscal Information:
CFDA Name: Allergy and Infectious Diseases Research
CFDA Number: 93.855
EIN: 1311726494A1
Document Number: RA110964B
PMS Account Type: P (Subaccount)
Fiscal Year: 2019

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Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project.

NIH Administrative Data:
PCC: M51C B / OC: 414B / Released: [redacted] 07/18/2019
Award Processed: 07/24/2019 12:03:26 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 2R01AI110964-06

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 2R01AI110964-06

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AI110964. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.
Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

The Research Performance Progress Report (RPPR), Section G.9 (Foreign component), includes reporting requirements for all research performed outside of the United States. Research conducted at the following site(s) must be reported in your RPPR:

This award reflects current Federal policies regarding Facilities & Administrative (F&A) Costs for foreign grantees including foreign sub-awardees, and domestic awards with foreign sub-awardees. Please see: Chapter 16 Grants to Foreign Organizations, International Organizations, and Domestic Grants with Foreign Components, Section 16.6 “Allowable and Unallowable Cost” of the NIH Grants Policy.

This award may include collaborations with and/or between foreign organizations. Please be advised that short term travel visa expenses are an allowable expense on this grant, if justified as critical and necessary for the conduct of the project.

The budget period anniversary start date for future year(s) will be July 1.

Dissemination of study data will be in accord with the Recipient’s accepted genomic data sharing plan as stated in the page(s) 203 of the application. Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIAID may result in Enforcement Actions as described in the NIH Grants Policy Statement.

This award is subject to the Clinical Terms of Award referenced in the NIH Guide for Grants and Contracts, July 8, 2002, NOT AI-02-032. These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address: https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Award.
Awardees who conduct research involving Select Agents (see 42 CFR 73 for the Select Agent list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens at http://www.selectagents.gov/Regulations.html) must complete registration with CDC (or APHIS, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.

Prior to conducting a restricted experiment with a Select Agent or Toxin, awardees must notify the NIAID and must request and receive approval from CDC or APHIS.

Select Agents:
Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (http://www.cdc.gov/OD/ohs/biofety/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

   o A list of the new and/or additional Agent(s) that will be studied;
   o A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
   o The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

STAFF CONTACTS
The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

**Grants Management Specialist:** Tseday G Girma  
**Email:** [Redacted]  
**Phone:** [Redacted]  
**Fax:** 301-493-0597

**Program Official:** Erik J. Stemmy  
**Email:** [Redacted]  
**Phone:** [Redacted]

**SPREADSHEET SUMMARY**  
**GRANT NUMBER:** 2R01AI110964-06

**INSTITUTION:** ECOHEALTH ALLIANCE, INC.

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TOTAL COST  
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$709,750  
$709,750  
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Exhibit B
Date: April 19, 2020

From: Michael S Lauer, MD
NIH Deputy Director for Extramural Research

To: Kevin Olival, PhD
Vice-President for Research
EcoHealth Alliance

Naomi Schrag, JD
Vice-President for Research Compliance, Training, and Policy
Columbia University

Subject: Project Number 2R01AI110964-06

Dear Dr. Olival and Ms. Schrag:

EcoHealth Alliance, Inc. is the recipient, as grantee, of an NIH grant entitled “Understanding the Risk of Bat Coronavirus Emergence.” It is our understanding that one of the sub-recipients of the grant funds is the Wuhan Institute of Virology (“WIV”). It is our understanding that WIV studies the interaction between corona viruses and bats. The scientific community believes that the coronavirus causing COVID-19 jumped from bats to humans likely in Wuhan where the COVID-19 pandemic began. There are now allegations that the current crisis was precipitated by the release from WIV of the coronavirus responsible for COVID-19. Given these concerns, we are pursuing suspension of WIV from participation in Federal programs.

While we review these allegations during the period of suspension, you are instructed to cease providing any funds from the above noted grant to the WIV. This temporary action is authorized by 45 C.F.R. § 75.371(d) (“Initiate suspension or debarment proceedings as authorized under 2 C.F.R. part 180”). The incorporated OMB provision provides that the funding agency may, through suspension, immediately and temporarily exclude from Federal programs persons who are not presently responsible where “immediate action is necessary to protect the public interest.” 2 C.F.R. § 180.700(c). It is in the public interest that NIH ensure that a sub-recipient has taken all appropriate precautions to prevent the release of pathogens that it is studying. This suspension of the sub-recipient does not affect the remainder of your grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension.
Exhibit C
Dear Dr. Olival and Ms. Schrag

Please see attached. (Referring to Exhibit B)

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)
Dear Mike,

I received the attached letter, however please note:

1. I am not the PI on this award. You should contact Dr. Peter Daszak who is the PI and leading this project for EcoHealth Alliance.
2. Columbia University is not involved in this NIH project, and it is not clear to me why Naomi and Columbia University were included.

Thank you,
Kevin

Kevin J. Olival, PhD
Vice President for Research

EcoHealth Alliance
460 West 34th Street, Suite 1701
New York, NY 10001
Thank you Kevin

- We need to work with a senior responsible business official – usually PI’s and senior business officials are different people.
- When I looked you up on the web, I see the Columbia logo (see attached screenshot). Specifically, it appears to be Columbia University > Ecology, Evolution, and Environmental Biology > EcoHealth Alliance (labeled as an “Affiliation/Department”). Thus the web profile makes it look to me as if EcoHealth Alliance is linked to Columbia University.
- In any case, I’m looping in Dr. Daszak.
- We need to know all sites in China that have been in any way linked to this award (Type 1 and Type 2). We have data in NIH, but we want to make absolutely sure that we’re of the same understanding.

We greatly appreciate your prompt attention to this matter.

Best, Mike
Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

Michael Lauer email on 20 April 2020

Lauer, Michael (NIH/OD) [E] <...>

Mon 4/20/2020 6:34 PM

To: Naomi Schrag (b) (6); Kevin Olival (b) (6); Peter Daszak (b) (6)

Cc: Black, Jodi (NIH/OD) [E] <...>

(b) (6) Lauer, Michael (NIH/OD) [E] <...>

1 attachment

Screen Shot 2020-04-20 at 4.23.38 PM.png;

Thanks Naomi – not the impression an observer would get looking at the website (see screen shot), but we understand about the grant.

If they “are entirely separate entities” then why does Columbia identify EcoHealth Alliance as an “Affiliation/Department” on its website.

Maybe with the label “Affiliation/Department” you would have a clearly visible disclaimer that says, “EcoHealth Alliance is not affiliated with nor a department of Columbia”? – although even that is internally contradictory.

Best, Mike

From: Naomi Schrag <...>
Date: Monday, April 20, 2020 at 5:19 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6), Kevin Olival (b) (6)
Cc: Naomi Schrag <...> "Black, Jodi (NIH/OD) [E]" <...>
Subject: RE: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

Dear Dr. Lauer,

Columbia and EcoHealth Alliance are entirely separate entities. Some individuals affiliated with EcoHealth Alliance do have adjunct appointments in Columbia’s Ecology, Evolution, and Environmental Biology (“E3B”) department, but we are not aware of any Columbia involvement with the referenced grant, and have found no agreement or record in our grants system to the contrary.

We would be happy to answer any additional questions. Thank you.
Sincerely,
Naomi Schrag

Naomi J. Schrag

https://mex08.emailsrvr.com/owa/#view=ReadMessageItem&It...Q59cgEgOF2gAFWhHydwAAAA%3D%3D&IsPrintView=1&wid=59&ispopout=1
Vice President for Research Compliance, Training and Policy
Office of Research Compliance and Training
475 Riverside Drive, Suite 840
New York, New York 10115

www.researchcompliance.columbia.edu
RE: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

5 Peter Daszak email on 21 April 2020

Peter Daszak

Tue 4/21/2020 1:32 AM

To: Lauer, Michael (NIH/OD) [E] <[redacted]> (b) (6) Naomi Schrag <[redacted]> (b) (6) ; Kevin Olival
Cc: Black, Jodi (NIH/OD) [E] <[redacted]> (b) (6)

Dear Michael Lauer & Jodi Black – I now have your email and will deal with it directly with you and your staff. Naomi is correct that there is no involvement of Columbia University in this grant. I’m sure NIH has records to confirm that.

From this moment on, I will not cc any staff at Columbia as part of this discussion, and I hope you will also honor that. Respectfully, the discussion of whether or not EHA is an affiliate of CU is entirely irrelevant to the request that you contacted us about, and should remain a private matter between EcoHealth Alliance and Columbia University.

I’ll look over your email and respond tomorrow.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
460 West 34th Street
New York, NY 10001
USA

Tel.: +[redacted] (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation
RE: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

Peter Daszak

Tue 4/21/2020 7:03 PM

To: Lauer, Michael (NIH/OD) [E] (b) (6);
Cc: Black, Jodi (NIH/OD) [E] (b) (6); Aleksei Chmura Stemmy, Erik (NIH/NIAID) [E] (b) (6);

Importance: High

1 attachment

EcoHealth Alliance re Al grant 4 19 20.pdf;

Dear Michael – Confirming receipt of your email. I’m also cc’ing the following people so they’re aware of this request:

1. Our AOR – Dr. Aleksei Chmura, who has access to all our records
2. My Program Officer for this award, Dr. Erik Stemmy & the Division Director (DMID), Dr. Emily Erberding, so they are informed and aware of the request and our response.

That said we need some time to go through the request for information and will provide this as quickly as we can.

However, I can categorically state that no funds form 2R01AI110964-06 have been sent to Wuhan Institute of Virology, nor has any contract been signed. Furthermore, we will comply with NIAID requirements, of course.

Concerning the request for information on all of the sites linked to this award in China, you should be aware that these are documented in our progress reports over the course of the grant. As you can understand we are under enormous pressure to generate data related to the current pandemic, and we do not want to divert staff to this effort. We are hoping the previously filed reports will satisfy this request.

We are well aware of the political concerns over the origins of this outbreak. Our collaboration with Wuhan Institute of Virology has been scientific and we have been consistently impressed with the scientific capabilities of that laboratory and its research staff. Our joint work has led to a series of critical papers published in high impact journals that served to raise awareness of the future threat coronaviruses pose for global health and therefore US national security. Scientific insights with epidemiological significance have been jointly published and our relationship has always been open and transparent and with one concern only, scientific validity. We are concerned that current actions may jeopardize 15 years of fruitful collaboration with colleagues in Wuhan, who are working at the leading edge to design vaccines and drugs that could help us fight this new threat in future years. It is quite remarkable that of the 5 vaccine candidates listed by WHO that are already in human trials, 3 have been developed in China. That said, we of course will...
do all we can to make sure any further questions from NIH or any Federal agency are addressed to our fullest knowledge.

Yours sincerely,

Peter Daszak  
President

EcoHealth Alliance  
450 West 34th Street  
New York, NY 10001  
USA

Tel.: +(b)(6)  
Website: www.ecohealthalliance.org  
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation
Many thanks Peter for your response.

We note that:

- No monies have gone to WIV on the Type 2 award and no contract has been signed.
- You agree that you will not provide any funds to WIV until and unless directed otherwise by NIH.
- All foreign sites for the Type 1 and Type 2 awards have been documented in the progress reports submitted to NIH.

We appreciate your working with us.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)
Dear Mike,

I read that we are in agreement and in compliance with all requests. Please let us know if anything further is required. We will continue in our usual close communication with our Program Officer Erik Stemmy.

Sincerely,

-Aleksei

Aleksei Chmura  
Chief of Staff & Authorized Organizational Representative

EcoHealth Alliance  
460 West 34th Street, Suite 1701  
New York, NY 10001

www.ecohealthalliance.org

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation.
Many thanks Aleksei.

Best, Mike

9 Michael Lauer email on 21 April 2020
Dear Dr. Chmura and Dr. Daszak

Please see attached. *(Referring to Exhibit D)*

Sincerely,
Michael S Lauer, MD

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: *(b) (6)*
Email: *(b) (6)*
Dear Michael,

Could Peter and I have a quick chat with you sometime tomorrow (Tuesday) about your email, below?

Sincerely,

-Aleksel

Aleksei Chmura, PhD
Chief of Staff

EcoHealth Alliance
460 West 34th Street, Suite 1701
New York, NY 10001

www.ecohealthalliance.org

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation.
Drs. Aleksei Chmura and Peter Daszak  
EcoHealth Alliance, Inc.  
460 W 34th St  
Suite 1701  
New York, NY 10001  

Re: Termination of NIH Grant R01 AI 110964  

Dear Drs. Chmura and Daszak:  

I am writing to notify you that the National Institute of Allergy and Infectious Diseases (NIAID), an Institute within the National Institutes of Health (NIH), under the Department of Health and Human Services (HHS) has elected to terminate the project **Understanding the Risk of Bat Coronavirus Emergence**, funded under grant R01 AI 110964, for convenience. This grant project was issued under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284). This grant was funded as a discretionary grant as outlined in the NIH Grants Policy Statement, which states that the decision not to award a grant, or to award a grant at a particular funding level, is at the discretion of the agency, in accordance with NIH’s dual review system.  

At this time, NIH does not believe that the current project outcomes align with the program goals and agency priorities. NIAID has determined there are no animal and human ethical considerations, as this project is not a clinical trial, but rather an observational study.  

As a result of this termination, a total of $369,819.56 will be remitted to NIAID and additional drawdowns will not be supported. The remaining funds have been restricted in the HHS Payment Management System, effective immediately.  

Please let me know if you have any questions concerning the information in this letter.  

Sincerely,  

Michael S Lauer, MD  
NIH Deputy Director for Extramural Research  

cc: Dr. Erik Stemmy  
Ms. Emily Linde
Exhibit E
SPECIFIC AIMS
Zoonotic coronaviruses are a significant threat to global health, as demonstrated with the emergence of Severe Acute Respiratory Syndrome coronavirus (SARS-CoV) in 2002, and the continuing spread of Middle East Respiratory Syndrome (MERS-CoV). The wildlife reservoirs of SARS-CoV were identified by our group as bat species, and since then we have sequenced dozens of novel SARS-related CoV (SARSr-CoV) strains. Our previous R01 work demonstrates that bats in southern China harbor an extraordinary diversity of SARSr-CoVs, some of which are able to use human ACE2 to enter into human cells, can infect humanized mouse models to cause SARS-like illness, and evade available therapies or vaccines. We found that the bat hosts of SARSr-CoVs appear to no longer be traded in wildlife markets, and that people living close to bat habitats are the primary risk groups for spillover. At one of these sites, we found diverse SARSr-CoVs containing every genetic element of the wild-type SARS-CoV genome, and serological evidence of human exposure among people living nearby. Thus, there is significant potential for future spillover of SARSr-CoVs, and of public health impacts. Yet salient questions remain: Are there specific bat communities and sites that harbor CoV strains with higher risk for bat-to-human spillover? Which human behaviors drive risk of bat SARSr-CoV exposure that could lead to infection? Does human exposure to these viruses cause SARS-like or other illness? Can we characterize viral strain diversity, bat traits and human behaviors to assess risk of potential future CoV spillover? The proposed work in this renewal R01 builds on these findings to address these issues by conducting: 1) focused sampling of bats in southern China to identify viral strains with high predicted risk of spillover; 2) community-based, and clinic-based syndromic, sampling of people to identify spillover, and assess behavioral risk factors and evidence of illness; and 3) conduct in vitro and in vivo viral characterization and analyze epidemiological data to identify hotspots of future CoV spillover risk.
This work will follow 3 specific aims:

**Aim 1:** Characterize the diversity and distribution of high spillover-risk SARSr-CoVs in bats in southern China. We will conduct targeted bat sampling at sites where we predict that undiscovered high risk SARSr-CoV strains exist. Bat sampling will be targeted geographically and by host species to test predictions about evolutionary diversity of SARSr-CoV. We will analyze RdRp and S protein sequences to test their capacity for spillover to people in Aim 3.

**Aim 2:** Community- and clinic-based surveillance to capture SARSr-CoV spillover, routes of exposure and potential public health consequences. We will conduct focused, targeted human surveys and sampling to identify key risk factors for SARSr-CoV spillover and evidence of illness. To maximize our opportunity of capturing human exposure to bat CoVs, we will conduct community-based surveillance in regions with high SARSr-CoV prevalence and diversity, and individuals having contact with bats. We will assess bat-CoV seropositive status against a small number of questions about human-wildlife contact and exposure. We will conduct clinic-based syndromic surveillance close to these sites to identify patients presenting with influenza-like illness and severe acute respiratory illness, assess their exposure to bats via a questionnaire, and test samples for PCR- and serological evidence of SARSr-CoV infection. We will conduct follow-up sampling to capture patients who had not yet seroconverted at the time of clinic visit.

**Aim 3:** In vitro and in vivo characterization of SARSr-CoV spillover risk, coupled with spatial and phylogenetic analyses to identify the regions and viruses of public health concern. We will characterize the propensity of novel SARSr-CoVs to infect people in vitro using primary human airway epithelial cells and in vivo using the transgenic hACE2 mouse model. We will use mAb and vaccine treatments to test our hypothesis that SARSr-CoVs with 10-25% divergence in S protein sequences from SARS-CoV are likely able to infect human cells, and to evade mAb therapeutics and vaccines. We will then map the geographic distribution of their bat hosts and other ecological risk factors to identify the key ‘hotspots’ of risk for future spillover.

Overall, our SARSr-CoV program serves as a model platform to integrate virologic, molecular and ecologic factors contributing to CoV emergence while informing high impact strategies to intervene and prevent future pandemics. This includes providing critical reagents, therapeutic interventions and recombinant viruses for future SARSr-CoV pandemic and public health preparedness.
This scanning electron microscope image shows SARS-CoV-2 (yellow), the virus that causes COVID-19, isolated from a patient in the United States, emerging from the surface of cells (pink) cultured in the lab. Credit: NIAID-RML
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Executive Summary

The National Institute of Allergy and Infectious Diseases (NIAID) at the United States (U.S.) National Institutes of Health (NIH) is committed to safeguarding the health of Americans and people around the world by accelerating research efforts to prevent, diagnose, and treat COVID-19 and characterize the causative agent of this disease, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This NIAID Strategic Plan for COVID-19 Research builds on current trans-NIAID efforts to better understand SARS-CoV-2 pathogenesis, transmission, and mechanisms of protective immunity by expanding resources and activities that support rapid development of biomedical tools to more effectively combat this disease and pandemic. Given the urgency of the public health response, studies that inform efforts to control virus spread and mitigate morbidity and mortality, including therapeutic and vaccine development, are the priority. In addition, it is essential to develop rapid, accurate, point-of-care diagnostics—a critical asset to mitigating the spread of COVID-19.

The NIAID Strategic Plan for COVID-19 Research aligns with the priorities set by U.S. Government-wide task forces for the development of medical countermeasures. NIAID actively participates in COVID-19 task forces to identify opportunities, ensure open communication, encourage resource sharing, and avoid duplication of effort. The plan is structured around four strategic research priorities:

1. **Improve fundamental knowledge of SARS-CoV-2 and COVID-19**, including studies to characterize the virus and how it is transmitted and understand the natural history, epidemiology, host immunity, disease immunopathogenesis, and the genetic, immunologic, and clinical associations with more severe disease outcomes. This includes accelerating the development of small and large animal models that replicate human disease.

2. **Support the development of diagnostics and assays**, including point-of-care molecular and antigen-based diagnostics for identifying and isolating COVID-19 cases and serologic assays to better understand disease prevalence in the population. Diagnostics also will be essential for evaluating the effectiveness of candidate countermeasures.

3. **Characterize and test therapeutics**, including identifying and evaluating repurposed drugs and novel broad-spectrum antivirals, virus-targeted antibody-based therapies (including plasma-derived intravenous immunoglobulin (IVIG) and monoclonal antibodies), and host-directed strategies to combat COVID-19.

4. **Develop safe and effective vaccines against SARS-CoV-2**, including support of clinical trial testing.

To accelerate research, NIAID will leverage current resources and global collaborations, including existing research programs and clinical trials networks. NIAID’s research response to COVID-19 will build on experience with diseases caused by other zoonotic coronaviruses (CoVs), including severe acute
respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). NIAID will pursue public-private partnerships to facilitate the translation of research outcomes into life-saving public health interventions. Working with pharmaceutical companies, NIAID has already initiated Phase 1 clinical trials for candidate COVID-19 vaccines and therapeutics. A concerted effort will be made to include minority populations, as well as at-risk and vulnerable populations, in all aspects of NIAID-sponsored research to address health disparities between diverse groups. Characterization of the fundamental virology of SARS-CoV-2 and the immunological response to infection will inform future studies and facilitate the development of effective medical countermeasures. With collaboration from all agencies within the U.S. government and other key U.S. and global partners, NIAID will rapidly disseminate these results so that the information can be translated into clinical practice and public health interventions to combat the pandemic. As such, NIAID has already implemented open sharing of scientific data through publicly available websites and will continue to promote the prompt disclosure of SARS-CoV-2 and COVID-19 research data by the scientific community.

Research Plan

Priority 1: Improve fundamental knowledge of SARS-CoV-2 and COVID-19

Developing effective medical and public health countermeasures against a newly emergent virus like SARS-CoV-2 will require a better understanding of the complex molecular and immune mechanisms underlying infection and disease. Studies that delineate the viral lifecycle and host immune responses to infection can lead to the identification of novel targets for intervention against SARS-CoV-2 infection and COVID-19. Early studies suggest that the clinical manifestations of COVID-19 can vary significantly, and disease severity can range from mild to critical. Thus, a detailed understanding of the clinical course of disease, as well as the clinical, virologic, immunological, and genetic predictors of disease severity, are needed. Gaps also exist in our understanding of the dynamics of disease transmission in different populations over time, including the role of pediatric and elderly populations in viral spread, and the potential seasonality of viral circulation.

Objective 1.1: Characterize fundamental SARS-CoV-2 virology and immunological host response to infection

- **Support the development and distribution of reagents and viral isolates to researchers.** NIAID will continue to support both intramural and extramural researchers by developing reagents and assays for virus characterization and immunological analyses. NIAID will continue to accelerate SARS-CoV-2 research by sourcing viral isolates and clinical specimens for the research community and placing them in repositories to help advance research and countermeasure development. In addition, NIAID will place other critical reagents needed for assay development (e.g., pseudovirions and antigens) in publicly available repositories for distribution.

- **Characterize virus biology and immunological responses to disease.** A comprehensive understanding of the

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biological processes involved in SARS-CoV-2 infection and the pathogenesis of COVID-19 are paramount to developing new medical countermeasures to fight the spread of disease. Building on prior research related to MERS and SARS coronaviruses, early studies confirmed several critical features of SARS-CoV-2 infection, including the primary host receptor, angiotensin converting enzyme 2 (ACE-2), and the structure of the virus receptor-binding domain. Studies that delineate the viral lifecycle and host immune responses to infection can lead to the identification of novel targets for intervention against SARS-CoV-2 infection and COVID-19. Understanding the function of essential viral proteins will be necessary for improving diagnostic and immunological assays, in vitro and in vivo models, and other resources needed to advance safe and effective medical countermeasure development. In addition, evaluating the dynamics of host-pathogen interactions at the molecular and cellular levels will be critical to advancing our understanding of viral pathogenesis and immune responses that contribute to SARS-CoV-2 infection.

- **Determine viral evolution and molecular epidemiology.** With a newly emergent virus like SARS-CoV-2, studies to characterize genetic diversity, including those that assess the potential for the virus to evolve and escape host immunity, are pivotal for understanding disease progression and transmission dynamics and may have implications for countermeasure development. Viral genomic analysis matched with patient clinical data will be important to identify biomarkers of virulence and establish paradigms of sequence diversity. In addition, evaluating viral sequence associations with disease outcomes, immune status, and viral replication will provide crucial data to accelerate the development of effective medical countermeasures.

- **Develop low-containment assays to study virus neutralization.** Studies using non-infectious pseudovirions can be conducted in labs without BSL-3 capacity, making them an important tool to enhance understanding of SARS-CoV-2 infection. This capability would enable researchers without high-containment infrastructure to study the dynamics of virus neutralization in vitro.

- **Research into optimal public health prevention and mitigation modalities.** Clinical trials including family members of a COVID-19 positive individual can be devised to evaluate transmission, prevention, and other mitigation measures within the household.

Objective 1.2: Evaluate disease dynamics through natural history, transmission, and surveillance studies

- **Characterize disease incidence through surveillance studies.** Clinical manifestations of COVID-19 can vary greatly, ranging from asymptomatic or mildly symptomatic to the development of pneumonia, acute respiratory distress syndrome, and even death. The variation in clinical presentation of COVID-19, combined with the challenges in diagnostic capacity, have made accurate initial assessments of disease incidence a formidable challenge. However, rapid point-of-care and point-of-need molecular tests, which became available in March 2020, will enable hospitals and other healthcare facilities to make informed decisions regarding patient isolation and care. Studies that leverage existing high-throughput diagnostic capacity along with these rapid tests will advance our understanding of disease incidence across the nation and will be a critical component of strategies to implement effective medical countermeasures. Combining these studies with broad serosurveillance studies across existing surveillance networks, including blood bank studies, would

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provide a more complete picture of the scope of disease and the dynamics of infection. Detailed knowledge of host genetics and the human responses to infection across the lifespan will not only provide insights into new approaches for diagnosis, treatment, and prevention, but also may elucidate why individuals respond to SARS-CoV-2 in different ways. Reports to date suggest that COVID-19 resolves in most cases, implying that the immune system can keep the infection from progressing to severe disease in many individuals. However, additional research is needed to better understand why some people progress to severe disease, which will lend critical insights to medical countermeasure development.

- **Assess the dynamics of disease transmission.** Our current understanding of COVID-19 transmission is limited. While recent studies have suggested timeframes for virus survival in aerosols and on surfaces, the contributions of different routes of transmission and the dynamics of animal-to-human and human-to-human transmission remain unclear. The diverse clinical presentations of COVID-19, including a high prevalence of asymptomatic cases, add further complexity to understanding transmission dynamics. Providing a clearer picture of the natural history of viral shedding is a priority, both in acute cases and in asymptomatic infection. Given the challenges of accurately diagnosing asymptomatic individuals because they do not present for treatment, determining the role they play in transmission would provide valuable insights. Elucidating the role of pediatric cases in the spread of SARS-CoV-2 is particularly important. Although pediatric COVID-19 cases are generally asymptomatic or have less severe clinical manifestations than those of adults, the role that children play in spreading the virus is unknown. Additionally, studies to identify potential animal reservoirs and better understand transmission from animals to humans are a research priority, as these reservoirs may lead to future virus introductions and re-emergence of disease in humans. Virus transmission depends on a complex interplay of host, viral, and environmental factors that contribute to disease incidence and spread. Identifying the factors that maintain the disease transmission cycle is critical to developing effective medical countermeasures and public health interventions that will prevent future pandemics.

- **Determine disease progression through natural history studies.** Delineating the natural history of COVID-19 will inform immunopathogenesis, viral tropisms and length of shedding, immune phenotypes, and both protective immunity and host susceptibility. Disease assessment using longitudinal cohort studies, including among high-risk populations such as healthcare workers and the elderly, are important to better understand disease pathogenesis and immune responses to infection. Biomarkers identified from these studies may provide valuable insights into predictors of disease severity.

Objective 1.3: Develop animal models that recapitulate human disease

- **Develop small and large animal models that replicate SARS-CoV-2 pathogenesis.** Developing animal models that recapitulate human disease is a vital early step toward understanding disease pathogenesis and testing the efficacy of medical countermeasures. Small animal models enable rapid, scalable analyses that are particularly valuable for screening countermeasure candidates for efficacy and addressing issues concerning vaccine-induced immune enhancement. Among the small animal models being tested, transgenic mice expressing the human ACE-2 receptor are a promising candidate. In parallel, development and characterization of large animal models, including non-human primates (NHPs) that mimic human COVID-19, are a pivotal step to advance promising

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2 ibid.
countermeasure candidates. Previous experience with related coronavirus diseases such as MERS and SARS suggests that replicating human disease, particularly its more severe manifestations, in an animal model may be challenging. Fundamental research assessing animal models ranging from mice to NHPs is already underway. NIAID will continue to support the development of small and large animal model candidates to better understand this emerging infection and investigate optimal ways to treat and prevent COVID-19. NIAID also will ensure that validated animal models are made available to the scientific community for evaluating priority countermeasures.

Priority 2: Support the development of diagnostics and assays

Availability of rapid, accurate Food and Drug Administration (FDA)-cleared or authorized diagnostics will increase testing capacity and are critical for identifying and rapidly isolating cases, tracking spread of the virus, managing patient care, and supporting clinical trials. Molecular tests specifically designed to detect SARS-CoV-2 RNA in clinical samples are able to detect low levels of pathogen in clinical samples and offer robust specificity in differentiating SARS-CoV-2 from other related viruses. Continuing to improve the speed and accuracy of molecular and antigen-based diagnostics and making them available at point-of-care will be paramount to accelerating the ability to mitigate disease spread in the current outbreak and any future outbreaks. The development of serologic assays would further bolster surveillance efforts, including the ability to identify individuals who may have resolved prior infection with SARS-CoV-2.

Objective 2.1: Accelerate the development and evaluation of diagnostic platforms

- Support the development, characterization and availability of reagents for diagnostic validation.
  NIAID will support this effort through the development and testing of reagents for diagnostic validation that will be made available through NIAID-sponsored repositories.

- Support the development of new rapid diagnostics. NIAID will provide funding to support the development of new rapid diagnostics, including molecular tests and novel antigen detection tests with improved sensitivity, if deemed feasible based on natural history studies.

- Support the evaluation of promising diagnostics. In some cases, stakeholders that develop potential diagnostic tests do not have the infrastructure needed to rigorously validate those tests against clinical samples. NIAID will support the testing of promising diagnostics and provide the capacity for evaluating them with live virus samples using our biocontainment laboratories.

Objective 2.2: Develop assays to increase understanding of infection and disease incidence

- Develop and validate SARS-CoV-2 serological assays. Serological tests, which detect host antibodies to infectious agents, do not detect the presence of a pathogen directly but can be used as a surrogate marker of infection. Developing more effective serologic tests would help provide information on the extent of asymptomatic infections and cumulative disease incidence, for example through serosurveillance studies. NIAID, with the Centers for Disease Control and
Prevention and the FDA, is developing tests that identify antibodies to SARS-CoV-2 proteins to determine seroprevalence rates and potentially help distinguish antibody responses in individuals receiving vaccines. NIAID will support the development and validation of additional serological assays for serosurveillance studies and as tools for testing the efficacy of promising vaccine or therapeutic candidates.

Priority 3: Characterize and test therapeutics

Currently, there are no FDA-approved or licensed therapeutics specific for coronaviruses. While traditional development pathways for therapeutics can take years, the urgency of the current outbreak underscores the need for rapid development and testing of promising therapeutics. Possible avenues for developing therapeutics include the evaluation of broad-spectrum antiviral agents (antivirals) that have shown promise for other coronaviruses and the identification of novel monoclonal antibodies (mAbs). For broad-spectrum antivirals, Phase 2/2b testing of the RNA polymerase inhibitor developed by Gilead, remdesivir, is already underway. Additional studies will be critical to identify promising therapeutic candidates and to advance them through clinical trial testing. To optimize findings during the pandemic, multiple clinical trials will be conducted in parallel among various populations, including both inpatient and outpatient studies.

Objective 3.1: Identify promising candidates with activity against SARS-CoV-2

- **Screen protease inhibitor and nucleotide analogue class agents and other small molecules with documented activity against other coronaviruses SARS-CoV-2.** Screening drugs that are already licensed by the FDA for other indications and might be efficacious against SARS-CoV-2 infection may provide a route to identifying a therapeutic for use in the current pandemic. Broad-spectrum antivirals that are already FDA approved or in clinical development for other indications—including those previously targeting SARS-CoV-1 and MERS CoV—can be evaluated for their potential activity against SARS-CoV-2 infections. Approved therapeutics for other infectious diseases also are being evaluated as possible treatments for COVID-19. By leveraging their existing efficacy, safety, and manufacturability data, the time to development and production can be reduced. NIAID also will continue working with partners to screen compound libraries for potential activity against SARS-CoV-2. For these studies, priority will be given to compounds based on in vitro screening data and the existence of human safety data.

- **Identify viral targets for therapeutic development.** Advances in structural biology technology enable researchers to map key viral structures at an unprecedented level. The Structural Genomics Centers for Infectious Diseases (SGCID) apply state-of-the-art, high-throughput technologies and methodologies, including computational modeling, x-ray crystallography, nuclear magnetic resonance imaging, and cryogenic electron microscopy, to experimentally characterize the three dimensional atomic structure of proteins that play an important biological role in human pathogens and infectious diseases. NIAID will continue to support use of this powerful technology to identify viral targets of SARS-CoV-2 for therapeutics or vaccines.

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• **Identify novel mAbs for use as therapy or prophylaxis.** Data from early studies indicate that well-characterized convalescent plasma may provide a treatment benefit in COVID-19.⁴ Therefore, IVIG derived from convalescent plasma may also hold promise for treatment. Moreover, peripheral blood mononuclear cells and plasma are being used to identify novel neutralizing antibodies. Through collaborations with structural biologists, binding properties can be quickly assessed. Paired with assessment of neutralization activity, the most promising mAbs will be identified for further characterization in animal models and human trials.

**Objective 3.2: Conduct treatment studies to advance high-priority therapeutic candidates**

• **Characterize and evaluate host-directed strategies for treatment of disease.** Experience with other coronaviruses indicates that infection of the respiratory tract is rapid and damage is primarily mediated by the host inflammatory response.⁵ These conditions may make it difficult to modify COVID-19 with pathogen-directed therapeutics. Instead, host-directed strategies that target the immune response may exert a beneficial therapeutic effect. Host-directed strategies, including immune-modulating agents, will be investigated as potential therapeutic candidates.

• **Conduct clinical trials to demonstrate safety and efficacy of lead therapeutic candidates.** Many potential therapeutic candidates have been identified and are being tested in clinical trials.
  o In March 2020, NIAID launched a multicenter, adaptive, randomized controlled clinical trial to evaluate the safety and efficacy of the investigational antiviral drug remdesivir (GS-5734) for the treatment of COVID-19 in hospitalized adults with laboratory-confirmed SARS-CoV-2 infection and evidence of lung involvement. The trial builds on recent studies by NIAID scientists showing that remdesivir can improve the disease course in rhesus macaques when administered promptly after viral challenge with the MERS CoV.⁶ The trial is also adaptive, allowing for additional arms should other therapeutics warrant assessment for efficacy.
  o NIAID is finalizing the protocol for the Big Effect Trial (BET), in which putative therapeutics that have existing human data and are readily available will be tested in patients hospitalized with lower respiratory tract disease. Each potential intervention will be given to approximately 75 patients and evaluated for mitigating disease symptoms. Candidate therapeutics that meet the criteria in this initial study will be further evaluated in larger clinical trials for which the infrastructure is already in place.
  o As mentioned above, identification of novel mAbs for therapy or prophylaxis is another strategic priority. These mAbs should be safe, highly effective, amenable to fast manufacturing, and easy to administer. They will be tested in clinical trials to develop immunotherapies for the prevention and early treatment of COVID-19, potentially in high-risk populations including healthcare workers.

• **Conduct outpatient studies for mild COVID-19 cases.** In cases of mild COVID-19 that do not require hospitalization, outpatient studies could be extremely valuable for testing promising, orally administered FDA-approved drugs that have existing safety data. The antiviral activity of hydroxychloroquine and azithromycin against SARS-CoV-2 has been the focus of many early

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⁴ Roback JD and Guarner J. JAMA 2020 Mar 27. Epub. 32219429.
therapeutic studies.\textsuperscript{7,8,9} Testing of these and other candidates, including protease inhibitors and other molecules, in outpatient studies may provide critical efficacy data and could identify an existing drug or drug combination that is safe and effective against COVID-19.

- **Conduct outpatient studies in high-risk populations.** High-risk populations, including health care workers, the elderly or individuals with chronic conditions, are a critical target for the development of therapeutics. Conducting studies in patients with mild cases of COVID-19 among these high-risk groups would be of interest for identifying the benefits of early treatment strategies to mitigate the impact of infection. Therapeutic candidates that have once a day dosing could also be considered for pre-exposure prophylaxis (PrEP) in some of these populations.

**Priority 4: Develop safe and effective vaccines against SARS-CoV-2**

*Developing a safe and effective SARS-CoV-2 vaccine is a priority for preventing future outbreaks of the virus. As vaccine candidates for MERS-CoV, SARS-CoV-1 and other coronaviruses have previously been developed, NIAID Investigators and the scientific community are well poised to use similar approaches in the current pandemic. NIAID will leverage its broad intramural and extramural infrastructure to advance vaccine candidates through Phase 1 safety and dosing clinical trials, with considerations for Phase 2/2b clinical trials for the most promising candidates.*

**Objective 4.1: Advance promising vaccine candidates through clinical trial testing**

- **Conduct a Phase 1 clinical trial of (mRNA) platform candidate mRNA-1273.** Given the urgency of the response effort to develop a safe and effective vaccine, NIAID is prioritizing promising vaccine candidates that can be rapidly produced and tested. NIAID, in collaboration with the biotechnology company Moderna, is conducting a Phase 1 clinical trial of a vaccine candidate that uses a messenger RNA (mRNA) vaccine platform expressing a NIAID-designed recombinant spike protein of SARS-CoV-2. The trial is being conducted at NIAID-funded clinical research sites, with the first enrolled individual receiving the vaccine on March 16, 2020.

- **Prepare for a pivotal Phase 2/2b clinical trial of candidate mRNA-1273.** Preparing for the likelihood of a seasonal recurrence of SARS-CoV-2 is imperative to the public health response. Given the theoretical risk of vaccine-enhanced respiratory disease, large Phase 2 trials are unlikely to launch until this possibility is evaluated in animal models. Planning for those animal studies is underway, and, assuming favorable results, a Phase 2/2b study could be launched later in 2020. This represents a historically fast timeline for the development and testing of a vaccine candidate. Additionally, these studies will provide information on correlates of immunity that will help accelerate the advancement of other vaccine candidates. If the mRNA-1273 vaccine candidate shows protection against SARS-CoV-2 infection in a Phase 2/2b trial, NIAID will work with government partners to ensure that the vaccine is manufactured in sufficient quantities to allow prompt distribution to those at highest risk of acquiring disease.


