

From: [Lankford, David \(NIH/OD\) \[E\]](#)
To: [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
Subject: Talking Points for ACD
Date: Monday, November 16, 2020 11:30:13 AM

Glad to discuss if helpful.

On April 24, 2020, NIH terminated the grant to EcoHealth Alliance. On July 8, 2020, NIH withdrew the termination and reinstated the grant, but suspended activities under the award. NIH has asked EcoHealth a series of questions about the materials being studied, the safety of the subrecipient's laboratory, and about the adequacy of EcoHealth's oversight of this subrecipient to ensure compliance with the terms and conditions of award. EcoHealth Alliance has not satisfactorily addressed NIH's questions. Because the enforcement matter is pending, [REDACTED] (b) (5)

David W. Lankford
NIH Legal Advisor
Office of the General Counsel
Public Health Division, NIH Branch
NIH Building 31, Room 2B-50
Bethesda, MD 20892-2111
Telephone: [REDACTED] (b) (6)
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From: [Lankford, David \(NIH/OD\) \[E\]](#)
To: [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
Subject: RE: Note to ACD
Date: Monday, November 30, 2020 10:18:22 AM

That addition would be fine. Thanks for checking.

David W. Lankford
NIH Legal Advisor
Office of the General Counsel
Public Health Division, NIH Branch
NIH Building 31, Room 2B-50
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From: Tabak, Lawrence (NIH/OD) [E] <(b) (6)>
Sent: Monday, November 30, 2020 9:43 AM
To: Lankford, David (NIH/OD) [E] <(b) (6)>
Subject: FW: Note to ACD
Ok?

From: Francis Collins <(b) (6)>
Date: Monday, November 30, 2020 at 9:40 AM
To: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)>
Cc: "Lauer, Michael (NIH/OD) [E]" <(b) (6)>
Subject: RE: Note to ACD
How about adding (b) (5) See **below**.
FC

From: Tabak, Lawrence (NIH/OD) [E] <(b) (6)>
Sent: Monday, November 30, 2020 9:14 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Lauer, Michael (NIH/OD) [E] <(b) (6)>
Subject: Note to ACD

Francis,

Here is note (OGC approved) note that I propose to send to ACD. Please let me know if you have any concerns about the note.

Larry

(b) (5)



From: [David Glazer](#)
To: [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
Subject: Re: ACD Meeting December 10,11 2020
Date: Wednesday, December 2, 2020 8:53:25 AM

Thanks Larry -- understood that things are still in flux; looking forward to the update.

On Wed, Dec 2, 2020 at 2:35 AM Tabak, Lawrence (NIH/OD) [E]
<[REDACTED] (b) (6)> wrote:

David,

Yes; an update on transition will be provided, although a number of things are still unclear at the moment. I will be sending out final agenda later today.

Best wishes,

Larry

From: David Glazer <[REDACTED] (b) (6)>
Reply-To: "[REDACTED] (b) (6)" <[REDACTED] (b) (6)>
Date: Tuesday, December 1, 2020 at 9:41 AM
To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] (b) (6)>
Cc: "advisory-committee-1@list. gov" <[REDACTED] (b) (6)>
Subject: Re: ACD Meeting December 10,11 2020

Thank you Larry -- I'm looking forward to when we're past these information-sharing restrictions.

Not directly related to this one topic -- will the agenda for next week's meeting include an update on the in-progress administration transition planning, and what changes/choices are anticipated as a result?

On Mon, Nov 30, 2020 at 5:04 PM Tabak, Lawrence (NIH/OD) [E]
<[REDACTED] (b) (6)> wrote:

Colleagues,

We briefly discussed during the last ACD meeting a grant to EcoHealth Alliance.

To summarize the current status, on April 24, 2020, NIH terminated the grant to EcoHealth Alliance. On July 8, 2020, NIH withdrew the termination and reinstated the grant, but suspended activities under the award. NIH has asked EcoHealth a series of questions about the materials being studied, the safety of the subrecipient's laboratory, and about the adequacy of EcoHealth's oversight of this subrecipient to ensure compliance with the terms and conditions of award. EcoHealth Alliance has thus far not satisfactorily addressed NIH's questions.

Because the enforcement matter is pending, I have been advised by counsel not to provide further information.

Best wishes,

Larry

From: [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
To: [Wolinetz, Carrie \(NIH/OD\) \[E\]](#)
Subject: Re: : Review/Opinion of attached manuscript: Gain of function
Date: Tuesday, January 12, 2021 7:39:46 AM

Yes, let's do that please. Sorry for my delay.
Larry

From: "Wolinetz, Carrie (NIH/OD) [E]" <[REDACTED] (b) (6)>

Date: Tuesday, January 12, 2021 at 7:37 AM

To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] (b) (6)>

Subject: FW: : Review/Opinion of attached manuscript: Gain of function

Just wanted to top this up in your inbox – maybe we can talk about it at our 1:1 this afternoon?

From: Wolinetz, Carrie (NIH/OD) [E]

Sent: Thursday, January 7, 2021 6:32 PM

To: Tabak, Lawrence (NIH/OD) [E] <[REDACTED] (b) (6)>

Subject: FW:: Review/Opinion of attached manuscript: Gain of function

Hi Larry,

I wanted your input on something. Attached is a manuscript that was sent to me by the ethics officer at NIEHS – it is co-authored by David Resnick, and she was asking me to review it for any potential concerns/policy conformity. My team and I took a look, [REDACTED] (b) (5)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] I would very much appreciate your thoughts. Thank you!!

Cheers, Carrie

Concern: The authors' primary purpose seems to be taking a fresh look at the gain-of-function (GOF) issue given our shared and ongoing experience with the COVID-19 pandemic. While there is indeed much we can learn going forward, the manuscript often seems to ignore, discount, or inaccurately reflect current U.S. Government and HHS policies for the review and oversight of enhanced PPP research. A lot of work has been done in this space, but much of the text seems to suggest that increased/additional oversight of enhanced PPP research is needed; in fact, most of the suggestions made in the paper are already captured in the existing policies. In addition to those types of comments, I have some more global concerns with the notion that an NIH employee would be providing what amounts to critiques of HHS policy that is implemented by NIH, or suggestions that contradict messaging by NIH leadership, in this type of article.

For example, NIH has taken a pretty clear stand on the question of the origins of SARS-CoV-2- in this [blog](#), the NIH Director clearly states that the evidence overwhelming suggests that SARS-CoV-2 evolved naturally. As written, the authors appear to suggest parity between unsubstantiated man-made and/or laboratory origin theories and peer reviewed studies which provide scientific evidence that the virus is of natural origin. Despite included disclaimers about the independence of the authors' views, I am concerned that such suggestions by a researcher employed by NIH, as well as the statement that this work was supported by NIEHS, will feed unsubstantiated narratives that are not based in fact. The NIH Director and/or HHS officials may have to respond to this should questions be raised. Dr. Resnik also ties questions about a release from a lab in China directly to

research partly funded by NIH in 2015; which makes this more problematic and specious, since there is no evidence for lab release.

As noted above, Dr. Resnik's analysis indicates the oversight of work involving enhanced PPPs needs to be strengthened, which amounts to a critique of HHS policies that NIH currently implements. On top of that, many of the details about the content of those policies are not quite right, so, on several fronts, it raises some issues.

From: Stillwell, Jackie (NIH/NIEHS) [E] <[REDACTED] (b) (6)>

Sent: Wednesday, December 30, 2020 4:31 PM

To: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED] (b) (6)>

Cc: Resnik, David (NIH/NIEHS) [E] <[REDACTED] (b) (6)>

Subject: Review/Opinion of attached manuscript

Dear Dr. Wolinetz,

I am writing to ask if you have time to review and provide comments on the attached paper written by Dr. David Resnik, Bioethicist at NIEHS on "How the COVID-19 Pandemic Impacts the Risk/Benefit Calculus for the Gain of Function Experiments with Pathogens of Pandemic Potential." I am not familiar with this topic and would like to ensure this paper wouldn't cause any concerns with NIH policy. Given your work at the NIH and your knowledge of NIH Policy on gain of function experiments and dual use research, Dr. Resnik recommended that we ask you to critique his paper and that it conforms with NIH policy.

We appreciate and thank you for your comments.

Best to you!

Jackie

Jackie Stillwell

Director, Ethics

Deputy Ethics Counselor

NIH|NIEHS|OD

[REDACTED] (b) (6)

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From: [Wolinetz, Carrie \(NIH/OD\) \[E\]](#)
To: [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
Subject: FW: : Review/Opinion of attached manuscript: Gain of function
Date: Wednesday, January 13, 2021 9:16:42 AM

Just FYI

From: Resnik, David (NIH/NIEHS) [E] <(b) (6)>
Sent: Wednesday, January 13, 2021 9:16 AM
To: Wolinetz, Carrie (NIH/OD) [E] <(b) (6)> Stillwell, Jackie (NIH/NIEHS) [E]
<(b) (6)>
Subject: RE: : Review/Opinion of attached manuscript: Gain of function

Carrie:

Thanks for reviewing this. I will not pursue publication of this manuscript.

Best,

David B. Resnik, JD, PhD, Bioethicist
National Institute of Environmental Health Sciences
National Institutes of Health
111 TW Alexander Drive
PO Box 12233, Mail Drop E1-06
Research Triangle Park, NC, 27709 USA
Email: (b) (6)
Phone, Office: (b) (6) Cell: (b) (6)

From: [Wojtowicz, Emma \(NIH/OD\) \[E\]](#)
To: [Collins, Francis \(NIH/OD\) \[E\]](#); [Wood, Gretchen \(NIH/OD\) \[E\]](#); [McManus, Ayanna \(NIH/OD\) \[E\]](#)
Cc: [Burklow, John \(NIH/OD\) \[E\]](#); [Myles, Renate \(NIH/OD\) \[E\]](#); [Fine, Amanda \(NIH/OD\) \[E\]](#); [Roberts, Jacqueline \(NIH/OD\) \[E\]](#); [NIH NMB \(NIH/OD\)](#)
Subject: RE: Interview Request for Dr. Collins: Fox News Shannon Bream
Date: Tuesday, February 9, 2021 1:11:32 PM

We will check, thanks-

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Tuesday, February 9, 2021 1:03 PM
To: Wojtowicz, Emma (NIH/OD) [E] <(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)> McManus, Ayanna (NIH/OD) [E] <(b) (6)>
Cc: Burklow, John (NIH/OD) [E] <(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)> Fine, Amanda (NIH/OD) [E] <(b) (6)> Roberts, Jacqueline (NIH/OD) [E] <(b) (6)> NIH NMB (NIH/OD) <(b) (6)>
Subject: RE: Interview Request for Dr. Collins: Fox News Shannon Bream

This is not a good week, how about next week?

From: Wojtowicz, Emma (NIH/OD) [E] <(b) (6)>
Sent: Tuesday, February 9, 2021 11:53 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)> McManus, Ayanna (NIH/OD) [E] <(b) (6)>
Cc: Burklow, John (NIH/OD) [E] <(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)> Fine, Amanda (NIH/OD) [E] <(b) (6)> Roberts, Jacqueline (NIH/OD) [E] <(b) (6)> NIH NMB (NIH/OD) <(b) (6)>
Subject: Interview Request for Dr. Collins: Fox News Shannon Bream

Interview Request for Dr. Collins
February 9, 2021

Request: Topic – COVID-19

Deadline: 15 minutes (10 minutes for tech check, 5 minutes for interview); pre-tape at 9:15 p.m. via mobile studio van one night this week

Additional information:

Producer Brigid Mary McDonnell with Fox News @ Night w/ Shannon Bream asked Dr. Collins to be a guest on the show to discuss getting kids back to school, the new strains of COVID-19, and vaccines. Fox would send the mobile studio van to pre-tape the interview at 9:15 p.m. and the interview would air during the 11:00 p.m. broadcast the same day.

For awareness, Fox News' Steve Hilton, host of The Next Revolution which airs on Sunday nights at 9:00 p.m., has been reporting on the EcoHealth Alliance grant claiming that SARS-CoV-2 was created in the Wuhan Institute of Virology lab through NIH/NIAID-funded gain-of-function research; links to the clips:

February 7: <https://video.foxnews.com/v/6229978391001#sp=show-clips>

January 31: <https://video.foxnews.com/v/6227902415001#sp=show-clips>

January 24: <https://video.foxnews.com/v/6225847837001#sp=show-clips>

Should Dr. Collins accept, we wanted him to be aware of Steve Hilton's reporting and the possibility that Shannon Bream may ask him about the origin pandemic or the EcoHealth Alliance grant.

Recommendation:

We recommend Dr. Collins accept.

Submitted by:

Emma Wojtowicz, (b) (6)

NIH News Media Branch

Contact information:

Brigid Mary McDonnell

Fox News @ Night w/ Shannon Bream

Cell: (b) (6)

(b) (6)

Other important notes:

Accept: _____

Decline: _____

Need more information: _____

From: [Hallett, Adrienne \(NIH/OD\) \[E\]](#)
To: [Collins, Francis \(NIH/OD\) \[E\]](#)
Cc: [Tabak, Lawrence \(NIH/OD\) \[E\]](#); [Jorgenson, Lyric \(NIH/OD\) \[E\]](#); [Lauer, Michael \(NIH/OD\) \[E\]](#); [Gottesman, Michael \(NIH/OD\) \[E\]](#); [Burklow, John \(NIH/OD\) \[E\]](#)
Subject: Re: Endless Frontiers Act Substitute - NIH related provisions
Date: Wednesday, May 19, 2021 7:45:00 AM

They are tracking the bill as a whole and have been negotiating to get to this point. If it's in this package, I suspect they signaled it was okay.

When we get our TA pulled together, I'll share it with their leg person and Carrie.

On May 19, 2021, at 7:39 AM, Collins, Francis (NIH/OD) [E] <(b) (6)> wrote:

Thanks. Can I assume that OSTP is aware of all this? If not, can you forward your note to Carrie?

FC

From: Hallett, Adrienne (NIH/OD) [E] <(b) (6)>
Sent: Tuesday, May 18, 2021 9:34 PM
To: Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Jorgenson, Lyric (NIH/OD) [E] <(b) (6)> Lauer, Michael (NIH/OD) [E] <(b) (6)> Gottesman, Michael (NIH/OD) [E] <(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)>
Subject: Endless Frontiers Act Substitute - NIH related provisions

Hi all,

We got a draft of the substitute amendment for the Endless Frontiers Act this morning. That means, this will be the base text that will be brought up in the Senate later this week. OER, OIR, and OSP have already been engaged in reviewing and providing TA but I thought a high level summary for this group would be helpful.

Also, for your situational awareness: ASL is preparing a memo for the Secretary tonight and this is the information I provided.

Below is a summary of provisions we have identified as relating to HHS, NIH, and science agencies government wide. Attached is a document with the bill language in case you'd like a deeper dive.

HHS (implying NIH but may also touch AHRQ, CDC, and HRSA):

- Sec 6101 requires recipients of HHS funding awards related to biomedical research to disclose any participation in any foreign talent program.
- Sec 6104 requires the Secretary of HHS to identify risks, establish frameworks to decipher emerging areas of research at risk, develop ideas and strategies to protect against threats to intellectual property and threats within biomedical research. Report within 1 year.

- Sec. 6105 (on page 1305) calls for a GAO study on how HHS utilizes or provides funding for human genome sequencing.

Specific to NIH:

- Sec. 6102(a) (on page 1299) requires that biomedical research supported or conducted by NIH involving the sequencing of human genomic information is conducted “in a manner that appropriately considers national security risks.”
- Sec. 6102(a)(1)-(3) (on pgs. 1300-1) also requires NIH to create a framework for assessing and managing national security risks in our research. This came up in the recent HELP hearing with Fauci on 5/11 when Sen. Marshall questioned him on whether national security advisors have any input on research grants that NIH fund. This was in the context of GoF research.
- Sec. 6103 (on pgs. 1301-2) requires the NIH director to consult with the directors of ONS, DNI, the FBI, and the ASPR on a regular basis regarding biomedical research conducted or supported by NIH that may affect national security. It also requires NIH to ensure that NIH grantees adhere to appropriate technology practices and policies for the security of identifiable, sensitive information.
- Sec. 6106 (on page 1307) requires a report no later than 1 year after this bill is enacted on the number of potential noncompliance cases being investigated by NIH, number of cases referred to OIG, and law enforcement action taken.

Science Agencies Generally:

- Sec 2215 requires OSTP to develop guidance for Federal Science agencies on caregiver policies
- Sec 2302 requires OSTP to contract with “a qualified independent organization” to establish a research security and integrity information analysis organization. Contract will be funded by user fees assessed to institutions of higher education, nonprofit research institutions, and small and medium sized businesses.
- Sec 2303 requires OSTP to issue guidance to all Federal Science agencies prohibiting scientists who are employed by such agencies or whose work is funded by such agencies from participating in foreign talent recruitment programs sponsored by China, Korea, Russia, and Iran.
- Sec 2507 provides science agencies with flexibilities and authorities to support researchers whose careers were harmed by the pandemic.
- Sec 2521 is a modified version of the Combating Sexual Harassment in Science bill that we have provided TA on in the past.
- Sec 2526 has two very different provisions:
 - prohibits any science agency from disclosing the identity of peer reviewers to the applicant whose research is being evaluated by the peer reviewer.
 - Enacts a strict and very detailed Public Access policy government wide.
- Sec 3138 relates to foreign gifts to institutions of higher education and involves both the Defense Production Act and CFIUS. Still deciphering it.

Adrienne

Weekly Report - NIH

Submitted on 02/02/2021

Weekly reports limited to 3 pgs., size 14 font; additional information, if necessary, may be included in the appendix

WEEKLY REPORT

February 2, 2021

MEMORANDUM FOR THE CABINET SECRETARY

FROM: National Institutes of Health, Executive Secretariat, (b) (6)

SUBJECT: NIH WEEKLY REPORT

Past Week Accomplishments and Setbacks

- VPOTUS Kamala Harris and Second Gentleman Doug Emhoff visited the National Institutes of Health (NIH) to receive second coronavirus vaccination (1/27).
- NIH [Council of Councils](#) Meetings Presentation: NIH Updates.
- Internal NIH Anti-harassment Steering Committee and UNITE Initiative Meetings – internal discussions focused on Strengthening Diversity, Inclusion, and Racial Equity.
- Internal NIH Meetings of the NIH COVID-19 Response Team, The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Team, and Rapid Acceleration of Diagnostics (RADx) Teams to coordinate and drive NIH response to COVID-19.
- Re-launched Implicit Bias Education online eLearning contract engagement; initiated plans to re-launch NIH-wide mandatory eLearning implicit bias online training modules.
- Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Director Dr. Diana Bianchi was interviewed by Seattle NPR affiliate regarding pregnant women and COVID-19 vaccination, including the decision that pregnant people are facing concerning vaccination. Provided background context regarding the Federal Task Force on Research Specific to Pregnant and Lactating Women: <https://www.nichd.nih.gov/about/advisory/PRGLAC>.
- NICHD issued a media advisory based on research results from NICHD-supported research related to COVID-19 and pregnant

Weekly Report - NIH

Printed on 02/02/2021

people: [“Severe COVID-19 in pregnancy associated with pre-term birth, other complications.”](#)

- Introductory meeting with CVS Healthcare and NIH Leadership (1/29).
- [Announcement](#) of interim analysis of Johnson & Johnson Janssen’s vaccine candidate.
- NIH Director Dr. Francis Collins spoke to [Washington Post reporter Ariana Cha](#) about how vaccines and variants may change course of pandemic.
- Continued media inquiries regarding NIH funding to EcoHealth Alliance and the subaward to Wuhan Institute of Virology.
- [Announcement](#) of grant extensions for NIH Fellowship (“F”) and Career Development (“K”) awards to early career scientists whose career trajectories have been significantly impacted by COVID-19.

Obstacles and Requests for White House Collaboration (as needed)

Nothing to report.

Next Week – Upcoming Events / Tasks / Developments

- Internal NIH Meetings of the Anti-harassment Steering Committee and UNITE Initiative focused on Strengthening Diversity, Inclusion, and Racial Equity
- Internal NIH Meetings of the NIH COVID-19 Response Team, ACTIV Team, and RADx Team to coordinate and drive NIH response to COVID-19
- FLOTUS will visit virtually with National Cancer Institute (NCI) staff (2/3) to thank them for their efforts and to hear from several NCI researchers.
- National Institute of Biomedical Imaging and Bioengineering (NIBIB) issuing two contracts for Phase 2 awards in the RADx Tech program, part of the NIH RADx Initiative (tentative issue date 2/2):
 - Meridian Bioscience – lab-based technology to increase testing capacity (\$5.5 million); company based in Cincinnati, OH
 - GenBody Inc. – point of care, rapid antigen test (\$10 million); South Korean company

Weekly Report - NIH

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- NIH Director Dr. Francis Collins will speak to *60 Minutes* on COVID-19 treatment efforts (interview date 2/11; air date TBD).

Appendix

Congressional Engagement:

- National Heart, Lung, and Blood Institute (NHLBI) Director Dr. Gary Gibbons spoke at the Congressional Black Caucus Health Braintrust Town Hall about COVID-19 vaccine hesitancy and the Community Engagement Alliance Against COVID-19 (CEAL) program (1/25).
- National Institute of Allergy and Infectious Diseases (NIAID) Director Dr. Anthony Fauci and NHLBI Director Dr. Gary Gibbons spoke at the House Democratic Caucus COVID-19 meeting (1/26).
- NIH Director Dr. Francis Collins had a phone call with House Democratic Leader Steny Hoyer about the availability of vaccines for NIH staff (1/28).
- NIH Principal Deputy Director Dr. Lawrence Tabak and NIH Chief Information Officer (CIO) Andrea Norris briefed the Senate HELP Committee and Senate Homeland Security and Governmental Affairs Committee staff on the recent cyber attack and NIH's response (2/1).
- NIH Principal Deputy Director Dr. Lawrence Tabak and NIH CIO Andrea Norris briefed the House and Senate Labor/HHS Appropriations Subcommittee staff on the recent cyber attack and NIH's response (2/2).
- NIH Principal Deputy Director Dr. Lawrence Tabak and NIH CIO Andrea Norris will brief House Energy and Commerce Committee staff on the recent cyber-attack and NIH's response (2/3).

McMahon, Christine (NIH/OD) [E]

Subject: RE: Interview request from senior journalism student at University of North Carolina at Pembroke. Stephanie M. Sellers.

From: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>

Sent: Thursday, February 18, 2021 11:33 AM

To: Wooldridge, Shannon (NIH/OD) [E] <[REDACTED] (b) (6)>

Subject: RE: Interview request from senior journalism student at University of North Carolina at Pembroke. Stephanie M. Sellers.

Carrie Wolinetz would be well positioned to respond to these questions.

From: Wooldridge, Shannon (NIH/OD) [E] <[REDACTED] (b) (6)>

Sent: Thursday, February 18, 2021 9:17 AM

To: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>

Subject: FW: Interview request from senior journalism student at University of North Carolina at Pembroke. Stephanie M. Sellers.

Hi Dr. Collins,

Please see the interview request from a journalism student below, concerning biosecurity and GOF/DURC. Would you like us to triage this to OSP or another subject matter expert?

Thank you,

Shannon Wooldridge
NIH Exec Sec

From: Stephanie Sellers <[REDACTED] (b) (6)>

Sent: Wednesday, February 17, 2021 1:37 PM

To: NIH Executive Secretariat <[REDACTED] (b) (6)>

Subject: Interview request from senior journalism student at University of North Carolina at Pembroke. Stephanie M. Sellers.

Dear Dr. Francis S. Collins,

I am reaching out to request an interview for my senior journalism capstone project at UNCP. The article will be published.

The article discusses America's biosecurity infrastructure. With your expertise in gain-of-function and dual-use-research-of-concern and your position in government, you are most likely to know the answers to my questions.

Thank you for your consideration.

For your convenience, these are the questions.

1. *Background: In 2011, Prof. Ron Fouchier presented data at a conference from experiments of modified human isolate of H5N1 avian-origin influenza to acquire mutations to adapt it to human-to-human transmission. A virus capable of small-droplet transmission from one infected ferret to another, according to Lipsitch in a 2018 article in National Center for Biotechnology Information. The 2011 event began the conversation about biosecurity and the threat of this biotechnology ending up in the wrong hands became public knowledge.*

Debates on research ethics grew and in 2012, the U.S. Government (USG) released a four-page Dual Use Research of Concern (DURC) policy in 2012. It states that a “DURC is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public Section II: Definitions 2 health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.”

DURCs 2. (d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin, explains how research may be considered dual use research of concern when the research is not directly related to a pathogen.

1. ***The first question is: Researchers who have been federally funded have also worked under China's Thousand Talents Plan (TTP). What screening/biosecurity measures was completed, with a paperwork trail, on American scientists working on projects that fall into the DURC 2. (d) category? Please provide a copy.***

2. *Background: Former White House staff leave positions and join lobbying organizations. Their former positions afford leverage and can lead to compromised ethics. UnitedHealth Group alone has given over \$19.5 million in lobbying towards the healthcare industry. **The second question is: When it comes to health, should there be stricter lobbying ethical guidelines?***

3. *The FBI is currently investigating 300 cases of American scientific researchers working with China. **The third question is: What biosecurity measures will be enacted to***

strengthen public safety from threats of GOF and DURC being in the hands of aggressors?

4. **May I have one of your profile photos, sent as an attachment, for my article?**

Thank you for your consideration in participating.

Also, I was delighted to learn you wrote a book connecting God and creation. I must read it - after graduation when I have more time.

Sincerely,

*Stephanie M. Sellers
Journalist*

(b) (6)

(b) (6)

or

(b) (6)

As a reporter, I am a privacy safeguarder. Your statements are protected and much appreciated, whether you decide to be on the record, in the background identifying only your organization, or deep background by not identifying your organization, or completely off the record. Thank you.

All contents of this e-mail are considered intellectual property and may contain research that is copyrighted. Do not share, copy, or express contents without my permission. Violation results in prosecution.

All contents of this e-mail and any attachments thereto are confidential unless explicitly specified otherwise in this e-mail. If you are not the intended recipient, you are hereby formally notified, that any use, copying or distribution of this e-mail, in whole or in part, is strictly prohibited. Please notify the sender by return e-mail and delete this e-mail from your system.

From: [Tucker, Jessica \(NIH/OD\) \[E\]](#)
To: [Plude, Denise \(NIH/OD\) \[E\]](#)
Cc: [Ramkissoon, Kevin \(NIH/OD\) \[C\]](#)
Subject: FW: Interview request from senior journalism student at University of North Carolina at Pembroke. Stephanie M. Sellers.
Date: Friday, March 12, 2021 4:02:57 PM
Attachments: [image001.png](#)

From: Tucker, Jessica (NIH/OD) [E]
Sent: Friday, March 12, 2021 4:03 PM
To: Stephanie Sellers <[REDACTED]> (b) (6)
Subject: RE: Interview request from senior journalism student at University of North Carolina at Pembroke. Stephanie M. Sellers.

Dear Ms. Sellers,

Thank you for your questions regarding dual use research and biosecurity. As the Director of the Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy within NIH's Office of Science Policy, I am pleased to respond on behalf of Dr. Collins.

NIH research is built on the bedrock principles of scientific excellence, unassailable integrity, and fair competition. NIH's commitment to these principles is unwavering and NIH expects NIH-supported research — both domestic and foreign — to abide by these principles. These rules of engagement also are designed to limit bias in the design, conduct, and reporting of NIH-supported research. It is critical for NIH-supported institutions and their researchers to be wholly transparent about financial support from and affiliations with international institutions.

NIH requires the [disclosure](#) of all sources of research support, foreign components, and financial conflicts of interest and uses this information when making its funding decisions to determine if the research being proposed is receiving other sources of funding that could be duplicative, has the necessary time allocation, or if financial interests may affect objectivity in the conduct of the research. Transparency helps ensure that NIH's funding decisions are fair and appropriate, and that U.S. institutions and the American public benefit from their investment in biomedical research, including research that is categorized as dual use research of concern (DURC). Such research is often vitally important to science, public health, and agriculture, and its findings contribute to the broader base of knowledge that advances science and public health objectives. The fundamental purpose of [U.S. policies for the oversight of life sciences DURC](#) is to preserve such benefits while minimizing the potential for misuse. The DURC polices are just one component of a comprehensive biosafety and biosecurity oversight system made up of best practices, guidelines, policies, and regulations. Included among these are the [Department of Health and Human Services \(HHS\) Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens](#), which provides an additional level of review and oversight to help ensure research that is reasonably anticipated to create, transfer, or use potential pandemic pathogens resulting from the enhancement of a pathogen's transmissibility or virulence in humans is conducted with the utmost regard to safety and security; as well as the [Select Agent Regulations \(SAR\)](#) and the [Export](#)

[Administration Regulations](#). One of the fundamental elements of the aforementioned regulations is to keep certain high-consequence agents and toxins out of the possession of individuals who might intend to misuse them. The SAR, for example, requires individuals or entities that possess, use, or transfer certain high-consequence biological select agents and toxins to register under the [Federal Select Agent Program](#) and individuals must undergo a security risk assessment conducted by the Federal Bureau of Investigation.

NIH takes the need to help ensure the safety of the public very seriously. We have a responsibility to help ensure that research with infectious agents is conducted responsibly, and that we consider the potential biosafety and biosecurity risks associated with such research. NIH will continue to work with other government agencies, NIH-funded academic institutions, professional organizations, and the biomedical research community to protect public health and our national security interests; and continue to support long-standing U.S. efforts to enhance national preparedness and global health security through international fora such as the [Biological Weapons Convention](#) and [Global Health Security Agenda](#) to minimize biological threats whether naturally occurring, accidental, or deliberate in origin.

Regarding your request for a photo of Dr. Collins, there are several available on the [NIH website](#), though these may require permissions to use if you plan to publish any likenesses.

Thanks again for your e-mail to NIH.

Sincerely,

Jessica Tucker, Ph.D.
Director, Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health

(b) (6)



OSP Blog: [Under the Poliscopes](#)

Twitter: @CWolinetzNIH

From: Stephanie Sellers <(b) (6)>

Sent: Wednesday, February 17, 2021 1:37 PM

To: NIH Executive Secretariat <(b) (6)>

Subject: Interview request from senior journalism student at University of North Carolina at Pembroke. Stephanie M. Sellers.

Dear Dr. Francis S. Collins,

I am reaching out to request an interview for my senior journalism capstone project at UNCP. The article will be published.

The article discusses America's biosecurity infrastructure. With your expertise in gain-of-function and dual-use-research-of-concern and your position in government, you are most likely to know the answers to my questions.

Thank you for your consideration.

For your convenience, these are the questions.

- 1. Background: In 2011, Prof. Ron Fouchier presented data at a conference from experiments of modified human isolate of H5N1 avian-origin influenza to acquire mutations to adapt it to human-to-human transmission. A virus capable of small-droplet transmission from one infected ferret to another, according to Lipsitch in a 2018 article in National Center for Biotechnology Information. The 2011 event began the conversation about biosecurity and the threat of this biotechnology ending up in the wrong hands became public knowledge.*

Debates on research ethics grew and in 2012, the U.S. Government (USG) released a four-page Dual Use Research of Concern (DURC) policy in 2012. It states that a “DURC is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public Section II: Definitions 2 health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.”

DURCs 2. (d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin, explains how research may be considered dual use research of concern when the research is not directly related to a pathogen.

- 1. The first question is: Researchers who have been federally funded have also worked under China's Thousand Talents Plan (TTP). What screening/biosecurity measures was completed, with a paperwork trail, on American scientists working on projects that***

fall into the DURC 2. (d) category? Please provide a copy.

2. *Background: Former White House staff leave positions and join lobbying organizations. Their former positions afford leverage and can lead to compromised ethics. UnitedHealth Group alone has given over \$19.5 million in lobbying towards the healthcare industry. **The second question is: When it comes to health, should there be stricter lobbying ethical guidelines?***
3. *The FBI is currently investigating 300 cases of American scientific researchers working with China. **The third question is: What biosecurity measures will be enacted to strengthen public safety from threats of GOF and DURC being in the hands of aggressors?***
4. **May I have one of your profile photos, sent as an attachment, for my article?**

Thank you for your consideration in participating.

Also, I was delighted to learn you wrote a book connecting God and creation. I must read it - after graduation when I have more time.

Sincerely,

Stephanie M. Sellers
Journalist

(b) (6)

(b) (6)

or

(b) (6)

As a reporter, I am a privacy safeguarder. Your statements are protected and much appreciated, whether you decide to be on the record, in the background identifying only your organization, or deep background by not identifying your organization, or completely off the record. Thank you.

All contents of this e-mail are considered intellectual property and may contain research that is copyrighted. Do not share, copy, or express contents without my permission. Violation results in prosecution.

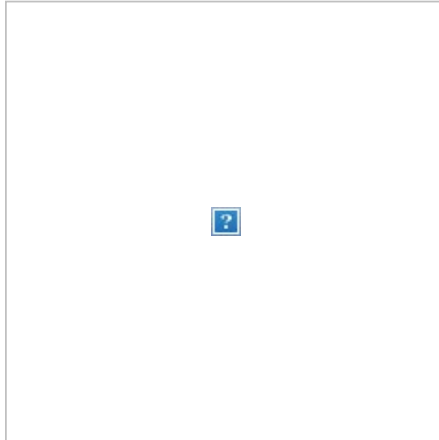
All contents of this e-mail and any attachments thereto are confidential unless explicitly specified otherwise in this e-mail. If you are not the intended recipient, you are hereby formally notified, that any use, copying or distribution of this e-mail, in whole or in part, is strictly prohibited. Please notify the sender by return e-mail and delete this e-mail from your system.

From: [Gabriella Pate](#)
To: [Bradway, Courtney \(HHS/ASL\)](#)
Subject: From the Office of Rep. Van Taylor
Date: Friday, October 16, 2020 5:54:28 PM
Attachments: [Hill Robert Authorization.pdf](#)

----- Please reply ABOVE this line -----

VAN TAYLOR
3RD DISTRICT, TEXAS

COMMITTEE ON
FINANCIAL SERVICES



October 16, 2020

Sarah C. Arbes
Assistant Secretary for Legislation
U S Department of Health and Human Services Hubert Humphrey Building, Room
200 Independence Ave SW
Washington, DC 20201-0001

Dear Sarah,

The attached correspondence has been submitted to my office by my constituent, Robert Hill. Please review the information and advise my office as to what action can be taken on behalf of your agency within its applicable laws and regulations to be of assistance in this matter. Respectfully, I would also ask that you notify my office as to whether you are in need of additional information to process this inquiry and what the expected time frame might be on a response.

You may forward your response via email to (b) (6) or to my District Office at the following address:

U.S. Congressman Van Taylor
5600 Tennyson Parkway, Ste. 275
Plano, Texas 75024

Should you have questions or updates with regards to this inquiry, please contact Gabriella Pate of my district staff at (b) (6) Thank you in advance for your assistance with this matter.

Semper Fidelis,

Congressman Van Taylor



Van Taylor
Member of Congress

VT/GP

WASHINGTON
1404 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-4201

COLLIN COUNTY
5600 TENNYSON PARKWAY, #275
PLANO, TX 75024
(972) 202-4150

VANTAYLOR.HOUSE.GOV



CONGRESSMAN VAN TAYLOR

PRIVACY AUTHORIZATION FORM

(b) (6)

October 16, 2020

Honorable U.S. Congressman Van Taylor; Ms. Gabriella Pate,

I have attached my completed Privacy Authorization Form. I have signed it electronically with my authorized legal signature giving your office full authority under this authorization process.

I am attaching a copy of my original August 5, 2020 legal FOIA request which I made to the NIH/NIAID (see below).

A copy of the NIH/NIAID denial of my FOIA request is attached above (Final response 54886 Hill).

I am also including relevant copies of communication with the HHS regarding my legal appeal of the arbitrary and unjustified denial of my legal FOIA request to NIH/NIAID.

FOIA represents a significant right of American citizens to obtain information regarding the allocation and use of tax dollars that U.S. citizens pay each year. Those tax dollars, when used to fund federal programs, make information about the details of those programs legally available to legal U.S. citizens via a responsibly filed legal FOIA request.

You and/or your office can read my legal FOIA request which I made to NIH/NIAID.

You and/or your office can read the arbitrary and unjustified denial of my FOIA request which NIH/NIAID issued.

You and/or your office can read my immediate legal appeal of the arbitrary and unjustified denial issued by the NIH's FOIA office which I submitted legally to the HHS FOIA office.

I followed all Federal appeal filing rules and instructions as stated on the relevant Federal internet websites.

I have received no response from the HHS or the NIH-NIAID FOIA offices since my recent status requests to Ray Nossoukpoe of the HHS FOIA office.

Legal American citizens should not be forced to file lawsuits in order to obtain legally accessible government documents via legally prescribed FOIA rules, regulations, and procedures.

I filed a legal FOIA request for legally accessible Federal government agency documents on August 5, 2020 and I am still being denied access to those documents.

In addition, I immediately appealed the arbitrary and unjustified denial issued by the NIH/NIAID to the HHS FOIA office, and following an initial e-mail exchange, have heard nothing from the HHS FOIA office in response to my multiple recent status requests.

This kind of "silence" essentially erases FOIA as a citizen's avenue to obtain transparent access to documents that are defined as public rather than the private confidential information store of a tax payer funded government agency.

I will continue to pursue full successful resolution of my original August 5, 2020 FOIA request.

I will accept nothing other than full compliance and full disclosure of all requested documents.

That is my legal right as a legal U.S. citizen filing a legal and properly completed and submitted FOIA request under the U.S. federal government's FOIA statute.

Thank you for your help in securing release of all requested documents from the NIH/NIAID.

Robert Hill

(b) (6)
(b) (6) office
(b) (6) cell

(b) (6)

////////////////////////////////////// copy of my original August 5, 2020 FOIA request to the NIH/NIAID
//////////////////////////////////////

August 5, 2020 – sent via internet e-mail communication as instructed on the NIAID website

Dear NIAID:

I am requesting the following under the authority of the Federal Freedom of Information Act (FOIA):

- Documents that summarize any and all NIAID authorized infectious disease research grants to EcoHealth Alliance, a New York based organization that conducts research and outreach programs on global health, regarding infectious disease research at the Wuhan Institute of Virology (WIV), authorized by the Director of the NIAID, Dr. Anthony Fauci, his office, and/or his immediate NIAID subordinates
- Documents that summarize any and all direct or indirect infectious disease research grants to the Wuhan Institute of Virology (WIV) in Wuhan, China, authorized by the Director of the NIAID, Dr. Anthony Fauci, his office, or his immediate NIAID subordinates
- Documents related to the training of infectious disease research employees and the establishment of operational management protocols and infectious disease research safety procedures by University of Texas Medical Branch employees at the Wuhan Institute of Virology (WIV)
- Documents related to any and all communication between the Director of the NIAID, Dr. Anthony Fauci, his office, or his immediate NIAID subordinates and any and all employees of the World Health Organization, specifically discussing information regarding the Covid-19 outbreak/epidemic/pandemic in Wuhan, China for the months of November and December 2019, and the months of January, February, March, April, May, June, and July of 2020
- Documents related to any and all communication between the Director of the NIAID, Dr. Anthony Fauci, his office, or his immediate NIAID subordinates and any and all employees of the Wuhan Institute of Virology in Wuhan China specifically discussing information regarding the Covid-19 outbreak/epidemic/pandemic in Wuhan, China for the months of November and December 2019, and the months of January, February, March, April, May, June, and July of 2020
- Documents related to any and all communication between the Director of the NIAID, Dr. Anthony Fauci, his office, or his immediate NIAID subordinates and Dr. Peter Daszak, President of EcoHealth Alliance, for the years 2014 to 2020 beginning with January 2014 and inclusive of July 2020, regarding bat virus research in the United States and/or at the Wuhan Institute of Virology in Wuhan, China; Dr. Peter Daszak’s management role regarding the transfer and/or allocation of NIAID infectious disease research grant funds to the Wuhan Institute of Virology (WIV), under the oversight of Dr. Shi Zhengli or any other Wuhan Institute of Virology (WIV) management authority; as well as any reference or relationship to the Obama administration’s gain of function (GOF) legislation passed into law in 2014
- Documents related to any and all communication between the Director of the NIAID, Dr. Anthony Fauci, his office, or his immediate NIAID subordinates and Dr. Shi Zhengli, for the years 2014 to 2020 beginning with January 2014 and inclusive of July 2020, regarding bat virus research in the United States and/or at the Wuhan Institute of

Virology (WIV) in Wuhan, China; Dr. Shi Zhengli's management role at the Wuhan Institute of Virology (WIV); as well as any reference or relationship to the Obama administration's gain of function (GOF) legislation passed into law in 2014

Please confirm receipt of this FOIA request dated August 5, 2020.

Sincerely,

Robert Hill

(b) (6)
(b) (6) office
(b) (6) cell

(b) (6)

////////////////////////////////////// copies of e-mails regarding my appeal of the denial of my original FOIA request //

From: Nussoukpoe, Ray (OS/ASPA) [mailto: (b) (6)]
Sent: Friday, August 28, 2020 3:56 PM
To: (b) (6)
Subject: RE: PHS FOIA Acknowledgement Email 2020-00293-A-PHS

Dear Robert Hill,

Thank you for your inquiry.

No worries! HHS FOIA Office sent your original appeal request to NIH the same day 8/25 for documents/records and are waiting for their response.
Attached is what we sent to NIH.

The acknowledgement letter is automatically generated through the system to just let you know that we receive your request and working on it.
It does not repeat all.

Thank you for your understanding when we are working to help you.

Best Regards,

Ray



*Ray Nussoukpoe, MPA
Government Information Specialist
FOI/PA / ASPA / OS
US Dept. of HHS / HHH Bldg. / Room 729H
200 Independence Avenue, SW
Washington, DC 20201
Office: (202) 690-6887
Fax (202) 690-8300*

(b) (6)

list of reasons for overturning the NIH/NIAID denial of my August 5, 2020 FOIA request as encouraged for submission in federal appeal filing instructions

October 16, 2020

Dear Ms. Pate,

As encouraged to do so in instructions regarding filing a FOIA appeal, I shared these reasons, although not exhaustive, to support my request for overturning the arbitrary and unjustified denial of my FOIA requests by the NIH/NIAID FOIA office.

The FOI Appeal Regulations encourage providing a reason for overturning the denial of my original legal NIH/NIAID FOIA request:

- The NIH/NIAID has refused to provide any information, description, or details of the referenced “pending investigations” which “justify” not fulfilling my legal FOIA request
- The NIH/NIAID references “investigatory records” but does not say if those “investigatory records” are responsive to my very specific FOIA requests
- One must assume they are directly responsive given the logic of the NIH’s language: “We queried NIAID for records responsive to your request. The records you requested involve pending investigations.”
- The NIH/NIAID fails to indicate whether information in the referenced “investigatory records” could be shared by the NIH in response to my original FOIA request at a future date
- There is no legitimate reason to refuse to provide a meaningful description of the “pending investigations” that the NIH/NIAID is referencing as justification for denying a legal FOIA request by a citizen of the United States of America
- A meaningful description of the “pending investigations” would under no circumstance “reasonably be expected to interfere with enforcement proceedings”
- The “final” denial order of the NIH/NIAID is premature, at minimum. It excludes any and all opportunity for explanation as to why a summary denial order was justified and issued – seemingly dictated as a shockingly arbitrary response to a legitimate, factual, objective and LEGAL FOIA request from a taxpaying American citizen
- In addition, any further refusal to provide a meaningful description of the “pending investigations” would also be arbitrary and unsubstantiated – a gross violation of the spirit and reason for FOIA statutes in the United States of America
- Common sense argues that simply describing the nature of the “pending investigations” would not create the risk or harm that the NIH’s invoked FOIA exception is designed to prevent
- Once the “pending investigations,” having FIRST been meaningfully described by the NIH/NIAID (meaning NOW not LATER), are complete, the FOIA information originally requested from the NIH/NIAID in my August 5, 2020 legal FOIA request, should no longer have any restrictions placed upon it
- It should be released in full

I have not received any response from the NIH/NIAID or HHS FOIA offices as of October 16, 2020 addressing these logical reasons for overturning their arbitrary and unjustified FOIA denial.

From: Bob Hill (b) (6)
Sent: Friday, August 28, 2020 2:59 PM
To: PSC FOIA Request (OS/ASA/PSC/FMP) <(b) (6)> Bordine, Roger (NIH/OD) [E]
(b) (6) 'Congressman Van Taylor' (b) (6)
'Congresswoman Kay Granger' (b) (6)
(b) (6)
Cc: (b) (6)
Subject: PHS FOIA Acknowledgement Email 2020-00293-A-PHS

August 28, 2020,

RE: Case No. 2020-00293-A-PHS

Dear Mr. Ray Noussoukpo; Mr. Brandon J. Gaylord, Director FOI/Privacy Act Division; Mr. Roger Bordine:

I am requesting immediate confirmation of your receipt of my original FOIA request to the NIH/NIAID and my appeal to the HHS FOIA office to deny the NIH/NIAID's premature and unjustified refusal to fulfill my original, still active, legal FOIA request which the NIH/NIAID received on August 5, 2020.

Robert Hill

(b) (6)
(b) (6) **office**
(b) (6) **cell**

(b) (6)

//////////////////////////////////// original FOIA request and appeal of the
original FOIA request sent August 27, 2020 //////////////////////////////////

August 27, 2020

RE: Case No. 2020-00293-A-PHS

Dear Mr. Ray Noussoukpo; Mr. Brandon J. Gaylord, Director FOI/Privacy Act Division; Mr. Roger Bordine:

Excerpt from LETTER from Mr. Ray Noussoukpo to Robert Hill

August 25, 2020

Robert Hill

(b) (6)

Sent via email: (b) (6)

Dear Robert Hill:

This letter acknowledges receipt of your **Freedom of Information Act (FOIA) appeal**, submitted to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division. **We received your appeal on August 24, 2020.** Your appeal **challenges the NIH's response to your original request # 54886.** Your appeal has been assigned the above-stated case number based on when it was received in this office. Please reference this number on your correspondence.

Mr. Noussoukpo, I am copying the entire text of my original FOIA request that the NIH FOIA office received from me on August 5, 2020. This is to ensure that your HHS FOIA office has the original correct text:

August 5, 2020 – sent via internet e-mail communication as instructed on the NIAID website

Dear NIAID:

I am requesting the following under the authority of the Federal Freedom of Information Act (FOIA):

- Documents that summarize any and all NIAID authorized infectious disease research grants to EcoHealth Alliance, a New York based organization that conducts research and outreach programs on global health, regarding infectious disease research at the Wuhan Institute of Virology (WIV), authorized by the Director of the NIAID, Dr. Anthony Fauci, his office, and/or his immediate NIAID subordinates

- Documents that summarize any and all direct or indirect infectious disease research grants to the Wuhan Institute of Virology (WIV) in Wuhan, China, authorized by the Director of the NIAID, Dr. Anthony Fauci, his office, or his immediate NIAID subordinates
- Documents related to the training of infectious disease research employees and the establishment of operational management protocols and infectious disease research safety procedures by University of Texas Medical Branch employees at the Wuhan Institute of Virology (WIV)
- Documents related to any and all communication between the Director of the NIAID, Dr. Anthony Fauci, his office, or his immediate NIAID subordinates and any and all employees of the World Health Organization, specifically discussing information regarding the Covid-19 outbreak/epidemic/pandemic in Wuhan, China for the months of November and December 2019, and the months of January, February, March, April, May, June, and July of 2020
- • Documents related to any and all communication between the Director of the NIAID, Dr. Anthony Fauci, his office, or his immediate NIAID subordinates and any and all employees of the Wuhan Institute of Virology in Wuhan China specifically discussing information regarding the Covid-19 outbreak/epidemic/pandemic in Wuhan, China for the months of November and December 2019, and the months of January, February, March, April, May, June, and July of 2020
- Documents related to any and all communication between the Director of the NIAID, Dr. Anthony Fauci, his office, or his immediate NIAID subordinates and Dr. Peter Daszak, President of EcoHealth Alliance, for the years 2014 to 2020 beginning with January 2014 and inclusive of July 2020, regarding bat virus research in the United States and/or at the Wuhan Institute of Virology in Wuhan, China; Dr. Peter Daszak's management role regarding the transfer and/or allocation of NIAID infectious disease research grant funds to the Wuhan Institute of Virology (WIV), under the oversight of Dr. Shi Zhengli or any other Wuhan Institute of Virology (WIV) management authority; as well as any reference or relationship to the Obama administration's gain of function (GOF) legislation passed into law in 2014
- Documents related to any and all communication between the Director of the NIAID, Dr. Anthony Fauci, his office, or his immediate NIAID subordinates and Dr. Shi Zhengli, for the years 2014 to 2020 beginning with January 2014 and inclusive of July 2020, regarding bat virus research in the United States and/or at the Wuhan Institute of Virology (WIV) in Wuhan, China; Dr. Shi Zhengli's management role at the Wuhan Institute of Virology (WIV); as well as any reference or relationship to the Obama administration's gain of function (GOF) legislation passed into law in 2014

Please confirm receipt of this FOIA request dated August 5, 2020.

Sincerely,
Robert Hill

(b) (6)

(b) (6) office

(b) (6) cell

(b) (6)

Gorka Garcia-Malene, the FOIA officer at NIH, in a letter to me dated August 19, 2020, denied my legal FOIA request, FOI Case No. 54886, as follows:

“We queried NIAID for records responsive to your request. The records you requested involve pending investigations. I have determined to withhold those records pursuant to Exemption 7(A), 5 U.S.C. § 552 and (b)(7)(a), and section 5.31 (g)(l) of the HHS FOIA Regulations, 45 CFR Part 5. Exemption 7(A) permits the withholding of investigatory records compiled for law enforcement purposes when disclosure could reasonably be expected to interfere with enforcement proceedings.”

In a return letter from me to Roger Bordine, Program Support, Freedom of Information Office, National Institutes of Health, Building 31, Room 5B35, 31 Center Drive, Bethesda, MD 20892, Phone: 301-496-5633, Fax: 301-402-4541, (b) (6) I asked Mr. Bordine to share a description of the “pending investigations” that Gorka Garcia-Malene used to deny my legal FOIA request. Mr. Bordine replied that the NIH’s response was final, and that I should address any appeal to Brandon Lancey.

Following the instructions for filing an appeal in Subpart F of the HHS FOIA Regulations, I have provided the HHS FOIA Office with all required appeal documents and information.

The FOI Appeal Regulations encourage providing a reason for overturning the denial of my original legal NIH/NIAID FOIA request:

- The NIH/NIAID has refused to provide any information, description, or details of the referenced “pending investigations” which “justify” not fulfilling my legal FOIA request
- The NIH/NIAID references “investigatory records” but does not say if those “investigatory records” are responsive to my very specific FOIA requests
- One must assume they are directly responsive given the logic of the NIH’s language: “We queried NIAID for records responsive to your request. The records you requested involve pending investigations.”
- The NIH/NIAID fails to indicate whether information in the referenced “investigatory records” could be shared by the NIH in response to my original FOIA request at a future date
- There is no legitimate reason to refuse to provide a meaningful description of the “pending investigations” that the NIH/NIAID is referencing as justification for denying a legal FOIA request by a citizen of the United States of America
- A meaningful description of the “pending investigations” would under no circumstance “reasonably be expected to interfere with enforcement proceedings”
- The “final” denial order of the NIH/NIAID is premature, at minimum. It excludes any and all opportunity for explanation as to why a summary denial order was justified and issued – seemingly dictated as a shockingly arbitrary response to a legitimate, factual, objective and LEGAL FOIA request from a taxpaying American citizen
- In addition, any further refusal to provide a meaningful description of the “pending investigations” would also be arbitrary and unsubstantiated – a gross violation of the spirit and reason for FOIA statutes in the United States of America
- Common sense argues that simply describing the nature of the “pending investigations” would not create the risk or harm that the NIH’s invoked FOIA exception is designed to prevent
- Once the “pending investigations,” having FIRST been meaningfully described by the NIH/NIAID (meaning NOW not LATER), are complete, the FOIA information originally

requested from the NIH/NIAID in my August 5, 2020 legal FOIA request, should no longer have any restrictions placed upon it

- It should be released in full

I am asking for the HHS FOIA office to require the NIH/NIAID to provide a meaningful description (appropriately detailed) of the “pending investigations” which today so mysteriously and unjustifiably hide and restrict from release NIH/NIAID information and documents which should be made available under FOIA law in response to a legal American citizen’s FOIA request.

I am asking for a full response, explanation, and most importantly a description of the “pending investigations” which are unjustifiably blocking fulfillment of a legal FOIA request to the NIH/NIAID by a legal, taxpaying citizen of the United States of America.

Sincerely,

Robert Hill

(b) (6)
(b) (6) **office**
(b) (6) **cell**

(b) (6)

From: (b) (6) [mailto:(b) (6)]
Sent: Tuesday, August 25, 2020 12:24 PM
To: (b) (6)
Subject: PHS FOIA Acknowledgement Email 2020-00293-A-PHS

Dear Robert Hill,

Please see the attached acknowledgement letter for information concerning your FOIA matter. The tracking number for your request is 2020-00293-A-PHS. For status updates or other inquiries, please contact our office via email (b) (6) or call (202)260-6933.

Sincerely,

Ray Noussokpoe

From: Lancey, Brandon (OS/ASPA) (b) (6)
Sent: Monday, August 24, 2020 10:12 AM
To: PSC FOIA Request (OS/ASA/PSC/FMP) <(b) (6)>
Cc: Jones, Mary (HHS/ASPA) (CTR) (b) (6)
Subject: FW: NIH FOIA Request 54886 Hill - Final response

New NIH FOIA appeal to log in. Please see below. Thanks.

Brandon L

From: Bob Hill (b) (6)
Sent: Friday, August 21, 2020 9:23 PM
To: NIH FOIA <(b) (6)> 'Congressman Van Taylor' (b) (6)
'Congresswoman Kay Granger' (b) (6)
Cc: Lancey, Brandon (OS/ASPA) (b) (6) (b) (6)
Subject: RE: NIH FOIA Request 54886 Hill - Final response

August 21, 2020

Dear Mr. Bordine and Mr. Lancey,

You may imagine my FOIA request is closed but my FOIA request to the NIH FOIA office, filed on August 5, 2020, is open and active, and will not close until I receive a full response to all my requests.