\textsuperscript{9} Chen Z et al. medRxiv 2020;2020.03.22.20040758. https://www.medrxiv.org/content/10.1101/2020.03.22.20040758v2
• **Investigate additional candidates through NIAID vaccine programs.** Although promising candidates may show efficacy in preclinical studies, many do not translate into effective vaccines in clinical trials. Therefore, it is crucial to support multiple promising preclinical candidates in the research and development pipeline. To that end, NIAID is advancing multiple additional SARS-CoV-2 vaccine candidates through its Rocky Mountain Laboratories (RML), including approaches that have shown promise against coronaviruses that cause SARS and MERS. Building on previous research to develop a MERS-CoV vaccine, scientists at RML are collaborating with Oxford University investigators to develop a SARS-CoV-2 vaccine that uses a chimpanzee adenovirus vector. RML investigators also are partnering with the biopharmaceutical company CureVac on an mRNA vaccine candidate and collaborating with the University of Washington on a universal coronavirus vaccine development. By leveraging its extensive expertise and research infrastructure, NIAID will continue working with partners and collaborators to advance promising SARS-CoV-2 vaccine candidates.

• **Leverage existing vaccine approaches to target SARS-CoV-2.** NIAID is pursuing multiple strategies to develop a COVID-19 vaccine. Building on past research on emerging pathogens, especially MERS-CoV and SARS-CoV-1 (the virus that causes SARS), NIAID is using previously developed vaccine platforms to rapidly assess the potential of SARS-CoV-2 vaccine candidates. This approach has already resulted in several promising strategies that may be leveraged for SARS-CoV-2, including vaccination using recombinant spike protein, chimpanzee adenovirus vaccine vector, virus-like particles, and live attenuated virus. In addition, NIAID is funding the development of novel vaccine candidates that will be efficacious across the lifespan, including in the elderly.

**Objective 4.2: Advance vaccine development through assay and reagent development**

• **Develop critical reagents to support vaccine development.** Appropriate tools are needed to identify the most promising vaccine candidates and advance the development of lead candidates as rapidly as possible. To accelerate the vaccine pipeline, NIAID is generating master and working SARS-CoV-2 virus stocks and other reagents critical for developing SARS-CoV-2 immune assays, developing quantitative tests for characterizing SARS-CoV2 assay material, developing a quantitative SARS-CoV-2-specific ELISA, developing virus-specific neutralization assays, and developing quantitative assays for assessing SARS-CoV-2 viral load.

**Objective 4.3: Advance vaccine development through adjuvant characterization and development**

• **Provide adjuvants to support vaccine development.** Adjuvants are vaccine components that improve vaccine efficacy by inducing long-lived protective immunity. Selection of appropriate adjuvants is crucial for developing safe and effective vaccines. NIAID is working with multiple collaborators to provide adjuvants to the research community for use in SARS-CoV-2 vaccine candidates. These adjuvants are at various stages of development and include compounds that
specifically improve vaccine efficacy in elderly individuals or modulate host immunity toward protective responses while limiting or preventing harmful inflammatory responses.

Conclusion

The sudden emergence and rapid global spread of the novel coronavirus SARS-CoV-2 has created a daunting public health challenge. To address this challenge, NIAID is focusing its considerable expertise and emerging infectious disease resources to facilitate the development of medical countermeasures including diagnostics, therapeutics, and vaccines. The resulting discoveries will not only help mitigate the current pandemic, but also inform prevention, diagnosis, and treatment of future emerging infectious diseases.

A comprehensive strategy requires a coordinated effort among governmental, academic, private, and community-based organizations. The NIAID Strategic Plan for COVID-19 Research defines the areas of COVID-19 research within the NIAID mission and outlines the institute’s research priorities and goals. This strategic plan builds on many other national efforts and represents a commitment from multiple U.S. government agencies to improve coordination of COVID-19 research and discovery efforts and the development of medical countermeasures.
May 20, 2020

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
1 Center Drive, Building 1, Room 126
Bethesda, MD 20814

Dear Dr. Collins:

We are writing on behalf of The American Association of Immunologists (AAI), the nation’s largest professional association of research scientists and clinicians who are dedicated to studying the immune system. As you know, many of our members are deeply immersed in research that may lead to needed vaccines and treatments for COVID-19. This research and development, while potentially lifesaving during this pandemic, will no doubt also help prepare our nation and the world for future pandemics.

We were concerned, therefore, to learn of a decision by the National Institutes of Health (NIH) to revoke grant funding for the EcoHealth Alliance project entitled, “Understanding the Risk of Bat Coronavirus Emergence.” As scientists who support merit-based peer review, we believe it is important for NIH to explain why this grant – which appears to fund research of great relevance to the COVID-19 pandemic – was abruptly terminated. While we understand there could be legitimate reasons for this action, the NIH response has been unsatisfactory. According to NPR, the email NIH sent to EcoHealth Alliance President Peter Daszak, Ph.D., informed him that, “at this time NIH does not believe the current project outcomes align with the program goals and agency priorities.” NIH subsequently refused to answer questions regarding this grant termination or whether NIH had taken similar actions previously. This response is both confusing and troubling. Your explanation could reinforce confidence in the NIH grant review system at a time when many are concerned that world and national events may be politicizing the science we need the most. We support the request made in a community letter organized by our colleagues at the American Society for Biochemistry and Molecular Biology (ASBMB) for a full explanation of the reasoning for this grant termination.

AAI greatly appreciates your ongoing leadership and support for the nation’s medical researchers and remains ready to assist you in these most challenging times.

Sincerely,

Jeremy M. Boss, Ph.D.
President

Ross M. Kedl, Ph.D.
Chair, AAI Committee on Public Affairs

M. Michele Hogan, Ph.D.
Executive Director
Director Collins,

I recently saw a CBS report claiming that an NIH research grant held by Dr. Peter Daszak and the Eco Health Alliance has been unexpectedly terminated (https://www.cbsnews.com/news/trump-administration-coronavirus-vaccine-researcher-covid-19-cure-60-minutes/).

I haven’t been able to find an official NIH response or explanation related to this report. But did find in the NIH reporter a grant held by Dr. Daszak and the Eco Health Alliance that shows an unusual end date that is less than 1 year from the approval data (see below).

Could you direct me to the NIH’s response or explanation for the situation? I’d like to know if this grant (or another held by these researchers) was terminated before the date initially specified in the award letter. And if so, I’d like to know more about the process that led to the early termination. If there’s a better contact person, I’d be happy to be directed to them.

Thanks,

Bob

Robert Calin-Jageman
Professor, Psychology
Neuroscience Program Director
Dominican University
Parmer 210
7900 West Division
River Forest, IL 60305
Shameless Self-Promotion: *Introduction to the New Statistics* is the first statistics textbook to focus on Open Science and the New Statistics. Instructors can obtain a free desk copy here: https://www.routledge.com/resources/deskcopy. Or, order on Amazon.
May 11, 2020

President Donald J. Trump
The White House
1600 Pennsylvania Ave. NW
Washington, DC 20500

Dear President Trump:

We write on behalf of the Infectious Diseases Society of America (IDSA), the HIV Medicine Association (HIVMA), American Society of Tropical Medicine and Hygiene (ASTMH), and the Pediatric Infectious Diseases Society of America (PIDS) to raise serious concerns regarding what appears to have been political interference in the scientific process with the termination of an EcoHealth Alliance grant that included a partnership with the Wuhan Institute of Virology (WIV).

Our organizations represent physicians, scientists and other healthcare professionals committed to infectious diseases, pediatric infectious diseases, tropical medicine, and global health. We were dismayed to learn about the termination of the National Institutes of Health (NIH) grant supporting an important international collaboration with WIV studying the transmission of coronaviruses from bats to humans, microbial genetics, and drug and vaccine development. Such studies are critical to understand the viruses, their transmission, and approaches for prevention and treatment of this dangerous illness. As of May 11, the current SARS-CoV-2 pandemic has resulted in more than 284,628 deaths globally, including more than 80,087 deaths in the U.S.

The grant from the NIH National Institute of Allergy and Infectious Diseases was in its sixth year and was renewed in 2019 for five years through the NIH peer review process, which is the gold standard for identifying and supporting the most promising biomedical research without bias. Basic research completed under the grant has been critical to the evaluation of remdesivir as a treatment for COVID-19, the first drug receiving FDA Emergency Use Authorization to treat hospitalized patients. The ongoing work of the Alliance has become more important than ever to help prevent future coronavirus pandemics. Furthermore, the NIH has not provided a legitimate cause for terminating the EcoHealth Alliance grant, which was given superb ratings in its renewal evaluation. There is no scientific evidence that SARS-CoV-2 originated at WIV or any other laboratory, and the NIH has not responded to inquiries asking for additional clarification and rationale.

An independent and impartial scientific process and robust support for global research collaborations have been indispensable in making the United States the world leader in biomedical research and establishing the NIH as the world’s premier medical research enterprise. Continued independent and impartial processes are absolutely essential to the successful development of effective treatments, vaccines, and cures for many infectious diseases and the epidemics and pandemics they can cause. This includes SARS-CoV-2, the cause of severe COVID-19 disease.
We urge immediate reconsideration of the termination of the EcoHealth Alliance grant, with assurances that politics will not influence the scientific process. A failure to set strong boundaries between politics and science will set back future medical discoveries for years to come and leave the U.S. poorly prepared to respond to current and future pandemics, health crisis. If you have questions or require additional information, please do not hesitate to contact Amanda Jezek, IDSA Senior Vice President for Public Policy and Government Relations at (b)(6) or Andrea Weddle, HIVMA Executive Director at (b)(6).

Sincerely,

Thomas File  
Thomas M. File, Jr., MD, MSc  
President, IDSA

Judith Feinberg, MD  
Chair, HIVMA

Karen A. Goraleski  
CEO, ASTMH

Kristina Bryant, MD, FPIDS  
President, PIDS

CC: Francis S. Collins, MD, PhD, Director, NIH  
Anthony S. Fauci, MD, Director, NIH’s NIAID
Dr. Collins,

Today, the COVID-19 Working Group–NY (CWG-NY) is sending a letter, signed by 29 organizations, more than 300 scientists, physicians, and community health advocates, to Dr. Francis Collins, Director of the US National Institutes of Health (NIH), Dr. Anthony Fauci, Director of the National Institute for Allergy and Infectious Diseases (NIAID), and Alex Azar, Secretary of Health and Human Services, along with officials on the House Oversight Committee and the Senate Health Committee.

The letter expresses outrage at the canceling of a major R01 grant to the EcoHealth Alliance, an international collaboration that studies coronaviruses in bats to determine how they may evolve to transmit in human populations. **We demand immediate reinstatement of the R01 to EcoHealth Alliance.**

Signatories of the letter – which include scientists from many top research institutions across the US including Harvard, Yale, Stanford, University of Michigan, University of Pennsylvania, University of Wisconsin, University of Florida, University of California San Francisco, University of Washington, AstraZeneca, and Columbia University – called for immediate release of the NIH R01 funds to EcoHealth and for an investigation into the decision-making process that canceled the grant funding in the first place.

Best,

Joseph Osmundson
COVID-19 Working Group NY
The NIH must not cancel awarded grants for purely political reasons

On May 1, 2020, *Science Magazine* reported the cancelation of a major grant to the EcoHealth Alliance, an international collaboration studying how coronaviruses transmitting in bats can evolve to spread in human populations. Based on emails reviewed by *Science*, this decision appears to be directly related to the Trump administration’s belief in the conspiracy theory that the SARS-CoV-2 virus, the cause of COVID-19, was purposefully or accidentally released from the Wuhan Institute of Virology. The Wuhan Institute of Virology was a participant in the EcoHealth Alliance grant that was canceled.

We ask for the immediate reinstatement of the grant to EcoHealth Alliance and for a congressional investigation into the decision making process at the NIH that canceled the funding in the first place. A vibrant community of independent scientists is crucial to a functioning democracy and will be the first line of defense against another crisis that costs as many lives as the COVID-19 pandemic.

To be clear, there is no evidence of human engineering of the SARS-CoV-2 virus nor of accidental release of a laboratory viral strain. Phylogenetic analyses clearly support the evolution of the SARS-CoV-2 virus from bats in the wild.

We write in strong condemnation of political interference in scientific grantmaking. The NIH has a long and well-established protocol for scoring and funding grants, including decisions on scientific merit, productivity, and the import of research by large panels of expert scientists. During the course of an NIH grant, alterations in funding are incredibly disruptive to ongoing research projects, many of which span years if not decades.

Cancelation of a grant mid-term will disrupt the progress of research in how coronaviruses can evolve to infect humans, the exact process that birthed SARS-CoV-2, leading to hundreds of thousands of deaths worldwide. This research was always critical given the possibility of a coronavirus pandemic; it is now absolutely essential to understand how this crisis originated and to avoid another pandemic in the
future. Bowing to conspiracy theories in this time of crisis to prevent necessary research may, therefore, be sowing the seeds of another crisis in the future.

In fact, the grant to EcoHealth Alliance provided critical data—including the sequences of closely related bat coronaviruses to SARS-CoV-2—that both helped identify the origin of COVID-19 and identified remdesivir as a potential drug for the disease, allowing it to be rapidly moved into clinical trials. It is absurd and horrifying that the Trump administration would shut down a research program that led to the first promising treatment for COVID-19.

Beyond the critical importance of the research the NIH defunded, political interference in grantmaking is a disturbing trend that would allow politicians to effectively squash research that does not align with their political desires. Industry influence in research, the silencing of climate science, and long term harm of American science in the global climate become increasingly likely if politicians can easily meddle in grantmaking. We must stand united as a community of clinicians, scientists, activists, and citizens to demand the best—most transparent—scientific decision making process in this moment of crisis, and always.

Signed:

Organizations Signed On:

COVID-19 Working Group, New York City
The PrEP4All Collaboration
AVAC – AIDS Vaccine Advocacy Coalition
ICAP at Columbia University
ACT-UP
AIDS Foundation Chicago
Universities Allied for Essential Medicines (UAEM)
Center for Science in the Public Interest
Equity Forward
National Black Leadership Commission on Health
Association of Nurses in AIDS Care
Progressive Doctors
Black AIDS Institute
Latino Commission on AIDS
Treatment Action Group
AIDS Action Baltimore
TPAN – Test Positive Aware Network
HIV + Aging Research Project – Palm Springs
HealthxDesign
Georgia AIDS Coalition
Climate Health Now
National Working Positive Coalition
Prevention Access Campaign
The Well Project
Map Data Science
American Academy of HIV Medicine
GCCDC – Gowanus Canal Community Development Corporation
Bannon Consulting Services

Individuals Signed On:

David Ho, Director, Aaron Diamond AIDS Research Center of Columbia University
Vagelos College of Physicians and Surgeons
Gregg Gonsalves, Yale School of Public Health
Sten H. Vermund, Yale School of Public Health
Martin S. Hirsch, Harvard University
Seth Darst, The Rockefeller University
Anthony Eller, Yale AIDS Program
A. David Paltiel, Yale School of Public Health
Ted Cohen, Yale School of Public Health
Nathan Grubaugh, Yale School of Public Health
Robert Heimer, Yale School of Public Health
Taiga Christie, Yale School of Public Health
Eli Fenichel, Yale University
Samy Galvez, Yale University
David Vlahov, Yale University
Nathan Price, Yale University
Walther Mothes, Yale University
Nancy Stanwood, Yale University
Frederick L. Altice, Yale University School of Medicine
Akiko Iwasaki, Yale University School of Medicine
Angela L. Rasmussen, Columbia Mailman School of Public Health
Mady Hornig, Columbia University
Jacqueline Klopp, Columbia University
Sarah Lima, Columbia University Mailman School of Public Health
Maimuna S. Majumder, Boston Children’s Hospital & Harvard Medical School
Donald Thea, Boston University School of Public Health
Jerry Avorn, Harvard Medical School
Julia Marcus, Harvard Medical School
Aaron Kesselheim, Harvard Medical School/Brigham and Women’s Hospital
Ameet Sarpatwari, Brigham & Women’s Hospital/Brigham Medical School
Robyn Lee, Harvard School of Public Health
Keletso Makofane, Harvard University
Bryan Terrazas, Harvard University
Grace Mosley, Icahn School of Medicine at Mount Sinai
Alice O Kamphorst, Icahn School of Medicine at Mount Sinai
AMIR HOROWITZ, Icahn School of Medicine at Mount Sinai
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Thomas Marron, Tisch Cancer Institute - Icahn School of Medicine at Mount Sinai
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Edward Banigan, Massachusetts Institute of Technology
Mila González, Columbia University/NewYork Presbyterian Hospital
Meredith Whittaker, Co-director, AI Now Institute at NYU
Joseph Osmundson, New York University
ENRIQUE R ROJAS, New York University
Brendan Parent, New York University
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Cesar Augusto Lopez, UNC Chapel Hill
Catherine Eliza Kehl, UNC Chapel Hill
Joseph M McCune, Bill & Melinda Gates Foundation
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Lukasz Kowalik, Cornell University
Matthew Herder, Dalhousie University, Health Law Institute
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Lisa Kearns, Division of Medical Ethics NYU Grossman School of Medicine
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Kendra Phelps, EcoHealth Alliance
Kathrine Meyers, Aaron Diamond AIDS Research Center of Columbia University Vagelos College of Physicians and Surgeons
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Elisa Mandell Keller, EMK Strategic Consulting
Olivier Pernet, EnViro International Laboratories
Susan Tsang, American Museum of Natural History
Jonathan Silver, AstraZeneca
Alexi Grousis-Henderson, Audubon
Dr Alison Cameron, Bangor University
Paul Henry Tremblay, Best Buy Technology
Kimberly Piper, Beth Israel Deaconess Medical Center
Donald Thea, Boston University School of Public Health
Ameet Sarpatwari, Brigham & Women's Hospital/Harvard Medical School
Marcello Graziano, Central Michigan University
M. Drew LaMar, College of William and Mary
Graham J McDougall Jr, Florida State University College of Nursing
Jeffrey Levi, George Washington University
Adam R. Ward, George Washington University, Milken Institute School of Public Health
Kristin Harper, Harper Health & Science Communications LLC
Simon Collins, HIV i-Base
Isaiah Sumner, James Madison University
Bruce Jennison, JENNISONFYI
Emmy Killett, Jet Propulsion Lab
Jennifer Chang, Kaiser Permanente at Los Angeles Medical Center
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Kimberly Stone, Kimberly C Stone PA
Lorna B. Hall, La Cheim Behavioral Health
Stephan R. Glicken, Lehigh Valley Physician Group
Jeremy P. Kamil, LSU Health Sciences Center
Meredith Clement, LSU Health Sciences Center
Lydia Wills, Lydia Wills LLC
Amy H. Fitzpatrick, Marine Institute
Tony Mistretta, Medical Management
Wendell Bell, Minnesota State Bar Assn.
Ellyse A. Vitiello, Morningside Monthly Meeting (Quakers)
Greta J. Quintin, Morristown Emergency Services
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Mark Cutis, Nihon Phoenix Advisors
Leo Beletsky, Northeastern University
Katrina Kuh, Pace Law School
Aaron Steiner, Pace University
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Lliliana M Davalos, Stony Brook University
Stephen B Baines, Stony Brook University
Frances Ryan, Commission for Persons with disAbilities
Matt Sharp, The Reunion Project
Thomas St. Julien Lankiewicz, The University of California, Santa Barbara
Arthur R. James, Three Peas in a Pod
Amelia Gifford, Toxics Use Reduction Institute
Perry Mitchell, Truckee Meadows Community College
Lawrence Hunter, University of Colorado School of Medicine
Blair T. Johnson, University of Connecticut
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Michael Riley II, University of Florida
Adria LeBoeuf, University of Fribourg
Jason Kindrachuk, University of Manitoba
Michael C. Bazaco, University of Maryland
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Monique, University of Michigan
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Kathryn Anderson, UW School of Medicine
Face Pickens, Virginia Commonwealth University
Stephanie Hart, Virginia Commonwealth University
Mary Loos, Virginia Commonwealth University
Zachary Pincus, Washington University in St. Louis
John Moore, Weill Cornell School of Medicine
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Bella Berly
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Wendy Wifler
Peggy Hamilton
Tim Mackey
Joanne Baio
Leslie Sude
Nicola Chamberlain
Arthur Rourke
Tara Martinez
Ken Kidd
Carly Harrison
K Barrett
Val Barton
Elizabeth Eisen
Catherine Koebel
Victoria Sharp
Diane Tabellija
Kristen Boyle-Heimann
M. Maggie O'Meara
Laura Hanson
Lina Correa Cerro
Jennifer Thompson
Katie Love
Karen Smith-McCune
Tiffany Doherty
Robin Schwartz
Gabrielle Lopez
Danelle Forseth
Tina
Jess Seline
Nina Lee
Callie Preheim
Ysabel Beatrice Floresca
LIPI ROY
Elizabeth Spradley
Gregory G. Sarno
Eric Neumann
Anna Costello
Liz Kroboth
Carol Kessler
Karyn Pomerantz
Keshet Ronen
Danielle Francois
Jeff Sheehy
Rachel Barr
Ann Hartzler
Arturo Garcia Jr
Natan Vega Potler
Ben Stoner-Duncan
Daniel Lugassy
Kate Mastroianni
Pam Kolber zicca
John True
May 12, 2020

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar,

On behalf of Research!America, I am writing to request that you clarify the decision to end National Institutes of Health (NIH) grant funding for the EcoHealth Alliance project entitled “Understanding the Risk of Bat Coronavirus Emergence.” We believe the American people, whose tax dollars enable federal grants for life-saving research and other national priorities, deserve more clarity on the basis of this decision than has thus far been provided.

The abrupt termination of this grant has generated concern, not only because of the relevance of this research to COVID-19 and future pandemics, but because the lack of transparency surrounding the termination creates uncertainty about the integrity of federal grant-making.

We certainly appreciate there may be facets of this decision that cannot be made public, but given the high degree of integrity expected of the NIH extramural grant program, we urge the Administration to bring as much information to light as possible surrounding this decision.

We respectfully request that you provide the American public with insight into the basis of the decision to end funding for the EcoHealth grant and how this decision conforms to the circumstances in which grant terminations are permitted under the United States Code of Federal Regulations.

We are grateful for your leadership during this profoundly challenging period in our nation’s history, and appreciate your consideration of this request.

Sincerely,

[Signature]

The Honorable Michael N. Castle
Chair, Member of Congress 1983-2011

Mary Woolley
President and CEO
Dear XXX:

Thank you for your letter to Dr. Francis Collins, Director of the National Institutes of Health, regarding a grant to EcoHealth Alliance. I have been asked to reply.

The National Institutes of Health (NIH) can confirm that a grant issued to EcoHealth Alliance was terminated. The NIH does not publicly discuss or comment on the specific deliberations or plans regarding individual grants.

Sincerely yours,

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Dear Dr. Chmura and Dr. Daszak

Please see attached.

Sincerely,

Michael S Lauer, MD

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)
8 July 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

In follow-up to my previous letter of April 24, 2020, I am writing to notify you that the National Institute of Allergy and Infectious Diseases (NIAID), an Institute within the National Institutes of Health (NIH), under the Department of Health and Human Services (HHS), has withdrawn its termination of grant R01AI110964, which supports the project *Understanding the Risk of Bat Coronavirus Emergence*. Accordingly, the grant is reinstated.

However, as you are aware, the NIH has received reports that the Wuhan Institute of Virology (WIV), a subrecipient of EcoHealth Alliance under R01AI110964, has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, create health and welfare threats to the public in China and other countries, including the United States. Grant award R01AI110964 is subject to biosafety requirements set forth in the NIH Grants Policy Statement (e.g., NIH GPS, Section 4.1.24 “Public Health Security”) and the Notice of Award (e.g., requiring that “Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)].”). Moreover, NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients. 45 C.F.R. § 75.101.

As the grantee, EcoHealth Alliance was required to “monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . .” 45 C.F.R. § 75.352(d). We have concerns that WIV has not satisfied safety requirements under the award, and that EcoHealth Alliance has not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance.

Moreover, as we have informed you through prior Notices of Award, this award is subject to the Transparency Act subaward and executive compensation reporting requirement of 2 C.F.R. Part
170. To date you have not reported any subawards in the Federal Subaward Reporting System.

Therefore, effective the date of this letter, July 8, 2020, NIH is suspending all activities related to R01AI110964, until such time as these concerns have been addressed to NIH’s satisfaction. This suspension is taken in accordance with 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. This action is not appealable in accordance with 42 C.F.R. § 50.404 and the NIH GPS Section 8.7, Grant Appeals Procedures. However, EcoHealth Alliance has the opportunity to provide information and documentation demonstrating that WIV and EcoHealth Alliance have satisfied the above-mentioned requirements.

Specifically, to address the NIH’s concerns, EcoHealth must provide the NIH with the following information and materials, which must be complete and accurate:

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.
2. Explain the apparent disappearance of Huang Yanling, a scientist/technician who worked in the WIV lab but whose lab web presence has been deleted.
3. Provide the NIH with WIV’s responses to the 2018 U.S. Department of State cables regarding safety concerns.
4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.
5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.
6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.
7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System

During this period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further assess compliance by EcoHealth Alliance and WIV, including compliance with other terms and conditions of award that may be implicated. Additionally, during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance’s responsibility as the
recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. Once the original award is reinstated, NIH will take additional steps to restrict all funding in the HHS Payment Management System in the amount of $369,819. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 CFR Part 75, including, but not limited to, terminating the grant award. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

Sincerely,

Michael S. Lauer

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: [b][b][b][b][b][b][b]

cc: Dr. Erik Stemmy
Ms. Emily Linde
Many thanks, Karen, happy to help however I can.

Best, Mike

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Hi, Dr. Lauer,

FYI – wanted to make sure you have the attached. We are working with HHS on a potential briefing in response to this letter to Secy. Azar from all House E&C and House SST full- and Oversight subcommittee chairs. I will keep you posted and work with Melanie to schedule.

Karen

Karen LaMontagne
Office of Legislative Policy & Analysis
National Institutes of Health
P: (b)(6)
June 26, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Azar,

We write with strong concerns surrounding the Administration’s termination of the National Institutes of Health (NIH) grant to EcoHealth Alliance on April 24, 2020. In the letter communicating the grant’s termination, NIH Deputy Director for Extramural Research, Dr. Michael Lauer, wrote that “At this time, NIH does not believe the current project outcomes align with the program goals and agency priorities.” However, press reports indicate that the grant was canceled because a small portion of the funding was to be given to the Wuhan Institute of Virology for on-the-ground sample collection and analysis. Given the potential for this study to inform our knowledge of coronavirus disease 2019 (COVID-19) transmission, it is deeply concerning that it may have been canceled for political reasons in the midst of the current pandemic.

It is always important that federal research priorities are driven by science-based decisions. This is especially true in a time that requires unparalleled investment in research that may help bring an end to this public health crisis. It is therefore troubling that this abrupt grant cancellation came just a week after President Trump announced that the Administration was looking into “grants going to that area” and continued that “we will end that grant very quickly.” This was in response to a reporter referencing false claims that COVID-19 “likely

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3 Id.

came from a Level 4 lab in Wuhan.” The Administration has been pushing this theory despite scientific experts saying this path of transmission would be virtually impossible given what is known about the virus and lab safety protocols. If this theory is the basis for the grant termination, it would be an egregious example of the Administration politicizing scientific decision making in order to further a politically convenient narrative.

EcoHealth Alliance’s grant was renewed in 2019 after an initial five-year grant on the same topic. The grant it received was extremely competitive – only 22 percent of proposals were funded in 2019. The July 2019 project proposal was titled, “Understanding the Risk of Bat Coronavirus Emergence.” In the midst of the COVID-19 pandemic that has taken over 115,000 American lives, it is inconceivable that this project would no longer “align with the program goals and agency priorities” of NIH. Any termination of a grant that has gone through NIH’s rigorous scientific review process must be adequately justified on a scientific basis – particularly a grant which would appear to be so relevant to understanding our current health crisis.

As the Committees of jurisdiction over public health and science, we need to better understand the decision to terminate EcoHealth Alliance’s NIH grant. We are especially concerned given Dr. Anthony Fauci’s, Director of NIH’s National Institute of Allergy and Infectious Diseases, assertion at a Committee on Energy and Commerce hearing on June 23 that “the grant was canceled because NIH was told to cancel it.” In order to understand how this decision was reached, we request a briefing to be delivered by July 15, 2020. At this briefing, we ask that you be prepared to address the following questions:

1. When the decision was made to terminate the grant to EcoHealth Alliance;
2. Who at HHS was involved in the decision to terminate the grant;
3. Whether entities outside HHS, including but not limited to the White House, the State Department, the National Security Council, and intelligence agencies, were involved in this decision;

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5 Id.
4. The analysis conducted to determine that the EcoHealth Alliance grant’s project outcomes did not align with program goals and NIH priorities;

5. Any analysis conducted to determine EcoHealth Alliance’s alleged improper disbursal of NIH funds to the Wuhan Institute of Virology;

6. Any other decision NIH has made to terminate grants since January 1, 2020; and

7. Any further action NIH is considering taking regarding EcoHealth Alliance or any other grant holder regarding alleged relationships with international laboratories.

In addition to the briefing, we request the following materials be provided to the Committees no later than July 10, 2020. Please provide these materials in a searchable electronic format.

1. All documents and communications relating to the cancellation of EcoHealth Alliance’s grant, including the notification to and any response from EcoHealth Alliance;

2. All documents and communications regarding any potential direction from outside entities, including the White House or other Agencies or Departments, to terminate grants based on suspicion of collaboration with international laboratories;

3. All documentation of audits or other analyses conducted to determine improper disbursement of federal grant money from grant-holding institutions to other entities; and

4. The criteria that NIH used to assess the EcoHealth Alliance grant and determine that such grant merited cancelation, and documentation thereof.

Any decision to terminate a research grant should be conducted in a deliberative and transparent process that adheres to the highest standards of scientific integrity. Especially in this unprecedented time, it is important that our public health and science agencies remain free from political pressure and be allowed to pursue federally-funded research based on scientific merit.

Thank you for your attention to this matter. We look forward to speaking with you and reviewing the relevant materials.

Sincerely,

Eddie Bernice Johnson
Chairwoman
Committee on Science, Space, and Technology

Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce
Bill Foster  
Chairman  
Subcommittee on Investigations and Oversight

Diana DeGette  
Chair  
Subcommittee on Oversight and Investigations
Hi David – sorry, here it is.

Thanks, Mike

Hi Mike – Would it be possible for you to send me a copy of the letter NIH sent to EcoHealth? Bob Charrow would like a copy of the signed letter. Not urgent – thanks, and please let me know if you have any questions.

David W. Lankford  
NIH Legal Advisor  
Office of the General Counsel  
Public Health Division, NIH Branch  
NH Building 31, Room 2B-50  
Baltimore, MD 20892-2111  
Telephone: (301) 402-1034  
Fax: (301) 402-1034  
E-Mail: 

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Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

In follow-up to my previous letter of April 24, 2020, I am writing to notify you that the National Institute of Allergy and Infectious Diseases (NIAID), an Institute within the National Institutes of Health (NIH), under the Department of Health and Human Services (HHS), has withdrawn its termination of grant R01AI110964, which supports the project Understanding the Risk of Bat Coronavirus Emergence. Accordingly, the grant is reinstated.

However, as you are aware, the NIH has received reports that the Wuhan Institute of Virology (WIV), a subrecipient of EcoHealth Alliance under R01AI110964, has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, create health and welfare threats to the public in China and other countries, including the United States. Grant award R01AI110964 is subject to biosafety requirements set forth in the NIH Grants Policy Statement (e.g., NIH GPS, Section 4.1.24 “Public Health Security”) and the Notice of Award (e.g., requiring that “Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)].”). Moreover, NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients. 45 C.F.R. § 75.101.

As the grantee, EcoHealth Alliance was required to “monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . .” 45 C.F.R. § 75.352(d). We have concerns that WIV has not satisfied safety requirements under the award, and that EcoHealth Alliance has not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance.

Moreover, as we have informed you through prior Notices of Award, this award is subject to the Transparency Act subaward and executive compensation reporting requirement of 2 C.F.R. Part
170. To date you have not reported any subawards in the Federal Subaward Reporting System.

Therefore, effective the date of this letter, July 8, 2020, NIH is suspending all activities related to R01AI110964, until such time as these concerns have been addressed to NIH’s satisfaction. This suspension is taken in accordance with 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. This action is not appealable in accordance with 42 C.F.R. § 50.404 and the NIH GPS Section 8.7, Grant Appeals Procedures. However, EcoHealth Alliance has the opportunity to provide information and documentation demonstrating that WIV and EcoHealth Alliance have satisfied the above-mentioned requirements.

Specifically, to address the NIH’s concerns, EcoHealth must provide the NIH with the following information and materials, which must be complete and accurate:

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5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.
6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.
7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System.

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Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 CFR Part 75, including, but not limited to, terminating the grant award. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

Sincerely,

Michael S. Lauer

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: 

cc: Dr. Erik Stemmy
Ms. Emily Linde
Drs. Aleksei Chmura and Peter Daszak  
EcoHealth Alliance, Inc.  
460 W 34th St  
Suite 1701  
New York, NY 10001

Re: NIH Grant R01AI110964

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5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.
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Sincerely,

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: 

cc: Dr. Erik Stemmy
    Ms. Emily Linde
Taking FC off. The grant has been officially reinstated; the revised NoA was sent on July 15, 2020. The NoA indicated that the grant was reinstated, but all activities suspended pending satisfactory answers to all of NIH’s questions.

The grant is once again identified as active on RePORTER.

Best, Mike

I think the time has come when we will have to admit that we reinstated the EcoHealth grant. Please see attached Oversight investigation into the issue. Please note the signers:

Frank Pallone, Chair of E&C Cmte
Diana DeGette, Chair of E&C Subcmte on Investigations
Eddie Bernice Johnson, Chair of Science Cmte
Bill Foster, Chair of Science Subcmte on Investigations
### Project Information

**Project Number:** 2R01AI110964-06  
**Title:** UNDERSTANDING THE RISK OF BAT CORONAVIRUS EMERGENCE

**Contact PI / Project Leader Information:**
- **Name:** DASZAK, PETER
- **Email:** Click to view Contact PI / Project Leader email address

**Program Official Information:**
- **Name:** STEMMY, ERIK J
- **Email:** Click to view PD email address

**Awardee Organization:** ECOHEALTH ALLIANCE, INC.

**Other PI Information:** Not Applicable

**Organization:**
- **Name:** ECOHEALTH ALLIANCE, INC.
- **City:** NEW YORK  
- **Country:** UNITED STATES (US)

**Department Type/ Organization Type:**
- **Unavailable**
- **Other Domestic Non-Profits**

**Congressional District:**
- **State Code:** NY  
- **District:** 10

**Other Information:**
- **FOA:** PA-18-464
- **Study Section:** Clinical Research and Field Studies of Infectious Diseases  
- **Study Section (CRS):**
- **Fiscal Year:** 2019  
- **Award Notice Date:** 24-JUL-2019

**DUNS Number:** 077090066  
**CFDA Code:** 855

**Project Start Date:** 1-JUN-2014  
**Budget Start Date:** 24-JUL-2019

**Project End Date:** 30-JUN-2025  
**Budget End Date:** 30-JUN-2021

**Administering Institutes or Centers:**
- NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

**Project Funding Information for 2019:**
- **Total Funding:** $661,980  
- **Direct Costs:** $538,926  
- **Indirect Costs:** $123,054

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<th>Year</th>
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<th>FY Total Cost by IC</th>
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</thead>
<tbody>
<tr>
<td>2019</td>
<td>NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES</td>
<td>$661,980</td>
</tr>
</tbody>
</table>

**Categorical Spending by IC:** Click here for more information on NIH Categorical Spending
June 26, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Azar,

We write with strong concerns surrounding the Administration’s termination of the National Institutes of Health (NIH) grant to EcoHealth Alliance on April 24, 2020.¹ In the letter communicating the grant’s termination, NIH Deputy Director for Extramural Research, Dr. Michael Lauer, wrote that “At this time, NIH does not believe the current project outcomes align with the program goals and agency priorities.”² However, press reports indicate that the grant was canceled because a small portion of the funding was to be given to the Wuhan Institute of Virology for on-the-ground sample collection and analysis.³ Given the potential for this study to inform our knowledge of coronavirus disease 2019 (COVID-19) transmission, it is deeply concerning that it may have been canceled for political reasons in the midst of the current pandemic.

It is always important that federal research priorities are driven by science-based decisions. This is especially true in a time that requires unparalleled investment in research that may help bring an end to this public health crisis. It is therefore troubling that this abrupt grant cancellation came just a week after President Trump announced that the Administration was looking into “grants going to that area” and continued that “we will end that grant very quickly.”⁴ This was in response to a reporter referencing false claims that COVID-19 “likely

³ Id.
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EcoHealth Alliance’s grant was renewed in 2019 after an initial five-year grant on the same topic. The grant it received was extremely competitive – only 22 percent of proposals were funded in 2019. The July 2019 project proposal was titled, “Understanding the Risk of Bat Coronavirus Emergence.” In the midst of the COVID-19 pandemic that has taken over 115,000 American lives, it is inconceivable that this project would no longer “align with the program goals and agency priorities” of NIH. Any termination of a grant that has gone through NIH’s rigorous scientific review process must be adequately justified on a scientific basis – particularly a grant which would appear to be so relevant to understanding our current health crisis.

As the Committees of jurisdiction over public health and science, we need to better understand the decision to terminate EcoHealth Alliance’s NIH grant. We are especially concerned given Dr. Anthony Fauci’s, Director of NIH’s National Institute of Allergy and Infectious Diseases, assertion at a Committee on Energy and Commerce hearing on June 23 that “the grant was canceled because NIH was told to cancel it.” In order to understand how this decision was reached, we request a briefing to be delivered by July 15, 2020. At this briefing, we ask that you be prepared to address the following questions:

1. When the decision was made to terminate the grant to EcoHealth Alliance;

2. Who at HHS was involved in the decision to terminate the grant;

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5 Id.
4. The analysis conducted to determine that the EcoHealth Alliance grant’s project outcomes did not align with program goals and NIH priorities;

5. Any analysis conducted to determine EcoHealth Alliance’s alleged improper disbursal of NIH funds to the Wuhan Institute of Virology;

6. Any other decision NIH has made to terminate grants since January 1, 2020; and

7. Any further action NIH is considering taking regarding EcoHealth Alliance or any other grant holder regarding alleged relationships with international laboratories.

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3. All documentation of audits or other analyses conducted to determine improper disbursement of federal grant money from grant-holding institutions to other entities; and

4. The criteria that NIH used to assess the EcoHealth Alliance grant and determine that such grant merited cancelation, and documentation thereof.

Any decision to terminate a research grant should be conducted in a deliberative and transparent process that adheres to the highest standards of scientific integrity. Especially in this unprecedented time, it is important that our public health and science agencies remain free from political pressure and be allowed to pursue federally-funded research based on scientific merit.

Thank you for your attention to this matter. We look forward to speaking with you and reviewing the relevant materials.

Sincerely,

Eddie Bernice Johnson  
Chairwoman  
Committee on Science, Space, and Technology

Frank Pallone, Jr.  
Chairman  
Committee on Energy and Commerce
Bill Foster
Chairman
Subcommittee on Investigations and Oversight

Diana DeGette
Chair
Subcommittee on Oversight and Investigations
Good morning,

Updated agenda and background document attached.

Thank you,

Gretchen

Good afternoon,

Attached please find the agenda for tomorrow's meeting.

Thank you,

Gretchen
Executive Committee Meeting
Tuesday, July 21, 2020
9:00 AM to 10:00 AM
Via Zoom

AGENDA

- NIH response to COVID-19 (Alfred/Larry)
- ACTIV Update (Francis/Larry/John)
- RADx and outreach to universities (Francis, Larry, Carrie)
- 7/17 CCRHB Meeting (Larry)
- AMA2 meeting 7/23 (Francis, Larry, Carrie, Ashley)
- EcoHealth Grant (Adrienne, Mike, Larry)
June 26, 2020

The Honorable Alex M. Azar II  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

Dear Secretary Azar,

We write with strong concerns surrounding the Administration’s termination of the National Institutes of Health (NIH) grant to EcoHealth Alliance on April 24, 2020.¹ In the letter communicating the grant’s termination, NIH Deputy Director for Extramural Research, Dr. Michael Lauer, wrote that “At this time, NIH does not believe the current project outcomes align with the program goals and agency priorities.”² However, press reports indicate that the grant was canceled because a small portion of the funding was to be given to the Wuhan Institute of Virology for on-the-ground sample collection and analysis.³ Given the potential for this study to inform our knowledge of coronavirus disease 2019 (COVID-19) transmission, it is deeply concerning that it may have been canceled for political reasons in the midst of the current pandemic.

It is always important that federal research priorities are driven by science-based decisions. This is especially true in a time that requires unparalleled investment in research that may help bring an end to this public health crisis. It is therefore troubling that this abrupt grant cancellation came just a week after President Trump announced that the Administration was looking into “grants going to that area” and continued that “we will end that grant very quickly.”⁴ This was in response to a reporter referencing false claims that COVID-19 “likely


³ Id.

came from a Level 4 lab in Wuhan.”\textsuperscript{5} The Administration has been pushing this theory\textsuperscript{6} despite scientific experts saying this path of transmission would be virtually impossible given what is known about the virus and lab safety protocols.\textsuperscript{7} If this theory is the basis for the grant termination, it would be an egregious example of the Administration politicizing scientific decision making in order to further a politically convenient narrative.

EcoHealth Alliance’s grant was renewed in 2019 after an initial five-year grant on the same topic. The grant it received was extremely competitive – only 22 percent of proposals were funded in 2019.\textsuperscript{8} The July 2019 project proposal was titled, “Understanding the Risk of Bat Coronavirus Emergence.”\textsuperscript{9} In the midst of the COVID-19 pandemic that has taken over 115,000 American lives, it is inconceivable that this project would no longer “align with the program goals and agency priorities” of NIH. Any termination of a grant that has gone through NIH’s rigorous scientific review process must be adequately justified on a scientific basis – particularly a grant which would appear to be so relevant to understanding our current health crisis.

As the Committees of jurisdiction over public health and science, we need to better understand the decision to terminate EcoHealth Alliance’s NIH grant. We are especially concerned given Dr. Anthony Fauci’s, Director of NIH’s National Institute of Allergy and Infectious Diseases, assertion at a Committee on Energy and Commerce hearing on June 23 that “the grant was canceled because NIH was told to cancel it.”\textsuperscript{10} In order to understand how this decision was reached, we request a briefing to be delivered by July 15, 2020. At this briefing, we ask that you be prepared to address the following questions:

1. When the decision was made to terminate the grant to EcoHealth Alliance;

2. Who at HHS was involved in the decision to terminate the grant;

3. Whether entities outside HHS, including but not limited to the White House, the State Department, the National Security Council, and intelligence agencies, were involved in this decision;

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5. Any analysis conducted to determine EcoHealth Alliance’s alleged improper disbursal of NIH funds to the Wuhan Institute of Virology;

6. Any other decision NIH has made to terminate grants since January 1, 2020; and

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4. The criteria that NIH used to assess the EcoHealth Alliance grant and determine that such grant merited cancelation, and documentation thereof.

Any decision to terminate a research grant should be conducted in a deliberative and transparent process that adheres to the highest standards of scientific integrity. Especially in this unprecedented time, it is important that our public health and science agencies remain free from political pressure and be allowed to pursue federally-funded research based on scientific merit.

Thank you for your attention to this matter. We look forward to speaking with you and reviewing the relevant materials.

Sincerely,

Eddie Bernice Johnson
Chairwoman
Committee on Science, Space, and Technology

Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce
Bill Foster  
Chairman  
Subcommittee on Investigations and Oversight  

Diana DeGette  
Chair  
Subcommittee on Oversight and Investigations
Hi Tony,

I wanted to be sure you were aware that the letter to the EcoHealth PI went out yesterday. This reinstates the grant but immediately suspends it, pending responses to a number of important questions about WIV.

I don’t know whether the PI will make this public, but I’d be surprised if the press doesn’t get wind of this somehow.

Francis
8 July 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

In follow-up to my previous letter of April 24, 2020, I am writing to notify you that the National Institute of Allergy and Infectious Diseases (NIAID), an Institute within the National Institutes of Health (NIH), under the Department of Health and Human Services (HHS), has withdrawn its termination of grant R01AI110964, which supports the project Understanding the Risk of Bat Coronavirus Emergence. Accordingly, the grant is reinstated.

However, as you are aware, the NIH has received reports that the Wuhan Institute of Virology (WIV), a subrecipient of EcoHealth Alliance under R01AI110964, has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, create health and welfare threats to the public in China and other countries, including the United States. Grant award R01AI110964 is subject to biosafety requirements set forth in the NIH Grants Policy Statement (e.g., NIH GPS, Section 4.1.24 “Public Health Security”) and the Notice of Award (e.g., requiring that “Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)].”). Moreover, NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients. 45 C.F.R. § 75.101.

As the grantee, EcoHealth Alliance was required to “monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . .” 45 C.F.R. § 75.352(d). We have concerns that WIV has not satisfied safety requirements under the award, and that EcoHealth Alliance has not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance.

Moreover, as we have informed you through prior Notices of Award, this award is subject to the Transparency Act subaward and executive compensation reporting requirement of 2 C.F.R. Part
170. To date you have not reported any subawards in the Federal Subaward Reporting System.

Therefore, effective the date of this letter, July 8, 2020, NIH is suspending all activities related to R01AI110964, until such time as these concerns have been addressed to NIH’s satisfaction. This suspension is taken in accordance with 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. This action is not appealable in accordance with 42 C.F.R. § 50.404 and the NIH GPS Section 8.7, Grant Appeals Procedures. However, EcoHealth Alliance has the opportunity to provide information and documentation demonstrating that WIV and EcoHealth Alliance have satisfied the above-mentioned requirements.

Specifically, to address the NIH’s concerns, EcoHealth must provide the NIH with the following information and materials, which must be complete and accurate:

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.
2. Explain the apparent disappearance of Huang Yanling, a scientist/technician who worked in the WIV lab but whose lab web presence has been deleted.
3. Provide the NIH with WIV’s responses to the 2018 U.S. Department of State cables regarding safety concerns.
4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.
5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.
6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.
7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System.

During this period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further assess compliance by EcoHealth Alliance and WIV, including compliance with other terms and conditions of award that may be implicated. Additionally, during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance’s responsibility as the
recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. Once the original award is reinstated, NIH will take additional steps to restrict all funding in the HHS Payment Management System in the amount of $369,819. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 CFR Part 75, including, but not limited to, terminating the grant award. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

Sincerely,

Michael S. Lauer

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: [b][b][b][b]

cc: Dr. Erik Stemmy
Ms. Emily Linde
Let’s discuss at ExComm tomorrow. I note the letter is dated June 26 – is the first time we’ve seen it?

FC

I think the time has come when we will have to admit that we reinstated the EcoHealth grant. Please see attached Oversight investigation into the issue. Please note the signers:

Frank Pallone, Chair of E&C Cmte
Diana DeGette, Chair of E&C Subcmte on Investigations
Eddie Bernice Johnson, Chair of Science Cmte
Bill Foster, Chair of Science Subcmte on Investigations
June 26, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Azar,

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Thank you for your attention to this matter. We look forward to speaking with you and reviewing the relevant materials.

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Committee on Science, Space, and Technology

Frank Pallone, Jr.
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Committee on Energy and Commerce
Bill Foster  
Chairman  
Subcommittee on Investigations and Oversight  

Diana DeGette  
Chair  
Subcommittee on Oversight and Investigations
Adding EH discussion and letter—should discuss first.

1:1 w/ Jodi Black

6/30/20

COVID-19

- Updated COVID-19 External FAQs and Staff Guidance [reserved]

Personnel

- Updated Org Chart (See OPERA Future Org Chart_6.29)
OPERA IMOD

DGP

DGCO/DEITR Compliance

Integrity Cases
Audit of the Pre-Award Risk Assessment Process at the National Human Genome Research Institute – NIH responses to questions 5 and 6.
TO: Operating Division Chief Grants Management Officers  
Staff Division Chief Grants Management Officers  

FROM: Renee Cooper  
Associate Deputy Assistant Secretary for Grants  

DATE: June 26, 2020  


On June 18, 2020, the Office of Management and Budget (OMB) issued updated administrative relief guidance for recipients and applicants of federal financial assistance as federal awarding agencies continue to address COVID-19 related activities. The updated memorandum is limited in scope, only extending the expiration dates of two (2) of the flexibilities contained within OMB Memoranda M-20-17 “Administrative Relief for Recipients and Applicants of Federal Financial Assistance Directly Impacted by the Novel Coronavirus (COVID-19) due to Loss of Operations”. Effective as of the date of M-20-26, HHS extends the two (2) flexibilities to 45 CFR 75. These two flexibilities are time limited and will expire on the date referenced in M-20-26 or sooner should OMB withdraw the authority.

Any requests for use of the flexibilities specified in OMB Memoranda M-20-17 and M-20-20 that were submitted directly to HHS awarding agencies prior to June 16, 2020, are actionable by HHS awarding agencies, with the exception of the SAM registration flexibility specified in OMB M-20-17, which was only applicable to registrants with active registrations that expired before May 16, 2020.

As HHS awarding agencies are considering administrative relief, they should consult across all potential offices, including their Chief Financial Officer and Budget Officer as necessary. HHS awarding agencies should be prudent in their stewardship of federal resources that includes giving consideration of potential offsets (e.g. reduction in training and travel). HHS awarding agencies are also reminded of their existing flexibility, in accordance with 45 CFR § 75.102, Exceptions, to consider and issue additional exceptions on a case-by-case basis.

HHS awarding agencies must communicate allowable flexibilities to their respective recipient communities with the following specific parameters:

1. Allowability of salaries and other project activities.

HHS awarding agencies must advise recipients that due to the limited funding resources under each federal award to achieve its specific public program goals, recipients must exhaust other available funding sources to sustain its workforce and implement necessary steps to save overall operational costs (such as rent negotiations) during this pandemic period in order to preserve federal funds for an eventual ramping-up effort. Recipients should not assume additional funds will be available should the charging of cancellation or other fees result in a shortage of funds to eventually carry out the event or travel. HHS awarding agencies allowing this flexibility must require recipients to maintain appropriate records and cost documentation as required by 2 CFR §
200.302 - Financial management and 2 CFR § 200.333 - Retention requirement of records to substantiate the charging of any salaries and other project activities costs related to interruption of operations or services.

Under this flexibility, payroll costs paid with the Paycheck Protection Program (PPP) loans or any other federal CARES Act programs must not also be charged to current federal awards, as it would result in the federal government paying for the same expenditures twice.

For additional questions, please contact your DGPOE desk officer liaison and email GrantPolicyREQ@hhs.gov.

Attachment
Thanks Aesha – we’re working on it (second attachment).

Mike

From: OER Executive Secretariat <b>(b)(6)>
Date: Tuesday, May 11, 2021 at 1:37 PM
To: "Lauer, Michael [NIH/OD] [E]" <b>(b)(6)>
Cc: "Bundesen, Liza (NIH/OD) [E]" <b>(b)(6)>
"Kosub, David (NIH/OD) [E]"
"Joshi, Pritty (NIH/OD) [E]"
"Showe, Melanie (NIH/OD) [E]"
"Lauer, Michael (NIH/OD) [E]"
"OER Executive Secretariat <b>(b)(6)>
"Bundesen, Liza (NIH/OD) [E]"
"Kosub, David (NIH/OD) [E]"
"Joshi, Pritty (NIH/OD) [E]"
"Showe, Melanie (NIH/OD) [E]"
"Lauer, Michael (NIH/OD) [E]"
Subject: Necessary Action - Origins of the Coronavirus - Due by 4pm Friday May 14th (WF399541)
Hi Dr. Lauer -
Please see Senator Charles Grassley's letter to Acting Secretary Norris Cochran and Avril Haines (National Intelligence) regarding the work the government has done to determine the origins of the coronavirus. NIH is responsible for answer to question #9, and per OLPA OER is aware of this letter. Would you please provide a response for question #9 and forward back to me by 4pm, Friday, May 14th.

Let me know if you have any questions or feel this should be assigned to another SME for necessary action.

Thanks.

Best Regards,

Aesha Brandy, MBA
Management and Program Analyst
NIH Office of Extramural Research
Immediate Office of the Director

Building 1, Room 150
Bethesda, MD 20814

(b)(6)
(b)(6)
Hi Dr. Lauer -

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Thanks.

Best Regards,

Aesha Brandy, MBA
Management and Program Analyst
NIH Office of Extramural Research
Immediate Office of the Director

Building 1, Room 150
Bethesda, MD 20814

(b)(6)

(b)(6)
March 8, 2021

VIA ELECTRONIC TRANSMISSION

The Honorable Avril Haines
Director of National Intelligence

Mr. Norris Cochran
Acting Director
Department of Health and Human Services

Dear Director Haines and Acting Director Cochran:

On February 4, 2020, my oversight and investigations staff received a classified briefing from the Department of Health and Human Services (HHS), Office of National Security regarding the SARS-CoV-2 (hereinafter “coronavirus”) threat and the status of the U.S. government’s efforts to combat the spread of the deadly virus.\(^1\) From the beginning, my goal has been to ensure a robust federal response to the threat and to better understand the origins of the virus. For example, there is still considerable debate about whether the coronavirus is a naturally occurring virus, a naturally occurring virus that escaped from a lab, or a laboratory manipulated virus that escaped from a lab.

In December 2020, a team of World Health Organization (WHO) researchers and scientists traveled to Wuhan, China to investigate the origins of coronavirus. However, according to recent reports, China refused to grant WHO researchers access to anonymized raw data from the earliest days of the outbreak which would help pinpoint the origins of the virus.\(^2\) Instead, China produced self-generated summaries and analyses of the data which could have been manipulated by the communist Chinese government, effectively preventing a real review.\(^3\)

In early February last year, I warned about China’s reluctance to share data regarding the coronavirus outbreak.\(^4\) I also noted that China’s failure to cooperate made it more important for the Intelligence Community and HHS to work together to ensure information is efficiently

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\(^3\) Ibid.

shared between them. The Trump administration ensured that federal health agencies had a seat at the table within the Intelligence Community and access to information relating to the pandemic. That cooperation and access must continue and be built upon to better combat the virus and determine its origins.

More than 500,000 Americans have died as a result of the coronavirus pandemic and trillions of taxpayer dollars have been spent to shore up our economy and take care of our citizens. Congress and the American public have a right to know and understand what work the government has done to determine the origins of the coronavirus. Accordingly, in light of your agency’s role with respect to the pandemic, no later than March 22, 2021, please provide the following:

1. All information disseminated to the National Intelligence Council relating to the coronavirus pandemic.

2. All records relating to detailed genomic sequencing analyses for SARS-CoV-2 and related coronaviruses, including all records relating to research about the receptor binding domain of pangolin origin coronavirus and furin-cleavage site insertion.

3. All records relating to detailed genomic sequencing analyses on the similarities between SARS-CoV-2 and any previous published and/or unpublished work by the Wuhan Institute of Virology on coronavirus chimeras.

4. All records relating to detailed genomic sequencing analyses on the similarities between SARS-CoV-2 and genomic sequencing analyses on miners that were hospitalized in Yunnan Province in and around 2012.

5. All records relating to all analyses with respect to the capabilities of the Wuhan Institute of Virology to manipulate bat coronaviruses using reverse genetic technologies.

6. All records relating to illnesses at the Wuhan Institute of Virology among its personnel and scientific staff during the Fall of 2019. In your answer, please describe the type of work these employees were engaged in.

7. All records relating to work conducted at the Wuhan Institute of Virology by Chinese government agencies prior to and during Fall of 2019.

8. Please describe the steps you have taken to continue to incorporate the Department of Health and Human Services into missions involving threats to the nation’s health care, including access to Intelligence Community information, and the steps you have taken to improve upon the information access provided by the Trump administration.
9. In light of the National Institutes of Health funding operations at the Wuhan Institute of Virology, please describe the steps you took to oversee the research done at the Wuhan Institute of Virology.

Please send all unclassified material directly to the Committee. In keeping with the requirements of Executive Order 13526, if any of the responsive documents do contain classified information, please segregate all unclassified material within the classified documents, provide all unclassified information directly to the Committee, and provide a classified addendum to the Office of Senate Security. Although the Committee complies with all laws and regulations governing the handling of classified information, it is not bound, absent its prior agreement, by any handling restrictions.

Thank you for your attention to this important matter.

Sincerely,

Charles E. Grassley
Ranking Member
Committee on the Judiciary
FW: Grassley letter re COVID

From: "Schmalz, Jennifer (HHS/ASL)" <(b)(6)
Date: Monday, May 3, 2021 at 5:00 PM
To: "Lohmann, Larry (NIH/OD) [E]" <(b)(6)
Subject: FW: Grassley letter re COVID

Circling back on this one, can NIH draft a narrative response to #9?

From: Lohmann, Larry (NIH/OD) [E] <(b)(6)
Sent: Friday, March 26, 2021 11:52 AM
To: Schmalz, Jennifer (HHS/ASL) <(b)(6)
Subject: Re: Grassley letter re COVID

Good morning Jennifer,

If you have a second to chat about this, it might be helpful. I’m free until 2:30.

For #9 Dr. Lauer said we have the letters we sent to EcoHealth Alliance(attached). We also sent a letter to UC Irvine suspending a subaward (attached).

On May 20, 2020, NIH sent a letter to the University of California, Irvine, suspending all activities related to RF1 MH120020-01, Genetically engineered anterograde monosynaptic viral tracers for multi-species neural circuit analysis, Dr. Xiangmin Xu (Contact PI), for which the Wuhan Institute of Virology is a subaward participant, awarded by the National Institute of Mental Health (NIMH).

On July 8, 2020, NIH sent a letter to EcoHealth Alliance (enclosed) indicating the grant was reinstated; however, funding and activities were suspended pending complete, accurate, and satisfactory answers, materials, and information regarding a number of specific concerns about biosafety and other practices at its sub-recipient, WIV. Furthermore, EcoHealth Alliance was instructed to correct its repeated noncompliance due to its failure to report all sub-awards in the Federal Subaward Report System. EcoHealth Alliance had been directed in NIH Notices of
FW: Grassley letter re COVID

Award to generate these reports as required by the Transparency Act sub-award and executive compensation reporting requirement of 2 C.F.R. Part 170.

The July 8 letter to EcoHealth Alliance indicated that the suspension of the grant was taken in accordance with 45 C.F.R. § 75.371, which permits suspension of award activities in cases of non-compliance, and the NIH Grants Policy Statement (GPS) Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. This action is not appealable under 42 C.F.R. § 50.404 and the NIH GPS, Section 8.7.

On October 23, 2020, NIH sent a letter to EcoHealth Alliance in response to their response to suspension. The letter noted while, EcoHealth does not currently have a subrecipient relationship with WIV and had not issued subawards to WIV at the time of suspension did not absolve EcoHealth of any past non-compliance with the terms and conditions of award for grant R01AI110964

For #8 we would defer to ODNI.

Very respectfully,

Larry

From: "Schmalz, Jennifer (HHS/ASL)" <(b)(6)>
Date: Tuesday, March 23, 2021 at 2:55 PM
To: "Lohmann, Larry (NIH/OD) [E]" <(b)(6)>
Subject: FW: Grassley letter re COVID

Here’s the SFC letter.

Can you advise on whether NIH could respond to #8 and #9?
Hi David, Michelle, and Kristin — Here’s my draft response to Q9.

Thanks, Mike

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Good day Mike, Michelle, and Kristin,

HHS requested Mike draft a response to Q#9 from Senator Grassley’s letter (first attachment) regarding the origins of COVID-19: “In light of the National Institutes of Health funding operations at the Wuhan Institute of Virology, please describe the steps you took to oversee the research done at the Wuhan Institute of Virology.”

Mike previously shared the additional EcoHealth correspondence with OLPA to address this question. Please advise who should take lead on drafting the proposed answer.

Thank you

David

---

Good Morning, David,
HHS came back to us on the attached letter from Sen. Grassley to ODNI. They are asking us to draft a narrative response to question #9. Dr. Lauer had previously indicated that we might base that response on the letters that we sent to EcoHealth.

I’ve looped in Larry who can help answer any questions on the background on this letter.

Thank you,
Karen

From: "Lohmann, Larry (NIH/OD) [E]" (b)(6)
Date: Tuesday, May 4, 2021 at 4:58 PM
To: Karen LaMontagne (b)(6)
Subject: Re: Grassley letter re COVID

Good afternoon,

This is back again. HHS asked if we could draft a narrative response to question number 9, “In light of the National Institutes of Health funding operations at the Wuhan Institute of Virology, please describe the steps you took to oversee the research done at the Wuhan Institute of Virology.” Can you see if OER would be willing to draft it, guessing NIAID might have to look at it as well?

Very respectfully,
Larry

From: "Lauer, Michael (NIH/OD) [E]" (b)(6)
Date: Tuesday, March 23, 2021 at 6:21 PM
To: "LaMontagne, Karen (NIH/OD) [E]" (b)(6)
Cc: "Kosub, David (NIH/OD) [E]" (b)(6) "Rabin, Elise (NIH/OD) [E]" (b)(6) "Lohmann, Larry (NIH/OD) [E]" (b)(6) "Lauer, Michael (NIH/OD) [E]" (b)(6)
Subject: Re: Grassley letter re COVID

Thanks Karen – agree ODNI for #8. For #9 we have the letters we sent to EcoHealth Alliance. We also sent a letter to UC Irvine suspending a subaward.

Mike

From: "LaMontagne, Karen (NIH/OD) [E]" (b)(6)
Date: Tuesday, March 23, 2021 at 3:36 PM
To: "Lauer, Michael (NIH/OD) [E]" (b)(6)
Cc: "Kosub, David (NIH/OD) [E]" (b)(6) "Rabin, Elise (NIH/OD) [E]" (b)(6) "Lohmann, Larry (NIH/OD) [E]" (b)(6)
Subject: FW: Grassley letter re COVID

Hi, Dr. Lauer,

Flagging the attached letter to ODNI from Senator Grassley. You will recall that Sen. Grassley is the former Chairman of the Senate Finance Committee. He now serves as the Ranking Minority Member of the Senate Judiciary Committee.
HHS/ASL reached out to OLPA to gauge whether NIH can answer #8 & #9. (Although I would think ODNI should answer #8?) Would you please let us know what you think?

Thanks very much,
Karen

Karen LaMontagne
Office of Legislative Policy & Analysis
National Institutes of Health

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Date: Tuesday, March 23, 2021 at 2:55 PM
To: "Lohmann, Larry (NIH/OD) [E]" <(b)(6)>
Subject: FW: Grassley letter re COVID

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Thank you
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Thank you,
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Very respectfully,
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Date: Tuesday, March 23, 2021 at 6:21 PM
To: "LaMontagne, Karen (NIH/OD) [E]" (b)(6)
Cc: "Kosub, David (NIH/OD) [E]" (b)(6) "Rabin, Elise (NIH/OD) [E]" (b)(6) "Lohmann, Larry (NIH/OD) [E]" (b)(6) "Lauer, Michael (NIH/OD) [E]"

Subject: Re: Grassley letter re COVID

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Mike

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Date: Tuesday, March 23, 2021 at 3:36 PM
To: "Lauer, Michael (NIH/OD) [E]" (b)(6)
Cc: "Kosub, David (NIH/OD) [E]" (b)(6) "Rabin, Elise (NIH/OD) [E]" (b)(6) "Lohmann, Larry (NIH/OD) [E]" (b)(6)

Subject: FW: Grassley letter re COVID

Hi, Dr. Lauer,

Flagging the attached letter to ODNI from Senator Grassley. You will recall that Sen. Grassley is the former Chairman of the Senate Finance Committee. He now serves as the Ranking Minority Member of the Senate Judiciary Committee.

HHS/ASL reached out to OLPA to gauge whether NIH can answer #8 & #9. (Although I would think ODNI should answer #8?) Would you please let us know what you think?

Thanks very much,
Karen

Karen LaMontagne
Office of Legislative Policy & Analysis
National Institutes of Health
Here's the SFC letter.

Can you advise on whether NIH could respond to #8 and #9?
March 8, 2021

VIA ELECTRONIC TRANSMISSION

The Honorable Avril Haines
Director of National Intelligence

Mr. Norris Cochran
Acting Director
Department of Health and Human Services

Dear Director Haines and Acting Director Cochran:

On February 4, 2020, my oversight and investigations staff received a classified briefing from the Department of Health and Human Services (HHS), Office of National Security regarding the SARS-CoV-2 (hereinafter “coronavirus”) threat and the status of the U.S. government’s efforts to combat the spread of the deadly virus. From the beginning, my goal has been to ensure a robust federal response to the threat and to better understand the origins of the virus. For example, there is still considerable debate about whether the coronavirus is a naturally occurring virus, a naturally occurring virus that escaped from a lab, or a laboratory manipulated virus that escaped from a lab.

In December 2020, a team of World Health Organization (WHO) researchers and scientists traveled to Wuhan, China to investigate the origins of coronavirus. However, according to recent reports, China refused to grant WHO researchers access to anonymized raw data from the earliest days of the outbreak which would help pinpoint the origins of the virus. Instead, China produced self-generated summaries and analyses of the data which could have been manipulated by the communist Chinese government, effectively preventing a real review.

In early February last year, I warned about China’s reluctance to share data regarding the coronavirus outbreak. I also noted that China’s failure to cooperate made it more important for the Intelligence Community and HHS to work together to ensure information is efficiently

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3 Id.
shared between them. The Trump administration ensured that federal health agencies had a seat at the table within the Intelligence Community and access to information relating to the pandemic. That cooperation and access must continue and be built upon to better combat the virus and determine its origins.

More than 500,000 Americans have died as a result of the coronavirus pandemic and trillions of taxpayer dollars have been spent to shore up our economy and take care of our citizens. Congress and the American public have a right to know and understand what work the government has done to determine the origins of the coronavirus. Accordingly, in light of your agency’s role with respect to the pandemic, no later than March 22, 2021, please provide the following:

1. All information disseminated to the National Intelligence Council relating to the coronavirus pandemic.

2. All records relating to detailed genomic sequencing analyses for SARS-CoV-2 and related coronaviruses, including all records relating to research about the receptor binding domain of pangolin origin coronavirus and furin-cleavage site insertion.

3. All records relating to detailed genomic sequencing analyses on the similarities between SARS-CoV-2 and any previous published and/or unpublished work by the Wuhan Institute of Virology on coronavirus chimeras.

4. All records relating to detailed genomic sequencing analyses on the similarities between SARS-CoV-2 and genomic sequencing analyses on miners that were hospitalized in Yunnan Province in and around 2012.

5. All records relating to all analyses with respect to the capabilities of the Wuhan Institute of Virology to manipulate bat coronaviruses using reverse genetic technologies.

6. All records relating to illnesses at the Wuhan Institute of Virology among its personnel and scientific staff during the Fall of 2019. In your answer, please describe the type of work these employees were engaged in.

7. All records relating to work conducted at the Wuhan Institute of Virology by Chinese government agencies prior to and during Fall of 2019.

8. Please describe the steps you have taken to continue to incorporate the Department of Health and Human Services into missions involving threats to the nation’s health care, including access to Intelligence Community information, and the steps you have taken to improve upon the information access provided by the Trump administration.
9. In light of the National Institutes of Health funding operations at the Wuhan Institute of Virology, please describe the steps you took to oversee the research done at the Wuhan Institute of Virology.

Please send all unclassified material directly to the Committee. In keeping with the requirements of Executive Order 13526, if any of the responsive documents do contain classified information, please segregate all unclassified material within the classified documents, provide all unclassified information directly to the Committee, and provide a classified addendum to the Office of Senate Security. Although the Committee complies with all laws and regulations governing the handling of classified information, it is not bound, absent its prior agreement, by any handling restrictions.

Thank you for your attention to this important matter.

Sincerely,

Chuck Grassley
Charles E. Grassley
Ranking Member
Committee on the Judiciary
Drs. Aleksei Chmura and Peter Daszak  
EcoHealth Alliance, Inc.  
460 W 34th St  
Suite 1701  
New York, NY 10001  

Re: NIH Grant R01AI110964  

Dear Drs. Chmura and Daszak:  

I am following up on Mr. Krinsky’s August 13, 2020, letter on behalf of EcoHealth Alliance, Inc. (“EcoHealth”) responding to NIH’s suspension of grant R01AI110964, which funds the project *Understanding the Risk of Bat Coronavirus Emergence* (the "Project"). Per my letter of July 8, 2020, NIH reinstated the grant but suspended all award activities because we have concerns that the Wuhan Institute of Virology (WIV), which previously served as a subrecipient of the Project, had not satisfied safety requirements that applied to its subawards with EcoHealth, and that EcoHealth had not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance. EcoHealth objected to the suspension on the grounds that WIV has no current connection to the Project or EcoHealth’s research, and EcoHealth had not issued any subawards in connection with the Grant at the time of the suspension.

The fact that EcoHealth does not currently have a subrecipient relationship with WIV and had not issued subawards to WIV at the time of suspension does not absolve EcoHealth of any past non-compliance with the terms and conditions of award for grant R01AI110964. While EcoHealth did not issue a subaward to WIV for year 6 of the grant, WIV served as a subrecipient for years 1 through 5. NIH awarded EcoHealth grant R01AI110964 in 2014, with a project period of June 1, 2014, through June 30, 2024, as renewed. In EcoHealth’s grant application, EcoHealth listed Drs. Zheng Li Shi and Xing Yi Ge of WIV as co-investigators and senior/key personnel. It stated that “Drs. Shi, Zhang, and Daszak have collaborated together since 2002 and have been involved in running joint conferences, and shipping samples into and out of China.” EcoHealth listed WIV as a Project/Performance Site Location. In describing WIV’s facilities, EcoHealth described WIV as China’s premier institute for virological research” and touted WIV’s “fully equipped biosafety level 3 laboratory” and “a newly opened BLS-4 laboratory.” In support of the application, Dr. Zheng Li Shi’s personal statement indicated that “My lab will be responsible for diagnosis, genomics and isolation of coronavirus from wild and domestic animals in Southern China and for analyzing their receptor binding domains.” The application stated that “Wuhan Institute of Virology and the Wuhan University Center for Animal Experiment BSL-3
lab have an Internal Biosafety Committee and are accredited BSL-2 and BSL 3 laboratories. All experimental work using infectious material will be conducted under appropriate biosafety standards. Disposal of hazardous materials will be conducted according to the institutional biosafety regulations.”

EcoHealth requested funding specifically for activities to be carried out by WIV. NIH awarded EcoHealth a total of $749,976 for WIV’s work in the following annual amounts for years 1 through 5:

<table>
<thead>
<tr>
<th></th>
<th>-Yr 1</th>
<th>-Yr 2</th>
<th>-Yr 3</th>
<th>-Yr 4</th>
<th>-Yr 5</th>
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<td>Total Direct Costs</td>
<td>$123,699</td>
<td>$128,718</td>
<td>$147,335</td>
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<tr>
<td>F&amp;A Costs @ 8%</td>
<td>$9,896</td>
<td>$10,297</td>
<td>$11,787</td>
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<tr>
<td>TOTAL COSTS</td>
<td>$133,595</td>
<td>$139,015</td>
<td>$159,122</td>
<td>$159,122</td>
<td>$159,122</td>
</tr>
</tbody>
</table>

As stated in the Notices of Award for each budget period of the grant, the awards were subject to terms and conditions, which include the NIH Grants Policy Statement (GPS) and applicable HHS grant regulations. As I indicated in my letter of July 8, 2020, as a term and condition of award EcoHealth was required to “monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . .” 45 C.F.R. § 75.352(d). See also, 45 C.F.R. § 75.342(a) (“The non-Federal entity is responsible for oversight of the operations of the Federal award supported activities.”). Moreover, EcoHealth was required to “Establish and maintain effective internal control over the Federal award that provides reasonable assurance that the non-Federal entity is managing the Federal award in compliance with Federal statutes, regulations, and the terms and conditions of the Federal award[.]” 45 C.F.R. § 75.303(a). The Notice of Award stated that as a term and condition of award, “Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)].” Moreover, the NIH GPS provides that NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients, so these terms applied to WIV. 45 C.F.R. § 75.101.

As I stated, NIH has concerns of non-compliance with terms and conditions of award—namely, that WIV had not satisfied safety requirements under the award and that EcoHealth Alliance had not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance. Accordingly, NIH suspended all activities related to R01AI110964, pursuant to 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare.

In my letter of July 8, 2020, I provided EcoHealth with the opportunity to object and to provide information and documentation challenging the suspension. Specifically, I sought information and materials that speak to WIV’s lab safety and EcoHealth’s oversight of its subrecipient, and an inspection of WIV’s laboratory records and facilities. I indicated that as a specific condition of award, during the period of suspension, EcoHealth Alliance may not allow research under this
project to be conducted and that no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients.

EcoHealth objected to the requests on the grounds that “NIAID is not authorized under 45 CFR §§ 75.371, 75.205, and 75.207, entitled Specific Award Conditions, to impose, inter alia, conditions that consist of demands for information regarding entities that are neither subrecipients of grant funds nor project affiliates.”

These provisions are irrelevant to NIH’s requests. NIH is required to permit the opportunity for recipients to object and provide information and documentation challenging a suspension, 45 C.F.R. § 75.374, so we specifically gave EcoHealth the opportunity to provide information that speaks to NIH’s concerns. Moreover, as a granting agency, NIH is required to “manage and administer the Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented in full accordance with U.S. statutory and public policy requirements: Including, but not limited to, those protecting public welfare [and] the environment[.]” 45 C.F.R. § 75.300(a). In addition to seeking information that speaks to compliance with terms and conditions of award, NIH is entitled to “make site visits as warranted by program needs.” 45 C.F.R. § 75.342. As a term and condition of award, NIH “must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts” (45 C.F.R. § 75.364); and must have “timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents” (id.). These requirements flow down to subawards to subrecipients. 45 C.F.R. § 75.101. “Non-Federal entities must comply with requirements in [45 C.F.R. Part 75] regardless of whether the non-Federal entity is a recipient or subrecipient of a Federal award.” 45 C.F.R. 75.101. As the grantee, EcoHealth was required to have in place, “A requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part.” 45 C.F.R. § 75.352(a)(5). For each of these reasons, NIH is justified in seeking the materials, information, and a site visit specified in my letter of July 8, 2020.

In addition to objecting to NIH’s authority to seek the materials, information, and a site visit, EcoHealth has responded that it lacks knowledge or information regarding the requests; that it is not in possession, custody, or control of the specified items; and that it has no authority to grant NIAID and the U.S. National Academy of Sciences access to WIV’s facility to conduct an inspection. EcoHealth’s responses have not satisfied NIH’s concerns that EcoHealth had failed to adequately monitor the compliance of its subrecipient, and that the subrecipient, WIV, had failed to comply with safety requirements.

Notwithstanding this, NIH is providing an additional opportunity for EcoHealth to provide information and documentation challenging these concerns of non-compliance. Accordingly, in addition to reiterating our prior requests (1) through (6) per our letter of July 8, 2020, NIH requests the following information and materials, which must be complete and accurate:
1. Provide copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any other documents and information describing how EcoHealth Alliance monitored WIV’s compliance with the terms and conditions of award, including with respect to biosafety.
2. Describe EcoHealth’s efforts to evaluate WIV’s risk of noncompliance with Federal statutes, regulations, and the terms and conditions of the subaward.
3. Provide copies of all WIV biosafety reports from June 1, 2014 through May 31, 2019.