You didn't share any details on the "pending investigations" that justify your denial of a legal American citizen's FOIA request.

I am contacting Mr. Brandon Lancey by means of this message.

Mr. Lancey, please read the exchange below to understand my FOIA request which the NIH FOIA office received on August 5, 2020.

I am filing an appeal, and would like to talk with you to understand the "mysterious" aura which seems to circle around the four words: "Wuhan Institute of Virology."

Could you please provide a phone number to reach you directly?

I have a legal right as a U.S. citizen and federal taxpayer to access the records that I specify in my FOIA request – which appear below in the letter from the NIH FOIA officer.

I will be in touch.

I can fly to D.C. at my own expense to meet with you if that would be more effective. I am seeking objective, factual information. It shouldn't be so alarming to so many – but for some reason it registers as a seismic event.

Wonder why?

Sincerely,

Robert Hill

(b) (6)
(b) (6) **office**
(b) (6) **cell**

(b) (6)

From: NIH FOIA [[\(mailto:\(b\) \(6\)\)](mailto:(b) (6))]
Sent: Friday, August 21, 2020 3:14 PM
To: Bob Hill; Congressman Van Taylor; Congresswoman Kay Granger
Cc: NIH FOIA; Lancey, Brandon (OS/ASPA)
Subject: RE: NIH FOIA Request 54886 Hill - Final response

Good Afternoon,

Your request is closed at NIH, as noted in the final response letter sent to you, and if you have any further inquiries regarding your request, please contact Brandon Lancey at the HHS Appeals Office.

Thank you.

Roger Bordine
Program Support
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633
Fax: 301-402-4541

(b) (6)



From: Bob Hill (b) (6)
Sent: Friday, August 21, 2020 3:05 PM
To: Bordine, Roger (NIH/OD) [E] (b) (6) Congressman Van Taylor
<(b) (6)> Congresswoman Kay Granger (b) (6)
Cc: NIH FOIA <(b) (6)> (b) (6)
Subject: NIH FOIA Request 54886 Hill - Final response

August 21, 2020

Via e-mail: (b) (6) (b) (6)

Attention Mr. Roger Bordine

RE: NIH FOIA Request 54886 Hill - Final response

Dear Mr. Roger Bordine:

In the attachment to your correspondence, dated August 19, 2020, the letter states:

We queried NIAID for records responsive to your request. The records you requested involve pending investigations. I have determined to withhold those records pursuant to Exemption 7(A), 5 U.S.C. § 552, and section 5.31 (g)(1) of the HHS FOIA Regulations, 45 CFR Part 5. Exemption 7(A) permits the withholding of investigatory records compiled for law enforcement purposes when disclosure could reasonably be expected to interfere with enforcement proceedings.

Please share in detail what the ***“pending investigations”*** are that permit ***“the withholding of investigatory records compiled for law enforcement purposes when disclosure could reasonably be expected to interfere with enforcement proceedings.”***

The phone contacts on your e-mail and on the attached letter, from Gorka Garcia-Malene, 301 496 5633, are the same. When I dial this number a recording says the number “is not available” and that “the mailbox is full,” followed by “Good-bye.”

There is no e-mail listing for Gorka Garcia-Malene in the letter.

Hence my only option to deliver this question is to reply to your original e-mail.

I am in the process of filing an appeal as instructed in Gorka Garcia-Malene’s letter. I do not accept this initial response to my legal FOIA request as “final.” I am asking to have my FOIA request answered in full. As a legal taxpaying citizen of the United States of America I have that legal right.

It is important to transparently share all information related to the current pandemic as it tragically impacts all 7 billion people on our planet.

The research relationships, objectives, funding grants, and results for all relevant Wuhan Institute of Virology Laboratory infectious disease activity should already be fully understood by the world community. Unfortunately, this information has not been publicly shared.

Communist China has chosen, apparently - and successfully, to block all public cooperative scientific investigation and understanding of the true source of the virus.

This hurts our world community, unnecessarily increasing mortality and irresponsibly fueling further economic collapse. Every single human being on planet Earth is negatively impacted by this wall of secrecy.

This seems categorically contradictory to the mantra of the NIH, NIAID, CDC, FDA, and even the WHO - that science and data should pave the path to solving this global catastrophe.

Please answer my question: what are the specific “pending investigations” which prevent the NIH FOIA office from answering my legal and current FOIA requests as listed in Gorka Garcia-Malene’s letter below and originally delivered to the NIH FOIA office on August 5, 2020.

Sincerely,

Robert Hill

(b) (6)
(b) (6) **office**
(b) (6) **cell**
(b) (6)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

Via email: [REDACTED] (b) (6)

August 19, 2020

Robert Hill
3500 Grand Mesa Drive
Plano, TX 75025

Re: FOI Case No. 54886

Dear Mr. Hill:

This is the final response to your August 5, 2020, Freedom of Information Act (FOIA) request addressed to National Institute of Allergy and Infectious Diseases (NIAID) FOIA Office, which was received in the National Institutes of Health (NIH) FOIA office on the same day. You requested copies of the following:

- Documents that summarize any and all NIAID authorized infectious disease research grants to EcoHealth Alliance, a New York based organization that conducts research and outreach programs on global health, regarding infectious disease research at the Wuhan Institute of Virology (WIV), authorized by the Director of the NIAID, Dr. Anthony Fauci, his office, and/or his immediate NIAID subordinates;
- Documents that summarize any and all direct or indirect infectious disease research grants to the Wuhan Institute of Virology (WIV) in Wuhan, China, authorized by the Director of the NIAID, Dr. Anthony Fauci, his office, or his immediate NIAID subordinates;
- Documents related to the training of infectious disease research employees and the establishment of operational management protocols and infectious disease research safety procedures by University of Texas Medical Branch employees at the Wuhan Institute of Virology (WIV);
- Documents related to any and all communication between the Director of the NIAID, Dr. Anthony Fauci, his office, or his immediate NIAID subordinates and any and all employees of the World Health Organization, specifically discussing information regarding the Covid-19 outbreak/epidemic/pandemic in Wuhan, China for the months of November and December 2019, and the months of January, February, March, April, May, June, and July of 2020;

· Documents related to any and all communication between the Director of the NIAID, Dr. Anthony Fauci, his office, or his immediate NIAID subordinates and any and all employees of the Wuhan Institute of Virology in Wuhan China specifically discussing information regarding the Covid-19 outbreak/epidemic/pandemic in Wuhan, China for the months of November and December 2019, and the months of January, February, March, April, May, June, and July of 2020;

· Documents related to any and all communication between the Director of the NIAID, Dr. Anthony Fauci, his office, or his immediate NIAID subordinates and Dr. Peter Daszak, President of EcoHealth Alliance, for the years 2014 to 2020 beginning with January 2014 and inclusive of July 2020, regarding bat virus research in the United States and/or at the Wuhan Institute of Virology in Wuhan, China; Dr. Peter Daszak's management role regarding the transfer and/or allocation of NIAID infectious disease research grant funds to the Wuhan Institute of Virology (WIV), under the oversight of Dr. Shi Zhengli or any other Wuhan Institute of Virology (WIV) management authority; as well as any reference or relationship to the Obama administration's gain of function (GOF) legislation passed into law in 2014; and

· Documents related to any and all communication between the Director of the NIAID, Dr. Anthony Fauci, his office, or his immediate NIAID subordinates and Dr. Shi Zhengli, for the years 2014 to 2020 beginning with January 2014 and inclusive of July 2020, regarding bat virus research in the United States and/or at the Wuhan Institute of Virology (WIV) in Wuhan, China; Dr. Shi Zhengli's management role at the Wuhan Institute of Virology (WIV); as well as any reference or relationship.

We queried NIAID for records responsive to your request. The records you requested involve pending investigations. I have determined to withhold those records pursuant to Exemption 7(A), 5 U.S.C. § 552, and section 5.31 (g)(1) of the HHS FOIA Regulations, 45 CFR Part 5. Exemption 7(A) permits the withholding of investigatory records compiled for law enforcement purposes when disclosure could reasonably be expected to interfere with enforcement proceedings.

You have the right to appeal this determination to deny you access to information in the Agency's possession. Should you wish to do so, your appeal must be sent within ninety (90) days of the date of this letter, following the procedures outlined in Subpart F of the HHS FOIA Regulations (<https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations>) to:

Assistant Secretary for Public Affairs
Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs, Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201

Clearly mark both the envelope and your letter "Freedom of Information Act Appeal."

If you are not satisfied with the processing and handling of this request, you may contact the NIH FOIA Public Liaison and/or the Office of Government Information Services (OGIS):

NIH FOIA Public Liaison

Stephanie Clipper
Public Affairs Specialist
Office of Communications and Public Liaison
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20814
301-496-5633 (phone)
301-496-0818 (fax)
[nihfoia@od.nih.gov](mailto:.nihfoia@od.nih.gov) (email)

OGIS

National Archives and Records Admin.
8601 Adelphi Rd - OGIS
College Park, MD 20740-6001
202-741-5770 (phone)
1-877-684-6448 (toll-free)
202-741-5769 (fax)
ogis@nara.gov (email)

Sincerely,

Gorka Garcia-
malene -S

Digitally signed by
Gorka Garcia-malene -S
Date: 2020.08.19
09:49:29 -04'00'

Gorka Garcia-Malene
Freedom of Information Officer, NIH

From: Bordine, Roger (NIH/OD) [E] (b) (6)
Sent: Wednesday, August 19, 2020 11:51 AM
To: (b) (6)
Cc: NIH FOIA
Subject: NIH FOIA Request 54886 Hill - Final response

Good Afternoon,

Please see the attached final letter in response to your NIH FOIA request.

Thank you.

Roger Bordine
Program Support
Freedom of Information Office
National Institutes of Health
Building 31, Room 5B35
31 Center Drive
Bethesda, MD 20892

Phone: 301-496-5633

Fax: 301-402-4541

(b) (6)



DATE: February 2, 2021

TO: DEPD, ADEPD, CoS, OSP, COSWD, DPCPSI, EDI, OCPL, OER, OLPA, OMA, NIAID

FYI TO: AoU, OB, OHR, OIR, OM, FIC, NCATS, NHLBI, NIBIB, NIEHS, NIMHD, NIDDK, NICHD, NCI

FROM: HHS Reports Team, Executive Secretariat

SUBJECT: Updated Procedures for HHS Reporting; Weekly Cabinet Report

ISSUE

This memo is to inform you that, effective Monday, February 1, 2021, NIH Exec Sec implemented new data call procedures for the Weekly Cabinet Report to the Department.

HHS requires OpDivs to submit a weekly report to the HHS Chief of Staff that will include—among items detailed below and in the attached template—principal-level activity, congressional interactions, and requests for assistance. HHS will highlight appropriate submissions to the President’s Cabinet Secretary.

DEPD, ADEPD, CoS, OSP, COSWD, DPCPSI, EDI, OCPL, OER, OLPA, OMA, and NIAID will receive the assignment for **necessary action** each week. **You will receive the assignment on Tuesdays and your submissions will be due at 3:00 p.m. each Friday.** We will provide additional guidance as soon as we receive it from OS.

AoU, OB, OHR, OIR, OM, FIC, NCATS, NHLBI, NIBIB, NIEHS, NIMHD, NIDDK, NICHD, and NCI will receive this assignment as an FYI and should let ES know as soon as possible if you have a submission for the report in any given week.

REQUIRED CONTENT

Please submit notable items on the following topics that: (1) occurred in the past week; or (2) will occur or require action during the two weeks following the date of the submission. Please see template for specific topics to be included in the report, including:

- Key accomplishments and high priority agency goals
- Obstacles and requests for White House collaboration
- Upcoming Principal level activity, including speeches, travel, media interviews, and engagement with Governors, Mayors, or Members of Congress
- Implementation plans and actions for recent Executive Orders and policy agendas
- Noteworthy rulemakings
- Congressional engagement

SUBMISSION PROCEDURE

All submissions must be formatted using the attached template and include all relevant information.

DUE DATE

The timeframe for ES to prepare and NIH senior leadership to review these reports is very tight. Please submit all submissions in SAAVI by **3:00 p.m. every Friday**. If you do not have a submission, please indicate so in the remarks tab and close the assignment. For questions, please contact the NIH ES HHS Reports team, Christine McMahon and Greta Doswell, at

(b) (6)

ES HHS Reports Team

Attachment

From: [Doswell, Greta \(NIH/OD\) \[E\]](#)
To: [Hawkins, Jamar \(HHS/OS\)](#); [Nguyen, Josephine \(HHS/IOS\)](#)
Cc: [Allen-Gifford, Patrice \(NIH/OD\) \[E\]](#); [Pollock, Rachel \(NIH/OD\) \[E\]](#)
Subject: NIH Bi-Weekly Meeting Agenda - February 4, 2021
Date: Thursday, February 4, 2021 12:02:00 PM
Attachments: [image001.png](#)
[NIH Bi-Weekly Agenda 02 04 2021 Final.docx](#)
[NIH Agency Weekly Cabinet Report 02.02.21 Submission.docx](#)

Good afternoon Jamar and Josephine,

Attached is the agenda for today's meeting scheduled for 2:30 p.m. As background, we are also attaching a copy of the NIH Weekly Cabinet Report.

Many thanks,

Greta

Greta L. Doswell
Executive Secretariat
Office of the NIH Director

(b) (6)



Weekly Report - NIH

Submitted on 02/02/2021

Weekly reports limited to 3 pgs., size 14 font; additional information, if necessary, may be included in the appendix

WEEKLY REPORT

February 2, 2021

MEMORANDUM FOR THE CABINET SECRETARY

FROM: National Institutes of Health, Executive Secretariat, 301.496.8276

SUBJECT: NIH WEEKLY REPORT

Past Week Accomplishments and Setbacks

- VPOTUS Kamala Harris and Second Gentleman Doug Emhoff visited the National Institutes of Health (NIH) to receive second coronavirus vaccination (1/27).
- NIH [Council of Councils](#) Meetings Presentation: NIH Updates.
- Internal NIH Anti-harassment Steering Committee and UNITE Initiative Meetings – internal discussions focused on Strengthening Diversity, Inclusion, and Racial Equity.
- Internal NIH Meetings of the NIH COVID-19 Response Team, The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Team, and Rapid Acceleration of Diagnostics (RADx) Teams to coordinate and drive NIH response to COVID-19.
- Re-launched Implicit Bias Education online eLearning contract engagement; initiated plans to re-launch NIH-wide mandatory eLearning implicit bias online training modules.
- Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Director Dr. Diana Bianchi was interviewed by Seattle NPR affiliate regarding pregnant women and COVID-19 vaccination, including the decision that pregnant people are facing concerning vaccination. Provided background context regarding the Federal Task Force on Research Specific to Pregnant and Lactating Women: <https://www.nichd.nih.gov/about/advisory/PRGLAC>.
- NICHD issued a media advisory based on research results from NICHD-supported research related to COVID-19 and pregnant

Weekly Report - NIH

Printed on 02/02/2021

people: "[Severe COVID-19 in pregnancy associated with pre-term birth, other complications.](#)"

- Introductory meeting with CVS Healthcare and NIH Leadership (1/29).
- [Announcement](#) of interim analysis of Johnson & Johnson Janssen's vaccine candidate.
- NIH Director Dr. Francis Collins spoke to [Washington Post reporter Ariana Cha](#) about how vaccines and variants may change course of pandemic.
- Continued media inquiries regarding NIH funding to EcoHealth Alliance and the subaward to Wuhan Institute of Virology.
- [Announcement](#) of grant extensions for NIH Fellowship ("F") and Career Development ("K") awards to early career scientists whose career trajectories have been significantly impacted by COVID-19.

Obstacles and Requests for White House Collaboration (as needed)

Nothing to report.

Next Week – Upcoming Events / Tasks / Developments

- Internal NIH Meetings of the Anti-harassment Steering Committee and UNITE Initiative focused on Strengthening Diversity, Inclusion, and Racial Equity
- Internal NIH Meetings of the NIH COVID-19 Response Team, ACTIV Team, and RADx Team to coordinate and drive NIH response to COVID-19
- FLOTUS will visit virtually with National Cancer Institute (NCI) staff (2/3) to thank them for their efforts and to hear from several NCI researchers.
- National Institute of Biomedical Imaging and Bioengineering (NIBIB) issuing two contracts for Phase 2 awards in the RADx Tech program, part of the NIH RADx Initiative (tentative issue date 2/2):
 - Meridian Bioscience – lab-based technology to increase testing capacity (\$5.5 million); company based in Cincinnati, OH
 - GenBody Inc. – point of care, rapid antigen test (\$10 million); South Korean company

Weekly Report - NIH

Printed on 02/02/2021

- NIH Director Dr. Francis Collins will speak to *60 Minutes* on COVID-19 treatment efforts (interview date 2/11; air date TBD).

Appendix

Congressional Engagement:

- National Heart, Lung, and Blood Institute (NHLBI) Director Dr. Gary Gibbons spoke at the Congressional Black Caucus Health Braintrust Town Hall about COVID-19 vaccine hesitancy and the Community Engagement Alliance Against COVID-19 (CEAL) program (1/25).
- National Institute of Allergy and Infectious Diseases (NIAID) Director Dr. Anthony Fauci and NHLBI Director Dr. Gary Gibbons spoke at the House Democratic Caucus COVID-19 meeting (1/26).
- NIH Director Dr. Francis Collins had a phone call with House Democratic Leader Steny Hoyer about the availability of vaccines for NIH staff (1/28).
- NIH Principal Deputy Director Dr. Lawrence Tabak and NIH Chief Information Officer (CIO) Andrea Norris briefed the Senate HELP Committee and Senate Homeland Security and Governmental Affairs Committee staff on the recent cyber attack and NIH's response (2/1).
- NIH Principal Deputy Director Dr. Lawrence Tabak and NIH CIO Andrea Norris briefed the House and Senate Labor/HHS Appropriations Subcommittee staff on the recent cyber attack and NIH's response (2/2).
- NIH Principal Deputy Director Dr. Lawrence Tabak and NIH CIO Andrea Norris will brief House Energy and Commerce Committee staff on the recent cyber-attack and NIH's response (2/3).

DATE: February 2, 2021

TO: DEPD, ADEPD, OSP, COSWD, DPCPSI, EDI, OCPL, OER, OLPA, OMA, FIC, NIAID

FYI TO: AoU, CoS, OB, OHR, OIR, OM, NCATS, NHLBI, NIBIB, NIEHS, NIMHD, NIDDK, NICHD, NCI

FROM: HHS Reports Team, Executive Secretariat

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- Congressional engagement

SUBMISSION PROCEDURE

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DUE DATE

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(b) (6)

ES HHS Reports Team

Attachment

WEEKLY REPORT

February 11, 2021

MEMORANDUM FOR THE CABINET SECRETARY

FROM: Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

SUBJECT: National Institutes of Health (NIH) Weekly Report | Week
ending February 12, 2021

AMERICAN RESCUE PLAN (ARP) / ECONOMY

- N/A

COVID-19

- **Significant activity to raise to the attention of POTUS**
 - POTUS visited NIH campus to tour the NIH Vaccine Research Center and deliver remarks to staff. (2/11)
- **Past Week Accomplishments and Setbacks/Obstacles**
 - *TIME Magazine* profile entitled “NIH Director Francis Collins Is Fighting This Coronavirus While Preparing for the Next One.”¹ (published 2/4)
- **Requests for White House Collaboration**
 - N/A
- **Next Week – Upcoming Events / Tasks / Developments**
 - NIH news release re: upcoming *Journal of the American Medical Association (JAMA) Internal Medicine* article, which demonstrates that people who show evidence of previous COVID infection are well protected, for at least a few months, from reinfection: (issue date 2/17)

¹<https://time.com/5935658/nih-director-francis-collins-interview>

Briefing Memo – NIH Weekly Report

Printed on 02/11/2021

- NIH Director Dr. Francis Collins interview by *Axios* on HBO regarding vaccines, emerging coronavirus variants, and what the American public can do while they wait for the vaccine. (air date 2/21)

CLIMATE

- N/A

RACIAL EQUITY

- **Significant activity to raise to the attention of POTUS**
 - N/A
- **Past Week Accomplishments and Setbacks/Obstacles**
 - Re-launched NIH-wide mandatory eLearning implicit bias online training modules (2/8). All of NIH must complete this training by 5/28.
- **Requests for White House Collaboration**
 - N/A
- **Next Week – Upcoming Events / Tasks / Developments**
 - As part of a broader action plan developed through the trans-NIH UNITE Initiative, the Common Fund will launch an “Innovation in Health Disparities and Health Inequities Research” program in FY21. The concept for this initiative is to be discussed with the NIH Advisory Committee to the Director at their February 26 meeting.

SIGNIFICANT EXECUTIVE ORDER (EO) & AGENCY ACTIVITY:

- N/A

Appendix

• Congressional Engagement

- NIH Principal Deputy Director Dr. Lawrence Tabak and NIH Chief Information Officer (CIO) Andrea Norris provided briefings on the recent cyber attack and NIH's response to: (1) Senate HELP and HSGAC staff (2/1); (2) House and Senate Labor/HHS Appropriations Subcommittee staff (2/2); and (3) House E&C staff (2/3). (reported last week)
- NIH Principal Deputy Director Dr. Lawrence Tabak had a call with Rep. David Rouzer (R-NC) and the National Association for Biomedical Research on animal transportation for medical research (2/4).
- National Human Genome Research Institute Director Dr. Eric Green briefed the House Energy and Commerce Oversight and Investigations Subcommittee staff on COVID-19 genetic sequencing (2/8).
- NIH Director Dr. Francis Collins had a call with Rep. Lisa Blunt Rochester (D-DE) on post-acute COVID-19 syndrome (2/10).
- NIH Deputy Director for Extramural Research Dr. Michael Lauer briefed the House and Senate L/HHS Appropriations Subcommittee staff on Foreign Influence (2/10).
- National Institute on Aging Director Dr. Richard Hodes briefed the House and Senate L/HHS Appropriations Subcommittee staff on Alzheimer's Disease research (2/10).
- NIH Office of Data Science Strategy Director Dr. Susan Gregurick and NIH CIO Andrea Norris briefed the House and Senate L/HHS Appropriations Subcommittee staff on big data and artificial intelligence (2/11).
- Sexual & Gender Minority Research Office (SGMRO) Director Dr. Karen Parker will participate in a congressional roundtable on equity and justice with Rep. David Trone (D-MD) (2/12).

• Other Items

- NIH Acting Chief of Staff Dr. Carrie Wolinetz will meet with White House Office of Science and Technology Policy (OSTP) Chief of Staff Kei Koizumi to discuss upcoming OSTP plans and potential NIH detailees.

Briefing Memo – NIH Weekly Report

Printed on 02/11/2021

- Receiving inquiries about EcoHealth because of a Fox News segment² reporting misinformation that the original grant supported gain-of-function research. NIH is providing corrections to media.
- Notice of Special Interest (NOSI): Urgent Competitive Revisions and Administrative Supplements for Research at National Institute on Minority Health and Health Disparities-funded Research Centers in Minority Institutions (RCMI U54s) on SARS-CoV-2 Vaccine Hesitancy, Uptake, and Implementation. This NOSI solicits community-engaged research to: (1) evaluate innovative interventions to facilitate vaccination uptake in clinical and community contexts; and (2) address the barriers to increasing reach, access, and uptake of vaccinations among health disparity populations. (NOSI published³ 2/4.)
- Decision memo rescinding the HHS policy on Human Fetal Tissue (HFT) research sent to the Secretary, via HHS Deputy Chief of Staff and OS Exec Sec (2/5).
- *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Director Dr. Diana Bianchi co-authored a *Journal of the American Medical Association (JAMA)* Viewpoint article, “Pregnant People and Their Clinicians Need Evidence to Guide Vaccination Decisions,” using COVID-19 as a case study for reasons to include pregnant people in research. (The article will be published online the week of 2/8.)

² <https://www.facebook.com/NextRevFNC/videos/751055602196267>

³ <https://grants.nih.gov/grants/guide/notice-files/NOT-MD-21-012.html>

From: [Tucker, Jessica \(NIH/OD\) \[E\]](#)
To: [Plude, Denise \(NIH/OD\) \[E\]](#)
Cc: [Ramkissoon, Kevin \(NIH/OD\) \[C\]](#)
Subject: FW: Interview request from senior journalism student at University of North Carolina at Pembroke. Stephanie M. Sellers.
Date: Friday, March 12, 2021 4:02:57 PM
Attachments: [image001.png](#)

From: Tucker, Jessica (NIH/OD) [E]
Sent: Friday, March 12, 2021 4:03 PM
To: Stephanie Sellers <[REDACTED]> (b) (6)
Subject: RE: Interview request from senior journalism student at University of North Carolina at Pembroke. Stephanie M. Sellers.

Dear Ms. Sellers,

Thank you for your questions regarding dual use research and biosecurity. As the Director of the Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy within NIH's Office of Science Policy, I am pleased to respond on behalf of Dr. Collins.

NIH research is built on the bedrock principles of scientific excellence, unassailable integrity, and fair competition. NIH's commitment to these principles is unwavering and NIH expects NIH-supported research — both domestic and foreign — to abide by these principles. These rules of engagement also are designed to limit bias in the design, conduct, and reporting of NIH-supported research. It is critical for NIH-supported institutions and their researchers to be wholly transparent about financial support from and affiliations with international institutions.

NIH requires the [disclosure](#) of all sources of research support, foreign components, and financial conflicts of interest and uses this information when making its funding decisions to determine if the research being proposed is receiving other sources of funding that could be duplicative, has the necessary time allocation, or if financial interests may affect objectivity in the conduct of the research. Transparency helps ensure that NIH's funding decisions are fair and appropriate, and that U.S. institutions and the American public benefit from their investment in biomedical research, including research that is categorized as dual use research of concern (DURC). Such research is often vitally important to science, public health, and agriculture, and its findings contribute to the broader base of knowledge that advances science and public health objectives. The fundamental purpose of [U.S. policies for the oversight of life sciences DURC](#) is to preserve such benefits while minimizing the potential for misuse. The DURC polices are just one component of a comprehensive biosafety and biosecurity oversight system made up of best practices, guidelines, policies, and regulations. Included among these are the [Department of Health and Human Services \(HHS\) Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens](#), which provides an additional level of review and oversight to help ensure research that is reasonably anticipated to create, transfer, or use potential pandemic pathogens resulting from the enhancement of a pathogen's transmissibility or virulence in humans is conducted with the utmost regard to safety and security; as well as the [Select Agent Regulations \(SAR\)](#) and the [Export](#)

[Administration Regulations](#). One of the fundamental elements of the aforementioned regulations is to keep certain high-consequence agents and toxins out of the possession of individuals who might intend to misuse them. The SAR, for example, requires individuals or entities that possess, use, or transfer certain high-consequence biological select agents and toxins to register under the [Federal Select Agent Program](#) and individuals must undergo a security risk assessment conducted by the Federal Bureau of Investigation.

NIH takes the need to help ensure the safety of the public very seriously. We have a responsibility to help ensure that research with infectious agents is conducted responsibly, and that we consider the potential biosafety and biosecurity risks associated with such research. NIH will continue to work with other government agencies, NIH-funded academic institutions, professional organizations, and the biomedical research community to protect public health and our national security interests; and continue to support long-standing U.S. efforts to enhance national preparedness and global health security through international fora such as the [Biological Weapons Convention](#) and [Global Health Security Agenda](#) to minimize biological threats whether naturally occurring, accidental, or deliberate in origin.

Regarding your request for a photo of Dr. Collins, there are several available on the [NIH website](#), though these may require permissions to use if you plan to publish any likenesses.

Thanks again for your e-mail to NIH.

Sincerely,

Jessica Tucker, Ph.D.
Director, Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health

(b) (6)



OSP Blog: [Under the Poliscopes](#)

Twitter: @CWolinetzNIH

From: Stephanie Sellers <(b) (6)>

Sent: Wednesday, February 17, 2021 1:37 PM

To: NIH Executive Secretariat (b) (6)

Subject: Interview request from senior journalism student at University of North Carolina at Pembroke. Stephanie M. Sellers.

Dear Dr. Francis S. Collins,

I am reaching out to request an interview for my senior journalism capstone project at UNCP. The article will be published.

The article discusses America's biosecurity infrastructure. With your expertise in gain-of-function and dual-use-research-of-concern and your position in government, you are most likely to know the answers to my questions.

Thank you for your consideration.

For your convenience, these are the questions.

- 1. Background: In 2011, Prof. Ron Fouchier presented data at a conference from experiments of modified human isolate of H5N1 avian-origin influenza to acquire mutations to adapt it to human-to-human transmission. A virus capable of small-droplet transmission from one infected ferret to another, according to Lipsitch in a 2018 article in National Center for Biotechnology Information. The 2011 event began the conversation about biosecurity and the threat of this biotechnology ending up in the wrong hands became public knowledge.*

Debates on research ethics grew and in 2012, the U.S. Government (USG) released a four-page Dual Use Research of Concern (DURC) policy in 2012. It states that a “DURC is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public Section II: Definitions 2 health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.”

DURCs 2. (d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin, explains how research may be considered dual use research of concern when the research is not directly related to a pathogen.

- 1. The first question is: Researchers who have been federally funded have also worked under China's Thousand Talents Plan (TTP). What screening/biosecurity measures was completed, with a paperwork trail, on American scientists working on projects that***

fall into the DURC 2. (d) category? Please provide a copy.

2. *Background: Former White House staff leave positions and join lobbying organizations. Their former positions afford leverage and can lead to compromised ethics. UnitedHealth Group alone has given over \$19.5 million in lobbying towards the healthcare industry. **The second question is: When it comes to health, should there be stricter lobbying ethical guidelines?***
3. *The FBI is currently investigating 300 cases of American scientific researchers working with China. **The third question is: What biosecurity measures will be enacted to strengthen public safety from threats of GOF and DURC being in the hands of aggressors?***
4. **May I have one of your profile photos, sent as an attachment, for my article?**

Thank you for your consideration in participating.

Also, I was delighted to learn you wrote a book connecting God and creation. I must read it - after graduation when I have more time.

Sincerely,

*Stephanie M. Sellers
Journalist*

(b) (6)

(b) (6)

or

(b) (6)

As a reporter, I am a privacy safeguarder. Your statements are protected and much appreciated, whether you decide to be on the record, in the background identifying only your organization, or deep background by not identifying your organization, or completely off the record. Thank you.

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From: [Lauer, Michael \(NIH/OD\) \[E\]](#)
To: [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
Cc: [Lauer, Michael \(NIH/OD\) \[E\]](#)
Subject: FW: Action: By COB Thursday, September 23, Please provide Dr. Lauer's availability for an interview request Scientific Integrity at NIH (104613)
Date: Thursday, September 23, 2021 10:11:30 PM
Attachments: [FY21 ALL STAFF-#962682-v14-104613 QUESTIONS FOR DR LAUER.DOCX](#)
[FW Question re OGC comments on May 14 GAO questions on EcoH.msg](#)

Hi Larry – FYI ...
Mike

From: "Bundesen, Liza (NIH/OD) [E]" [REDACTED] (b) (6)

Date: Thursday, September 23, 2021 at 4:26 PM

To: "Lauer, Michael (NIH/OD) [E]" [REDACTED] (b) (6) "Showe, Melanie (NIH/OD) [E]" [REDACTED] (b) (6)

Subject: FW: Action: By COB Thursday, September 23, Please provide Dr. Lauer's availability for an interview request Scientific Integrity at NIH (104613)

Hi Mike,

GAO is requesting a 60 minute interview with you regarding the "Scientific Integrity" (i.e., EcoHealth) audit over the next few weeks. They have sent another extensive set of questions that I imagine you'll want to discuss with OPERA and OGC. Would you like to set up a time to talk with OPERA and OGC first and then schedule something with OIG, or do you want to get OIG on the calendar and work backwards? I'm copying Melanie to facilitate.

Thanks,
Liza

From: Simanich, Sasha (NIH/OD) [E] [REDACTED] (b) (6)

Sent: Wednesday, September 22, 2021 5:02 PM

To: Bundesen, Liza (NIH/OD) [E] [REDACTED] (b) (6)

Subject: Action: By COB Thursday, September 23, Please provide Dr. Lauer's availability for an interview request Scientific Integrity at NIH (104613)

Hi Liza,

The GAO Scientific Integrity engagement (104613) has an interview request and would like to schedule a 60-minute discussion with Dr. Lauer. Specifically, the team would like to speak to Dr. Lauer about the following topics:

- Scientific integrity policies and processes at NIH;
- Agency independence and insulation from political interference; and
- EcoHealth Alliance's 2019 grant: "Understanding the Risk of Bat Coronavirus Emergence" (project number 2R01AI110964-06).

I went ahead and requested written questions to ensure Dr. Lauer is prepared and there are no surprises – see attached. I would appreciate your assistance to get this scheduled over the next week or two. Once you provide me a few dates/times, I will reach out to GAO to confirm and schedule the meeting. I plan to attend but I cannot interject or re-direct questions and only Dr. Lauer will attend from OER team.

Let me know if you have any questions or concerns.

Thank you!

Sasha Simanich

Audit Liaison, OIG/GAO Reviews
NIH/OD/OMA/RMAL
6705 Rockledge Dr., Rm. 60
Bethesda, MD 20817
Email: [REDACTED] (b) (6)

GAO Scientific Integrity Engagement (104613)

Questions for Dr. Lauer, NIH Deputy Director for Extramural Research

Background

GAO is reviewing issues related to scientific integrity and potential political interference at the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), National Institutes of Health (NIH), and the Office of the Assistant Secretary for Preparedness and Response (ASPR). For the purposes of this review, the term “scientific integrity” refers to the use of scientific evidence and data to make policy decisions that are based on established scientific methods and processes, are not inappropriately influenced by political considerations, and are shared openly and transparently with the public. The term “political interference” refers to undue political and external influences that seek to undermine impartiality, nonpartisanship, and professional judgment. Specifically, our researchable questions are:

- (1) What policies and procedures have selected HHS agencies developed to address scientific integrity, and how have those policies and procedures been implemented?
- (2) To what extent have selected HHS agencies received allegations or identified instances of political interference that compromised scientific decision making, and what steps have been taken to address those potential issues?
- (3) What key characteristics insulate agencies from political interference, and which characteristics do selected HHS agencies have in place?
- (4) How, if at all, have selected HHS agencies experienced potential political interference while carrying out their missions and what steps, if any, can be taken to protect against such interference?

Discussion Questions

The questions below are general questions about your views on NIH’s scientific integrity policies.

1. What are the key policies and processes in place at NIH that help ensure or promote scientific integrity, transparent public communications, and insulation from political interference? How, if at all, have these changed during the agency’s response to the COVID-19 pandemic?
2. In your opinion, what is the role of NIH and NIAID senior leadership in ensuring or promoting scientific integrity, insulation from political interference, and transparent public communications at the agency? Please discuss how, if at all, this role has changed over time and why it may have changed.

The questions below are in response to NIH’s August 25, 2021 written response to GAO Data Request #2 and address EcoHealth Alliance’s 2019 grant (referred to below as “the grant”) entitled “Understanding the Risk of Bat Coronavirus Emergence” (project number 2R01AI110964-06).

3. In response to question 6, NIH wrote that, “NIH was informed that senior administration officials were concerned about WIV and therefore issued directions to suspend the subaward, and then, some days later, to terminate the entire grant.”
 - a. Please clarify what individuals or offices are being referenced with the term “senior administration officials.”
 - b. Please confirm whether the directions from senior administration officials were the sole reason that the subaward was suspended. If not, please discuss the other reason(s) for suspension.
 - c. Please clarify whether NIH pursued suspension of the subaward, suspension of WIV from participation in federal programs, or both.
 - d. Please identify the cause(s) for termination of the entire grant.
 - e. Please describe the policies and procedures NIH followed in suspending the subaward and then terminating the entire grant.
4. Please explain why NIH decided to reinstate the grant (July 8, 2020). In your response, please discuss:
 - a. The officials or offices involved in the decision to reinstate the grant, including those both internal and external to NIH;
 - b. What information or data led NIH to determine that grant reinstatement was appropriate;
 - c. The policies and procedures NIH followed in reinstating the grant; and
 - d. Whether NIH has terminated and then reinstated any other grants within the past ten years. If so, please state how many times this has occurred within that timeframe and provide an example of such an occurrence.
5. Please explain why NIH imposed certain requirements on this grant when it was reinstated (i.e., both the original seven requirements from July 8, 2020 and the additional three requirements from October 23, 2020).¹ In your response, please discuss:
 - a. The officials or offices involved in the decision to impose requirements on the grant after it was reinstated, including those both internal and external to NIH;

¹ For the original seven requirements, see NIH’s July 8, 2020 letter to EcoHealth Alliance: <https://republicans-oversight.house.gov/wp-content/uploads/2021/05/Eco-Health-Lab-letter-July-8.pdf>. The October 23, 2020 letter is not publically available, but NIH provided a copy of it in response to GAO Data Request #2.

- b. What information or data led NIH to determine that requirements were necessary after the grant was reinstated, and why the specific requirements were selected;
 - c. The policies and procedures NIH followed in selecting and imposing the requirements after the grant was reinstated; and
 - d. Whether NIH has imposed requirements on any other reinstated grants in the past ten years. If so, please state how many times this has occurred within that timeframe and provide an example of such an occurrence.
6. From your perspective, to what extent, if any, did the suspension of the subaward and termination, reinstatement, and suspension of the grant represent a departure from the following policies and procedures? In your response, please explain which policies and procedures were deviated from and why.
 - a. NIH's Grants Policy Statement (GPS);
 - b. NIH's Policies and Procedures for Promoting Scientific Integrity; and
 - c. Any other formal or informal NIH or HHS policies and procedures that are relevant.
7. Also in response to question 6, NIH wrote that, "After receiving and reviewing the materials that EcoHealth sent on April 23, 2021, NIH sought to refer the matter to the DHHS OIG."
 - a. Please explain why NIH referred the matter to the OIG and what NIH is hoping that the OIG investigation will accomplish.
 - b. What is the current status of the grant?
8. Please describe the concerns, if any, that you had with the suspension of the subaward and termination, reinstatement, and suspension of the grant.
 - a. Are you aware of any other concerns raised by NIAID, NIH, or HHS officials regarding the suspension of the subaward and termination, reinstatement, and suspension of the grant?
 - b. If you or others had concerns, to the best of your knowledge, did anyone attempt to elevate those concerns to senior leadership or other officials within NIAID, NIH, or HHS? If so, what was the outcome of those attempts? If such attempts were not made, please discuss the why such steps were not taken.
9. What do you believe is the acceptable or appropriate level of involvement of political appointees and administration officials in NIH's grants process?
 - a. Do you think that the involvement of senior administration officials in the termination of the grant was appropriate? Please explain your response.

10. In your opinion, what are the key challenges, if any, that confront NIH and NIAID with respect to ensuring scientific integrity throughout the grants process and protecting that process from political interference?
 - a. What steps, if any, are being taken to address these challenges?
 - b. In your opinion, what can HHS, NIH, or NIAID do in the future to protect the agency from potential scientific integrity violations and instances of political interference throughout the grants process?

From: [Bundesen, Liza \(NIH/OD\) \[E\]](#)
To: [Simanich, Sasha \(NIH/OD\) \[E\]](#)
Cc: [Lauer, Michael \(NIH/OD\) \[E\]](#)
Subject: FW: Question re: OGC comments on May 14 GAO questions on EcoH
Attachments: [EcoHealth Alliance grant R01AI110964 timeline 6 13 21.docx](#)
[FY21_ALL_STAFF-#611820-v7-104613_NIH_DATA_INFORMATION_REQUEST_#2_NIH_Response_8.16.21.docx](#)
[NIAID Strategic Plan 2013.DOCX](#)
[QVR snapshot_2014.pdf](#)
[QVR snapshot_2015.pdf](#)
[QVR snapshot_2016.pdf](#)
[QVR snapshot_2017.pdf](#)
[QVR snapshot_2018.pdf](#)
[QVR snapshot_2019.pdf](#)
[QVR snapshot_2021.pdf](#)

Hi Sasha

Please note that I made some edits to the response to Question #2 in the Q&A document.

For the files--

- **Grant file:** depending on how you transmit the information to GAO, you could assemble the following under something labeled "grant file"
 - OIG box file Notices of Award: <https://nih.app.box.com/folder/139846712994>
 - OIG box file on Proposals, Summary Statements, and RPPRs: <https://nih.app.box.com/folder/139856444593>
- **QVR snapshots** - attached
- **Timeline** - attached
- **EcoHealth appeal of the termination; NIH's response; subsequent letters to/from EcoHealth** – you can send the entire contents of the OIG box file on correspondence: <https://nih.app.box.com/folder/139844793573>
- **FOIA documents-** [REDACTED] (b) (5)

Please let me know if you'd like to chat.

Best,

Liza

From: Simanich, Sasha (NIH/OD) [E] <[REDACTED]> (b) (6)
Sent: Thursday, August 5, 2021 11:35 AM
To: Bundesen, Liza (NIH/OD) [E] <[REDACTED]> (b) (6)
Cc: Lauer, Michael (NIH/OD) [E] <[REDACTED]> (b) (6)
Subject: FW: OGC comments on May 14 GAO questions on EcoH

Hi Liza,

Based on OGCs input and Dr. Lauer's review, it appears that we're ready to share our responses with GAO auditors. Before I can run it through our regular channels for final approval, I would need the following documents referenced in the attached file:

- **Grant file**
- **QVR snapshots**
- **Timeline**
- **EcoHealth appeal of the termination; NIH's response; subsequent letters to/from EcoHealth**
- **FOIA documents-** [REDACTED] (b) (5)

If you could please provide me these documents by **COB Wednesday, August 11**, I would really

appreciate it.

Best,

Sasha

From: Jacobs, Anna (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Monday, August 2, 2021 3:54 PM
To: Simanich, Sasha (NIH/OD) [E] <[REDACTED] (b) (6)>
Cc: Lankford, David (NIH/OD) [E] <[REDACTED] (b) (6)> Clark, Tamara (OS/OGC) <[REDACTED] (b) (6)> Yueh, Lena (CDC/OCOO/OGC) <[REDACTED] (b) (6)> Lauer, Michael (NIH/OD) [E] <[REDACTED] (b) (6)> Stein, Meredith (NIH/OD) [E] <[REDACTED] (b) (6)> Brown, Tiffany (NIH/OD/OMA) [E] <[REDACTED] (b) (6)>
Subject: RE: OGC comments on May 14 GAO questions on EcoH

Hi Sasha,

For the FOIA documents, OMA should work directly with the NIH FOIA Office to obtain the documents that the FOIA Office has released. For the remaining documents, I recommend that OMA work with OER to compile those documents. Most of these documents may already be on the Box file for the OIG Audit--although I do not know what is contained in the grant file, so I do not know if those documents are on Box. OER should confirm what is contained in the grant file.

Thanks,

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

[REDACTED] (b) (6) *(phone)*

301-402-1034 (fax)

[REDACTED] (b) (6)

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From: Simanich, Sasha (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Monday, August 2, 2021 3:27 PM
To: Jacobs, Anna (NIH/OD) [E] <[REDACTED] (b) (6)>
Cc: Lankford, David (NIH/OD) [E] <[REDACTED] (b) (6)> Clark, Tamara (OS/OGC) <[REDACTED] (b) (6)> Yueh, Lena (CDC/OCOO/OGC) <[REDACTED] (b) (6)> Lauer, Michael (NIH/OD) [E] <[REDACTED] (b) (6)> Stein, Meredith (NIH/OD) [E] <[REDACTED] (b) (6)> Brown, Tiffany (NIH/OD/OMA) [E] <[REDACTED] (b) (6)>
Subject: RE: OGC comments on May 14 GAO questions on EcoH

Hi Anna,

Thanks for your reply. I have the latest version of responses from OER, the GPS Grants Policy Statement, and the Delegation of Authority (HHS GPAM was removed). Are you able to share with

me the remaining documents outlined below to prepare the package for HHS/ASL approval?

Thanks again,

Sasha

From: Jacobs, Anna (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Friday, July 30, 2021 3:20 PM
To: Simanich, Sasha (NIH/OD) [E] <[REDACTED] (b) (6)>
Cc: Lankford, David (NIH/OD) [E] <[REDACTED] (b) (6)> Clark, Tamara (OS/OGC) <[REDACTED] (b) (6)> Yueh, Lena (CDC/OCOO/OGC) <[REDACTED] (b) (6)> Lauer, Michael (NIH/OD) [E] <[REDACTED] (b) (6)> Stein, Meredith (NIH/OD) [E] <[REDACTED] (b) (6)> Brown, Tiffany (NIH/OD/OMA) [E] <[REDACTED] (b) (6)>
Subject: RE: OGC comments on May 14 GAO questions on EcoH

Hi Sasha,

We recommend sending the proposed responses and documents to ASL for their review. ASL should identify who else needs to review the package and what documents should ultimately be included. We note that deliberative and confidential commercial information is in the documents (especially the grant file), so to the extent ASL clears the production of the documents referenced in the responses, we request that the production to GAO be accompanying by the following disclaimer:

This is not a public disclosure, but instead a good faith effort to assist the GAO in its inquiry. This production includes protected confidential and privileged information and we respectfully request that the GAO not disseminate or otherwise disclose these documents outside of GAO without prior consultation with HHS. The production of these materials does not waive any applicable privilege.

Whatever documents are provided to GAO, we also request that OGC be provided a copy of the documents (or be given access to a shared file that contains the documents) for our awareness only, so that we can know what is going out. We presume these are the documents that will be provided, but please let us know if we've missed any:

Grant file

QVR snapshots

Timeline

EcoHealth appeal of the termination; NIH's response; subsequent letters to/from EcoHealth

FOIA documents

Please let me know if you have any further questions.

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

[REDACTED] (b) (6) *(phone)*

301-402-1034 (fax)

[REDACTED] (b) (6)

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From: Simanich, Sasha (NIH/OD) [E] < (b) (6) >

Sent: Thursday, July 29, 2021 1:44 PM

To: Jacobs, Anna (NIH/OD) [E] < (b) (6) > Lauer, Michael (NIH/OD) [E]
< (b) (6) > Stein, Meredith (NIH/OD) [E] < (b) (6) > Brown, Tiffany
(NIH/OD/OMA) [E] < (b) (6) > Bulls, Michelle G. (NIH/OD) [E]
< (b) (6) > Ta, Kristin (NIH/OD) [E] < (b) (6) >

Cc: Lankford, David (NIH/OD) [E] < (b) (6) > Clark, Tamara (OS/OGC)
< (b) (6) > Yueh, Lena (CDC/OCOO/OGC) < (b) (6) > Lauer, Michael (NIH/OD)
[E] < (b) (6) >

Subject: RE: OGC comments on May 14 GAO questions on EcoH

Hi Anna,

Just to confirm that OMA can release the responses/documents to GAO? Does it need to go through another HHS/ASL/OGC approval?

Thanks,

Sasha

From: Jacobs, Anna (NIH/OD) [E] < (b) (6) >

Sent: Thursday, July 29, 2021 9:02 AM

To: Lauer, Michael (NIH/OD) [E] < (b) (6) > Stein, Meredith (NIH/OD) [E]
< (b) (6) > Simanich, Sasha (NIH/OD) [E] < (b) (6) > Brown, Tiffany
(NIH/OD/OMA) [E] < (b) (6) > Bulls, Michelle G. (NIH/OD) [E]
< (b) (6) > Ta, Kristin (NIH/OD) [E] < (b) (6) >

Cc: Lankford, David (NIH/OD) [E] < (b) (6) > Clark, Tamara (OS/OGC)
< (b) (6) > Yueh, Lena (CDC/OCOO/OGC) < (b) (6) > Lauer, Michael (NIH/OD)
[E] < (b) (6) >

Subject: Re: OGC comments on May 14 GAO questions on EcoH

Great— thanks, Mike and Michelle. That sounds good.

OMA, please let us know if you need anything further from OGC.

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)*

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(b) (6)

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From: Lauer, Michael (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Thursday, July 29, 2021 5:31:33 AM
To: Jacobs, Anna (NIH/OD) [E] <[REDACTED] (b) (6)> Stein, Meredith (NIH/OD) [E] <[REDACTED] (b) (6)> Simanich, Sasha (NIH/OD) [E] <[REDACTED] (b) (6)> Brown, Tiffany (NIH/OD/OMA) [E] <[REDACTED] (b) (6)> Bulls, Michelle G. (NIH/OD) [E] <[REDACTED] (b) (6)> Ta, Kristin (NIH/OD) [E] <[REDACTED] (b) (6)>
Cc: Lankford, David (NIH/OD) [E] <[REDACTED] (b) (6)> Clark, Tamara (OS/OGC) <[REDACTED] (b) (6)> Yueh, Lena (CDC/OCOO/OGC) <[REDACTED] (b) (6)> Lauer, Michael (NIH/OD) [E] <[REDACTED] (b) (6)>
Subject: Re: OGC comments on May 14 GAO questions on EcoH

Good morning – Michelle Bulls and I discussed this. Again, the edits are great, but we ask for one change, [REDACTED] (b) (5)

[REDACTED]

I've attached the latest version (3rd attachment).

Many thanks!

Mike

From: "Jacobs, Anna (NIH/OD) [E]" <[REDACTED] (b) (6)>
Date: Tuesday, July 27, 2021 at 12:51 PM
To: "Lauer, Michael (NIH/OD) [E]" <[REDACTED] (b) (6)> "Stein, Meredith (NIH/OD) [E]" <[REDACTED] (b) (6)> "Simanich, Sasha (NIH/OD) [E]" <[REDACTED] (b) (6)> "Brown, Tiffany (NIH/OD/OMA) [E]" <[REDACTED] (b) (6)> "Bulls, Michelle G. (NIH/OD) [E]" <[REDACTED] (b) (6)> "Ta, Kristin (NIH/OD) [E]" <[REDACTED] (b) (6)>
Cc: "Lankford, David (NIH/OD) [E]" <[REDACTED] (b) (6)> "Clark, Tamara (OS/OGC)" <[REDACTED] (b) (6)> "Yueh, Lena (CDC/OCOO/OGC)" <[REDACTED] (b) (6)>
Subject: RE: OGC comments on May 14 GAO questions on EcoH

Excellent—thanks, Mike!

Anna L. Jacobs, J.D., M.S.

Senior Attorney

HHS Office of the General Counsel

Public Health Division, NIH Branch

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From: Lauer, Michael (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Tuesday, July 27, 2021 12:49 PM
To: Jacobs, Anna (NIH/OD) [E] <[REDACTED] (b) (6)> Stein, Meredith (NIH/OD) [E] <[REDACTED] (b) (6)> Simanich, Sasha (NIH/OD) [E] <[REDACTED] (b) (6)> Brown, Tiffany (NIH/OD/OMA) [E] <[REDACTED] (b) (6)> Bulls, Michelle G. (NIH/OD) [E] <[REDACTED] (b) (6)> Ta, Kristin (NIH/OD) [E] <[REDACTED] (b) (6)>
Cc: Lankford, David (NIH/OD) [E] <[REDACTED] (b) (6)> Clark, Tamara (OS/OGC) <[REDACTED] (b) (6)> Yueh, Lena (CDC/OCOO/OGC) <[REDACTED] (b) (6)> Lauer, Michael (NIH/OD) [E] <[REDACTED] (b) (6)>
Subject: Re: OGC comments on May 14 GAO questions on EcoH
Thanks so much, Anna, I think these edits look fine. I'm looping in Michelle Bulls and Kristin Ta of OPERA so they can take a look.
Mike

From: "Jacobs, Anna (NIH/OD) [E]" <[REDACTED] (b) (6)>
Date: Tuesday, July 27, 2021 at 12:04 PM
To: "Lauer, Michael (NIH/OD) [E]" <[REDACTED] (b) (6)> "Stein, Meredith (NIH/OD) [E]" <[REDACTED] (b) (6)> "Simanich, Sasha (NIH/OD) [E]" <[REDACTED] (b) (6)> "Brown, Tiffany (NIH/OD/OMA) [E]" <[REDACTED] (b) (6)> <[REDACTED] (b) (6)>
Cc: "Lankford, David (NIH/OD) [E]" <[REDACTED] (b) (6)> "Clark, Tamara (OS/OGC)" <[REDACTED] (b) (6)> "Yueh, Lena (CDC/OCOO/OGC)" <[REDACTED] (b) (6)>

Subject: OGC comments on May 14 GAO questions on EcoH
Hi all,
Attached please find OGC's suggested edits to NIH's responses to the May 14, 2021 GAO add-on questions regarding EcoHealth Alliance. OER should review these edits and note any concerns or questions OER might have. Most of the edits are self-explanatory, but I have included comments where it was not. I have also attached two documents referenced in the edits to the response to question 1 (the HHS Grants Policy Administration Manual—Part H—Ch 4; and the NIH Delegation of Authority for Grants-in-Aid). OMA may wish to include these documents, if OER agrees.
Please let us know if you have any questions or would like to discuss.