During the ongoing period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further assess whether EcoHealth Alliance and WIV complied with the terms and conditions of award, including compliance with other terms and conditions of award that may be implicated. We remind you that during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance’s responsibility as the recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the continued suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 C.F.R. Part 75, including, but not limited to, terminating the grant award or disallowing costs. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

Sincerely,

Michael S. Lauer

Michael S Lauer, MD
NIH Deputy Director for Extramural Research

Email: (b)(6)

cc: Dr. Erik Stemmy (NIAID)
Ms. Emily Linde (NIAID)
May 20, 2020

Mr. Mark Bourbonnais
Director
Research Support Services
School of Medicine
University of California, Irvine

Dear Mr. Bourbonnais:

I am writing to inform you that the National Institutes of Health (NIH) has been made aware of reports that Wuhan Institute of Virology (WIV) has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, health and welfare threats to the public, both in China and other countries, including the United States. The University of California, Irvine (UCI) has an NIH grant award that supports Wuhan Institute of Virology as a subrecipient consortium.

It is the NIH mission to protect public health and welfare from a serious deficiency such as unsafe laboratory practices. Therefore, effective the date of this letter, May 20, 2020, NIH is suspending all activities related to RF1 MH120020-01, *Genetically engineered anterograde monosynaptic viral tracers for multi-species neural circuit analysis*, Dr. Xiangmin Xu (Contact PI), for which the Wuhan Institute of Virology is a subaward participant, awarded by the National Institute of Mental Health (NIMH).

This action is taken in accordance with the NIH Grants Policy Statement (GPS), a term and condition all NIH grant awards, Section 8.5.2, Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support, which implements our governing regulations 45 CFR Part 75.371, Remedies for Noncompliance. This section states that NIH may take immediate action to terminate a grant when necessary to protect the public health and welfare. However, in this case NIH has chosen to suspend the sub-contractual activities directly supporting WIV, while the safety measures outlined in the NIH GPS Section 4.1.12 Health and Safety Regulations and Guidelines, are reviewed. This action is not appealable in accordance with the NIH GPS Section 8.7, Grant Appeals Procedures.

During the period of suspension, UCI may not allow research under this project to be conducted by WIV. Further, no funds may be provided to or expended by WIV; all such charges are unallowable. Other grant funding for this project will remain available for the conduct of research that is not subject to this suspension action. It is UCI’s responsibility as the recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by WIV. UCI must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms must be immediately reported to NIH. NIH has taken additional steps to restrict funding in the HHS Payment Management System in the amount of $660,054, the total costs awarded for the research that is being conducted at WIV. UCI will receive a revised Notice of Award from NIMH indicating the suspension of these research activities and funding restrictions as a specific condition of award.
Please note that this action does not preclude NIH from imposing additional special award conditions, corrective actions, or enforcement actions pursuant to 45 CFR including, but not limited to, terminating the grant award.

Please let me know if you have any questions concerning the information in this letter. My complete contact information follows my signature below.

Sincerely,

Michael S. Lauer, M.D.
Deputy Director Extramural Research
1 Center Drive, Room 144
Bethesda, MD 20892

2.
8 July 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

In follow-up to my previous letter of April 24, 2020, I am writing to notify you that the National Institute of Allergy and Infectious Diseases (NIAID), an Institute within the National Institutes of Health (NIH), under the Department of Health and Human Services (HHS), has withdrawn its termination of grant R01AI110964, which supports the project Understanding the Risk of Bat Coronavirus Emergence. Accordingly, the grant is reinstated.

However, as you are aware, the NIH has received reports that the Wuhan Institute of Virology (WIV), a subrecipient of EcoHealth Alliance under R01AI110964, has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, create health and welfare threats to the public in China and other countries, including the United States. Grant award R01AI110964 is subject to biosafety requirements set forth in the NIH Grants Policy Statement (e.g., NIH GPS, Section 4.1.24 “Public Health Security”) and the Notice of Award (e.g., requiring that “Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)].”). Moreover, NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients. 45 C.F.R. § 75.101.

As the grantee, EcoHealth Alliance was required to “monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . .” 45 C.F.R. § 75.352(d). We have concerns that WIV has not satisfied safety requirements under the award, and that EcoHealth Alliance has not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance.

Moreover, as we have informed you through prior Notices of Award, this award is subject to the Transparency Act subaward and executive compensation reporting requirement of 2 C.F.R. Part
170. To date you have not reported any subawards in the Federal Subaward Reporting System.

Therefore, effective the date of this letter, July 8, 2020, NIH is suspending all activities related to R01AI110964, until such time as these concerns have been addressed to NIH’s satisfaction. This suspension is taken in accordance with 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. This action is not appealable in accordance with 42 C.F.R. § 50.404 and the NIH GPS Section 8.7, Grant Appeals Procedures. However, EcoHealth Alliance has the opportunity to provide information and documentation demonstrating that WIV and EcoHealth Alliance have satisfied the above-mentioned requirements.

Specifically, to address the NIH’s concerns, EcoHealth must provide the NIH with the following information and materials, which must be complete and accurate:

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.
2. Explain the apparent disappearance of Huang Yanling, a scientist/technician who worked in the WIV lab but whose lab web presence has been deleted.
3. Provide the NIH with WIV’s responses to the 2018 U.S. Department of State cables regarding safety concerns.
4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.
5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.
6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.
7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System.

During this period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further assess compliance by EcoHealth Alliance and WIV, including compliance with other terms and conditions of award that may be implicated. Additionally, during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance’s responsibility as the
recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. Once the original award is reinstated, NIH will take additional steps to restrict all funding in the HHS Payment Management System in the amount of $369,819. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 CFR Part 75, including, but not limited to, terminating the grant award. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

Sincerely,

Michael S. Lauer, MD
NIH Deputy Director for Extramural Research

cc: Dr. Erik Stemmy
Ms. Emily Linde
Response to Senator Grassley re WIV
Draft May 10, 2021
Mike Lauer (OER)

Q: In light of the National Institutes of Health funding operations at the Wuhan Institute of Virology, please describe the steps you took to oversee the research done at the Wuhan Institute of Virology.
From: Jacobs, Anna (NIH/OD) [E] /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP [FYDIH0F23SPDLT]/CN=RECIPIENTS/CN=E76EEB11DF9A4024B53864FFAC4C4C56-1ACOBSAL]
Sent: 5/12/2021 2:15:37 PM
To: Lauer, Michael (NIH/OD) [E] /[O=ExchangeLabs/ou=Exchange Administrative Group [FYDIH0F23SPDLT]/cns=Recipients/cn=90fe9cae30c64c6bb67abd568e882796-lauerm]
Subject: for your files--congressional letters

Mike,

For your files, in case you do not already have them, I am sending you all of the letters that I am aware various members of Congress have sent regarding the origins of the virus and the EcoHealth grant. The most recent was a letter sent yesterday to the director of a DOE laboratory that apparently did an investigation some time last year of WIV’s work. I hadn’t previously known about DOE’s role, and it was a helpful reminder of all of the various components of the executive branch that are looking into the issues.

Best,

Anna L. Jacobs, J.D., M.S.
Senior Attorney
HHS Office of the General Counsel
Public Health Division, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
(b)(6) (phone)
301-402-1034 (fax)
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Kimberly S. Budil, Ph.D.
Laboratory Director
Lawrence Livermore National Laboratory
P.O. Box 808
Livermore, CA 94551-0808

Dear Dr. Budil,

We write to request a classified briefing that will assist us in our inquiry into the origins of SARS-CoV-2, the virus that causes COVID-19. As leaders on the Committee on Energy and Commerce, the Congressional committee with jurisdiction over public health, we strongly support a comprehensive investigation into the origins of the COVID-19 pandemic, including the possibility of an accidental laboratory leak. Accordingly, we request a classified briefing from Lawrence Livermore National Laboratory (LLNL) related to LLNL’s Z Division’s May 27, 2020 report on the origin of SARS-CoV-2.

The Sinclair Broadcast Group (SBG) recently reported that a classified study of the origin of SARS-CoV-2 conducted a year ago by scientists at the Z Division had concluded that the novel coronavirus at the heart of the current pandemic may have originated in a laboratory in China.\(^1\) According to SBG, the Z Division report assessed that both the lab-origin theory and the zoonotic theory were plausible and warranted further investigation. A LLNL spokesperson confirmed the existence of the report to SBG.\(^2\)

SBG also reported that Dr. David J. Rakestraw, a senior science adviser who formerly directed LLNL’s biodefense programs and has been coordinating the lab’s technical response to COVID-19, was intimately involved in the preparation of the Z Division report.\(^3\) It would be greatly appreciated if Dr. Rakestraw could be included in the requested LLNL briefing.

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\(^2\) *Id.*

\(^3\) *Id.*
Please respond by May 25, 2021. If you have any questions, please contact Alan Slobodin or Diane Cutler of the Minority Committee staff.

Sincerely,

Cathy McMorris Rodgers  
Republican Leader  
Committee on Energy and Commerce

Brett Guthrie  
Republican Leader  
Subcommittee on Health

H. Morgan Griffith  
Republican Leader  
Subcommittee on Oversight and Investigations

CC: The Honorable Frank Pallone, Chairman  
The Honorable Anna Eshoo, Chair, Subcommittee on Health  
The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations
May 6, 2021

The Honorable Antony J. Blinken
Secretary of State
U.S. Department of State
2201 C Street, N.W.
Washington, D.C. 20520

Dear Secretary Blinken:

We write to request documents that will assist us in our inquiry into the origins of SARS-CoV-2, the virus that causes COVID-19. As leaders on the Congressional Committee with jurisdiction over public health, we strongly support a comprehensive investigation into the origins of the COVID-19 pandemic, including the possibility of an accidental laboratory leak. Accordingly, we request that the U.S. Department of State release unclassified documents and declassify other documents for public release, as appropriate, related to the assertion in the Department’s January 15, 2021 Fact Sheet that the Wuhan Institute of Virology (WIV) in Wuhan, China collaborated with the Chinese military in conducting classified research, including laboratory animal experiments.¹

The WIV has been a major focus for the U.S. government and the World Health Organization (WHO) in examining the origins of COVID-19 and the possibility of a laboratory leak. In addition, the release of these documents from the Department could help to refute contradictory statements that have been made regarding the possibility of a laboratory leak from the WIV.

The Department’s January 15 Fact Sheet notes that the WIV has collaborated on “secret projects” with China’s military. Further, the Fact Sheet claims that “[d]espite the WIV presenting itself as a civilian institution, the United States has determined that the WIV has collaborated on publications and secret projects with China’s military. The WIV has engaged in

classified research, including laboratory animal experiments, on behalf of the Chinese military since at least 2017.\textsuperscript{2}

However, the Director of the Center of Emerging Infectious Diseases at the WIV, Dr. Shi Zhengli, made contradictory comments about the Department’s claims in the January 15 Fact Sheet. During a March 23, 2021 seminar at Rutgers University, a WHO advisory committee member asked Dr. Shi if she had “knowledge of all of the research that was being done by everyone at the WIV and the full repository of viruses that were being held there by everybody, all the laboratories?”\textsuperscript{3} She was also asked whether “the U.S. government claims of classified Chinese military research being carried out at the WIV [are] correct, and if so, did you have full awareness of and access to all aspects of this research?”\textsuperscript{4} Dr. Shi answered:

> From my knowledge, all our research work is open, is transparent. At the beginning of COVID-19, we heard the rumors that claimed our laboratory would have some project blah blah with army blah ... but this is not correct, because I am the director and responsible for research activity. I don’t know any kind of research work performed in this lab.\textsuperscript{5}

Regarding a full investigation of COVID-19 origins, you recently stated that “[w]e need to get to the bottom of this. We need to do that precisely so we fully understand what happened, in order to have the best shot possible preventing it from happening again.”\textsuperscript{6} However, \textit{The Wall Street Journal} recently reported that a government official said that the U.S. government’s recommendations to the WHO on further investigation of COVID-19 origins would not include pressing China for a deeper investigation into the laboratory accident hypothesis, unless a whistleblower emerged.\textsuperscript{7}

If this individual’s statement reflects the official position of the U.S. government, this would undermine the WHO, including the WHO’s Director-General, Dr. Tedros. In addition, this would undermine the efforts of public health officials around the world to learn more about the origins of COVID-19, and to prepare better for future pandemics. Any credible investigation into COVID-19 origins must include an examination of the laboratory leak hypothesis. Dr. Tedros has stated that he supports further investigation into all COVID-19 origin hypotheses,

\textsuperscript{2} \textit{Id.}
\textsuperscript{4} \textit{Id.}
\textsuperscript{5} \textit{Id.}
Letter to The Honorable Antony J. Blinken  
May 6, 2021  
Page 3  

including the laboratory leak hypothesis. ⁸ Further, The Washington Post Editorial Board recently noted that a group of scientists in an open letter “correctly called for a ‘full scientific and forensic investigation into all possible origins’ of the virus and provided a set of unanswered questions about the [WIV] laboratory and its work.”⁹

We hope your statement about getting to the bottom of the origins of this pandemic includes looking at all possible causes, including the possibility of an accidental leak from a laboratory. Further, the disclosure of unclassified documents and the declassification of any documents regarding connections between the Chinese military and the WIV would help advance a comprehensive investigation into the origins of COVID-19 by bringing transparency to this matter and advancing the public’s interest and understanding of the issue.

Please respond by May 20, 2021. If you have any questions, please contact Alan Slobodin or Diane Cutler of the Minority Committee staff.

Sincerely,

Cathy McMorris Rodgers  
Republican Leader  
Committee on Energy and Commerce

Brett Guthrie  
Republican Leader  
Subcommittee on Health

H. Morgan Griffith  
Republican Leader  
Subcommittee on Oversight and Investigations

CC: The Honorable Frank Pallone, Chairman  
The Honorable Anna Eshoo, Chair, Subcommittee on Health  
The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations

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March 18, 2021

The Honorable Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Collins,

We write to request information, assistance, and needed-leadership from the National Institutes of Health (NIH) to advance an independent, scientific investigation into the origins of the COVID-19 pandemic.

The COVID-19 pandemic has been the worst public health crisis in the U.S. in about a hundred years. Over a year has passed since the deadly virus reached our shores and yet, the origin of the virus has yet to be determined. An independent, expert investigation of the origin of COVID-19 is of paramount importance to public health and biosecurity. As noted by Stanford Medical School Professor David Relman:

A more complete understanding of the origins of COVID-19 clearly serves the interests of every person in every country on this planet. It will limit further recriminations and diminish the likelihood of conflict; it will lead to more effective responses to this pandemic, as well as efforts to anticipate and prevent the next one. It will also advance our discussions about risky science. And it will do something else: Delineating COVID-19’s origin story will help elucidate the nature of our very precarious coexistence within the biosphere.¹

Recently, the World Health Organization (WHO) attempted to investigate the origin of COVID-19. The WHO said that this investigative mission would be guided by the science, be

¹ David A. Relman, Opinion: To stop the next pandemic, we need to unravel the origins of COVID-19, PNAS (Nov. 2020), available at https://www.pnas.org/content/117/47/29246.
"open-minded," and "not exclude[e] any hypothesis." Unfortunately, China did not provide complete access or independence for the critical WHO mission. On February 13, 2021, National Security Advisor Jake Sullivan issued the following statement:

We have deep concerns about the way in which the early findings of the COVID-19 investigation were communicated and questions about the process used to reach them. It is imperative that this report be independent, with expert findings free from intervention or alteration by the Chinese government. To better understand this pandemic and prepare for the next one, China must make available its data from the earliest days of the outbreak.³

Because of rising tensions between the U.S. and China, the WHO scrapped plans for an interim report.⁴ An international group of science experts, including specialists in virology, microbiology, and zoology, asked for a new review.⁵

The NIH, as a premier scientific institution, must lead in order to foster a transparent, independent, and science-based investigation into the origin of the COVID-19 pandemic. Such an effort must meet the WHO’s stated goals of an open-minded investigation that does not exclude any plausible hypothesis.⁶ In addition, the NIH is well-positioned to gather and provide information through oversight of its grants and other federal awards. Thus, the NIH is in a unique position to investigate the possibility that the pandemic stemmed from a laboratory accident or leak, especially regarding the Wuhan Institute of Virology (WIV).

NIH raised concerns over a possible link between WIV and the COVID-19 outbreak during its review of federal awards to EcoHealth Alliance, a global environmental health nonprofit organization dedicated to protecting wildlife and public health from the emergence of disease. Of the $13.7 million in federal awards that NIH authorized for EcoHealth Alliance, 17

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⁵ Jaime Metzl, et al, Call for a Full and Unrestricted International Forensic Investigation into the Origins of COVID-19 (March 4, 2021), available at https://s.wsj.net/public/resources/documents/COVID%20OPEN%20LETTER%20FINAL%20030421%201.pdf. The co-organizer of the letter and a WHO advisor on human genome editing, Jaime Metzl, PhD, said there is an eighty-five percent chance the pandemic started with an accidental leak from the WIV or Wuhan CDC laboratory, available at https://jamiemetzl.com/origins-of-sars-cov-2/1. (“I have no definitive way of proving this thesis but the evidence is, in my view, extremely convincing. If forced to place odds on the confidence of my hypothesis, I would say there’s an 85% chance the pandemic started with an accidental leak from the Wuhan Institute of Virology or Wuhan CDC and a 15% chance it began in some other way (in fairness, here is an article making the case for a zoonotic jump “in the wild”). If China keeps preventing a full and unrestricted international forensic investigation into the origins of the pandemic, I believe it is fair to deny Beijing the benefit of the doubt.”)
projects sponsored by the National Institute of Allergy and Infectious Disease (NIAID) have provided over $7.9 million in federal awards for research of viral emergence from bats in Southeast Asia. EcoHealth Alliance passed some of its funding to the WIV, and in 2020, NIH made efforts to obtain information from EcoHealth Alliance about WIV related to concerns about the origins of COVID-19. In April 2020, NIH wrote to EcoHealth Alliance and Columbia University about an NIH-funded project entitled, “Understanding the Risk of Bat Coronavirus Emergency:”

It is our understanding that one of the sub-recipients of the grant funds is the Wuhan Institute of Virology (‘WIV’). It is our understanding that WIV studies the interaction between corona viruses and bats. The scientific community believes that the coronavirus causing COVID-19 jumped from bats to humans likely in Wuhan where the COVID-19 pandemic began. There are now allegations that the current crisis was precipitated by the release from WIV of the coronavirus responsible for COVID-19. Given these concerns, we are pursuing suspension of WIV from participation in Federal programs. It is in the public interest that NIH ensure that a sub-recipient has taken all appropriate precautions to prevent the release of pathogens that it is studying. This suspension of the sub-recipient does not affect the remainder of your grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension.

In January 2021, the U.S. Department of State issued a fact sheet about the activity at the WIV. Among other revelations, it reported the following:

- The U.S. government has reason to believe that several researchers inside the WIV became sick in autumn 2019, before the first identified case of the outbreak, with symptoms consistent with both COVID-19 and common seasonal illnesses. This raises questions about the credibility of WIV senior researcher Shi Zhengli’s public claim that there was “zero infection” among the WIV’s staff and students of SARS-CoV-2 or SARS-related viruses.

- Starting in at least 2016, WIV researchers conducted experiments involving RaTG13, the bat coronavirus identified by the WIV in January 2020 as the closest sample to SARS-CoV-2 (96.2 percent similar). There was no indication that this research was suspended at any time prior to the COVID-19 outbreak.

- The WIV has a published record of conducting “gain-of-function” research to engineer chimeric viruses. But the WIV has not been transparent or consistent about its record of...
studying viruses similar to the COVID-19 virus, including “RaTG13,” which was sampled from a cave in Yunnan Province in 2013 after several miners died of SARS-like illness.\textsuperscript{13}

- WHO investigators must have access to the records of the WIV’s work on bat and other coronaviruses before the COVID-19 outbreak. As part of a thorough inquiry, they must have a full accounting of why the WIV altered and then removed online records of its work with RaTG13 and other viruses.\textsuperscript{14}

- Despite the WIV presenting itself as a civilian institution, the U.S. has determined that the WIV has collaborated on projects with China’s military.\textsuperscript{15} The WIV has engaged in classified research, including laboratory animal experiments, on behalf of the Chinese military since at least 2017.\textsuperscript{16}

- The U.S. and other donors who funded or collaborated on civilian research at the WIV have a right and obligation to determine whether any of our research funding was diverted to secret Chinese military projects at the WIV.\textsuperscript{17}

Notably, the State Department’s former lead investigator who oversaw the Task Force into the COVID-19 virus origin stated recently that he not only believes the virus escaped from the WIV, but that it may have been the result of research that the Chinese military, or People’s Liberation Army, was doing on a bioweapon.\textsuperscript{18}

Accordingly, it is imperative to determine not only where SARS-CoV-2 originated, but also how and if NIH’s funding and research to projects at the WIV could have contributed to SARS CoV-2. To assist our requests and inquiry, please provide the following by April 19, 2021:

1. An assessment from a classified U.S. Defense Intelligence Agency (DIA) report included the possibility that the origins of SARS CoV-2 could have emerged accidentally from a laboratory in Wuhan, China due to unsafe laboratory practices.\textsuperscript{19} The DIA report cited U.S. government and Chinese researchers who found “about 33 percent of the original 41 identified cases did not have direct exposure” to the market.\textsuperscript{20} That, along with what is known of the WIV’s work in past few years, raised reasonable suspicion that the

\textsuperscript{13} Id.
\textsuperscript{14} Id.
\textsuperscript{15} Id.
\textsuperscript{16} Id.
\textsuperscript{17} Id.
\textsuperscript{18} Jennifer Griffin, Former top State Dept. investigator says COVID-19 outbreak may have resulted from bioweapons research accident, Fox News (March 13, 2021), available at https://www.foxnews.com/world/top-state-official-coronavirus-bioweapon-accident


\textsuperscript{20} Id.
pandemic may have been caused by a lab error, not a wet market. Further, a WHO inspector on the recent mission noted that “we know not all of those first 174 early COVID-19 cases visited the market, including the man diagnosed in December 2019 with the earliest onset date.” What information does the NIH have on the earliest COVID-19 cases?

2. According to an editorial on February 23, 2021, in *The Wall Street Journal* by former Secretary of State Mike Pompeo and Miles Yu, “[China’s] army of scientists claim to have discovered almost 2,000 new viruses in a little over a decade.” How many of these discovered viruses does the NIH have information on and were any of these viruses discovered at the WIV?

3. According to *The Wall Street Journal* editorial mentioned in the previous question, some have alleged that the WIV’s virus-carrying animals were sold as pets and may even show up at local wet markets. Is the NIH aware of these allegations? If so, please provide any information the NIH has related to these allegations.

4. Please provide all information that NIH has about laboratory accidents and/or biosafety practices at the WIV since January 1, 2015.

5. Please provide all information that NIH has from NIH staff, grantees, subcontractors about communications and events at the WIV from August 2019 to the present.

6. Please provide all information that NIH has from NIH staff, grantees, contractors, or subcontractors about their communications with China-based NIH, Chinese National Science Foundation, CDC, and China CDC about events at the WIV from August 2019 to the present.

State Department Cables

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21 *Id.*

22 Dominic Dwyer, I was the Australian doctor on the WHO’s COVID-19 mission to China. Here’s what we found about the origins of the coronavirus, *The Conversation* (Feb. 21, 2021), available at https://www.theguardian.com/commentisfree/2021/feb/22/i-was-on-the-whos-covid-mission-to-china-heres-what-we-found. See also Jeremy Page and Drew Hinshaw, *China Refuses to Give WHO Raw Data on Early Covid-19 Cases*, *The Wall Street Journal* (Feb. 12, 2021), available at https://www.wsj.com/articles/china-refuses-to-give-who-raw-data-on-early-covid-19-cases-11613150580#:~:text=BEIJING%E2%80%94Chinese%20authorities%20refused%20to,over%20the%20lack%20of%20detail. (“Chinese authorities refused to provide World Health Organization investigators with raw, personalized data on early Covid-19 cases that could help them determine how and when the coronavirus first began to spread in China, according to WHO investigators who described heated exchanges over the lack of detail. The Chinese authorities turned down requests to provide such data on 174 cases of Covid-19 that they have identified from the early phase of the outbreak in the Chinese city of Wuhan in December 2019. Investigators are part of a WHO team that this week completed a monthlong mission in China aimed at determining the origins of the pandemic.”)

23 *Id.*

7. What information does NIH have about the WIV’s responses to the 2018 U.S. Department of State cables (attached to this letter) regarding safety concerns?

8. The April 2018 cable from the U.S. Department of State stated that the WIV planned to invite University of Texas Medical Branch Galveston (UTMBG) researchers to do research in Wuhan’s labs. Please provide any information NIH received that indicates whether the WIV invited UTMBG researchers, and whether UTMBG researchers conducted any research in Wuhan’s labs.

   a. If there was such research, please provide information and any documents related to this research.

9. Why was it pertinent to the NIH investigation that the “nonprofit [EcoHealth Alliance] must provide the “WIV’s responses to the 2018 Department of State cables regarding safety concerns”?25

   a. Did EcoHealth Alliance provide this information? If so, how did NIH use the information to further its investigation?

EcoHealth Alliance, Columbia University Health Sciences

10. Was the 2019 NIH federal award to EcoHealth Alliance reviewed and approved by the HHS Potential Pandemic Pathogen Care and Oversight (P3CO) committee?26

   a. If so, please provide the documentation with the committee’s decision.

   b. Please also provide the names of the individuals who were members of the committee at the time.

11. Please provide all correspondence and communications between NIH and EcoHealth Alliance, since January 1, 2020, related to federal funding involving the WIV. The documentation should include, but not be limited to, correspondence between NIH and EcoHealth Alliance dated sometime in April 2020, on July 8, 2020, and sometime in August 2020.

12. In April 2020, NIH suspended a 2019 federal award to EcoHealth Alliance, in part, because NIH did not believe the work aligned with “program goals and agency priorities.”27 Please specify the work that was done by the EcoHealth Alliance that did

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27 Id.
not align with the agency’s program goals and priorities, and when that work was conducted.

a. Was an evaluation of EcoHealth Alliance’s work and whether it aligned with the agency’s program goals and priorities conducted by the NIH before the award was issued? If yes, please provide any related documentation. If not, why not?

13. In April 2020 correspondence with EcoHealth Alliance, NIH wrote that it “received reports that the Wuhan Institute of Virology...has been conducting research at its facilities in China that pose serious bio-safety concerns.” What are the sources for those reports to NIH and what were the specific allegations reported?

14. Why did the NIH request that EcoHealth Alliance provide a sample of the pandemic coronavirus that the WIV used to determine its genetic sequence for SARS CoV-2?

a. Why is this information important to NIH’s investigation?

b. Has NIH obtained the sample and if so, what evaluations have been done, and for what purpose?

c. If NIH has not yet obtained the sample, what are the planned studies and evaluations NIH will conduct with the sample when it is obtained?

15. What is the nature of NIH’s concerns about purported restrictions at the WIV including “diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019[,]” about the WIV lab or virus origin?

a. What is the basis of information to NIH about the purported restrictions at the WIV?

b. What are the other purported restrictions at the WIV in October 2019?

16. After terminating EcoHealth Alliance’s 2019 project entitled “Understanding the Risk of Bat Coronavirus Emergence,” the NIH later offered to reinstate the EcoHealth Alliance funding in July 2020 if EcoHealth Alliance agreed to meet certain conditions.

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30 *Id.*

Letter to the Honorable Francis Collins, M.D., Ph.D.

Page 8

a. Please provide all of the information presented to NIH from EcoHealth Alliance in response to NIH’s conditions for reinstatement.

b. What actions did NIH take based upon the information received? How has the information been used in NIH’s investigation?

c. One condition for the federal award reinstatement was for EcoHealth Alliance to arrange for an outside inspection of the WIV and its records, “with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019.” Why is it pertinent to the NIH’s investigation if staff at WIV had SARS-CoV-2 in their possession prior to December 2019? What is the potential significance if the staff did have the virus in their possession prior to December 2019?

d. What information does NIH have that was used for the basis of requesting that the EcoHealth Alliance “must ‘explain the apparent disappearance’ of a scientist who worked in the Wuhan lab,” and on social media was rumored to be “patient zero” of the pandemic?

i. What is the potential significance about the whereabouts of this scientist and the photo being removed from the website?

17. Please provide all correspondence and communications between NIH and Columbia University related to federal funding involving the WIV, including email correspondence in April 2020 between Dr. Michael Lauer, Deputy Director of extramural research, and Naomi Schrag of Columbia University.

a. In an April 2020 email, Dr. Lauer advised Naomi Schrag of Columbia University that it would be helpful for NIH “to know about all China-based participants in this work since the Type 1 grant started in 2014 - who they were and how much money they received.” Why did NIH request that Columbia University provide information about all of the China-based participants?

i. What is the pertinence of the timeframe starting in 2014 for the requested information?

ii. Did Columbia University provide the NIH with the requested information about all of the China-based participants from all grantees since 2014? If so, please provide the information. If not, why not?

Federal Funding Records

32 Id.
33 Id.
18. Please provide ledgers or any accounting for dispersion of all NIH federal funding awards that EcoHealth Alliance has sent to the WIV, including through contracts, grants, donations, cooperative agreements, staffing, or any other support or means. In addition, please provide the results and outcomes from the funding and support.\textsuperscript{35}

19. What is the total amount of NIH federal funding per year from 2017 through 2021 that has directly or indirectly supported the WIV scientists or research through grant recipients, including to EcoHealth Alliance; Wildlife Trust, Inc.; Columbia University Health Sciences; Trustees of Columbia University; University of North Carolina Chapel Hill; Vanderbilt University; University of Virginia; and Oregon Health and Science University?\textsuperscript{36}

20. According to a report in \textit{The Washington Post} on April 14, 2020, the WIV issued a news release in English about the final visit from U.S. Embassy scientist diplomats in Beijing, which occurred on March 27, 2018.\textsuperscript{37} Does the NIH have a copy of this news release? If so, please provide a copy.

21. For NIH award recipients that have provided support to the WIV since January 1, 2012, please provide annual reports, trip reports related to the WIV, documentation of any survey or field trips by the WIV, and interim data summaries from the WIV.

22. Please provide copies of all grantee annual reports, progress reports, projects, studies, and observations since 2014 where foreign sites for all Type 1 and Type 2 awards have been documented as involving the WIV.

23. Please provide copies of all grantee annual reports, progress reports, projects, studies, and observations since 2014 for NIH domestic grantee awards with a foreign component involving the WIV.

24. Please provide the name(s) of the NIH program manager(s) or officer(s) responsible for overseeing the grants to EcoHealth Alliance and time period(s) of responsibility.

25. Please provide the name(s) of the NIH Scientific Review Officers responsible for reviewing and approving any NIH financial awards to EcoHealth Alliance and any other funding recipients that supported the WIV.


\textsuperscript{36} National Institutes of Health, Research Portfolio online Reporting Tools, NIH RePorter available at https://report.nih.gov/ (last accessed March 6, 2020).

26. According to an editorial in *The Wall Street Journal*, the WIV housed tens of thousands of bat samples and laboratory animals in 2019.\textsuperscript{38} Please provide any information the NIH has on the number of bat samples and animals at the WIV.

   a. Did any NIH scientists who are fluent in Mandarin review the Chinese scientific literature on the WIV research related to coronaviruses that is dated before February 1, 2020?

27. Does the NIH have the unpublished sequences of bat coronaviruses that were maintained in the WIV database before December 30, 2019, or before the database was removed from the internet?\textsuperscript{39} Does NIH have the full sequences of the eight viruses sampled in the Yunnan province on an EcoHealth Alliance bat-virus sampling trip in 2015?

   a. Please provide NIH’s analysis if the sequences have been analyzed.

   b. If NIH does not have the sequences, can NIH get this information from the EcoHealth Alliance or from other NIH-funded sources?

28. Please provide the original version of “Origin and cross-species transmission of bat coronaviruses in China” that was submitted to *Nature* by EcoHealth Alliance on October 6, 2019, published August 25, 2020, and funded in part by NIAID (award number R01AI110964).\textsuperscript{40} If NIH does not have the October 6, 2019 report, can NIH obtain it from EcoHealth Alliance for this response? If so, please provide the report.

29. Have NIH, EcoHealth Alliance, or other NIH award recipient(s) been denied permission or access to results of any WIV research, which indirectly received financial support from NIH awards? If so, please provide the date(s), individuals involved, and circumstances of each denial.

We request that the NIH provide the requested documents and information in a coordinated response from all stakeholders and the appropriate divisions within NIH, including but not limited to subject matter experts from NIH’s Division of Security and Emergency Response, the Office of Management Assessment, the Center for Scientific Review, the National Institute of Allergy and Infectious Diseases, and the Office of Extramural Research. After the requested information has been provided, we ask that the NIH provide a briefing to the Minority Committee staff to discuss the information that the NIH has related to the origins of SARS-CoV-2, including any potential links to the WIV. Finally, we request that you appoint an NIH working group representing an appropriate diversity of scientific disciplines to collect data and


\textsuperscript{39} Washington Post Editorial Board, *We’re still missing the origin story of this pandemic. China is sitting on the answers*, *The WASHINGTON POST* (Feb. 5, 2021), available at https://www.washingtonpost.com/opinions/2021/02/05/coronavirus-origins-mystery-china/?arc404=true.

information related to COVID-19 origins (including the WIV), and that the NIH working group coordinate and consult with foreign scientific agencies involved in similar work.

Your assistance with this request is greatly appreciated. If you have any questions, please contact Alan Slobodin or Diane Cutler of the Minority Committee staff.

Sincerely,

Cathy McMorris Rodgers  Brett Guthrie
Republican Leader Republican Leader
Committee on Energy and Commerce Subcommittee on Health

H. Morgan Griffith
Republican Leader
Subcommittee on Oversight and Investigations

Attachment

Cc: The Honorable Frank Pallone, Chairman
    The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations
    The Honorable Anna Eshoo, Chair, Subcommittee on Health
Mr. Peter Daszak, PhD
President
EcoHealth Alliance
460 West 34th Street, 17th Floor
New York, NY 10001

Dear Dr. Daszak:

We write to request information and documents from EcoHealth Alliance (EHA) related to the origins of SARS-CoV-2, the virus that causes COVID-19, including possible pandemic links to the Wuhan Institute of Virology (WIV). ¹

EHA has an extensive history with research into bat coronaviruses in China, some of which are presumed progenitors of SARS CoV-2. ² In addition, EHA has partnered with the WIV in this area of research, and WIV lists EHA as one of its eight international partners, and the only one in the U.S. ³ For example, last year EHA, the WIV, and others co-authored an article on the origin and cross-species transmission of bat coronaviruses in China, and presented phylogenetic analysis suggesting a likely origin of SARS-CoV-2 in horseshoe (Rhinolophus spp.) bats. ⁴ Further, for several years, EHA has provided some of its National Institutes of Health (NIH) federal funding to WIV as a federal sub-award recipient for bat coronavirus research to conduct high-quality testing, sequencing, field sample analyses, sample storage and

¹ All references to the WIV include the former names of the Chinese establishment, that include the Wuhan Institute of Microbiology, the Wuhan Microbiology Research Laboratory, the Hubei Provincial Institute of Microbiology and the Chinese Academy of Sciences. Wuhan Institute of Virology, CAS, About WIV (last accessed Apr. 9, 2021), available at http://english.wi.vi.ou.cn/About Us2016/Brief_Introduction2016/.
testing, and collaboration on scientific publications and programmatic reporting. It has been reported that EHA’s China bat research project was funded entirely through NIH awards.

We believe through its research activities, collaborations, and EHA’s relationship with the WIV as a federal award subrecipient, that EHA has information and documents that will provide insight into the WIV’s bat coronavirus information and pathways for further research in this area. We are interested in EHA’s knowledge of and access to the WIV’s virus samples, genomic sequences, and research afforded to EHA as a NIH federal award recipient who established a sub-recipient relationship with the WIV for grants including R01 AI110964, and as a subrecipient of NIH awards. We are also interested in EHA’s knowledge of and access to a password-protected virus database for which external access ended on September 12, 2019. The database is administered by the WIV’s researcher Dr. Shi Zhengli, with whom you and your team have had professional and financial ties since at least 2003. The database is estimated to contain 500 coronaviruses identified by EHA, and at least 100 unpublished sequences of bat beta coronaviruses that are relevant to the investigation of the SARS-CoV-2 origin.

We anticipate that EHA and the WIV share access to samples and virus sequences based on the terms of the NIH grant and based in part on a recent interview discussing the EHA and WIV joint effort to capture 10,000 bats, draw and test their blood, and create a catalogue of all of the viruses, including 50 new coronaviruses. You stated that Remdesivir was tested against the viruses EHA and the WIV discovered through NIH funded research, and that Remdesivir testing “would not have been able to happen and we wouldn’t have known how good this drug Remdesivir is” without EHA’s work.

We are interested in learning about what EHA knows regarding a Chinese national security review team finding in 2019 that the WIV did not meet national standards in five categories and when or if those standards were met before 2020. Additionally, EHA was

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5 USAspending, EcoHealth Alliance Sub-Awards (last accessed Apr. 8, 2021), available at https://www.usaspending.gov/award/ASST_NON_R01AI110964_7529.
7 USAspending, EcoHealth Alliance Sub-Awards (last accessed Apr. 8, 2021), available at https://www.usaspending.gov/award/ASST_NON_R01AI110964_7529.
12 Id.
working with the WIV when in 2016, an independent American review found that China’s biosafety controls had a shortage of officials, experts, and scientists who specialize in laboratory biosafety. As a research partner of WIV, we would expect EHA to have been a first-hand witness to the WIV operations as the China’s first BioSafety Level-4 laboratory.”

In July 2020, the NIH sought information from EHA related to the WIV, and suspended one of EHA’s grants until certain questions were answered and certain conditions were met, pursuant to EHA’s obligations under the agreement and federal regulations. As an NIH federal award recipient, EHA is required to “monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with federal statutes, regulations, and the terms and conditions of the subaward.” It is EHA’s responsibility to ensure the WIV met all NIH grant requirements. The EHA grant suspended by the NIH in July 2020 remains suspended per NIH public records, suggesting that EHA still has not cooperated with the NIH nor met its federal requirements as an award recipient with mandatory terms and conditions. In addition, researchers and scientists in the scientific community have unanswered questions about the WIV, its operations and research activities, and whether a possible lab incident at the WIV could have been related to the origins of SARS-CoV-2.

EHA officials have repeatedly stated that they do not believe the pandemic was caused by a lab leak and have solicited support for others to advance that position publicly. However, there is substantial and increasing support from the international scientific community and public health experts, including from the World Health Organization Director-General Tedros, for further investigation into COVID origins, including the possibility of a lab leak. Since EHA is

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14 Id.
17 45 C.F.R. § 75.352(d).
confident that a lab leak is not the cause, we expect you to welcome the opportunity to share any and all information, documents, and expertise you have related to bat coronavirus research at the WIV. Accordingly, to assist our inquiry, please provide the following by May 17, 2021:

Documents and Information Related to NIH Federal Awards

1. Please provide all federal award applications, progress reports, and research or project results prepared for NIH by EHA related to NIH award number R01AI110964.

2. Please provide all financial conflict of interest disclosures, and disclosures of financial foreign support or foreign components prepared for NIH by EHA for NIH award number R01AI110964.

3. Please provide all applications EHA submitted for Potential Pandemic Pathogen research review and the review results.\(^{22}\)

4. Please provide all letters, emails, and other communications between EHA and NIH Institutes related to NIH award number R01AI110964, including EHA’s conditions of awards, requests for information, and responses.

5. Please provide all letters, emails, and other communications between EHA and grant sub-recipient, the WIV, related to terms of agreements, bat coronaviruses, genome or genetic sequencing, SARS-CoV-2, and/or laboratory safety practices pursuant to NIH award number R01AI110964.

6. What does EHA know about research involving bat coronaviruses in the WIV laboratories in 2019, including but not limited to: possible bat coronavirus vaccine development; pathogenicity studies involving animal experiments; usage of passaging; Dual-Use Research of Concern; nucleotide synthesis; mutagenesis; genetic manipulation and gain of function techniques?\(^{23}\)

7. Please identify all federal awards for which EHA has been an award subrecipient and describe when any of those funds were used to support the WIV or WIV’s activities from 2015 to present.

8. Has any research supported in whole or in part by NIH award number R01AI110964 been published in Mandarin only and is therefore not readily accessible for use by U.S. researchers? If so, please identify such research and articles.


\(^{23}\) U.S. National Institutes of Health, *Dual-Use Research* (Sept. 9, 2019), available at https://or.nih.gov/sourcebook/ethical-conduct/special-research-considerations/dual-use-research#text=Dual%20Use%20Research%20of%20Concern,to%20public%20health%20and%20safety%2C.
9. Did EHA or the WIV use translators while conducting NIH award number R01AI110964 together? If so, please describe all procurements and other arrangements for translation services, including the identity of the translators.

10. For all NIH funded work, please identify all Mandarin-fluent EHA personnel and English-fluent WIV personnel who worked on the projects related to NIH award number R01AI110964.

11. Pursuant to 45 C.F.R. sec. 75.352(d), how does EHA monitor the handling and use of samples by its subrecipient, the WIV, to ensure the sub-award is used for authorized purposes?24

12. Of the bat viruses EHA finds in China, where are samples and the genomic or genetic sequences stored in the United States and how are the samples transported?25

13. Does EHA have any virus samples or sequences related to the bats or pneumonia-like illness that sickened six miners in the Mojiang mine in southwestern China’s Yunnan Province, killing three, after their work removing bat feces?26 If so, please provide the location and identification information for the samples and/or sequences.

14. In 2020, Dr. Shi Zhengli of WIV published a genomic sequence for RaTG13. According to available information first published in 2016, RaTG13 is 96.2 percent similar to SARS-CoV-2 and was gathered in 2012 from bat caves in the Yunnan Province, then.27 This sequence is the most similar to SARS-CoV2 that is publicly known.

   a. Why was the sample sequence not published until 2020?

   b. Does EHA have any reason to know if RaTG13 was ever used in research at WIV, including gain of function studies?

   c. Does EHA have any other sequences or samples from the bat cave that were collected from the Yunnan bat caves in 2012?

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24 45 C.F.R. sec. 75.352(d).
d. Does EHA have the WIV genome that corroborates their renaming of RaBtCoV/4991 to RaTG13?²⁸

e. Does EHA have the genome or genetic sequences of the eight other related coronaviruses found in the same mine (the 7896 clade) that can be seen in slides shown by Dr. Shi Zhengli in webinars?²⁹ If so, please provide.

15. In addition to the eleven SARS-related bat coronavirus sequences EHA and the WIV discovered in Yunnan Province, have any other genomic or genetic sequences for bat coronaviruses resulting from EHA’s five-year surveillance of SARS-CoVs in Yunnan Province bat caves, funded in part by NIH, been deposited in GenBank? If so, what accession numbers have been assigned to these sequences?³⁰

16. Does EHA have copies of the virus samples and sequences maintained in Dr. Shi Zhengli’s database that was taken offline in September 2019?³¹ If so, please describe what EHA has in this collection, and to what extent EHA would make this collection publicly available.

17. EHA has stated that it has unpublished data gathered over 15 years of working in China, and five years under a previous NIH grant.³² Please describe these records and to what extent EHA will make these publicly available.

18. Prior to April 2020, did EHA have access to the WIV databases that were made possible in whole or in part by NIH award number R01AI110964?

19. It was reported that EHA and the WIV caught and sampled the blood of 10,000 bats, resulting in a discovery of 50 new coronaviruses and creating a virus genomes catalog.³³ Please produce a copy of this virus genomes catalog created by EHA and the WIV.


20. The EHA and WIV collected 15,000 bat samples, of which a subset of 50 bat samples “fall into a category that caused the 2002 outbreak of severe acute respiratory syndrome (SARS), and, now, the COVID-19 pandemic.”

   a. How many of that 50-sample subset are closely related to SARS-CoV-2?
   
   b. Please provide any identifying information for each sample in this category.

21. External access ended on September 12, 2019, to the WIV password protected Batvirus.whiov.ac.cn database containing at least 100 unpublished bat virus sequences, for which Dr. Shi Zhengli is the administrator.

   a. Did the WIV solely maintain the database related to research conducted under NIH funding or is the database jointly maintained by EHA and the WIV?
   
   b. Does EHA maintain an independent database from the WIV related to research conducted under NIH funding?

22. Does EHA have copies of a virus database portal, created by China’s National Virus Resource Center in Beijing, which is affiliated with the WIV? If so, describe these records, and to what extent EHA will make these publicly available.

23. Please identify research project(s) that tested Remdesivir on the viruses EHA discovered through its NIH-funded research and identify which EHA-discovered viruses were used.

24. A patent application related to use of Remdesivir and chloroquine in the treatment for COVID-19 was submitted jointly by the WIV with the Military Medicine Institute of the People’s Liberation Army Academy of Military Science in January 2020. Were samples or sequences derived from EHA’s work with the WIV used in research for this patent? If so, please describe the samples or sequences used.

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25. Does EHA maintain its own laboratories? If so, what are the biosafety levels (BSL) for these laboratories, and have researchers from the WIV worked there? If so, please describe the type of research conducted at these laboratories, and at what BSL.

26. Was the WIV lab work funded by EHA carried out at BSL-2, BSL-3 or BSL-4 level? If WIV work was carried out at various BSLs, please explain what type of work was conducted at each of the different BSLs.

27. What types of animal models does WIV work with?

   a. Are the animals housed in separate facilities with separate ventilation systems?

   b. Was the animal work performed in an Animal Biosafety Level (ABSL) laboratory, and if so, at what Biosafety Level?

28. Did the WIV have any laboratory environmental monitoring or surveillance program in place to minimize hazards to employees in 2019? If so, please provide details and include all WIV violations for which EHA has direct or indirect knowledge.

29. What engineering and administrative controls as well as Personal Protective Equipment were observed or leveraged at WIV in 2019? Please provide details and include all times for which EHA has direct or indirect knowledge when safety protocols were not followed.

30. Please provide a list of all the coronaviruses that the WIV laboratories were working with in 2019 related to NIH award number R01AI110964.

EHA Financial Reporting

31. *The Wall Street Journal* reported that EHA received a July 8, 2020 letter from NIH suspending award number R01AI110964 pending seven conditions reported by *Nature*, but not all of those demands were specified in the *Nature* article. Did one of the unspecified conditions of grant reinstatement relate to reporting of subawards or reporting about subrecipients?

   a. EHA is required to file end-of-month reports into the Federal Subaward Reporting System (FSRS) following its issuance of sub-grant awards, then the report becomes publicly available on the USAspending.gov website, which is the official open source of federal spending. Five days after the NIH July 8, 2020 letter, according to


USAspending.gov records, EHA entered multiple years of reports all on July 13, 2020, for NIH award number R01AI110964 subrecipients into the FSRs.41 Does EHA’s July 13, 2020 data modifications in USA Spending reflect actions taken in response to the July 8, 2020 NIH letter requesting EHA’s compliance with its award terms and responsibilities?

32. EHA reported a $195,498 cash award disbursed by wire to “Institute of Microbiology of Chinese Institute of” for “Grants and Assistance to Individuals Outside the U.S.” on its IRS Form 990, calendar year 2019.42 Please provide the full name and address of this recipient institution, the nature of its relationship with EHA, and whether this institution has any relation to the WIV.

   a. Please identify U.S. government source(s) or agency for the $195,498 award, if applicable.

33. EHA reported a $319,570 cash award grant and a $126,792 cash award grant disbursed by wire to China for the purpose of “[u]nderstanding the risk of bat coronavirus emergence” on its IRS Form 990, calendar year 2016.43 The name of the organizations receiving the awards were left blank.44 Please provide the full name and address of the organization(s) that received these cash award grants.45

   a. What is relationship between these organizations and EHA? Are these organizations related to the WIV?
   b. Please identify the U.S. government source(s) or agency for the $319,570 award and the $126,792 award, if applicable.

34. EHA reported a $291,507 cash award disbursed by wire transfer to an unnamed recipient in China for “Grants and Assistance to Individuals Outside the U.S.” on its calendar year 2016, IRS Form 990.46 The grant assistance was described as “Coronavirus & Emerging Diseases.”47 Please provide the full name and address of the recipient, the relationship between the recipient and EHA, and whether the recipient has any relationship to the WIV.

   a. Please identify the U.S. government source(s) or agency for the $291,507 award, if applicable.

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41 USAspending.gov, EcoHealth Alliance Sub-Awards (last accessed Apr. 8, 2021), available at https://www.usaspending.gov/award/ASST_NON_R01AI110964_7529.
44 Id., Schedule F, Part II.
45 Id.
47 Id.
After the requested information has been provided, we ask that EHA provide a briefing to Minority Committee staff to discuss the information that EHA has related to COVID-19 origins and WIV. Your assistance with this request is greatly appreciated. If you have any questions, please contact Alan Slobodin or Diane Cutler of the Minority Committee staff.

Sincerely,

Cathy McMorris Rodgers  
Republican Leader  
Committee on Energy and Commerce

Brett Guthrie  
Republican Leader  
Subcommittee on Health

H. Morgan Griffith  
Republican Leader  
Subcommittee on Oversight and Investigations

Attachment

CC: The Honorable Frank Pallone, Chairman  
The Honorable Anna Eshoo, Chair, Subcommittee on Health  
The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations
February 23, 2021

Ms. Christi Grimm
Principal Deputy Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue SW
Washington, D.C. 20201

Dear Principal Deputy Inspector General Grimm:

We write to request a prompt and thorough investigation into the National Institutes of Health’s (NIH) response to biosafety concerns raised about taxpayer-funded coronavirus research at the Wuhan Institute of Virology (WIV) in Wuhan, China.

Recently, the Washington Post, which had regularly dismissed the theory that the COVID-19 pandemic resulted from a lab leak at WIV, finally published an editorial board column embracing the lab leak hypothesis and calling for investigation into the research lab that was funded in part with U.S. tax dollars from the NIH.\(^1\)\(^2\) The Post’s about-face follows growing belief among experts, including the U.S. State Department, that the pandemic that has killed over 500,000 people in the U.S. and 2 million people worldwide may have been caused by dangerous coronavirus research gone awry at the Chinese Communist Party (CCP)-run bioagent laboratory.\(^3\)\(^4\)\(^5\)\(^6\)

The NIH, unfortunately, has played a major role in supporting WIV and this treacherous research and the promotion of spurious claims dismissing the NIH-funded lab’s potential role in the COVID-19 pandemic.

In 2017, NIH Director Francis Collins personally supported and celebrated the resumption of dangerous taxpayer-funded “gain-of-function” research designed to make viruses more transmissible and fatal.\(^7\) Subsequently, Dr. Collins’ NIH allowed U.S. Taxpayer dollars to be secretly funneled to WIV’s reckless coronavirus experiments through grants awarded to the U.S.-based EcoHealth Alliance, Inc.\(^8\)\(^9\) The Pentagon also apparently funded WIV via a grant to EcoHealth.\(^10\)

In March 2020, as questions arose about the safety of WIV’s NIH-funded coronavirus research, Dr. Collins wrote a blog that is still published, which states, “Some folks are even making outrageous

\(^1\) https://www.washingtonpost.com/opinions/2021/02/05/coronavirus-origins-mystery-china/?sc=opinion
\(^2\) https://www.foxnews.com/media/washington-post-editorial-board-calls-for-answers-from-china-on-pandemic
\(^3\) https://nymag.com/intelligencer/article/coronavirus-lab-escape-theory.html
\(^4\) https://video.foxnews.com/video/6227902415001
\(^7\) https://www.nih.gov/about-nih/who-we-are/nih-director/statement/nih-lifts-funding-pause-gain-function-research
\(^8\) https://www.newsweek.com/dr-fauci-backed-controversial-wuhan-lab-millions-us-dollars-risky-coronavirus-research-1500741
\(^10\) https://americanpriority.com/news/congressman-probes-into-pentagon-wmd-grant-to-firm-that-funded-wuhan-lab/
claims that the new coronavirus causing the pandemic was engineered in a lab.\textsuperscript{11} He even tweeted a link to his article, writing, "New genomic study debunks claims that the novel #coronavirus causing #COVID-19 was created in a lab."\textsuperscript{12} Yet, experts now claim that WIV’s gain-of-function research could very well have engineered the novel coronavirus that caused the pandemic from a virus collected from bats in caves in China.

EcoHealth’s President has also sided with the CCP and openly criticized the U.S. government for investigating the theory that SARS-CoV-2 originated in the WIV lab to which he directed NIH funds and has closely collaborated with for decades.\textsuperscript{13,14}

\textbf{In light of all this, we are gravely concerned about the NIH’s relationship with both EcoHealth and WIV, and the Agency’s handling of allegations that the COVID-19 pandemic was potentially caused by an NIH-funded laboratory at WIV. We also are alarmed that WIV is eligible to receive additional funding from the NIH through 2024.}\textsuperscript{15}

We request a prompt and thorough investigation into the NIH’s response to biosafety concerns raised about WIV, including, but not limited to:

1. When was the NIH first aware that coronavirus experiments were being conducted at WIV with taxpayer funds (via EcoHealth Alliance or otherwise)?
2. Did NIH officials review WIV’s coronavirus experiments to assess compliance with Potential Pathogen Care and Oversight (P3CO) guidelines?
3. When was the NIH first aware of biosafety or other concerns at WIV?
4. Was the NIH briefed on the concerns raised by the State Department in 2018 about the potential pandemic risk of WIV’s research?
5. Did Dr. Collins or other NIH officials communicate with EcoHealth Alliance and/or WIV to coordinate responses to lab leak allegations?
6. When does WIV’s current eligibility to receive NIH funding expire?
7. Is WIV currently receiving any NIH support directly or indirectly?
8. How much NIH funding - directly or indirectly - has WIV received from the NIH including grants, sub-grants, and other funding sources.

Thank you for your cooperation in our effort to protect public health and national security. We look forward to your reply.

Sincerely,

\begin{center}
\textit{[Signatures]}
\end{center}

\textbf{SCOTT PERRY} \\
Member of Congress

\textbf{NANCY MACE} \\
Member of Congress

\begin{footnotes}
\item[12] https://twitter.com/nihdirector/status/1243172927913222312?lang=en
\item[14] https://www.wsj.com/articles/who-are-the-covid-investigators-11613401955
\item[15] https://dailycaller.com/2021/02/16/wuhan-lab-eligible-taxpayer-funding/
\end{footnotes}
ANDY BIGGS  
Member of Congress

DIANA HARBURGER  
Member of Congress

ELISE STEFANIK  
Member of Congress

CHIP ROY  
Member of Congress

JEFF VAN DREW  
Member of Congress

DANIEL WEBSTER  
Member of Congress

DOUG LAMBORN  
Member of Congress

BOB GIBBS  
Member of Congress

TED BUDD  
Member of Congress

AUSTIN SCOTT  
Member of Congress
RALPH NORMAN
Member of Congress

DAN NEWHOUSE
Member of Congress

DAN CRENSHAW
Member of Congress

GUY RESCHENTHALER
Member of Congress

LOUIE GOHMERT
Member of Congress

KEN BUCK
Member of Congress
### A. COVER PAGE

**Project Title:** Understanding the Risk of Bat Coronavirus Emergence

<table>
<thead>
<tr>
<th>Grant Number: 5R01AI110664-03</th>
<th>Project/Grant Period: 06/01/2014 - 05/31/2019</th>
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<tr>
<td>Reporting Period: 06/01/2015 - 05/31/2016</td>
<td>Requested Budget Period: 06/01/2016 - 05/31/2017</td>
</tr>
<tr>
<td>Report Term Frequency: Annual</td>
<td>Date Submitted: 05/13/2016</td>
</tr>
</tbody>
</table>

**Program Director/Principal Investigator Information:**

PETER DASZAK, BS PHD

**Phone number:**

| Email: (b) (6) |

**Recipient Organization:**

ECOHEALTH ALLIANCE, INC.
ECOHEALTH ALLIANCE, INC.
460 W 34TH ST
17TH FLOOR
NEW YORK, NY 100012320

DUNS: 077090066
EIN: 1311726494A1

**Change of Contact PD/PI:** N/A

**Administrative Official:**

ALEKSEI CHMURA
460 W 34th St., 17th Floor
New York, NY 10001

**Phone number:**

| Email: (b) (6) |

**Signing Official:**

ALEKSEI CHMURA
460 W 34th St., 17th Floor
New York, NY 10001

**Phone number:**

| Email: (b) (6) |

**Human Subjects:** Yes
**HS Exempt:** No
**Exemption Number:** Phase III Clinical Trial:

**Vertebrate Animals:** Yes

**hESC:** No

**Inventions/Patents:** No
B. ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

Zoonotic coronaviruses are a significant threat to global health, as demonstrated with the emergence of severe acute respiratory syndrome coronavirus (SARS-CoV) in 2002, and the recent emergence Middle East Respiratory Syndrome (MERS-CoV). The wildlife reservoirs of SARS-CoV were identified by our group as bat species, and since then hundreds of novel bat-CoVs have been discovered (including >260 by our group). These, and other wildlife species, are hunted, traded, butchered and consumed across Asia, creating a largescale human-wildlife interface, and high risk of future emergence of novel CoVs.

To understand the risk of zoonotic CoV emergence, we propose to examine 1) the transmission dynamics of bat-CoVs across the human-wildlife interface, and 2) how this process is affected by CoV evolutionary potential, and how it might force CoV evolution. We will assess the nature and frequency of contact among animals and people in two critical human-animal interfaces: live animal markets in China and people who are highly exposed to bats in rural China. In the markets we hypothesize that viral emergence may be accelerated by heightened mixing of host species leading to viral evolution, and high potential for contact with humans. In this study, we propose three specific aims and will screen free ranging and captive bats in China for known and novel coronaviruses; screen people who have high occupational exposure to bats and other wildlife; and examine the genetics and receptor binding properties of novel bat-CoVs we have already identified and those we will discover. We will then use ecological and evolutionary analyses and predictive mathematical models to examine the risk of future bat-CoV spillover to humans. This work will follow 3 specific aims:

Specific Aim 1: Assessment of CoV spillover potential at high risk human-wildlife interfaces. We will examine if: 1) wildlife markets in China provide enhanced capacity for bat-CoVs to infect other hosts, either via evolutionary adaptation or recombination; 2) the import of animals from throughout Southeast Asia introduces a higher genetic diversity of mammalian CoVs in market systems compared to within intact ecosystems of China and Southeast Asia; We will interview people about the nature and frequency of contact with bats and other wildlife; collect blood samples from people highly exposed to wildlife; and collect a full range of clinical samples from bats and other mammals in the wild and in wetmarkets; and screen these for CoVs using serological and molecular assays.

Specific Aim 2: Receptor evolution, host range and predictive modeling of bat-CoV emergence risk. We propose two competing hypotheses: 1) CoV host-range in bats and other mammals is limited by the phylogenetic relatedness of bats and evolutionary conservation of CoV receptors; 2) CoV host-range is limited by geographic and ecological opportunity for contact between species so that the wildlife trade disrupts the ‘natural’ co-phylogeny, facilitates spillover and promotes viral evolution. We will develop CoV phylogenies from sequence data collected previously by our group, and in the proposed study, as well as from Genbank. We will examine co-evolutionary congruence of bat-CoVs and their hosts using both functional (receptor) and neutral genes. We will predict host-range in unsampled species using a generalizable model of host and viral ecological and phylogenetic traits to explain patterns of viral sharing between species. We will test for positive selection in market vs. wild-sampled viruses, and use data to parameterize mathematical models that predict CoV evolutionary and transmission dynamics. We will then examine scenarios of how CoVs with different transmissibility would likely emerge in wildlife markets.

Specific Aim 3: Testing predictions of CoV inter-species transmission. We will test our models of host range (i.e. emergence potential) experimentally using reverse genetics, pseudovirus and receptor binding assays, and virus infection experiments in cell culture and humanized mice. With bat-CoVs that we’ve isolated or sequenced, and using live virus or pseudovirus infection in cells of different origin or expressing different receptor molecules, we will assess potential for each isolated virus and those with receptor binding site sequence, to spill over. We will do this by sequencing the spike (or other receptor binding/fusion) protein genes from all our bat-CoVs, creating mutants to identify how significantly each would need to evolve to use ACE2, CD26/DPP4 (MERS-CoV receptor) or other potential CoV receptors. We will then use receptor-mutant pseudovirus binding assays, in vitro studies in bat, primate, human and other species’ cell lines, and with humanized mice where particularly interesting viruses are identified phylogenetically, or isolated. These tests will provide public health-relevant data, and also iteratively improve our predictive model to better target bat species and CoVs during our field studies to obtain bat-CoV strains of the greatest interest for understanding the mechanisms of cross-species transmission.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File uploaded: Year 2 NIAID CoV Report Final.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

For this reporting period, is there one or more Revision/Supplement associated with this award for which reporting is required?

No

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

File uploaded: Year 2 NIAID CoV Report Professional Development.pdf
B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

1) Conference and University lectures: PI Daszak, and Co-investigators Shi, Epstein, Olival, Ge, and Zhang gave >100 invited University and Conference lectures including Forum on Microbial Threats (National Academies of Science), Symposium at Ecole du Val-de-Grâce in Paris, Leadership Roundtable at Concordia University Montreal, 1st annual Global Pandemic Policy Summit at Texas A&M Univ., Intl. Conf. of the Wildlife Disease Association in Australia, Intl. Conf. of Conservation Biol in Montpellier France, Michigan State University, Duke University, WDA, ISID conference, Zoological Society of London Symposium, Future Earth meeting, North American Bat Research Symposium, and others that included specific discussion of the current project and results.

2) Agency and other briefings: PI Daszak and Research Technician Dr. Guangjian Zhu introduced this project to potential collaborators within the following agencies: Forestry Dept of Peoples’ Republic of China, FAO, TNC, TRAFFIC, China CDC, and TA Foundation in Beijing China in meetings (2015) and also at presentations at the first Wildlife and Public Health Workshop in China (2016) co-hosted by EcoHealth Alliance, the State Forestry Administration of China, and China CDC.

3) Public outreach: PI Daszak presented this work to members of the NIH, NSF, DoD, IUCN, EPA, and the general public, at an EcoHealth Alliance meeting hosted by the Cosmos Club, Washington D.C. (2015); PI Daszak and Co-investigator Zhu reported on this project at a Wildlife Trade and Public Health Seminar, Beijing (2016); PI Daszak introduced this project in a lecture on Pandemics at a New York Academy of Science Panel (2016); Co-PI Y-Z Zhang presented project and results-to-date to department heads and senior researchers at Infectious Disease Departments of four Yunnan Hospitals (2015)

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

Specific Aim 1: Assessment of CoV spillover potential at high risk human-wildlife interfaces.

- Given the reduced amount of wildlife in the local markets within Southern China, and the continued expansion of the Chinese wildlife trade within SE Asia, we would like to conduct short field trips to assess markets, identify wildlife in them, and sample species of bats and other high-risk hosts in countries that neighbor China (Myanmar, Vietnam, Cambodia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia). EcoHealth Alliance has other activities in these countries which would provide leverage to reduce costs of fieldwork, and samples would be tested in Wuhan, China.

- Following the successful collection of ethnographic interviews and focus groups in Year 2, we will be analyzing the qualitative data collection from Years 1 and 2.

- Finalize and conduct survey collection tool for a network study of wildlife farmers using a questionnaire to characterize and map the wildlife value chain.

- After the success of our pilot studies in Year 2, we will continue targeted (at individuals with high risk of exposure to bats), integrated behavioral and biological survey work in Yunnan and expand to Guangxi and Guangdong provinces.

- We will commence our anonymized, surveillance data collection from acutely ill hospital in-patients who satisfy syndromic eligibility criteria; have complete medical records; non-normative laboratory confirmed diagnostic results; and suspected acute viral infection. Eligibility criteria are: (a) suspected acute viral infection; (b) fever > 38°C, and (c) presenting symptoms of at least one of the following:
  • Encephalitis of unknown origin
  • Hemorraghic fever of unknown origin
  • Respiratory disease
  • Influenza-like illness (ILI)
  • Severe Acute Respiratory like Illness (SARI)
  • Rash
  • Diarrhea

Some patients with particular infections such as with HIV, HCV, and HBV, may be excluded from the study on that basis. Hospital surveillance has the advantage of monitoring an acutely ill population. Anonymized, passive hospital surveillance allows for data collection and viral testing from all eligible hospital patients thereby limiting population sample bias and increasing the likelihood of identifying positive cases. The strengths of this approach are enormous: an unbiased patient population; prospectively collected, anonymized patient data; a low resource effort with a high efficiency design; and impactful research potential for both case series and case control studies. We have already secured approval from the Institutional Review Boards of the Wuhan School of Public Health and Hummingbird IRB.

Specific Aim 2: Receptor evolution, host range and predictive modeling of bat-CoV emergence risk.

Future steps to optimize the model of role of species diversity in CoV emergence risk will include:

- Test and implement our respondent-driven survey to collect specific data on the diversity, abundance, and turnover of species along the wildlife trade network in south China.

- Model viral mixing across the full range parameters found along the wildlife trade network to identify the trade nodes with highest mixing potential. This will include a network analysis of market facility/site connectivity including wild harvest sites, wildlife farming operations, transit holding facilities, and small and large wildlife markets.

- Phylogeographic study of bat-CoV to better understand the geographic distribution and evolution of bat-CoV genetic diversity in south
China.

- Phylogeographic study of bat host (Rhinolophus) species to assess the connectivity of bat populations and infer their historical movements and demographic history to improve our understanding of CoV transmission among bat populations in southern China. Preliminary sequences data has been generated and will be completed and analyzed.

- Cophylogenetic analyses of bat host and CoV phylogenies to assess frequency of cross-species transmission. Comparison of Alpha- and Beta-CoV cophylogenetic patterns building on Year 2 analyses using published sequences and also including Spike gene and additional sequences obtained in Year 2.

- Test and implement our respondent-driven survey to assess diversity, abundance, and turnover of species along the wildlife trade network.

- Examine co-evolutionary congruence of bat-CoVs and their hosts using both functional (receptor) and neutral genes;

- Parameterize mathematical models that predict CoV evolutionary and transmission dynamics

- Continued surveillances of SARS-like CoVs and lineage C betacoronaviruses (MERS-related CoVs) in Southern China;

- Full-length genome sequencing and evolution analysis of SARS-like coronaviruses identified from different bat species and different geographical locations across China;

- Full-length genome sequencing and evolution analysis of Lineage C betacoronaviruses identified from different bat species and different geographical locations across China;

- Full-length genome sequencing and evolution analysis of HKU9-related and HKU10-related bat coronaviruses in China;

Specific Aim 3: Testing predictions of CoV inter-species transmission. The following experiments will be undertaken in Year 2:

- Humanized mice with human ACE2 receptors will be infected with WIV1 and the two rescued chimeric SARS-like coronaviruses to determine the tissue tropism and pathogenicity of bat SL-CoV

- Isolation of novel bat coronaviruses. Live virus or pseudovirus will be used to infect cells of different origin or expressing different receptor molecules. Spillover potential for each isolated virus will be assessed.

- An infectious clone of full-length MERS-CoV will be constructed using reverse genetic method. Using the S sequence of different MERS-related viruses identified from Chinese bats, the chimeric viruses with S gene of bat MERS-related coronaviruses and backbone of the infectious clone of MERS-CoV will be constructed to study the receptor usage and infectivity of bat MERS-related coronavirus.

- Surveillance of infection in human populations by SARS-like CoVs. This work will be performed at locations in Yunnan, Guangxi, and Guangdong provinces, in previously identified areas with human populations of high risk of exposure to bats. PCR and ELISA will be used, respectively, for detection of viral replicase gene and antibodies against the viral nucleocapsid protein.
**Year 1 Report:** Understanding the Risk of Bat Coronavirus Emergence

**Award Number:** 1R01AI110964-02

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**Section B: Accomplishments**

**B.1 What are the Major Goals of the Project**

Zoonotic coronaviruses are a significant threat to global health, as demonstrated with the emergence of severe acute respiratory syndrome coronavirus (SARS-CoV) in 2002, and the recent emergence Middle East Respiratory Syndrome (MERS-CoV). The wildlife reservoirs of SARS-CoV were identified by our group as bat species, and since then hundreds of novel bat-CoVs have been discovered (including >260 by our group). These, and other wildlife species, are hunted, traded, butchered and consumed across Asia, creating a large-scale human-wildlife interface, and high risk of future emergence of novel CoVs. To understand the risk of zoonotic CoV emergence, we propose to examine 1) the transmission dynamics of bat-CoVs across the human-wildlife interface, and 2) how this process is affected by CoV evolutionary potential, and how it might force CoV evolution. We will assess the nature and frequency of contact among animals and people in two critical human-animal interfaces: live animal markets in China and people who are highly exposed to bats in rural China. In the markets we hypothesize that viral emergence may be accelerated by heightened mixing of host species leading to viral evolution, and high potential for contact with humans. In this study, we propose three specific aims and will screen free ranging and captive bats in China for known and novel coronaviruses; screen people who have high occupational exposure to bats and other wildlife; and examine the genetics and receptor binding properties of novel bat-CoVs we have already identified and those we will discover. We will then use ecological and evolutionary analyses and predictive mathematical models to examine the risk of future bat-CoV spillover to humans. This work will follow 3 specific aims:

**Specific Aim 1:** Assessment of CoV spillover potential at high risk human-wildlife interfaces. We will examine if: 1) wildlife markets in China provide enhanced capacity for bat-CoVs to infect other hosts, either via evolutionary adaptation or recombination; 2) the import of animals from throughout Southeast Asia introduces a higher genetic diversity of mammalian CoVs in market systems compared to within intact ecosystems of China and Southeast Asia; We will interview people about the nature and frequency of contact with bats and other wildlife; collect blood samples from people highly exposed to wildlife; and collect a full range of clinical samples from bats and other mammals in the wild and in wetmarkets; and screen these for CoVs using serological and molecular assays.

**Specific Aim 2:** Receptor evolution, host range and predictive modeling of bat-CoV emergence risk. We propose two competing hypotheses: 1) CoV host-range in bats and other mammals is limited by the phylogenetic relatedness of bats and evolutionary conservation of CoV receptors; 2) CoV host-range is limited by geographic and ecological opportunity for contact between species so that the wildlife trade disrupts the ‘natural’ co-phylogeny, facilitates spillover and promotes viral evolution. We will develop CoV phylogenies from sequence data collected previously by our group, and in the proposed study, as well as from Genbank. We will examine co-evolutionary congruence of bat-CoVs and their hosts using both functional (receptor) and neutral genes. We will predict host-range in unsampled species using a generalizable model of host and viral ecological and phylogenetic traits to explain patterns of viral sharing between species. We will test for positive selection in market vs. wild-sampled viruses, and use
data to parameterize mathematical models that predict CoV evolutionary and transmission dynamics. We will then examine scenarios of how CoVs with different transmissibility would likely emerge in wildlife markets.

Specific Aim 3: Testing predictions of CoV inter-species transmission. We will test our models of host range (i.e. emergence potential) experimentally using reverse genetics, pseudovirus and receptor binding assays, and virus infection experiments in cell culture and humanized mice. With bat-CoVs that we’ve isolated or sequenced, and using live virus or pseudovirus infection in cells of different origin or expressing different receptor molecules, we will assess potential for each isolated virus and those with receptor binding site sequence, to spill over. We will do this by sequencing the spike (or other receptor binding/fusion) protein genes from all our bat-CoVs, creating mutants to identify how significantly each would need to evolve to use ACE2, CD26/DPP4 (MERS-CoV receptor) or other potential CoV receptors. We will then use receptor-mutant pseudovirus binding assays, in vitro studies in bat, primate, human and other species’ cell lines, and with humanized mice where particularly interesting viruses are identified phylogenetically, or isolated. These tests will provide public health-relevant data, and also iteratively improve our predictive model to better target bat species and CoVs during our field studies to obtain bat-CoV strains of the greatest interest for understanding the mechanisms of cross-species transmission.

B.1a Have the major goals changed since the initial competing award or previous report? No.

B.2 What was accomplished under these goals?

Specific Aim 1: Assessment of CoV spillover potential at high risk human-wildlife interfaces

In year 2, we continued and expanded the qualitative research begun at the end of Year 1. In addition, a community based integrated biological behavioral surveillance system was developed and pilot tested to identify specific animal exposure risk factors associated with biological evidence of exposure to SARS-like CoV (i.e., seropositive status).

QUALITATIVE RESEARCH

Targeted, in-depth ethnographic interviews were conducted with 47 individuals (18 women; 29 men) in rural Southern China where wildlife trade routes have been documented. Yunnan, Guangxi and Guangdong provinces were specifically selected for study because they have large wildlife populations, a diversity of wildlife species and numerous live animal markets. Individuals who were 18 years of age or older and who were able to provide informed consent were eligible to participate. Twenty-three (49%) in-depth interviews were conducted in Yunnan province at nine different sites, 24 (51%) in Guangxi province at six different sites. In addition, one focus group was conducted in Guangxi. The study was approved by the Institutional Review Boards of the Wuhan School of Public Health and Hummingbird IRB.

Recruitment sites in each province included forested areas or preserves, wildlife farms, hunting areas, wildlife restaurants, live animal markets, caves where people dwell or collect guano and residential areas/farms near known bat caves or roosts. Participants were recruited primarily through local contacts developed as part of wildlife conservation and health research conducted by team members over the past decade. Contacts including wildlife conservationists and researchers, local government health outreach workers and wildlife farmers facilitated introductions and provided referrals. To achieve a sample with sufficient representation of categories of interest, participants were recruited using
purposive sampling, which provides minimum quotas in terms of sex, age and wildlife exposure setting (e.g., live animal market, forest preserve).

The five core themes that guided the in-depth discussions are: 1) human-animal contact, 2) unusual illness experience and response, 3) socioeconomics and daily living, 4) biosafety and 5) human environments and movement/travel. An ethnographic interview guide was developed with examples of questions that could be asked for each theme. In addition, field based participant-observation was ongoing throughout the study and involved observing and talking informally with people in their own natural setting. Field notes were maintained of these ongoing observations and discussions.

<table>
<thead>
<tr>
<th>Genus species</th>
<th>Common Name</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Prionailurus bengalensis</em></td>
<td>Leopard Cat</td>
</tr>
<tr>
<td><em>Nyctereutes procyonoides</em></td>
<td>Raccoon Dog</td>
</tr>
<tr>
<td><em>Sus scrofa</em></td>
<td>Wild Boar</td>
</tr>
<tr>
<td><em>Lepus sinensis</em></td>
<td>Chinese Hare</td>
</tr>
<tr>
<td><em>Arctonyx collaris</em></td>
<td>Hog Badger</td>
</tr>
<tr>
<td><em>Hystrix brachyura</em></td>
<td>Porcupine</td>
</tr>
<tr>
<td><em>Marmota sp.</em></td>
<td>Marmot</td>
</tr>
<tr>
<td><em>Rhizomes sinensis</em></td>
<td>Bamboo Rat</td>
</tr>
<tr>
<td><em>Erinaceus sp.</em></td>
<td>Hedgehog</td>
</tr>
<tr>
<td><em>Mustela putorius</em></td>
<td>Ferrets</td>
</tr>
<tr>
<td><em>Muridae</em></td>
<td>Rat (species unknown)</td>
</tr>
<tr>
<td><em>Myocastor coypus</em></td>
<td>Nutria</td>
</tr>
<tr>
<td><em>Vulpes sp.</em></td>
<td>Fox</td>
</tr>
<tr>
<td><em>Mustela sibirica</em></td>
<td>Siberian weasel</td>
</tr>
<tr>
<td><em>Paguma larvata</em></td>
<td>Masked Palm Civet</td>
</tr>
<tr>
<td><em>Felis catus</em></td>
<td>Domestic Cat</td>
</tr>
<tr>
<td><em>Canis lupus familiaris</em></td>
<td>Domestic Dog</td>
</tr>
<tr>
<td><em>Cervinae</em></td>
<td>Sambar Deer</td>
</tr>
<tr>
<td><em>Ovis aries</em></td>
<td>Sheep</td>
</tr>
<tr>
<td><em>Capra sp.</em></td>
<td>Domestic Goat</td>
</tr>
<tr>
<td><em>Ratus norvegicus</em></td>
<td>Common Rat</td>
</tr>
</tbody>
</table>

Interviews were conducted between March and June 2105 by 10 trained interviewers, none of whom had social science training. Interviewers conducted between one and 22 interviews; three interviewers conducted two thirds of all interviewers. Interviews lasted between 20 and 60 minutes, and were tape-recorded and transcribed verbatim before they were translated into English. All participants received cooking oil valued at US$10 in appreciation of their time.