Best,
Anna L. Jacobs, J.D., M.S.
Senior Attorney
HHS Office of the General Counsel

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EcoHealth Alliance grant R01AI110964 timeline

Mike Lauer (OER)

June 13, 2021

- June 5, 2013: Type 1 proposal submitted
- December 18, 2013: Reviewed, PS 20, percentile 8
- May 27, 2014: Type 1 awarded
 - Proposals and RPPRs in separate folder
 - NOAs in separate folder
- July 7, 2016: Letter from NIAID with determination that this is not “Gain-of-Function” research
- January 19, 2018: State Department Cables re WIV
- November 5, 2018: Type 2 submitted
- February 14, 2019: Type 2 reviewed, PS 20, percentile 3
- July 24, 2019: Type 2 awarded
- April 14, 2020: Larry Tabak (“LT”) loops in Mike Lauer (“ML”) on email string regarding Animal Rights and Congressional complaints
- April 19, 2020: ML sends letter to EcoHealth suspending WIV subaward
- April 20, 2020: Joshua Rogin Op-Ed in Washington Post about State Department cables
- April 22, 2020: ML send LT detailed information about EcoHealth and WIV
- April 24, 2020: ML sends letter to EcoHealth terminating entire grant (appealable under 42 CFR 50, subpart D)
- May 6, 2020: ML sends detailed information about EcoHealth and WIV to OIG OI / ONS
- May 21, 2020: Protest letter from 77 Nobel laureates
- May 22, 2020: Letter from Krinsky (attorney) to ML appealing termination
- July 8, 2020: Letter from ML to EcoHealth – grant reinstated but suspended (not appealable under 42 CFR 50, subpart D); request information and answers to questions; note failure to submit required reports to Federal Subaward Reporting System
- August 13, 2020: Letter from Krinsky (attorney) to ML objecting to suspension
- October 23, 2020: Letter from ML to EcoHealth rebutting Krinsky and requesting additional documents
- February 16, 2021: News story about WIV receiving OLAW assurance
- March 4, 2021: Daszak send email to ML requesting phone call; ML speaks with NIAID DEA; ML re-sends two prior letters (July 8, 2020 and October 23, 2020) to Daszak on March 10, 2021
- March 18, 2021: CMR letter (one of many Congressional queries)
- April 11, 2021: Daszak response to ML; no documents
- April 13, 2021: ML again asks Daszak for documents
- April 23, 2021: Daszak submits some documents to ML, being reviewed by OPERA and OGC
- May 16, 2021: OPERA analyses complete, multiple deficiencies
- May 26, 2021: DDER, OPERA, and OGC meeting: suggest OIG audit of EcoHealth
- June 11, 2021: OIG notifies NIH of planned audit of NIH and EcoHealth

GAO Data Request for the National Institutes of Health (NIH)
Scientific Integrity Engagement 104613

GAO ENGAGEMENT: 104613—Scientific Integrity

REQUEST #: 2

DATE REQUESTED: May 14, 2021

DUE DATE: June 4, 2021

Description of Request(s):

1. Please describe and provide any documentation that exists illustrating NIH's processes for suspending and terminating a grant and reinstating grant funds. In your descriptions, please include information about:
 - a. The chain of command or clearance process for these decisions;



- b. How, if at all, the peer review process is involved;



- c. How, if at all, the process changes based on where a grant is in its award period (e.g., converting from Type 1 to Type 2 or 5 or in the middle of its current award period); and



GAO Data Request for the National Institutes of Health (NIH)
Scientific Integrity Engagement 104613

(b) (5)

- d. Any pre-determined timeframes (e.g., the amount of time a grantee is given to take corrective action following suspension).

(b) (5)

- 2. Please provide a copy of the grant file for the 2019 grant titled "Understanding the Risk of Bat Coronavirus Emergence," (project number 2R01AI110964-06). Please also provide the following information, if the grant file does not contain it:

- a. A description of the research and how it fit into NIH/NIAID's goals, priorities, and objectives at the time of approval.

(b) (5)

- b. 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. (Please include the Grants Management Officer (GMO); Chief Grants Management Officer (CGMO); Scientific Review Officer (SRO); and Authorized Organization Representative (AOR) for the grant in this list.)

(b) (5)

GAO Data Request for the National Institutes of Health (NIH)
Scientific Integrity Engagement 104613

- c. According to the April 2021 *NIH Grants Policy Statement* (p.IIA-12 and IIA-13), there are two types of grants that could possibly contain foreign subcomponents: 1) A domestic grant with a foreign subcomponent; or 2) A consortium/subaward. What type of grant is the grant in question with respect to its inclusion of the Wuhan Institute of Virology (WIV) as a foreign subcomponent?

(b) (5)

3. According to the *NIH Grants Policy Statement* (p. I-43), other NIH, HHS, and federal agency staff (e.g., Office of the Inspector General (OIG) and the Office of Research Integrity (ORI)) coordinate with the GMO, when necessary. Which offices and officials were involved in the suspension and cancellation of the 2019 grant titled "Understanding the Risk of Bat Coronavirus Emergence" (project number 2R01AI110964-06)? Please describe the date and nature of each office and officials' involvement.

(b) (5)

4. According to *SCIENCE*, on April 19, 2020, NIH Deputy Director for Extramural Research Michael Lauer wrote to EcoHealth Alliance and referenced allegations that COVID-19 was released from the WIV, stating: "While we review these allegations during the period of suspension, you are instructed to cease providing any funds to Wuhan Institute of Virology."¹ Please explain whether NIH conducted an investigation into the allegations involving WIV, and if so, please describe the findings of this investigation and provide any documentation associated with this review.

(b) (5)

5. According to the *NIH Grants Policy Statement* (p. IIA-155), a grant recipient may file a grant appeal following an adverse determination. Did EcoHealth Alliance file a grant appeal for the 2019 grant titled "Understanding the Risk of Bat Coronavirus Emergence"

¹ See <https://www.sciencemag.org/news/2020/04/nih-s-axing-bat-coronavirus-grant-horrible-precedent-and-might-break-rules-critics-say>.

GAO Data Request for the National Institutes of Health (NIH)
Scientific Integrity Engagement 104613

(project number 2R01AI110964-06)? If so, please provide all documentation related to EcoHealth Alliance's grant appeal and its outcome.

(b) (5)

6. According to *Politico*, on March 18, 2021, the House Committee on Energy and Commerce wrote a letter to NIH Director Collins 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.”² GAO is interested in reviewing several of the items that were contained in this request, which are listed below: *(Note: If it is easier for NIH to provide the full document request, as opposed to the individual documents requested here, feel free to do so.)*

NIH has not produced documents in response to this letter from minority members of the House Committee on Energy and Commerce. NIH has, however, produced a number of documents in response to FOIA requests seeking information similar to the requests made by minority members of the House Committee on Energy and Commerce. These documents are attached.

- a. “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.” (Item 11.)

(b) (5)

- b. “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.” Please specify the work that was done by the EcoHealth Alliance that did not align with the agency’s program goals and priorities, and when that work was conducted.” (Item 12.)

(b) (5)

² See <https://www.politico.com/f/?id=00000178-460d-d27f-ad7e-57cd8e6c0000>.

GAO Data Request for the National Institutes of Health (NIH)
Scientific Integrity Engagement 104613

- c. “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?” (Item 13.)

(b) (5)

- d. “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.” (Item 16.)

(b) (5)

- e. “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.” (Item 17.)

(b) (5)

- f. “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.” (Item 18.)

(b) (5)



NIAID Strategic Plan

2013



A Letter from the Director

Dear Colleagues:

For more than six decades, scientists supported by the National Institute of Allergy and Infectious Diseases (NIAID) have been at the forefront of important research in infectious and immune-mediated diseases, microbiology, immunology, and related disciplines. Their work has contributed to the development of new and improved medical tools to detect, treat, and protect against illness, alleviate suffering and prevent death in the United States and around the world.

The purpose of this document is to articulate the current strategic priorities of the Institute according to our four main scientific areas of emphasis: HIV/AIDS; Infectious Diseases (Non-AIDS), Including Emerging and Re-emerging Diseases and Biodefense; Allergy, Immunology, and Immune-Mediated Diseases; and Global Health Research. NIAID has built up a robust portfolio of basic, translational, and clinical research to sustain and advance these core areas. The Institute also has carried out its mandate to respond rapidly to emerging and re-emerging infectious diseases that occur periodically but unexpectedly. Since the publication of the last NIAID Strategic Plan in 2008, we have witnessed dozens of such threats to public health. The most prominent was the global 2009 H1N1 influenza pandemic, during which NIAID coordinated a series of clinical trials that led to the licensure of an effective vaccine against this new virus in just a few months. Other examples include the emergence of a novel pathogenic coronavirus, the increasing spread of dengue fever, and the development of multidrug-resistant gonorrhea and extensively drug-resistant tuberculosis.

Since 2008, however, we also have seen the rapid evolution of technological capabilities and research tools that offer an unprecedented range of new scientific opportunities. These tools include high-throughput genomic sequencing and bioinformatics, as well as the multidisciplinary approach to research known as systems biology. As always, although the fundamental mission of the Institute has not changed, we continually re-examine and update both our research approaches and our research priorities.

The 2013 NIAID Strategic Plan outlines our current research priorities that will help guide our future decision making. Strategic planning is especially important in our present environment of constrained research resources. In this regard, the 2013 Plan reflects increased opportunities for collaboration across our four major scientific areas of emphasis. With a strong research base, talented investigators in the United States and abroad, and the availability of powerful new research tools, we are confident that this Plan will help guide our research programs toward our ultimate goal of improving global health.

Sincerely,

Anthony S. Fauci, M.D.
Director, NIAID

The NIAID Mission

The mission of the National Institute of Allergy and Infectious Diseases (NIAID) is to conduct and support basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. Infectious diseases include global killers such as human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), tuberculosis (TB), and malaria; emerging or re-emerging threats such as influenza, multiple drug-resistant tuberculosis (MDR TB), and methicillin-resistant *Staphylococcus aureus* (MRSA); and “deliberately emerging” threats from potential agents of bioterrorism. Immune-mediated disorders include autoimmune diseases, such as lupus and type 1 diabetes; asthma; allergies; and graft rejection and other problems associated with tissue and organ transplantation.

The strategic management of such a complex research mission has two core components: 1) maintaining a breadth and depth of knowledge in all areas of infectious and immune-related diseases, and 2) developing flexible domestic and international capacity to efficiently undertake research required in response to newly emerging threats wherever they occur.

To accomplish its mission, NIAID conducts and supports a comprehensive portfolio of research on the biology of pathogenic organisms, the host response to microbes, the mechanisms of normal immune function, and immune dysfunction that results in autoimmunity, immunodeficiency, allergy, and transplant rejection. This basic research provides the scientific understanding and research platform for translational and clinical research to develop and test vaccines, therapeutics, and diagnostics to prevent and treat the many infectious, immune-mediated, and allergic diseases that afflict people throughout the world.

After the events of September 11, 2001, and the subsequent release of anthrax spores, biodefense became an important element of the NIAID mission. In 2003, NIAID was assigned lead responsibility within the U.S. Department of Health and Human Services (HHS) and the National Institutes of Health (NIH) for civilian biodefense research. Since then, NIAID has supported research and early development of medical countermeasures against terrorist threats from infectious diseases and radiation exposure. NIAID later assumed responsibility for coordinating the NIH-wide effort to develop medical countermeasures against chemical threats to the civilian population. Because new potentially deadly pathogens, such as avian influenza, may be naturally occurring as well as deliberately introduced by terrorists, NIAID’s biodefense research is integrated into its larger emerging and re-emerging infectious diseases portfolio. While NIAID continues to focus on developing drugs, vaccines, and diagnostics for these disease agents, the research focus has evolved from the traditional “one bug–one drug” approach to a more flexible strategy using sophisticated genomic and proteomic platforms focused on developing broad-spectrum therapies effective against entire classes of pathogens.

NIAID is dedicated to building and sustaining a comprehensive research infrastructure to support its mission. Such infrastructure includes adequate, well-placed facilities for conducting research on highly infectious pathogens, and expertise to facilitate product development leading to approval by the U.S. Food and Drug Administration (FDA) of vaccines, therapeutics, and diagnostics. NIAID also supports an extensive clinical trials infrastructure. Recently, NIAID expanded the long-standing HIV/AIDS clinical trials networks to support critical research efforts on tuberculosis and hepatitis C, common co-infections in HIV-infected people. In addition, the Institute has established a new clinical trial network to address antibacterial resistance research, a growing public health concern. NIAID also fosters the organization of consortia, repositories, and databases, thus providing critical resources to support its scientific research. Finally, NIAID supports the training and professional development of scientists in the fields of infectious diseases and immunology.

Given the global impact of infectious diseases, a key aspect of the Institute's mission is to foster and maintain a strong program of international research and research capacity building. Clinical research on HIV/AIDS, TB, malaria, neglected tropical diseases, and other leading infectious causes of global mortality is best pursued through mutually beneficial partnerships that engage researchers and institutions in countries where these diseases are endemic. Thus, NIAID supports networks of U.S. and international scientists, trains American and foreign investigators to work internationally, and enhances research facilities around the world. NIAID recognizes that international research must involve shared leadership, a commitment to long-term sustainability, and the engagement of local communities if it is to contribute substantially to improvements in global public health.

An overarching priority in all NIAID research programs is to reduce health disparities and improve health for all people as research advances are translated into clinical practice. Many NIAID advances have helped to address health disparities. Examples include the development of effective therapies for hepatitis B and C virus infection and interventions to reduce the burden of asthma on children residing in inner cities. In addition, NIAID actively seeks the participation of diverse populations in clinical studies to ensure the scientific validity and broad applicability of research findings.

For nearly 60 years, NIAID research has led to new vaccines, therapeutics, diagnostics, and other technologies that have improved health and saved millions of lives in the United States and around the world. NIAID will continue to play a leading role in advancing knowledge of infectious and immune-mediated diseases and in accelerating the development of treatments and prevention strategies to respond to emerging public health threats.

Infectious Diseases (non-AIDS) Including Emerging and Re-emerging Diseases and Biodefense

Throughout history, infectious diseases have posed a major threat to human health. Their impact continues to be an important human health concern, in the United States and around the world. Although advances in medicine and public health—such as antibiotics, vaccines, and improved sanitation—have helped control many endemic diseases, infectious diseases remain the second leading cause of death throughout the world. In 2002, infectious diseases were the cause for more than one-quarter of approximately 57 million deaths worldwide.¹ Approximately two-thirds of all deaths in developing countries among children younger than 5 years of age² are due to infectious diseases.

New challenges arise continually, including the emergence of new infectious diseases, the re-emergence of drug-resistant bacterial strains, such as *Neisseria gonorrhoeae* and multi- and extensively drug-resistant TB, which are no longer responsive to traditional treatments; and the global persistence of respiratory, sexually transmitted, and enteric pathogens that can become epidemics.

Natural genetic variations also allow novel strains of known pathogens to appear, such as the 2009 outbreak of a new strain of H1N1 influenza A. NIAID support for influenza research over the past several years has greatly improved our preparedness for and ability to respond to a pandemic, and reaffirms that continued vigilance, planning, and strong biomedical research capability and public health response are essential defenses against emerging health threats.

Despite advances, many infectious diseases are not adequately controlled. Some that pose ongoing health problems in developing countries emerged recently in the United States, including food- and waterborne (e.g., *Shigella*) and vector-borne (e.g., West Nile virus) infections. Some diseases, such as Lyme disease, continue to be a problem in the United States. In addition, the resurgence of some diseases, such as TB, resulted from evolution of pathogen strains that are highly resistant to available treatments. Neglected tropical diseases (NTDs), such as dengue, lymphatic filariasis, trachoma, and leishmaniasis, are of particular concern. These infectious diseases take a tremendous toll on global health and can cause significant, lifelong disability.

Since the terrorist attacks of Sept. 11, 2001, and the subsequent anthrax mailings of that fall, NIAID has played a role in the national strategy to develop medical products and approaches to counter bioterrorism and emerging and re-emerging infectious diseases. NIAID supports basic research to better understand infectious agents and host-pathogen interactions. As described in NIAID's *Strategic Plan for*

¹ World Health Organization (WHO). *The world health report: 2004—Changing history*; <http://www.who.int/whr/2004/en/>.

² WHO. *The world health report: 2005—Make every mother and child count*; <http://www.who.int/whr/2005/en/index.html>.

Biodefense Research,³ NIAID's research has evolved from a focus on individual pathogens to a broad-spectrum approach to vaccines, diagnostics, and therapeutics that address multiple pathogens. This move from the "one bug–one drug" approach toward a more flexible, comprehensive strategy using sophisticated genomic and bioinformatics technologies is yielding numerous scientific advances and equips the nation with an integrated, coordinated approach to addressing public health crises.

NIAID's work is part of a national and international effort to reduce morbidity and mortality from infectious diseases, develop defenses against emerging or deliberately introduced infectious diseases, and improve public health around the world. NIAID partners with many organizations, including other government agencies, foundations, nonprofit organizations, foreign governments, and pharmaceutical and biotechnology companies.

Area of Emphasis: Biology of pathogens and host-pathogen interactions

NIAID supports basic research to elucidate pathogen biology; interactions among pathogens, hosts, and the environment; and the varied and ingenious ways that microbes survive and multiply. Discoveries made through basic research expand the biomedical knowledge base, lay the foundation for applied research, and pave the way for new treatment and prevention strategies. For example, NIAID's longstanding support of basic research studies of the hepatitis C virus (HCV) enhanced understanding of how HCV replicates, enabling the development of two new anti-HCV drugs and several promising drugs now being evaluated in clinical trials.

Several key NIAID efforts may lead scientists to identify potential new targets for therapeutics and vaccines. Scientists increasingly pursue systems biology approaches to identify host-pathogen interactions that help explain and predict clinical manifestations of infectious diseases, including disease progression and outcomes. Experimental technologies used include high-throughput genomics, transcriptomics, proteomics, metabolomics, and lipidomics, all of which enable scientists to examine biological processes of infectious diseases at the molecular level. Bioinformatics approaches are key to analyzing and understanding large data sets generated by these high-throughput technologies. NIAID-supported Bioinformatics Research Centers collect, integrate, and provide easy access to research data on microbial organisms and vectors of infectious diseases as well as novel analytical tools to facilitate data interpretation by the broader scientific community. NIAID also partners with other NIH Institutes and Centers to support the NIH Human Microbiome Project. The goal of this project is to enable comprehensive characterization of human microbiota and analyze their role in health and disease.

These enterprising research efforts continue to uncover the mysteries of infectious pathogens, and provide an important knowledge base that enhances our ability to identify and characterize newly emerging or re-emerging threats.

³ NIAID Strategic Plan for Biodefense Research (2007 update); <http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Documents/biosp2007.pdf>

PRIORITY 1: Through basic research, increase understanding of the molecular structure and function of known viral, bacterial, fungal, prion, and parasitic pathogens and identify new pathogens.

PRIORITY 2: Use advanced technologies, including next-generation genomic technologies, to extend insights into mechanisms of infection, pathogenicity, virulence, host-pathogen interactions, and development of drug resistance for diseases such as TB.

PRIORITY 3: Characterize microbial communities throughout the human body in an effort to understand the role of the innate immune system in protecting the host from infectious pathogens.

PRIORITY 4: Determine the influence of co-infecting microbes on the pathogenesis of infectious diseases in order to better understand the impact of eliminating secondary infections on disease outcomes.

Area of Emphasis: Medical interventions

Insights from basic research often yield concepts for new vaccines, therapeutics, and diagnostics that are validated in model systems and then further developed and tested in applied research settings. Promising candidates advance through the research and development pipeline to human testing in clinical trials. NIAID supports studies throughout the development pipeline, from early discovery to clinical evaluations of candidate diagnostics, vaccines, and therapeutics.

Diagnostics

As infectious diseases continue to take their toll around the world, there is an urgent need for rapid, highly sensitive, and specific clinical diagnostics that are easy to use, cost-effective, suitable for use in point-of-care settings, and able to determine a pathogen's drug sensitivities. Many of the initial symptoms caused by bacterial, viral, or parasitic infections, or by exposure to toxins, may be nonspecific, making it difficult for clinicians to identify appropriate treatment options. The introduction of the Xpert MTB/RIF test for diagnosing TB, developed in part through NIAID support, addresses the urgent need for new tools to rapidly diagnose TB and its drug-resistant forms. This new test is expected to help stem the tide of new TB infections.

Researchers are using advanced technologies to identify diagnostic targets and develop new diagnostic methods. For example, NIAID-supported scientists are developing simple tests that can quickly and accurately determine whether a person is infected with *Borrelia burgdorferi*, the bacterium that causes Lyme disease. NIAID also supports research to develop multiplex platforms capable of detecting multiple pathogens and/or toxins in a single test. The multiplex diagnostic platform FilmArray®, developed with NIAID support and approved by the FDA, can detect 21 respiratory pathogens from patient samples and differentiate among particular influenza strains.

NIAID continues to support clinical validation of new infectious disease diagnostics. The Institute also supports studies to improve sample processing and preparation, decrease time to diagnosis, and develop instrumentation and platforms for primary healthcare settings.

PRIORITY 1: Conduct basic research, including using advanced genomics technologies, to develop a clearer understanding of pathogens, disease, and host immunity and to discover unique characteristics that could be used as specific and sensitive targets for preventing, diagnosing, monitoring, and treating infectious diseases.

PRIORITY 2: Develop and expand diagnostic platforms and technologies that can identify multiple pathogens, distinguish pathogen strains, recognize early infection or exposure, and detect drug sensitivity and resistance. These platforms and technologies must be reliable, rapid, sensitive, specific, cost-effective, and easy to use in a variety of settings.

Vaccines

Vaccines have led to many of the greatest improvements in public health. Exciting developments in vaccine research methodology are emerging as scientists improve their understanding of the immune system and how it fights harmful microbes. These advances lead to clinical trials to evaluate candidate vaccines developed to protect against diseases such as malaria and influenza. Many of these trials are conducted through NIAID's longstanding Vaccine and Treatment Evaluation Units (VTEUs). NIAID is expanding the VTEUs to enable the conduct of studies in disease-endemic areas. Technological advances continue to improve existing vaccines and allow identification of vaccine candidates to prevent diseases for which no vaccines are currently available. For example, NIAID is conducting a trial to evaluate the safety, immune response, and initial efficacy of a vaccine to prevent acute and chronic hepatitis C infection.

As new pathogens and novel strains of existing pathogens emerge, new vaccines are needed, and NIAID will continue responding to this challenge through vaccine research. An integral part of this challenge is the quest to better understand innate and adaptive immune responses and advance the development of cross-protective vaccine strategies. NIAID's funding for projects focused on the development of a universal influenza vaccine illustrates the commitment to cutting-edge vaccine research.

PRIORITY 1: Conduct basic research to elucidate mechanisms of host-pathogen interactions, to better understand and enhance immune responses, and to identify promising new vaccine targets for diseases of global health importance.

PRIORITY 2: Design new or improved vaccines that are safe and effective, with particular emphasis on multivalent and cross-protective vaccine strategies such as a universal influenza vaccine.

PRIORITY 3: Use advanced technologies to rapidly determine safety and immunogenicity of candidate vaccine products and to streamline manufacturing.

PRIORITY 4: Support the advanced development of candidate vaccines that are easy to deliver, produce protective immunity with fewer doses of vaccine, and are readily stored and easily distributed.

Therapeutics

NIAID supports a variety of approaches to identify potential targets for intervention and to engineer new therapeutics. The ability of pathogens to develop drug resistance makes establishing an arsenal of safe and effective antimicrobials especially challenging, particularly for many of the NTDs for which only

limited drug regimens are available. Exciting progress is being made by screening existing products for activity against different pathogens, or, in the case of malaria, by combining new or existing compounds into better multidrug regimens. In the area of biodefense, NIAID-supported animal model studies played a major role in the FDA decision to approve levofloxacin to treat and prevent pneumonic plague. Rising rates of antimicrobial resistance are another area of concern. NIAID supports multiple clinical trials designed to provide vital information on the optimal use of currently available antibacterial drugs. The goal is to find treatment regimens that limit the emergence of drug resistance. Identifying and approving new uses for existing antimicrobials will facilitate an effective response in the event of a public health emergency. For example, such medications can be stored in the Strategic National Stockpile, a national repository of life-saving pharmaceuticals and medical supplies that may be dispensed to meet urgent public health needs.

While repurposing existing drugs holds promise, new treatments that are effective against a range of pathogens are also needed. This broad-spectrum approach would allow a small number of drugs to replace dozens of pathogen-specific drugs, thereby improving preparedness for all infectious threats, whether naturally occurring or deliberately introduced (i.e., bioterror threats).

PRIORITY 1: Conduct basic research to understand how pathogens develop drug resistance.

PRIORITY 2: Identify potential targets for developing novel approaches to broad-spectrum interventions.

PRIORITY 3: Identify new strategies for developing immunotherapies, including those based on host responses.

PRIORITY 4: Use advanced technologies to screen, test, and develop novel and improved chemotherapies, biopharmaceuticals, and immunotherapies that offer broad-spectrum coverage.

PRIORITY 5: Conduct clinical research to investigate new strategies for using existing drugs to limit antimicrobial resistance.

Global Health Research

For nearly 60 years, NIAID research has led to new vaccines, diagnostics, and therapeutics that improved the health of millions of people in the United States and around the world. International research at NIAID addresses a multitude of infectious diseases that cause millions of death worldwide each year, such as TB and malaria. These research activities span the spectrum from basic through applied research. Research conducted in international settings can enable scientists to conduct studies in disease-endemic areas and benefit populations most affected by particular diseases. NIAID does not target specific countries or geographical regions for funding. The Institute recognizes, however, that this solid foundation of global health research and collaboration enhances capacity for infectious disease surveillance and the ability to respond to newly emerging threats, including diseases with potential to cause global pandemics, such as influenza. Moreover, NIAID has employed creative solutions to address

global health priorities, such as supporting the discovery and development of drugs for NTDs through public-private partnerships in collaboration with non-federal entities.

PRIORITY 1: Continue to build a solid base of diverse research expertise to quickly address the emergence and re-emergence of new and existing infectious diseases around the globe.

PRIORITY 2: Support the participation of international investigators in the conduct of infectious diseases research in order to enhance our understanding of these diseases in their natural environments.

PRIORITY 3: Continue to support existing partnerships and develop new collaborations with institutions and organizations involved in global research. Partnerships and collaborations enable NIAID to leverage its resources for international research.

For more information, please see the section on Global Health Research.

Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome

Extraordinary progress has been made in HIV/AIDS research since the disease was first noted in published case reports more than 30 years ago. Researchers now understand HIV and its pathogenesis, can rapidly and specifically diagnose HIV infection, and can profoundly suppress HIV replication with highly active antiretroviral therapy (HAART). These potent antiretroviral drugs have saved an estimated 3 million years of life in the United States alone⁴, nearly eliminated mother-to-child transmission (MTCT) of HIV infection in many parts of the developed world, and reduced the incidence of HIV infection in some developing-world settings.

HAART also effectively prevents sexual transmission of HIV in adults, as demonstrated by results from the HIV Prevention Trials Network Study 052 (HPTN 052).⁵ This NIAID-supported study evaluated whether antiretroviral drugs can prevent the sexual transmission of HIV among couples in which one partner is HIV-infected and the other is not (sero-discordant couples). The study found that if HIV-infected heterosexual individuals begin taking antiretroviral medicines when their immune systems are relatively healthy—rather than delaying therapy until the disease has advanced—they are as much as 96 percent less likely to transmit the virus to their uninfected partners. *Science* selected this landmark study as the 2011 Breakthrough of the Year.

Recognizing the considerable advances made in HIV/AIDS research and the opportunity to build on these advances, Secretary of State Hillary Clinton unveiled a blueprint for an “AIDS-free generation” in November 2012. The blueprint focuses on preventing new HIV infections and stemming the progression of HIV infection to AIDS in infected persons. In addition to this goal, scientists are working to truly control and ultimately end the HIV and AIDS pandemic by curing HIV infection.

Transformative successes in HIV prevention will require multiple versions of combination prevention strategies that are well-suited to specific target populations. A safe and effective HIV vaccine has long been, and continues to be, a major goal of HIV-prevention research domestically and internationally. Researchers now see the vaccine as an essential complement to combinations of existing prevention strategies that will curtail the HIV/AIDS pandemic. Developing an effective HIV vaccine has been particularly challenging; an HIV vaccine must show significant and durable protection against all methods of transmission and all clades and strains of HIV. New biomedical prevention tools that can be

⁴ Vermund SH. *J Infect Dis.* 2006 Jul 1; 194(1):1-5.

⁵ M.S. Cohen *et al.* Prevention of HIV-1 Infection with Early Antiretroviral Therapy. *New England Journal of Medicine* DOI: 10.1056/NEJMoa1105243 (2011).

integrated with or enhance currently available prevention strategies are also needed. All of these prevention tools must be linked with social and behavioral interventions.

As NIAID joins international partners in aggressively pursuing research to control and ultimately end the HIV/AIDS pandemic, the Institute's HIV/AIDS research agenda increasingly addresses common co-infections, such as TB in global populations and hepatitis globally and domestically.

Area of Emphasis: Halt the spread of HIV infection by defining highly effective prevention strategies, including a preventive HIV vaccine

The most compelling goal in HIV research is prevention of HIV infection, which is critical to the long-term goal of controlling and ultimately ending the HIV pandemic. While scientists are making progress, an HIV vaccine is likely still years away. Importantly, a number of prevention methods with a strong evidence base already exist, including proper use of condoms, needle exchange, adult male circumcision, pre-exposure prophylaxis (PrEP), and treatment as prevention (TaP). Lack of HIV testing and linkage to care must be addressed in order to advance TaP from a proof of principle in a clinical trial to a viable public health intervention. Identifying HIV-infected people through HIV testing is the single most important step toward improving the impact of treatment, care, and prevention services. For testing to be maximally effective it must be provided routinely, and, when an HIV-positive person is identified, linkage and retention in care must occur quickly and seamlessly. This “test and treat” concept is currently under investigation through the HPTN 065 study, TLC-Plus: A Study to Evaluate the Feasibility of an Enhanced Test, Link to Care, Plus Treat Approach for HIV Prevention in the United States.

On a global scale, these proven prevention approaches, alone or in combination, are accessible to only a fraction of those who would benefit from their implementation. Devising ways to scale up proven, integrated prevention methods would have an important impact on the HIV epidemic. Implementing these prevention methods, along with effective social mobilization and behavioral interventions, must be bolstered by developing and validating additional, potent prevention tools, such as antiretroviral therapy (ART)-based prevention strategies and a safe and effective HIV vaccine. All future prevention research must integrate an understanding of behavioral factors, adherence, and acceptability at the earliest stages of product discovery.

PRIORITY 1: Devise strategies to block HIV infection at mucosal surfaces and other tissues by defining the early steps in HIV acquisition that lead to the establishment and systemic spread of HIV.

PRIORITY 2: Study the interaction of HIV with the human immune system at the organism level through the integrated use of bioinformatics, computational approaches, and systems biology to better understand how the virus causes disease and what aspects of the host influence vulnerability to infection.

PRIORITY 3: Establish pathways for rational development of effective HIV vaccines by building a better foundation of basic knowledge about innate and adaptive immune responses to HIV infection and to experimental vaccines.

PRIORITY 4: Drive research to discover safe and effective vaccine candidates, including:

- Following up on the results of the Thai Phase III HIV vaccine trial, also known as RV144, to capitalize on the only demonstration of vaccine efficacy to date and attempt to expand potency and durability
- Facilitating rational, structure-driven vaccine design
- Developing strategies to optimize the evaluation of B-cell responses
- Identifying vaccine adjuvants and immune modulators that enhance vaccine activity and extend the breadth and/or duration of the protective immune response

PRIORITY 5: Design and conduct clinical trials that demonstrate the safety and efficacy of HIV vaccine candidates by:

- Building on the success of existing vaccines to create more effective vaccines
- Expediting the identification and evaluation of immunogens
- Efficiently assessing vaccine effect
- Rapidly assessing potential correlates of immunogenicity and of protection elicited by experimental vaccines
- Producing a vaccine that is effective for various risk groups and demographics and protects against different modes of transmission

PRIORITY 6: Advance a comprehensive research program aimed at developing and evaluating safe, effective, and acceptable non-vaccine prevention methods and optimal formulations, dosage, and product delivery methods, including but not limited to topical microbicides and pre- and post-exposure prophylaxis.

PRIORITY 7: Establish partnerships to better understand biologic-behavioral interactions and devise and test optimal combination HIV prevention packages (combination interventions) for specific settings and populations.

PRIORITY 8: Collaborate with other institutes and organizations, both domestic and international, to characterize acceptability, adherence, durability, and optimal delivery modes of prevention interventions.

Area of Emphasis: Cure HIV Infection

ART can be extremely effective in suppressing detectable viral replication for extended periods, but no documented cases of a true cure have occurred in the 30-year duration of the HIV epidemic. It is claimed that one HIV-infected individual was “cured” after receiving stem-cell transplants for a complicating leukemia. The transplanted cells expressed a genetic defect that does not allow the replication of R5 HIV viruses. This case, while not a practical approach for treating the millions of HIV-infected people, provides proof of concept that under certain circumstances HIV can be controlled in the absence of ART.

When considering a cure for HIV infection at least two related lines of research should be considered: 1) developing a true sterilizing cure, with complete eradication of the virus; and 2) permanently suppressing the virus such that there is no significant replication even in the absence of ART, i.e., a functional cure. A cure for HIV infection must be safe, scalable, and less traumatic to patients than current treatment regimens.

PRIORITY 1: Broaden understanding of the basic biology of both latent and persistently replicating HIV reservoirs by:

- Determining if additional reservoirs of HIV infection exist
- Defining the processes that govern reservoir establishment and maintenance
- Understanding the mechanisms of persistence in persons receiving effective ART

PRIORITY 2: Develop methods to accurately measure the reservoir in patients.

PRIORITY 3: Identify and test concepts or strategies for eradication of HIV reservoirs.

PRIORITY 4: Explore methods of establishing a functional cure that would allow subjects to discontinue antiretroviral treatment for extended periods without viral rebound.

PRIORITY 5: Clinically test novel strategies that target and eliminate viral reservoirs or bring about a functional cure.

Area of Emphasis: Establish treatment and prevention strategies for HIV-associated infections of highest morbidity and mortality, especially TB and hepatitis

AIDS-associated co-infections are potentially life-threatening conditions caused by a wide range of microorganisms, including protozoa, viruses, fungi, and bacteria. HIV-associated co-infections such as TB and hepatitis C complicate the medical management of HIV-infected people and result in significant morbidity and mortality, especially in resource-limited settings. HIV infection is a risk factor for conversion of latent TB infection to active TB, and TB accelerates the progression of HIV to AIDS. Furthermore, TB is harder to diagnose and progresses faster in HIV-infected people. TB is the cause of death for as many as half of all people who are co-infected with HIV. Similarly, co-infection with HCV has been associated with decreased effectiveness of ART and higher rates of morbidity and mortality. Current treatment of HCV is not well tolerated in HIV-infected patients on ART and not very effective. Newer agents to treat hepatitis C are being developed and will need to be investigated in the co-infected population. Researchers are working to determine when best to initiate ART in persons with active co-infections in order to maximize the effects of treatment and minimize the risks of immune reconstitution inflammatory syndrome.

PRIORITY 1: Elucidate the pathogenic mechanisms and consequences of high-priority co-infections in the context of HIV infection through epidemiological and clinical research.

PRIORITY 2: Expand understanding of TB as an HIV-associated infection by:

- Developing improved diagnostics and prognostic biomarkers for TB (in all age groups)
- Advancing improved and/or shorter-course combination drug therapy for both active and latent TB (including drug-sensitive and drug-resistant TB)

PRIORITY 3: Facilitate large-scale efficacy testing of promising TB treatments and vaccines through coordination with HIV clinical trials capability.

PRIORITY 4: Expand research for infectious hepatitis as an HIV-associated infection by:

- Developing all-oral treatment regimens that cure HCV and are safe and well tolerated
- Developing improved diagnostics, noninvasive indicators of liver injury, and prognostic biomarkers for treatment outcomes
- Identifying pathways and mechanisms that accelerate the course of HCV disease in HIV co-infected individuals

PRIORITY 5: Support clinical studies of other high-priority co-infections to improve diagnostic, treatment, and prevention strategies.

Area of Emphasis: Improve outcomes of treated HIV disease

The greatest achievement in HIV research has been the discovery, development, and delivery of ART to millions of HIV-infected people. Treatment blocks further disease progression, preserves remaining immune function, and can also prevent HIV transmission. This advance creates areas of research synergy where improvements in the delivery of HIV testing and care can have a profound benefit for HIV-negative and positive people alike. Continuing to improve the safety and durability of therapeutic regimens will also enhance the treatment and prevention effects of ART. Through focused research to define how best to use these tools, we can begin to control the global HIV epidemic.

PRIORITY 1: Define long-term consequences of treated HIV infection and the mechanisms of morbidity associated with treated HIV disease.

PRIORITY 2: Develop understanding of chronic immune activation and associated co-morbidities in HIV-infected individuals who are on suppressive ART through:

- Research of basic pathways and mechanisms
- Use of animal models of chronic inflammation as models for pathogenesis due to chronic immune activation and for preclinical studies of possible interventions

PRIORITY 3: Develop and evaluate potential therapies to eliminate or suppress immune activation and associated clinical consequences.

PRIORITY 4: Explore the role of HIV in the development of premature aging of the immune system in HIV-infected individuals on suppressive ART.

PRIORITY 5: Discover and evaluate novel interventions, long-acting formulations, and drug delivery technologies to diagnose and treat HIV, leading to significant, durable improvements in therapy.

Global Health Research on HIV/AIDS

NIAID supports a broad portfolio of international research on HIV/AIDS that reflects the global impact of the disease. This research addresses the critical need for cost-effective prevention and treatment strategies, particularly in areas of the world with limited resources and where more than 95 percent of HIV infections occur.

Examples of major ongoing international clinical studies include:

- The Promoting Maternal and Infant Survival Everywhere (PROMISE) study, which is designed to determine the best treatment regimen for: 1) preventing antenatal mother-to-child transmission (MTCT), 2) preventing MTCT during breastfeeding, 3) maintaining the health of the mother, and 4) protecting the infant during weaning in high-, middle-, and low-resource settings. The study will enroll approximately 8,000 HIV-infected women who are pregnant or have recently given birth and approximately 6,000 HIV-exposed infants from as many as 18 countries.
- A Study to Prevent Infection with a Ring for Extended Use (ASPIRE), which is a Phase III microbicide study to determine whether a woman's use of a vaginal ring containing the antiretroviral drug dapivirine is safe and effective for protecting against HIV infection. The study will enroll approximately 3,500 women at several sites in Africa and is expected to be completed in 2014.
- The Strategic Timing of Antiretroviral Treatment (START) trial, which is a randomized clinical trial designed to provide definitive evidence of the risks and benefits of early antiretroviral treatment and to more clearly define the optimal time to begin treatment. The study is being conducted in 30 countries and will enroll approximately 4,000 HIV-infected men and women who are 18 years of age and older, have CD4 counts above 500 cells/mm³, and have never taken antiretroviral drugs.

NIAID also funds the International Epidemiologic Databases to Evaluate AIDS (IeDEA) consortium, which is composed of seven regional databases in the Caribbean, Central and South America region; North America; West Africa; East Africa; Central Africa; Southern Africa; and Asia/Australia/China. IeDEA collected and analyzed data from more than 1 million patients. This wealth of information enabled IeDEA to contribute substantially to the effort to evaluate and describe the roll-out of therapy around the world, define outcomes for adult and pediatric patients, evaluate the success of programs in care and treatment delivery, define new approaches to managing care in resource-limited settings, and describe the epidemiology of cancer in HIV-infected persons around the world.

The expansion of HIV care and treatment to the developing world is a major success in ongoing efforts to address the HIV/AIDS epidemic. The President's Emergency Plan for AIDS Relief (PEPFAR), initiated in 2003 by President George W. Bush, together with the multilateral Global Fund to Fight AIDS, Tuberculosis and Malaria and non-government organizations such as the Bill & Melinda Gates Foundation, the Clinton Foundation, and Médecins Sans Frontières (Doctors Without Borders), have transformed the fate of countless HIV-infected people in the developing world, particularly southern Africa, by providing treatment and care for those who are infected as well as prevention methods for those at risk of infection. As of September 2012, PEPFAR alone had provided ART for more than 5 million infected individuals; provided antiretroviral mother-to-child transmission prevention for more than 750,000 HIV-infected pregnant women; and provided care for approximately 15 million people, including AIDS orphans.⁶ Yet even with current efforts, approximately 2.5 million people become infected with HIV each year, and for every two people that begin treatment with ART, five become newly infected. NIAID helps support PEPFAR by providing staff management and oversight support for supplements to existing NIAID grantees and other NIH Institutes and Centers (ICs). Most recently, in

⁶ U.S. Department of State. PEPFAR Blueprint: Creating an AIDS-free Generation, Nov 2012; <http://www.pepfar.gov/documents/organization/201386.pdf>

collaboration with the Office of the Global AIDS Coordinator and other ICs, NIAID established the NIH/PEPFAR Collaboration for Implementation Science and Impact Evaluation program to support research studies to help inform PEPFAR on more efficient and cost-effective methods to deliver HIV prevention, treatment, and care on a large scale in resource-limited countries.

PRIORITY 1: Establish, enhance, and build on the in-country research capacity of low- and middle-income countries. The aim is for these nations to develop sustainable research programs focused on developing biomedical strategies to prevent transmission of HIV and to treat HIV disease and its associated co-infections and co-morbidities.

PRIORITY 2: Assist in developing vaccines, other prevention strategies, and therapeutic interventions that reflect local population/regional determinants, processes, and cultural and contextual issues and that will be widely affordable, accessible, and practical in those settings.

For more information on NIAID's global health research, please see the section on Global Health Research.

Partnerships

The development and testing of successful therapies, diagnostics, and prevention technologies relies on partnerships between the Institute and the private sector. NIAID invests in the development of biomedical research capacity around the world by fostering research collaborations between U.S. and international scientists, many of whom are based in developing countries. For example, through an Interagency Agreement, NIAID collaborates with the Department of Defense's U.S. Military HIV Research Program (MHRP) to support and conduct relevant clinical research and evaluation of candidate HIV vaccines worldwide. This partnership led to the first HIV vaccine trial (RV144) to demonstrate modest efficacy, which in turn led to the creation of the Pox-Protein Public-Private Partnership (P5). The P5 is a collaboration of key funders and implementers of HIV vaccine research, which aims to conduct research critical to advancing and ultimately licensing HIV pox-protein vaccine candidates that have the potential to achieve broad public health impact. Partners of P5 include NIAID, MHRP, the Bill & Melinda Gates Foundation, the HIV Vaccine Trials Network, Sanofi Pasteur, Novartis, and Eurovacc. By partnering with academia, private industry, philanthropic foundations, and other research-supporting agencies, NIAID is able to guide, enhance, and support ongoing HIV/AIDS research activities around the world.

HIV infection is associated with significant end-organ morbidity, such as endothelial damage, neurocognitive defects, and renal failure. To understand the pathogenic mechanisms and to test interventions, NIAID partners with other ICs to fund research in these areas. Furthermore, strong psychological, sociological, and structural factors combine to create vulnerabilities that promote HIV transmission and worsen the AIDS epidemic. Interventions to address these vulnerabilities require integration of behavioral and biomedical expertise at all stages of research. The results of recent prevention trials highlight this need and underscore the importance of collaborating with other ICs that have a significant investment in behavioral research. Once effective interventions have been developed and licensed, other government agencies, such as the Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration, Office of the Global AIDS Coordinator, and U.S. Agency

for International Development, are critical partners in designing research on the best approaches for implementing and scaling-up those interventions.

PRIORITY 1: Enable and encourage collaborations across public- and private-sector partners to optimize efficient use of resources including facilities, expertise, data and data analysis, specimens, reagents, and access to populations.

PRIORITY 2: Foster and support community involvement to ensure that communities heavily impacted by HIV/AIDS participate in all stages of planning and implementing HIV/AIDS research.

Allergy, Immunology, and Immune-Mediated Diseases

The human immune system has evolved to protect against harmful pathogens in the external environment. The ability to recognize pathogens and distinguish them from one's own cells and tissues is the first requirement of such a protective system. This task of distinguishing "self" from "non-self" initially falls to the innate immune system: the inborn capacity to constantly monitor the body's fluids, cells, and tissues for pathogens and provide a broad and immediate immune response. The innate immune system also activates the adaptive immune system, which, over time, generates unique T and B cells that specifically target a pathogen invading the body. Once the pathogen is cleared from the body, the immune system returns to its resting state, leaving behind long-lasting antibodies and a small number of memory T and B cells that can quickly reactivate if the pathogen reappears. Vaccines harness the innate and adaptive responses by partially mimicking a natural infection, but without causing disease. As with most naturally occurring infections, vaccines stimulate the formation of antibodies and memory cells that protect in the event of true infection.

Over the course of a lifetime, many immune responses arise that are potentially detrimental. These responses can lead to a wide range of immune-mediated diseases in susceptible individuals. For example, generally innocuous or harmless substances, including house dust mites, pollen, or foods such as peanut, activate the immune system, leading to asthma and allergic diseases. When the ability to distinguish self from non-self fails, autoimmune diseases occur. In organ transplantation, the recipient's immune system recognizes the donor organ as non-self, resulting in rejection of the transplant.

Asthma

A 2012 report⁷ from the CDC showed that the prevalence of asthma in the United States increased from 7.3 percent to 8.4 percent between 2001 and 2010, and an estimated 25.7 million people, including 7 million children, had asthma in 2010. African Americans had the highest prevalence rates and children and adolescents under 18 had higher rates than adults. Among individuals whose family income was below the federal poverty level, the prevalence of asthma was 53 percent higher than that for individuals whose family income was at least twice the poverty level. Overall, asthma is associated with an estimated \$56 billion in healthcare costs and lost productivity in the United States each year.⁸

Allergic Disease

Allergic diseases include a wide range of chronic illnesses, including food allergies. The prevalence of allergic rhinitis—more commonly known as hay fever—is 7.8 percent in adults aged 18 and older and 9.8

⁷ National Health Care Surveys Data Brief, Number 94. May 2012. Trends in Asthma Prevalence, Health Care Use, and Mortality in the United States, 2001-2010.

⁸ Centers for Disease Control. CDC VitalSigns: Asthma in the US, May 2011; <http://www.cdc.gov/vitalsigns/asthma/>

percent in children.^{9,10} According to the CDC,¹¹ 3.9 percent of children under age 18 (3 million people) reported having food allergy in the previous 12 months, and the prevalence of food allergy increased by 18 percent from 1997 to 2007, with peanut allergy increasing substantially. Children with food allergy are two- to four-fold more likely to have other allergic diseases, such as asthma, atopic dermatitis, and respiratory allergy, than children without food allergy.

Autoimmune Disease

More than 80 autoimmune diseases have been identified, and collectively they are estimated to affect five to seven percent of people in the United States (15 to 24 million people). Many of these diseases, such as systemic lupus erythematosus (SLE) and rheumatoid arthritis (RA), disproportionately affect women, especially during their childbearing years. These diseases are chronic and often debilitating, and associated medical and other social costs are high.¹² Examples of prevalence include:

- 15,600 youth under the age of 20 in the United States were newly diagnosed with type 1 diabetes each year for the years 2002 to 2005, and approximately 1 in every 400 to 500 children and adolescents had the disease.¹³
- An estimated 1.5 million Americans have RA.^{14,15}
- As many as 322,000 Americans have been diagnosed with, or are suspected of having, SLE,¹⁶ which disproportionately afflicts African American women.

Many other autoimmune diseases are rare and largely unknown, but, collectively, they affect a large number of people. In all cases, although treatments may alleviate symptoms, there are no cures, and the incidence of many autoimmune diseases appears to be increasing for reasons that are poorly understood.

Research on Immune-Mediated Diseases

The NIAID mission encompasses basic, preclinical, and clinical research on the causes, treatment, and prevention of a wide range of immune-mediated disorders. Across this spectrum, NIAID-sponsored research is contributing to fundamental discoveries that will lead to comprehensive understanding of the mechanisms involved in immune regulation and immune protection, with wide application in the development of vaccines and therapies for immune-mediated disorders.

⁹ [Summary Health Statistics for U.S. Adults: National Health Interview Survey, 2009, tables 3 and 4.](#)

¹⁰ [Summary Health Statistics for U.S. Children: National Health Interview Survey, 2009, table 2.](#)

¹¹ [NCHS data brief no.10, NCHS, Sept 2008.](#)

¹² The Autoimmune Diseases Coordinating Committee, NIH: [Progress in Autoimmune Diseases Research 2005](#) (NIH Pub. No. 05-5140).

¹³ [National Diabetes Fact Sheet, 2011](#) (Source: CDC).

¹⁴ Myasoedova E et al., [Arthritis Rheum. 2010 Jun;62\(6\):1576-82.](#)

¹⁵ Helmick CG et al., [Arthritis Rheum 58\(1\):15–25, 2008.](#)

¹⁶ Laurence RC et al., [Arthritis Rheum 41: 778, 1998.](#)

Research on asthma and allergic diseases focuses on preventing detrimental immune responses to generally innocuous or harmless substances. Research on autoimmune disease aims to identify ways to “re-educate” the immune system so that it becomes tolerant to the “self” antigens and tissues that are the targets of attack. In organ transplantation, which prolongs survival and improves the quality of life for people suffering from a wide range of end-stage organ diseases, research aims to selectively block immune responses directed against the foreign antigens of the graft to allow long-term graft survival without the risks of broadly immunosuppressive therapies.

NIAID’s robust research portfolio in basic immunology provides fundamental insights into the principles of immunology and identifies the cells, molecules, and pathways of the immune system. For many years, scientists have relied heavily on inbred mouse models because of their ease of use and the wide availability of many mouse-specific laboratory reagents. These models are highly successful tools for the discovery of immunologic mechanisms that allow dissection of interconnected pathways with a high degree of resolution. In addition, genetic analysis has shown that there is considerable conservation of genes and gene regulation between mice and humans. Findings in mouse studies are not always reproducible in human studies, however, and it is clear that mice have considerable limitations as models of human disease and for drug discovery and development. Therefore, a major challenge in immunology is to characterize the human immune system in health and disease to provide a solid foundation for the translation of basic research into clinical research.

To meet this challenge, the NIAID research portfolio has evolved to include increased emphasis on human immunology. This is enabled by the emergence of new technologies, advances in systems biology approaches, expanding capabilities in bioinformatics, and the development of sophisticated data analysis tools. Together, these offer unprecedented opportunities to measure immune responses in individuals and large human cohorts. Recognizing the opportunities, NIAID has initiated new programs in human immunology that will increase our understanding of the causes of immune-mediated diseases and lead to the development of strategies for their prevention, diagnosis, and treatment. In addition, these studies will lead to more effective vaccination and other prevention strategies for infectious diseases.

NIAID’s clinical trial networks remain in the forefront of clinical immunology research, and strongly emphasize studies of asthma, allergy, autoimmune diseases, and the immune-mediated rejection of transplanted organs. The networks evaluate a variety of treatment and prevention strategies, including immune tolerance induction, withdrawal from immunosuppressive therapies, and immune modulation. All network studies include mechanistic studies to better understand the clinical outcomes. Notable science advances include the development of novel immunotherapeutic approaches that show promise in the treatment and prevention of food allergy; FDA approval of the first treatment for Wegener’s granulomatosis and microscopic polyangiitis, two rare forms of autoimmune disorders; and the demonstration that 60 percent of pediatric liver transplant recipients remain rejection free for 5 years after the withdrawal of immunosuppressive drugs.

In addition to the broadly stated priorities presented in this section and the published documents that were listed in [NIAID: Planning for the 21st Century 2008 Update](#), two published documents focus on specific goals. These documents include:

- [NIAID Strategic Plan for Research on Vaccine Adjuvants \(2011\)](#)
- [Strategic Plan and Research Agenda for Medical Countermeasures Against Radiological and Nuclear Threats Progress Report: 2005–2011 and Future Research Directions: 2012–2016](#)

Area of Emphasis: Apply knowledge of basic immunology to support preclinical research in infectious and immune-mediated diseases

Building on an increased understanding of the human immune system, NIAID supports a robust portfolio of applied immunology research that provides preclinical information critical for developing and evaluating novel strategies to diagnose, treat, and prevent infectious and immune-mediated diseases. A major scientific area with critical need is the development of new vaccines to protect against emerging or re-emerging infectious diseases, and the improvement of current vaccines, especially to protect populations such as the very young, the elderly, and those with compromised immune responses. Therefore, in recent years, NIAID launched, and is continuing to expand, programs to discover and develop adjuvants—components of vaccines that stimulate the immune response. NIAID also has increased its focus on the mucosal immune system, initiating programs to improve our understanding of its unique protective mechanisms and to develop targeted mucosal vaccines against infection. As part of its commitment to improving transplant outcomes, the Institute also supports programs to identify biomarkers of transplant rejection and characterize gene variants and expression patterns that predict transplantation outcome.

PRIORITY 1: Continue supporting research in basic immunology.

PRIORITY 2: Apply increasing knowledge of the complex interactions between microbes and the immune system to develop and test diagnostics, therapeutic strategies, and vaccine strategies for infectious diseases.

PRIORITY 3: Advance promising adjuvant candidates through optimization and preclinical testing.

PRIORITY 4: Apply knowledge of the processes and events that occur at mucosal surfaces to facilitate the design of vaccines and immunotherapies that protect mucosal surfaces from infection and disease.

PRIORITY 5: Evaluate reagents for the development of diagnostics, immunotherapeutics, and vaccines against infectious diseases and immune-mediated diseases.

PRIORITY 6: Develop novel strategies to prevent, treat, and detect immune-mediated diseases.

PRIORITY 7: Develop and enhance approaches through preclinical research to extend the survival of transplants.

Area of Emphasis: Determine the precise mechanisms of human immune regulation

Recognizing the recent advances in biotechnology and bioinformatics and the opportunities they offer, NIAID has increased its support of human immune studies within its basic immunology portfolio. In 2010, for example, NIAID established seven U.S. research centers comprising the Human Immunology Project Consortium (HIPC). HIPC investigators are using new research approaches to better understand the human immune system in health and in response to infection and vaccination. HIPC also has been supported to expand its focus internationally through research partnerships in India and elsewhere. In addition, NIAID supports and collaborates with the trans-NIH Center for Human Immunology, which uses novel technologies to translate our understanding of immune function and pathophysiology to clinical practice. These and other programs in basic human immunology are providing answers to fundamental questions about the components of our immune system and how they interact in health and disease.

PRIORITY 1: Further characterize the human innate and adaptive immune systems, both at rest and in response to infection and vaccination and as a consequence of immune-mediated disease.

PRIORITY 2: Identify the underlying genes and develop new approaches to analyze the cellular and molecular pathways involved in maintaining the human immune system at rest and after activation.

PRIORITY 3: Analyze the influence of the human microbiome on mucosal and systemic immune responses, and on the outcome of infectious diseases and immune-mediated diseases.

Area of Emphasis: Develop immune-based and tolerogenic approaches to treat and prevent allergic and autoimmune diseases and to prevent graft rejection

NIAID's clinical studies encompass a broad range of immune-mediated disorders, including asthma, allergic and autoimmune diseases, primary immunodeficiency disorders, and transplant rejection. All clinical trials include associated mechanistic studies to further our understanding of disease onset and progression and response to therapy. Various biological agents and novel approaches to induce and restore immune tolerance show promise in clinical trials and will continue to be pursued. These include cellular immunotherapeutics, which are potent immune cells that can be engineered to localize to specific organs and tissues and may eventually provide long-lasting efficacy and specificity unattainable with many drugs.

PRIORITY 1: Clinically evaluate anti-inflammatory, immunomodulatory, and immune tolerance approaches to prevent and treat immune-mediated diseases.

PRIORITY 2: Support integrated mechanistic studies with clinical trials to better understand the role of immune factors in immune-mediated disease susceptibility, disease progression, and treatment outcome.

PRIORITY 3: Support clinical evaluations of immune-based treatment, tolerance approaches, and other strategies to improve transplant survival and prevent graft rejection.

Essential Foundations for the Future

The biomedical advances made possible by NIAID-supported research increasingly depend on flexible and comprehensive infrastructure as products move from basic laboratory findings to preclinical models, product development, clinical trials, and, ultimately, licensure. Indeed, research resources and physical infrastructure underpin the full spectrum of NIAID-supported biomedical exploration and discovery. NIAID aggressively develops technologies needed to advance its mission, and makes these critical resources available to grantees in the United States and in international settings. Research infrastructure requires substantial financial resources, but this investment reaps even greater rewards. For example, high-throughput genetic sequencing makes it possible to identify new microbes at an unprecedented pace, track outbreaks of antimicrobial resistant bacteria, and probe the functions and dysfunctions of the human microbiome. NIAID's commitment to develop and use innovations such as systems biology approaches, structural biology, sample-sparing assays, the range of scientific "omics," and new imaging and computational technologies ensures that the Institute and its grantees are poised to act as scientific opportunities and public health needs arise.

Research Resources and Infrastructure

NIAID is dedicated to building and sustaining comprehensive domestic and international resources that provide expertise and services throughout the research and product development lifecycle. These resources support scientists worldwide in conducting the highest quality research, by leveraging state-of-the-art technology; accessing critical data and materials through registries and repositories; and establishing and supporting networks of collaborating institutions, Centers of Excellence, and clinical trials networks.

Biodefense and Emerging and Re-emerging Infectious Diseases

Key resources and infrastructure are necessary to facilitate basic research and support the development of new vaccines, therapeutics, and diagnostics for infectious diseases. The availability of state-of-the-art DNA sequencing, bioinformatics, computational tools, and databases, as well as product development services, provides the scientific community with the tools that are critical to better understanding and limiting the impact of these diseases. These services have been instrumental in advancing products for numerous pathogens, including new drugs for influenza and malaria. Future scientific advances require continued development of such critical resources for conducting research on highly infectious pathogens.

PRIORITY 1: Develop and provide resources to facilitate basic and applied infectious disease research. Resources include biological materials, genomic sequencing, bioinformatics, and systems biology tools.

PRIORITY 2: Provide the infectious disease research community with access to a comprehensive suite of preclinical development services that can fill particular knowledge gaps critical to moving products

along the product development pathway, including *in vitro* and *in vivo* assays and animal models of infectious diseases.

PRIORITY 3: Provide the infectious disease research community with access to clinical evaluation services to facilitate clinical trials of vaccines, therapeutics, and other biologics and drugs to prevent and treat infectious diseases.

PRIORITY 4: Conduct outreach efforts to inform the research community of scientific resources readily available to authorized users, clearly delineating information on access and requirements for use. Support mechanisms for sharing data within the scientific community and assess the need for additional services.

HIV/AIDS

NIAID is committed to developing and supporting the research infrastructure and scientific expertise needed to enable innovative approaches to HIV/AIDS research. Toward that end, NIAID has worked to restructure its clinical trials networks to 1) allow for a multi-disease research capacity; 2) focus on targeted scientific opportunities and priorities, including community engagement; and 3) increase flexibility within the network infrastructure to ensure the efficient use of resources. With regard to research resources for HIV/AIDS research, NIAID has the following priorities.

PRIORITY 1: Establish and maintain the robust and flexible resources required to facilitate and advance HIV/AIDS research.

PRIORITY 2: Stimulate and strengthen HIV/AIDS research by:

- Nurturing cross-disciplinary scientific and scholarly opportunities
- Creating research and training opportunities that enable scientists and those in related fields of scholarship to engage in interdisciplinary research, including epidemiology, bioethics, immunology, and infectious diseases, to advance discovery in HIV/AIDS and HIV-associated infections
- Supporting development of a diverse pool of researchers in basic, preclinical, and clinical HIV/AIDS research

PRIORITY 3: Establish and maintain support for product development activities for high-priority vaccine, other prevention, and therapeutic approaches.

PRIORITY 4: Develop and support efficient, flexible, and responsive clinical trial capability and observational cohorts required to translate scientific discoveries into clinical advances and to correlate biologic factors with clinical outcomes.

PRIORITY 5: Foster and support community engagement and education programs to ensure that communities heavily affected by HIV and HIV-associated infections participate in all stages of planning and implementation of HIV/AIDS research.

PRIORITY 6: Take steps to enable and encourage collaborations across public and private sector partners to optimize efficient use of resources, including facilities, expertise, data and data analysis, specimens, reagents, and access to populations.

Infectious and Immunological Diseases

NIAID supports the development of a diverse array of immunologic resources that are available to the scientific community at no or minimal cost. These resources, which include research databases, analytic tools, mathematical models, bioinformatics support, reagents, and animal models, will enable the continued advancement of immunological discovery and its application.

PRIORITY 1: Provide bioinformatics support for NIAID-supported researchers to include optimized methods for data collection, storage, exchange, and interoperability; analytical tools; and data visualization tools.

PRIORITY 2: Support the discovery, validation, development, and standardization of specialized reagents, assays, and technologies that are needed to facilitate basic, preclinical, and clinical research programs in immunology and immune-mediated diseases.

PRIORITY 3: Support the development of animal models for research on immunology and immune-mediated diseases; the housing of widely used rodents and large animals and their distribution to the research community; and breeding and genetic characterization of specialized animal resources, including nonhuman primates.

Research Training and Career Development

Sustaining a broad research program requires support to help investigators develop the knowledge and skills required by changing public health needs and new scientific opportunities. The complexity of contemporary research and the emergence of new fields of study, such as bioinformatics, and of new technologies, increasingly demand that investigators take an integrated, multidisciplinary approach to solving scientific problems. In addition, NIAID is committed to encouraging a diverse research workforce equipped to conduct research in the fields of infectious diseases, allergy, and immunology, including those diseases within the Institute's research portfolio that disproportionately affect underserved populations.

PRIORITY 1: Utilize the full variety of available extramural and intramural award mechanisms to attract and develop the next generation of talented U.S. and international research investigators, including the transition to the first independent academic research appointment and grant. Equip them to engage in interdisciplinary research in immunology and infectious diseases that incorporates state-of-the-art and emerging technologies.

PRIORITY 2: Support extramural and intramural training and career development programs to expand the pool of well-trained U.S. and foreign investigators capable of designing and conducting patient-oriented research. This research includes international clinical trials that ensure the ethical treatment of human subjects and consider social, cultural, and local community concerns.

PRIORITY 3: Provide a broad spectrum of research training and career development opportunities at various educational and career stages to help ensure that diverse pools of highly trained scientists will be available to conduct infectious disease and allergy/immunology research, with an emphasis on the elimination of health disparities.

Communications and Outreach

The full benefit of research through translation into medical practice can be realized only when new knowledge is disseminated, not only to other scientists but also to voluntary and scientific organizations, health care providers, and the general public in the United States and internationally. An important part of the NIAID mission is to disseminate research results to the media, health professionals, and the general public; and to facilitate recruitment of volunteers into clinical trials of candidate vaccines, diagnostics, and therapeutics, and into other clinical research studies.

PRIORITY 1: Promote and sustain interactions with researchers, healthcare professionals, and the general public by: 1) communicating research priorities and results using a range of digital and traditional media tools; and 2) targeting outreach activities via professional and community meetings, workshops, seminars, and conferences.

PRIORITY 2: Maintain effective communication with Congress and other branches of the U.S. government to delineate clearly the role of NIAID in improving public health, both domestically and internationally.

PRIORITY 3: Enhance the recruitment and retention of volunteers into domestic and international clinical research studies through the production and dissemination of culturally appropriate educational materials and outreach to relevant communities, with special attention to those communities most affected by the diseases being addressed.

Global Health Research

“It is imperative that we use our current momentum to move forward, recognizing that the enormous challenges of global health...will require a long-term commitment that is sustained even when global health and those fighting to improve it are no longer in the headlines.” —Anthony S. Fauci, M.D.

To comprehensively execute its mission, NIAID must support research on infectious diseases within the populations and in locations where these diseases are prevalent. In addition, the Institute must have the ability to respond rapidly to emerging and re-emerging infectious diseases. In today’s interconnected world, health threats that emerge or remain common in distant regions can threaten the health and stability of the United States and other nations around the world. To respond to such threats, it is essential that NIAID support and conduct the best science possible, wherever the scientific opportunities present themselves. HIV/AIDS, tuberculosis, malaria, neglected tropical diseases, and other leading causes of infectious disease affect global health. Accordingly, research on these infectious diseases is best pursued through mutually beneficial partnerships between U.S. scientists and scientists and institutions in countries where these conditions are endemic. NIAID recognizes that global health research must involve shared leadership, a commitment to long-term sustainability, and the engagement of local communities.

NIAID-supported global health research has yielded critically important basic science advances as well as new or improved diagnostics, therapies, and vaccines. NIAID will continue its commitment to well-designed and ethical global health studies, keeping pace with expanding opportunities in infectious disease and immunology research while staying ahead of expanding health threats that loom worldwide.

Area of Emphasis: Develop and maintain international scientific collaborations

La Red is a multi-site collaboration between NIAID and the Mexico Ministry of Health, designed to build capacity and promote sustainability to continue clinically relevant and high-quality research on emerging infectious diseases. La Red’s five sites in Mexico City include two sites focused on pediatric research.

Scientific collaborations are integral to the successful achievement of global health research priorities. Research must be performed in regions where diseases and health conditions of interest are endemic. Fostering and supporting international scientific collaborations is critical to the NIAID mission. Despite significant challenges, NIAID has a history of maintaining successful international collaborations while also exploring and pursuing opportunities to expand this effort.

PRIORITY 1: Support and strengthen international basic, applied, and clinical research to advance fundamental discovery and improve the prevention, treatment, and diagnosis of infectious and immune-mediated diseases.

PRIORITY 2: Support and establish targeted research collaborations in countries with emerging economies and a growing commitment to scientific excellence, such as Brazil, China, India, Indonesia, South Africa, and Turkey.

PRIORITY 3: Identify and provide access to research opportunities in regions where scientific collaboration previously has been limited.

PRIORITY 4: Advance opportunities for scientific engagement in regions of strategic importance for biodefense research.

PRIORITY 5: Foster and coordinate trans-NIAID engagement in international collaborations to enhance efficient program integration and cost effectiveness.

Area of Emphasis: Enhance research capacity where scientific opportunities exist

The individuals who conduct, support, and participate in international health research are critical in ensuring the success of studies and sustaining productive research sites. Qualified administrative and research staff with a firm understanding of the fundamental requirements of high-quality health research are essential. Also needed are personnel with clinical research expertise and the capacity to carry out the basic elements of a wide range of studies. To sustain productive research environments it is important to provide training opportunities and mentoring to local researchers to help them advance to leadership roles. In addition, researchers must engage positively with communities, gain the support of political and institutional leadership, and understand local norms and concerns.

NIAID's HIV/AIDS Clinical Trials Networks implement research focused on prevention, treatment, and vaccine development. The Networks have significantly expanded research capacity worldwide through mentorship and scientific engagement. NIAID is building on the success of its current HIV/AIDS Clinical Trials Networks to expand the infrastructure, supporting studies on HIV/AIDS; tuberculosis and hepatitis C, common co-infections in HIV-positive individuals; and antibacterial resistance.

Capable, well-trained administrative staff, research support resources, policies, and procedures must be in place to ensure efficient, effective, and ethical management of sustainable, multi-discipline research sites. Administrators need to develop procedures to accept electronic transmissions of award funds, accounting systems, and computer systems for fiduciary tracking and reporting. Functional Institutional Review Boards or Ethics Review Committees that are qualified to review and monitor a variety of studies in a timely manner are essential to international clinical research. Sites require leadership with strong human resource management skills, with the flexibility to identify and recruit appropriate staff or shift them easily between assignments to address specific research requirements for specific studies.

PRIORITY 1: Invest in scientific activities that help expand research capacity, including laboratories, field sites, scientific and support personnel, and modern research infrastructure such as data repositories.

PRIORITY 2: Develop, maintain and enhance training to increase foreign scientists and institutions' ability to implement high-quality research, comply with NIH administrative and fiduciary requirements, and manage complex laboratory and field-site challenges, including the safe management of biosafety facilities.

PRIORITY 3: Collaborate with other research support organizations to leverage investments that enhance international research capacity and expertise development.

PRIORITY 4: Utilize networks of U.S. and foreign investigators to expand research capacity by fostering international scientific leadership through mentoring and career partnerships.

Area of Emphasis: Expand international research partnerships and policies

In 1980, the International Collaborations in Infectious Disease Research (ICIDR) program was established to provide funding to U.S. institutions that engage with foreign institutions in tropical medicine and emerging infectious diseases research. ICIDR establishes a relationship between foreign (non-U.S.) and U.S. institutions to support the study of infectious diseases of global health importance, particularly in resource-constrained countries. Through these collaborations, investigators increase scientific knowledge, promote research capacity, and enhance the international research experience of all the involved investigators.

Through its global health investment, NIAID has had an impact on research policy and practice, often working in partnership with others. Establishing and maintaining partnerships within the Department of Health and Human Services (HHS), with other U.S. government agencies and their counterparts in other countries, and with many nongovernmental organizations helps NIAID accomplish its legislative mandate and enhance and expand its global research activities. In recent years, NIAID has enhanced its collaborations with other NIH Institutes and Centers that share a global research interest. Other key partnerships include the Centers for Disease Control and Prevention (CDC), the Department of Defense, and large philanthropic organizations such as the Bill &

Melinda Gates Foundation and the Wellcome Trust. In developing partnerships, NIAID collaborates with organizations that have a shared vision and can complement NIAID's investments to advance global health research.

PRIORITY 1: Form strategic partnerships with U.S. government agencies, other governments' biomedical research funding entities, multilateral organizations, and civil society/nongovernmental groups.

PRIORITY 2: Assign NIAID scientists and science administrators in countries of key scientific interest, including China, India, Mali, South Africa, and Uganda.

PRIORITY 3: Foster health and science diplomacy by facilitating the exchange of scientists and the engagement of NIAID leadership in global health research activities and interactions.

PRIORITY 4: Assure the representation of NIAID priorities in senior-level U.S. delegations to countries or regions of scientific interest.

PRIORITY 5: Negotiate and enter international agreements to advance NIAID's global health agenda.

PRIORITY 6: Ensure integration of the NIAID research objectives into the U.S. government's global health programs and priorities.

PRIORITY 7: Disseminate scientific knowledge and study findings to facilitate global utilization of research results and enhance evidence-based biomedical and public health practice.

Principles for Global Health Research

NIAID implements all of its international activities in keeping with four core principles, which also are reflected in the HHS Global Health Strategy.

1. Research should reflect the highest possible scientific standards.

NIAID-supported global research reflects the scientific mission, strategic priorities, and research agendas of the Institute and of the collaborating institutions. All NIAID-supported research should be based on the best-available, current scientific knowledge, including appropriate epidemiology, and adhere to the highest standards of scientific quality and integrity. To conduct the highest quality research with the greatest scientific impact, researchers must be prepared to work collaboratively in regions where diseases and health conditions of interest are endemic.

2. Research should adhere to the highest possible ethical and regulatory standards.

Investigators and institutions conducting global health research must adhere to the highest ethical and regulatory standards for the oversight of research, as established and recognized by international, host country, and U.S. ethics committees. Research should take place within a framework developed to assure the equitable and fair sharing of intellectual property and materials, using transfer agreements that are consistent with legal and ethical standards and scientific needs. Global health research should always reflect an awareness of, respect for, and responsiveness to diverse contextual and cultural realities and perspectives.

3. Research should reflect shared interests and international and local public health needs and priorities.

Global health research should be based on shared scientific interests and mutually agreed-on priorities. In community-based clinical studies, local communities should be involved, to the greatest degree possible, in research planning and implementation, and in the dissemination of study findings to local stakeholders. In undertaking international research the investigators and NIAID should assure that the studies have been designed and conducted with local public health needs and priorities in mind.

4. Research should involve mutually advantageous collaborations with institutions and communities of the host country and other partners.

U.S. investigators should establish and maintain respectful, mutually beneficial collaborations and partnerships with host country scientists and institutions, local partners, funders, and other organizations. All stakeholders should be substantively engaged in the joint planning, development, and dissemination of research findings, including arrangements for the transfer and sharing of technology and knowledge.

Current and Future Global Health Research

The principles, priorities, and strategies presented here are embedded within the programs and activities of NIAID's intramural and extramural divisions. Although NIAID is a long-recognized leader in global health research, its programs and approaches to this research continue to evolve in response to both challenges and emerging opportunities. Global research requires a significant investment in

funding, time, dedication, and a commitment to long-term engagement. Through its programmatic divisions, NIAID conducts basic research, supports networks of U.S. and international scientists, trains U.S. and foreign investigators to work internationally, and enhances research facilities around the world. NIAID's commitment to international research is reflected in the actions of its director, the Institute's strategic priorities, and the programs implemented by the Divisions as they pursue scientific opportunities throughout the world to improve the health of Americans and of individuals worldwide.

Project Information		Review Detail		Admin Codes (in alpha order)	
Grant #:	1-R01-AI-110964-01	Council Date:	201401	AIDS Related:	N
Title:	Understanding the Risk of Bat Coronavirus Emergence	Study Section:	CRFS	Animal:	30
Status:	05 Awarded, Non-fellowships only	Reviewing IC:	CSR	Appl New Investigator:	No
Primary PCC:	M51C	Rev Mtg Start Date:	12/18/2013	Appl Early Stage Investigator:	No
Multi PIs:	N	Initial SS Release Date:	01/02/2014	Biohazard:	N
Future Years:		SS Release Date:	01/02/2014	Carryover Authority:	Y
Document #:	RAI110964A	Priority Score:	(b) (5)	Child:	3A
Modular Grant:	N	Percentile:		Clinical Trial Code:	0
FOA:	<u>PA-11-260</u>	Ref.Code:		Diversity Reentry Flag:	
FOA Diversity Flag:	N	Spc Consider:		Foreign Grant:	2
Agency Routing/NOSI ID:		IRG Action:		Gender:	1A
Appl ID:	8674931	CNL Action:		Human:	54
Accession Num:	3595101	Intent To Pay:		Minority:	5A
Former Grant #:				Phase 3 Clinical Trial:	N
Congressional District:	NY-12			SNAP Awd:	Y
				Special Topics:	
				Stem Cells Used:	N
				Tracking Exception:	00

Project Dates		Status History			
Project Start Date:	2014/06/01	Seq	Eftv Dt	Status Code	Description
Project End Date:	2019/05/31	1	2013-06-05 18:06	70	Application has been entered into computer
Actual NoA Issue Dt:	2014/05/27	2	2013-06-25 19:06	17	Pending IRG Review
Initial Encumbrance Dt:	2014/05/27	3	2013-12-20 15:12	12	Pending Council Review
Latest Encumbrance Dt:	2014/05/27	4	2014-01-28 10:01	07	Pending Award. Non-fellowships
		5	2014-02-11 18:02	35	To be Paid
		6	2014-05-20 12:05	19	Award prepared, not funded
		7	2014-05-27 19:05	05	Awarded. Non-fellowships only

Dual IC/PCC					
ICD	Primary?	PCC	Main	Council	Action (IC)
AI	Primary	M51C	Y	1	To be considered for funding (CF)

PI Addr Information (from Commons Record)		PI Degree Information (from Commons Record)					
PI Name:	<u>DASZAK, PETER</u>	Earned?	Degree	Degree Category	Degree Subcategory	Study Field	Other Deg
Contact PI:	Y	Earned	PHD - DOCTOR OF PHILOSOPHY	PhD Equivalent (PhD, SCD, DSC, DPH, DRPH)	Academic Doctorate held	Not Available	N/A
Profile Person:	6575431 Person Info	Earned	BS - BACHELOR OF SCIENCE	Baccalaureate	Baccalaureate held	Not Available	N/A
Commons Acct:	DASZAK						
Address:	520 Eighth Avenue						
HOM	Suite 1200 New York, NY 100181620						
E-mail:	(b) (6)						
Phone #:	(b) (6)						
Ext:							
Fax #:							

Institution Information					
Institution Name	Address	IPF CODE	EIN	Submitting Dept	Dept Category E-mail
<u>ECOHEALTH ALLIANCE, INC.</u>	EcoHealth Alliance, Inc. 460 West 34th Street 17th Floor New York, NY 100012317	4415701	1311726494A1		(b) (6)

Performance Site Information						
Organization Name	Address	Country	Duns ID	Duns Extension ID	Congressional District	
Center for Disease Control and Prevention of Guangdong	176 Xigang Xilu Guangzhou 5103000	CHINA			n/a	
East China Normal University	3663 Zhongshan Beilu Shanghai 200062	CHINA	420945495	0000	n/a	
EcoHealth Alliance, Inc.	460 West 34th Street 17th Floor New York, NY 100012317	UNITED STATES	077090066	0000	NY-10	
Wuhan Institute of Virology	Xiao Hong Shan, No. 44 Wuchang District Wuhan 430071	CHINA	529027474	0000	n/a	
Yunnan Institute of Endemic Diseases Control and Prevention	33 Wenhua Road Dali 650201	CHINA			n/a	

*Congressional District for Performance Sites may differ from the [official Congressional District](#) for the External Org. [Details.](#)

Preaward Budget Detail					
Type	Period#	FY	Direct Cost Amt	Indirect Cost Amt	Total Cost Amt
CNL	1		\$516,857	\$0	\$0
CNL	2		\$515,150	\$0	\$0
CNL	3		\$515,774	\$0	\$0
CNL	4		\$514,873	\$0	\$0
CNL	5		\$514,165	\$0	\$0
REQ	1	2014	\$516,857	\$149,585	\$666,442
REQ	2	2015	\$515,150	\$155,872	\$671,022
REQ	3	2016	\$515,774	\$155,468	\$671,242
REQ	4	2017	\$514,873	\$160,282	\$675,155
REQ	5	2018	\$514,165	\$164,312	\$678,477

Award Budget										
Period#	FY	Budget Start Date	Budget End Date	Non-Federal Share Amt.	Direct Cost	Indirect Cost	Fee Amount	Unobligated Balance Amt.	Total Cost Amt.	
1	2014	2014/06/01	2015/05/31	\$0	\$516,857	\$149,585	\$0	\$0	\$666,442	
2	2015			\$0	\$502,293	\$128,152	\$0	\$0	\$630,445	
3	2016			\$0	\$489,333	\$121,757	\$0	\$0	\$611,090	
4	2017			\$0	\$476,016	\$121,096	\$0	\$0	\$597,112	
5	2018			\$0	\$462,270	\$119,376	\$0	\$0	\$581,646	

CANS										
Period#	ICD	CFDA	CAN	CAN Task(s)	Enterprise Program /Special Tracking	Direct Cost	Indirect Cost	Fee Amount	Unobligated Balance Amt.	Total Cost Amt
1	AI	855	8472350	2014.100	-	\$516,857	\$149,585	\$0	\$0	\$666,442
2	AI	855	8472350		-	\$502,293	\$128,152	\$0	\$0	\$630,445
3	AI	855	8472350		-	\$489,333	\$121,757	\$0	\$0	\$611,090
4	AI	855	8472350		-	\$476,016	\$121,096	\$0	\$0	\$597,112
5	AI	855	8472350		-	\$462,270	\$119,376	\$0	\$0	\$581,646

CFY Line Items					
Type	IC-CAN	Account Code	Line Item Description	Amount	Item Cnt
Total		3111	Salaries and Wages	\$167,708	
Total		3112	Fringe Benefits	\$54,168	
Total		3411	Travel Costs	\$35,918	
Total		3422	Consortium/ Contractual Cost	\$227,663	
Total		3426	Supplies	\$21,400	
Total		3431	Other Costs	\$10,000	

Other Persons Associated with Grant <i>Address update needed? Contact your IMPACII coordinator</i>										
ICD	Role	Name	Address	Addr Typ	E-Mail	Phone	Fax	Signed Off?	Signed By	Signed Date
AI	GMO	KIRKER, MARY C	Grants Management Program Division of Extramural Activities, RM 4E11 National Institutes of Health/NIAID 5601 Fishers Lane, MSC 9833 Bethesda, MD 208929833	WRK	(b) (6)	(b) (6)	301-493-0597	Y-Last Official	PONE, LAURA A	2014-05-20
AI	GS	PONE, LAURA A	Grants Management Program Division of Extramural Activities, RM 4E41 National Institutes of Health/NIAID 5601 Fishers Lane, MSC 9833 Bethesda, MD 208929833	WRK	(b) (6)	(b) (6)	301-493-0597	Y-Last Official	PONE, LAURA A	2014-05-20
AI	PO	STEMMY, ERIK J	INFLUENZA, SARS & OTHER VIRAL RESPIRATORY DISEASES DMID, Room 8E18 National Institutes of Health/ NIAID 5601 Fishers Ln, MSC 9825 Rockville, MD 208529825	WRK	(b) (6)	(b) (6)		Y-Last Official	STEMMY, ERIK J	2014-02-12
RG	SRA	SAADI, SOHEYLA	Center for Scientific Review National Institutes of Health 6701 Rockledge Drive, Room 3211, MSC 7808 Bethesda, MD 20892	MLG	(b) (6)	(b) (6)	301-480-0940			

Project Information		Review Detail		Admin Codes (in alpha order)	
Grant #:	5-R01-AI-110964-02	Council Date:	201500	AIDS Related:	N
Title:	Understanding the Risk of Bat Coronavirus Emergence	Study Section:	CRFS	Animal:	30
Status:	05 Awarded, Non-fellowships only	Reviewing IC:	n/a	Appl New Investigator:	
Primary PCC:	M51C	Rev Mtg Start Date:		Appl Early Stage Investigator:	n/a
Multi PIs:	N	Initial SS Release Date:		Biohazard:	N
Future Years:		SS Release Date:		Carryover Authority:	Y
Document #:	RAI110964A	Priority Score:	(b) (5)	Child:	3A
Modular Grant:	N	Percentile:		Clinical Trial Code:	0
FOA:	<u>PA-11-260</u>	Ref.Code:		Diversity Reentry Flag:	
FOA Diversity Flag:	N	Spc Consider:		Foreign Grant:	2
Agency Routing/NOSI ID:		IRG Action:		Gender:	1A
Appl ID:	8853810	CNL Action:		Human:	54
Accession Num:		Intent To Pay:		Inclusion Monitoring:	Must be monitored (Yes)
Former Grant #:				Minority:	5A
Congressional District:	NY-12			Phase 3 Clinical Trial:	N
				SNAP Awd:	Y
				Special Topics:	
				Stem Cells Used:	N

Project Dates		Status History			
Project Start Date:	2014/06/01	Seq	Eftv Dt	Status Code	Description
Project End Date:	2019/05/31	1	2014-05-27 19:05	35	To be Paid
Actual NoA Issue Dt:	2015/06/10	2	2015-06-09 17:06	19	Award prepared, not funded
Initial Encumbrance Dt:	2015/06/10	3	2015-06-10 00:06	05	Awarded. Non-fellowships only
Latest Encumbrance Dt:	2015/06/10				

Dual IC/PCC	
ICD Primary?	PCC Main Council Action (IC)
AI Primary	M51C Y

PI Addr Information (from Commons Record)		PI Degree Information (from Commons Record)					
PI Name:	<u>DASZAK, PETER</u>	Earned?	Degree	Degree Category	Degree Subcategory	Study Field	Other Deg
Contact PI:	Y	Earned	PHD - DOCTOR OF PHILOSOPHY	PhD Equivalent (PhD, SCD, DSC, DPH, DRPH)	Academic Doctorate held	Not Available	N/A
Profile Person:	6575431 Person Info	Earned	BS - BACHELOR OF SCIENCE	Baccalaureate	Baccalaureate held	Not Available	N/A
Commons Acct:	DASZAK						
Address:	520 Eighth Avenue						
HOM	Suite 1200 New York, NY 100181620						
E-mail:	(b) (6)						
Phone #:	(b) (6)						
Ext:							
Fax #:							

Institution Information						
Institution Name	Address	IPF CODE	EIN	Submitting Dept	Dept Category	E-mail
<u>EcoHEALTH ALLIANCE, INC.</u>	EcoHealth Alliance, Inc. 460 West 34th Street 17th Floor New York, NY 100012317	4415701	1311726494A1			(b) (6)

Performance Site Information						
Organization Name	Address	Country	Duns ID	Duns Extension ID	Congressional District*	
East China Normal University	3663 Zhongshan Beilu Shanghai	CHINA	420945495	0000	n/a	
EcoHealth Alliance, Inc.	460 West 34th Street 17th Floor New York, NY 100012317	UNITED STATES	077090066	0000	NY-10	
Wuhan Institute of Virology	Xiao Hong Shan, No. 44 Wuchang District Wuhan	CHINA	529027474	0000	n/a	

*Congressional District for Performance Sites may differ from the [official Congressional District](#) for the External Org. [Details.](#)

Award Budget									
Period#	FY	Budget Start Date	Budget End Date	Non-Federal Share Amt.	Direct Cost	Indirect Cost	Fee Amount	Unobligated Balance Amt.	Total Cost Amt.
2	2015	2015/06/01	2016/05/31	\$0	\$502,293	\$128,152	\$0	\$0	\$630,445
3	2016			\$0	\$489,333	\$121,757	\$0	\$0	\$611,090
4	2017			\$0	\$476,016	\$121,096	\$0	\$0	\$597,112
5	2018			\$0	\$462,270	\$119,376	\$0	\$0	\$581,646

CANS										
Period#	ICD	CFDA	CAN	CAN Task(s)	Enterprise Program /Special Tracking	Direct Cost	Indirect Cost	Fee Amount	Unobligated Balance Amt.	Total Cost Amt
2	AI	855	8472350	2015.100	-	\$502,293	\$128,152	\$0	\$0	\$630,445
3	AI	855	8472350		-	\$489,333	\$121,757	\$0	\$0	\$611,090
4	AI	855	8472350		-	\$476,016	\$121,096	\$0	\$0	\$597,112
5	AI	855	8472350		-	\$462,270	\$119,376	\$0	\$0	\$581,646

CFY Line Items					
Type	IC-CAN	Account Code	Line Item Description	Amount	Item Cnt
Total		3110	Personnel Costs (Subtotal)	\$221,876	
Total		3111	Salaries and Wages	\$167,708	
Total		3112	Fringe Benefits	\$54,168	
Total		3411	Travel Costs	\$35,918	
Total		3422	Consortium/ Contractual Cost	\$211,699	
Total		3426	Supplies	\$19,250	
Total		3431	Other Costs	\$13,550	

Other Persons Associated with Grant

Address update needed? Contact your [IMPACII coordinator](#)

ICD	Role	Name	Address	Addr Typ	E-Mail	Phone	Fax	Signed Off?	Signed By	Signed Date
AI	GMO	KIRKER, MARY C	Grants Management Program Division of Extramural Activities, RM 4E11 National Institutes of Health/NIAID 5601 Fishers Lane, MSC 9833 Bethesda, MD 208929833	WRK	(b) (6)	(b) (6)	301-493-0597	Y-Last Official	PONE, LAURA A	2015-06-09
AI	GS	PONE, LAURA A	Grants Management Program Division of Extramural Activities, RM 4E41 National Institutes of Health/NIAID 5601 Fishers Lane, MSC 9833 Bethesda, MD 208929833	WRK	(b) (6)	(b) (6)	301-493-0597	Y-Last Official	PONE, LAURA A	2015-06-09
AI	GS	GREER, JENNY L	Grants Management BRANCH DIVISION OF EXTRAMURAL RESEARCH AND TRAINING NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES RESEARCH TRIANGLE PARK, NC 27709	WRK	(b) (6)	(b) (6)	301-493-0597			
AI	PO	STEMMY, ERIK J	INFLUENZA, SARS & OTHER VIRAL RESPIRATORY DISEASES DMID, Room 8E18 National Institutes of Health/ NIAID 5601 Fishers Ln, MSC 9825 Rockville, MD 208529825	WRK	(b) (6)	(b) (6)		Y-Last Official	STEMMY, ERIK J	2015-05-08

Training Appointments Not Applicable

Project Information	Review Detail	Admin Codes (in alpha order)
Grant #: 5-R01-AI-110964-03	Council Date: 201600	AIDS Related: N
Title: Understanding the Risk of Bat Coronavirus Emergence	Study Section: CRFS	Animal: 30
Status: 05 Awarded, Non-fellowships only	Reviewing IC: n/a	Appl New Investigator:
Primary PCC: M51C	Rev Mtg Start Date:	Appl Early Stage Investigator: n/a
Multi PIs: N	Initial SS Release Date:	Biohazard: N
Future Years:	SS Release Date:	Carryover Authority: Y
Document #: RAI110964A	Priority Score: (b) (5)	Child: 3A
Modular Grant: N	Percentile:	Clinical Trial Code: 0
FOA: PA-11-260	Ref.Code:	Diversity Reentry Flag:
FOA Diversity Flag: N	Spc Consider:	Foreign Grant: 2
Agency Routing/NOSI ID:	IRG Action:	Gender: 1A
Appl ID: 9086286	CNL Action:	Human: 54
Accession Num:	Intent To Pay:	Inclusion Monitoring: Must be monitored (Yes)
Former Grant #:		Minority: 5A
Congressional District: NY-12		Phase 3 Clinical Trial: N
		SNAP Awd: Y
		Special Topics:
		Stem Cells Used: N

Project Dates	Status History
Project Start Date: 2014/06/01	Seq Eftv Dt Status Code Description
Project End Date: 2019/05/31	1 2015-06-10 00:06 35 To be Paid
Actual NoA Issue Dt: 2017/05/05 (originally sent: 2016/07/22)	2 2016-07-21 08:07 19 Award prepared, not funded
Initial Encumbrance Dt: 2016/07/26	3 2016-07-26 10:07 05 Awarded. Non-fellowships only
Latest Encumbrance Dt: 2016/07/26	

Dual IC/PCC
ICD Primary? PCC Main Council Action (IC)
AI Primary M51C Y

PI Addr Information (from Commons Record)	PI Degree Information (from Commons Record)
PI Name: <u>DASZAK, PETER</u>	Earned? Degree Degree Category Degree Subcategory Study Field Other Deg
Contact PI: Y	Earned PHD - DOCTOR OF PHILOSOPHY PhD Equivalent (PhD, SCD, DSC, DPH, DRPH) Academic Doctorate held Not Available N/A
Profile Person: 6575431 Person Info	Earned BS - BACHELOR OF SCIENCE Baccalaureate Baccalaureate held Not Available N/A
Commons Acct: DASZAK	
Address: 520 Eighth Avenue	
HOM Suite 1200	
New York, NY 100181620	
E-mail: (b) (6)	
Phone #: (b) (6)	
Ext:	
Fax #:	

Institution Information					
Institution Name	Address	IPF CODE	EIN	Submitting Dept	Dept Category E-mail
ECOHEALTH ALLIANCE, INC.	EcoHealth Alliance, Inc. 460 West 34th Street 17th Floor New York, NY 100012317	4415701	1311726494A1		(b) (6)

Performance Site Information						
Organization Name	Address	Country	Duns ID	Duns Extension ID	Congressional District*	
ECOHEALTH ALLIANCE	ECOHEALTH ALLIANCE, INC. 460 W 34TH ST NEW YORK, NY 100012320	UNITED STATES	077090066	0000	NY-	
East China Normal University	3663 Zhongshan Beilu Shanghai	CHINA	420945495	0000	n/a	
East China Normal University	3663 Zhongshan Beilu Shanghai	CHINA	420945495	0000	n/a	
EcoHealth Alliance, Inc.	460 West 34th Street 17th Floor New York, NY 100012317	UNITED STATES	077090066	0000	NY-10	
EcoHealth Alliance, Inc.	460 West 34th Street 17th Floor New York, NY 100012317	UNITED STATES	077090066	0000	NY-10	
Wuhan Institute of Virology	Xiao Hong Shan, No. 44 Wuchang District Wuhan	CHINA	529027474	0000	n/a	
Wuhan Institute of Virology	Xiao Hong Shan, No. 44 Wuchang District Wuhan	CHINA	529027474	0000	n/a	

*Congressional District for Performance Sites may differ from the [official Congressional District](#) for the External Org. [Details.](#)

Award Budget									
Period#	FY	Budget Start Date	Budget End Date	Non-Federal Share Amt.	Direct Cost	Indirect Cost	Fee Amount	Unobligated Balance Amt.	Total Cost Amt.
3	2016	2016/06/01	2017/05/31	\$0	\$489,333	\$121,757	\$0	\$0	\$611,090
4	2017			\$0	\$476,016	\$121,096	\$0	\$0	\$597,112
5	2018			\$0	\$462,270	\$119,376	\$0	\$0	\$581,646

CANS										
Period#	ICD	CFDA	CAN	CAN Task(s)	Enterprise Program /Special Tracking	Direct Cost	Indirect Cost	Fee Amount	Unobligated Balance Amt.	Total Cost Amt
3	AI	855	8472350	2016.100	-	\$489,333	\$121,757	\$0	\$0	\$611,090
4	AI	855	8472350		-	\$476,016	\$121,096	\$0	\$0	\$597,112
5	AI	855	8472350		-	\$462,270	\$119,376	\$0	\$0	\$581,646

CFY Line Items					
Type	IC-CAN	Account Code	Line Item Description	Amount	Item Cnt
Total		3110	Personnel Costs (Subtotal)	\$221,876	
Total		3111	Salaries and Wages	\$167,708	
Total		3112	Fringe Benefits	\$54,168	
Total		4225	Other	\$11,050	
Total		4226	Materials & Supplies	\$7,250	
Total		4321	Travel	\$35,918	
Total		4422	Subawards/ Consortium/ Contractual Costs	\$213,239	

Other Persons Associated with Grant

Address update needed? Contact your [IMPACII coordinator](#)

ICD	Role	Name	Address	Addr Typ	E-Mail	Phone	Fax	Signed Off?	Signed By	Signed Date
AI	GMO	LINDE, EMILY	Grants Management Program Division of Extramural Activities, RM 4E11 DHHS/NIH/NIAID 5601 Fishers Lane, MSC 9833 Bethesda, MD 208929833	WRK	(b) (6)	(b) (6)	301-493-0597	Y-Last Official	SMITH, PHILIP E	2017-05-05
AI	GS	GREER, JENNY L	Grants Management BRANCH DIVISION OF EXTRAMURAL RESEARCH AND TRAINING NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES RESEARCH TRIANGLE PARK, NC 27709	WRK	(b) (6)	(b) (6)	301-493-0597	Y-Last Official	SMITH, PHILIP E	2017-05-05
AI	PO	STEMMY, ERIK J	INFLUENZA, SARS & OTHER VIRAL RESPIRATORY DISEASES DMID, Room 8E18 National Institutes of Health/ NIAID 5601 Fishers Ln, MSC 9825 Rockville, MD 208529825	WRK	(b) (6)	(b) (6)		Y-Last Official	STEMMY, ERIK J	2016-07-19

Training Appointments Not Applicable

Project Information	Review Detail	Admin Codes (in alpha order)
Grant #: 5-R01-AI-110964-04	Council Date: 201700	AIDS Related: N
Title: Understanding the Risk of Bat Coronavirus Emergence	Study Section: CRFS	Animal: 30
Status: 05 Awarded, Non-fellowships only	Reviewing IC: n/a	Appl New Investigator:
Primary PCC: M51C	Rev Mtg Start Date:	Appl Early Stage Investigator: n/a
Multi PIs: N	Initial SS Release Date:	Biohazard: N
Future Years:	SS Release Date:	Carryover Authority: Y
Document #: RAI110964A	Priority Score: (b) (5)	Child: 3A
Modular Grant: N	Percentile:	Clinical Trial Code: 0
FOA: PA-11-260	Ref.Code:	Diversity Reentry Flag:
FOA Diversity Flag: N	Spc Consider:	Foreign Grant: 2
Agency Routing/NOSI ID:	IRG Action:	Gender: 1A
Appl ID: 9320765	CNL Action:	Human: 54
Accession Num:	Intent To Pay:	Inclusion Monitoring: Must be monitored (Yes)
Former Grant #:		Minority: 5A
Congressional District: NY-12		Phase 3 Clinical Trial: N
		SNAP Awd: Y
		Special Topics:
		Stem Cells Used: N

Project Dates	Status History
Project Start Date: 2014/06/01	Seq Eftv Dt Status Code Description
Project End Date: 2019/05/31	1 2016-07-26 10:07 35 To be Paid
Actual NoA Issue Dt: 2017/05/26	2 2017-05-25 16:05 19 Award prepared, not funded
Initial Encumbrance Dt: 2017/05/26	3 2017-05-26 00:05 05 Awarded. Non-fellowships only
Latest Encumbrance Dt: 2017/05/26	

Dual IC/PCC
ICD Primary? PCC Main Council Action (IC)
AI Primary M51C Y

PI Addr Information (from Commons Record)	PI Degree Information (from Commons Record)
PI Name: DASZAK, PETER	Earned? Degree Degree Category Degree Subcategory Study Field Other Deg
Contact PI: Y	Earned PHD - DOCTOR OF PHILOSOPHY PhD Equivalent (PhD, SCD, DSC, DPH, DRPH) Academic Doctorate held Not Available N/A
Profile Person: 6575431 Person Info	Earned BS - BACHELOR OF SCIENCE Baccalaureate Baccalaureate held Not Available N/A
Commons Acct: DASZAK	
Address: 520 Eighth Avenue	
HOM Suite 1200	
New York, NY 100181620	
E-mail: (b) (6)	
Phone #: (b) (6)	
Ext:	
Fax #:	

Institution Information						
Institution Name	Address	IPF CODE	EIN	Submitting Dept	Dept Category	E-mail
ECOHEALTH ALLIANCE, INC.	EcoHealth Alliance, Inc. 460 West 34th Street 17th Floor New York, NY 100012317	4415701	1311726494A1			(b) (6)

Performance Site Information						
Organization Name	Address	Country	Duns ID	Duns Extension ID	Congressional District*	
ECOHEALTH ALLIANCE	ECOHEALTH ALLIANCE, INC. 460 W 34TH ST NEW YORK, NY 100012320	UNITED STATES	077090066	0000	NY-	
East China Normal University	3663 Zhongshan Beilu Shanghai	CHINA	420945495	0000	n/a	
East China Normal University	3663 Zhongshan Beilu Shanghai	CHINA	420945495	0000	n/a	
EcoHealth Alliance, Inc.	460 West 34th Street 17th Floor New York, NY 100012317	UNITED STATES	077090066	0000	NY-10	
EcoHealth Alliance, Inc.	460 West 34th Street 17th Floor New York, NY 100012320	UNITED STATES	077090066	0000	NY-10	
Wuhan Institute of Virology	Xiao Hong Shan, No. 44 Wuchang District Wuhan	CHINA	529027474	0000	n/a	
Wuhan Institute of Virology	Xiao Hong Shan, No. 44 Wuchang District Wuhan	CHINA	529027474	0000	n/a	

*Congressional District for Performance Sites may differ from the [official Congressional District](#) for the External Org. [Details.](#)

Award Budget									
Period#	FY	Budget Start Date	Budget End Date	Non-Federal Share Amt.	Direct Cost	Indirect Cost	Fee Amount	Unobligated Balance Amt.	Total Cost Amt.
4	2017	2017/06/01	2018/05/31	\$0	\$476,016	\$121,096	\$0	\$0	\$597,112
5	2018			\$0	\$462,270	\$119,376	\$0	\$0	\$581,646

CANS										
Period#	ICD	CFDA	CAN	CAN Task(s)	Enterprise Program /Special Tracking	Direct Cost	Indirect Cost	Fee Amount	Unobligated Balance Amt.	Total Cost Amt
4	AI	855	8472350	2017.100	-	\$476,016	\$121,096	\$0	\$0	\$597,112
5	AI	855	8472350		-	\$462,270	\$119,376	\$0	\$0	\$581,646

CFY Line Items					
Type	IC-CAN	Account Code	Line Item Description	Amount	Item Cnt
Total		3110	Personnel Costs (Subtotal)	\$221,876	
Total		3111	Salaries and Wages	\$167,708	
Total		3112	Fringe Benefits	\$54,168	
Total		4225	Other	\$9,800	
Total		4226	Materials & Supplies	\$7,000	
Total		4321	Travel	\$35,918	
Total		4422	Subawards/ Consortium/ Contractual Costs	\$201,422	

Other Persons Associated with Grant

Address update needed? Contact your [IMPACII coordinator](#)

ICD	Role	Name	Address	Addr Typ	E-Mail	Phone	Fax	Signed Off?	Signed By	Signed Date
AI	GMO	LINDE, EMILY	Grants Management Program Division of Extramural Activities, RM 4E11 DHHS/NIH/NIAID 5601 Fishers Lane, MSC 9833 Bethesda, MD 208929833	WRK	(b) (6)	(b) (6)	301-493-0597	Y-Last Official	PONE, LAURA A	2017-05-25
AI	GS	NORMIL, CARINE	Grants Management Branch - NINDS Neuroscience Center - Room 3248 6001 Executive Boulevard Bethesda, MD 20892	WRK	(b) (6)	(b) (6)		Y-Last Official	NORMIL, CARINE	2017-05-23
AI	PO	STEMMY, ERIK J	INFLUENZA, SARS & OTHER VIRAL RESPIRATORY DISEASES DMID, Room 8E18 National Institutes of Health/ NIAID 5601 Fishers Ln, MSC 9825 Rockville, MD 208529825	WRK	(b) (6)	(b) (6)		Y-Last Official	STEMMY, ERIK J	2017-05-09

Training Appointments Not Applicable

Project Information	Review Detail	Admin Codes (in alpha order)
Grant #: 5-R01-AI-110964-05	Council Date: 201800	AIDS Related: N
Title: Understanding the Risk of Bat Coronavirus Emergence	Study Section: CRFS	Animal: 30
Status: 05 Awarded, Non-fellowships only	Reviewing IC: n/a	Appl New Investigator:
Primary PCC: M51C	Rev Mtg Start Date:	Appl Early Stage Investigator: n/a
Multi PIs: N	Initial SS Release Date:	Biohazard: N
Future Years:	SS Release Date:	Carryover Authority: Y
Document #: RAI110964A	Priority Score: (b) (5)	Child: 3A
Modular Grant: N	Percentile:	Clinical Trial Code: 0
FOA: PA-11-260	Ref.Code:	Diversity Reentry Flag: N
FOA Diversity Flag: N	Spc Consider:	Foreign Grant: 2
Agency Routing/NOSI ID:	IRG Action:	Gender: 1A
Appl ID: 9491676	CNL Action:	Human: 30
Accession Num:	Intent To Pay:	Inclusion Monitoring: Must be monitored (Yes)
Former Grant #:		Minority: 5A
Congressional District: NY-12		Phase 3 Clinical Trial: N
		SNAP Awd: Y
		Special Topics:
		Stem Cells Used: N

Project Dates	Status History
Project Start Date: 2014/06/01	Seq Eftv Dt Status Code Description
Project End Date: 2019/05/31	1 2017-05-26 00:05 35 To be Paid
Actual NoA Issue Dt: 2018/06/18	2 2018-06-15 16:06 19 Award prepared, not funded
Initial Encumbrance Dt: 2018/06/18	3 2018-06-18 00:06 05 Awarded. Non-fellowships only
Latest Encumbrance Dt: 2018/06/18	

Dual IC/PCC	ICD Primary?	PCC	Main Council Action (IC)
AI	Primary	M51C	Y

PI Addr Information (from Commons Record)	PI Degree Information (from Commons Record)
PI Name: DASZAK, PETER	Earned? Degree Degree Category Degree Subcategory Study Field Other Deg
Contact PI: Y	Earned BS - BACHELOR OF SCIENCE Baccalaureate Baccalaureate held Not Available N/A
Profile Person: 6575431 Person Info	Earned PHD - DOCTOR OF PHILOSOPHY PhD Equivalent (PhD, SCD, DSC, DPH, DRPH) Academic Doctorate held Not Available N/A
Commons Acct: DASZAK	
Address: 520 Eighth Avenue	
HOM Suite 1200	
New York, NY 100181620	
E-mail: (b) (6)	
Phone #: (b) (6)	
Ext:	
Fax #:	

Institution Information						
Institution Name	Address	IPF CODE	EIN	Submitting Dept	Dept Category	E-mail
ECOHEALTH ALLIANCE, INC.	EcoHealth Alliance, Inc. 460 West 34th Street 17th Floor New York, NY 100012317	4415701	1311726494A1			(b) (6)

Performance Site Information						
Organization Name	Address	Country	Duns ID	Duns Extension ID	Congressional District*	
ECOHEALTH ALLIANCE	ECOHEALTH ALLIANCE, INC. 460 W 34TH ST NEW YORK, NY 100012320	UNITED STATES	077090066	0000	NY-	
East China Normal University	3663 Zhongshan Beilu Shanghai, NONE	CHINA	420945495	0000	n/a	
EcoHealth Alliance, Inc.	460 West 34th Street 17th Floor New York, NY 100012320	UNITED STATES	077090066	0000	NY-10	
Wuhan Institute of Virology	Xiao Hong Shan, No. 44 Wuchang District Wuhan, NONE	CHINA	529027474	0000	n/a	

*Congressional District for Performance Sites may differ from the [official Congressional District](#) for the External Org. [Details.](#)

Award Budget									
Period#	FY	Budget Start Date	Budget End Date	Non-Federal Share Amt.	Direct Cost	Indirect Cost	Fee Amount	Unobligated Balance Amt.	Total Cost Amt.
5	2018	2018/06/01	2019/05/31	\$0	\$462,270	\$119,376	\$0	\$0	\$581,646

CANS										
Period#	ICD	CFDA	CAN	CAN Task(s)	Enterprise Program /Special Tracking	Direct Cost	Indirect Cost	Fee Amount	Unobligated Balance Amt.	Total Cost Amt
5	AI	855	8472350	2018.100	-	\$462,270	\$119,376	\$0	\$0	\$581,646

CFY Line Items					
Type	IC-CAN	Account Code	Line Item Description	Amount	Item Cnt
Total		3110	Personnel Costs (Subtotal)	\$221,876	
Total		3111	Salaries and Wages	\$167,708	
Total		3112	Fringe Benefits	\$54,168	
Total		4225	Other	\$9,400	
Total		4226	Materials & Supplies	\$3,500	
Total		4321	Travel	\$35,918	
Total		4422	Subawards/ Consortium/ Contractual Costs	\$191,576	

Other Persons Associated with Grant

Address update needed? Contact your [IMPACII coordinator](#)

ICD	Role	Name	Address	Addr Typ	E-Mail	Phone	Fax	Signed Off?	Signed By	Signed Date
AI	GMO	LINDE, EMILY	Grants Management Program Division of Extramural Activities, RM 4E11 DHHS/NIH/NIAID 5601 Fishers Lane, MSC 9833 Bethesda, MD 208929833	WRK	(b) (6)	(b) (6)	301-493-0597	Y-Last Official	GIRMA, TSEDAY G	2018-06-15
AI	GS	GIRMA, TSEDAY G	Grants Management Program Division of Extramural Activities, RM 4E49 National Institutes of Health/NIAID 5601 Fishers Lane, MSC 9833 Bethesda, MD 208929833	WRK	(b) (6)	(b) (6)	301-493-0597			
AI	GS	GRAHAM, ADAM	Grants Management Program Division of Extramural Activities, RM 4E40B National Institutes of Health/NIAID 5601 Fishers Lane, MSC 9824 Bethesda, MD 208929833	WRK	(b) (6)	(b) (6)	301-493-0597	Y-Last Official	GRAHAM, ADAM	2018-06-15
AI	PO	STEMMY, ERIK J	INFLUENZA, SARS & OTHER VIRAL RESPIRATORY DISEASES DMID, Room 8E18 National Institutes of Health/ NIAID 5601 Fishers Ln, MSC 9825 Rockville, MD 208529825	WRK	(b) (6)	(b) (6)		Y-Last Official	STEMMY, ERIK J	2018-06-12
OD	CS	CAMPBELL, DESIREE	Grants Closeout Specialist DHHS/NIH/OD/OER/OAO Division of Central Grants Processing (DCGP) 6705 Rockledge Dr, Suite 5016, Rm. 5214 Bethesda, MD 20892	WRK	(b) (6)	(b) (6)	301-480-4776			

Training Appointments Not Applicable

Project Information		Review Detail		Admin Codes (in alpha order)	
Grant #:	2-R01-AI-110964-06	Council Date:	201905	AIDS Related:	N
Title:	Understanding the Risk of Bat Coronavirus Emergence	Study Section:	CRFS	Animal:	30
Status:	05 Awarded, Non-fellowships only	Reviewing IC:	CSR	Appl New Investigator:	No
Primary PCC:	M51C B	Rev Mtg Start Date:	02/14/2019	Appl Early Stage Investigator:	No
Multi PIs:	N	Initial SS Release Date:	03/06/2019	Biohazard:	N
Future Years:		SS Release Date:	03/06/2019	Carryover Authority:	Y
Document #:	RAI110964B	Priority Score:	(b) (5)	Child:	1A
Modular Grant:	N	Percentile:		Clinical Trial Code:	0
FOA:	<u>PA-18-484</u>	Ref.Code:		Diversity Reentry Flag:	N
FOA Diversity Flag:	N	Spc Consider:		Foreign Grant:	2
Agency Routing/NOSI ID:		IRG Action:		Gender:	1A
Appl ID:	9819304	CNL Action:		Human:	30
Accession Num:	4237214	Intent To Pay:		Inclusion Monitoring:	Must be monitored (Yes)
Former Grant #:				Minority:	5A
Congressional District:	NY-12			Phase 3 Clinical Trial:	N
				SNAP Awd:	Y
				Special Topics:	
				Stem Cells Used:	N