The data are currently being coded and an analytic database is being constructed. Initial insights include observations by a number of participants, especially those who are older, that there has been a decrease in wildlife in the surrounding environment. This decrease is attributed to many factors including infrastructure development. The government has invested resources to build new roads and renovate local infrastructure with the intention of increasing tourism. This has reduced forested area.

Observations by research staff in live animal markets in Guangzhou found wildlife to be plentiful (see Table 1), although no bats were seen for sale during the observation period.

In contrast, wildlife was not found in live animal markets at the sites we visited in either Yunnan or Guangxi. This is a change from previous research visits to the same or similar communities, when bats, rodents and wild boar could be found. Locals in Yunnan and Guangxi attribute the change to conservation law enforcement. The success of conservation enforcement may have moved hunting and trapping underground and made the capture of local wildlife less economically feasible than other income generating activities.
Preliminary analyses are underway. Three specific studies in support of Specific Aim 1 are being developed: the changing wildlife trade in Southern China, the economics of wildlife farming, and zoonotic disease risks resulting from a rapidly changing wildlife trade.

INTEGRATED BIOLOGICAL BEHAVIORAL SURVEILLANCE PILOT STUDY
Currently, mechanisms of zoonotic viral spillover are unknown. In order to evaluate potential risk factors, it is necessary to measure both exposure and outcome data. Therefore, a behavioral risk survey was developed that assessed both animal exposure and experiences of unusual illness both during lifetime and in the past 12 months. In addition, participants were requested to provide serum to test for previous exposure to SARS-like CoV. The integrated surveillance was pilot tested in October 2015 among residents living near bat caves or roosts where SARS-like-CoV has been previously detected in the bat population in Jinning County, Yunnan. Please view the full survey here:

https://www.dropbox.com/s/sv62neywul027r/Questionnaire%20Complete.docx?dl=0

Of 218 participants, 139 (64%) were women and 79 (36%) were men, with a mean age of 48 (range: 12-80). Most reported being farmers (87%, and see chart to left); a majority were long term residents (97%). Animal exposures in the past year were extensive, including general (e.g., buying live animals at markets [61%]) and intimate (e.g., being scratched or bitten [9%], slaughter [38%]). In fact, two-thirds of participants reported handling recently killed animal parts and 2 out of 5 reported slaughtering animals. Only 20 (9%) participants reported known exposure to bats.

Standardized syndromic case definitions informed questions concerning unusual illness experience (e.g. severe acute respiratory infections [SARI], influenza-like illness [ILI]). Lifetime, 12 month and unusual illness experience in family for the past 12 months were assessed for all participants. In the past year, SARI was reported by 4 (2%) respondents and for 4 additional family members. Table 2 provides data for all unusual illness experience assessed. None of the participants were found to be seropositive for SARS-like CoV.

Table 2. Unusual Illness Experience

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Ever</th>
<th>Past 12 months</th>
<th>Family (12m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe Acute Respiratory Infections (SARI)</td>
<td>15 (6.9%)</td>
<td>4 (1.8%)</td>
<td>4 (1.8%)</td>
</tr>
<tr>
<td>Influenza Like Illness (ILI)</td>
<td>54 (24.8%)</td>
<td>16 (7.3%)</td>
<td>26 (11.9%)</td>
</tr>
<tr>
<td>Encephalitis</td>
<td>19 (8.7%)</td>
<td>4 (1.8%)</td>
<td>3 (1.4%)</td>
</tr>
<tr>
<td>Hemorrhagic Fever</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Fever with Diarrhea /Vomiting</td>
<td>12 (5.5%)</td>
<td>2 (0.9%)</td>
<td>3 (1.4%)</td>
</tr>
<tr>
<td>Fever with Rash</td>
<td>2 (0.9%)</td>
<td>2 (0.9%)</td>
<td>3 (1.4%)</td>
</tr>
</tbody>
</table>
Although the sample size was small, animal exposures among those who reported unusual illness experiences in the past 12 months were evaluated. Of the four respondents who reported SARI symptoms, 75% reported: raising animals, animals in the home, preparing recently killed animals and buying live animals; 50% reported slaughter. Among the 16 respondents who reported ILL symptoms, 12 (75%) reported handling/preparing recently killed animals, 11 (69%) Handling live animals or having animals in the home, 10 (63%) reported slaughtering/killing animals or buying live animals at wet market, 9 (56%) raised live animals, 7 (44%) reported a pet, and 1 (6%) reported animal feces near food or eating animal touched or damaged food, hunting, or eating raw/undercooked animal products. Finally, among the four respondents who reported encephalitis symptoms, 3 (75%) reported hunting, handling or raising animals, 2 (50%) reported animals in the home, 1 (25%) reported having animals as pets, slaughtering/killing animals, or having bought live animals at wet market.

Respondents were asked about the source of their unusual illnesses. None reported any kind of animal exposure as a potential source of infection and most stated they had no idea how they had become infected. However, when asked about potential behavior changes made at live animal markets in the last 12 months, participants reported a great deal of change. In particular, respondents reported buying live animals less often (38%), only buying farmed wildlife (54%) or buying meat at the supermarket (23%). (See Table 3).

### Table 3: Behavior Change at Wet Market in the last 12 months

<table>
<thead>
<tr>
<th>Behavior</th>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wear a mask</td>
<td>4</td>
<td>(3.0)</td>
</tr>
<tr>
<td>Wear gloves</td>
<td>5</td>
<td>(3.8)</td>
</tr>
<tr>
<td>Wash hands</td>
<td>80</td>
<td>(60.6)</td>
</tr>
<tr>
<td>Sometimes shop for meat at supermarket</td>
<td>30</td>
<td>(22.7)</td>
</tr>
<tr>
<td>Buy live animals less often</td>
<td>50</td>
<td>(37.9)</td>
</tr>
<tr>
<td>Buy only farmed wildlife</td>
<td>71</td>
<td>(53.8)</td>
</tr>
<tr>
<td>No longer buy wildlife at wet market</td>
<td>39</td>
<td>(29.5)</td>
</tr>
</tbody>
</table>

The results of this pilot study conducted with a largely female farmer population found high levels of unusual illness, as well as high levels of exposure to animals. There was a notable lack of knowledge of animals’ ability to transmit infection. Despite this lack of knowledge, there may be a sense of unease about animal exposures, given the fairly dramatic behavior changes reported at live animal markets. The finding of a reduction in wildlife purchase may be due to sensitivity to the legality of wildlife trade, biasing respondents towards not admitting purchasing wildlife. Although, there were no participants seropositive for SARS-like CoV, serological data may add support to the findings from self-reported syndromic surveillance, once serological assays are optimized.

In preparation for full implementation of the integrated biological behavioral surveillance, the survey has been programmed as an application for use on either a mobile device or computer. Electronic data collection will facilitate survey implementation in the field and quality control of the data being collected. Four field team leads were trained on behavioral survey data collection, data collection technologies (the tablet application) and analysis.

Nucleic acid test results of human biological samples

*Testing High-Risk Human Populations for Coronavirus Infection*
Surveillance of CoV infections in human populations by SARS-like CoVs was significantly expanded in Year 2, including both custom-built ELISA serology (an assay developed by the Wuhan Institute of Virology to test antibodies against the N protein of SL-CoV) and PCR detection of viral RNA.

**Serological test for SL-CoV antibodies in human samples from Jinning, Yunnan Province**

In order to assess past exposure to bat CoVs, 223 human sera samples were collected in villages in proximity to the bat habitat from which two SL-CoVs with potential for interspecies infection, WIV1 and WIV16, were discovered in our previous research. An ELISA developed by the Wuhan Institute of Virology was used to test antibodies against the N protein of SL-CoV. A number of human specimens generated high OD values and neutralization test to WIV1 and WIV16 was then performed. These findings are encouraging; however, no neutralization antibodies were detected. In Year 3, we will continue to validate and optimize these ELISA assays and other serological tests to obtain data on past CoV exposure.

**PCR test for CoV Nucleic Acid in human samples from several Provinces**

We tested 405 individual human samples for CoV RNA to identify evidence of active infection in human populations and to obtain sequence data on strain variation. Individual samples (4 each) were pooled prior to nucleic acid extraction then tested using PCR. When a group tested positive, we then conducted the confirmation test in the individual samples. One single sample (14XN611) from someone who had identified as having had a fever and suffered both a cough and headache in the past 7-days was then identified to be positive for HCoV-HKU1. The low number of PCR detections in human specimens is not unexpected, and will be improved in Year 3-5 by better targeting syndromic individuals for specimen collection and continuing to optimize PCR assays. Refined serological assays (above) will provide sufficient data to assess past exposure to specific CoV lineages, and optimizing of PCR detections will allow for more CoV positive human sequences moving forward.

**Specific Aim 2: Receptor evolution, host range and predictive modeling of bat-CoV emergence risk**

**Bat CoV PCR detection and sequencing from live-sampled bat populations**

We collected 1,714 anal swab samples, 677 fecal samples, 53 blood samples, and 38 serum samples from 15 bat genera in Guangdong, Yunnan, Sichuan, Hubei, Hunan, Guizhou, Guangxi provinces (Table 4).

**Table 4 Bat Samples collected for CoV surveillance in 2015**

<table>
<thead>
<tr>
<th>Sample date</th>
<th>Sample location</th>
<th>Anal</th>
<th>Fecal</th>
<th>Blood</th>
<th>Serum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar. 2015</td>
<td>Huidong, Guangdong</td>
<td>69</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Jun. 2015</td>
<td>Guangdong</td>
<td>495</td>
<td>--</td>
<td>12</td>
<td>--</td>
</tr>
<tr>
<td>Apr. 2015</td>
<td>Menglun, Yunnan</td>
<td>51</td>
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<td>Jul</td>
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We tested 2,256 samples for CoV RNA and 280 tested positive. The total positive rate is 12.4% (Table 5). Diverse alphacoronaviruses related to Bat CoV 1A, 1B, HKU2, HKU6, HKU7, HKU8 and HKU10 were identified; SARS-like coronaviruses were detected in *Rhinolophus* bats in both Yunnan and Guangdong (Fig 1). Novel lineage B betacoronaviruses more distantly related to SARS-CoV than other SL-CoVs were detected in *Vespertilio superans* in Sichuan. HKU4-related coronaviruses were found in *Tynolyceteris pachypus* in Guangdong and Guangxi while HKU5-related coronaviruses were found to be highly prevalent in *Vespertilio superans* in Zigong, Sichuan (41 bats out of 128 tested positive).
### Table 5  Test result of bat CoV surveillance in 2015 – 12% positive (280/2,256)

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<th>Hubei</th>
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<th>Hunan</th>
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<td></td>
<td>16/225</td>
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<td>8/63</td>
<td>83/489</td>
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<td>0/131</td>
<td>0/91</td>
<td>26/460</td>
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<td>0/19</td>
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<td>0/2</td>
<td>0/4</td>
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<td>34/83</td>
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<td>2/6</td>
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<td>42/96</td>
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<td><strong>Vespertilio superans</strong></td>
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<td><strong>Fecal samples</strong></td>
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<td>18/438</td>
<td>8/204</td>
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<td><strong>Sub-total</strong></td>
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<td>56/326</td>
<td>48/332</td>
<td>41/128</td>
<td>27/191</td>
<td>18/438</td>
<td>8/204</td>
<td><strong>280/2256</strong></td>
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Fig 1 Phylogenetic analysis of partial RdRp gene of CoV (440-nt partial sequence). CoVs identified in 2015 are named by the sample numbers. Sequence amplified from samples co-infected with two CoV strains are indicated in red. (A) CoVs detected in Guangdong. (B) CoVs detected in Yunnan.
Cophylogenetic analysis of CoV host switching

We completed preliminary cophylogenetic analysis of bat host – CoV sequences using data published in the literature and available on Genbank. Two figures from these analyses are highlighted below (Figs 2 and 3) and these methods are currently being extended using partial RdRp CoV and bat mitochondrial DNA sequences from a large number of bat specimens found CoV positive in Year 2 (Table 5, above).

Figure 2: Tanglegram depicting the pattern of infection of bats (and outlier mammalian hosts) by CoVs. The CoV tree was reconstructed from DNA sequences available in GenBank (partial RdRp gene) using Bayesian inference (MrBayes). The topology of host tree was reconstructed using the mammal and bat phylogenies available in Asher & Helgen (2010) and Agnarsson et al. (2011), using methods our group has previously applied to bat parasite cophylogenetic analyses (Lei and Olival 2014). Both ParaFit (ParaFitGlobal = 64957.61, p-value = 0.001) and PACo (m2 = 366.44, p-value = 0.013) provided evidence for significant global congruence between the two topologies, and evidence for coevolution. Lines connecting taxa indicate host-CoV associations. Red lines indicate significant host-CoV associations as indicated by ParaFit (p < 0.05, 999 permutations).

Figure 3: Reconstruction of one of 3 potentially optimal solutions of reconciled host-CoV trees recovered from a Jane analysis. Black and blue lines represent the host and CoV trees, respectively. For each solution, the number of co-speciation events inferred by Jane was always significantly greater than expected by chance. Jane inferred 4 co-speciation events (hollow colored circles), 1 duplication (solid
colored circle), 14 host switches (solid colored circle with arrow), 0 loss and 0 failure to diverge.

Our findings demonstrate co-speciation alone is not sufficient to explain the observed co-phylogenetic pattern and several host switches can be specifically identified. This is the case even if a significant global signal of co-speciation has been detected. This work highlights, the need for these types of detailed cophylogenetic analyses to best explain the evolutionary history and host-switching of bat-CoVs.


**Market Characterization Model Parameterization**

Our ongoing observational research and mapping of farms and markets suggests that rapid changes in the market and regulatory environment are changing the nature and location of the wildlife market trade. The nexus of the wildlife trade and the potential hotspots of interspecies viral mixing is now in many cases in animal storage facilities and transport between high-volume customers. To define realistic parameters for intermixing wildlife species in areas of high potential mixing, we have developed a preliminary survey and sampling protocol to assess these values as animals move along the value chain – through these storage facilities - using respondent-driven questionnaires to follow and sample along the wildlife trade network and reveal hidden nodes and sites of intermixing of species.

We have expanded our intermixing modeling framework to incorporate the variations along this value chain, where the diversity, abundance, residence time, and contact rates between species change as animals move through the trade network.

**Specific Aim 3: Testing predictions of CoV inter-species transmission.**

In Year 2, we continued surveillance for novel SARS-like CoVs from bats in Yunnan and Guangdong provinces and obtained full genome sequence for 11 CoV isolates. Full genome analysis of these CoV isolates was completed, including phylogenetic and recombination analyses. Importantly, recombination analysis of the full-length SL-CoV genome sequences from a single bat population revealed that frequent recombination events among different SL-CoV strains occur. Several SL-CoVs that are more genetically similar to SARS-CoV (2003) than any previously discovered were also identified from bat populations in Yunnan province. Full genome analysis suggests that an epicenter of SL-CoV occurs in rhinolophid bats and provides more insight into the evolutionary origin of SARS-CoV.

**Full-length genome sequencing of SL-CoVs identified from a single bat colony**

To date, including preliminary data submitted for this R01 that we are now analyzing under the current funding, we have conducted 5-years of surveillance of SL-CoV in a single bat colony in Yunnan Province (from 2011 to 2015), leading to the discovery of diverse novel SL-CoVs. Based on genotyping of these SL-CoVs by the region corresponding to the receptor-binding domain (RBD) of SARS-CoVs, 11 isolates were selected and full-length genome sequencing was performed in Year 2.

These SL-CoVs, including four others isolated previously from this colony, Rs3367, RsSHC014, WIV1 and WIV16, are highly diversified in the S gene, but share similar sequence identity to SARS-CoV in ORF1ab (Fig 4). Genomic phylogenetic analysis showed that the SL-CoVs detected in this colony are more closely
related to SARS-CoVs from other geographic regions, especially three isolates, WIV16, Rs4874 and Rs4231 (Fig 5). Notably, among the 15 SL-CoVs, two isolates, Rs4084 from *Rhinolophus sinicus* and Rf4092 from *Rhinolophus ferrumequinum*, are highly similar to SARS-CoV in the ORF8 region (Fig 5). Rf4092 possessed a single ORF8 of the same length (369bp) as that in civet SARS-CoV SZ3, and the sequence showed only 10 nucleotide substitution (Fig 6). The ORF8 sequence of Rs4084 is highly similar to that of Rf4092, however in the region corresponding to the 29-bp deletion acquired in human SARS CoVs (e.g Tor2), a shorter deletion of only 5-bp is present, resulting in two overlapping ORF8s, ORF8a and ORF8b. The position of start codon and stop codon of the two ORFs were consistent with those in human strains (Fig 6).

Fig 4. Simplot analysis of the 15 SL-CoVs identified from a single bat colony in Yunnan. SARS-CoV SZ3 is used as query sequence.
Fig 5. Phylogenetic analysis of full-length genome sequences of SL-CoVs and SARS-CoVs. Isolates identified in the single investigated bat colony in Yunnan in in bold.

Fig 6. Alignment of ORF8 nucleotide sequences of SARS-CoV and bat SL-CoVs. The red box indicates the 29-nt deletion present in SARS-CoV of middle and late phase.
Recombination analysis of the full-length genome sequences reveals frequent recombination events among different SL-CoV strains circulating in this bat population. For example, WIV16 appears to be a recombination product of WIV1 and Rs4231. An important breakpoint is identified between the N-terminal domain (NTD) and RBD region in the S gene (Fig 7A). Consequently, WIV16 is identical to Rs4231 and WIV1 in NTD and RBD of the spike protein, respectively, and is highly homologous to SARS-CoV in both NTD and RBD. This makes it the SL-CoV most closely related to the direct progenitor of SARS-CoV discovered to date. Moreover, evidence is found to support the hypothesis that the direct progenitor of SARS-CoV was generated from recombination of WIV16 with Rf4092 at the site near ORF8. This work, which identifies diverse SL-CoVs highly homologous to SARS-CoV in different regions of the genome, suggests that rhinolophid bats are an evolutionary epicenter of SL-CoV and offers more insights into the evolutionary origin of SARS-CoV.

Fig 7  Bootscan analysis of full-length genome sequences of SL-CoVs. (A) WIV16 is used as query sequence. (B) SARS-CoV SZ3 is used as the query sequence. (Kimura model, window size, 1500bp, step size, 300bp)
Additional Year 2 Items for Specific Aim 3:

- The infectious clone of WIV1 was successfully constructed using reverse genetic methods;
- Two chimeric bat SARS-like coronavirus strains were constructed by replacing the S gene in the backbone of WIV1;
- Permission to import mice with human ACE2 to China was obtained, so as to conduct the experimental infections proposed in our R01 specific aims.

Specific Goals Not Met.

- Comparative cophylogenetic analyses of bat host and CoV RdRp and Spike gene phylogenies, to assess patterns of evolutionary congruence and frequency of cross-species transmission (This will be conducted in year 3);
- Animal infection experiments of SARS-like coronaviruses were not done, because of the unavailability of mice with human ACE2 in Year 2. We now have secured these mice and will begin this work in year 3.
- Sampling of bat and other mammalian species in markets to screen for CoVs. We will begin this work in year 3.

Section C: Accomplishments: Publications

PUBLISHED


Kevin J. Olival. To Cull, or Not To Cull, Bat is the Question. *Ecohealth* 13, 6–8 (2015).


ACCEPTED, IN PRESS
B.4 What opportunities for training and professional development has the project provided?

We presented our project to graduate students, laboratory personnel, directors, and doctors from three Hospitals in Yunnan Province: Yunnan Provincial Institute of Endemic Diseases Control & Prevention (YNCDC); Dali Provincial Hospital; and The Third People’s Hospital of Kunming. Select doctors at YNCDC (1) and Dali Provincial Hospital (3) were trained in the passive Hospital surveillance project protocols.

We trained graduate students from Dali School of Public Health (1) and the Wuhan University School of Public Health (3) in qualitative behavioral risk data collection methodologies and data collection technologies, survey data collection and analysis. These were also enrolled in and passed the Human Subjects Research Course provided by the Collaborative Institutional Training Initiative (CITI Program) at the University of Miami (http://citiprogram.org). The CITI Program is a leading provider of research education content with web based training materials serving millions of learners at academic institutions, government agencies, and commercial organizations in the U.S. and around the world.
C. PRODUCTS

C.1 PUBLICATIONS

Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph) during the reporting period resulting directly from this award?

Yes

<table>
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<th>Public Access Compliance</th>
<th>Citation</th>
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| Complete                 | Olival KJ. To Cull, or Not To Cull, Bat is the Question. Ecohealth. 2016 Mar;13(1):6-8. PubMed PMID: 26631385; PubMed Central PMCID: PMC46833651. |

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

NOTHING TO REPORT

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Have inventions, patent applications and/or licenses resulted from the award during the reporting period?

No

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

NOTHING TO REPORT
### D. PARTICIPANTS

#### D.1 WHAT INDIVIDUALS HAVE WORKED ON THE PROJECT?

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</table>

### D.2 PERSONNEL UPDATES

#### D.2.a Level of Effort

Will there be, in the next budget period, either (1) a reduction of 25% or more in the level of effort from what was approved by the agency for the PD/PI(s) or other senior/key personnel designated in the Notice of Award, or (2) a reduction in the level of effort below the minimum amount of effort required by the Notice of Award?

No

#### D.2.b New Senior/Key Personnel

Are there, or will there be, new senior/key personnel?

Yes

File uploaded: Noam Ross CV 2016.pdf

#### D.2.c Changes in Other Support

Has there been a change in the active other support of senior/key personnel since the last reporting period?

No

#### D.2.d New Other Significant Contributors

Are there, or will there be, new other significant contributors?

No

#### D.2.e Multi-PI (MPI) Leadership Plan

Will there be a change in the MPI Leadership Plan for the next budget period?

NA
Noam Ross

EDUCATION

University of California
Doctoral Candidate in Ecology

- Dissertation Committee: Alan Hastings (major professor, Ecology), David Rizzo (Plant Pathology), Jim Sanchirico (Natural Resource Economics)
- Dissertation Research: "Managing Emerging Forest Disease Under Uncertainty"

Brown University
Bachelor of Science in Environmental Science, Magna Cum Laude
May 2006
- Phi Beta Kappa, Sigma Xi, Environmental Science Honors, Rosenberger Prize for Outstanding Service

SCIENTIFIC PUBLICATIONS


In preparation

*Co-equal authorship

POSTERS

- Ross, Noam. "Optimal Control of Forest Disease Under Changing Community and Spatial Structure," November 4-18, 2013. Sustainable Management of Natural Resources Workshop, Mathematical Biosciences Institute, Columbus, OH.

PRESENTATIONS

- Ross, Noam, "Fungal Disease Mortality: Modeling for Management of Sudden Oak Death." Dec 1, 2014 Invited talk at EcoHealth Alliance, New York, NY.

RPPR
**AWARDS + FELLOWSHIPS (Total received $225,429)**

- Don Dahlsten Memorial Grant ($325)  
  **California Forest Pest Council, 2012**
  *Designing Protective Treatments for Forest Disease Using Spatial Point Process Models*

- NSF IGERT Bridge Fellowship ($57,500)  
  **UC Davis, CA, 2012**
  *Managing Emerging Forest Disease Under Uncertainty*

- NSF IGERT Traineeship in Rapid Environmental Change ($115,000)  
  **UC Davis, CA, 2010**
  *Modifying River-Floodplain Systems: A Historical and Ecological Approach*

- UC Davis Graduate Group in Ecology Fellowship ($40,604)  
  **UC Davis, CA, 2010**

- NSF Research Experience for Undergraduates Fellowship ($8,000)  
  **Acad. of Natural Sciences, PA, 2005**

- Undergraduate Research Fellowship ($4,000)  
  **Brown University, RI, 2003**

**SERVICE + PROJECTS**

- **Workshop Instructor**, Software Carpentry and Data Carpentry Foundations  
  Jan 2015–Present

- **Student Rep**, UC Davis Graduate Group in Ecology Executive Committee  
  Sep 2013–Present

- **Reviewer, Theoretical Ecology (4 reviews)**  
  Feb 2013–Present

- **Web Developer and Technology Chair**, Ecology Graduate Student Association  
  June 2013–Present  
  *Creator + Maintainer of graduate student blog, resources, and news site (egsa.ucdavis.edu)*

- **Founder + Organizer**, Davis R Users' Group  
  Sep 2012–Present  
  *Created users group that provides tutoring and seminars to graduate students in 10+ departments*

- **Contributor**, R packages knitr, knitr citations, rcrossref, rethinking  
  2012–Present

- **Organizer**: NSF REACH IGERT Workshop on Multiple Goals in Floodplain Restoration  
  Sep 2012

- **Organizer, UC Davis Conference on Ecology and the Business Sector**  
  Apr 2011

- **Organizer, UC Davis Graduate Group in Ecology Symposium**  
  May 2010–2011

- **External Reviewer**, World Resources Institute Corporate Ecosystem Services Review  
  Jan 2008

- **External Reviewer**, McKinsey-Clinton Global Initiative Forestry Project  
  Mar 2008

- **Business Stewardship Volunteer**, NY Coastal Marine Resources Center  
  Feb–Apr 2007

**OTHER WORK EXPERIENCE**

- **GreenOrder**  
  New York, NY  
  *Analyst, Senior Analyst: Corporate Environmental Strategy & Governance*  
  Sep 2006–Oct 2009

  - Conducted environmental performance analysis for products in energy, transportation, and water sectors
  - Created green product metrics system R&D stage-gating system for construction products manufacturer
  - Managed engagement with equipment rental company to identify growth opportunities in green building
  - Performed market and competitive analyses for a wide array of clients in retail, real estate financial and cleantech sectors; prepared and delivered client presentations; managed projects
  - Managed analysts performing environmental product certifications and market research
  - Developed firm seminar series and analyst training materials; conducted trainings on topics including auditing, statistical analysis, and environmental performance benchmarking
  - Audited certifications for environmental products and facility performance

- **Wal-Mart**  
  Providence, RI  
  *Contract Researcher/Consultant: Energy Efficient Products Initiative*  
  May–Sep 2006

  - Developed forecasting model for sales of energy-efficient lamps at Wal-Mart stores
  - Created guidelines for design of lamp recycling program
Brown University Facilities Management  Providence, RI  
- Developed energy-use and financial projections for university energy usage scenarios  
- Performed background research and feasibility analysis for university energy efficiency projects  
- Provided tutoring, logistical support and web design for two courses in sustainable design  
- Responsible for maintenance of energy efficient, low-impact building

Hovsgol Lake Global Environmental Facility and Brown University  Mongolia + Providence, RI  
Advisor: Clyde Goulden  
- Independent research on climate-land use interactions on permafrost soil carbon storage  
- Plant surveys, soil pit excavation, soil physical and chemical analysis, soil microbial process incubations

Marine Biological Laboratory Ecosystems Center  Woods Hole, MA  
Semester in Environmental Science Student  Aug-Dec 2004  
Advisor: Charles Hopkinson  
- Examined effects of nitrogen pollution on structure of microplankton food webs  
- Microcosm experiments, fluorescence microscopy, dissolved nutrient analysis, planktonic growth incubations

Brown Center for Environmental Studies  Providence, RI  
Undergraduate Research Fellow  Jun-Aug 2003  
Advisor: Steven Hamburg  
- Conducted research in biogeochemistry at Hubbard Brook Experimental Forest and surrounding region; oversaw soil pit excavation by undergraduate and graduate field crew  
- Plant surveys, forest floor measurements, litter collection, soil pit excavation, soil physical and chemical analysis, GIS analysis in ESRI ArcMap

PUBLICATIONS IN POPULAR PRESS

  http://en.wikipedia.org/wiki/Extinction_debt
- “If Everyone Moves to the City, What Gets Left Behind?” Good.is, January 17, 2011.  
  http://www.good.is/post/if-everyone-moves-to-the-city-what-is-left-behind/
  http://www.greenbiz.com/blog/2009/06/03/why-ethanol-debate-isnt-helping-anyone
  http://blogs.hbr.org/2008/10/4-lean-green-strategies-for-an/
  http://www.greenbiz.com/blog/2007/03/05/what-silent-spring-means-business-risk
E. IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?
Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?
NOTHING TO REPORT

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?
Not Applicable

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

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<thead>
<tr>
<th>Dollar Amount</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>211699</td>
<td>CHINA</td>
</tr>
</tbody>
</table>
## F. CHANGES

### F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE
Not Applicable

### F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM
NOTHING TO REPORT

### F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

#### F.3.a Human Subjects
No Change

#### F.3.b Vertebrate Animals
No Change

#### F.3.c Biohazards
No Change

#### F.3.d Select Agents
No Change
G. SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS
NOTHING TO REPORT

G.2 RESPONSIBLE CONDUCT OF RESEARCH
Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS
Not Applicable

G.4 HUMAN SUBJECTS
G.4.a Does the project involve human subjects?
Yes
Is the research exempt from Federal regulations?
No
Does this project involve a clinical trial?
No

G.4.b Inclusion Enrollment Data
Report Attached: Understanding the Risk of Bat Coronavirus Emergence-PROTOCOL-001

G.4.c ClinicalTrials.gov
Does this project include one or more applicable clinical trials that must be registered in ClinicalTrials.gov under FDAAA?
No

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT
Are there personnel on this project who are newly involved in the design or conduct of human subjects research?
No

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)
Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?
No

G.7 VERTEBRATE ANIMALS
Does this project involve vertebrate animals?
Yes

G.8 PROJECT/PERFORMANCE SITES

<table>
<thead>
<tr>
<th>Organization Name</th>
<th>DUNS</th>
<th>Congressional</th>
<th>Address</th>
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RPPR
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<th>077090066</th>
<th>NY-010</th>
<th>460 West 34th Street 17th Floor New York NY 100012317</th>
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<td>529027474</td>
<td></td>
<td>Xiao Hong Shan, No. 44 Wuchang District Wuhan</td>
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<tr>
<td>East China Normal University</td>
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<td></td>
<td>3663 Zhongshan Bei Lu Shanghai</td>
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<tr>
<td>East China Normal University</td>
<td>420945495</td>
<td></td>
<td>3663 Zhongshan Bei Lu Shanghai</td>
</tr>
</tbody>
</table>

G.9 FOREIGN COMPONENT

**Organization Name:** Wuhan Institute of Virology  
**Country:** CHINA  
**Description of Foreign Component:** Principal Laboratory for all Research in China as per section G8 (above) and detailed in our Specific Aims

**Organization Name:** East China Normal University  
**Country:** CHINA  
**Description of Foreign Component:** Principal Coordinating Team for all project field work as per section G8 (above) and detailed in our Specific Aims

G.10 ESTIMATED UNOBLIGATED BALANCE

G.10.a Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year's total approved budget?

No

G.11 PROGRAM INCOME

Is program income anticipated during the next budget period?

No

G.12 F&A COSTS

Is there a change in performance sites that will affect F&A costs?

No
### Planned Enrollment

**Planned Enrollment Total:** 2,460

**NOTE:** Planned enrollment data exists in the previous format; the PD/PI did not enter the planned enrollment information in the modified format and was not required to do so. Only the total can be provided.

### Cumulative Enrollment

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<th>Racial Categories</th>
<th>Ethnic Categories</th>
<th>Total</th>
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</thead>
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<td>Not Hispanic or Latino</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Female</td>
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<td>157</td>
<td>108</td>
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<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
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<td>0</td>
</tr>
<tr>
<td>Black or African American</td>
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<td>0</td>
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<tr>
<td>White</td>
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<tr>
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[FYDIBOHF23SPDLT]/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E82796-LA UERM]

Sent: 5/16/2021 1:53:29 AM
To: Tabak, Lawrence (NIH/OD) [E] /O=ExchangeLabs/ou=Exchange Administrat ive Group
[FYDIBOHF23SPDLT]/cn=Recipients/cn=02e22836b5ff4e9988e3770cfcf7ee770-tabakl]; Myles, Renate (NIH/OD) [E] /O=ExchangeLabs/ou=Exchange Administrative Group
[FYDIBOHF23SPDLT]/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]

CC: Aklin, Courtney (NIH/OD) [E] /O=ExchangeLabs/ou=Exchange Administrator Group
[FYDIBOHF23SPDLT]/cn=Recipients/cn=c77a5e163144bb8abe376bc81d01065-cferrel]; Burklow, John (NIH/OD) [E] /O=ExchangeLabs/ou=Exchange Administrative Group
[FYDIBOHF23SPDLT]/cn=Recipients/cn=2e57f267323b43c08be856acb5b964aca-burklowj]; Lauer, Michael (NIH/OD) [E] /O=ExchangeLabs/ou=Exchange Administrative Group
[FYDIBOHF23SPDLT]/cn=Recipients/cn=90fe9cae30c64c7fbb67abd568e82796-lauerm]

Subject: Re: Please read: time sensitive
Attachments: Re: Sarah will get a draft of edits circulated; Re: Please read: time sensitive

Taking out FC, ASF, and NIAID. 

Thanks, Mike

They have since sent me their version attached. We may have to get on a call with them tomorrow or Monday.

Larry

From: Anthony Fauci <(b)(6)>
Date: Saturday, May 15, 2021 at 9:32 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <(b)(6)>, "Myles, Renate (NIH/OD) [E]" <(b)(6)>, "Collins, Francis (NIH/OD) [E]" <(b)(6)>, "Lauer, Michael (NIH/OD) [E]" <(b)(6), "Burklow, John (NIH/OD) [E]" <(b)(6), "Billet, Courtney (NIH/NIAID) [E]" <(b)(6), "Francis, Larry, et al:"

Subject: RE: Please read: time sensitive
I have rearranged it in the attached document. Please let me know what you think.

Thanks,
Tony

From: Tabak, Lawrence (NIH/OD) [E] <(b)(5)
Sent: Saturday, May 15, 2021 9:00 PM
To: Myles, Renate (NIH/OD) [E] <(b)(5)
Collins, Francis (NIH/OD) [E] <(b)(5)
Fauci, Anthony (NIH/NIAID) [E] <(b)(6)
Lauer, Michael (NIH/OD) [E] <(b)(6)
Cc: Aklín, Courtney (NIH/OD) [E] <(b)(6)
Burklow, John (NIH/OD) [E] <(b)(6)
Billet, Courtney (NIH/NIAID) [E] <(b)(6)
Subject: Re: Please read: time sensitive

Francis, Tony – (+Mike)
Please let me know what you think. Stephen wants this looped back through him.
Larry

From: "Myles, Renate (NIH/OD) [E]" <(b)(6)
Date: Saturday, May 15, 2021 at 8:20 PM
To: Francis Collins <(b)(6)
Tabak, Lawrence (NIH/OD) [E]" <(b)(6)
Anthony Fauci <(b)(6)
Cc: "Aklín, Courtney (NIH/OD) [E]" <(b)(6)
Burklow, John (NIH/OD) [E]" <(b)(6)
"Billet, Courtney (NIH/NIAID) [E]" <(b)(6)
Subject: RE: Please read: time sensitive

Hi all:

Attached is a proposed revised statement. Note that I inserted the new language at the top, which is untracked, but also suggest some areas that we could cut, which are tracked. The digital media kit provides the full background, which we will point to from the statement, so not sure it’s worth diluting the primary messages with that information. I’ve also attached a clean version. Let me know what you think.

Thanks,
Renate

From: Myles, Renate (NIH/OD) [E] <(b)(6)
Sent: Saturday, May 15, 2021 7:06 PM
To: Tabak, Lawrence (NIH/OD) [E] <(b)(6)
Cc: Collins, Francis (NIH/OD) [E] <(b)(6)
Fauci, Anthony (NIH/NIAID) [E] <(b)(6)
Aklín, Courtney (NIH/OD) [E] <(b)(6)
Burklow, John (NIH/OD) [E] <(b)(6)
Subject: Re: Please read: time sensitive

Got it.

From: Tabak, Lawrence (NIH/OD) [E] <(b)(6)
Sent: Saturday, May 15, 2021 6:58:56 PM
To: Myles, Renate (NIH/OD) [E] <(b)(6)
Cc: Collins, Francis (NIH/OD) [E] <(b)(6)
Fauci, Anthony (NIH/NIAID) [E] <(b)(6)
On May 15, 2021, at 6:41 PM, Myles, Renate (NIH/OD) [E] wrote:

Hi all:

Just so I’m clear, [b]Let me know if that’s your assessment as well and I can recraft.[/b]

Thanks,
Renate

Fair enough. Renate and John, let me know what help you need to do this reframing.

Francis

Just spoke with Stephen (this is our new HHS Counselor)

If you want to get us all on the phone today or tomorrow, please let me know. Stephen indicated he would be willing to facilitate this.
Larry
Just received the signed letter. It will be mailed Monday but our team will share electronically today.

Alison Schaeffer, M.S. (she/her)
Deputy Chief of Staff
Office of Global Affairs
U.S. Department of Health & Human Services
Main: (b) (b) Direct: (b) (b) Mobile: (b) (b)

Bill:

Here are the NSC press points for us to use.