Project Dates		Status History			
Project Start Date:	2014/06/01	Seq	Eftv Dt	Status Code	Description
Project End Date:	2025/06/30	1	2018-11-05 16:11	70	Application has been entered into computer
Actual NoA Issue Dt:	2020/07/13 (originally sent: 2019/07/24)	2	2018-11-20 20:11	17	Pending IRG Review
Initial Encumbrance Dt:	2019/07/24	3	2019-02-19 15:02	12	Pending Council Review
Latest Encumbrance Dt:	2020/07/14	4	2019-04-15 16:04	07	Pending Award. Non-fellowships
		5	2019-04-23 19:04	35	To be Paid
		6	2019-07-18 10:07	19	Award prepared, not funded
		7	2019-07-24 00:07	05	Awarded. Non-fellowships only

Dual IC/PCC				
ICD	Primary?	PCC	Main	Council Action (IC)
AI	Primary	M51C B	Y	1 To be considered for funding (CF)

PI Addr Information (from Commons Record)		PI Degree Information (from Commons Record)					
PI Name:	<u>DASZAK, PETER</u>	Earned?	Degree	Degree Category	Degree Subcategory	Study Field	Other Deg
Contact PI:	Y	Earned	PHD - DOCTOR OF PHILOSOPHY	PhD Equivalent (PhD, SCD, DSC, DPH, DRPH)	Academic Doctorate held	Not Available	N/A
Profile Person:	6575431 Person Info	Earned	BS - BACHELOR OF SCIENCE	Baccalaureate	Baccalaureate held	Not Available	N/A
Commons Acct:	DASZAK						
Address:	520 Eighth Avenue						
HOM	Suite 1200 New York, NY 100181620						
E-mail:	(b) (6)						
Phone #:	(b) (6)						
Ext:							
Fax #:							

Institution Information						
Institution Name	Address	IPF CODE	EIN	Submitting Dept	Dept Category	E-mail
ECOHEALTH ALLIANCE, INC.	ECOHEALTH ALLIANCE, INC. 460 W 34TH ST NEW YORK, NY 100012320	4415701	1311726494A1			(b) (6)

Performance Site Information						
Organization Name	Address	Country	Duns ID	Duns Extension ID	Congressional District*	
ECOHEALTH ALLIANCE, INC.	ECOHEALTH ALLIANCE, INC. 460 W 34TH ST NEW YORK, NY 100012320	UNITED STATES	077090066	0000	NY-10	
Institute of Pathogen Biology	Dong Dan San Tiao, No. 9 Dongcheng District Beijing 100730	CHINA	528156357	0000	n/a	
University of North Carolina at Chapel Hill	McGavran-Greenberg Hall Campus Box 7435 Chapel Hill, NC 275997435	UNITED STATES	608195277	0000	NC-04	
Wuhan Institute of Virology	Xiao Hong SHan, No. 44 Wuchang District Wuhan 430071	CHINA	529027474	0000	n/a	

*Congressional District for Performance Sites may differ from the [official Congressional District](#) for the External Org. [Details.](#)

Preaward Budget Detail					
Type	Period#	FY	Direct Cost Amt	Indirect Cost Amt	Total Cost Amt
*	5	2018	\$462,270	\$119,376	\$581,646
* this detail reflects prior award (5-R01-AI110964-05)					
CNL	6	2019	\$554,360	\$0	\$0
CNL	7	2020	\$554,360	\$0	\$0
CNL	8	2021	\$554,360	\$0	\$0
CNL	9	2022	\$554,360	\$0	\$0
CNL	10	2023	\$554,360	\$0	\$0
REQ	6	2019	\$554,360	\$182,636	\$736,996
REQ	7	2020	\$554,360	\$158,081	\$712,441
REQ	8	2021	\$554,360	\$158,081	\$712,441
REQ	9	2022	\$554,360	\$158,081	\$712,441
REQ	10	2023	\$554,360	\$158,081	\$712,441

Award Budget										
Period#	FY	Budget Start Date	Budget End Date	Non-Federal Share Amt.	Direct Cost	Indirect Cost	Fee Amount	Unobligated Balance Amt.	Total Cost Amt.	
6	2019	2019/07/24	2021/06/30	\$0	\$538,926	\$123,054	\$0	\$0	\$661,980	
7	2021			\$0	\$538,991	\$98,989	\$0	\$0	\$637,980	
8	2022			\$0	\$538,991	\$98,989	\$0	\$0	\$637,980	
9	2023			\$0	\$538,991	\$98,989	\$0	\$0	\$637,980	
10	2024			\$0	\$538,991	\$98,989	\$0	\$0	\$637,980	

CANS										
Period#	ICD	CFDA	CAN	CAN Task(s)	Enterprise Program /Special Tracking	Direct Cost	Indirect Cost	Fee Amount	Unobligated Balance Amt.	Total Cost Amt
6	AI	855	8472364	2019.100	-	\$538,926	\$123,054	\$0	\$0	\$661,980
7	AI	855	8472364		-	\$538,991	\$98,989	\$0	\$0	\$637,980
8	AI	855	8472364		-	\$538,991	\$98,989	\$0	\$0	\$637,980
9	AI	855	8472364		-	\$538,991	\$98,989	\$0	\$0	\$637,980
10	AI	855	8472364		-	\$538,991	\$98,989	\$0	\$0	\$637,980

CFY Line Items					
Type	IC-CAN	Account Code	Line Item Description	Amount	Item Cnt
Total		3110	Personnel Costs (Subtotal)	\$223,979	
Total		3111	Salaries and Wages	\$170,325	
Total		3112	Fringe Benefits	\$53,654	
Total		4121	Consultant Services	\$49,809	
Total		4226	Materials & Supplies	\$20,170	
Total		4321	Travel	\$15,045	
Total		4422	Subawards/ Consortium/ Contractual Costs	\$229,923	

Other Persons Associated with Grant

Address update needed? Contact your [IMPACII coordinator](#)

ICD	Role	Name	Address	Addr Typ	E-Mail	Phone	Fax	Signed Off?	Signed By	Signed Date
AI	GMO	LINDE, EMILY	Grants Management Program Division of Extramural Activities, RM 4E11 DHHS/NIH/NIAID 5601 Fishers Lane, MSC 9833 Bethesda, MD 208929833	WRK	(b) (6)	(b) (6)	301-493-0597	Y-Last Official	LINDE, EMILY	2020-07-13
AI	GS	GRATTON, SHAUN W	Grants Management Program Division of Extramural Activities, RM 4E30B National Institutes of Health/NIAID 5601 Fishers Lane, MSC 9833 Bethesda, MD 208929833	WRK	(b) (6)	(b) (6)	301-493-0597	Y-Last Official	LINDE, EMILY	2020-07-13
AI	PO	STEMMY, ERIK J	INFLUENZA, SARS & OTHER VIRAL RESPIRATORY DISEASES DMID, Room 8E18 National Institutes of Health/ NIAID 5601 Fishers Ln, MSC 9825 Rockville, MD 208529825	WRK	(b) (6)	(b) (6)		Y-Last Official	STEMMY, ERIK J	2019-05-10
OD	CS	CAMPBELL, DESIREE	Grants Closeout Specialist DHHS/NIH/OD/OER/OAO Division of Central Grants Processing (DCGP) 6705 Rockledge Dr, Suite 5016, Rm. 5214 Bethesda, MD 20892	WRK	(b) (6)	(b) (6)	301-480-4776			
RG	SRA	SAADI, SOHEYLA	Center for Scientific Review National Institutes of Health 6701 Rockledge Drive, Room 3211, MSC 7808 Bethesda, MD 20892	MLG	(b) (6)	(b) (6)	301-480-0940			

Training Appointments Not Applicable

Project Information		Review Detail		Admin Codes (in alpha order)	
Grant #:	5-R01-AI-110964-07	Council Date:	202100	AIDS Related:	N
Title:	Understanding the Risk of Bat Coronavirus Emergence	Study Section:	CRFS	Animal:	30
Status:	35 To be Paid	Reviewing IC:	n/a	Appl New Investigator:	
Primary PCC:	M51C B	Rev Mtg Start Date:		Appl Early Stage Investigator:	n/a
Multi Pls:	N	Initial SS Release Date:		Biohazard:	N
Future Years:		SS Release Date:		Carryover Authority:	Y
Document #:	RAI110964B	Priority Score:	(b) (5)	Child:	1A
Modular Grant:	N	Percentile:		Clinical Trial Code:	0
FOA:	PA-18-484	Ref.Code:		Diversity Reentry Flag:	N
FOA Diversity Flag:	N	Spc Consider:		Foreign Grant:	2
Agency Routing/NOSI ID:		IRG Action:		Gender:	1A
Appl ID:	10216930	CNL Action:		Human:	30
Accession Num:		Intent To Pay:		Inclusion Monitoring:	Must be monitored (Yes)
Former Grant #:				Minority:	5A
Congressional District:	NY-12			Phase 3 Clinical Trial:	N
				SNAP Awd:	Y
				Special Topics:	
				Stem Cells Used:	N

Project Dates		Status History			
Project Start Date:	2014/06/01	Seq	Eftv Dt	Status Code	Description
Project End Date:	2025/06/30	1	2020-07-15 00:07	35	To be Paid
Actual NoA Issue Dt:					
Initial Encumbrance Dt:					
Latest Encumbrance Dt:					

Dual IC/PCC	
ICD Primary? PCC	Main Council Action (IC)
AI Primary M51C B Y	

PI Addr Information (from Commons Record)		PI Degree Information (from Commons Record)					
PI Name:	DASZAK, PETER	Earned?	Degree	Degree Category	Degree Subcategory	Study Field	Other Deg
Contact PI:	Y	Earned	PHD - DOCTOR OF PHILOSOPHY	PhD Equivalent (PhD, SCD, DSC, DPH, DRPH)	Academic Doctorate held	Not Available	N/A
Profile Person:	6575431 Person Info	Earned	BS - BACHELOR OF SCIENCE	Baccalaureate	Baccalaureate held	Not Available	N/A
Commons Acct:	DASZAK						
Address:	520 Eighth Avenue						
HOM	Suite 1200 New York, NY 100181620						
E-mail:	(b) (6)						
Phone #:	(b) (6)						
Ext:							
Fax #:							

Institution Information						
Institution Name	Address	IPF CODE	EIN	Submitting Dept	Dept Category	E-mail
ECOHEALTH ALLIANCE, INC.	ECOHEALTH ALLIANCE, INC. ECOHEALTH ALLIANCE, INC. 460 W 34TH ST NEW YORK, NY 100012320	4415701	1311726494A1			(b) (6)

Performance Site Information						
Organization Name	Address	Country	Duns ID	Duns Extension ID	Congressional District*	
EcoHealth Alliance	ECOHEALTH ALLIANCE, INC. 520 EIGHTH AVENUE NEW YORK, NY 100184183	UNITED STATES	077090066	0000	NY-12	

*Congressional District for Performance Sites may differ from the [official Congressional District](#) for the External Org. [Details.](#)

Award Budget									
Period#	FY	Budget Start Date	Budget End Date	Non-Federal Share Amt.	Direct Cost	Indirect Cost	Fee Amount	Unobligated Balance Amt.	Total Cost Amt.
7	2021	2021/07/01	2022/06/30	\$0	\$538,991	\$98,989	\$0	\$0	\$637,980
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9	2023			\$0	\$538,991	\$98,989	\$0	\$0	\$637,980
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CANS										
Period#	ICD	CFDA	CAN	CAN Task(s)	Enterprise Program /Special Tracking	Direct Cost	Indirect Cost	Fee Amount	Unobligated Balance Amt.	Total Cost Amt
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8	AI	855	8472364		-	\$538,991	\$98,989	\$0	\$0	\$637,980
9	AI	855	8472364		-	\$538,991	\$98,989	\$0	\$0	\$637,980
10	AI	855	8472364		-	\$538,991	\$98,989	\$0	\$0	\$637,980

CFY Line Items					
Type	IC-CAN	Account Code	Line Item Description	Amount	Item Cnt
Total		3110	Personnel Costs (Subtotal)	\$223,713	
Total		3111	Salaries and Wages	\$170,123	
Total		3112	Fringe Benefits	\$53,590	
Total		4121	Consultant Services	\$49,750	
Total		4226	Materials & Supplies	\$14,850	
Total		4321	Travel	\$15,027	
Total		4422	Subawards/ Consortium/ Contractual Costs	\$229,651	
Total		4433	Publication Costs	\$6,000	

Other Persons Associated with Grant *Address update needed? Contact your [IMPACII coordinator](#)*

ICD	Role	Name	Address	Addr Typ	E-Mail	Phone	Fax	Signed Off?	Signed By	Signed Date
AI	GMO	LINDE, EMILY	Grants Management Program Division of Extramural Activities, RM 4E11 DHHS/NIH/NIAID 5601 Fishers Lane, MSC 9833 Bethesda, MD 208929833	WRK	(b) (6)	(b) (6)	301-493-0597			
AI	GS	GRATTON, SHAUN W	Grants Management Program Division of Extramural Activities, RM 4E30B National Institutes of Health/NIAID 5601 Fishers Lane, MSC 9833 Bethesda, MD 208929833	WRK	(b) (6)	(b) (6)	301-493-0597			
AI	PO	STEMMY, ERIK J	INFLUENZA, SARS & OTHER VIRAL RESPIRATORY DISEASES DMID, Room 8E18 National Institutes of Health/ NIAID 5601 Fishers Ln, MSC 9825 Rockville , MD 208529825	WRK	(b) (6)	(b) (6)				

Training Appointments Not Applicable

From: [Lauer, Michael \(NIH/OD\) \[E\]](#)
To: [Collins, Francis \(NIH/OD\) \[E\]](#)
Cc: [Tabak, Lawrence \(NIH/OD\) \[E\]](#); [Lauer, Michael \(NIH/OD\) \[E\]](#)
Subject: Re: book excerpt for fact checking
Date: Wednesday, March 24, 2021 1:58:16 PM
Attachments: [Collins fact check EcoHealth\[86\]_lat\[1\].docx](#)

Working on it ...

From: "Collins, Francis (NIH/OD) [E]" <[REDACTED] (b) (6)>
Date: Wednesday, March 24, 2021 at 1:32 PM
To: "Lauer, Michael (NIH/OD) [E]" <[REDACTED] (b) (6)>
Cc: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] (b) (6)>
Subject: FW: book excerpt for fact checking

Hi Mike,

See below. Can you have a quick look at this book excerpt and offer any additional corrections about what happened with EcoHealth?

Thanks, Francis

From: Tabak, Lawrence (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Wednesday, March 24, 2021 1:30 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>
Subject: Re: book excerpt for fact checking

The only thing that I can note is in the attached. You may wish Mike to look at as well. As I recall you were unavailable, and I told you after the fact.

Sorry for the delay.
Larry

From: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>
Date: Wednesday, March 24, 2021 at 1:23 PM
To: Tabak, Lawrence (NIH/OD) [E] <[REDACTED] (b) (6)>
Subject: FW: book excerpt for fact checking

Sorry to hit you with this request. Would it be more appropriate for me to ask Mike Lauer for a quick review?

Tx, FC

From: Collins, Francis (NIH/OD) [E]

Sent: Tuesday, March 23, 2021 8:26 PM

To: Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> (b) (6)

Subject: book excerpt for fact checking

See attached for excerpt from a book being written by two WaPo reporters. Please mark up as needed to reflect the actual facts.

Thanks, FC

- In late April, articles were published in *Science* and *Politico* detailing how, at Trump's direction, the NIH abruptly terminated a grant for a study examining how coronaviruses spread from bats to humans. This was an area of research that had renewed importance given the pandemic. The study's sponsor was a New York-based research nonprofit called EcoHealth Alliance, but reports linked the grant to the Wuhan Institute of Virology at the same time right-wing media was seizing on the theory that the coronavirus either escaped from, or was engineered in, a lab in Wuhan, China. (Navarro, characteristically, was the most bullish of those inside the White House peddling the Wuhan lab theory. He even suggested the virus could have been designed by the Chinese military as a type of biological weapon, an argument in line with his 2011 book, *Death by China*.) A reporter from One America News Network — a tiny conservative outlet that was even more loyal to the president than Fox News — asked Trump about the grant in a briefing one week before it was terminated. "We will end that grant very quickly," Trump replied.
- The NIH, peer-reviewed grant had already come under scrutiny within the federal government as soon as officials realized the Wuhan Institute of Virology had a subgrant under the contract. The institute had the most expertise in studying which bat viruses might be the next to come out of China and pose a major threat. But with questions swirling about the origins of COVID-19 — experts had determined the virus was not man made, but could not rule out that it may have slipped out of a lab — the NIH had gone to the principal investigator on the grant in March and asked that payments be halted to the subcontract in Wuhan until they had more answers.
- Several weeks later, the relatively small grant had garnered new attention. The chatter by Navarro and the other White House hawks who were convinced China had deliberately unleashed the virus on the world, had found a welcome audience among right-wing conspiracy theorists. On the afternoon of April 29, NIH Director Francis Collins and Fauci received notice that Trump wanted to formally announce the grant had been terminated in a 5 pm press conference. Collins and Fauci told the White House and HHS they were not sure the NIH actually had the authority to terminate a peer-reviewed grant. The White House told them to do it anyway and made clear it was a direct order from the president — implying their jobs were on the line if they didn't comply. Fauci and Collins reluctantly agreed to cancel the grant.
- Collins and Fauci heard from many members of the scientific community that they should have resigned. The NIH's own experts later found the agency probably did not have the authority to terminate the grant. Instead, they had to reinstate the grant but stop all of its funding.

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- Collins and Fauci heard from many members of the scientific community that they should have resigned. The NIH's own experts later found the agency probably did not have the authority to terminate the grant. Instead, they had to reinstate the grant but stop all of its funding.

From: [Fine, Amanda \(NIH/OD\) \[E\]](#)
To: [Collins, Francis \(NIH/OD\) \[E\]](#); [Myles, Renate \(NIH/OD\) \[E\]](#); [Wood, Gretchen \(NIH/OD\) \[E\]](#); [McManus, Ayanna \(NIH/OD\) \[E\]](#)
Cc: [Burklow, John \(NIH/OD\) \[E\]](#); [Wojtowicz, Emma \(NIH/OD\) \[E\]](#); [Roberts, Jacqueline \(NIH/OD\) \[E\]](#); [NIH NMB \(NIH/OD\)](#)
Subject: RE: FOR REVIEW: WaPo Reporters Working on Book about Administration's Pandemic Response
Date: Wednesday, March 24, 2021 8:02:27 PM

Ok, we will share and get confirmation.

Thanks,
Amanda

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, March 24, 2021 6:30 PM
To: Fine, Amanda (NIH/OD) [E] <(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)> McManus, Ayanna (NIH/OD) [E] <(b) (6)>
Cc: Burklow, John (NIH/OD) [E] <(b) (6)> Wojtowicz, Emma (NIH/OD) [E] <(b) (6)> Roberts, Jacqueline (NIH/OD) [E] <(b) (6)> NIH NMB (NIH/OD) <(b) (6)>
Subject: RE: FOR REVIEW: WaPo Reporters Working on Book about Administration's Pandemic Response

Hi all,

See edits and comments on the attached. These are all important, so I would like to hear back from the book authors that they have accepted them.

Francis

From: Fine, Amanda (NIH/OD) [E] <(b) (6)>
Sent: Tuesday, March 23, 2021 5:07 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)> McManus, Ayanna (NIH/OD) [E] <(b) (6)>
Cc: Burklow, John (NIH/OD) [E] <(b) (6)> Wojtowicz, Emma (NIH/OD) [E] <(b) (6)> Roberts, Jacqueline (NIH/OD) [E] <(b) (6)> NIH NMB (NIH/OD) <(b) (6)>
Subject: RE: FOR REVIEW: WaPo Reporters Working on Book about Administration's Pandemic Response

Yes we should definitely push back on those kinds of items.

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Tuesday, March 23, 2021 5:06 PM

To: Fine, Amanda (NIH/OD) [E] <[REDACTED] (b) (6)> Myles, Renate (NIH/OD) [E]
<[REDACTED] (b) (6)> Wood, Gretchen (NIH/OD) [E] <[REDACTED] (b) (6)> McManus, Ayanna
(NIH/OD) [E] <[REDACTED] (b) (6)>
Cc: Burklow, John (NIH/OD) [E] <[REDACTED] (b) (6)> Wojtowicz, Emma (NIH/OD) [E]
<[REDACTED] (b) (6)> Roberts, Jacqueline (NIH/OD) [E] <[REDACTED] (b) (6)> NIH NMB
(NIH/OD) <[REDACTED] (b) (6)>
Subject: RE: FOR REVIEW: WaPo Reporters Working on Book about Administration's Pandemic
Response

Am I allowed also to challenge some of the statements in the excerpt provided?

For instance, I never had a shouting match with Steve Hahn.

Francis

From: Fine, Amanda (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Tuesday, March 23, 2021 3:16 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)> Myles, Renate (NIH/OD) [E]
<[REDACTED] (b) (6)> Wood, Gretchen (NIH/OD) [E] <[REDACTED] (b) (6)> McManus, Ayanna
(NIH/OD) [E] <[REDACTED] (b) (6)>
Cc: Burklow, John (NIH/OD) [E] <[REDACTED] (b) (6)> Wojtowicz, Emma (NIH/OD) [E]
<[REDACTED] (b) (6)> Roberts, Jacqueline (NIH/OD) [E] <[REDACTED] (b) (6)> NIH NMB
(NIH/OD) <[REDACTED] (b) (6)>
Subject: FOR REVIEW: WaPo Reporters Working on Book about Administration's Pandemic Response

Hi Francis-

As promised, Yasmeen has reached out to request your review/approval of two quotes they would like to use in the book. Attaching what she shared with us for your review. Your quotes are highlighted. Yasmeen said they'd work with us if you are uncomfortable with either of them.

Additionally, she shared that they interviewed nearly 200 people for this book, including people from the White House, HHS, FDA, NIH, CDC and outside advisers. They want to assure us that everything included comes from numerous sources, across the federal bureaucracy.

Their deadline for this fact check is Thursday, March 25.

Let us know if you need any additional information.

Thanks,
Amanda

From: Fine, Amanda (NIH/OD) [E]
Sent: Tuesday, January 26, 2021 5:21 PM

To: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)> Myles, Renate (NIH/OD) [E]
<[REDACTED] (b) (6)> Wood, Gretchen (NIH/OD) [E] <[REDACTED] (b) (6)> McManus, Ayanna
(NIH/OD) [E] <[REDACTED] (b) (6)>
Cc: Burklow, John (NIH/OD) [E] <[REDACTED] (b) (6)> Wojtowicz, Emma (NIH/OD) [E]
<[REDACTED] (b) (6)> Roberts, Jacqueline (NIH/OD) [E] <[REDACTED] (b) (6)> NIH NMB
(NIH/OD) <[REDACTED] (b) (6)>
Subject: RE: Interview request for Dr. Collins: WaPo Reporters Working on Book about
Administration's Pandemic Response

Good point. I will be sure to clarify that to them.

From: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Tuesday, January 26, 2021 5:09 PM
To: Fine, Amanda (NIH/OD) [E] <[REDACTED] (b) (6)> Myles, Renate (NIH/OD) [E]
<[REDACTED] (b) (6)> Wood, Gretchen (NIH/OD) [E] <[REDACTED] (b) (6)> McManus, Ayanna
(NIH/OD) [E] <[REDACTED] (b) (6)>
Cc: Burklow, John (NIH/OD) [E] <[REDACTED] (b) (6)> Wojtowicz, Emma (NIH/OD) [E]
<[REDACTED] (b) (6)> Roberts, Jacqueline (NIH/OD) [E] <[REDACTED] (b) (6)> NIH NMB
(NIH/OD) <[REDACTED] (b) (6)>
Subject: RE: Interview request for Dr. Collins: WaPo Reporters Working on Book about
Administration's Pandemic Response

[REDACTED] (b) (5)

FC

From: Fine, Amanda (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Tuesday, January 26, 2021 4:37 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)> Myles, Renate (NIH/OD) [E]
<[REDACTED] (b) (6)> Wood, Gretchen (NIH/OD) [E] <[REDACTED] (b) (6)> McManus, Ayanna
(NIH/OD) [E] <[REDACTED] (b) (6)>
Cc: Burklow, John (NIH/OD) [E] <[REDACTED] (b) (6)> Wojtowicz, Emma (NIH/OD) [E]
<[REDACTED] (b) (6)> Roberts, Jacqueline (NIH/OD) [E] <[REDACTED] (b) (6)> NIH NMB
(NIH/OD) <[REDACTED] (b) (6)>
Subject: RE: Interview request for Dr. Collins: WaPo Reporters Working on Book about
Administration's Pandemic Response

Hi Francis-

Following up on your conversation with Yasmeen and Damien today—Yasmeen reached out with a note to thank you for your time and to confirm their understanding of how they can use the

information you shared. Just want to confirm that the below was also your understanding:

I just wanted to clarify one thing. Our understanding is we can use the information Dr. Collins gave us to construct scenes in the book and inform our reporting, but not attribute it specifically to him or NIH. Since it's a book, we don't have to attribute every single sentence. And we'll of course come back to you guys and do a full fact check of everything that pertains to Dr. Collins and NIH. And we'll let you know if there's something we want to use attributable to Dr. Collins and see if that's okay.

Thanks,
Amanda

From: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Tuesday, January 19, 2021 9:49 PM
To: Myles, Renate (NIH/OD) [E] <[REDACTED] (b) (6)> Wood, Gretchen (NIH/OD) [E] <[REDACTED] (b) (6)> McManus, Ayanna (NIH/OD) [E] <[REDACTED] (b) (6)>
Cc: Burklow, John (NIH/OD) [E] <[REDACTED] (b) (6)> Fine, Amanda (NIH/OD) [E] <[REDACTED] (b) (6)> Wojtowicz, Emma (NIH/OD) [E] <[REDACTED] (b) (6)> Roberts, Jacqueline (NIH/OD) [E] <[REDACTED] (b) (6)> NIH NMB (NIH/OD) <[REDACTED] (b) (6)>
Subject: RE: Interview request for Dr. Collins: WaPo Reporters Working on Book about Administration's Pandemic Response

Zoom is fine, thanks.

From: Myles, Renate (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Tuesday, January 19, 2021 6:22 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)> Wood, Gretchen (NIH/OD) [E] <[REDACTED] (b) (6)> McManus, Ayanna (NIH/OD) [E] <[REDACTED] (b) (6)>
Cc: Burklow, John (NIH/OD) [E] <[REDACTED] (b) (6)> Fine, Amanda (NIH/OD) [E] <[REDACTED] (b) (6)> Wojtowicz, Emma (NIH/OD) [E] <[REDACTED] (b) (6)> Roberts, Jacqueline (NIH/OD) [E] <[REDACTED] (b) (6)> NIH NMB (NIH/OD) <[REDACTED] (b) (6)>
Subject: RE: Interview request for Dr. Collins: WaPo Reporters Working on Book about Administration's Pandemic Response

Hi Francis:

If you're okay with using Zoom for this discussion, we can use this Zoom link:

[REDACTED] (b) (6)

Thanks,
Renate

From: Myles, Renate (NIH/OD) [E] <[REDACTED] (b) (6)>

Sent: Tuesday, January 19, 2021 12:48 PM

To: Collins, Francis (NIH/OD) [E] <[REDACTED]> (b) (6) Wood, Gretchen (NIH/OD) [E] <[REDACTED]> (b) (6) McManus, Ayanna (NIH/OD) [E] <[REDACTED]> (b) (6)

Cc: Burklow, John (NIH/OD) [E] <[REDACTED]> (b) (6) Fine, Amanda (NIH/OD) [E] <[REDACTED]> (b) (6) Wojtowicz, Emma (NIH/OD) [E] <[REDACTED]> (b) (6) Roberts, Jacqueline (NIH/OD) [E] <[REDACTED]> (b) (6) NIH NMB (NIH/OD) <[REDACTED]> (b) (6)

Subject: RE: Interview request for Dr. Collins: WaPo Reporters Working on Book about Administration's Pandemic Response

Hi Gretchen:

Yasmeen said this time works. Both she and Damian will participate. She did ask if they could conduct the interview by Zoom. If FC agrees, OCPL can make a Zoom link available for the discussion.

Thanks,
Renate

From: Wood, Gretchen (NIH/OD) [E] <[REDACTED]> (b) (6)

Sent: Tuesday, January 19, 2021 11:29 AM

To: Myles, Renate (NIH/OD) [E] <[REDACTED]> (b) (6) McManus, Ayanna (NIH/OD) [E] <[REDACTED]> (b) (6)

Cc: Burklow, John (NIH/OD) [E] <[REDACTED]> (b) (6) Fine, Amanda (NIH/OD) [E] <[REDACTED]> (b) (6) Wojtowicz, Emma (NIH/OD) [E] <[REDACTED]> (b) (6) Roberts, Jacqueline (NIH/OD) [E] <[REDACTED]> (b) (6) NIH NMB (NIH/OD) <[REDACTED]> (b) (6)

Subject: Re: Interview request for Dr. Collins: WaPo Reporters Working on Book about Administration's Pandemic Response

Good morning, Renate,

Will Tuesday, January 26, from 1:00 PM to 1:45 PM work?

Thank you,

Gretchen

From: Renate Myles <[REDACTED]> (b) (6)

Date: Tuesday, January 19, 2021 at 10:54 AM

To: "McManus, Ayanna (NIH/OD) [E]" <[REDACTED]> (b) (6) Gretchen Wood <[REDACTED]> (b) (6)

Cc: John Burklow <[REDACTED]> (b) (6) Amanda Fine <[REDACTED]> (b) (6) "Wojtowicz, Emma (NIH/OD) [E]" <[REDACTED]> (b) (6) Jacqueline Roberts <[REDACTED]> (b) (6) "NIH NMB (NIH/OD)" <[REDACTED]> (b) (6)

Subject: RE: Interview request for Dr. Collins: WaPo Reporters Working on Book about Administration's Pandemic Response

Hi Gretchen and Ayanna:

Checking back on this one to see if we can set up a time after tomorrow.

Thanks,
Renate

From: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Saturday, January 9, 2021 8:34 PM
To: Myles, Renate (NIH/OD) [E] <[REDACTED] (b) (6)> McManus, Ayanna (NIH/OD) [E]
<[REDACTED] (b) (6)> Wood, Gretchen (NIH/OD) [E] <[REDACTED] (b) (6)>
Cc: Burklow, John (NIH/OD) [E] <[REDACTED] (b) (6)> Fine, Amanda (NIH/OD) [E]
<[REDACTED] (b) (6)> Wojtowicz, Emma (NIH/OD) [E] <[REDACTED] (b) (6)> Roberts,
Jacqueline (NIH/OD) [E] <[REDACTED] (b) (6)> NIH NMB (NIH/OD) <[REDACTED] (b) (6)>
Subject: RE: Interview request for Dr. Collins: WaPo Reporters Working on Book about
Administration's Pandemic Response

OK for after January 20

From: Myles, Renate (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Saturday, January 9, 2021 12:24 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)> McManus, Ayanna (NIH/OD) [E]
<[REDACTED] (b) (6)> Wood, Gretchen (NIH/OD) [E] <[REDACTED] (b) (6)>
Cc: Burklow, John (NIH/OD) [E] <[REDACTED] (b) (6)> Fine, Amanda (NIH/OD) [E]
<[REDACTED] (b) (6)> Wojtowicz, Emma (NIH/OD) [E] <[REDACTED] (b) (6)> Roberts,
Jacqueline (NIH/OD) [E] <[REDACTED] (b) (6)> NIH NMB (NIH/OD) <[REDACTED] (b) (6)>
Subject: Interview request for Dr. Collins: WaPo Reporters Working on Book about Administration's
Pandemic Response

Interview Request for Dr. Collins
January 9, 2021

Request: Topic – Book on Administration’s Response to the Pandemic

Deadline: 45 minutes by phone in January

Additional information:

Washington Post reporters Yasmeen Abutaleb (health policy) and Damian Paletta, (economics editor) are working on a book about the administration’s response to the pandemic from January through November. Both are taking book leave from the Post through April. The book will cover vaccines and treatments and the politicization around their development. They also want to cover people that the President had around him and what it meant for the people in the NIH, CDC, and FDA responsible for the pandemic response. She is particularly interested in discussing how Dr. Collins was able to protect the NIH and stay for the most part out of the political fray. Yasmeen indicated that you can set the rules and do it on background and if they

want to put something on the record, they will send it for your review. She will also give us a heads up on what they plan to use, and work with us on heavy fact-checking. Their schedule is as follows:

- Manuscript due in mid-March
- April-May will be heavy fact checking, and opportunity for you to clarify anything

Recommendation:

Recommend Dr. Collins accepts this interview.

Submitted by:

Renate Myles, (b) (6)
NIH News Media Branch

Contact information:

Yasmeen Abutaleb
301-910-6615
Yasmeen.Abutaleb@washpost.com

Other important notes:

Accept: _____
Decline: _____
Need more information: _____

- When Chinese researchers released the virus's genetic code on Jan. 11 on an open-access repository for genetic information, scientists jumped at the opportunity to see what they were dealing with. The NIH's director, Francis Collins, and Anthony Fauci, head of the NIH affiliate National Institute of Allergy and Infectious Diseases (NIAID) convened global experts on viral genome evolution to scrutinize the sequence and try to determine whether it was a human-engineered virus or a naturally occurring one. Initially, there were fears that someone may have deliberately engineered a virus to harm the United States and other countries, a scenario that several administrations spent considerable time contemplating and preparing for.
- What the experts found stunned them — and left them certain there was no way a human could have designed the virus. "It violated what we thought we knew about what would make a coronavirus dangerous," Collins said. "It had features that were really surprising and unheard of that nobody could have imagined would actually work, but there it was."
- In late April, articles were published in *Science* and *Politico* detailing how, at Trump's direction, the NIH abruptly terminated a grant for a study examining how coronaviruses spread from bats to humans. This was an area of research that had renewed importance given the pandemic. The study's sponsor was a New York-based research nonprofit called EcoHealth Alliance, but reports linked the grant to the Wuhan Institute of Virology at the same time right-wing media was seizing on the theory that the coronavirus either escaped from, or was engineered in, a lab in Wuhan, China. (Navarro, characteristically, was the most bullish of those inside the White House peddling the Wuhan lab theory. He even suggested the virus could have been designed by the Chinese military as a type of biological weapon, an argument in line with his 2011 book, *Death by China*.) A reporter from One America News Network — a tiny conservative outlet that was even more loyal to the president than Fox News — asked Trump about the grant in a briefing one week before it was terminated. "We will end that grant very quickly," Trump replied.
- The NIH, peer-reviewed grant had already come under scrutiny within the federal government as soon as officials realized the Wuhan Institute of Virology had a subgrant under the contract. The institute had the most expertise in studying which bat viruses might be the next to come out of China and pose a major threat. But with questions swirling about the origins of COVID-19 — experts had determined the virus was not man made, but could not rule out that it may have slipped out of a lab — the NIH had gone to the principal investigator on the grant on April 19 and asked that payments be halted to the subcontract in Wuhan until they had more answers.
- A few days later, the relatively small grant had garnered new attention. The chatter by Navarro and the other White House hawks who were convinced China had deliberately unleashed the virus on the world, had found a welcome audience among right-wing conspiracy theorists. On the afternoon of April 24, NIH Director Francis Collins and Fauci received notice that Trump wanted to formally announce the grant had been terminated in a 5 pm press conference. Collins and Fauci told the White House and HHS they were not sure the NIH actually had the authority to terminate a peer-reviewed grant in the middle of a budget cycle. The HHS General Counsel told them to do it anyway and made clear it was a direct order from the president — implying their jobs were on the line if they didn't comply. Fauci and Collins reluctantly agreed to cancel the grant.
- Collins heard from many members of the scientific community that he should have resigned. The HHS General Counsel later found the agency probably did not have the authority to terminate the grant. Instead, NIH had to reinstate the grant but stop all of its funding.
- There were plenty of scientists and researchers who thought the government was making a huge mistake by allowing convalescent plasma to be administered freely — in an NIH-funded program, no less. Without a placebo group, how would they even know if it worked?

“This is one of those lessons we should learn from,” said Francis Collins, the NIH director. “This was a failure of the academic, clinical research enterprise. We lost an early opportunity to get an answer about whether convalescent plasma really worked.”

- The FDA then made a larger presentation to several members of the task force and top White House aides during a Zoom call on July 29. Peter Marks, director of the FDA’s Center for Biologics Evaluation and Research, went through the results, which included several analyses of the Mayo data, animal studies and clinical reports, convinced the agency had enough evidence to show that plasma met the relatively low bar for an emergency use authorization. It was safe, and it looked like it could benefit patients; in other words, the benefits outweighed the risks.
- But the NIH director, Francis Collins, objected. It was bad enough they hadn’t been able to conduct a randomized, controlled clinical trial. Now, it would look like they were cherry picking the data they wanted to use to show that it worked by excluding some patients from their analysis. A participant on the phone call paraphrased Collins’ warning to the FDA: If you do this, you are going to bring down the wrath of the academic world. There was silence on the call. Then Birx interjected. “Francis,” she said, “it sounds like you’re threatening the FDA.”
- By August 12, Marks reviewed additional data from Mayo Clinic and believed the agency now had enough to move forward with the emergency use authorization. But Collins still did not think the data was sufficient. Hahn asked Marks what he thought they should do. If we get some additional data that helps answer your questions, Marks asked Collins, would that help? Collins said that was what he wanted. But it would take another seven to 10 days.
- Just days before the FDA and NIH expected to be able to review Mayo Clinic’s additional data — and days before the start of the RNC — Collins received a phone call while trying to take a short vacation in Chincoteague, Virginia. It was the president. *(This entire call, including quotes, is confirmed with two other sources - Dr. Collins is not the sole source.)*
- “You know, my polling numbers are looking really good,” Trump began. “But you doctors are killing me!” Trump then launched into a tirade about convalescent plasma and accused Collins and the NIH of standing in the way of its authorization. Didn’t Collins and other scientists recognize they were hurting people? “People are dying,” Trump told him. Collins could barely get a word in, but tried to reassure the volatile president. “You know, Mr. President, you don’t want to make a decision on data that turns out to be wrong,” Collins said. “It’ll come back to haunt you.”
- Trump then went another rant, this time about how the doctors also killed hydroxychloroquine. Even though the FDA had revoked its emergency use authorization two months earlier and it was clear the drug did not work — and could actually cause heart problems in some covid patients — Trump never gave up on it, even if he talked about it less in public.
- Collins found another opening. “We are within a week of having a much larger dataset where I know I can trust the antibody levels,” Collins explained. “Can we please just put this off until next week?” “No. Absolutely not,” Trump said, emphatically. “We’ve gotta have the data on Friday or it doesn’t matter.” Friday was Aug. 21, just three days before the RNC. The inference was that they needed this before the huge political rally, otherwise it was of no value to Trump.
- On Sunday, Hahn, Azar, Collins, Marks and others showed up at the White House for the planned announcement, gathering in the Roosevelt Room. This was the last place Marks and Collins wanted to be. They both tried to avoid the White House after quickly determining the White House was focused on touting “wins” ahead of the election — real or not — and expected everyone in its orbit to go along. Yet after being asked to attend the event, the two were left out of the announcement. Hahn and Azar took the stage with Trump, who began

by touting the news as a “truly historic announcement.” Azar followed Trump, praising the president’s “bold leadership” for helping to bring about the emergency authorization.

- Collins and Marks watched the press conference on Caputo’s cell phone, and “both immediately have their hair on fire,” one senior administration official recalled. Hahn, Azar and Trump had completely misrepresented the data which indicated a relative reduction in mortality, not an absolute reduction. That meant there was a 35% improvement among patients who received plasma with a high level of antibodies, compared to a group that received a low level of antibodies. That was not at all the same thing as saying 35 out of 100 patients would have been saved. Results like that simply didn’t exist. Marks and Collins were in disbelief that Hahn, an oncologist, could misunderstand the results so horribly. The politicization of the FDA had reached its ultimate low point.
- Some health officials, including Marks and NIH Director Francis Collins, decided they would try to avoid the White House as much as they could in the coming months to escape unnecessary political pressure.

From: [Hallett, Adrienne \(NIH/OD\) \[E\]](#)
To: [Lauer, Michael \(NIH/OD\) \[E\]](#); [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
Subject: FW: Rep. Perry - Letter to HHS OIG
Date: Tuesday, February 23, 2021 1:58:07 PM
Attachments: [NIH Letter re Wuhan Institute of Virology FINAL.pdf](#)

FYI. Attached is a letter to HHS OIG requesting investigation into NIH's response to biosafety at the Wuhan Institute of Virology signed by 28 Members.

Congress of the United States
Washington, DC 20515

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/?arc404=true>

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/v/6227902415001>

⁵ <https://www.washingtonexaminer.com/policy/pompeo-us-wuhan-lab-staff-caught-covid-19-before-pandemic>

⁶ <https://2017-2021.state.gov/fact-sheet-activity-at-the-wuhan-institute-of-virology//index.html>

⁷ <https://www.nih.gov/about-nih/who-we-are/nih-director/statements/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>

⁹ <https://reschenthaler.house.gov/media/press-releases/reschenthaler-introduces-bill-defund-ecohealth-alliance>

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.”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.”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.^{13,14}

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 2024.¹⁵

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 Pandemic 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,



SCOTT PERRY
Member of Congress



NANCY MACE
Member of Congress

¹¹ <https://directorsblog.nih.gov/2020/03/26/genomic-research-points-to-natural-origin-of-covid-19/>

¹² <https://twitter.com/nihdirector/status/124317292793322912?lang=en>

¹³ <https://nymag.com/intelligencer/article/coronavirus-lab-escape-theory.html>

¹⁴ <https://www.wsj.com/articles/who-are-the-covid-investigators-11613401955>

¹⁵ <https://dailycaller.com/2021/02/16/wuhan-lab-eligible-taxpayer-funding/>



BILL POSEY
Member of Congress



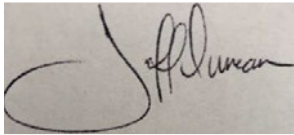
RICK CRAWFORD
Member of Congress



W. GREGORY STEUBE
Member of Congress



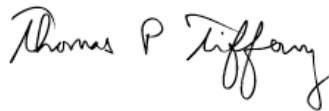
JODY HICE
Member of Congress



JEFF DUNCAN
Member of Congress



MATT GAETZ
Member of Congress



TOM TIFFANY
Member of Congress



RONNY L. JACKSON
Member of Congress



TROY BALDERSON
Member of Congress



PETE SESSIONS
Member of Congress



ANDY BIGGS
Member of Congress



DIANA HARSHBARGER
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

From: [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
To: [Collins, Francis \(NIH/OD\) \[E\]](#)
Subject: Re: EcoHealth Alliance
Date: Wednesday, March 17, 2021 8:54:18 AM

Mike and I will draft a response for you – (b) (5)

From: "Roberts, Rich" <(b) (6)>
Date: Wednesday, March 17, 2021 at 8:51 AM
To: Francis Collins <(b) (6)>
Cc: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)>
Subject: EcoHealth Alliance

Dear Francis:

You may remember the letter that was sent last year protesting the treatment of Dr. Peter Daszak and the EcoHealth Alliance. We laureates would like to bring this matter to your attention once again. With the current change in Administration it seems to us that this matter needs to be re-opened and dealt with promptly to ensure that the grant is reinstated as soon as can be managed.

Rich

Sir Richard J. Roberts Ph.D. F.R.S.
1993 Nobel Laureate in Physiology or Medicine
Chief Scientific Officer
New England Biolabs
240 County Road
Ipswich, MA 01938-2723 USA

Tel: (b) (6)
Fax: (978) 412 9910
email: (b) (6)

Executive Assistant: Karen Otto

Tel: (b) (6)
Fax: (978) 412 9910
email: (b) (6)

-----original letter-----

The 81 signatories of this letter, American Nobel Laureates in Physiology or Medicine, Chemistry, and Physics, are gravely concerned about the recent cancellation of a grant from the National Institutes of Health (NIH) to Dr. Peter Daszak at the EcoHealth Alliance in New York. We believe that this action sets a dangerous precedent by interfering in the conduct of science and jeopardizes public trust in the process of awarding federal funds for research.

For many years, Dr. Daszak and his colleagues have been conducting highly regarded, NIH-supported research on coronaviruses and other infectious agents, focusing on the transmission of these viruses from animal hosts to human beings. Their work depends on productive collaborations with scientists in other countries, including scientists in Wuhan,

China, where the current pandemic caused by a novel coronavirus arose. Now is precisely the time when we need to support this kind of research if we aim to control the pandemic and prevent subsequent ones.

As has now been widely reported, the grant to the EcoHealth Alliance was abruptly terminated by NIH on April 24, 2020, just a few days after President Trump responded to a question from a reporter who erroneously claimed that the grant awarded millions of dollars to investigators in Wuhan. Despite the misrepresentation of Dr. Daszak's grant, despite the high relevance of the studies to the current pandemic, and despite the very high priority score that his application for renewal had received during peer review, the NIH informed Dr. Daszak and his colleagues that the grant was being terminated because "NIH does not believe that the current project outcomes align with the program goals and agency priorities." Such explanations are preposterous under the circumstances.

We are scientists who have devoted our careers to research, both in medical and related scientific disciplines that bear on the overall health and well-being of society, as well as fundamental scientific research, much of it supported by NIH and other federal agencies. We take pride in our nation's widely admired system for allocating funds based on expert review and public health needs. The abrupt revoking of the award to Dr. Daszak contravenes these basic tenets and deprives the nation and the world of highly regarded science that could help control one of the greatest health crises in modern history and those that may arise in the future.

We ask that you act urgently to conduct and release a thorough review of the actions that led to the decision to terminate the grant, and that, following this review, you take appropriate steps to rectify the injustices that may have been committed in revoking it.

Peter Agre	Chemistry	2003
Sidney Altman	Chemistry	1989
Frances H. Arnold	Chemistry	2018
Paul Berg	Chemistry	1980
Thomas R. Cech	Chemistry	1989
Martin Chalfie	Chemistry	2008
Elias James Corey	Chemistry	1990
Robert F. Curl Jr.	Chemistry	1996
Johann Deisenhofer	Chemistry	1988
Joachim Frank	Chemistry	2017
Walter Gilbert	Chemistry	1980
Dudley R. Herschbach	Chemistry	1986
Roald Hoffmann	Chemistry	1981
Brian K. Kobilka	Chemistry	2012
Roger D. Kornberg	Chemistry	2006
Robert J. Lefkowitz	Chemistry	2012
Michael Levitt	Chemistry	2013
Roderick MacKinnon	Chemistry	2003

William E. Moerner	Chemistry	2014
Mario J. Molina	Chemistry	1995
Richard R. Schrock	Chemistry	2005
George P. Smith	Chemistry	2018
James P. Allison	Medicine	2018
Richard Axel	Medicine	2004
David Baltimore	Medicine	1975
J. Michael Bishop	Medicine	1989
Elizabeth H. Blackburn	Medicine	2009
Michael S. Brown	Medicine	1985
Linda B. Buck	Medicine	2004
William C. Campbell	Medicine	2015
Mario R. Capecchi	Medicine	2007
Andrew Z. Fire	Medicine	2006
Edmond H. Fischer	Medicine	1992
Joseph L. Goldstein	Medicine	1985
Carol W. Greider	Medicine	2009
Roger Guillemin	Medicine	1977
Leland H. Hartwell	Medicine	2001
H. Robert Horvitz	Medicine	2002
Louis J. Ignarro	Medicine	1998
William G. Kaelin Jr.	Medicine	2019
Eric R. Kandel	Medicine	2000
Craig C. Mello	Medicine	2006
Ferid Murad	Medicine	1998
Sir Richard J. Roberts	Medicine	1993
Michael Rosbash	Medicine	2017
James E. Rothman	Medicine	2013
Randy W. Schekman	Medicine	2013
Gregg L. Semenza	Medicine	2019
Phillip A. Sharp	Medicine	1993
Hamilton O. Smith	Medicine	1978
Thomas C. Sudhof	Medicine	2013
Jack W. Szostak	Medicine	2009
Susumu Tonegawa	Medicine	1987
Harold E. Varmus	Medicine	1989
Eric F. Wieschaus	Medicine	1995
Torsten N. Wiesel	Medicine	1981
Michael W. Young	Medicine	2017
Barry Clark Barish	Physics	2017
Steven Chu	Physics	1997
Jerome I. Friedman	Physics	1990
Sheldon Glashow	Physics	1979
David J. Gross	Physics	2004
Wolfgang Ketterle	Physics	2001

Anthony J. Leggett	Physics	2003
John C. Mather	Physics	2006
Douglas D. Osheroff	Physics	1996
James Peebles	Physics	2019
Saul Perlmutter	Physics	2011
William D. Phillips	Physics	1997
H. David Politzer	Physics	2004
Adam G. Riess	Physics	2011
George F. Smoot	Physics	2006
Horst L. Stormer	Physics	1998
Joseph H. Taylor Jr.	Physics	1993
Kip Stephen Thorne	Physics	2017
Daniel C. Tsui	Physics	1998
Steve Weinberg	Physics	1979
Rainer Weiss	Physics	2017
Carl E. Wieman	Physics	2001
Frank Wilczek	Physics	2004
Robert Woodrow Wilson	Physics	1978

From: [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
To: [Collins, Francis \(NIH/OD\) \[E\]](#)
Subject: Re: EcoHealth Alliance
Date: Wednesday, March 17, 2021 8:11:01 PM

Ok, will try.

From: Francis Collins <[REDACTED] (b) (6)>
Date: Wednesday, March 17, 2021 at 8:10 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] (b) (6)>
Subject: RE: EcoHealth Alliance

[REDACTED] (b) (5)

FC

From: Tabak, Lawrence (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Wednesday, March 17, 2021 7:56 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>
Subject: FW: EcoHealth Alliance

Francis,

The OGC recommended response is:

[REDACTED] (b) (5)

Do you want changes? I will need to run by OGC of course.

Thanks,

Larry

From: "Roberts, Rich" <[REDACTED] (b) (6)>
Date: Wednesday, March 17, 2021 at 8:51 AM
To: Francis Collins <[REDACTED] (b) (6)>
Cc: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] (b) (6)>
Subject: EcoHealth Alliance

Dear Francis:

You may remember the letter that was sent last year protesting the treatment of Dr. Peter Daszak and the EcoHealth Alliance. We laureates would like to bring this matter to your attention once again. With the current change in Administration it seems to us that this matter needs to be re-opened and dealt with promptly to ensure that the grant is reinstated as soon as can be managed.

Rich

Sir Richard J. Roberts Ph.D. F.R.S.
1993 Nobel Laureate in Physiology or Medicine
Chief Scientific Officer
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240 County Road
Ipswich, MA 01938-2723 USA

Tel: (b) (6)
Fax: (978) 412 9910
email: (b) (6)

Executive Assistant: Karen Otto
Tel: (b) (6)
Fax: (978) 412 9910
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-----original letter-----

The 81 signatories of this letter, American Nobel Laureates in Physiology or Medicine, Chemistry, and Physics, are gravely concerned about the recent cancellation of a grant from the National Institutes of Health (NIH) to Dr. Peter Daszak at the EcoHealth Alliance in New York. We believe that this action sets a dangerous precedent by interfering in the conduct of science and jeopardizes public trust in the process of awarding federal funds for research.

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control one of the greatest health crises in modern history and those that may arise in the future.

We ask that you act urgently to conduct and release a thorough review of the actions that led to the decision to terminate the grant, and that, following this review, you take appropriate steps to rectify the injustices that may have been committed in revoking it.

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From: [Lauer, Michael \(NIH/OD\) \[E\]](#)
To: [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
Cc: [Lauer, Michael \(NIH/OD\) \[E\]](#)
Subject: Re: EcoHealth Alliance
Date: Wednesday, March 17, 2021 8:38:13 PM

I'll work with Anna on this one.

Thanks, Mike

From: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> (b) (6)
Date: Wednesday, March 17, 2021 at 8:12 PM
To: "Lauer, Michael (NIH/OD) [E]" <[REDACTED]> (b) (6)
Subject: Re: EcoHealth Alliance

Francis prefers:

[REDACTED] (b) (5)

Will that work.

Larry

From: "Lauer, Michael (NIH/OD) [E]" <[REDACTED]> (b) (6)
Date: Wednesday, March 17, 2021 at 4:43 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> (b) (6)
Cc: "Lauer, Michael (NIH/OD) [E]" <[REDACTED]> (b) (6)
Subject: Re: EcoHealth Alliance

Hi Larry – here's OGC cleared language.

Thanks, Mike

[REDACTED] (b) (5)

From: "Lauer, Michael (NIH/OD) [E]" <[REDACTED]> (b) (6)
Date: Wednesday, March 17, 2021 at 9:00 AM
To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> (b) (6)
Subject: Re: EcoHealth Alliance

I'll work with Anna.

Mike

From: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> (b) (6)
Date: Wednesday, March 17, 2021 at 8:59 AM
To: "Lauer, Michael (NIH/OD) [E]" <[REDACTED]> (b) (6)
Subject: Re: EcoHealth Alliance

Right; and we can get OGC to bless whatever it is.

From: "Lauer, Michael (NIH/OD) [E]" <[REDACTED]> (b) (6)
Date: Wednesday, March 17, 2021 at 8:55 AM
To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> (b) (6)
Cc: "Lauer, Michael (NIH/OD) [E]" <[REDACTED]> (b) (6)
Subject: Re: EcoHealth Alliance

Hi Larry – We can discuss at our 1:1 this afternoon. [REDACTED] (b) (5)

[REDACTED]

Thanks, Mike

From: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] (b) (6)>
Date: Wednesday, March 17, 2021 at 8:53 AM
To: "Lauer, Michael (NIH/OD) [E]" <[REDACTED] (b) (6)>
Subject: FW: EcoHealth Alliance

Proposed response?

From: "Roberts, Rich" <[REDACTED] (b) (6)>
Date: Wednesday, March 17, 2021 at 8:51 AM
To: Francis Collins <[REDACTED] (b) (6)>
Cc: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] (b) (6)>
Subject: EcoHealth Alliance

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From: [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
To: [Collins, Francis \(NIH/OD\) \[E\]](#)
Subject: Re: EcoHealth Alliance
Date: Thursday, March 18, 2021 6:05:46 PM

How about:

[REDACTED] (b) (5)

Larry

From: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>
Date: Wednesday, March 17, 2021 at 8:10 PM
To: Tabak, Lawrence (NIH/OD) [E] <[REDACTED] (b) (6)>
Subject: RE: EcoHealth Alliance

[REDACTED] (b) (5)

FC

From: Tabak, Lawrence (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Wednesday, March 17, 2021 7:56 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>
Subject: FW: EcoHealth Alliance

Francis,

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[REDACTED] (b) (5)

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Robert Woodrow Wilson

Physics

1978

From: [Collins, Francis \(NIH/OD\) \[E\]](#)
To: [Roberts, Rich](#)
Cc: [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
Subject: RE: EcoHealth Alliance
Date: Thursday, March 18, 2021 9:08:57 PM

Hi Rich,

Thanks for writing again. I wish I could provide you and your colleagues with a more direct response, but NIH is not in a position to discuss publicly internal deliberations on grants or on administrative or compliance matters related to grants.

Regards, Francis

From: Roberts, Rich <[REDACTED] (b) (6)>
Sent: Wednesday, March 17, 2021 8:51 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>
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Daniel C. Tsui Physics 1998
Steve Weinberg Physics 1979
Rainer Weiss Physics 2017
Carl E. Wieman Physics 2001
Frank Wilczek Physics 2004
Robert Woodrow Wilson Physics 1978

From: [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
To: [Lauer, Michael \(NIH/OD\) \[E\]](#)
Subject: FW: EcoHealth Alliance
Date: Thursday, March 18, 2021 9:09:24 PM

fyi

From: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>
Date: Thursday, March 18, 2021 at 9:08 PM
To: Roberts, Rich <[REDACTED] (b) (6)>
Cc: Tabak, Lawrence (NIH/OD) [E] <[REDACTED] (b) (6)>
Subject: RE: EcoHealth Alliance

Hi Rich,

Thanks for writing again. I wish I could provide you and your colleagues with a more direct response, but NIH is not in a position to discuss publicly internal deliberations on grants or on administrative or compliance matters related to grants.

Regards, Francis

From: Roberts, Rich <[REDACTED] (b) (6)>
Sent: Wednesday, March 17, 2021 8:51 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>
Cc: Tabak, Lawrence (NIH/OD) [E] <[REDACTED] (b) (6)>
Subject: EcoHealth Alliance

Dear Francis:

You may remember the letter that was sent last year protesting the treatment of Dr. Peter Daszak and the EcoHealth Alliance. We laureates would like to bring this matter to your attention once again. With the current change in Administration it seems to us that this matter needs to be re-opened and dealt with promptly to ensure that the grant is reinstated as soon as can be managed.

Rich

Sir Richard J. Roberts Ph.D. F.R.S.
1993 Nobel Laureate in Physiology or Medicine
Chief Scientific Officer
New England Biolabs
240 County Road
Ipswich, MA 01938-2723 USA

Tel: [REDACTED] (b) (6)
Fax: (978) 412 9910
email: [REDACTED] (b) (6)

Executive Assistant: Karen Otto
Tel: [REDACTED] (b) (6)

Fax: (978) 412 9910
email: [REDACTED] (b) (6)

-----original letter-----

The 81 signatories of this letter, American Nobel Laureates in Physiology or Medicine, Chemistry, and Physics, are gravely concerned about the recent cancellation of a grant from the National Institutes of Health (NIH) to Dr. Peter Daszak at the EcoHealth Alliance in New York. We believe that this action sets a dangerous precedent by interfering in the conduct of science and jeopardizes public trust in the process of awarding federal funds for research.

For many years, Dr. Daszak and his colleagues have been conducting highly regarded, NIH-supported research on coronaviruses and other infectious agents, focusing on the transmission of these viruses from animal hosts to human beings. Their work depends on productive collaborations with scientists in other countries, including scientists in Wuhan, China, where the current pandemic caused by a novel coronavirus arose. Now is precisely the time when we need to support this kind of research if we aim to control the pandemic and prevent subsequent ones.

As has now been widely reported, the grant to the EcoHealth Alliance was abruptly terminated by NIH on April 24, 2020, just a few days after President Trump responded to a question from a reporter who erroneously claimed that the grant awarded millions of dollars to investigators in Wuhan. Despite the misrepresentation of Dr. Daszak’s grant, despite the high relevance of the studies to the current pandemic, and despite the very high priority score that his application for renewal had received during peer review, the NIH informed Dr. Daszak and his colleagues that the grant was being terminated because “NIH does not believe that the current project outcomes align with the program goals and agency priorities.” Such explanations are preposterous under the circumstances.

We are scientists who have devoted our careers to research, both in medical and related scientific disciplines that bear on the overall health and well-being of society, as well as fundamental scientific research, much of it supported by NIH and other federal agencies. We take pride in our nation’s widely admired system for allocating funds based on expert review and public health needs. The abrupt revoking of the award to Dr. Daszak contravenes these basic tenets and deprives the nation and the world of highly regarded science that could help control one of the greatest health crises in modern history and those that may arise in the future.

We ask that you act urgently to conduct and release a thorough review of the actions that led to the decision to terminate the grant, and that, following this review, you take appropriate steps to rectify the injustices that may have been committed in revoking it.

Peter Agre	Chemistry	2003
Sidney Altman	Chemistry	1989
Frances H. Arnold	Chemistry	2018
Paul Berg	Chemistry	1980
Thomas R. Cech	Chemistry	1989
Martin Chalfie	Chemistry	2008

Elias James Corey	Chemistry	1990
Robert F. Curl Jr.	Chemistry	1996
Johann Deisenhofer	Chemistry	1988
Joachim Frank	Chemistry	2017
Walter Gilbert	Chemistry	1980
Dudley R. Herschbach	Chemistry	1986
Roald Hoffmann	Chemistry	1981
Brian K. Kobilka	Chemistry	2012
Roger D. Kornberg	Chemistry	2006
Robert J. Lefkowitz	Chemistry	2012
Michael Levitt	Chemistry	2013
Roderick MacKinnon	Chemistry	2003
William E. Moerner	Chemistry	2014
Mario J. Molina	Chemistry	1995
Richard R. Schrock	Chemistry	2005
George P. Smith	Chemistry	2018
James P. Allison	Medicine	2018
Richard Axel	Medicine	2004
David Baltimore	Medicine	1975
J. Michael Bishop	Medicine	1989
Elizabeth H. Blackburn	Medicine	2009
Michael S. Brown	Medicine	1985
Linda B. Buck	Medicine	2004
William C. Campbell	Medicine	2015
Mario R. Capecchi	Medicine	2007
Andrew Z. Fire	Medicine	2006
Edmond H. Fischer	Medicine	1992
Joseph L. Goldstein	Medicine	1985
Carol W. Greider	Medicine	2009
Roger Guillemin	Medicine	1977
Leland H. Hartwell	Medicine	2001
H. Robert Horvitz	Medicine	2002
Louis J. Ignarro	Medicine	1998
William G. Kaelin Jr.	Medicine	2019
Eric R. Kandel	Medicine	2000
Craig C. Mello	Medicine	2006
Ferid Murad	Medicine	1998
Sir Richard J. Roberts	Medicine	1993
Michael Rosbash	Medicine	2017
James E. Rothman	Medicine	2013
Randy W. Schekman	Medicine	2013
Gregg L. Semenza	Medicine	2019
Phillip A. Sharp	Medicine	1993
Hamilton O. Smith	Medicine	1978
Thomas C. Sudhof	Medicine	2013

Jack W. Szostak	Medicine	2009
Susumu Tonegawa	Medicine	1987
Harold E. Varmus	Medicine	1989
Eric F. Wieschaus	Medicine	1995
Torsten N. Wiesel	Medicine	1981
Michael W. Young	Medicine	2017
Barry Clark Barish	Physics	2017
Steven Chu	Physics	1997
Jerome I. Friedman	Physics	1990
Sheldon Glashow	Physics	1979
David J. Gross	Physics	2004
Wolfgang Ketterle	Physics	2001
Anthony J. Leggett	Physics	2003
John C. Mather	Physics	2006
Douglas D. Osheroff	Physics	1996
James Peebles	Physics	2019
Saul Perlmutter	Physics	2011
William D. Phillips	Physics	1997
H. David Politzer	Physics	2004
Adam G. Riess	Physics	2011
George F. Smoot	Physics	2006
Horst L. Stormer	Physics	1998
Joseph H. Taylor Jr.	Physics	1993
Kip Stephen Thorne	Physics	2017
Daniel C. Tsui	Physics	1998
Steve Weinberg	Physics	1979
Rainer Weiss	Physics	2017
Carl E. Wieman	Physics	2001
Frank Wilczek	Physics	2004
Robert Woodrow Wilson	Physics	1978

From: [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
To: [Collins, Francis \(NIH/OD\) \[E\]](#); [Hallett, Adrienne \(NIH/OD\) \[E\]](#)
Subject: Re: CMR +HHS -WH
Date: Friday, May 21, 2021 2:23:58 PM

Based on their edits you are correct.

From: Francis Collins <[REDACTED] (b) (6)>
Date: Friday, May 21, 2021 at 2:23 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] (b) (6)> "Hallett, Adrienne (NIH/OD) [E]" <[REDACTED] (b) (6)>
Subject: RE: CMR +HHS -WH

[REDACTED] (b) (5)

FC

From: Tabak, Lawrence (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Friday, May 21, 2021 2:22 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)> Hallett, Adrienne (NIH/OD) [E] <[REDACTED] (b) (6)>
Subject: Re: CMR +HHS -WH

He agreed to send it on to WH; let's see if we get to yes quickly.

I also told him no cover letters; a separate response must be sent to each Member.

From: Francis Collins <[REDACTED] (b) (6)>
Date: Friday, May 21, 2021 at 2:19 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] (b) (6)> "Hallett, Adrienne (NIH/OD) [E]" <[REDACTED] (b) (6)>
Subject: RE: CMR +HHS -WH

I say we send this version, [REDACTED] (b) (5)

FC

From: Tabak, Lawrence (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Friday, May 21, 2021 2:17 PM
To: Hallett, Adrienne (NIH/OD) [E] <[REDACTED] (b) (6)> Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>
Subject: Re: CMR +HHS -WH

Just got off phone with Stephen; sent him this bc he was going to send me yet another version... he will let me know if he is willing to go back to WH.

From: "Hallett, Adrienne (NIH/OD) [E]" <[REDACTED] (b) (6)>
Date: Friday, May 21, 2021 at 2:16 PM
To: Francis Collins <[REDACTED] (b) (6)> "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] (b) (6)>
Subject: CMR +HHS -WH



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

May XX, 2021

The Honorable Cathy McMorris Rodgers
U.S. House of Representatives
Washington, DC 20515

(b) (5)



From: [Hallett, Adrienne \(NIH/OD\) \[E\]](#)
To: [Collins, Francis \(NIH/OD\) \[E\]](#)
Cc: [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
Subject: Re: CMR +HHS -WH
Date: Friday, May 21, 2021 3:29:37 PM
Attachments: [Grassley_2021-03-08_CEG to ODNI HHS \(COVID Origins\)_49370227\[1\].pdf](#)
[1 Rep. Guy Reschenthaler to Secretary Cochran\[1\]\[1\].pdf](#)

Grassley is all about GOF, Reschenthaler is EcoHealth (b) (5)

From: Francis Collins <(b) (6)>
Date: Friday, May 21, 2021 at 3:03 PM
To: Adrienne Hallett <(b) (6)>
Cc: Lawrence Tabak <(b) (6)>
Subject: RE: CMR +HHS -WH

I don't think I have ever seen the Grassley letter or the Reschenthaler letter. (b) (5)

FC

From: Hallett, Adrienne (NIH/OD) [E] <(b) (6)>
Sent: Friday, May 21, 2021 2:57 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6)>
Subject: Re: CMR +HHS -WH

(b) (5)

Do you want to reconsider that?

On May 21, 2021, at 2:56 PM, Collins, Francis (NIH/OD) [E] <(b) (6)> wrote:

(b) (5)

FC

From: Hallett, Adrienne (NIH/OD) [E] <(b) (6)>
Sent: Friday, May 21, 2021 2:53 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)>
Subject: Re: CMR +HHS -WH

(b) (5)

From: Francis Collins <(b) (6)>
Date: Friday, May 21, 2021 at 2:49 PM

To: Lawrence Tabak <[REDACTED] (b) (6)> Adrienne Hallett
<[REDACTED] (b) (6)>

Subject: RE: CMR +HHS -WH

If I'm going to call White House counsel before our mock hearing, it will have to be in the next 45 minutes. [REDACTED] (b) (5)

[REDACTED] Can you get Stephen to provide the contact so I can just take care of this? [REDACTED] (b) (5)

[REDACTED]
FC

From: Tabak, Lawrence (NIH/OD) [E] <[REDACTED] (b) (6)>

Sent: Friday, May 21, 2021 2:38 PM

To: Hallett, Adrienne (NIH/OD) [E] <[REDACTED] (b) (6)> Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>

Subject: Re: CMR +HHS -WH

Agree; let's ask ES to prepare in the hopes that they approve. (please confirm that they can use my electronic signature or if I need to come in to sign).

Thanks

Larry

From: "Hallett, Adrienne (NIH/OD) [E]" <[REDACTED] (b) (6)>

Date: Friday, May 21, 2021 at 2:36 PM

To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] (b) (6)> Francis Collins <[REDACTED] (b) (6)>

Subject: Re: CMR +HHS -WH

If we are down to just discussing the briefing paragraph, can I have Exec Sec start formatting the Reschenthaler (13 signers) and Grassley letters?

[REDACTED] (b) (5) I can prep that for Exec Sec now.

From: Lawrence Tabak <[REDACTED] (b) (6)>

Date: Friday, May 21, 2021 at 2:25 PM

To: Francis Collins <[REDACTED] (b) (6)> Adrienne Hallett <[REDACTED] (b) (6)>

Subject: Re: CMR +HHS -WH

agree

From: Francis Collins <[REDACTED] (b) (6)>

Date: Friday, May 21, 2021 at 2:25 PM

To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] (b) (6)> "Hallett, Adrienne (NIH/OD) [E]" <[REDACTED] (b) (6)>

Subject: RE: CMR +HHS -WH

I hope he is pushing hard. [REDACTED] (b) (5) But to do so, I would ideally need to call the counsel directly and inform them.

FC

From: Tabak, Lawrence (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Friday, May 21, 2021 2:24 PM
To: Hallett, Adrienne (NIH/OD) [E] <[REDACTED] (b) (6)> Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>
Subject: Re: CMR +HHS -WH
It appears he is willing to push back.

From: "Hallett, Adrienne (NIH/OD) [E]" <[REDACTED] (b) (6)>
Date: Friday, May 21, 2021 at 2:22 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] (b) (6)> Francis Collins <[REDACTED] (b) (6)>
Subject: Re: CMR +HHS -WH
This is the exact letter draft that went to the WH General Counsel's office at 8:30 this morning. Is he sending it to different people hoping to get even more advice?

From: Lawrence Tabak <[REDACTED] (b) (6)>
Date: Friday, May 21, 2021 at 2:21 PM
To: Francis Collins <[REDACTED] (b) (6)> Adrienne Hallett <[REDACTED] (b) (6)>
Subject: Re: CMR +HHS -WH
He agreed to send it on to WH; let's see if we get to yes quickly.
I also told him no cover letters; a separate response must be sent to each Member.

From: Francis Collins <[REDACTED] (b) (6)>
Date: Friday, May 21, 2021 at 2:19 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] (b) (6)> "Hallett, Adrienne (NIH/OD) [E]" <[REDACTED] (b) (6)>
Subject: RE: CMR +HHS -WH
I say we send this version, [REDACTED] (b) (5)
FC

From: Tabak, Lawrence (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Friday, May 21, 2021 2:17 PM
To: Hallett, Adrienne (NIH/OD) [E] <[REDACTED] (b) (6)> Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>
Subject: Re: CMR +HHS -WH
Just got off phone with Stephen; sent him this bc he was going to send me yet another version... he will let me know if he is willing to go back to WH.

From: "Hallett, Adrienne (NIH/OD) [E]" <[REDACTED] (b) (6)>
Date: Friday, May 21, 2021 at 2:16 PM
To: Francis Collins <[REDACTED] (b) (6)> "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] (b) (6)>
Subject: CMR +HHS -WH

United States Senate
WASHINGTON, DC 20510

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

¹ Press Release, Grassley Receives Classified Briefing on Coronavirus (Feb. 4, 2020),

<https://www.grassley.senate.gov/news/news-releases/grassley-receives-classified-briefing-coronavirus>.

² Jeremy Page et al., *China Refuse to Give WHO Raw Data on Early COVID-19 Cases*, WALL ST. J. (Feb. 12, 2021), <https://www.wsj.com/articles/china-refuses-to-give-who-raw-data-on-early-covid-19-cases-11613150580>.

³*Id.*

⁴ Press Release, Grassley Urges More Information Sharing Between Health, Intelligence Agencies (Mar. 24, 2020), <https://www.grassley.senate.gov/news/news-releases/grassley-urges-more-information-sharing-between-health-intelligence-agencies>; Press Release, Grassley Receives Classified Briefing on Coronavirus (Feb. 4, 2020), <https://www.grassley.senate.gov/news/news-releases/grassley-receives-classified-briefing-coronavirus>.

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

Congress of the United States
Washington, DC 20515

March 15, 2021

The Honorable Norris Cochran
Acting Secretary
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201

Dear Secretary Cochran:

We write regarding a grant awarded by the National Institute of Allergy and Infectious Diseases (NIAID) to EcoHealth Alliance Inc. (EcoHealth), a New York-based non-profit organization with a history of collaborating with the Wuhan Institute of Virology (WIV).

In 2014, EcoHealth received more than \$3 million in grant funding from NIAID to study the risk of bat coronavirus emergence. According to federal spending data, from 2015 to 2019, EcoHealth provided approximately \$598,500 of this funding to the WIV. More recently, in 2019, the grant was reauthorized for \$3.7 million over five years. This is deeply concerning given the WIV is a possible origin site of the COVID-19 pandemic, and the lab has significant ties to the Chinese Communist Party (CCP) and military biological research.

According to the *Wall Street Journal* and other news outlets, EcoHealth's grant was suspended in April 2020 by the Trump Administration. In July 2020, the grant funding was reportedly reinstated, however, grant activities were suspended until certain conditions of cooperation were met by the non-profit.¹

In a 2017 research paper, EcoHealth and WIV researchers demonstrated their ability to modify a coronavirus found from bats in China and efficiently bind their man-made virus to the human ACE2-expressing cells.² Some have described this research, which was funded by the aforementioned NIAID grant, as Gain of Function (GOF) research, which was paused by the Obama Administration in October 2014.

Following the GOF research moratorium, future grant funding and activities were placed on hold and several previously funded GOF research projects received voluntary pause requests. It is worth noting that EcoHealth and WIV researchers did not receive a voluntary pause request for this research funding, however, they did receive such a request for a separate U.S. Agency for International Development grant, which was a partnership between EcoHealth, the WIV, and other U.S. researchers.

¹ <https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400>

² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5708621/>

Additionally, it is extremely concerning that one year into the COVID-19 pandemic, the WIV is authorized to receive U.S. taxpayer dollars for animal research until January 2024.³ According to the NIH, the WIV, along with twenty-six other organizations in China, have an active Foreign Assurance on file with the NIH Office of Laboratory Animal Welfare.⁴ The *Daily Caller* recently reported that a NIH spokesperson would not confirm if the WIV is currently receiving direct or indirect taxpayer funding.

Given these concerns, we respectfully request answers to the following questions:

1. How much funding awarded to EcoHealth through the Department of Health and Human Services (HHS) has been given to or used in collaboration with the WIV?
2. Since the Trump Administration's suspension, has the NIAID grant been reinstated?
3. Will NIH consider revoking the WIV's authorization to receive funding before January 2024?
4. Was GOF research conducted with this funding? If so, did HHS request that EcoHealth voluntarily pause their GOF research?
5. Given the U.S. Department of State's determination that the CCP is committing genocide against Chinese dissidents, has HHS reviewed partnerships with laboratories or organizations with ties to the CCP?
6. Has any other HHS, NIH, or NIAID grant, contract, or subcontract been used to fund work at the WIV?

Thank you for your consideration of our request. We look forward to hearing from you.

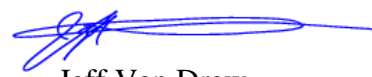
Very respectfully,



Guy Reschenthaler
Member of Congress



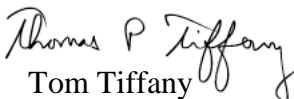
Matt Gaetz
Member of Congress



Jeff Van Drew
Member of Congress



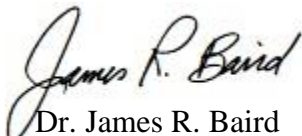
Michael Cloud
Member of Congress



Thomas P. Tiffany
Tom Tiffany
Member of Congress



Louie Gohmert
Member of Congress



Dr. James R. Baird
Member of Congress



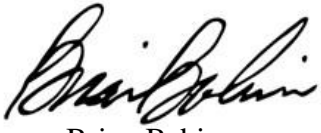
W. Gregory Steube
Member of Congress



Bill Posey
Member of Congress

³ <https://dailycaller.com/2021/02/16/wuhan-lab-eligible-taxpayer-funding/>

⁴ <https://olaw.nih.gov/assured/app/index.html#ALL>



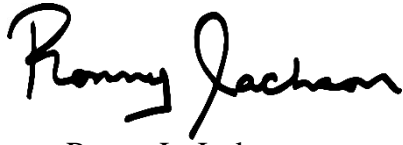
Brian Babin
Member of Congress



Scott Perry
Member of Congress



Fred Keller
Member of Congress



Ronny L. Jackson
Member of Congress



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

May XX, 2021

The Honorable Guy Reschenthaler
U.S. House of Representatives
Washington, DC 20515

(b) (5)





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

May XX, 2021

The Honorable Cathy McMorris Rodgers
U.S. House of Representatives
Washington, DC 20515

(b) (5)



Sincerely,

Lawrence A. Tabak, D.D.S., Ph.D.
Principal Deputy Director



DEPARTMENT OF HEALTH & HUMAN SERVICES

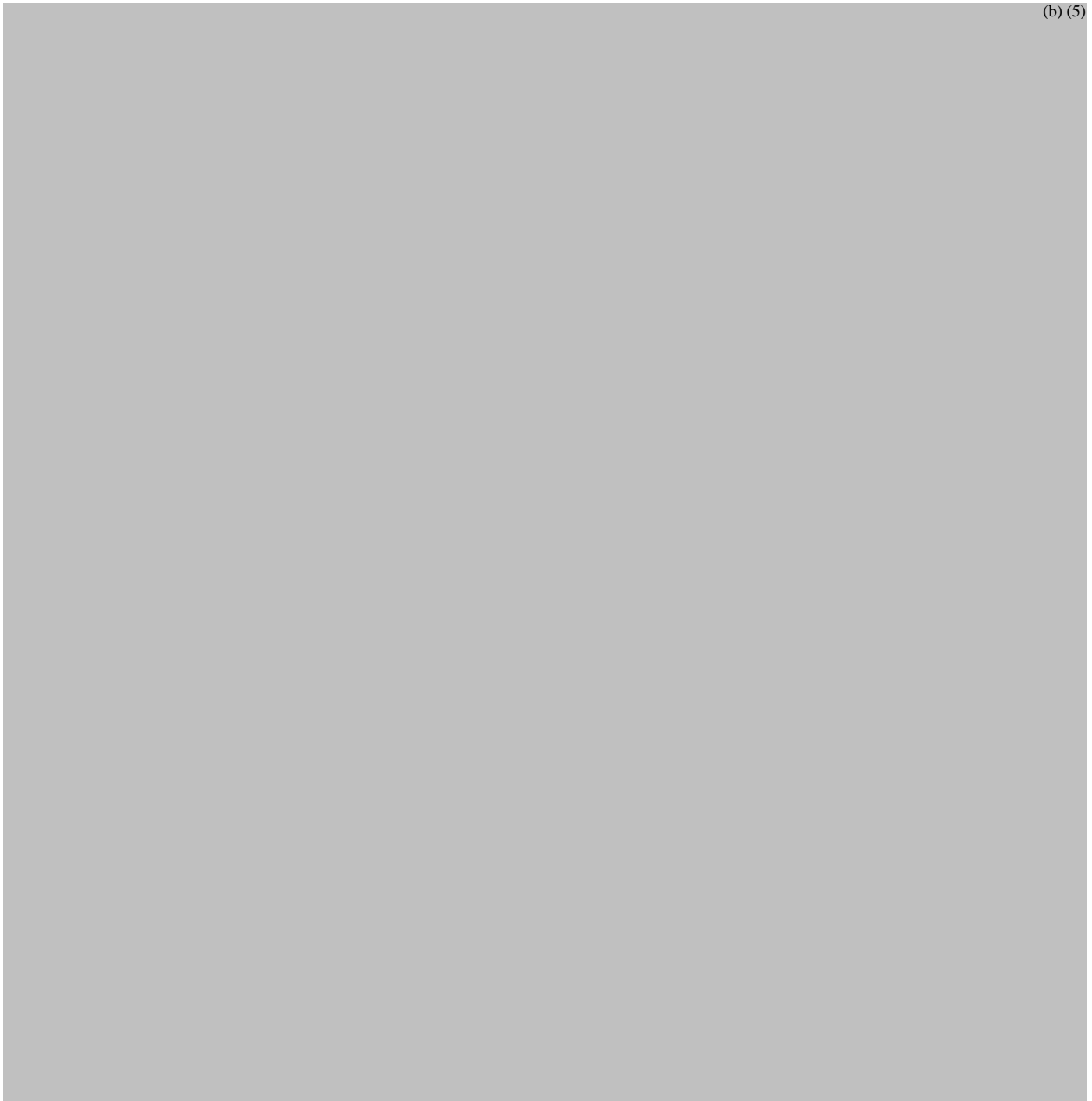
Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

May XX, 2021

The Honorable Charles Grassley
United States Senate
Washington, D.C. 20510

(b) (5)







May 21, 2021

The Honorable Cathy McMorris Rodgers
U.S. House of Representatives
Washington, DC 20515

Dear Representative McMorris Rodgers:

Thank you for your letter regarding the National Institutes of Health's (NIH) support for biomedical research related to SARS-CoV-2, "gain of function" (GOF) research, and the NIH grant to the EcoHealth Alliance. As Principal Deputy Director of NIH, I am pleased to respond to your inquiry.

Neither NIH nor the National Institute of Allergy and Infectious Diseases has ever approved any grant that would have supported GOF research on coronaviruses that would have increased their transmissibility or lethality for humans.

Some scientists use the term GOF research broadly to refer to *any* modification of a biological agent that confers new or enhanced activity to that agent. In some cases, this research is performed to give new properties to agents to allow them to grow and be studied in the lab; for example, the agent may be modified so that it can be studied in research animals. However, not all research that some label as GOF research entails the same level of risk. The subset of GOF research that is anticipated to enhance the *transmissibility* and/or *virulence* of potential pandemic pathogens, which could make them more dangerous to humans, has been the subject of substantial scrutiny and deliberation.

In 2017, the U.S. Department of Health and Human Services (HHS) issued its [Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens \(HHS P3CO Framework\)](#). The HHS P3CO Framework is intended to guide HHS funding decisions on proposed research that is reasonably anticipated to create, transfer, or use Potential Pandemic Pathogens (PPPs) resulting from the enhancement of a pathogen's transmissibility or virulence in humans (enhanced PPP) and seeks to preserve the benefits of life sciences research involving enhanced PPPs while minimizing potential biosafety and biosecurity risks.

As your letter notes and has been publicly stated, NIH awarded a [grant to EcoHealth Alliance Inc.](#), a research organization based in New York City, in June 2014. The application was subjected to rigorous peer review and did not propose research to enhance any coronavirus to be more transmissible or virulent.

The research proposed in the grant application sought to understand how bat coronaviruses evolve naturally in the environment to become transmissible to the human population. This

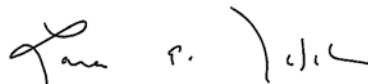
included studying viral diversity in bat reservoirs, surveying people who work in live animal markets or other jobs with high exposure to wildlife for evidence of bat-coronavirus infection, and analyzing data to predict which newly discovered viruses pose the greatest threat to human health. To support its work, EcoHealth made sub-awards to the Wuhan Institute of Virology and other institutions based in East Asia where coronaviruses tend to emerge and are prevalent. NIH is not currently funding the Wuhan Institute of Virology.

I would be happy to further discuss this grant, and this issue, at your convenience. NIH is committed to upholding the highest standards within the conduct of science and the oversight of federal funding.

In conclusion, NIH strongly supports the need for further investigation by the World Health Organization (WHO) into the origins of the SARS-CoV-2 coronavirus. Working with [a cross-regional coalition of 13 countries](#), we urge the WHO to begin the second phase of their study without delay.

Thank you again for the opportunity to address these questions. An identical response has been sent to the co-signers of your letter.

Sincerely,

A handwritten signature in black ink, appearing to read "Lawrence A. Tabak".

Lawrence A. Tabak, D.D.S., Ph.D.
Principal Deputy Director

cc: The Honorable Frank Pallone
Chairman, House Committee on Energy and Commerce



May 21, 2021

The Honorable Brett Guthrie
U.S. House of Representatives
Washington, DC 20515

Dear Representative Guthrie:

Thank you for your letter regarding the National Institutes of Health's (NIH) support for biomedical research related to SARS-CoV-2, "gain of function" (GOF) research, and the NIH grant to the EcoHealth Alliance. As Principal Deputy Director of NIH, I am pleased to respond to your inquiry.

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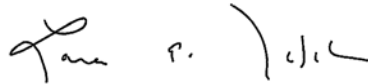
included studying viral diversity in bat reservoirs, surveying people who work in live animal markets or other jobs with high exposure to wildlife for evidence of bat-coronavirus infection, and analyzing data to predict which newly discovered viruses pose the greatest threat to human health. To support its work, EcoHealth made sub-awards to the Wuhan Institute of Virology and other institutions based in East Asia where coronaviruses tend to emerge and are prevalent. NIH is not currently funding the Wuhan Institute of Virology.

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Sincerely,

A handwritten signature in black ink, appearing to read "Lawrence A. Tabak".

Lawrence A. Tabak, D.D.S., Ph.D.
Principal Deputy Director

cc: The Honorable Frank Pallone
Chairman, House Committee on Energy and Commerce



May 21, 2021

The Honorable Morgan Griffith
U.S. House of Representatives
Washington, DC 20515

Dear Representative Griffith:

Thank you for your letter regarding the National Institutes of Health's (NIH) support for biomedical research related to SARS-CoV-2, "gain of function" (GOF) research, and the NIH grant to the EcoHealth Alliance. As Principal Deputy Director of NIH, I am pleased to respond to your inquiry.

Neither NIH nor the National Institute of Allergy and Infectious Diseases has ever approved any grant that would have supported GOF research on coronaviruses that would have increased their transmissibility or lethality for humans.

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As your letter notes and has been publicly stated, NIH awarded a [grant to EcoHealth Alliance Inc.](#), a research organization based in New York City, in June 2014. The application was subjected to rigorous peer review and did not propose research to enhance any coronavirus to be more transmissible or virulent.

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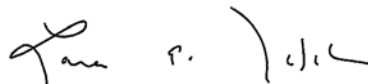
included studying viral diversity in bat reservoirs, surveying people who work in live animal markets or other jobs with high exposure to wildlife for evidence of bat-coronavirus infection, and analyzing data to predict which newly discovered viruses pose the greatest threat to human health. To support its work, EcoHealth made sub-awards to the Wuhan Institute of Virology and other institutions based in East Asia where coronaviruses tend to emerge and are prevalent. NIH is not currently funding the Wuhan Institute of Virology.

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Thank you again for the opportunity to address these questions. An identical response has been sent to the co-signers of your letter.

Sincerely,

A handwritten signature in black ink, appearing to read "Lawrence A. Tabak".

Lawrence A. Tabak, D.D.S., Ph.D.
Principal Deputy Director

cc: The Honorable Frank Pallone
Chairman, House Committee on Energy and Commerce

From: [Lauer, Michael \(NIH/OD\) \[E\]](#)
To: [Hallett, Adrienne \(NIH/OD\) \[E\]](#); [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
Cc: [Lauer, Michael \(NIH/OD\) \[E\]](#)
Subject: Re: Draft letter for WIV
Date: Wednesday, May 19, 2021 4:04:11 PM
Attachments: [WIV response draft\[1\].docx](#)

Many thanks, Adrienne, looks good to me.

Mike

From: "Hallett, Adrienne (NIH/OD) [E]" <[REDACTED] (b) (6)>
Date: Wednesday, May 19, 2021 at 1:27 PM
To: "Lauer, Michael (NIH/OD) [E]" <[REDACTED] (b) (6)> "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] (b) (6)>
Subject: Draft letter for WIV
Rose and I agree on this draft, [REDACTED] (b) (5)





From: [Hallett, Adrienne \(NIH/OD\) \[E\]](#)
To: [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
Subject: HHS proposed edits
Date: Thursday, May 20, 2021 7:34:49 PM
Attachments: [CMR Response 5.20 HHS proposed edits.docx](#)

Attached. Calling you now.



May XX, 2021

The Honorable Cathy McMorris Rodgers
U.S. House of Representatives
Washington, DC 20515

(b) (5)



From: [Hallett, Adrienne \(NIH/OD\) \[E\]](#)
To: [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
Subject: Re: Proposal for CMR letter
Date: Friday, May 21, 2021 1:42:19 PM
Attachments: [CMR_WH_proposed_Response.docx](#)

Proposed change #1 is reflected in the attached.

Proposed change #2 [REDACTED] (b) (5)

From: Lawrence Tabak <[REDACTED]> (b) (6)
Date: Friday, May 21, 2021 at 1:36 PM
To: Adrienne Hallett <[REDACTED]> (b) (6)
Subject: Re: Proposal for CMR letter

Thanks -

From: "Hallett, Adrienne (NIH/OD) [E]" <[REDACTED]> (b) (6)
Date: Friday, May 21, 2021 at 1:36 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> (b) (6)
Subject: Re: Proposal for CMR letter

This was ours. Will modify for theirs.
2 minutes.

From: Lawrence Tabak <[REDACTED]> (b) (6)
Date: Friday, May 21, 2021 at 1:35 PM
To: Adrienne Hallett <[REDACTED]> (b) (6)
Subject: Re: Proposal for CMR letter

Is this what they want to send out or are there additional edits that are not incorporated?

From: "Hallett, Adrienne (NIH/OD) [E]" <[REDACTED]> (b) (6)
Date: Friday, May 21, 2021 at 1:34 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> (b) (6)
Subject: FW: Proposal for CMR letter

From: Adrienne Hallett <[REDACTED]> (b) (6)
Date: Thursday, May 20, 2021 at 10:28 PM
To: "Sullivan, Rose (HHS/ASL)" <[REDACTED]> (b) (6)
Subject: Proposal for CMR letter

Hey Rose,

I worked with my leadership to come up with a compromise that:

[REDACTED] (b) (5)

I am sending the compromise to you in two formats. Below is the before and after language.
Attached is the draft in the official letterhead formatting and adhering to the HHS Exec Sec Style

Guide, in an attempt to ensure that there are no surprises. The proposed compromise changes are noted in track changes so they are easy to spot.

I hope that this shows a good faith effort to come to agreement and get this letter out tomorrow.

Adrienne

Language From Wednesday:

[Redacted] (b) (5)

HHS Position: Strike paragraph

NIH Proposed Compromise:

[Redacted] (b) (5)

HHS Proposed New Sentence:

[Redacted] (b) (5)

NIH Comment: [Redacted] (b) (5)

[Redacted]

NIH proposed edit:

[Redacted] (b) (5)



May XX, 2021

The Honorable Cathy McMorris Rodgers
U.S. House of Representatives
Washington, DC 20515

(b) (5)

(b) (5)



From: [Stein, Meredith \(NIH/OD\) \[E\]](#)
To: [Lauer, Michael \(NIH/OD\) \[E\]](#); [Schwetz, Tara \(NIH/OD\) \[E\]](#); [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
Cc: [Johnson, Alfred \(NIH/OD\) \[E\]](#)
Subject: RE: US Nonprofit With Ties To Wuhan Lab Violated Federal Law By Failing To Disclose Taxpayer Funding, Complaint Alleges
Date: Wednesday, March 17, 2021 5:09:24 PM

Good Afternoon Drs. Tabak, Schwetz, and Lauer,
OMA acknowledged receipt of the letter from the White Coat Waste Project and assigned an allegation case number. If the matter is criminal in nature or outside of the purview of our office, we will refer it to the appropriate organization.
It is the policy of NIH to neither confirm nor deny that a review or investigation has been initiated.
Thank you,
Meredith

From: Lauer, Michael (NIH/OD) [E] <(b) (6)>
Sent: Tuesday, March 16, 2021 8:19 PM
To: Schmoyer, Michael W. EOP/OSTP <(b) (6)> Hollie, Les W (OIG/OI) <(b) (6)> Aguirre, Lisa (IOS/ONS) <(b) (6)> Stein, Meredith (NIH/OD) [E] <(b) (6)>
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Bulls, Michelle G. (NIH/OD) [E] <(b) (6)> Schwetz, Tara (NIH/OD) [E] <(b) (6)> Ta, Kristin (NIH/OD) [E] <(b) (6)> Lauer, Michael (NIH/OD) [E] <(b) (6)>
Subject: Re: US Nonprofit With Ties To Wuhan Lab Violated Federal Law By Failing To Disclose Taxpayer Funding, Complaint Alleges
Thanks Michael – yes, we’re aware of this.
Mike

From: "Schmoyer, Michael W. EOP/OSTP" <(b) (6)>
Date: Tuesday, March 16, 2021 at 6:08 PM
To: "Lauer, Michael (NIH/OD) [E]" <(b) (6)> "Hollie, Les W (OIG/OI)" <(b) (6)> "Aguirre, Lisa (IOS/ONS)" <(b) (6)> "Stein, Meredith (NIH/OD) [E]" <(b) (6)>
Subject: US Nonprofit With Ties To Wuhan Lab Violated Federal Law By Failing To Disclose Taxpayer Funding, Complaint Alleges
Assume u saw?

Sent from my iPhone

Michael W. Schmoyer, PhD

Assistant Director for Health Security Threats
Executive Office of the President
Office of Science and Technology Policy (OSTP)
EEOB, Room 490

[1650 Pennsylvania Ave, NW](#)

[Washington, DC 20502](#)

(O) (b) (6)

(C) (b) (6)

(JWICS) (b) (6)

Begin forwarded message:

US Nonprofit With Ties To Wuhan Lab Violated Federal Law By Failing To Disclose Taxpayer Funding, Complaint Alleges

<image001.jpg>

[Andrew Kerr](#) Investigative Reporter

March 15, 2021 9:00 AM ET

Font Size:

- **The nonprofit group EcoHealth Alliance violated federal law by failing to disclose that its work was supported by taxpayer funds, according to a complaint filed Monday.**
- **“Virtually all of EHA’s press releases reporting its taxpayer-funded experiments over the last three years violate the Stevens Amendment,” the White Coat Waste Project wrote in the complaint.**
- **Iowa Sen. Joni Ernst said she will demand the Department of Health and Human Services enforce the Stevens Amendment in light of the complaint.**
- **“This isn’t Communist China; the law isn’t optional,” Ernst said.**

A U.S. nonprofit with close ties to the Wuhan Institute of Virology violated federal law by failing to disclose that taxpayer funds supported its work, according to a complaint a taxpayer watchdog group filed Monday.

EcoHealth Alliance (EHA) diverted \$600,000 in taxpayer funds to the WIV in the form of National Institutes of Health subgrants between 2014 and 2019 as part of a research project studying coronaviruses from Chinese bats. But press [releases](#) from EHA describing the project failed to disclose that the project was backed by federal dollars, an omission that, according to the White Coat Waste Project, is a violation of a federal law known as the Stevens Amendment.

“Virtually all of EHA’s press releases reporting its taxpayer-funded experiments over the last three years violate the Stevens Amendment,” the White Coat Waste Project wrote in its [complaint](#) filed Monday with the National Institutes of Health Office of Management Assessment. “The releases fail to acknowledge federal funding, and/or fail to report the amount of taxpayer money spent, and/or fail to report the percentage of the project paid for with taxpayer funds.”

The Stevens Amendment requires that any group that receives funding from the departments of Labor, Health and Human Services and Education disclose the percentage of costs financed with federal funds and the federal dollar amount in any statements, press releases, bid solicitations and other documents describing a project supported by those agencies, according to the [Government Accountability Office](#).

Approximately 92% of EHA’s revenue in 2018 was from government contracts, the group disclosed in its 2018 [financial statements](#). The bulk of EHA’s [funding](#) comes from the Department of Defense, however, the group has received over [\\$14.7 million](#) from the Department of Health and Human Services since 2002.

The White Coat Waste project flagged in its complaint three EHA press releases that touted its work on bat-based coronaviruses in China that did not disclose the percentage or dollar amount of project

costs financed with federal dollars. EHA's work with the WIV studying bat-based coronaviruses was funded with a \$3.4 million NIH grant, according to [The Wall Street Journal](#).

While some [press releases](#) on EHA's website do disclose that NIH funded its work, the Daily Caller News Foundation did not locate any that indicated the dollar amount or percentage of costs funded by federal funds.

The White Coat Waste Project's complaint called on the NIH, an agency within the HHS, "permanently disqualify EHA from receiving taxpayer funding" in light of its alleged transparency violations.

"Taxpayers have a right to know — and federal law requires that we're told — exactly how much of our money EcoHealth has shipped to the notorious CCP-run Wuhan animal lab for reckless coronavirus experiments that may have caused the pandemic," White Coat Waste Project spokesman Justin Goodman told the DCF. "EcoHealth's rampant violations of federal transparency law are yet another example of the group and its President Peter Daszak obscuring their close ties to — and financial support for — the Wuhan Animal Lab."

Sen. Joni Ernst told the DCF that she will demand an investigation into the federal government's failure to enforce the Stevens Amendment in light of the revelations in the White Coat Waste Project's letter.

"The federal government is failing to comply with the law and disclose how many American taxpayer dollars go to research labs around the world, like the Wuhan Institute of Virology—a reported and potential origin of the novel coronavirus," the Iowa Republican said. "The American people deserve answers."

"I'm demanding an investigation to compel HHS to comply with the law," Ernst continued. "This isn't Communist China; the law isn't optional."

EHA's alleged failure to comply with the Stevens Amendment is emblematic of widespread non-enforcement of the law. The Government Accountability Office [reported](#) in March 2019 that most subagencies under the departments of Labor, Health and Human Services and Education do not monitor grantees for compliance with the Stevens Amendment.

Ernst issued a [letter](#) to HHS Principal Deputy Inspector General Christi Grimm on Thursday urging a thorough review of the department's enforcement and compliance of the Stevens Amendment. The WIV's past work conducting gain-of-function research on bat-based coronaviruses, its proximity to the first known cases of COVID-19 and China's lack of transparency surrounding the lab has led to widespread speculation that the virus could have entered the human population due to an accidental leak from the institution.

Gain-of-function is a type of research in which scientists intentionally make pathogens more deadly in a lab setting with the intention of getting ahead of any future outbreaks. Critics of the procedure say it's not worth the risk as it introduces the possibility that a non-natural pathogen could enter into the human population.

The NIH [banned](#) funding of gain-of-function research in 2014 due to safety concerns, but the ban was lifted in 2017.

U.S. diplomats wrote two cables to Washington D.C. in 2018 warning of safety issues at WIV. The cables specifically noted that researchers at the lab had discovered new bat-based coronaviruses that could easily infect human, [Politico](#) reported. Their warnings went ignored.

<image004.jpg>

WHO team members Marion Koopmans (L), Peter Daszak (3rd R) and Peter Ben Embarek (2nd R) pose for a picture as Koopmans and Daszak leave their hotel after the World Health Organization

(WHO) team wrapped up its investigation into the origins of the COVID-19 coronavirus in Wuhan.
(HECTOR RETAMAL/AFP via Getty Images)

Daszak, the EHA president, was the only American member of the World Health Organization's 2021 team that investigated the origins of COVID-19 in China. Daszak [said](#) Wednesday that the WHO team did not ask to review a database of at least 16,000 virus samples that the WIV deleted in September 2019 because he personally vouched for the lab, saying the data did not contain relevant information on the pandemic's origins.

Daszak's involvement in the WHO probe has been described as a major conflict of interest due to his financial and professional ties with the WIV. Critics have also noted that Daszak appeared to have made up his mind on the lab leak theory at the onset of the pandemic, having organized a statement in The Lancet medical journal in February 2020 condemning "conspiracy theories" suggesting that COVID-19 does not have a natural origin.

A spokesperson for Daszak later admitted to The Wall Street Journal that Daszak's letter was intended to protect Chinese scientists from online criticism. [\(RELATED: The Man At The Center Of The World's Biggest Story Has A Conflict Of Interest. Why Won't The Media Report It?\)](#)

The WHO team announced during a joint press conference with Chinese officials in February that their investigation concluded that it's "highly unlikely" that COVID-19 could have accidentally leaked from a Chinese lab and that the theory was not worth further investigation.

WHO Director-General Tedros Ghebreyesus [walked back](#) the announcement just days later, saying that all theories on the origins of the pandemic, including the lab leak hypothesis, "remain open and require further study."

The WHO scrapped earlier plans to release an interim report on its investigation in China amid growing scientific concerns over the legitimacy of its investigation. The team said on [March 4](#) that it plans to release a full report on its findings "in coming weeks."

EHA did not immediately return a request for comment.

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From: [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
To: [Judith Kimble](#)
Subject: Re: NIH
Date: Tuesday, March 16, 2021 2:21:51 PM

Judith,
Feel free to provide him my email address. A google search reveals this in about < 1 sec.
Parenthetically, we may have a new administration, but still do not have a Secretary of HHS...
Best wishes,
Larry

From: Judith Kimble <[REDACTED] (b) (6)>
Date: Tuesday, March 16, 2021 at 2:09 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] (b) (6)>
Subject: FW: NIH

Larry, I had not wanted to serve as an intermediary between the Nobel activists, and did not forward this letter as requested by Rich about a month ago. Now he wants your email. I can ignore the request if you prefer but would like your advice.

Judith

Judith:

Can you give me Larry's email contact information please? I will write directly to him myself.

Rich

[Richard J. Roberts](#)

[New England Biolabs](#)

[240 County Road](#)

[Ipswich, MA 01938-2723](#)

[USA](#)

Tel: [REDACTED] (b) (6)

Fax: (978) 412 9910

email: [REDACTED] (b) (6)

From: Judith Kimble <[REDACTED] (b) (6)>

Sent: Tuesday, March 16, 2021 1:22 PM

To: Roberts, Rich <[REDACTED] (b) (6)>

Subject: Re: NIH

EXTERNAL SENDER

No, I did not deliver the letter – not a great idea for me to be an intermediary. I did talk to Larry about the issue, without mentioning your letter, reminded him of ACD interest and urged him to send an update to us, but that was a month ago and no action so far. Apparently things are happening but nothing Larry was not willing to talk about specifics.

I'm also vaccinated but not much wiser (though I did get the Pfizer vaccine)!

From: "Roberts, Rich" <[REDACTED] (b) (6)>
Date: Tuesday, March 16, 2021 at 12:16 PM
To: Judith Kimble <[REDACTED] (b) (6)>
Subject: RE: NIH

Judith:

Did the attached letter get delivered to Francis? I am wondering if there has been any action on the EcoAlliance grant?

I am now vaccinated and hence "Older and Pfizer"

How about you?

Rich

Richard J. Roberts

New England Biolabs

240 County Road

Ipswich, MA 01938-2723

USA

Tel: (b) (6)

Fax: (978) 412 9910

email: (b) (6)

From: JUDITH KIMBLE <(b) (6)>

Sent: Saturday, January 16, 2021 12:03 PM

To: Roberts, Rich <(b) (6)>

Subject: Re: NIH

EXTERNAL SENDER

The ACS is intact and functional, though less so than before the pandemic because the meetings are much shorter and all virtual.

We'll be bringing up Daszak as soon as Biden is inaugurated.

Hope you are staying safe – are you vaccinated?

Judith

From: "Roberts, Rich" <(b) (6)>

Date: Saturday, January 16, 2021 at 10:52 AM

To: Judith Kimble <(b) (6)>

Subject: NIH

Judith:

I was rather disappointed to see that Francis has been reappointed.

<https://www.reuters.com/article/us-health-coronavirus-usa-nih/biden-will-keep-dr-francis-collins-as-national-institutes-of-health-director-statement-idUSKBN29K2KG>

Is the Advisory Committee still intact and functional?

If so, then one urgent piece of business is to get Peter Daszak's grant reinstated. Is there some way I and my fellow NLs can help with that?

Rich

Richard J. Roberts

New England Biolabs

240 County Road

Ipswich, MA 01938-2723

USA

Tel: (b) (6)

Fax: (978) 412 9910

email: (b) (6)

Dear Francis:

You may remember the letter that was sent last year protesting the treatment of Dr. Peter Daszak and the EcoHealth Alliance. We laureates would like to bring this matter to your attention once again. With the current change in Administration it seems to us that this matter needs to be re-opened and dealt with promptly to ensure that the grant is reinstated as soon as can be managed.

Rich

Sir Richard J. Roberts Ph.D. F.R.S.
1993 Nobel Laureate in Physiology or Medicine
Chief Scientific Officer
New England Biolabs
240 County Road
Ipswich, MA 01938-2723 USA

Tel: (b) (6)
Fax: (978) 412 9910
email: (b) (6)

Executive Assistant: Karen Otto
Tel: (b) (6)
Fax: (978) 412 9910
email: (b) (6)

-----original letter-----

The 81 signatories of this letter, American Nobel Laureates in Physiology or Medicine, Chemistry, and Physics, are gravely concerned about the recent cancellation of a grant from the National Institutes of Health (NIH) to Dr. Peter Daszak at the EcoHealth Alliance in New York. We believe that this action sets a dangerous precedent by interfering in the conduct of science and jeopardizes public trust in the process of awarding federal funds for research.

For many years, Dr. Daszak and his colleagues have been conducting highly regarded, NIH-supported research on coronaviruses and other infectious agents, focusing on the transmission of these viruses from animal hosts to human beings. Their work depends on productive collaborations with scientists in other countries, including scientists in Wuhan, China, where the current pandemic caused by a novel coronavirus arose. Now is precisely the time when we need to support this kind of research if we aim to control the pandemic and prevent subsequent ones.

As has now been widely reported, the grant to the EcoHealth Alliance was abruptly terminated by NIH on April 24, 2020, just a few days after President Trump responded to a question from a reporter who erroneously claimed that the grant awarded millions of dollars to investigators in Wuhan. Despite the misrepresentation of Dr. Daszak's grant, despite the high relevance of the

studies to the current pandemic, and despite the very high priority score that his application for renewal had received during peer review, the NIH informed Dr. Daszak and his colleagues that the grant was being terminated because “NIH does not believe that the current project outcomes align with the program goals and agency priorities.” Such explanations are preposterous under the circumstances.

We are scientists who have devoted our careers to research, both in medical and related scientific disciplines that bear on the overall health and well-being of society, as well as fundamental scientific research, much of it supported by NIH and other federal agencies. We take pride in our nation’s widely admired system for allocating funds based on expert review and public health needs. The abrupt revoking of the award to Dr. Daszak contravenes these basic tenets and deprives the nation and the world of highly regarded science that could help control one of the greatest health crises in modern history and those that may arise in the future.

We ask that you act urgently to conduct and release a thorough review of the actions that led to the decision to terminate the grant, and that, following this review, you take appropriate steps to rectify the injustices that may have been committed in revoking it.