Mara

(U) PRESS POINTS – cleared as of APR 28

- Since the release of the Phase 1 WHO-led study report into the origins of COVID-19, U.S. government scientists and experts have continued to evaluate it, to provide an independent technical assessment of the evidence provided, including what further studies would be critical in determining the source of the virus.

- In the U.S.-led joint statement issued by a cross-regional coalition of 13 other countries, we urged the WHO to commence phase 2 without further delay, in
a way that is transparent, expert-led, science-based, and free from interference.

- It is a completely normal scientific process—in the middle of an ongoing pandemic no less—to have experts review emerging data and information, and discuss openly the optimal studies for better understanding the origins of the pandemic.

- To that end, the United States stands ready to collaborate with the WHO and other Member States on key elements that would strengthen experts’ ability to determine the origins of the virus as they embark on Phase 2 of the study.

Mara M. Burr, JD, LL.M
Director, Multilateral Relations
Office of the Secretary
Office of Global Affairs
U.S. Department of Health and Human Services

From: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov> (b) (6)
Sent: Friday, May 7, 2021 9:52 AM
To: Burr, Mara (HHS/OS/OGA) <mara.burr@hhs.gov> (b) (6) Sams, Ian (HHS/ASPA) <ian.sams@hhs.gov> (b) (6) Mciff, Colin (HHS/OS/OGA) <colin.mciff@hhs.gov> (b) (6)
Cc: Despres, Sarah (HHS/IOS) <sarah.despres@hhs.gov> (b) (6) Schaeffer, Alison (HHS/OS/OGA) <alison.schaeffer@hhs.gov> (b) (6) Cha, Stephen (HHS/IOS) <stephen.cha@hhs.gov> (b) (6)
Subject: RE: WHO letter transmitting HHS recommendations

Yes, we should have a reactive statement. Do we know if the GVA Mission PA shop is looped in, as they would also get media inquiries. I can connect with them when the time is right.

From: Burr, Mara (HHS/OS/OGA) <mara.burr@hhs.gov> (b) (6)
Sent: Friday, May 7, 2021 9:48 AM
To: Sams, Ian (HHS/ASPA) <ian.sams@hhs.gov> (b) (6) Mciff, Colin (HHS/OS/OGA) <colin.mciff@hhs.gov> (b) (6)
Cc: Despres, Sarah (HHS/IOS) <sarah.despres@hhs.gov> (b) (6) Schaeffer, Alison (HHS/OS/OGA) <alison.schaeffer@hhs.gov> (b) (6) Cha, Stephen (HHS/IOS) <stephen.cha@hhs.gov> (b) (6) Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov> (b) (6)
Subject: RE: WHO letter transmitting HHS recommendations

Ian:

We will put together a draft statement for you to use if you get any questions on the origins letter or recommendations.
Once Secretary Becerra signs the letter, OGA will transmit it and the recommendations to Mission GVA to officially transmit it to Dr. Tedros.

I hope this is helpful.

Mara

Mara M. Burr, JD, LL.M
Director, Multilateral Relations
Office of the Secretary
Office of Global Affairs
U.S. Department of Health and Human Services
Telephone: (b)(6)
Mobile: (b)(6)

From: Sams, Ian (HHS/ASPA) <(b)(6)>
Sent: Friday, May 7, 2021 9:13 AM
To: Burr, Mara (HHS/OS/OGA) <(b)(6)>
Mciff, Colin (HHS/OS/OGA) <(b)(6)>
<Coli (b)(6)>
Cc: Despres, Sarah (HHS/IOS) <(b)(6)>
Schaeffer, Alison (HHS/OS/OGA) <(b)(6)>
Cha, Stephen (HHS/IOS) <(b)(6)>
Hall, Bill (HHS/ASPA) <(b)(6)>
Subject: RE: WHO letter transmitting HHS recommendations

(b)(5) Just mainly looking for:
1. What is the timeline this will be sent to WHO?
2. Do we have a reactive statement prepared if asked about this?

Thank you!

From: Burr, Mara (HHS/OS/OGA) <(b)(6)>
Sent: Friday, May 7, 2021 9:11 AM
To: Mciff, Colin (HHS/OS/OGA) <Coli (b)(6)>
Cc: Sams, Ian (HHS/ASPA) <(b)(6)>
Despres, Sarah (HHS/IOS) <(b)(6)>
Schaeffer, Alison (HHS/OS/OGA) <(b)(6)>
Cha, Stephen (HHS/IOS) <(b)(6)>
Hall, Bill (HHS/ASPA) <(b)(6)>
Subject: Re: WHO letter transmitting HHS recommendations

We can discuss.

Sent from my iPhone

On May 7, 2021, at 9:09 AM, Mciff, Colin (HHS/OS/OGA) <(b)(6)>
wrote:

(b)(5)

Best,
From: Sams, Ian (HHS/ASPA) <b>(6)</b>
Sent: Friday, May 7, 2021 9:07 AM
To: Despres, Sarah (HHS/IOS) <b>(6)
Mciff, Colin (HHS/OS/OGA) <b>(6)
Schaeffer, Alison (HHS/OS/OGA) <b>(6)
Cha, Stephen (HHS/IOS) <b>(6)
Hall, Bill (HHS/ASPA) <b>(6)

Subject: RE: WHO letter transmitting HHS recommendations

+ Bill too

From: Despres, Sarah (HHS/IOS) <b>(6)
Sent: Friday, May 7, 2021 9:06 AM
To: Mciff, Colin (HHS/OS/OGA) <b>(6)
Schaeffer, Alison (HHS/OS/OGA) <b>(6)
Sams, Ian (HHS/ASPA) <b>(6)
Cha, Stephen (HHS/IOS) <b>(6)

Subject: WHO letter transmitting HHS recommendations

Colin and Alison,

I should have asked this two days ago... I'm cc'ing Ian Sams with ASPA and also Steve Cha, the new public health counselor who will be working with FDA, NIH and AHRQ. This is an issue that Congress is also interested in, particularly as it relates to NIH research.

Thank you!
Sarah
Love it. Maybe add in somewhere:

Sent from my iPhone

On May 15, 2021, at 9:05 PM, Lovenheim, Sarah (HHS/ASPA) <b>(6)

wrote:

This is my recommendation <b>(5)

Sent from my iPhone

---Original Message---
From: Cha, Stephen (HHS/IOS) <b>(6)
Sent: Saturday, May 15, 2021 7:35 PM
To: Tabak, Lawrence (NIH/OD) [E] <b>(6)
Cc: Lovenheim, Sarah (HHS/ASPA) <b>(6)
Subject: Sarah will get a draft of edits circulated

Putting us all in a chain. Add Mike when you think makes sense
**A. COVER PAGE**

**Project Title:** Understanding the Risk of Bat Coronavirus Emergence

<table>
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<tr>
<th>Grant Number: 5R01AI110864-03</th>
<th>Project/Grant Period: 06/01/2014 - 05/31/2019</th>
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<th>Requested Budget Period: 06/01/2016 - 05/31/2017</th>
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<table>
<thead>
<tr>
<th>Report Term Frequency: Annual</th>
<th>Date Submitted: 05/13/2016</th>
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</table>

**Program Director/Principal Investigator Information:**

- PETER DASZAK, BS PHD
- **Phone number:** (b) (6)
- **Email:** (b) (6)

**Recipient Organization:**

- ECOHEALTH ALLIANCE, INC.
- 460 W 34TH ST
- 17TH FLOOR
- NEW YORK, NY 100012320
- **DUNS:** 077090066
- **EIN:** 1311726494A1

**Change of Contact PD/PI:** N/A

**Administrative Official:**

- ALEKSEI CHMURA
- 460 W 34th St., 17th Floor
- New York, NY 10001
- **Phone number:** (b) (6)
- **Email:** (b) (6)

**Signing Official:**

- ALEKSEI CHMURA
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**Human Subjects:** Yes

**HS Exempt:** No

**Exemption Number:**

**Phase III Clinical Trial:**

**Vertebrate Animals:** Yes

**hESC:** No

**Inventions/Patents:** No
B. ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

Zoonotic coronaviruses are a significant threat to global health, as demonstrated with the emergence of severe acute respiratory syndrome coronavirus (SARS-CoV) in 2002, and the recent emergence Middle East Respiratory Syndrome (MERS-CoV). The wildlife reservoirs of SARS-CoV were identified by our group as bat species, and since then hundreds of novel bat-CoVs have been discovered (including >260 by our group). These, and other wildlife species, are hunted, traded, butchered and consumed across Asia, creating a largescale human-wildlife interface, and high risk of future emergence of novel CoVs.

To understand the risk of zoonotic CoV emergence, we propose to examine 1) the transmission dynamics of bat-CoVs across the human-wildlife interface, and 2) how this process is affected by CoV evolutionary potential, and how it might force CoV evolution. We will assess the nature and frequency of contact among animals and people in two critical human-animal interfaces: live animal markets in China and people who are highly exposed to bats in rural China. In the markets we hypothesize that viral emergence may be accelerated by heightened mixing of host species leading to viral evolution, and high potential for contact with humans. In this study, we propose three specific aims and will screen free ranging and captive bats in China for known and novel coronaviruses; screen people who have high occupational exposure to bats and other wildlife; and examine the genetics and receptor binding properties of novel bat-CoVs we have already identified and those we will discover. We will then use ecological and evolutionary analyses and predictive mathematical models to examine the risk of future bat-CoV spillover to humans. This work will follow 3 specific aims:

Specific Aim 1: Assessment of CoV spillover potential at high risk human-wildlife interfaces. We will examine if: 1) wildlife markets in China provide enhanced capacity for bat-CoVs to infect other hosts, either via evolutionary adaptation or recombination; 2) the import of animals from throughout Southeast Asia introduces a higher genetic diversity of mammalian CoVs in market systems compared to within intact ecosystems of China and Southeast Asia; We will interview people about the nature and frequency of contact with bats and other wildlife; collect blood samples from people highly exposed to wildlife; and collect a full range of clinical samples from bats and other mammals in the wild and in wetmarkets; and screen these for CoVs using serological and molecular assays.

Specific Aim 2: Receptor evolution, host range and predictive modeling of bat-CoV emergence risk. We propose two competing hypotheses: 1) CoV host-range in bats and other mammals is limited by the phylogenetic relatedness of bats and evolutionary conservation of CoV receptors; 2) CoV host-range is limited by geographic and ecological opportunity for contact between species so that the wildlife trade disrupts the ‘natural’ co-phylogeny, facilitates spillover and promotes viral evolution. We will develop CoV phylogenies from sequence data collected previously by our group, and in the proposed study, as well as from Genbank. We will examine co-evolutionary congruence of bat-CoVs and their hosts using both functional (receptor) and neutral genes. We will predict host-range in unsampled species using a generalizable model of host and viral ecological and phylogenetic traits to explain patterns of viral sharing between species. We will test for positive selection in market vs. wild-sampled viruses, and use data to parameterize mathematical models that predict CoV evolutionary and transmission dynamics. We will then examine scenarios of how CoVs with different transmissibility would likely emerge in wildlife markets.

Specific Aim 3: Testing predictions of CoV inter-species transmission. We will test our models of host range (i.e. emergence potential) experimentally using reverse genetics, pseudovirus and receptor binding assays, and virus infection experiments in cell culture and humanized mice. With bat-CoVs that we’ve isolated or sequenced, and using live virus or pseudovirus infection in cells of different origin or expressing different receptor molecules, we will assess potential for each isolated virus and those with receptor binding site sequence, to spill over. We will do this by sequencing the spike (or other receptor binding/fusion) protein genes from all our bat-CoVs, creating mutants to identify how significantly each would need to evolve to use ACE2, CD26/DPP4 (MERS-CoV receptor) or other potential CoV receptors. We will then use receptor-mutant pseudovirus binding assays, in vitro studies in bat, primate, human and other species’ cell lines, and with humanized mice where particularly interesting viruses are identified phylogenetically, or isolated. These tests will provide public health-relevant data, and also iteratively improve our predictive model to better target bat species and CoVs during our field studies to obtain bat-CoV strains of the greatest interest for understanding the mechanisms of cross-species transmission.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

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B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

For this reporting period, is there one or more Revision/Supplement associated with this award for which reporting is required?

No

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

File uploaded: Year 2 NIAID CoV Report Professional Development.pdf
B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

1) Conference and University lectures: PI Daszak, and Co-investigators Shi, Epstein, Olival, Ge, and Zhang gave >100 invited University and Conference lectures including Forum on Microbial Threats (National Academies of Science), Symposium at Ecole du Val-de-Grâce in Paris, Leadership Roundtable at Concordia University Montreal, 1st annual Global Pandemic Policy Summit at Texas A&M Univ., Intl. Conf. of the Wildlife Disease Association in Australia, Intl. Conf. of Conservation Biol in Montpellier France, Michigan State University, Duke University, WDA, ISID conference, Zoological Society of London Symposium, Future Earth meeting, North American Bat Research Symposium, and others that included specific discussion of the current project and results.

2) Agency and other briefings: PI Daszak and Research Technician Dr. Guangjian Zhu introduced this project to potential collaborators within the following agencies: Forestry Dept of Peoples Republic of China, FAO, TNC, TRAFFIC, China CDC, and TA Foundation in Beijing China in meetings (2015) and also at presentations at the first Wildlife and Public Health Workshop in China (2016) co-hosted by EcoHealth Alliance, the State Forestry Administration of China, and China CDC.

3) Public outreach: PI Daszak presented this work to members of the NIH, NSF, DoD, IUCN, EPA, and the general public, at an EcoHealth Alliance meeting hosted by the Cosmos Club, Washington D.C. (2015); PI Daszak and Co-investigator Zhu reported on this project at a Wildlife Trade and Public Health Seminar, Budapest (2016); PI Daszak introduced this project in a lecture on Pandemics at a New York Academy of Science Panel (2016); Co-PI Y-Z Zhang presented project and results-to-date to department heads and senior researchers at Infectious Disease Departments of four Yunnan Hospitals (2015)

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

Specific Aim 1: Assessment of CoV spillover potential at high risk human-wildlife interfaces.

- Given the reduced amount of wildlife in the local markets within Southern China, and the continued expansion of the Chinese wildlife trade within SE Asia, we would like to conduct short field trips to assess markets, identify wildlife in them, and sample species of bats and other high-risk hosts in countries that neighbor China (Myanmar, Vietnam, Cambodia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia). EcoHealth Alliance has other activities in these countries which would provide leverage to reduce costs of fieldwork, and samples would be tested in Wuhan, China.

- Following the successful collection of ethnographic interviews and focus groups in Year 2, we will be analyzing the qualitative data collection from Years 1 and 2.

- Finalize and conduct survey collection tool for a network study of wildlife farmers using a questionnaire to characterize and map the wildlife value chain.

- After the success of our pilot studies in Year 2, we will continue targeted (at individuals with high risk of exposure to bats), integrated behavioral and biological survey work in Yunnan and expand to Guangxi and Guangdong provinces.

- We will commence our anonymized, surveillance data collection from acutely ill hospital in-patients who satisfy syndromic eligibility criteria; have complete medical records; non-normative laboratory confirmed diagnostic results; and suspected acute viral infection. Eligibility criteria are: (a) suspected acute viral infection; (b) fever > 38°C, and (c) presenting symptoms of at least one of the following:
  • Encephalitis of unknown origin
  • Hemorrhagic fever of unknown origin
  • Respiratory disease
  • Influenza-like illness (ILI)
  • Severe Acute Respiratory like Illness (SARI)
  • Rash
  • Diarrhea

Some patients with particular infections such as with HIV, HCV, and HBV, may be excluded from the study on that basis. Hospital surveillance has the advantage of monitoring an acutely ill population. Anonymized, passive hospital surveillance allows for data collection and viral testing from all eligible hospital patients thereby limiting population sample bias and increasing the likelihood of identifying positive cases. The strengths of this approach are numerous: an unbiased patient population; prospectively collected, anonymized patient data; a low resource effort with a high efficiency design; and impactful research potential for both case series and case control studies. We have already secured approval from the Institutional Review Board of the Wuhan School of Public Health and Hummingbird IRB.

Specific Aim 2: Receptor evolution, host range and predictive modeling of bat-CoV emergence risk. Future steps to optimize the model of role of species diversity in CoV emergence risk will include:

- Test and implement our respondent-driven survey to collect specific data on the diversity, abundance, and turnover of species along the wildlife trade network in south China.

- Model viral mixing across the full range parameters found along the wildlife trade network to identify the trade nodes with highest mixing potential. This will include a network analysis of market facility/site connectivity including wild harvest sites, wildlife farming operations, transit holding facilities, and small and large wildlife markets.

- Phylogeographic study of bat-CoV to better understand the geographic distribution and evolution of bat-CoV genetic diversity in south
China.

- Phylogeographic study of bat host (Rhinolophus) species to assess the connectivity of bat populations and infer their historical movements and demographic history to improve our understanding of CoV transmission among bat populations in southern China. Preliminary sequences data has been generated and will be completed and analyzed.

- Cophylogenetic analyses of bat host and CoV phylogenies to assess frequency of cross-species transmission. Comparison of Alpha- and Beta-CoV cophylogenetic patterns building on Year 2 analyses using published sequences and also including Spike gene and additional sequences obtained in Year 2.

- Test and implement our respondent-driven survey to assess diversity, abundance, and turnover of species along the wildlife trade network.

- Examine co-evolutionary congruence of bat-CoVs and their hosts using both functional (receptor) and neutral genes;

- Parameterize mathematical models that predict CoV evolutionary and transmission dynamics

- Continued surveillances of SARS-like CoVs and lineage C betacoronaviruses (MERS-related CoVs) in Southern China;

- Full-length genome sequencing and evolution analysis of SARS-like coronaviruses identified from different bat species and different geographical locations across China;

- Full-length genome sequencing and evolution analysis of Lineage C betacoronaviruses identified from different bat species and different geographical locations across China;

- Full-length genome sequencing and evolution analysis of HKU9-related and HKU10-related bat coronaviruses in China;

Specific Aim 3: Testing predictions of CoV inter-species transmission. The following experiments will be undertaken in Year 2:

- Humanized mice with human ACE2 receptors will be infected with WIV1 and the two rescued chimeric SARS-like coronaviruses to determine the tissue tropism and pathogenicity of bat SL-CoV

- Isolation of novel bat coronaviruses. Live virus or pseudovirus will be used to infect cells of different origin or expressing different receptor molecules. Spillover potential for each isolated virus will be assessed.

- An infectious clone of full-length MERS-CoV will be constructed using reverse genetic method. Using the S sequence of different MERS-related viruses identified from Chinese bats, the chimeric viruses with S gene of bat MERS-related coronaviruses and backbone of the infectious clone of MERS-CoV will be constructed to study the receptor usage and infectivity of bat MERS-related coronavirus.

- Surveillance of infection in human populations by SARS-like CoVs. This work will be performed at locations in Yunnan, Guangxi, and Guangdong provinces, in previously identified areas with human populations of high risk of exposure to bats. PCR and ELISA will be used, respectively, for detection of viral replicase gene and antibodies against the viral nucleocapsid protein.
**Year 1 Report:** Understanding the Risk of Bat Coronavirus Emergence

**Award Number:** 1R01AI110964-02

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**Section B: Accomplishments**

**B.1 What are the Major Goals of the Project**

Zoonotic coronaviruses are a significant threat to global health, as demonstrated with the emergence of severe acute respiratory syndrome coronavirus (SARS-CoV) in 2002, and the recent emergence Middle East Respiratory Syndrome (MERS-CoV). The wildlife reservoirs of SARS-CoV were identified by our group as bat species, and since then hundreds of novel bat-CoVs have been discovered (including >260 by our group). These, and other wildlife species, are hunted, traded, butchered and consumed across Asia, creating a large-scale human-wildlife interface, and high risk of future emergence of novel CoVs. To understand the risk of zoonotic CoV emergence, we propose to examine 1) the transmission dynamics of bat-CoVs across the human-wildlife interface, and 2) how this process is affected by CoV evolutionary potential, and how it might force CoV evolution. We will assess the nature and frequency of contact among animals and people in two critical human-animal interfaces: live animal markets in China and people who are highly exposed to bats in rural China. In the markets we hypothesize that viral emergence may be accelerated by heightened mixing of host species leading to viral evolution, and high potential for contact with humans. In this study, we propose three specific aims and will screen free-ranging and captive bats in China for known and novel coronaviruses; screen people who have high occupational exposure to bats and other wildlife; and examine the genetics and receptor binding properties of novel bat-CoVs we have already identified and those we will discover. We will then use ecological and evolutionary analyses and predictive mathematical models to examine the risk of future bat-CoV spillover to humans. This work will follow 3 specific aims:

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B.1a Have the major goals changed since the initial competing award or previous report? No.

B.2 What was accomplished under these goals?

Specific Aim 1: Assessment of CoV spillover potential at high risk human-wildlife interfaces

In year 2, we continued and expanded the qualitative research begun at the end of Year 1. In addition, a community based integrated biological behavioral surveillance system was developed and pilot tested to identify specific animal exposure risk factors associated with biological evidence of exposure to SARS-like CoV (i.e., seropositive status).

QUALITATIVE RESEARCH

Targeted, in-depth ethnographic interviews were conducted with 47 individuals (18 women; 29 men) in rural Southern China where wildlife trade routes have been documented. Yunnan, Guangxi and Guangdong provinces were specifically selected for study because they have large wildlife populations, a diversity of wildlife species and numerous live animal markets. Individuals who were 18 years of age or older and who were able to provide informed consent were eligible to participate. Twenty-three (49%) in-depth interviews were conducted in Yunnan province at nine different sites, 24 (51%) in Guangxi province at six different sites. In addition, one focus group was conducted in Guangxi. The study was approved by the Institutional Review Boards of the Wuhan School of Public Health and Hummingbird IRB.

Recruitment sites in each province included forested areas or preserves, wildlife farms, hunting areas, wildlife restaurants, live animal markets, caves where people dwell or collect guano and residential areas/farms near known bat caves or roosts. Participants were recruited primarily through local contacts developed as part of wildlife conservation and health research conducted by team members over the past decade. Contacts including wildlife conservationists and researchers, local government health outreach workers and wildlife farmers facilitated introductions and provided referrals. To achieve a sample with sufficient representation of categories of interest, participants were recruited using
purposive sampling, which provides minimum quotas in terms of sex, age and wildlife exposure setting (e.g., live animal market, forest preserve).

The five core themes that guided the in-depth discussions are: 1) human-animal contact, 2) unusual illness experience and response, 3) socioeconomics and daily living, 4) biosafety and 5) human environments and movement/travel. An ethnographic interview guide was developed with examples of questions that could be asked for each theme. In addition, field based participant-observation was ongoing throughout the study and involved observing and talking informally with people in their own natural setting. Field notes were maintained of these ongoing observations and discussions.

Table 1: Species Observed in Wetmarkets in Guangdong Province from 2015 - 2016

<table>
<thead>
<tr>
<th>Genus species</th>
<th>Common Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prionailurus bengalensis</td>
<td>Leopard Cat</td>
</tr>
<tr>
<td>Nyctereutes procyonoides</td>
<td>Raccoon Dog</td>
</tr>
<tr>
<td>Sus scrofa</td>
<td>Wild Boar</td>
</tr>
<tr>
<td>Lepus sinensis</td>
<td>Chinese Hare</td>
</tr>
<tr>
<td>Arctonyx collaris</td>
<td>Hog Badger</td>
</tr>
<tr>
<td>Hystrix brachyura</td>
<td>Porcupine</td>
</tr>
<tr>
<td>Marmota sp.</td>
<td>Marmot</td>
</tr>
<tr>
<td>Rhabdomys sinensis</td>
<td>Bamboo Rat</td>
</tr>
<tr>
<td>Erinaceus sp.</td>
<td>Hedgehog</td>
</tr>
<tr>
<td>Mustela putorius</td>
<td>Ferrets</td>
</tr>
<tr>
<td>Muridae</td>
<td>Rat (species unknown)</td>
</tr>
<tr>
<td>Myocastor coypus</td>
<td>Nutria</td>
</tr>
<tr>
<td>Vulpes sp.</td>
<td>Fox</td>
</tr>
<tr>
<td>Mustela sibirica</td>
<td>Siberian weasel</td>
</tr>
<tr>
<td>Paguma larvata</td>
<td>Masked Palm Civet</td>
</tr>
<tr>
<td>Felis catus</td>
<td>Domestic Cat</td>
</tr>
<tr>
<td>Canis lupus familiaris</td>
<td>Domestic Dog</td>
</tr>
<tr>
<td>Cervinae</td>
<td>Sambar Deer</td>
</tr>
<tr>
<td>Ovis aries</td>
<td>Sheep</td>
</tr>
<tr>
<td>Capra sp.</td>
<td>Domestic Goat</td>
</tr>
<tr>
<td>Rattus norvegicus</td>
<td>Common Rat</td>
</tr>
</tbody>
</table>

Interviews were conducted between March and June 2105 by 10 trained interviewers, none of whom had social science training. Interviewers conducted between one and 22 interviews; three interviewers conducted two thirds of all interviewers. Interviews lasted between 20 and 60 minutes, and were tape-recorded and transcribed verbatim before they were translated into English. All participants received cooking oil valued at US$10 in appreciation of their time.

The data are currently being coded and an analytic database is being constructed. Initial insights include observations by a number of participants, especially those who are older, that there has been a decrease in wildlife in the surrounding environment. This decrease is attributed to many factors including infrastructure development. The government has invested resources to build new roads and renovate local infrastructure with the intention of increasing tourism. This has reduced forested area.

Observations by research staff in live animal markets in Guangzhou found wildlife to be plentiful (see Table 1), although no bats were seen for sale during the observation period.

In contrast, wildlife was not found in live animal markets at the sites we visited in either Yunnan or Guangxi. This is a change from previous research visits to the same or similar communities, when bats, rodents and wild boar could be found. Locals in Yunnan and Guangxi attribute the change to conservation law enforcement. The success of conservation enforcement may have moved hunting and trapping underground and made the capture of local wildlife less economically feasible than other income generating activities.
Preliminary analyses are underway. Three specific studies in support of Specific Aim 1 are being developed: the changing wildlife trade in Southern China, the economics of wildlife farming, and zoonotic disease risks resulting from a rapidly changing wildlife trade.

INTEGRATED BIOLOGICAL BEHAVIORAL SURVEILLANCE PILOT STUDY
Currently, mechanisms of zoonotic viral spillover are unknown. In order to evaluate potential risk factors, it is necessary to measure both exposure and outcome data. Therefore, a behavioral risk survey was developed that assessed both animal exposure and experiences of unusual illness both during lifetime and in the past 12 months. In addition, participants were requested to provide serum to test for previous exposure to SARS-like CoV. The integrated surveillance was pilot tested in October 2015 among residents living near bat caves or roosts where SARS-like-CoV has been previously detected in the bat population in Jinping County, Yunnan. Please view the full survey here:

https://www.dropbox.com/s/sv62nemywul027r/Questionnaire%20Complete.docx?dl=0

Of 218 participants, 139 (64%) were women and 79 (36%) were men, with a mean age of 48 (range: 12-80). Most reported being farmers (87%, and see chart to left); a majority were long term residents (97%). Animal exposures in the past year were extensive, including general (e.g., buying live animals at markets [61%]) and intimate (e.g., being scratched or bitten [9%], slaughter [38%]). In fact, two-thirds of participants reported handling recently killed animal parts and 2 out of 5 reported slaughtering animals. Only 20 (9%) participants reported known exposure to bats.

Standardized syndromic case definitions informed questions concerning unusual illness experience (e.g. severe acute respiratory infections [SARI], influenza-like illness [ILI]). Lifetime, 12 month and unusual illness experience in family for the past 12 months were assessed for all participants. In the past year, SARI was reported by 4 (2%) respondents and for 4 additional family members. Table 2 provides data for all unusual illness experience assessed. None of the participants were found to be seropositive for SARS-like CoV.

Table 2. Unusual Illness Experience

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Ever (%)</th>
<th>Past 12 months (%)</th>
<th>Family (12m) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe Acute Respiratory Infections (SARI)</td>
<td>15 (6.9%)</td>
<td>4 (1.8%)</td>
<td>4 (1.8%)</td>
</tr>
<tr>
<td>Influenza Like Illness (ILI)</td>
<td>54 (24.8%)</td>
<td>16 (7.3%)</td>
<td>26 (11.9%)</td>
</tr>
<tr>
<td>Encephalitis</td>
<td>19 (8.7%)</td>
<td>4 (1.8%)</td>
<td>3 (1.4%)</td>
</tr>
<tr>
<td>Hemorrhagic Fever</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Fever with Diarrhea /Vomiting</td>
<td>12 (5.5%)</td>
<td>2 (0.9%)</td>
<td>3 (1.4%)</td>
</tr>
<tr>
<td>Fever with Rash</td>
<td>2 (0.9%)</td>
<td>2 (0.9%)</td>
<td>3 (1.4%)</td>
</tr>
</tbody>
</table>
Although the sample size was small, animal exposures among those who reported unusual illness experiences in the past 12 months were evaluated. Of the four respondents who reported SARI symptoms, 75% reported: raising animals, animals in the home, preparing recently killed animals and buying live animals; 50% reported slaughter. Among the 16 respondents who reported ILL symptoms, 12 (75%) reported handling/preparing recently killed animals, 11 (69%) Handling live animals or having animals in the home, 10 (63%) reported slaughtering/killing animals or buying live animals at wet market, 9 (56%) raised live animals, 7 (44%) reported a pet, and 1 (6%) reported animal feces near food or eating animal touched or damaged food, hunting, or eating raw/undercooked animal products. Finally, among the four respondents who reported encephalitis symptoms, 3 (75%) reported hunting, handling or raising animals, 2 (50%) reported animals in the home, 1 (25%) reported having animals as pets, slaughter/killing animals, or having bought live animals at wet market.

Respondents were asked about the source of their unusual illnesses. None reported any kind of animal exposure as a potential source of infection and most stated they had no idea how they had become infected. However, when asked about potential behavior changes made at live animal markets in the last 12 months, participants reported a great deal of change. In particular, respondents reported buying live animals less often (38%), only buying farmed wildlife (54%) or buying meat at the supermarket (23%). (See Table 3).

**Table 3: Behavior Change at Wet Market in the last 12 months**

<table>
<thead>
<tr>
<th>Behavior</th>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wear a mask</td>
<td>4</td>
<td>(3.0)</td>
</tr>
<tr>
<td>Wear gloves</td>
<td>5</td>
<td>(3.8)</td>
</tr>
<tr>
<td>Wash hands</td>
<td>80</td>
<td>(60.6)</td>
</tr>
<tr>
<td>Sometimes shop for meat at supermarket</td>
<td>30</td>
<td>(22.7)</td>
</tr>
<tr>
<td>Buy live animals less often</td>
<td>50</td>
<td>(37.9)</td>
</tr>
<tr>
<td>Buy only farmed wildlife</td>
<td>71</td>
<td>(53.8)</td>
</tr>
<tr>
<td>No longer buy wildlife at wet market</td>
<td>39</td>
<td>(29.5)</td>
</tr>
</tbody>
</table>

The results of this pilot study conducted with a largely female farmer population found high levels of unusual illness, as well as high levels of exposure to animals. There was a notable lack of knowledge of animals’ ability to transmit infection. Despite this lack of knowledge, there may be a sense of unease about animal exposures, given the fairly dramatic behavior changes reported at live animal markets. The finding of a reduction in wildlife purchase may be due to sensitivity to the legality of wildlife trade, biasing respondents towards not admitting purchasing wildlife. Although, there were no participants seropositive for SARS-like CoV, serological data may add support to the findings from self-reported syndromic surveillance, once serological assays are optimized.

In preparation for full implementation of the integrated biological behavioral surveillance, the survey has been programmed as an application for use on either a mobile device or computer. Electronic data collection will facilitate survey implementation in the field and quality control of the data being collected. Four field team leads were trained on behavioral survey data collection, data collection technologies (the tablet application) and analysis.

Nucleic acid test results of human biological samples

*Testing High-Risk Human Populations for Coronavirus Infection*
Surveillance of CoV infections in human populations by SARS-like CoVs was significantly expanded in Year 2, including both custom-built ELISA serology (an assay developed by the Wuhan Institute of Virology to test antibodies against the N protein of SL-CoV) and PCR detection of viral RNA.

**Serological test for SL-CoV antibodies in human samples from Jinning, Yunnan Province**

In order to assess past exposure to bat CoVs, 223 human sera samples were collected in villages in proximity to the bat habitat from which two SL-CoVs with potential for interspecies infection, WIV1 and WIV16, were discovered in our previous research. An ELISA developed by the Wuhan Institute of Virology was used to test antibodies against the N protein of SL-CoV. A number of human specimens generated high OD values and neutralization test to WIV1 and WIV16 was then performed. These findings are encouraging; however, no neutralization antibodies were detected. In Year 3, we will continue to validate and optimize these ELISA assays and other serological tests to obtain data on past CoV exposure.

**PCR test for CoV Nucleic Acid in human samples from several Provinces**

We tested 405 individual human samples for CoV RNA to identify evidence of active infection in human populations and to obtain sequence data on strain variation. Individual samples (4 each) were pooled prior to nucleic acid extraction then tested using PCR. When a group tested positive, we then conducted the confirmation test in the individual samples. One single sample (14XN611) from someone who had identified as having had a fever and suffered both a cough and headache in the past 7-days was then identified to be positive for HCoV-HKU1. The low number of PCR detections in human specimens is not unexpected, and will be improved in Year 3-5 by better targeting syndromic individuals for specimen collection and continuing to optimize PCR assays. Refined serological assays (above) will provide sufficient data to assess past exposure to specific CoV lineages, and optimizing of PCR detections will allow for more CoV positive human sequences moving forward.

**Specific Aim 2: Receptor evolution, host range and predictive modeling of bat-CoV emergence risk**

**Bat CoV PCR detection and sequencing from live-sampled bat populations**

We collected 1,714 anal swab samples, 677 fecal samples, 53 blood samples, and 38 serum samples from 15 bat genera in Guangdong, Yunnan, Sichuan, Hubei, Hunan, Guizhou, Guangxi provinces (Table 4).

**Table 4 Bat Samples collected for CoV surveillance in 2015**

<table>
<thead>
<tr>
<th>Sample date</th>
<th>Sample location</th>
<th>Anal</th>
<th>Fecal</th>
<th>Blood</th>
<th>Serum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar. 2015</td>
<td>Huidong, Guangdong</td>
<td>69</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Jun. 2015</td>
<td>Guangdong</td>
<td>495</td>
<td>--</td>
<td>12</td>
<td>--</td>
</tr>
<tr>
<td>Apr. 2015</td>
<td>Menglun, Yunnan</td>
<td>51</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>May 2015</td>
<td>Jinning, Yunnan</td>
<td>--</td>
<td>193</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>May. 2015</td>
<td>Mojiang, Yunnan</td>
<td>93</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Oct. 2015</td>
<td>Jinning, Yunnan</td>
<td>30</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>
We tested 2,256 samples for CoV RNA and 280 tested positive. The total positive rate is 12.4% (Table 5). Diverse alphacoronaviruses related to Bat CoV 1A, 1B, HKU2, HKU6, HKU7, HKU8 and HKU10 were identified; SARS-like coronaviruses were detected in *Rhinolophus* bats in both Yunnan and Guangdong (Fig 1). Novel lineage B betacoronaviruses more distantly related to SARS-CoV than other SL-CoVs were detected in *Vespertilio superans* in Sichuan. HKU4-related coronaviruses were found in *Tynolycterus pachypus* in Guangdong and Guangxi while HKU5-related coronaviruses were found to be highly prevalent in *Vespertilio superans* in Zigong, Sichuan (41 bats out of 128 tested positive).
### Table 5  Test result of bat CoV surveillance in 2015 – 12% positive (280/2,256)

<table>
<thead>
<tr>
<th>Bat species</th>
<th>Yunnan</th>
<th>Guangdong</th>
<th>Hubei</th>
<th>Sichuan</th>
<th>Guangxi</th>
<th>Guizhou</th>
<th>Hunan</th>
<th>Total</th>
</tr>
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<tr>
<td><strong>No.positive/No.tested</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td><em>Rhinolophus spp.</em></td>
<td>47/98</td>
<td>12/103</td>
<td></td>
<td></td>
<td>16/225</td>
<td>8/63</td>
<td></td>
<td>83/489</td>
</tr>
<tr>
<td><em>Hipposideros spp.</em></td>
<td>0/35</td>
<td>0/51</td>
<td>26/152</td>
<td></td>
<td>0/131</td>
<td>0/91</td>
<td></td>
<td>26/460</td>
</tr>
<tr>
<td><em>Ia io</em></td>
<td>0/3</td>
<td></td>
<td></td>
<td>0/3</td>
<td></td>
<td>0/3</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Pipistrellus spp.</em></td>
<td>1/1</td>
<td>0/19</td>
<td></td>
<td>0/2</td>
<td>0/4</td>
<td></td>
<td>1/26</td>
<td></td>
</tr>
<tr>
<td><em>Miniopterus spp.</em></td>
<td>6/7</td>
<td>34/83</td>
<td></td>
<td>2/6</td>
<td></td>
<td></td>
<td></td>
<td>42/96</td>
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<td><em>Eonycteris spp.</em></td>
<td>0/3</td>
<td></td>
<td></td>
<td>0/3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Vespertilio superans</em></td>
<td>41/128</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>41/128</td>
</tr>
<tr>
<td><em>Myotis spp.</em></td>
<td>1/38</td>
<td></td>
<td></td>
<td>0/70</td>
<td>0/35</td>
<td>1/143</td>
<td></td>
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<tr>
<td><em>Taphozous spp.</em></td>
<td>0/25</td>
<td></td>
<td></td>
<td>0/1</td>
<td></td>
<td>0/26</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Tynolyceteris pachypus</em></td>
<td>8/25</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>35/216</td>
<td></td>
</tr>
<tr>
<td><em>Scotophilus kuhlii</em></td>
<td>1/1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1/1</td>
</tr>
<tr>
<td><em>Eptesicus fuscus</em></td>
<td>0/1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0/1</td>
</tr>
<tr>
<td><em>Tadrida spp.</em></td>
<td>0/5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0/5</td>
</tr>
<tr>
<td><em>Barbastella</em></td>
<td>0/1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0/1</td>
<td></td>
<td>0/1</td>
</tr>
<tr>
<td><em>Nyctalus velutia</em></td>
<td>0/10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0/10</td>
</tr>
<tr>
<td>Fecal samples</td>
<td>28/468</td>
<td>22/180</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50/648</td>
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<tr>
<td><strong>Sub-total</strong></td>
<td>82/637</td>
<td>56/326</td>
<td>48/332</td>
<td>41/128</td>
<td>27/191</td>
<td>18/438</td>
<td>8/204</td>
<td>280/2256</td>
</tr>
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</table>
**Fig 1** Phylogenetic analysis of partial RdRp gene of CoV (440-nt partial sequence). CoVs identified in 2015 are named by the sample numbers. Sequence amplified from samples co-infected with two CoV strains are indicated in red. (A) CoVs detected in Guangdong. (B) CoVs detected in Yunnan.
Cophylogenetic analysis of CoV host switching

We completed preliminary cophylogenetic analysis of bat host – CoV sequences using data published in the literature and available on Genbank. Two figures from these analyses are highlighted below (Figs 2 and 3) and these methods are currently being extended using partial RdRp CoV and bat mitochondrial DNA sequences from a large number of bat specimens found CoV positive in Year 2 (Table 5, above).