Peter Agre	Chemistry	2003
Sidney Altman	Chemistry	1989
Frances H. Arnold	Chemistry	2018
Paul Berg	Chemistry	1980
Thomas R. Cech	Chemistry	1989
Martin Chalfie	Chemistry	2008
Elias James Corey	Chemistry	1990
Robert F. Curl Jr.	Chemistry	1996
Johann Deisenhofer	Chemistry	1988
Joachim Frank	Chemistry	2017
Walter Gilbert	Chemistry	1980
Dudley R. Herschbach	Chemistry	1986
Roald Hoffmann	Chemistry	1981
Brian K. Kobilka	Chemistry	2012
Roger D. Kornberg	Chemistry	2006
Robert J. Lefkowitz	Chemistry	2012
Michael Levitt	Chemistry	2013
Roderick MacKinnon	Chemistry	2003
William E. Moerner	Chemistry	2014
Mario J. Molina	Chemistry	1995
Richard R. Schrock	Chemistry	2005
George P. Smith	Chemistry	2018
James P. Allison	Medicine	2018

Richard Axel	Medicine	2004
David Baltimore	Medicine	1975
J. Michael Bishop	Medicine	1989
Elizabeth H. Blackburn	Medicine	2009
Michael S. Brown	Medicine	1985
Linda B. Buck	Medicine	2004
William C. Campbell	Medicine	2015
Mario R. Capecchi	Medicine	2007
Andrew Z. Fire	Medicine	2006
Edmond H. Fischer	Medicine	1992
Joseph L. Goldstein	Medicine	1985
Carol W. Greider	Medicine	2009
Roger Guillemin	Medicine	1977
Leland H. Hartwell	Medicine	2001
H. Robert Horvitz	Medicine	2002
Louis J. Ignarro	Medicine	1998
William G. Kaelin Jr.	Medicine	2019
Eric R. Kandel	Medicine	2000
Craig C. Mello	Medicine	2006
Ferid Murad	Medicine	1998
Sir Richard J. Roberts	Medicine	1993
Michael Rosbash	Medicine	2017
James E. Rothman	Medicine	2013
Randy W. Schekman	Medicine	2013
Gregg L. Semenza	Medicine	2019
Phillip A. Sharp	Medicine	1993
Hamilton O. Smith	Medicine	1978
Thomas C. Sudhof	Medicine	2013
Jack W. Szostak	Medicine	2009
Susumu Tonegawa	Medicine	1987
Harold E. Varmus	Medicine	1989
Eric F. Wieschaus	Medicine	1995
Torsten N. Wiesel	Medicine	1981
Michael W. Young	Medicine	2017
Barry Clark Barish	Physics	2017
Steven Chu	Physics	1997
Jerome I. Friedman	Physics	1990
Sheldon Glashow	Physics	1979
David J. Gross	Physics	2004
Wolfgang Ketterle	Physics	2001
Anthony J. Leggett	Physics	2003
John C. Mather	Physics	2006
Douglas D. Osheroff	Physics	1996
James Peebles	Physics	2019
Saul Perlmutter	Physics	2011
William D. Phillips	Physics	1997
H. David Politzer	Physics	2004
Adam G. Riess	Physics	2011

George F. Smoot	Physics	2006
Horst L. Stormer	Physics	1998
Joseph H. Taylor Jr.	Physics	1993
Kip Stephen Thorne	Physics	2017
Daniel C. Tsui	Physics	1998
Steve Weinberg	Physics	1979
Rainer Weiss	Physics	2017
Carl E. Wieman	Physics	2001
Frank Wilczek	Physics	2004
Robert Woodrow Wilson	Physics	1978

From: [Fine, Amanda \(NIH/OD\) \[E\]](#)
To: [Myles, Renate \(NIH/OD\) \[E\]](#); [Collins, Francis \(NIH/OD\) \[E\]](#); [Wojtowicz, Emma \(NIH/OD\) \[E\]](#); [Roberts, Jacqueline \(NIH/OD\) \[E\]](#)
Cc: [Burklow, John \(NIH/OD\) \[E\]](#); [Wood, Gretchen \(NIH/OD\) \[E\]](#); [McManus, Ayanna \(NIH/OD\) \[E\]](#)
Subject: UPDATE ON TOPICS: Martha MacCallum
Date: Tuesday, March 30, 2021 11:34:56 AM
Attachments: [PRESS Points and Statements_Mar29-30_final.docx](#)

Hi Francis-

Here is the crew contact for today. Confirming the time the van will be there:

Op: Corey Frye C: [REDACTED] (b) (6)

[REDACTED] (b) (6)

Trey Howell [REDACTED] (b) (6)

[REDACTED] (b) (6)

Also, we got the topics from Martha MacCallum's producers this morning. She wants to ask you about the WHO report and vaccine passports. We pushed back on the WHO and recommended they reach out to the NSC, but apparently the NSC spokesperson will be on right before you so we anticipate they may ask anyway. Attaching the NSC talking points HHS shared with us. We prepped the following talking points to reference if you're asked. Let us know if it works:

[REDACTED] (b) (5)

For your reference, [here's is the AP story](#), and I pulled ASF's quote on it for your reference:

Dr. Anthony Fauci, the top U.S. infectious diseases expert, said he would like to see the report's raw information first before deciding about its credibility.

"I'd also would like to inquire as to the extent in which the people who were on that group had access directly to the data that they would need to make a determination," he said. "I want to read the report first and then get a feel for what they really had access to -- or did not have access to."

This is the WaPo article on vaccine cards that the producer referenced:

https://www.washingtonpost.com/health/2021/03/28/vaccine-passports-for-work/?utm_campaign=wp_main&utm_medium=social&utm_source=facebook&fbclid=IwAR3JWdeUB0Jk8uVt1_jO1h_SU0hZ8Jc0hToRVsgiyX8boGylsEZAzD1KfO4

Lastly, we did ask if they could give you an opportunity to talk about the importance of people getting vaccinated, how if the virus is around longer it can mutate more, so if we want the pandemic to end vaccination is important, and the importance of wearing masks even if you've been vaccinated.

Let us know if you need anything else in advance.

Thanks!
Amanda

From: Myles, Renate (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Wednesday, March 24, 2021 7:20 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)> Wojtowicz, Emma (NIH/OD) [E] <[REDACTED] (b) (6)> Roberts, Jacqueline (NIH/OD) [E] <[REDACTED] (b) (6)>
Cc: Burklow, John (NIH/OD) [E] <[REDACTED] (b) (6)> Wood, Gretchen (NIH/OD) [E] <[REDACTED] (b) (6)> McManus, Ayanna (NIH/OD) [E] <[REDACTED] (b) (6)> Fine, Amanda (NIH/OD) [E] <[REDACTED] (b) (6)>
Subject: RE: Martha MacCallum?

Hi Francis:

Jumping in for Emma; yes, the interview is happening. We're just waiting for specific hit time in the 3 p.m. hour and final topics. They'll send the mobile studio. Adding Jackie since she's taken this over for Emma since Emma was out.

Thanks,
Renate

From: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>
Sent: Wednesday, March 24, 2021 7:15 AM
To: Wojtowicz, Emma (NIH/OD) [E] <[REDACTED] (b) (6)>
Cc: Myles, Renate (NIH/OD) [E] <[REDACTED] (b) (6)> Burklow, John (NIH/OD) [E] <[REDACTED] (b) (6)> Wood, Gretchen (NIH/OD) [E] <[REDACTED] (b) (6)> McManus, Ayanna (NIH/OD) [E] <[REDACTED] (b) (6)>
Subject: Martha MacCallum?

Hi Emma,

I see a hold on my calendar for Fox/Martha MacCallum at 3 pm today -- is that happening?

Francis

PRESS GUIDANCE

- I. **March 28 – Embargo Day**
 - a. **After Leaked Embargo**
- II. **March 29 – Public Release**
 - a. **Holding, 12:30 PM EDT**
 - b. **Joint Statement, NLT 3:00 PM EDT**
 - c. **(Alternative) U.S. Solo Statement, 5:00 PM EDT**

PRESS GUIDANCE – MARCH 29

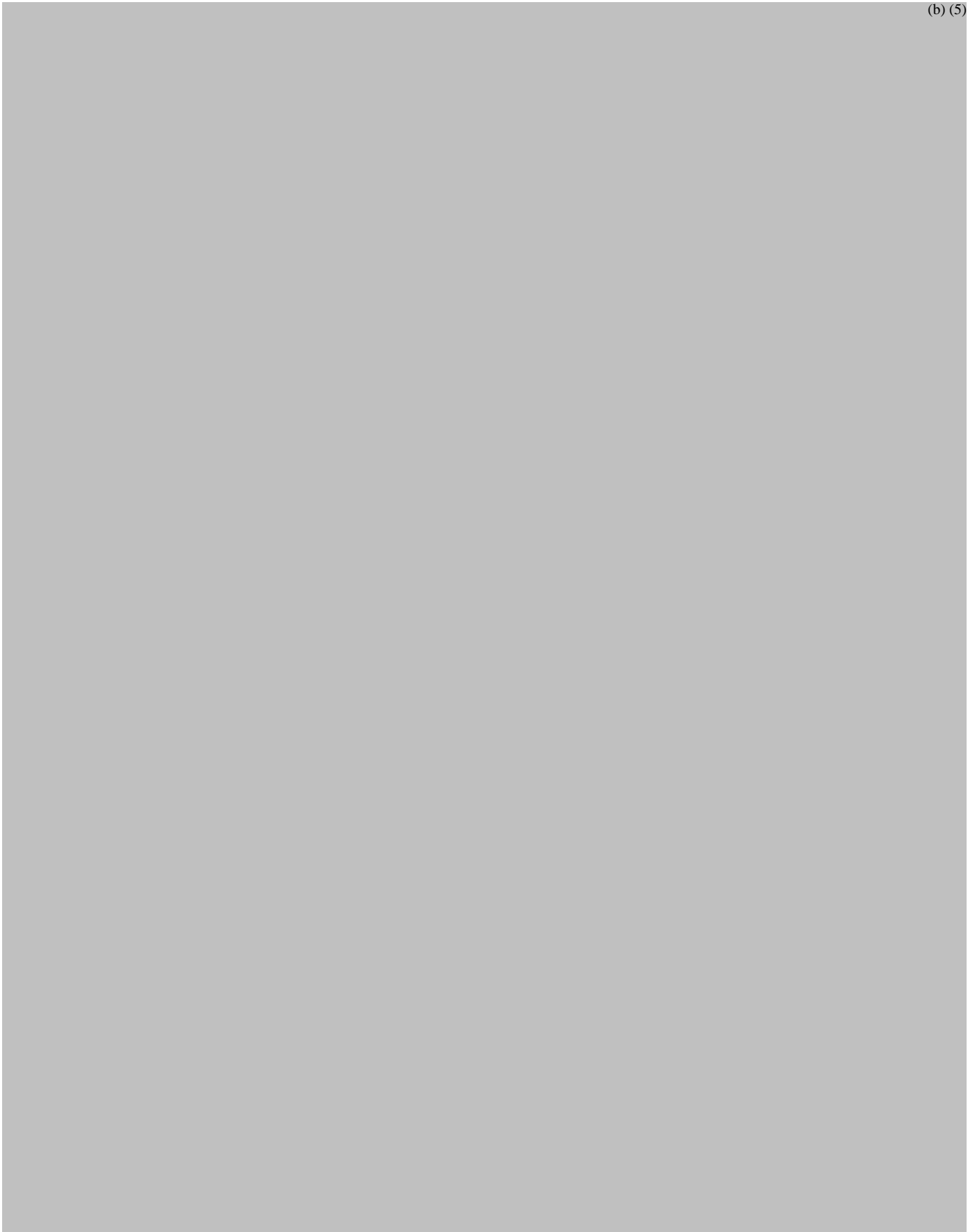
WHO Report on COVID origins has been released to Member States under embargo. These points are only IF RAISED – not to be delivered proactively. Podiums hold topline, thank experts, and say we are reviewing.

(b) (5)

PRESS GUIDANCE – MAR 30 – Public Release Day

(b) (5)











(b) (5)

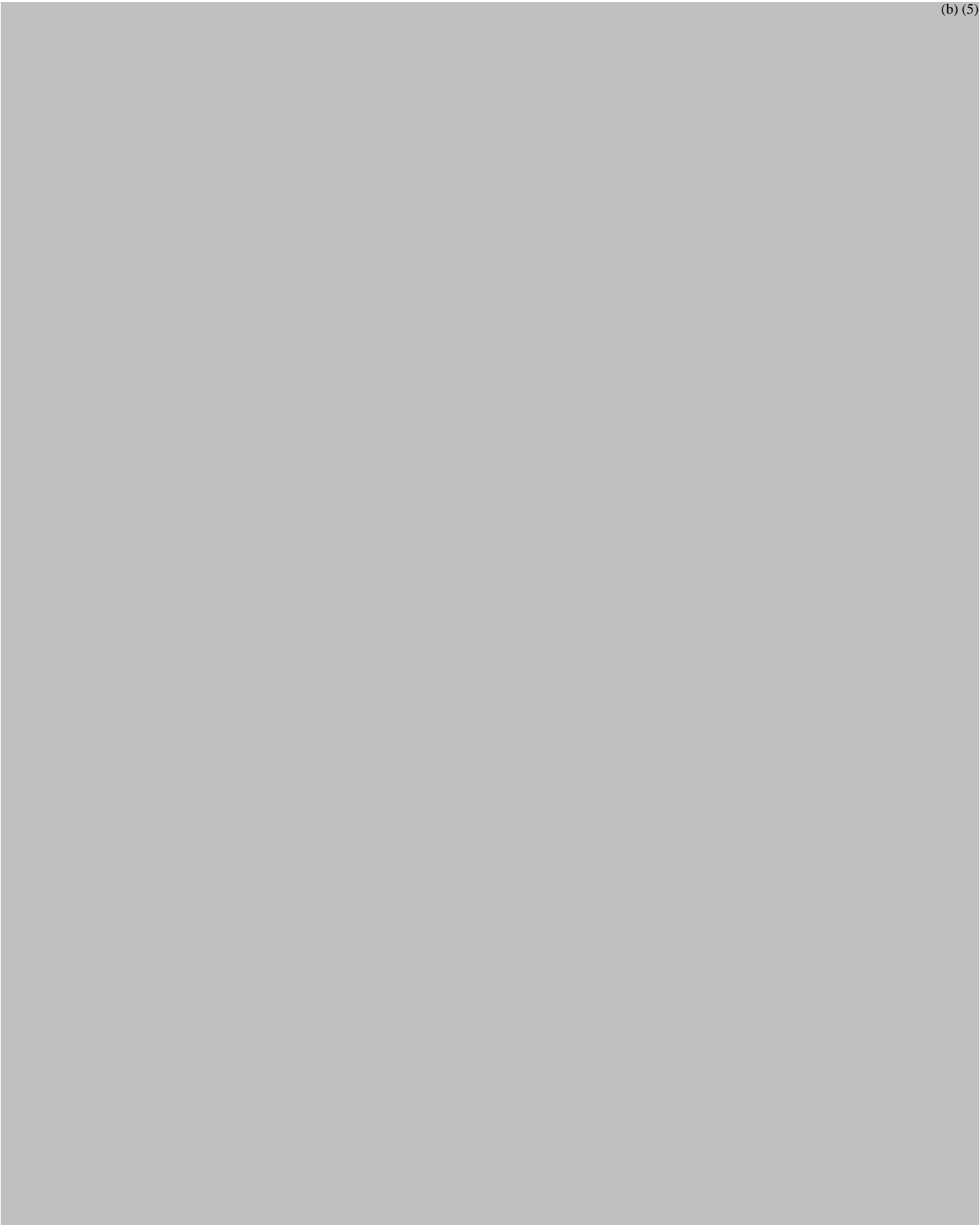
STATEMENTS

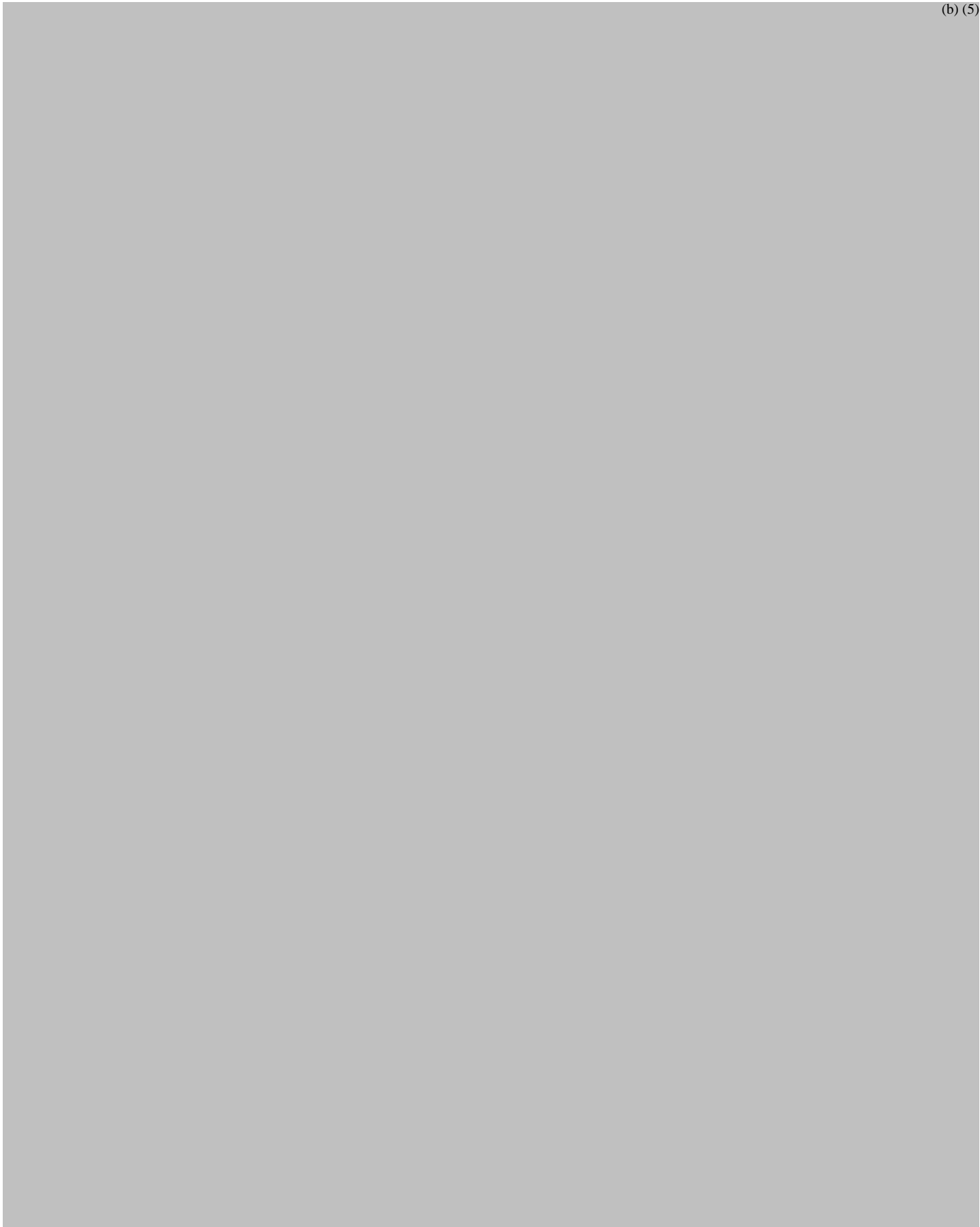
- I. USUN Holding Statement**
- II. Joint Statement**
- III. (Optional) U.S. Solo Statement**

USUN HOLDING STATEMENT – PUBLIC RELEASE DAY

*To be delivered by USUN Geneva in closed press, WHO MS-only briefing
Date and Time TBD*

(b) (5)





From: [Fine, Amanda \(NIH/OD\) \[E\]](#)
To: [Collins, Francis \(NIH/OD\) \[E\]](#); [Myles, Renate \(NIH/OD\) \[E\]](#); [Wood, Gretchen \(NIH/OD\) \[E\]](#); [McManus, Ayanna \(NIH/OD\) \[E\]](#)
Cc: [Burklow, John \(NIH/OD\) \[E\]](#); [Wojtowicz, Emma \(NIH/OD\) \[E\]](#); [Roberts, Jacqueline \(NIH/OD\) \[E\]](#); [NIH NMB \(NIH/OD\)](#)
Subject: RE: FOR REVIEW: WaPo Reporters Working on Book about Administration's Pandemic Response
Date: Friday, March 26, 2021 10:58:37 AM

Hi Francis-

We shared your input with the authors. We made a point to emphasize removing the shouting match reference. Yasmeeen said she can soften the language to say tense exchange, but wanted to make sure we knew that she had heard it described as a shouting match by several sources and didn't want us thinking she had editorialized. Are you comfortable with the change to "tense exchange?"

She confirmed all other input has been incorporated.

Thanks,
Amanda

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, March 24, 2021 6:30 PM
To: Fine, Amanda (NIH/OD) [E] <(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)> McManus, Ayanna (NIH/OD) [E] <(b) (6)>
Cc: Burklow, John (NIH/OD) [E] <(b) (6)> Wojtowicz, Emma (NIH/OD) [E] <(b) (6)> Roberts, Jacqueline (NIH/OD) [E] <(b) (6)> NIH NMB (NIH/OD) <(b) (6)>
Subject: RE: FOR REVIEW: WaPo Reporters Working on Book about Administration's Pandemic Response

Hi all,

See edits and comments on the attached. These are all important, so I would like to hear back from the book authors that they have accepted them.

Francis

From: Fine, Amanda (NIH/OD) [E] <(b) (6)>
Sent: Tuesday, March 23, 2021 5:07 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)> McManus, Ayanna (NIH/OD) [E] <(b) (6)>
Cc: Burklow, John (NIH/OD) [E] <(b) (6)> Wojtowicz, Emma (NIH/OD) [E] <(b) (6)> Roberts, Jacqueline (NIH/OD) [E] <(b) (6)> NIH NMB

(NIH/OD) < [REDACTED] (b) (6)

Subject: RE: FOR REVIEW: WaPo Reporters Working on Book about Administration's Pandemic Response

Yes we should definitely push back on those kinds of items.

From: Collins, Francis (NIH/OD) [E] < [REDACTED] (b) (6)

Sent: Tuesday, March 23, 2021 5:06 PM

To: Fine, Amanda (NIH/OD) [E] < [REDACTED] (b) (6) Myles, Renate (NIH/OD) [E] < [REDACTED] (b) (6) Wood, Gretchen (NIH/OD) [E] < [REDACTED] (b) (6) McManus, Ayanna (NIH/OD) [E] < [REDACTED] (b) (6)

Cc: Burklow, John (NIH/OD) [E] < [REDACTED] (b) (6) Wojtowicz, Emma (NIH/OD) [E] < [REDACTED] (b) (6) Roberts, Jacqueline (NIH/OD) [E] < [REDACTED] (b) (6) NIH NMB (NIH/OD) < [REDACTED] (b) (6)

Subject: RE: FOR REVIEW: WaPo Reporters Working on Book about Administration's Pandemic Response

Am I allowed also to challenge some of the statements in the excerpt provided?

For instance, I never had a shouting match with Steve Hahn.

Francis

From: Fine, Amanda (NIH/OD) [E] < [REDACTED] (b) (6)

Sent: Tuesday, March 23, 2021 3:16 PM

To: Collins, Francis (NIH/OD) [E] < [REDACTED] (b) (6) Myles, Renate (NIH/OD) [E] < [REDACTED] (b) (6) Wood, Gretchen (NIH/OD) [E] < [REDACTED] (b) (6) McManus, Ayanna (NIH/OD) [E] < [REDACTED] (b) (6)

Cc: Burklow, John (NIH/OD) [E] < [REDACTED] (b) (6) Wojtowicz, Emma (NIH/OD) [E] < [REDACTED] (b) (6) Roberts, Jacqueline (NIH/OD) [E] < [REDACTED] (b) (6) NIH NMB (NIH/OD) < [REDACTED] (b) (6)

Subject: FOR REVIEW: WaPo Reporters Working on Book about Administration's Pandemic Response

Hi Francis-

As promised, Yasmeen has reached out to request your review/approval of two quotes they would like to use in the book. Attaching what she shared with us for your review. Your quotes are highlighted. Yasmeen said they'd work with us if you are uncomfortable with either of them.

Additionally, she shared that they interviewed nearly 200 people for this book, including people from the White House, HHS, FDA, NIH, CDC and outside advisers. They want to assure us that everything included comes from numerous sources, across the federal bureaucracy.

Their deadline for this fact check is Thursday, March 25.

Let us know if you need any additional information.

Thanks,
Amanda

From: Fine, Amanda (NIH/OD) [E]
Sent: Tuesday, January 26, 2021 5:21 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Myles, Renate (NIH/OD) [E]
<(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)> McManus, Ayanna
(NIH/OD) [E] <(b) (6)>
Cc: Burklow, John (NIH/OD) [E] <(b) (6)> Wojtowicz, Emma (NIH/OD) [E]
<(b) (6)> Roberts, Jacqueline (NIH/OD) [E] <(b) (6)> NIH NMB
(NIH/OD) <(b) (6)>
Subject: RE: Interview request for Dr. Collins: WaPo Reporters Working on Book about
Administration's Pandemic Response

Good point. I will be sure to clarify that to them.

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Tuesday, January 26, 2021 5:09 PM
To: Fine, Amanda (NIH/OD) [E] <(b) (6)> Myles, Renate (NIH/OD) [E]
<(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)> McManus, Ayanna
(NIH/OD) [E] <(b) (6)>
Cc: Burklow, John (NIH/OD) [E] <(b) (6)> Wojtowicz, Emma (NIH/OD) [E]
<(b) (6)> Roberts, Jacqueline (NIH/OD) [E] <(b) (6)> NIH NMB
(NIH/OD) <(b) (6)>
Subject: RE: Interview request for Dr. Collins: WaPo Reporters Working on Book about
Administration's Pandemic Response

That sounds mostly right. Of course if the scene they are constructing could only be described if I had been the source (like a phone call with one other person), that would be particularly sensitive. When a story could have only one possible source, that doesn't seem like "off the record".

FC

From: Fine, Amanda (NIH/OD) [E] <(b) (6)>
Sent: Tuesday, January 26, 2021 4:37 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Myles, Renate (NIH/OD) [E]
<(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)> McManus, Ayanna
(NIH/OD) [E] <(b) (6)>
Cc: Burklow, John (NIH/OD) [E] <(b) (6)> Wojtowicz, Emma (NIH/OD) [E]
<(b) (6)> Roberts, Jacqueline (NIH/OD) [E] <(b) (6)> NIH NMB

(NIH/OD) < [REDACTED] (b) (6)

Subject: RE: Interview request for Dr. Collins: WaPo Reporters Working on Book about Administration's Pandemic Response

Hi Francis-

Following up on your conversation with Yasmeen and Damien today—Yasmeen reached out with a note to thank you for your time and to confirm their understanding of how they can use the information you shared. Just want to confirm that the below was also your understanding:

I just wanted to clarify one thing. Our understanding is we can use the information Dr. Collins gave us to construct scenes in the book and inform our reporting, but not attribute it specifically to him or NIH. Since it's a book, we don't have to attribute every single sentence. And we'll of course come back to you guys and do a full fact check of everything that pertains to Dr. Collins and NIH. And we'll let you know if there's something we want to use attributable to Dr. Collins and see if that's okay.

Thanks,
Amanda

From: Collins, Francis (NIH/OD) [E] < [REDACTED] (b) (6) >
Sent: Tuesday, January 19, 2021 9:49 PM
To: Myles, Renate (NIH/OD) [E] < [REDACTED] (b) (6) > Wood, Gretchen (NIH/OD) [E] < [REDACTED] (b) (6) > McManus, Ayanna (NIH/OD) [E] < [REDACTED] (b) (6) >
Cc: Burklow, John (NIH/OD) [E] < [REDACTED] (b) (6) > Fine, Amanda (NIH/OD) [E] < [REDACTED] (b) (6) > Wojtowicz, Emma (NIH/OD) [E] < [REDACTED] (b) (6) > Roberts, Jacqueline (NIH/OD) [E] < [REDACTED] (b) (6) > NIH NMB (NIH/OD) < [REDACTED] (b) (6) >
Subject: RE: Interview request for Dr. Collins: WaPo Reporters Working on Book about Administration's Pandemic Response

Zoom is fine, thanks.

From: Myles, Renate (NIH/OD) [E] < [REDACTED] (b) (6) >
Sent: Tuesday, January 19, 2021 6:22 PM
To: Collins, Francis (NIH/OD) [E] < [REDACTED] (b) (6) > Wood, Gretchen (NIH/OD) [E] < [REDACTED] (b) (6) > McManus, Ayanna (NIH/OD) [E] < [REDACTED] (b) (6) >
Cc: Burklow, John (NIH/OD) [E] < [REDACTED] (b) (6) > Fine, Amanda (NIH/OD) [E] < [REDACTED] (b) (6) > Wojtowicz, Emma (NIH/OD) [E] < [REDACTED] (b) (6) > Roberts, Jacqueline (NIH/OD) [E] < [REDACTED] (b) (6) > NIH NMB (NIH/OD) < [REDACTED] (b) (6) >
Subject: RE: Interview request for Dr. Collins: WaPo Reporters Working on Book about Administration's Pandemic Response

Hi Francis:

If you're okay with using Zoom for this discussion, we can use this Zoom link:

(b) (6)

Thanks,
Renate

From: Myles, Renate (NIH/OD) [E] <(b) (6)>
Sent: Tuesday, January 19, 2021 12:48 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Wood, Gretchen (NIH/OD) [E] <(b) (6)> McManus, Ayanna (NIH/OD) [E] <(b) (6)>
Cc: Burklow, John (NIH/OD) [E] <(b) (6)> Fine, Amanda (NIH/OD) [E] <(b) (6)> Wojtowicz, Emma (NIH/OD) [E] <(b) (6)> Roberts, Jacqueline (NIH/OD) [E] <(b) (6)> NIH NMB (NIH/OD) <(b) (6)>
Subject: RE: Interview request for Dr. Collins: WaPo Reporters Working on Book about Administration's Pandemic Response

Hi Gretchen:

Yasmeen said this time works. Both she and Damian will participate. She did ask if they could conduct the interview by Zoom. If FC agrees, OCPL can make a Zoom link available for the discussion.

Thanks,
Renate

From: Wood, Gretchen (NIH/OD) [E] <(b) (6)>
Sent: Tuesday, January 19, 2021 11:29 AM
To: Myles, Renate (NIH/OD) [E] <(b) (6)> McManus, Ayanna (NIH/OD) [E] <(b) (6)>
Cc: Burklow, John (NIH/OD) [E] <(b) (6)> Fine, Amanda (NIH/OD) [E] <(b) (6)> Wojtowicz, Emma (NIH/OD) [E] <(b) (6)> Roberts, Jacqueline (NIH/OD) [E] <(b) (6)> NIH NMB (NIH/OD) <(b) (6)>
Subject: Re: Interview request for Dr. Collins: WaPo Reporters Working on Book about Administration's Pandemic Response

Good morning, Renate,

Will Tuesday, January 26, from 1:00 PM to 1:45 PM work?

Thank you,

Gretchen

From: Renate Myles <(b) (6)>

Date: Tuesday, January 19, 2021 at 10:54 AM

To: "McManus, Ayanna (NIH/OD) [E]" <[REDACTED] (b) (6)> Gretchen Wood
<[REDACTED] (b) (6)>

Cc: John Burklow <[REDACTED] (b) (6)> Amanda Fine <[REDACTED] (b) (6)> "Wojtowicz,
Emma (NIH/OD) [E]" <[REDACTED] (b) (6)> Jacqueline Roberts
<[REDACTED] (b) (6)> "NIH NMB (NIH/OD)" <[REDACTED] (b) (6)>

Subject: RE: Interview request for Dr. Collins: WaPo Reporters Working on Book about
Administration's Pandemic Response

Hi Gretchen and Ayanna:

Checking back on this one to see if we can set up a time after tomorrow.

Thanks,
Renate

From: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>

Sent: Saturday, January 9, 2021 8:34 PM

To: Myles, Renate (NIH/OD) [E] <[REDACTED] (b) (6)> McManus, Ayanna (NIH/OD) [E]
<[REDACTED] (b) (6)> Wood, Gretchen (NIH/OD) [E] <[REDACTED] (b) (6)>

Cc: Burklow, John (NIH/OD) [E] <[REDACTED] (b) (6)> Fine, Amanda (NIH/OD) [E]
<[REDACTED] (b) (6)> Wojtowicz, Emma (NIH/OD) [E] <[REDACTED] (b) (6)> Roberts,
Jacqueline (NIH/OD) [E] <[REDACTED] (b) (6)> NIH NMB (NIH/OD) <[REDACTED] (b) (6)>

Subject: RE: Interview request for Dr. Collins: WaPo Reporters Working on Book about
Administration's Pandemic Response

OK for after January 20

From: Myles, Renate (NIH/OD) [E] <[REDACTED] (b) (6)>

Sent: Saturday, January 9, 2021 12:24 PM

To: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)> McManus, Ayanna (NIH/OD) [E]
<[REDACTED] (b) (6)> Wood, Gretchen (NIH/OD) [E] <[REDACTED] (b) (6)>

Cc: Burklow, John (NIH/OD) [E] <[REDACTED] (b) (6)> Fine, Amanda (NIH/OD) [E]
<[REDACTED] (b) (6)> Wojtowicz, Emma (NIH/OD) [E] <[REDACTED] (b) (6)> Roberts,
Jacqueline (NIH/OD) [E] <[REDACTED] (b) (6)> NIH NMB (NIH/OD) <[REDACTED] (b) (6)>

Subject: Interview request for Dr. Collins: WaPo Reporters Working on Book about Administration's
Pandemic Response

Interview Request for Dr. Collins
January 9, 2021

Request: Topic – Book on Administration's Response to the Pandemic

Deadline: 45 minutes by phone in January

Additional information:

Washington Post reporters Yasmeen Abutaleb (health policy) and Damian Paletta, (economics editor) are working on a book about the administration’s response to the pandemic from January through November. Both are taking book leave from the Post through April. The book will cover vaccines and treatments and the politicization around their development. They also want to cover people that the President had around him and what it meant for the people in the NIH, CDC, and FDA responsible for the pandemic response. She is particularly interested in discussing how Dr. Collins was able to protect the NIH and stay for the most part out of the political fray. Yasmeen indicated that you can set the rules and do it on background and if they want to put something on the record, they will send it for your review. She will also give us a heads up on what they plan to use, and work with us on heavy fact-checking. Their schedule is as follows:

- Manuscript due in mid-March
- April-May will be heavy fact checking, and opportunity for you to clarify anything

Recommendation:

Recommend Dr. Collins accepts this interview.

Submitted by:

Renate Myles, (b) (6)
NIH News Media Branch

Contact information:

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(b) (6)
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Other important notes:

Accept: _____
Decline: _____
Need more information: _____

- When Chinese researchers released the virus's genetic code on Jan. 11 on an open-access repository for genetic information, scientists jumped at the opportunity to see what they were dealing with. The NIH's director, Francis Collins, and Anthony Fauci, head of the NIH affiliate National Institute of Allergy and Infectious Diseases (NIAID) convened global experts on viral genome evolution to scrutinize the sequence and try to determine whether it was a human-engineered virus or a naturally occurring one. Initially, there were fears that someone may have deliberately engineered a virus to harm the United States and other countries, a scenario that several administrations spent considerable time contemplating and preparing for.
- What the experts found stunned them — and left them certain there was no way a human could have designed the virus. "It violated what we thought we knew about what would make a coronavirus dangerous," Collins said. "It had features that were really surprising and unheard of that nobody could have imagined would actually work, but there it was."
- In late April, articles were published in *Science* and *Politico* detailing how, at Trump's direction, the NIH abruptly terminated a grant for a study examining how coronaviruses spread from bats to humans. This was an area of research that had renewed importance given the pandemic. The study's sponsor was a New York-based research nonprofit called EcoHealth Alliance, but reports linked the grant to the Wuhan Institute of Virology at the same time right-wing media was seizing on the theory that the coronavirus either escaped from, or was engineered in, a lab in Wuhan, China. (Navarro, characteristically, was the most bullish of those inside the White House peddling the Wuhan lab theory. He even suggested the virus could have been designed by the Chinese military as a type of biological weapon, an argument in line with his 2011 book, *Death by China*.) A reporter from One America News Network — a tiny conservative outlet that was even more loyal to the president than Fox News — asked Trump about the grant in a briefing one week before it was terminated. "We will end that grant very quickly," Trump replied.
- The NIH, peer-reviewed grant had already come under scrutiny within the federal government as soon as officials realized the Wuhan Institute of Virology had a subgrant under the contract. The institute had the most expertise in studying which bat viruses might be the next to come out of China and pose a major threat. But with questions swirling about the origins of COVID-19 — experts had determined the virus was not man made, but could not rule out that it may have slipped out of a lab — the NIH had gone to the principal investigator on the grant on April 19 and asked that payments be halted to the subcontract in Wuhan until they had more answers.
- A few days later, the relatively small grant had garnered new attention. The chatter by Navarro and the other White House hawks who were convinced China had deliberately unleashed the virus on the world, had found a welcome audience among right-wing conspiracy theorists. On the afternoon of April 24, NIH Director Francis Collins and Fauci received notice that Trump wanted to formally announce the grant had been terminated in a 5 pm press conference. Collins and Fauci told the White House and HHS they were not sure the NIH actually had the authority to terminate a peer-reviewed grant in the middle of a budget cycle. The HHS General Counsel told them to do it anyway and made clear it was a direct order from the president — implying their jobs were on the line if they didn't comply. Fauci and Collins reluctantly agreed to cancel the grant.
- Collins heard from many members of the scientific community that he should have resigned. The HHS General Counsel later found the agency probably did not have the authority to terminate the grant. Instead, NIH had to reinstate the grant but stop all of its funding.
- There were plenty of scientists and researchers who thought the government was making a huge mistake by allowing convalescent plasma to be administered freely — in an NIH-funded program, no less. Without a placebo group, how would they even know if it worked?

"This is one of those lessons we should learn from," said Francis Collins, the NIH director. "This was a failure of the academic, clinical research enterprise. We lost an early opportunity to get an answer about whether convalescent plasma really worked."

- The FDA then made a larger presentation to several members of the task force and top White House aides during a Zoom call on July 29. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, went through the results, which included several analyses of the Mayo data, animal studies and clinical reports, convinced the agency had enough evidence to show that plasma met the relatively low bar for an emergency use authorization. It was safe, and it looked like it could benefit patients; in other words, the benefits outweighed the risks.
- But the NIH director, Francis Collins, objected. It was bad enough they hadn't been able to conduct a randomized, controlled clinical trial. Now, it would look like they were cherry picking the data they wanted to use to show that it worked by excluding some patients from their analysis. A participant on the phone call paraphrased Collins' warning to the FDA: If you do this, you are going to bring down the wrath of the academic world. There was silence on the call. Then Birx interjected. "Francis," she said, "it sounds like you're threatening the FDA."
- By August 12, Marks reviewed additional data from Mayo Clinic and believed the agency now had enough to move forward with the emergency use authorization. But Collins still did not think the data was sufficient. Hahn asked Marks what he thought they should do. If we get some additional data that helps answer your questions, Marks asked Collins, would that help? Collins said that was what he wanted. But it would take another seven to 10 days.
- Just days before the FDA and NIH expected to be able to review Mayo Clinic's additional data — and days before the start of the RNC — Collins received a phone call while trying to take a short vacation in Chincoteague, Virginia. It was the president. (*This entire call, including quotes, is confirmed with two other sources - Dr. Collins is not the sole source.*)
- "You know, my polling numbers are looking really good," Trump began. "But you doctors are killing me!" Trump then launched into a tirade about convalescent plasma and accused Collins and the NIH of standing in the way of its authorization. Didn't Collins and other scientists recognize they were hurting people? "People are dying," Trump told him. Collins could barely get a word in, but tried to reassure the volatile president. "You know, Mr. President, you don't want to make a decision on data that turns out to be wrong," Collins said. "It'll come back to haunt you."
- Trump then went another rant, this time about how the doctors also killed hydroxychloroquine. Even though the FDA had revoked its emergency use authorization two months earlier and it was clear the drug did not work — and could actually cause heart problems in some covid patients — Trump never gave up on it, even if he talked about it less in public.
- Collins found another opening. "We are within a week of having a much larger dataset where I know I can trust the antibody levels," Collins explained. "Can we please just put this off until next week?" "No. Absolutely not," Trump said, emphatically. "We've gotta have the data on Friday or it doesn't matter." Friday was Aug. 21, just three days before the RNC. The inference was that they needed this before the huge political rally, otherwise it was of no value to Trump.
- On Sunday, Hahn, Azar, Collins, Marks and others showed up at the White House for the planned announcement, gathering in the Roosevelt Room. This was the last place Marks and Collins wanted to be. They both tried to avoid the White House after quickly determining the White House was focused on touting "wins" ahead of the election — real or not — and expected everyone in its orbit to go along. Yet after being asked to attend the event, the two were left out of the announcement. Hahn and Azar took the stage with Trump, who began

by touting the news as a “truly historic announcement.” Azar followed Trump, praising the president’s “bold leadership” for helping to bring about the emergency authorization.

- Collins and Marks watched the press conference on Caputo’s cell phone, and “both immediately have their hair on fire,” one senior administration official recalled. Hahn, Azar and Trump had completely misrepresented the data which indicated a relative reduction in mortality, not an absolute reduction. That meant there was a 35% improvement among patients who received plasma with a high level of antibodies, compared to a group that received a low level of antibodies. That was not at all the same thing as saying 35 out of 100 patients would have been saved. Results like that simply didn’t exist. Marks and Collins were in disbelief that Hahn, an oncologist, could misunderstand the results so horribly. The politicization of the FDA had reached its ultimate low point.
- Some health officials, including Marks and NIH Director Francis Collins, decided they would try to avoid the White House as much as they could in the coming months to escape unnecessary political pressure.

From: [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
To: [Collins, Francis \(NIH/OD\) \[E\]](#); [Lauer, Michael \(NIH/OD\) \[E\]](#); [Wolinetz, Carrie \(NIH/OD\) \[E\]](#)
Subject: Re: A current issue and the possibility of a chat?
Date: Sunday, March 28, 2021 10:02:17 PM
Attachments: [2021.03.16 - NIH Letter on WIV\[2\].pdf](#)
[US STATE DEPT CABLES in Appendix to GOP-Report-OriginsOfCOVID-19-Global-Pandemic-Including-Roles-of-CCPandWHO.09.20.20\[2\].pdf](#)

Francis,

I agree; [REDACTED] (b) (5)

[REDACTED]

[REDACTED] (b) (5)

Larry

From: Francis Collins <[REDACTED] (b) (6)>
Date: Sunday, March 28, 2021 at 9:54 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] (b) (6)> "Lauer, Michael (NIH/OD) [E]" <[REDACTED] (b) (6)> "Wolinetz, Carrie (NIH/OD) [E]" <[REDACTED] (b) (6)>
Subject: FW: A current issue and the possibility of a chat?

See below. [REDACTED] (b) (5)

From: David A Relman <[REDACTED] (b) (6)>
Sent: Saturday, March 27, 2021 1:07 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] (b) (6)>
Cc: David A Relman <[REDACTED] (b) (6)>
Subject: A current issue and the possibility of a chat?

Francis—

I hope you are well (as well as one could hope given the times and circumstances).

I wonder whether you would have a bit of time for a chat with me about the current state of our understanding about the origins of the pandemic, and the increasingly divisive and polarized discussion about this topic, not only in the public forum but also within the scientific community?

I'm motivated to write you by three developments this past week: 1) a lengthy and pointed letter that was sent to you and made public by the Republican leadership of the House E&C Committee, which unfortunately featured my name and words on the front page; 2) calls yesterday from the Democratic leadership of the Maryland State Legislature for the dismissal of Robert Redfield as an advisor to the Governor for offering his opinion about the possibility of a lab leak in Wuhan; and 3) an email that was shared with me, written by a prominent ASM member and virologist chastising me out for raising questions about how much we don't know about the origins of the pandemic.

All of this is incredibly unfortunate, but it also highlights an important opportunity and need, that is, for the scientific community to step up and take an honest, dispassionate, deliberate, and impartial examination of the scientific data that bear on the origins question. There are some incredibly important questions, not just about what happened, but also about how we should go about understanding biological threats that arise from nature, as well as from the activities of humans, and how we should manage tradeoffs between benefits and risks in science. NIH can (and IMHO, really must) play a leading role in this discussion. This discussion will require a lot more transparency and humility (vice, confident assertions in the absence of good evidence), a willingness to listen to diverse points of view, as well as a willingness to acknowledge some important deficiencies in the current availability of data (that bear on the origins question).

All of this to say, might you be interested in discussing this?

Thanks for considering these thoughts and suggestions, at what I know must be a hectic time.

Best, David

David A. Relman, MD
Thomas C. and Joan M. Merigan Professor
Departments of Medicine, and of Microbiology & Immunology
Stanford University School of Medicine

Senior Fellow, Center for International Security and Cooperation
Stanford University

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ONE HUNDRED SEVENTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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Majority (202) 225-2927

Minority (202) 225-3641

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.”² 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

² Smriti Mallapaty, *Where did COVID come from? WHO investigation begins but faces challenges*, NATURE (Nov. 11, 2020), available at <https://www.nature.com/articles/d41586-020-03165-9>.

³ The White House, Statement of National Security Advisor Jake Sullivan (Feb. 13, 2021), available at <https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/13/statement-by-national-security-advisor-jake-sullivan/>.

⁴ Betsy McKay, Drew Hinshaw and Jeremy Page, *WHO Investigators to Scrap Plans for Interim Report on Probe of Covid-19 Origins*, THE WALL STREET JOURNAL (Mar. 4, 2021), available at https://www.wsj.com/articles/who-investigators-to-scrap-interim-report-on-probe-of-covid-19-origins-11614865067?mod=latest_headlines

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%20\(1\).pdf](https://s.wsj.net/public/resources/documents/COVID%20OPEN%20LETTER%20FINAL%20030421%20(1).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/>. (“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.”)

⁶ 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>.

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.⁷ 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.⁸

In January 2021, the U.S. Department of State issued a fact sheet about the activity at the WIV.⁹ 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.¹⁰
- 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).¹¹ 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.¹² But the WIV has not been transparent or consistent about its record of

⁷ NIH RePORTER, *Research Portfolio Online Reporting Tools* (queried Mar. 4, 2021), available at <https://reporter.nih.gov/search/qlYUeI9DIk2JfWUdCcWxcA/projects/charts>.

⁸ Mark Moore, *NIH investigating Wuhan lab at center of coronavirus pandemic*, NEW YORK POST (Apr. 28, 2020), available at <https://nypost.com/2020/04/28/nih-investigating-wuhan-lab-at-center-of-coronavirus-pandemic/>.

⁹ U.S. Department of State, *Fact Sheet: Activity at the Wuhan Institute of Virology*, Office of the Spokesperson (Jan. 15, 2021), available at <https://2017-2021.state.gov/fact-sheet-activity-at-the-wuhan-institute-of-virology//index.html>.

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

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.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.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.¹⁵ The WIV has engaged in classified research, including laboratory animal experiments, on behalf of the Chinese military since at least 2017.¹⁶
- 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.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.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.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.²⁰ That, along with what is known of the WIV’s work in past few years, raised reasonable suspicion that the

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

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>

¹⁹ Fred Guterl, Naveed Jamali and Tom O’Connor, *The Controversial Experiments at Wuhan Lab Suspected of Starting the Coronavirus Pandemic*, NEWSWEEK (Apr. 27, 2020), available at <https://www.newsweek.com/controversial-wuhan-lab-experiments-that-may-have-started-coronavirus-pandemic-1500503>.

²⁰ *Id.*

pandemic may have been caused by a lab error, not a wet market.²¹ 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.”²² 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.”²³ 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.²⁴ 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, sub-grantees, contractors, or 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, sub-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

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](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.*

²⁴ Mike Pompeo and Miles Yu, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, *THE WALL STREET JOURNAL* (Feb. 23, 2021), *available at* <https://www.wsj.com/articles/chinas-reckless-labs-put-the-world-at-risk-11614102828>.

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

²⁵ Meredith Wadman, *NIH imposes 'outrageous' conditions on resuming coronavirus grant targeted by Trump*, SCIENCEMAG (Aug. 19, 2020), available at <https://www.sciencemag.org/news/2020/08/nih-imposes-outrageous-conditions-resuming-coronavirus-grant-targeted-trump>.

²⁶ National Institutes of Health, *Notice Announcing the Removal of the Funding Pause for Gain-of-Function Research Project* (Dec. 19, 2017), available at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-071.html>.

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."²⁸ 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?²⁹
- 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?³⁰
- 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.³¹

²⁸ Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19, 2020), available at <https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400>.

²⁹ Meredith Wadman, *NIH imposes 'outrageous' conditions on resuming coronavirus grant targeted by Trump*, SCIENCEMAG (Aug. 19, 2020), available at <https://www.sciencemag.org/news/2020/08/nih-imposes-outrageous-conditions-resuming-coronavirus-grant-targeted-trump>.

³⁰ *Id.*

³¹ Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19, 2020), available at <https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400>.

- 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."³² 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?³³
 - 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."³⁴ 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.*

³⁴ Meredith Wadman and Jon Cohen, *NIH's axing of bat coronavirus grant a 'horrible precedent' and might break rules, critics say*, SCIENCEMAG (Apr. 30, 2020), available at <https://www.sciencemag.org/news/2020/04/nih-s-axing-bat-coronavirus-grant-horrible-precedent-and-might-break-rules-critics-say>.

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.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?³⁶
20. According to a report in *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, 2018.³⁷ 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.

³⁵ Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19, 2020), available at <https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400>.

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

³⁷ Josh Rogin, *Opinion: State Department cables warned of safety issues at Wuhan lab studying bat coronaviruses*, THE WASHINGTON POST (Apr. 14, 2020), available at <https://www.washingtonpost.com/opinions/2020/04/14/state-department-cables-warned-safety-issues-wuhan-lab-studying-bat-coronaviruses/>.

26. According to an editorial in *The Wall Street Journal*, the WIV housed tens of thousands of bat samples and laboratory animals in 2019.³⁸ 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?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).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

³⁸ Mike Pompeo and Miles Yu, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Feb. 23, 2021), available at <https://www.wsj.com/articles/chinas-reckless-labs-put-the-world-at-risk-11614102828>.

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>.

⁴⁰ Latinne, A., Hu, B., Olival, K.J. et al., *Origin and cross-species transmission of bat coronaviruses in China*, *Nature* (Aug. 25, 2020), available at <https://www.nature.com/articles/s41467-020-17687-3#Ack1>.

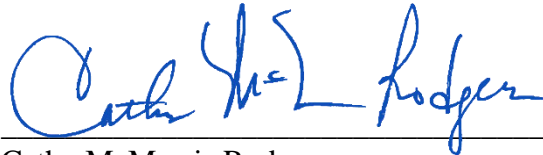
Letter to the Honorable Francis Collins, M.D., Ph.D.

Page 11

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.

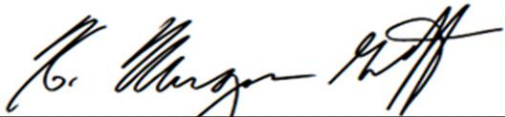
Sincerely,



Cathy McMorris Rodgers
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 Diana DeGette, Chair, Subcommittee on Oversight and Investigations
The Honorable Anna Eshoo, Chair, Subcommittee on Health

2018 Cables from Embassy Beijing and Consulate General Wuhan to State Department Headquarters in Washington, D.C.

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SBU



MRN: 18 BEIJING 138
Date/DTG: Jan 19, 2018 / 190739Z JAN 18
From: AMEMBASSY BEIJING
Action: WASHDC, SECSTATE ROUTINE
E.O.: 13526
TAGS: SHLH, ETRD, ECON, PGOV, CN
Captions: SENSITIVE
Reference: 17 WUHAN 48
Subject: China Opens First Bio Safety Level 4 Laboratory

1. (SBU) **Summary and Comment:** The Chinese Academy of Sciences (CAS) has recently established what is reportedly China's first Biosafety Level 4 (BSL-4) laboratory in Wuhan. This state-of-the-art facility is designed for prevention and control research on diseases that require the highest level of biosafety and biosecurity containment. Ultimately, scientists hope the lab will contribute to the development of new antiviral drugs and vaccines, but its current productivity is limited by a shortage of the highly trained technicians and investigators required to safely operate a BSL-4 laboratory and a lack of clarity in related Chinese government policies and guidelines. (b)(5)

(b)(5)

(b)(5) **End Summary and Comment.**

China Investing in Infectious Disease Control

2. (U) Between November 2002 and July 2003, China faced an outbreak of Severe Acute Respiratory Syndrome (SARS), which, according to the World Health Organization, resulting in 8,098 cases and leading to 774 deaths reported in 37 countries. A majority of cases occurred in China, where the fatality rate was 9.6%. This incident convinced China to prioritize international cooperation for infectious disease control. An aspect of this prioritization was China's work with the Jean Merieux BSL-4 Laboratory in Lyon, France, to build China's first high containment laboratory at Wuhan's Institute of Virology (WIV), an institute under the auspices of the Chinese Academy of Sciences (CAS). Construction took 11 years and \$44 million USD, and construction on the facility was completed on January 31, 2015. Following

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Page 1 of 3

two years of effort, which is not unusual for such facilities, the WIV lab was accredited in February 2017 by the China National Accreditation Service for Conformity Assessment. It occupies four floors and consists of over 32,000 square feet. WIV leadership now considers the lab operational and ready for research on class-four pathogens (P4), among which are the most virulent viruses that pose a high risk of aerosolized person-to-person transmission.

Unclear Guidelines on Virus Access and a Lack of Trained Talent Impede Research

3. (SBU) In addition to accreditation, the lab must also receive permission from the National Health and Family Planning Commission (NHFPCC) to initiate research on specific highly contagious pathogens. According to some WIV scientists, it is unclear how NHFPCC determines what viruses can or cannot be studied in the new laboratory. To date, WIV has obtained permission for research on three viruses: Ebola virus, Nipah virus, and Xinjiang hemorrhagic fever virus (a strain of Crimean Congo hemorrhagic fever found in China's Xinjiang Province). Despite this permission, however, the Chinese government has not allowed the WIV to import Ebola viruses for study in the BSL-4 lab. Therefore, WIV scientists are frustrated and have pointed out that they won't be able to conduct research project with Ebola viruses at the new BSL-4 lab despite of the permission.

(b)(6)

(b)(6) Thus, while the BSL-4 lab is ostensibly fully accredited, its utilization is limited by lack of access to specific organisms and by opaque government review and approval processes. As long as this situation continues, Beijing's commitment to prioritizing infectious disease control - on the regional and international level, especially in relation to highly pathogenic viruses, remains in doubt.

(b)(6) noted that the new lab has a serious shortage of appropriately trained technicians and investigators needed to safely operate this high-containment laboratory. University of Texas Medical Branch in Galveston (UTMB), which has one of several well-established BSL-4 labs in the United States (supported by the National Institute of Allergy and Infectious Diseases (NIAID of NIH)), has scientific collaborations with WIV, which may help alleviate this talent gap over time. Reportedly, researchers from UTMB are helping train technicians who work in the WIV BSL-4 lab. Despite this, (b)(6) they would welcome more help from U.S. and international organizations as they establish "gold standard" operating procedures and training courses for the first time in China. As China is building more BSL-4 labs, including one in Harbin Veterinary Research Institute subordinated to the Chinese Academy of Agricultural Sciences (CAAS) for veterinary research use, (b)(6) the training for technicians and investigators working on dangerous pathogens will certainly be in demand.