Figure 2: Tanglegram depicting the pattern of infection of bats (and outlier mammalian hosts) by CoVs. The CoV tree was reconstructed from DNA sequences available in GenBank (partial RdRp gene) using Bayesian inference (MrBayes). The topology of host tree was reconstructed using the mammal and bat phylogenies available in Asher & Helgen (2010) and Agnarsson et al. (2011), using methods our group has previously applied to bat parasite cophylogenetic analyses (Lei and Olival 2014). Both ParaFit (ParaFitGlobal = 64957.61, p-value = 0.001) and PACo (m2 = 356.44, p-value = 0.013) provided evidence for significant global congruence between the two topologies, and evidence for coevolution. Lines connecting taxa indicate host-CoV associations. Red lines indicate significant host-CoV associations as indicated by ParaFit (p ≤ 0.05, 999 permutations).

Figure 3: Reconstruction of one of 3 potentially optimal solutions of reconciled host-CoV trees recovered from a Jane analysis. Black and blue lines represent the host and CoV trees, respectively. For each solution, the number of co-speciation events inferred by Jane was always significantly greater than expected by chance. Jane inferred 4 co-speciation events (hollow colored circles), 1 duplication (solid
colored circle), 14 host switches (solid colored circle with arrow), 0 loss and 0 failure to diverge.

Our findings demonstrate co-speciation alone is not sufficient to explain the observed co-phylogenetic pattern and several host switches can be specifically identified. This is the case even if a significant global signal of co-speciation has been detected. This work highlights, the need for these types of detailed cophylogenetic analyses to best explain the evolutionary history and host-switching of bat-CoVs.


Market Characterization Model Parameterization
Our ongoing observational research and mapping of farms and markets suggests that rapid changes in the market and regulatory environment are changing the nature and location of the wildlife market trade. The nexus of the wildlife trade and the potential hotspots of interspecies viral mixing is now in many cases in animal storage facilities and transport between high-volume customers. To define realistic parameters for intermixing wildlife species in areas of high potential mixing, we have developed a preliminary survey and sampling protocol to assess these values as animals move along the value chain – through these storage facilities - using respondent-driven questionnaires to follow and sample along the wildlife trade network and reveal hidden nodes and sites of intermixing of species.

We have expanded our intermixing modeling framework to incorporate the variations along this value chain, where the diversity, abundance, residence time, and contact rates between species change as animals move through the trade network.

Specific Aim 3: Testing predictions of CoV inter-species transmission.

In Year 2, we continued surveillance for novel SARS-like CoVs from bats in Yunnan and Guangdong provinces and obtained full genome sequence for 11 CoV isolates. Full genome analysis of these CoV isolates was completed, including phylogenetic and recombination analyses. Importantly, recombination analysis of the full-length SL-CoV genome sequences from a single bat population revealed that frequent recombination events among different SL-CoV strains occur. Several SL-CoVs that are more genetically similar to SARS-CoV (2003) than any previously discovered were also identified from bat populations in Yunnan province. Full genome analysis suggests that an epicenter of SL-CoV occurs in rhinolophid bats and provides more insight into the evolutionary origin of SARS-CoV.

Full-length genome sequencing of SL-CoVs identified from a single bat colony
To date, including preliminary data submitted for this R01 that we are now analyzing under the current funding, we have conducted 5-years of surveillance of SL-CoV in a single bat colony in Yunnan Province (from 2011 to 2015), leading to the discovery of diverse novel SL-CoVs. Based on genotyping of these SL-CoVs by the region corresponding to the receptor-binding domain (RBD) of SARS-CoVs, 11 isolates were selected and full-length genome sequencing was performed in Year 2.

These SL-CoVs, including four others isolated previously from this colony, Rs3367, RsSHC014, WIV1 and WIV16, are highly diversified in the S gene, but share similar sequence identity to SARS-CoV in ORF1ab (Fig 4). Genomic phylogenetic analysis showed that the SL-CoVs detected in this colony are more closely
related to SARS-CoVs from other geographic regions, especially three isolates, WIV16, Rs4874 and Rs4231 (Fig 5). Notably, among the 15 SL-CoVs, two isolates, Rs4084 from *Rhinolophus sinicus* and Rf4092 from *Rhinolophus ferrumequinum*, are highly similar to SARS-CoV in the ORF8 region (Fig 5). Rf4092 possessed a single ORF8 of the same length (369bp) as that in civet SARS-CoV SZ3, and the sequence showed only 10 nucleotide substitution (Fig 6). The ORF8 sequence of Rs4084 is highly similar to that of Rf4092, however in the region corresponding to the 29-bp deletion acquired in human SARS CoVs (e.g Tor2), a shorter deletion of only 5-bp is present, resulting in two overlapping ORF8s, ORF8a and ORF8b. The position of start codon and stop codon of the two ORFs were consistent with those in human strains (Fig 6).

![Query sequence: SARS-CoV SZ3](image)

**Fig 4.** Simplot analysis of the 15 SL-CoVs identified from a single bat colony in Yunnan. SARS-CoV SZ3 is used as query sequence.
Fig 5. Phylogenetic analysis of full-length genome sequences of SL-CoVs and SARS-CoVs. Isolates identified in the single investigated bat colony in Yunnan in in bold.

Fig 6. Alignment of ORF8 nucleotide sequences of SARS-CoV and bat SL-CoVs. The red box indicates the 29-nt deletion present in SARS-CoV of middle and late phase.
Recombination analysis of the full-length genome sequences reveals frequent recombination events among different SL-CoV strains circulating in this bat population. For example, WIV16 appears to be a recombination product of WIV1 and Rs4231. An important breakpoint is identified between the N-terminal domain (NTD) and RBD region in the S gene (Fig 7A). Consequently, WIV16 is identical to Rs4231 and WIV1 in NTD and RBD of the spike protein, respectively, and is highly homologous to SARS-CoV in both NTD and RBD. This makes it the SL-CoV most closely related to the direct progenitor of SARS-CoV discovered to date. Moreover, evidence is found to support the hypothesis that the direct progenitor of SARS-CoV was generated from recombination of WIV16 with Rf4092 at the site near ORF8. This work, which identifies diverse SL-CoVs highly homologous to SARS-CoV in different regions of the genome, suggests that rhinolophid bats are an evolutionary epicenter of SL-CoV and offers more insights into the evolutionary origin of SARS-CoV.

Fig 7  Bootscan analysis of full-length genome sequences of SL-CoVs. (A) WIV16 is used as query sequence. (B) SARS-CoV SZ3 is used as the query sequence. (Kimura model, window size, 1500bp, step size, 300bp)
Additional Year 2 Items for Specific Aim 3:

- The infectious clone of WIV1 was successfully constructed using reverse genetic methods;
- Two chimeric bat SARS-like coronavirus strains were constructed by replacing the S gene in the backbone of WIV1;
- Permission to import mice with human ACE2 to China was obtained, so as to conduct the experimental infections proposed in our R01 specific aims.

Specific Goals Not Met.

- Comparative cophylogenetic analyses of bat host and CoV RdRp and Spike gene phylogenies, to assess patterns of evolutionary congruence and frequency of cross-species transmission (This will be conducted in year 3);
- Animal infection experiments of SARS-like coronaviruses were not done, because of the unavailability of mice with human ACE2 in Year 2. We now have secured these mice and will begin this work in year 3.
- Sampling of bat and other mammalian species in markets to screen for CoVs. We will begin this work in year 3.

Section C: Accomplishments: Publications

PUBLISHED


Kevin J. Olival. To Cull, or Not To Cull, Bat is the Question. *Ecohealth* 13, 6–8 (2015).


ACCEPTED, IN PRESS

B.4 What opportunities for training and professional development has the project provided?

We presented our project to graduate students, laboratory personnel, directors, and doctors from three Hospitals in Yunnan Province: Yunnan Provincial Institute of Endemic Diseases Control & Prevention (YNCDC); Dali Provincial Hospital; and The Third People’s Hospital of Kunming. Select doctors at YNCDC (1) and Dali Provincial Hospital (3) were trained in the passive Hospital surveillance project protocols.

We trained graduate students from Dali School of Public Health (1) and the Wuhan University School of Public Health (3) in qualitative behavioral risk data collection methodologies and data collection technologies, survey data collection and analysis. These were also enrolled in and passed the Human Subjects Research Course provided by the Collaborative Institutional Training Initiative (CITI Program) at the University of Miami (http://citiprogram.org). The CITI Program is a leading provider of research education content with web based training materials serving millions of learners at academic institutions, government agencies, and commercial organizations in the U.S. and around the world.
C. PRODUCTS

C.1 PUBLICATIONS
Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph) during the reporting period resulting directly from this award?
Yes

<table>
<thead>
<tr>
<th>Publications Reported for this Reporting Period</th>
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<tbody>
<tr>
<td>Public Access Compliance</td>
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Non-compliant Publications Previously Reported for this Project
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<thead>
<tr>
<th>Public Access Compliance</th>
<th>Citation</th>
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C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)
NOTHING TO REPORT

C.3 TECHNOLOGIES OR TECHNIQUES
NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES
Have inventions, patent applications and/or licenses resulted from the award during the reporting period?
No

C.5 OTHER PRODUCTS AND RESOURCE SHARING
C.5.a Other products
NOTHING TO REPORT

C.5.b Resource sharing
NOTHING TO REPORT
## D. PARTICIPANTS

### D.1 WHAT INDIVIDUALS HAVE WORKED ON THE PROJECT?

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<th>S/K</th>
<th>Name</th>
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<th>DOB</th>
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<th>Role</th>
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<th>Aca</th>
<th>Sum</th>
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<td>PD/IP</td>
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<tr>
<td>NOAMROSS</td>
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<tr>
<td>KE</td>
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<td></td>
<td></td>
<td></td>
<td>Center for Disease Control and Prevention of Guangdong Province</td>
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<tr>
<td>ZHANG,</td>
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<td>EPSTEIN</td>
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<td>JONATHAN</td>
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<td>CHMURA,</td>
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<td>ALEKSEI A</td>
<td></td>
<td></td>
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<tr>
<td>SHI,</td>
<td>N</td>
<td></td>
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</table>
Glossary of acronyms:
S/K - Senior/Key
DOB - Date of Birth
Cal - Person Months (Calendar)
Aca - Person Months (Academic)
Sum - Person Months (Summer)
Foreign Org - Foreign Organization Affiliation
SS - Supplement Support
RE - Reentry Supplement
DI - Diversity Supplement
OT - Other
NA - Not Applicable

D.2 PERSONNEL UPDATES

D.2.a Level of Effort

Will there be, in the next budget period, either (1) a reduction of 25% or more in the level of effort from what was approved by the agency for the PD/PI(s) or other senior/key personnel designated in the Notice of Award, or (2) a reduction in the level of effort below the minimum amount of effort required by the Notice of Award?

No

D.2.b New Senior/Key Personnel

Are there, or will there be, new senior/key personnel?

Yes

File uploaded: Noam Ross CV 2016.pdf

D.2.c Changes in Other Support

Has there been a change in the active other support of senior/key personnel since the last reporting period?

No

D.2.d New Other Significant Contributors

Are there, or will there be, new other significant contributors?

No

D.2.e Multi-PI (MPI) Leadership Plan

Will there be a change in the MPI Leadership Plan for the next budget period?

NA
Noam Ross

EDUCATION

University of California, Davis, CA

- Doctoral Candidate in Ecology
- Dissertation Committee: Alan Hastings (major professor, Ecology), David Rizzo (Plant Pathology), Jim Sanchirico (Natural Resource Economics)
- Dissertation Research: "Managing Emerging Forest Disease Under Uncertainty"

Brown University, Providence, RI

- Bachelor of Science in Environmental Science, Magna Cum Laude, May 2006
- Phi Beta Kappa, Sigma Xi, Environmental Science Honors, Rosenberger Prize for Outstanding Service

SCIENTIFIC PUBLICATIONS


In preparation

*Co-equal authorship

POSTERS

- Ross, Noam. "Optimal Control of Forest Disease Under Changing Community and Spatial Structure," November 4-18, 2013. Sustainable Management of Natural Resources Workshop, Mathematical Biosciences Institute, Columbus, OH.

PRESENTATIONS

- Ross, Noam, "Fungal Disease Mortality: Modeling for Management of Sudden Oak Death." Dec 1, 2014 Invited talk at EcoHealth Alliance, New York, NY.
AWARDS + FELLOWSHIPS (Total received $225,429)

- Don Dahlsten Memorial Grant ($325)  California Forest Pest Council, 2012
  Designing Protective Treatments for Forest Disease Using Spatial Point Process Models
- NSF IGERT Bridge Fellowship ($57,500)  UC Davis, CA, 2012
  Managing Emerging Forest Disease Under Uncertainty
- NSF IGERT Traineeship in Rapid Environmental Change ($115,000)  UC Davis, CA, 2010
  Modifying River-Floodplain Systems: A Historical and Ecological Approach
- UC Davis Graduate Group in Ecology Fellowship ($40,004)  UC Davis, CA, 2010
- NSF Research Experience for Undergraduates Fellowship ($8,000)  Acad. of Natural Sciences, PA, 2005
- Undergraduate Research Fellowship ($4,000)  Brown University, RI, 2003

SERVICE + PROJECTS

- **Workshop Instructor**, Software Carpentry and Data Carpentry Foundations Jan 2015–Present
- **Student Rep**, UC Davis Graduate Group in Ecology Executive Committee Sep 2013–Present
- **Reviewer**: *Theoretical Ecology* (4 reviews) Feb 2013–Present
- **Web Developer and Technology Chair**, Ecology Graduate Student Association June 2013–Present
  
  Creator + Maintainer of graduate student blog, resources, and news site (egsa.ucdavis.edu)
- **Founder + Organizer**, Davis R Users' Group Sep 2012–Present
  
  Created users group that provides tutoring and seminars to graduate students in 10+ departments
- **Contributor**, R packages knitr, knitr citations, rCrossref, rethinking 2012–Present
- **Organizer**: NSF REACH IGERT Workshop on Multiple Goals in Floodplain Restoration Sep 2012
- **Organizer**, UC Davis Conference on Ecology and the Business Sector Apr 2011
- **Organizer**, UC Davis Graduate Group in Ecology Symposium May 2010–2011
- **External Reviewer**, World Resources Institute Corporate Ecosystem Services Review Jan 2008
- **Business Stewardship Volunteer**, NY Coastal Marine Resources Center Feb-Apr 2007

OTHER WORK EXPERIENCE

**GreenOrder**  New York, NY

- **Analyst, Senior Analyst**: Corporate Environmental Strategy + Governance Sep 2006–Oct 2009
- Conducted environmental performance analysis for products in energy, transportation, and water sectors
- Created green product metrics system R&D stage-gating system for construction products manufacturer
- Managed engagement with equipment rental company to identify growth opportunities in green building
- Performed market and competitive analyses for a wide array of clients in retail, real estate financial and cleantech sectors; prepared and delivered client presentations; managed projects
- Managed analysts performing environmental product certifications and market research
- Developed firm seminar series and analyst training materials; conducted trainings on topics including auditing, statistical analysis, and environmental performance benchmarking
- Audited certifications for environmental products and facility performance

**Wal-Mart**  Providence, RI

- **Contract Researcher/Consultant**: Energy Efficient Products Initiative May–Sep 2006
  
  Developed forecasting model for sales of energy-efficient lamps at Wal-Mart stores
- Created guidelines for design of lamp recycling program
Brown University Facilities Management  Providence, RI
- Developed energy-use and financial projections for university energy usage scenarios
- Performed background research and feasibility analysis for university energy efficiency projects
- Provided tutoring, logistical support and web design for two courses in sustainable design
- Responsible for maintenance of energy efficient, low-impact building

Hovsgol Lake Global Environmental Facility and Brown University  Mongolia + Providence, RI
Advisor: Clyde Goulsen
- Independent research on climate-land use interactions on permafrost soil carbon storage
- Plant surveys, soil pit excavation, soil physical and chemical analysis, soil microbial process incubations

Marine Biological Laboratory Ecosystems Center  Woods Hole, MA
Semester in Environmental Science Student  Aug-Dec 2004
Advisor: Charles Hopkinson
- Examined effects of nitrogen pollution on structure of microplankton food webs
- Microcosm experiments, fluorescence microscopy, dissolved nutrient analysis, planktonic growth incubations

Brown Center for Environmental Studies  Providence, RI
Undergraduate Research Fellow  Jun-Aug 2003
Advisor: Steven Hamburg
- Conducted research in biogeochemistry at Hubbard Brook Experimental Forest and surrounding region; oversaw soil pit excavation by undergraduate and graduate field crew
- Plant surveys, forest floor measurements, litter collection, soil pit excavation, soil physical and chemical analysis, GIS analysis in ESRI ArcMap

Publications in Popular Press
### E. IMPACT

**E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?**

Not Applicable

**E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?**

NOTHING TO REPORT

**E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?**

Not Applicable

**E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?**

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<thead>
<tr>
<th>Dollar Amount</th>
<th>Country</th>
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<tbody>
<tr>
<td>211699</td>
<td>CHINA</td>
</tr>
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</table>
## F. CHANGES

### F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

### F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

NOTHING TO REPORT

### F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

#### F.3.a Human Subjects

No Change

#### F.3.b Vertebrate Animals

No Change

#### F.3.c Biohazards

No Change

#### F.3.d Select Agents

No Change
G. SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

NOTHING TO REPORT

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

G.4.a Does the project involve human subjects?
Yes

Is the research exempt from Federal regulations?
No

Does this project involve a clinical trial?
No

G.4.b Inclusion Enrollment Data

Report Attached: Understanding the Risk of Bat Coronavirus Emergence-PROTOCOL-001

G.4.c ClinicalTrials.gov

Does this project include one or more applicable clinical trials that must be registered in ClinicalTrials.gov under FDAAA?
No

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Are there personnel on this project who are newly involved in the design or conduct of human subjects research?
No

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?
No

G.7 VERTEBRATE ANIMALS

Does this project involve vertebrate animals?
Yes

G.8 PROJECT/PERFORMANCE SITES

<table>
<thead>
<tr>
<th>Organization Name</th>
<th>DUNS</th>
<th>Congressional</th>
<th>Address</th>
</tr>
</thead>
</table>

RPPR
<table>
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<tr>
<th>Organization Name</th>
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<tbody>
<tr>
<td>Primary: EcoHealth Alliance, Inc.</td>
<td>NY-010</td>
<td>460 West 34th Street 17th Floor New York NY 100012317</td>
</tr>
<tr>
<td>Wuhan Institute of Virology</td>
<td>529027474</td>
<td>Xiao Hong Shan, No. 44 Wuchang District Wuhan</td>
</tr>
<tr>
<td>East China Normal University</td>
<td>420945495</td>
<td>3663 Zhongshan Beilu Shanghai</td>
</tr>
<tr>
<td>ECOHEALTH ALLIANCE</td>
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<td>077090066</td>
<td>460 West 34th Street 17th Floor New York NY 100012317</td>
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<tr>
<td>Wuhan Institute of Virology</td>
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</tr>
<tr>
<td>East China Normal University</td>
<td>420945495</td>
<td>3663 Zhongshan Beilu Shanghai</td>
</tr>
</tbody>
</table>

G.9 FOREIGN COMPONENT

Organization Name: Wuhan Institute of Virology
Country: CHINA
Description of Foreign Component:
Principal Laboratory for all Research in China as per section G8 (above) and detailed in our Specific Aims

Organization Name: East China Normal University
Country: CHINA
Description of Foreign Component:
Principal Coordinating Team for all project field work as per section G8 (above) and detailed in our Specific Aims

G.10 ESTIMATED UNOBLIGATED BALANCE

G.10.a Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year's total approved budget?

No

G.11 PROGRAM INCOME

Is program income anticipated during the next budget period?

No

G.12 F&A COSTS

Is there a change in performance sites that will affect F&A costs?

No
Inclusion Enrollment Report

Inclusion Data Record (IDR) #: 166195
Using an Existing Dataset or Resource: No
Delayed Onset Study ?: No
Clinical Trial: No
Enrollment Location: Foreign
NIH Defined Phase III Clinical Trial: No

Study Title: Understanding the Risk of Bat Coronavirus Emergence-PROTOCOL-001

Planned Enrollment

Planned Enrollment Total: 2,460

NOTE: Planned enrollment data exists in the previous format; the PD/PI did not enter the planned enrollment information in the modified format and was not required to do so. Only the total can be provided.

Cumulative Enrollment

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<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td><strong>Total</strong></td>
<td>157</td>
<td>108</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Hi Stephen

- First: Version with FC's comments
- Second: My edits on top of FC's
- Third: Timeline with OGC comments
- Fourth: USASpending.gov data

Hope this helps

Many thanks, Mike

Could you review FC comments and send forward to Stephen what you feel is important to include?

See a few comments. It will be really important for Mike Lauer to review.

FC

As discussed,
For 2nd review, a draft of an email that would go from the Secretary to the acting Inspector General.

The first draft of this email was reviewed by Rose, Ian, Sarah, and Andrea, but now reflects substantial input from OGC (barb/David, thank you for quick turn!). A few outstanding q’s for NIH still included here, appreciate all the quick help already tonight, tho. Thank you all!

Before this goes out, we should alert WH Counsel (Barb/Rose?) as well as NSC (Andrea?) Would love to fill in the holes and get this out tomorrow or at latest Monday. Barb will be on a plane from early until 1 pm ET tomorrow. So if any additional edits can get done by 1 pm, we can be hopefully be ready to go tomorrow afternoon.

Again, very much appreciate the quick turn!

Details on email:
Structure: Email from XB to HHS OIG Principal Deputy IG Christi Grimm
CC: Collins, Fauci, key HHS and NIH staff
Subject: 
Target date: ASAP or Monday
Public release: No
EcoHealth Alliance grant R01AI110964 timeline
Mike Lauer (OER)
May 28, 2021
Department of Health and Human Services, Department of Allergy and Infectious Diseases, National Institutes of Health, Health and Human Services, "National Institute of Allergy and Infectious Diseases, National Institutes of Health, Health and Human Services", Department of Health and Human Services, Health, Health research and training, 075-0885, "National Institute of Allergy and Infectious Diseases, National Institutes of Health, Health and Human Services", 41.0, "Grants, subsidies, and contributions", 581666.00, ASST NON R01AI110964 7529, ASST NON R01AI110964, 2014-05-27, 2014-07-13, 2020, 2014-06-01, 2025-06-30, 04, PROJECT GRANT (B), UNDERSTANDING THE RISK OF BAT CORONAVIRUS EMERGENCE, 075, DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), 7529, NATIONAL INSTITUTES OF HEALTH, 75MN00, NIH NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, 075, DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), 7529, NATIONAL INSTITUTES OF HEALTH, 75MN00, NIH NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, 077090066, ECOHEALTH ALLIANCE INC, 077090066, ECOHEALTH ALLIANCE INC, USA, NY, NEW YORK, NEW YORK, 10, 100012317, UNITED STATES, NEW YORK, NEW YORK, 10, 10001-2320, 93.855, ALLERGY AND INFECTIOUS DISEASES RESEARCH, 41.0, https://www.uspending.gov/award/ASST_NON_R01AI110964_7529, 2018-08-14

Department of Health and Human Services, Department of Health and Human Services, 075, 2019, 2019, 0885, 000, 075-2019-2019-0885-000, "National Institute of Allergy and Infectious Diseases, National Institutes of Health, Health and Human Services", Department of Health and Human Services, Health, Health research and training, 075-0885, "National Institute of Allergy and Infectious Diseases, National Institutes of Health, Health and Human Services", 41.0, "Grants, subsidies, and contributions", 71770.00, 0.00, 0.00, 0.00, ASST NON R01AI110964 7529, ASST NON R01AI110964, 2014-05-27, 2014-07-13, 2020, 2014-06-01, 2025-06-30, 04, PROJECT GRANT (B), UNDERSTANDING THE RISK OF BAT CORONAVIRUS EMERGENCE, 075, DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), 7529, NATIONAL INSTITUTES OF HEALTH, 75MN00, NIH NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, 075, DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), 7529, NATIONAL INSTITUTES OF HEALTH, 75MN00, NIH NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, 077090066, ECOHEALTH ALLIANCE INC, 077090066, ECOHEALTH ALLIANCE INC, USA, NY, NEW YORK, NEW YORK, 10, 100012317, UNITED STATES, NEW YORK, NEW YORK, 10, 10001-2320, 93.855, ALLERGY AND INFECTIOUS DISEASES RESEARCH, 41.0, https://www.uspending.gov/award/ASST_NON_R01AI110964_7529, 2019-11-14

Department of Health and Human Services, Department of Health and Human Services, 075, 2019, 2019, 0885, 000, 075-2019-2019-0885-000, "National Institute of Allergy and Infectious Diseases, National Institutes of Health, Health and Human Services", Department of Health and Human Services, Health, Health research and training, 075-0885, "National Institute of Allergy and Infectious Diseases, National Institutes of Health, Health and Human Services", 41.0, "Grants, subsidies, and contributions", 733750.00, 0.00, 0.00, 0.00, ASST NON R01AI110964 7529, ASST NON R01AI110964, 2014-05-27, 2014-07-13, 2020, 2014-06-01, 2025-06-30, 04, PROJECT GRANT
UNDERSTANDING THE RISK OF BAT CORONAVIRUS EMERGENCE, 075, DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), 7529, NATIONAL INSTITUTES OF HEALTH, 75NMO0, NIH NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, 075, DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), 7529, NATIONAL INSTITUTES OF HEALTH, 75NMO0, NIH NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, 077090066, ECOHEALTH ALLIANCE INC., 077090066, ECOHEALTH ALLIANCE INC., USA, NY, NEW YORK, NEW YORK, 10, 10001-2320, UNITED STATES, NEW YORK, NEW YORK, 10, 10001-2320, 93.855, ALLERGY AND INFECTIOUS DISEASES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

RESEARCH, https://www.usaspending.gov/award/ASST_NON_R01AI110964_7529/, 2020-08-17

DEPARTMENT OF HEALTH AND HUMAN SERVICES

RESEARCH, https://www.usaspending.gov/award/ASST_NON_R01AI110964_7529/, 2020-08-28

DEPARTMENT OF HEALTH AND HUMAN SERVICES

RESEARCH, https://www.usaspending.gov/award/ASST_NON_R01AI110964_7529/, 2017-08-14
This ZIP file was generated from a specific Assistance Award Summary Page on USAspending.gov, located at https://www.usaspending.gov/award/49714040

Data Element Definitions: A searchable Data Dictionary that defines every data element in the included files can be found here: https://www.usaspending.gov/download_center/data_dictionary. We have also included a copy in this download for convenience. Note that the dictionary is updated periodically.

Empty Files: When no data is available for a given file, its contents will only contain column headers (no records will be included).

Split Files: The # in all filenames defaults to 1; if the number of rows in a given file is large enough to warrant breaking it into multiple files, then additional files will be present and appended with 2, 3, etc. instead.

Award ID Characters: In edge cases where the Award ID (PAIN or URI) contain characters that are file system unfriendly (e.g., '?' or '-'), they are converted to '__' characters for purposes of file names (no underlying data within the files is altered).

File: Assistance_[Award ID]_FederalAccountFunding_.csv

This file contains Account Breakdown By Award data, which is reported on a quarterly basis from audited agency financial systems as required by the DATA Act of 2014. It is a breakdown of funding for this award by Treasury Account, Budget Function, Object Class, and sometimes Program Activity—effectively linking the appropriation, budget, financial, and award spheres. Financial data is provided at the TAS level for increased granularity, but may easily be rolled up by Federal Account using the federal_account_symbol column. This data is also available from the Custom Account Download section of the site.

Note that the DATA Act of 2014 went into effect FY17Q2; as such, Account Breakdown by Award data is only available from January 2017 onward, and will not be present for award transactions that occurred prior to that point. Note also that a subset of agency-submitted Account Breakdown by Award data is not definitively linkable to a single Federal Award; unlinked data is available via Custom Account Download only.

File: Assistance_[Award ID]_Sub-Awards_.csv

This file contains all Sub-Grant data associated with this prime award. Sub-Grant data is also available from the Advanced Search or Custom Award Download sections of the site.

File: Assistance_[Award ID]_TransactionHistory_.csv

This file contains transaction-level data for all of the modifications made to this assistance award, including the base award. This data is also available from the Advanced Search, Award Data Archive, and Custom Award Download sections of the site.

File: Data_Dictionary_Crosswalk.xlsx

This file contains the data dictionary covering all elements available for download from USAspending.gov. You can find an online and up-to-date version of the data dictionary here: https://www.usaspending.gov/download_center/data_dictionary
Institution of Higher Education), SINGLE ZIP CODE, NEW YORK, NY, New York, 100012320, 08, USA, UNITED STATES, Understanding the Risk of Bat Coronavirus Emergence, "93.855: ALLERGY AND INFECTIOUS DISEASES RESEARCH; 93.855: ALLERGY, IMMUNOLOGY AND TRANSPLANTATION RESEARCH", subgrant, 03efa6efcdf7b1f85db03b2ead3c563, 2017, 5, 1R01AI110964-01, 159342.10, 2017-05-31, 2017, 5290449295, WUHAN UNIVERSITY SCHOOL OF PUBLIC HEALTH, ..., CN, "NO.185, DONGHU RD., HUBEI, 00, 430071, "Foreign Owned, Other Not for Profit Organization, Educational Institution", Hubei, 00, ..., CN, "Conduct targeted site-analyses, human behavioral surveillance including qualitative and quantitative surveys; analyses of data; collaborating on scientific publications and programmatic reporting."; https://www.usaspending.gov/award/ASST_NON_R01AI110964_7529/, 2020-07-13 16:10:31+00

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Mike, I know this is a big and somewhat fraught ask, but would you be willing to meet by phone or over zoom with Peter Daszak and Mary or me? (Or without us if you'd prefer -- we absolutely do not need to be in the meeting).

Having served as Senator Brown's LD for 11 years, handling all the casework that involved people he knew, I can't not be a caseworker now. Peter and his family are being tortured. I know that the timing couldn't be worse given the Republican E&C letter re reporting, etc., but a conversation with you or Larry -- whether an action step comes out of it -- may restore some of his completely shaken faith. He teared up during our conversation.

I am fully aware that:

- I am overstepping;
- my only sources are background research from the NIH system (attached); the R letters, and what the plethora of Nobels who’ve contacted us have said;
- there are reporting problems (although how common they are, I don’t know, and I also don’t know whether there are reasons (e.g. reporting depended on the size of the subgrant) for any glitches in IRS reporting); and
- there is no way of knowing whether all the Laureates and Peter are sharing the whole story.

My only goal is to see if Peter can get an audience with you or Larry. I’m going to forward an email from Peter with more info and a link to a 60 Minutes program he did years ago forewarning of coronavirus pandemics.

Thanks for considering this request.

I hope all is well!

Ellie

Eleanor (Ellie) Dehoney
Vice President of Policy and Advocacy
Research!America

www.researchamerica.org
Watch the recording here!
On EcoHealth:

- In July 2019, EcoHealth was awarded a grant renewal on NIH grant R01AI110964 for $661,980. The stated aims of the research performed under this grant were (1) to characterize distribution and diversity of SARSr-CoVs in bats in southern China; (2) to conduct surveillance on SARSr-CoV in high-risk populations with known bat contact; and (3) to identify viruses of concern using genetic analysis and in vivo and in vitro infection studies of existing SARSr-CoV viruses. No gain-of-function studies were proposed.
- On April 24, 2020, funding for the EcoHealth was cut after apparent political pressures related to a subgrant awarded to the Wuhan Institute of Virology (WHA) for bat surveillance.
- Shortly after funds were cut for EcoHealth, a group of 77 U.S. Nobel laureates in science sent a letter to Secretary Azar and Director Collins expressing concern that funds had been cut to a merit-based grant after the grant was mischaracterized as awarding “millions of dollars to investigators in Wuhan.”
- A sign-on letter from ASBMB was issued to Director Collins around the same time, expressing similar concerns and asserting that the move set a bad precedent. The letter was signed by 29 prominent scientific societies.
- On July 8, 2020, NIH converted the grant termination to a suspension pending EcoHealth’s response to requests related to WIV’s actions. The NIH requests have been described by former NIH director Harold Varmus as “outrageous,” and EcoHealth issued a letter stating that some of the requests, such as arranging an outside investigation into WIV and procuring SARS-CoV-2 samples from the WIV sequencing project (as far as I can tell, performed by an unconnected lab), would be impossible to complete.
- EcoHealth received two additional NIH grants in the latter half of 2020 totaling $2.1 million. The first (U01AI151797) was given to form a hub to track emerging infectious diseases in Southeast Asia. This U01 grant will fund collaborations between clinics, laboratories, and research institutions in USA, Thailand, Singapore, and Malaysia. The second grant, also a U01 (U01AI153420), was awarded to study Nipah virus in Bangladesh. Researchers will conduct questionnaires and do serological testing, as well as do field studies and infection studies on bats and Syrian hamsters. It is unclear whether all viruses tested in this study will be naturally occurring or not. It does not appear that any of these studies will be conducted in China.
- On June 10, 2021, House Republicans issued a letter to Dr. Collins with a list of complaints on NIH activities, partially in relation to EcoHealth.
- According to EcoHealth, the GAO is looking into the cancellation and subsequent reinstatement/suspension of the EcoHealth grant as part of an evaluation of the politicization of science.

On investigations into COVID origins:

- Early in the pandemic, the lab leak hypothesis was viewed as implausible by both scientists and the media. However, the absence of evidence of animal origin has prompted scientists to consider the lab leak hypothesis more seriously.
- In February 2021, after negotiating with the Chinese government, the WHO deployed a team of virology and policy experts to China, including Peter Daszak from EcoHealth. During the one-month investigation, researchers visited the Huanan market in Wuhan, interviewed early COVID patients, and questioned scientists at WIV. The investigation has been criticized for not being thorough enough.
• On May 26, 2021, President Biden ordered a 90-day review of intelligence data to try to find evidence of either zoonotic origin or a lab leak.
• At the G7 summit this weekend, leaders called for a more thorough investigation into the origins of COVID-19, including expert access to laboratories.
Hey all,

Attached is my proposal for how to structure the conversation for tomorrow’s prep session.

You will see that I’m proposing:

Please let me know if you think this is an okay plan or have edits/suggestions for me.

For your awareness, I’m including the letters that CMR wrote us and the one we wrote back on this topic.

Adrienne
Thank you — my edits attached, plus some other materials you might find helpful.

Adding Mike Lauer

See highlights for areas where I think NIH may know the answer — Larry (or David)— can you help fill in the gaps here?
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This ZIP file was generated from a specific Assistance Award Summary Page on USAspending.gov, located at https://www.usaspending.gov/award/49714040

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Split Files: The # in all filenames defaults to 1; if the number of rows in a given file is large enough to warrant breaking it into multiple files, then additional files will be present and appended with 2, 3, etc. instead.

Award ID Characters: In edge cases where the Award ID (PAIN or URI) contain characters that are file system unfriendly (e.g., '?' or '-'), they are converted to '_' characters for purposes of file names (no underlying data within the files is altered).

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File: Assistance_[ Award ID]_FederalAccountFunding_#.csv

This file contains Account Breakdown By Award data, which is reported on a quarterly basis from audited agency financial systems as required by the DATA Act of 2014. It is a breakdown of funding for this award by Treasury Account, Budget Function, Object Class, and sometimes Program Activity—effectively linking the appropriation, budget, financial, and award spheres. Financial data is provided at the TAS level for increased granularity, but may easily be rolled up by Federal Account using the federal_account_symbol column. This data is also available from the Custom Account Download section of the site.

Note that the DATA Act of 2014 went into effect FY17Q2; as such, Account Breakdown by Award data is only available from January 2017 onward, and will not be present for award transactions that occurred prior to that point. Note also that a subset of agency-submitted Account Breakdown by Award data is not definitively linkable to a single Federal Award; unlinked data is available via Custom Account Download only.

File: Assistance_[ Award ID]_Sub-Awards_#.csv

This file contains all Sub-Grant data associated with this prime award. Sub-Grant data is also available from the Advanced Search or Custom Award Download sections of the site.

File: Assistance_[ Award ID]_TransactionHistory_#.csv

This file contains transaction-level data for all of the modifications made to this assistance award, including the base award. This data is also available from the Advanced Search, Award Data Archive, and Custom Award Download sections of the site.

File: Data_Dictionary_Crosswalk.xlsx

This file contains the data dictionary covering all elements available for download from USAspending.gov. You can find an online and up-to-date version of the data dictionary here: https://www.usaspending.gov/download_center/data_dictionary
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