Despite Limitations, WIV Researchers Produce SARS Discoveries

6. (SBU) The ability of WIV scientists to undertake productive research despite limitations on the use of the new BSL-4 facility is demonstrated by a recent publication on the origins of SARS. Over a five-year study, (b)(6) (and their research team) widely sampled bats in Yunnan province with funding support from NIAID/NIH, USAID, and several Chinese funding agencies. The study results were published in PLoS Pathogens online on Nov. 30, 2017 (1), and it demonstrated that a SARS-like coronavirus isolated from horseshoe bats in a single cave contain all the building blocks of the pandemic SARS-coronavirus genome that caused the human outbreak. These results strongly suggest that the highly pathogenic SARS-coronavirus originated in this bat population. Most importantly, the researchers also showed that various SARS-like coronaviruses can interact with ACE2, the human receptor identified for SARS-coronavirus. This finding strongly suggests that SARS-like coronaviruses from bats can be transmitted to humans to cause SARS-like disease. From a public health perspective, this makes the continued surveillance of SARS-like coronaviruses in bats and study of the animal-human interface critical to future emerging coronavirus outbreak prediction and prevention. (b)(6)

(b)(5) WIV scientists are allowed to study the SARS-like coronaviruses isolated from bats while they are precluded from studying human-disease causing SARS coronavirus in their new BSL-4 lab until permission for such work is granted by the NHFCP.

1. Hu B, Zeng L-P, Yang X-L, Ge X-Y, Zhang W, Li B, et al. (2017) Discovery of a rich gene pool of bat SARS-related coronaviruses provides new insights into the origin of SARS coronavirus. PLoS Pathog 13(11): e1006698. <https://doi.org/10.1371/journal.ppat.1006698>

Signature: BRANSTAD

Drafted By: (b)(6)
Cleared By:
Approved By:
Released By:
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MRN: 18 WUHAN 38
Date/DTG: Apr 19, 2018 / 190551Z APR 18
From: AMCONSUL WUHAN
Action: WASHDC, SECSTATE *ROUTINE*
E.O.: 13526
TAGS: SHLH, PGOV, CN, PREL, TBIO, KGH, CDC, EAID, KHIV, IN, JP, TW, TSPL, PINS, SENV
Captions: SENSITIVE
Reference: A) 18 BEIJING 138
 B) 17 BEIJING 2458
 C) 11 MUMBAI 630
 D) 17 TOKYO 716
 E) 13 SEOUL 790
Subject: China Virus Institute Welcomes More U.S. Cooperation on Global Health Security

1. (SBU) **Summary with Comment:** China's Wuhan Institute of Virology, a global leader in virus research, is a key partner for the United States in protecting global health security. Its role as operator of the just-launched Biosafety Level 4 (or "P4") lab -- the first such lab in China -- opens up even more opportunities for expert exchange, especially in light of the lab's shortage of trained staff (Ref A). ^{(b)(5)}

(b)(5)

(b)(5) **End Summary with Comment.**

2. (U) Wuhan Institute of Virology researchers and staff gave an overview of the lab and current cooperation with the United States to visiting Environment, Science, Technology and Health Counsellor Rick Switzer and Consulate Wuhan Consul General Jamie Fouss in late March. In the last year, the institute has also hosted visits from the National Institutes of Health (NIH), National Science Foundation, and experts from the University of Texas Medical Branch in Galveston. The institute reports to the Chinese Academy of Sciences in Beijing.

P4 Lab is Open and Transparent, Officials Emphasize

3. (SBU) The Wuhan P4 lab, referring to labs with the highest level of safety precautions, became fully operational and began working with live viruses early this year. Institute officials said they believed it is the only operational P4 lab in Asia aside from a U.S. Centers for Disease

Control (CDC)-supported facility in Pune, India (Ref C). China plans to stand up a second P4 lab in Harbin. Institute officials said Japan's biosafety labs are "old" and lack cutting-edge equipment, so they consider Japan's labs to be "P3 Plus" (Note: the Japanese government says it has one P4-level lab in the Tokyo suburbs, though its activities are limited, and Japan is building a new P4 lab in Nagasaki, see Ref D. Taiwan operates at least one P4 lab. South Korea was close to opening a P4 lab as of last year, see Ref E. End Note.) Wuhan's lab is located about 20 miles from the city center in Zhengdian district, and the institute plans to gradually consolidate its other training, classroom and lab facilities at that location.

4. (U) Officials described the lab as a "regional node" in the global biosafety system and said it would play an emergency response role in an epidemic or pandemic. The lab's English brochure highlighted a national security role, saying that it "is an effective measure to improve China's availability in safeguarding national bio-safety if [a] possible biological warfare or terrorist attack happens."

5. (SBU) Institute officials said there would be "limited availability" for international and domestic scientists who had gone through the necessary approval process to do research at the lab. They stressed that the lab aimed to be a "worldwide, open platform" for virology. They said they welcomed U.S. Centers for Disease Control (CDC) experts, noting that the Chinese Academy of Sciences was not strong on human disease expertise, having only focused on it in the last 15 years, after the SARS outbreak. A Wuhan-based French consulate official who works on science and technology cooperation with China also emphasized that the lab, which was initiated in 2004 as a France-China joint project, was meant to be "open and transparent" to the global scientific community. "The intent was to set up a lab to international standards, and open to international research," he said. French experts have provided guidance and biosafety training to the lab, which will continue, the French official said. Institute officials said that France provided the lab's design and much of its technology, but that it is entirely China-funded and has been completely China-run since a "handover" ceremony in 2016.

6. (U) In addition to French assistance, experts from the NIH-supported P4 lab at the University of Texas Medical Branch in Galveston have trained Wuhan lab technicians in lab management and maintenance, institute officials said. The Wuhan institute plans to invite scientists from the Galveston lab to do research in Wuhan's lab. One Wuhan Institute of Virology researcher trained for two years at the Galveston lab, and the institute also sent one scientist to U.S. CDC headquarters in Atlanta for six months' work on influenza.

NIH-Supported Research Revises SARS Origin Story

7. (U) NIH was a major funder, along with the Natural Science Foundation of China (NSFC), of SARS research by the Wuhan Institute of Virology's (b)(6) (b)(6)
(b)(6) (b)(6)
This lends weight to the theory that SARS originated in bat populations before jumping first to civet cats (likely via bat feces) and then to humans. (b)(6)
(b)(6)
(b)(6) (b)(6) (b)(6)

(b)(6)
(b)(6) team has provided support in statistical modeling to assess the risk of more coronaviruses like SARS crossing over to human populations.

Ready to Help with the Global Virome Project

8. (U) Institute officials expressed strong interest in the Global Virome Project (GVP), and said Chinese funding for the project would likely come from Chinese Academy of Sciences funding already earmarked for One Belt, One Road-related initiatives. The GVP aims to launch this year as an international collaborative effort to identify within ten years virtually all of the planet's viruses that have pandemic or epidemic potential and the ability to jump to humans. "We hope China will be one of the leading countries to initiate the Global Virome Project," one Wuhan Institute of Virology official said. China attended a GVP unveiling meeting in January in Thailand and is waiting for more details on the initiative. The officials said that the Chinese government funds projects similar to GVP to investigate the background of viruses and bacteria. This essentially constituted China's own Virome Project, officials said, but they noted the program currently has no official name.

9. (SBU) The Wuhan Institute of Virology's (b)(6) is the (b)(6) (b)(6) (b)(6) which is designed to show "proof of concept" and be a forerunner to the Global Virome Project. (b)(6) with the EcoHealth Alliance (a New York City-based NGO that is working with the University of California, Davis to manage the (b)(6) recently planned to visit Wuhan to meet with (b)(6) (b)(6) noted that China has expressed interest in building the GVP database, which would put China in a leadership position. Other countries have confidence in China's ability to build such a database, but are skeptical on whether China could remain transparent as a "gatekeeper" for this information (b)(6) said (b)(6) expressed frustration with the slow progress so far in launching GVP, noting that the effort lacked funding sources, needed to hire a CEO, and would have to boost its profile at G7, G20 and other high-level international meetings.

U.S.-China Workshop Explores Research Partnerships

10. (U) The Institute also has ongoing collaboration with the U.S. National Science Foundation, including a just-concluded workshop in Shenzhen, involving about 40 scientists from the United States and China, on the topic of the "Ecology and Evolution of Infectious Diseases." Co-sponsored by the Natural Science Foundation of China (NSFC), (b)(6) (b)(6) (b)(6) The workshop explored opportunities for U.S.-China research cooperation in areas like using "big data" to predict emerging infectious diseases, climate change's effect on vector-borne diseases, and pathogen transmission between wildlife, domestic animals and humans.

11. (SBU) Some workshop participants also expressed skepticism about the Global Virome Project's (GVP) approach, saying that gaining a predictive understanding of viruses with pandemic potential would require going beyond the GVP's strategy of sample collection, to take an "ecological" approach that considers the virome beyond vertebrate systems to identify

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mechanisms driving pathogen evolution. A follow-on workshop will be held in June at the University of Berkeley. NSF and NSFC hope to jointly announce a funding call for collaborative projects later this year.

Signature: FOUSS

Drafted By:
Cleared By:

(b)(6)

Approved By:
Released By:
Info:

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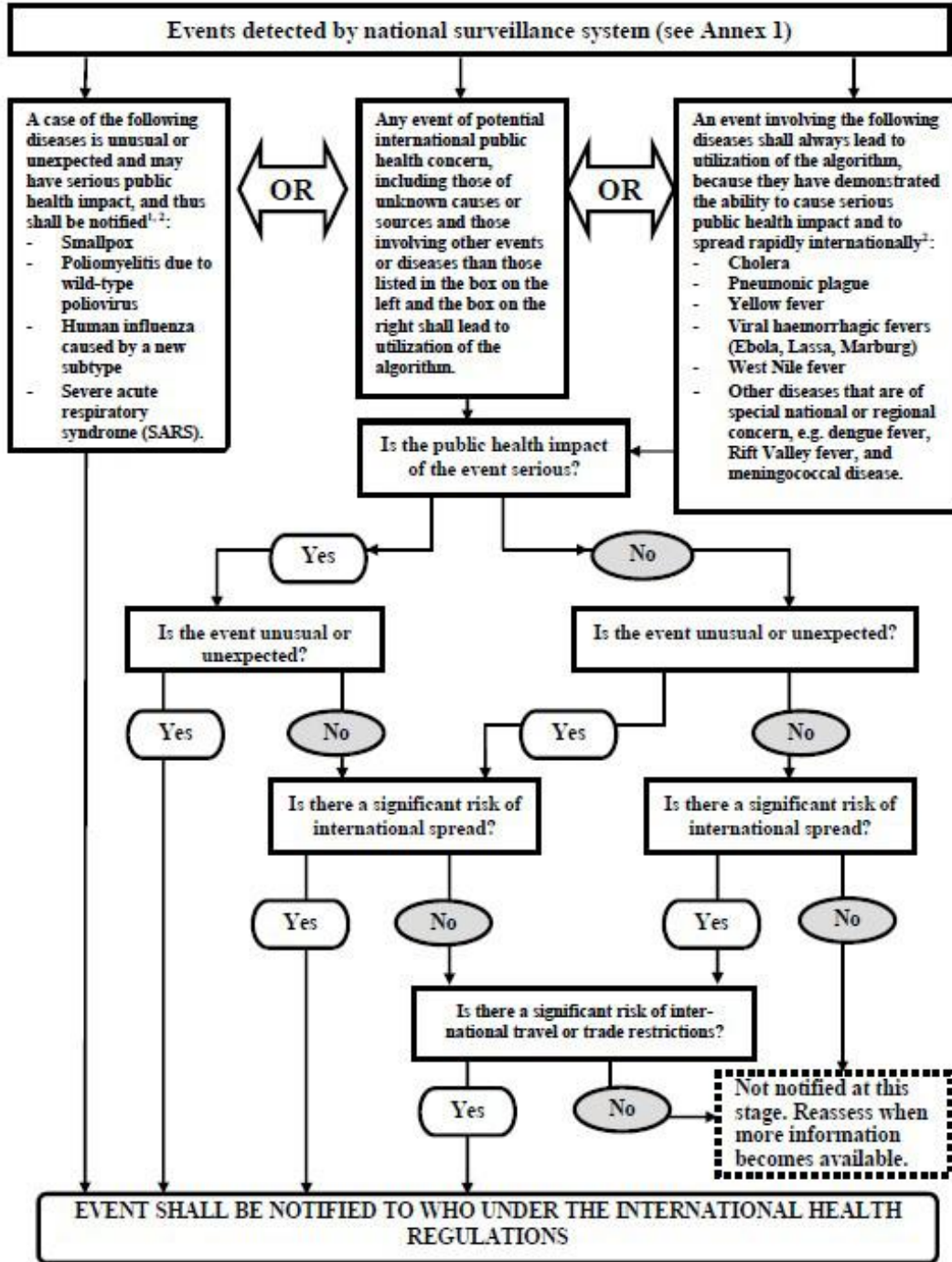
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Page 4 of 4

Annex 2 of the 2005 International Health Regulations

ANNEX 2
 DECISION INSTRUMENT FOR THE ASSESSMENT AND NOTIFICATION
 OF EVENTS THAT MAY CONSTITUTE A PUBLIC HEALTH EMERGENCY
 OF INTERNATIONAL CONCERN



¹ As per WHO case definitions.

² The disease list shall be used only for the purposes of these Regulations.

From: [Hallett, Adrienne \(NIH/OD\) \[E\]](#)
To: [Collins, Francis \(NIH/OD\) \[E\]](#)
Cc: [Tabak, Lawrence \(NIH/OD\) \[E\]](#); [Burklow, John \(NIH/OD\) \[E\]](#); [Higgins, Lauren \(NIH/OD\) \[E\]](#); [Berkson, Laura \(NIH/OD\) \[E\]](#); [Murray, Katie \(NIH/OD\) \[E\]](#); [Kolberg, Rebecca \(NIH/OD\) \[E\]](#); [George, Jill \(NIH/OD\) \[E\]](#); [Pelis, Kim \(NIH/OD\) \[E\]](#); [Wood, Gretchen \(NIH/OD\) \[E\]](#); [McManus, Ayanna \(NIH/OD\) \[E\]](#); [Allen-Gifford, Patrice \(NIH/OD\) \[E\]](#); [Casselle, Julia \(NIH/OD\) \[E\]](#)
Subject: Re: PASC Hearing 4/28 Final (?) Update
Date: Tuesday, April 27, 2021 10:10:57 PM

Yes, it's classic Alan. And it's important to note that this is not an Oversight subcommittee hearing so he won't be the primary staff making decisions on what gets presented to her.

The Health Subcommittee staffer, who is the primary, told us that Alan's proposed question has been re-worded in a more friendly manner. IE. "As you know I sent a letter. Do you agree with WHO Director that an independent investigation is warranted?"

That said, we are working on a response. (b) (5)

[Redacted]

On Apr 27, 2021, at 8:52 PM, Collins, Francis (NIH/OD) [E]

<(b) (6)> wrote:

Hi Adrienne et al.,

Thanks for these items. I will have a look at the opening statement shortly. But first, a question about the McM-R letter (attached again, presumably authored by Slobodin). Wow, 11 pages, 29 very detailed questions, 40 footnotes. Responses were due April 19. Where are we in the process of providing that response? We briefly discussed the appropriate answer to her question from the polling ("Do you agree with the Director-General of WHO..."), and seemed to agree (b) (5)

[Redacted]. In the March 18 letter, she suggests (page 2) that NIH should play a prominent role in such a follow up investigation, since we funded some of the research at WIV. She may well press that point. (b) (5)

[Redacted]

[Redacted] I would be grateful for some TPs on this – for which you might also need to consult NIAID.

Tx, FC

From: Hallett, Adrienne (NIH/OD) [E] <(b) (6)>

Sent: Tuesday, April 27, 2021 7:01 PM

To: Collins, Francis (NIH/OD) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E]

< (b) (6) Burklow, John (NIH/OD) [E] < (b) (6)
Cc: Higgins, Lauren (NIH/OD) [E] < (b) (6) Berkson, Laura (NIH/OD) [E]
< (b) (6) Murray, Katie (NIH/OD) [E] < (b) (6)
Kolberg, Rebecca (NIH/OD) [E] < (b) (6) George, Jill (NIH/OD) [E]
< (b) (6) Pelis, Kim (NIH/OD) [E] < (b) (6) Wood, Gretchen
(NIH/OD) [E] < (b) (6) McManus, Ayanna (NIH/OD) [E]
< (b) (6) Allen-Gifford, Patrice (NIH/OD) [E] <patrice.allen-
gifford@nih.gov>; Casselle, Julia (NIH/OD) [E] < (b) (6)

Subject: PASC Hearing 4/28 Final (?) Update

Hi FC,

I'm writing to share some prep materials for the hearing tomorrow including an updated draft of your oral testimony, an update to the polling chart, and the March 2021 letter from Rep. McMorris Rodgers on WIV.

Your testimony has suggested edits from both Rebecca and I. In addition to my suggested cuts, I proposed a sentence or two (b) (5). See what you think.

We made a number of updates to BRAIN, listed below. Higgins and Katie will be on BRAIN during the hearing to chat you records. I think you will only need them if a question comes up that is way off topic but we like to be prepared for anything. OLPA staff will be available tomorrow morning to answer any last minute questions. I will start the text chain about an hour before the hearing.

Adrienne

Logistics

- The hearing will take place on Wednesday, April 28th at 11am. It will be completely virtual, via WebEx.
- There will be two panels.
 - First Panel – Federal Witnesses
 - NIH Director Dr. Francis Collins
 - CDC Chief Medical Officer for COVID-19 Response Dr. John Brooks
 - Second Panel – Non-federal witnesses
 - [Steven Deeks](#), M.D., Professor of Medicine, University of California, San Francisco
 - [Jennifer Possick](#), M.D., Associate Professor, Section of Pulmonary, Critical Care and Sleep Medicine, Yale School of Medicine; Director, Post-COVID Recovery Program, Winchester Center for Lung Disease, Yale-New Haven Hospital
 - [Natalie Hakala](#), Patient, Eugene, OR
 - [Lisa McCorkell](#), Patient, Oakland, CA
 - [Chimere Smith](#), Patient, Baltimore, MD

Polling

- An updated polling document is attached. We will continue to update it if we received additional intel tonight or tomorrow morning.

WebEx

- The hearing will be conducted virtually via WebEx.
- Staff suggest you use the “grid view” so you can see Members and the 5 minute

countdown clock. They also suggest muting unless you are speaking and leaving your camera on at all times during the hearing.

- The virtual hearing room will open at 10:30am EDT Wednesday morning. The committee staff would like witnesses to join the WebEx by 10:45am EDT and turn their cameras on by 10:55am.
- On the day of the hearing, you will login using the event address for witnesses:
<https://ushr.webex.com/ushr/onstage/g.php?MTID=e3206c20ac92e14475ce98a6ec1a9eac4>

Email: (b) (6)

Passcode: (b) (6)

[Guides for Witnesses](#)

- OLPA staff will also be on the WebEx, but will use a staff login and will not have camera/microphone capabilities. There will be about a 60-90 second delay between the WebEx stream and the video stream on the committee's website.

BRAIN Logistics

- As we discussed on the prep call, BRAIN will be accessible to you during the if you want to use it, despite the fact that you will not be able to project images. I will start a text chain so you can ask questions in real-time during the hearing.
- BRAIN Records that have been updated today:
 - 01- Range of Symptoms - Long COVID
 - 02 - Incidence - Long COVID
 - 03 - Involvement of Children (Long COVID and MIS-C)
 - 04 - Vaccine Effects – Long COVID
 - 05 - NIH Research Plan Components and Timeline – Long COVID
 - 06 - Post-Acute COVID
 - 07 - PASC Initiative Slide Deck
 - 08 - COVID Origin (Letter from Rep. McMorris Rodgers is included in the record)
 - 09 – Long COVID and ME/CFS
 - GAO Audit on IT Security
 - A1 - COVID Understanding and combatting COVID19 (inc. natural history)
 - A2 - COVID Therapeutics
 - A3 - COVID Vaccines
 - A4 - COVID Diagnostics
 - A5 - COVID-19 Supplemental Appropriations

Let us know if you have questions or need any additional information.

Adrienne

Attachments:

- Polling Chart
- Bios of E&C Health Subcommittee Members
- Bios of E&C Full Committee Members that plan to “waive on”
- Updated Oral Testimony
- Letter from Rep. McMorris Rodgers and others on WIV

<2021.03.16 - NIH Letter on WIV[2][1].pdf>

FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

CATHY McMORRIS RODGERS, WASHINGTON
RANKING MEMBER

ONE HUNDRED SEVENTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6115

Majority (202) 225-2927

Minority (202) 225-3641

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.”² 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

² Smriti Mallapaty, *Where did COVID come from? WHO investigation begins but faces challenges*, NATURE (Nov. 11, 2020), available at <https://www.nature.com/articles/d41586-020-03165-9>.

³ The White House, Statement of National Security Advisor Jake Sullivan (Feb. 13, 2021), available at <https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/13/statement-by-national-security-advisor-jake-sullivan/>.

⁴ Betsy McKay, Drew Hinshaw and Jeremy Page, *WHO Investigators to Scrap Plans for Interim Report on Probe of Covid-19 Origins*, THE WALL STREET JOURNAL (Mar. 4, 2021), available at https://www.wsj.com/articles/who-investigators-to-scrap-interim-report-on-probe-of-covid-19-origins-11614865067?mod=latest_headlines

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%20\(1\).pdf](https://s.wsj.net/public/resources/documents/COVID%20OPEN%20LETTER%20FINAL%20030421%20(1).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/>. (“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.”)

⁶ 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>.

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.⁷ 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.⁸

In January 2021, the U.S. Department of State issued a fact sheet about the activity at the WIV.⁹ 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.¹⁰
- 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).¹¹ 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.¹² But the WIV has not been transparent or consistent about its record of

⁷ NIH RePORTER, *Research Portfolio Online Reporting Tools* (queried Mar. 4, 2021), available at <https://reporter.nih.gov/search/qlYUeI9DIk2JfWUdCcWxcA/projects/charts>.

⁸ Mark Moore, *NIH investigating Wuhan lab at center of coronavirus pandemic*, NEW YORK POST (Apr. 28, 2020), available at <https://nypost.com/2020/04/28/nih-investigating-wuhan-lab-at-center-of-coronavirus-pandemic/>.

⁹ U.S. Department of State, *Fact Sheet: Activity at the Wuhan Institute of Virology*, Office of the Spokesperson (Jan. 15, 2021), available at <https://2017-2021.state.gov/fact-sheet-activity-at-the-wuhan-institute-of-virology/index.html>.

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

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.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.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.¹⁵ The WIV has engaged in classified research, including laboratory animal experiments, on behalf of the Chinese military since at least 2017.¹⁶
- 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.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.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.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.²⁰ That, along with what is known of the WIV’s work in past few years, raised reasonable suspicion that the

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

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>

¹⁹ Fred Guterl, Naveed Jamali and Tom O’Connor, *The Controversial Experiments at Wuhan Lab Suspected of Starting the Coronavirus Pandemic*, NEWSWEEK (Apr. 27, 2020), available at <https://www.newsweek.com/controversial-wuhan-lab-experiments-that-may-have-started-coronavirus-pandemic-1500503>.

²⁰ *Id.*

pandemic may have been caused by a lab error, not a wet market.²¹ 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.”²² 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.”²³ 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.²⁴ 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, sub-grantees, contractors, or 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, sub-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

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](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.*

²⁴ Mike Pompeo and Miles Yu, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, *THE WALL STREET JOURNAL* (Feb. 23, 2021), *available at* <https://www.wsj.com/articles/chinas-reckless-labs-put-the-world-at-risk-11614102828>.

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

²⁵ Meredith Wadman, *NIH imposes 'outrageous' conditions on resuming coronavirus grant targeted by Trump*, SCIENCEMAG (Aug. 19, 2020), available at <https://www.sciencemag.org/news/2020/08/nih-imposes-outrageous-conditions-resuming-coronavirus-grant-targeted-trump>.

²⁶ National Institutes of Health, *Notice Announcing the Removal of the Funding Pause for Gain-of-Function Research Project* (Dec. 19, 2017), available at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-071.html>.

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."²⁸ 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?²⁹
- 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?³⁰
- 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.³¹

²⁸ Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19, 2020), available at <https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400>.

²⁹ Meredith Wadman, *NIH imposes 'outrageous' conditions on resuming coronavirus grant targeted by Trump*, SCIENCEMAG (Aug. 19, 2020), available at <https://www.sciencemag.org/news/2020/08/nih-imposes-outrageous-conditions-resuming-coronavirus-grant-targeted-trump>.

³⁰ *Id.*

³¹ Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19, 2020), available at <https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400>.

- 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."³² 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?³³
 - 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."³⁴ 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.*

³⁴ Meredith Wadman and Jon Cohen, *NIH's axing of bat coronavirus grant a 'horrible precedent' and might break rules, critics say*, SCIENCEMAG (Apr. 30, 2020), available at <https://www.sciencemag.org/news/2020/04/nih-s-axing-bat-coronavirus-grant-horrible-precedent-and-might-break-rules-critics-say>.

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.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?³⁶
20. According to a report in *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, 2018.³⁷ 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.

³⁵ Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19, 2020), available at <https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400>.

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

³⁷ Josh Rogin, *Opinion: State Department cables warned of safety issues at Wuhan lab studying bat coronaviruses*, THE WASHINGTON POST (Apr. 14, 2020), available at <https://www.washingtonpost.com/opinions/2020/04/14/state-department-cables-warned-safety-issues-wuhan-lab-studying-bat-coronaviruses/>.

26. According to an editorial in *The Wall Street Journal*, the WIV housed tens of thousands of bat samples and laboratory animals in 2019.³⁸ 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?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).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

³⁸ Mike Pompeo and Miles Yu, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Feb. 23, 2021), available at <https://www.wsj.com/articles/chinas-reckless-labs-put-the-world-at-risk-11614102828>.

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>.

⁴⁰ Latinne, A., Hu, B., Olival, K.J. et al., *Origin and cross-species transmission of bat coronaviruses in China*, *Nature* (Aug. 25, 2020), available at <https://www.nature.com/articles/s41467-020-17687-3#Ack1>.

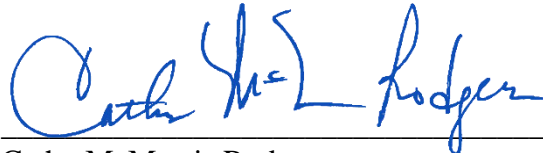
Letter to the Honorable Francis Collins, M.D., Ph.D.

Page 11

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.

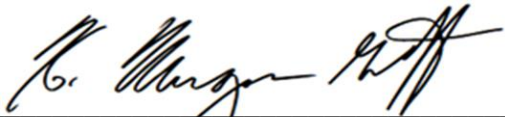
Sincerely,



Cathy McMorris Rodgers
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 Diana DeGette, Chair, Subcommittee on Oversight and Investigations
The Honorable Anna Eshoo, Chair, Subcommittee on Health

From: [Jorgenson, Lyric \(NIH/OD\) \[E\]](#)
To: [Collins, Francis \(NIH/OD\) \[E\]](#)
Cc: [Hallett, Adrienne \(NIH/OD\) \[E\]](#); [Burklow, John \(NIH/OD\) \[E\]](#)
Subject: RE: Gain of function research
Date: Wednesday, April 28, 2021 10:42:08 AM

(b) (5) However, NIAID asserts that the EcoHealth Alliance grant was not gain-of-function research because it did not involve the enhancement of the pathogenicity or transmissibility of the viruses studied. Therefore, the research was not subject to either the Gain-of-Function Research Funding Pause or its successor, the [DHHS Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens](#).

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, April 28, 2021 10:19 AM
To: Jorgenson, Lyric (NIH/OD) [E] <(b) (6)>
Cc: Hallett, Adrienne (NIH/OD) [E] <(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)>
Subject: RE: Gain of function research
Thanks. (b) (5)

FC

From: Jorgenson, Lyric (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, April 28, 2021 9:51 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Hallett, Adrienne (NIH/OD) [E] <(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)>
Subject: RE: Gain of function research

Hi Francis,

Please see attached. We've reached out to NIAID but have a strong suspicion they will also be confused. It wouldn't surprise me if the reporter was simply interchanging "Tony working with OSTP" for "NIH working with OSTP". The GOF funding pause and subsequent policy guidance was led through the White House.

Please let me know if any additional information would be useful here.

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, April 28, 2021 7:58 AM
To: Jorgenson, Lyric (NIH/OD) [E] <(b) (6)>
Cc: Hallett, Adrienne (NIH/OD) [E] <(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)>
Subject: Gain of function research

Hi Lyric,

Just saw this NR report: <https://www.nationalreview.com/corner/fauci-reportedly-relaunched-nih-gain-of-function-research-without-consulting-white-house/>

While this is unlikely to come up in this morning's House hearing on Long COVID, you can never tell. Can you provide me a quick set of TPs to respond to this confusing set of claims from Josh Rogin? What is this about Fauci contacting OSTP about GoF research?

FC

GOF Funding Pause and HHS P3CO Framework Implementation

(b) (5)



From: [Lauer, Michael \(NIH/OD\) \[E\]](#)
To: [Bulls, Michelle G. \(NIH/OD\) \[E\]](#); [Jacobs, Anna \(NIH/OD\) \[E\]](#)
Cc: [Lauer, Michael \(NIH/OD\) \[E\]](#); [Ta, Kristin \(NIH/OD\) \[E\]](#); [Tabak, Lawrence \(NIH/OD\) \[E\]](#)
Subject: FW: Regarding 2R01AI110964-06
Date: Sunday, April 11, 2021 5:18:38 PM
Attachments: [Response to NIH April 2021 re. reactivation and suspension of 2R01AI110964.pdf](#)
[NIH Response to EcoHealth Response to Suspension 10 23 20.pdf](#)
[Daszak 7 8 20.pdf](#)
Importance: High

Hi Michelle and Anna – please take a look and see what you think.

Of note, we're provided with no documents – no subaward agreements and no biosafety reports.

Many thanks, Mike

From: Peter Daszak <[REDACTED]> (b) (6)
Date: Sunday, April 11, 2021 at 4:39 PM
To: "Lauer, Michael (NIH/OD) [E]" <[REDACTED]> (b) (6)
Cc: Aleksei Chmura <[REDACTED]> (b) (6)
Subject: Regarding 2R01AI110964-06

Dear Dr. Lauer,

Please find attached a detailed response to your two previous letters.

I hope you will take our response in the way it was intended – a good faith effort to address as far as is reasonably possible the general concerns that NIH has expressed to us, with a goal of rapid and full removal of the suspension on funding for this critically important work.

Cheers,

Peter

Peter Daszak

President

EcoHealth Alliance

520 Eighth Avenue, Suite 1200

New York, NY 10018-6507

USA

Tel.: [REDACTED] (b) (6)

Website: www.ecohealthalliance.org

Twitter: [@PeterDaszak](https://twitter.com/PeterDaszak)

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: Lauer, Michael (NIH/OD) [E] <[REDACTED]> (b) (6)
Sent: Wednesday, March 10, 2021 5:37 AM
To: Peter Daszak <[REDACTED]> (b) (6)
Cc: Aleksei Chmura <[REDACTED]> (b) (6); Lauer, Michael (NIH/OD) [E] <[REDACTED]> (b) (6)
Subject: Re: Regarding 2R01AI110964-06

Dear Dr. Daszak

Attached please find two letters that I sent you previously.

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)

From: Peter Daszak <(b) (6)>
Date: Thursday, March 4, 2021 at 10:02 PM
To: "Lauer, Michael (NIH/OD) [E]" <(b) (6)>
Cc: Aleksei Chmura <(b) (6)> **Peter Daszak:] REDACTED<**
Subject: Regarding 2R01AI110964-06

Dear Dr. Lauer,

I spoke yesterday with my program officer and other NIAID staff regarding our grant on the risk of coronavirus emergence (2R01AI110964-06) that includes collaboration with scientists at the Wuhan Institute of Virology, China. **[Peter Daszak:] REDACTED** joined the meeting and told me about his conversation with you about the conditions currently in place on our grant and my efforts to address some of them via my recent work in Wuhan with the WHO. He also commented that you would be willing to talk with me, as PI of this award, about a pathway to reinstate this grant. I would very much value this and am emailing to see if we can arrange a time that's suitable for you, perhaps next week if possible?

I'm cc'ing my assistant **REDACTED**, who can help arrange a suitable time, and also our Chief of Staff Aleksei Chmura, who I would hope could join us, as someone who can access any relevant information on this award, and gained his own Ph.D as part of our original R01 work in China. I want to reassure you that I would not request to talk with legal counsel or bring them into a conversation, and that this would be a discussion with scientists focused on the goals of the grant, focused on research to protect us all against further coronavirus spillover.

Sincerely,

Peter

Peter Daszak

President

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

Tel.: (b) (6)

Website: www.ecohealthalliance.org

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

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EcoHealth Alliance

Dr. Michael Lauer
Deputy Director for Extramural Research,
NIH, Bethesda, MD.

Response to the Reinstatement and immediate suspension of 2R01AI110964
“Understanding the Risk of Bat Coronavirus Emergence”

April 11th 2021

Dear Dr. Lauer,

I am responding your letters of 7/8/2020 and 10/3/2020 regarding the reinstatement and immediate suspension of NIH grant 2R01AI110964 “*Understanding the Risk of Bat Coronavirus Emergence*”, that was terminated “for convenience” on 4/24/2020. In particular, this letter addresses the conditions you state would need to be fulfilled in order for us to have access to the funds to continue this work.

As you know, we had not set up any subcontracts to the Wuhan Institute of Virology under this renewal R01. Immediately following NIH's letter on 4/19/2020 that the WIV was being ‘investigated’, we suspended all plans for contractual work with WIV. This termination of a funded relationship with the institute makes it extraordinarily difficult and more likely impossible to provide the information requested about an autonomous foreign organization – as would also be the case for a domestic one - that our organization neither works with currently, nor has control over.

Additionally, our collaborative work with the Wuhan Institute of Virology prior to your grant termination letter of 4/24/2020 and that planned in the suspended grant, is wholly unrelated to many of the conditions listed below. These conditions also pertain to certain events and situations that in no way involve EcoHealth Alliance or are not under our control. Thus, most of the conditions below are either unrelated to EcoHealth Alliance’s planned research in our highly rated, approved and funded grant application, and/or to the biosafety of our continued research funded by the suspended grant when it is reinstated in full.

Furthermore, in our recent correspondence with NIH regarding the latest in a series of FOIA requests, we were informed (1/26/2021 – see email correspondence at the end of this letter) by an NIH staff member Garcia-Malene Gorka that “any indication from my program that there is an ongoing investigation into WIV can now be disregarded, as we recently confirmed there are no pending investigations into that organization.” Because this was the explanation in your initial letter of 4/19/2020 for the decisions from your office regarding restrictions on, termination of, then reinstatement and suspension of our grant, we believe that these decisions should now be reassessed.

Despite our concerns about the relevance, fairness, or ability to fulfil the conditions as set forth in detail below, I have made extensive efforts to satisfy NIH's broad concerns, and have provided details of how these are relevant to each condition below. This includes serving as an expert on the WHO-China joint Mission on the Animal Origins of COVID-19, which involved 1 month on the ground in China (including 2 weeks locked in quarantine), at great personal burden and risk to me, to our organization, and to my family. I undertook this mission at a time when I have had increasing levels of personal attack and harassment, including a white-powder letter to my home address a few weeks after the details of our grant termination went public, and death threats that begun at the same time and continue to this day. It is clear in the wording of these attacks that many are a direct result of dangerous conspiracy theories inadvertently amplified by NIH's grant termination, and repeated in the conditions listed below. This type of harassment has accelerated to the point that personal security guards are now stationed at my home address, where I have also had to install invasive equipment and set up procedures to protect my family against expected violent attacks. Additionally, I now meet regularly with FBI agents and others at my home to monitor these threats. As I am sure you appreciate, this has a significant toll on my work, my personal life and my family.

Below, I detail our response to each of the conditions placed on our suspended grant, in an effort to provide as much information as possible and to explain the limitations on what we can do to respond. I look forward to your reply and hope that these will allow NIH to lift the suspension on funding so that we can continue our work to help protect our nation, indeed the global population, against future coronavirus pandemics. Should you wish, I feel certain we may discuss these points without legal counsel in a scientist-to-scientist conversation, as you have suggested verbally to others at NIH, and they have conveyed to me.

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.

We believe this condition is effectively impossible for us to fulfil, for the following reasons. Firstly, there is no scientific nor administrative rationale for us to attempt to obtain a SARS-CoV-2 aliquot given that it is not part of our funded collaboration with WIV. Secondly, EcoHealth Alliance scientists do not have any capacity to work on such an aliquot (EHA does not conduct virological laboratory work on SARS-CoV-2) in the USA. This further reduces the validity of a scientific basis for this request to WIV. Thirdly, EcoHealth Alliance scientists were not part of the work that WIV conducted to determine the viral sequence of SARS-CoV-2, and this was not part of our (then active) R01 funded collaboration. This is publicly stated by the lack of EHA authors listed on the paper and the lack of acknowledgement of our grant as a funding source for this work. This publicly discounts any claim of sample ownership or control. Fourthly, the collaborative research laid out in our now-suspended grant does not include the shipping of human viral isolates out of China. Finally, during the last 16 months, there has been a series of vitriolic attacks from the US Government accusing China of bioengineering and releasing SARS-CoV-2 or of otherwise allowing COVID to become pandemic. Given these attacks, and WIV's status as a government entity, it seems to us incredulous that any request, particularly without scientific rationale, from a US non-profit to a Chinese Government laboratory for an active sample of a pathogenic human virus would likely be successful. We note that 1) to our knowledge China has not supplied such an aliquot to any formal request from a government; and 2) that if circumstances were reversed and a Chinese non-

governmental institution requested a similar pathogenic viral aliquot from a US government BSL-4 laboratory, this would also be unlikely to be fulfilled.

While we understand that it may be of scientific interest to some US-based researchers to analyze this viral sequence, this scientific interest could easily be satisfied without the need for an aliquot. The full genome of this viral sequence was uploaded to a freely accessible database on January 10 2020, and has been used widely by scientists in the USA (included those funded by NIH) and around the world in their work. Furthermore, isolates of the virus from patients in Thailand and Australia during early 2020 are essentially the same, and have been shared extensively.

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.

International experts on the WHO COVID-19 origins mission, including myself, asked direct questions on this issue to staff at WIV, including the Director of the institute, the P4 Lab Director, Dr. Shi and others. The response from all was consistent, as stated in the WHO mission report published 3/30/2020: “This person according the WIV staff was an alumnus who graduated in 2015 and was now working in a different province and did not accept to talk with media. The person had been contacted and tested and ascertained to be healthy.”

Given that the WHO team was not given access to this individual, and that China’s personal privacy laws are preclude our ability to insist on a meeting, it is difficult to see how a request from a US non-profit would have been approved. It seems at the least to be significantly outside the remit of a US-based non-profit organization to inquire further about the whereabouts of a citizen of a foreign country who has never to our knowledge been involved in our work, and over whom we have no control, influence, nor legal responsibility.

Finally, while many conspiracy theorists have suggested that the lack of a web presence of this person suggests some nefarious activity, there are dozens of unremarkable and routine reasons why a person may be removed from a web listing of employees or students. Not least of these is when a staff member leaves an institution, or a student graduates.

3. Provide the NIH with WIV’s responses to the 2018 U.S. Department of State cables regarding safety concerns.

We believe that WIV senior staff comments reported in the WHO COVID origins mission report directly address this request in that they publicly state that no significant safety issues were found in their laboratory prior to, or following, the emergence of COVID. Any questions regarding the safety of the WIV also need to be put into the context of the widely published history of this lab as being built to international safety engineering standards, adhering to international safety practice standards indicated in the BMBL, and with lead WIV staff trained in safety in the United States by a known authority running the BSL-4 lab at the University of Texas Medical Branch in Galveston (as reported in the U.S. Dept of State cables). Furthermore, no verifiable evidence of safety issues have been reported prior to, or following the U.S. Dept of State cables.

Regarding the U.S. Dept. of State cables, these do not in fact provide evidence of safety concerns at the laboratory. Neither do they convincingly imply safety issues. In fact, they may be simply interpreted as a request for funding from a diplomatic mission set up to further joint US-China research. It is important to note that initially only very limited phrases from these cables were selectively leaked by a Washington Post reporter in an opinion piece that did not verify nor quote direct sources. This opinion piece is demonstrably incomplete in its reporting, however it has been widely cited as providing evidence of safety issues at WIV (<https://www.washingtonpost.com/opinions/2020/04/14/state-department-cables-warned-safety-issues-wuhan-lab-studying-bat-coronaviruses/>). I have some detailed knowledge of the background to these cables because the diplomatic visit to WIV that they report was a direct result of our NIH-funded work. As part of EcoHealth Alliance's work in China over the past 15 years, including that funded by NIAID, I visited the US Embassy in Beijing regularly and was involved in discussions with US Embassy staff to set up a field visit to the WIV in order to generate goodwill between the US and China at a time when President Trump was planning a state visit. I did this out of a sense of duty to our government, and to the NIH so that our project could help foster goodwill between our countries, as well as provide an indication of the importance of NIH's work. Following the US Embassy staff mission, I was told by people privy to the cable's contents that the articles were positive and supportive of the work we were doing under NIAID funding, and that the trip was a success.

Now that the full text of these cables (embedded at the end of this letter) has been released with minor redactions (<https://news.slashdot.org/story/20/07/20/0611205/full-text-of-us-state-department-cables-finally-released-showing-safety-in-chinese-lab>), it seems that this more positive interpretation is justified. As you can see in the excerpts below, the request for more laboratory technician support could be reasonably interpreted as simply a request for the funding for more laboratory technician support, rather than a statement that the lab was unsafe, particularly given that the visit was set up as part of an effort to further develop US-China collaborative research opportunities. Furthermore, the cables are extremely positive about the importance of the collaborative work we were conducting with WIV under NIAID funding:

"REDACTED noted that the new lab has a serious shortage of appropriately trained technicians and investigators needed to safely operate this high-containment laboratory. University of Texas Medical Branch in Galveston (UTMB), which has one of several well-established BSL-4 labs in the United States (supported by the National Institute of Allergy and Infectious Diseases (NIAID of NIH)), has scientific collaborations with WIV, which may help alleviate this talent gap over time. Reportedly, researchers from GTMB are helping train technicians who work in the WIV BSL-4 lab. Despite this they would welcome more help from U.S. and international organizations as they establish "gold standard" operating procedures and training courses for the first time in China."

"The ability of WIV scientists to undertake productive research despite limitations on the use of the new BSL-4 facility is demonstrated by a recent publication on the origins of SARS. Over a five-year study REDACTED (and their research team) widely sampled bats in Yunnan province with funding support from NIAID/NIH, USAID, and several Chinese funding agencies. The study results were published in PLoS

Pathogens online on Nov. 30, 2017 (1), and it demonstrated that a SARS-like coronaviruses isolated from horseshoe bats in a single cave contain all the building blocks of the pandemic SARS-coronavirus genome that caused the human outbreak. These results strongly suggest that the highly pathogenic SARS-coronavirus originated in this bat population. Most importantly, the researchers also showed that various SARS-like coronaviruses can interact with ACE2, the human receptor identified for SARS coronavirus. This finding strongly suggests that SARS-like coronaviruses from bats can be transmitted to humans to cause SARS-like disease. From a public health perspective, this makes the continued surveillance of SARS-like corona viruses in bats and study of the animal-human interface critical to future emerging coronavirus outbreak prediction and prevention.”

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.

The WIV staff categorically stated to the WHO mission that their lab is audited annually and no unusual events have been identified. The reports of diminished cell-phone traffic and roadblocks have not been verified or published by reliable sources. Furthermore, should hard evidence of diminished cell-phone traffic and roadblocks exist, it is not necessarily indicative of any issues related to concerns about the laboratory studies underway or safety or security incidents within the laboratory. These issues could be explained by any one of a series of issues that occur regularly in the US without nefarious connotations. For example, they could be due to roadwork or other infrastructure repair or maintenance, technical problems with cell-phone transmission, or rerouting of traffic as regularly occurs in Washington DC and other cities due to transport of visiting dignitaries or other events. Finally, there is no credible reason to think that any request a US non-profit might make to the Chinese government for an explanation of traffic or cell-phone issues would result in any response.

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.

Since your letter of 7/8/2020, it has been widely reported that WIV scientists have published an addendum to their original paper in *Nature* that described SARS-CoV-2 and compared it phylogenetically to RaTG13. In this follow-up publication, they explain the rationale for conducting work in this mine, and any potential connection to the miner’s illnesses and deaths. Importantly, they state that serological results in their lab at the time of the incident did not show that these miners were positive for SARSr-CoVs as some media articles have suggested. They then re-tested the miner samples in 2020 using a range of assays, and found no evidence of SARS-related CoV, nor of SARS-CoV-2 specific antibodies or nucleic acid. During the meeting of the WHO mission team with WIV staff, they were asked a series of questions about the miner’s illnesses. The responses were that, while symptoms identified were similar to COVID in that they had pneumonia (a common occupational hazard for miners), their symptoms were also similar to other bacterial or fungal pneumonias. This, and the lack of evidence for SARSr-CoV infection, led them to conclude that SARS or COVID infection was not the cause of these miner’s illnesses.

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 fieldwork (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.

The WHO mission was negotiated at the very highest levels as the legitimate way to proceed in an investigation of COVID-19 origins, particularly with such critical geopolitical ramifications from this pandemic. Given the intensity of political attacks and conspiracy theories around this lab, it is unreasonable to expect that the Chinese government or WIV would respond to a request from a US non-profit for an outside inspection team. The 11 international expert members of the WHO team included authorities on epidemiology, animal-origin viral infections and One Health. Members of this team have extensive experience conducting lab audits (e.g. Dr. Peter Ben Embarek), running laboratories dealing with human clinical samples (e.g. Drs. Dominic Dwyer, Thea Fischer), and commissioning, managing and accrediting laboratories in foreign countries (myself, Dr. Fabian Leendertz). The WHO-China Joint Study report details the field site visits to multiple labs in Wuhan, including the WIV and summarizes our findings. This includes information on the management of the WIV, safety at the labs, audits and training and testing of staff. I acted in good faith to try to conform to the WHO terms of reference while ensuring that as much information on the laboratory was provided in the report. This information specifically addresses one of your questions above, with categorical statements from WIV senior staff that they did not have SARS-CoV-2 in their possession prior to December 2019.

After returning to the USA, and in the weeks prior to the publication of the report, I worked hard to make sure this critical information was shared as rapidly as possible with the US Government and agencies, including by:

- Briefing Drs. Anthony Fauci and Clifford Lane of NIAID on the findings of the mission;
- Presenting a full talk about the work to the NIAID COVID PI group that meets weekly
- Briefing FBI and other US Government intelligence agency staff
- Briefing members of the US NASEM Forum on Microbial Threats
- Briefing staff on the White House National Security Council
- Briefing staff on the House Committee for Science, Space, and Technology

7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System

This has been done and all subawards fully reported as soon as we could once you notified us of this requirement in your letter of 7/8/2020.

8. 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.

As we related in response to your letter of 4/19/2020 that asked us to suspend work with WIV, we had not yet set up a subcontract with WIV for the period of this award, therefore no such subrecipient agreements exist. Our plan was to monitor WIV's compliance as we had in the 5 years prior, by means of semi-annual meetings with the lead investigator and assessments of compliance against all conditions of the award. Additionally, following the NIH's termination, then reinstatement and suspension of our funding, we have contracted with a leading lab biosafety contractor based in Southeast Asia (Dr. Paul Selleck) who has extensive experience commissioning, accrediting and auditing BSL-2, -3, and -4 labs, and has worked for over a decade at the BSL-4 Australian Animal Health Lab. We will be using their services where appropriate for foreign lab subcontractees to assess lab biosafety procedures and conduct audits, including following the full reinstatement of 2R01AI110964. Finally, we have appointed a Senior Field Veterinarian who will oversee all EcoHealth Alliance fieldwork in the region and ensure continued compliance with biosafety when conducting animal capture, sampling and sample handling. We have done this at EcoHealth Alliance's own expense, despite our unblemished record on biosafety, to pre-empt calls for further sanctions against our work given the continued attacks against EcoHealth Alliance in the press after the termination of our NIH grant.

9. Describe EcoHealth's efforts to evaluate WIV's risk of noncompliance with Federal statutes, regulations, and the terms and conditions of the subaward.

Over a 15-year period of collaboration with WIV, we have found no evidence to suggest that there was any element of noncompliance with any of the conditions of the grants or contracts covering our collaboration. Our interactions with all staff at the institute have been professional, respectful, open, and with a focus on the science at a very high level. This has contributed to a relationship built on trust and one that is entirely comparable to our scientific collaborations with laboratories in the US, Europe, Australia, Thailand and over 20 other countries. We continue to believe that this laboratory is highly competent and is an extremely low risk for undisclosed accidental release of virus, and there is no verifiable indication as to why we should not continue to believe so. We would of course consider a change in this assessment if significant and verifiable evidence of lab biosafety issues or breach of other Federal statutes are brought forth, but to date we are aware of none.

10. Provide copies of all WIV biosafety reports from June 1, 2014 through May 31, 2019.

Given the intense geopolitical pressure around the accusations that WIV intentionally or accidentally released SARS-CoV-2 (something which the WHO mission deemed 'extremely unlikely'), obtaining such information is not a plausible option at present.

11. Additional information, re. Lack of ongoing investigation into Wuhan Institute of Virology by NIH:

From: Garcia-Malene, Gorka (NIH/OD) [E] <[REDACTED]> (b) (6)
Sent: Tuesday, January 26, 2021 12:20:51 PM
To: [REDACTED]
Cc: [REDACTED] Bartok, Lauren (NIH/NIAID) [E]; NIH FOIA
Subject: [EXT] FW: FOIA Case No. 55702 re: EcoHealth Alliance & Grant No. R01AI110964-6

Good afternoon, [REDACTED] –

I'd like to insert myself into the unfolding FOIA conversation in hopes of providing some helpful context. Our records show that this competing renewal has in fact been funded. In addition, any indication from my program that there is an ongoing investigation into WIV can now be disregarded, as we recently confirmed there are no pending investigations into that organization. If we can agree on the above, all that would remain is to receive your proposed redactions to the records sought under the FOIA request.

Please let me know if there are any questions. I look forward to facilitating the Pre-Disclosure Notification process as efficiently as possible.

Best regards.

Gorka Garcia-Malene | FOIA Officer for the National Institutes of Health

From: [REDACTED]

Sent: Monday, January 25, 2021 5:21 PM

To: Bartok, Lauren (NIH/NIAID) [E] <[REDACTED]> (b) (6)

Cc: [REDACTED]

Subject: FOIA Case No. 55702 re: EcoHealth Alliance & Grant No. R01AI110964-6

Dear Ms. Bartok:

As you may recall, this firm represents EcoHealth Alliance, Inc. ("EcoHealth Alliance"), with respect to certain FOIA requests, including the instant request, FOIA Case No. 55702. The instant request seeks the same documents sought last year in FOIA Case No. 53996, regarding the research project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant 2R01AI110964. A copy of our prior letter regarding FOIA 53996 is available via the link provided below using the password [REDACTED]. On the grounds set forth in the letter, FOIA 53996 was denied in its entirety.

Likewise, FOIA 55702 should be denied and the grant documents should be withheld. First, grant 2R01AI110964-06 remains an unfunded competing renewal grant that is the subject of a pending first-level appeal and, thus, the materials are not subject to disclosure under NIH Grants Policy Statement §2.3.11.2.2. Moreover, in the context of the appeal, NIH has made multiple requests for further information regarding The Wuhan Institute of Virology ("WIV"), which requests indicate that a law enforcement investigation concerning WIV remains ongoing. Second, as demonstrated by the recent attack on the US Capital fueled by disinformation and conspiracy theories, the need to protect the privacy of EcoHealth Alliance's employees and affiliates is more important than ever. Last, while EcoHealth Alliance did not initially identify that the grant proposal contained confidential-commercial and propriety information, this is not dispositive. Moreover, since the

filing of the renewal application, there has been a global COVID-19 pandemic, which has sparked international and highly competitive research in the area of bat coronaviruses.

At the very least, the responsive documents will require significant redactions. While the grant documents were previously reviewed and redacted in connection with FOIA 53996, we require a further opportunity to review the documents to confirm, *inter alia*, that all personnel information has been removed given the heightened risk of harm in this unprecedented political environment. Accordingly, EcoHealth Alliance respectfully requests a forty-five (45) day extension of time to respond to FOIA 55702, to allow sufficient time for EcoHealth Alliance to conduct a further review of the responsive documents and provide an updated letter response that incorporates recent developments and specific justifications for additional redactions.

Please confirm that NIH will deny FOIA 55702 in its entirety or that NIH is agreeable to EcoHealth Alliance's request for an extension of time to provide a particularized response to FOIA 55702. Please also confirm NIH's receipt of this email.

Thank you.

Best,
[REDACTED]

FOIA Case No. 53996 - EcoHealth Alliance's Letter Response to FOIA Request, dated June 5, 2020 (With Exhibits)

[REDACTED]



[REDACTED]

Tarter Krinsky & Drogin LLP
1350 Broadway | New York | NY | 10018
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[COVID-19 RESOURCE CENTER](#)

12. Publicly released details of U.S. Department of State Cables regarding visit to Wuhan Institute of Virology, as cited in condition #3 above. These are available from a number of sources, including the Washington Post and (<https://news.slashdot.org/story/20/07/20/0611205/full-text-of-us-state-department-cables-finally-released-showing-safety-in-chinese-lab>).

UNCLASSIFIED

SBU



MRN: 18 BEIJING 138
Date/DTG: Jan 19, 2018 / 190739Z JAN 18
From: AMEMBASSY BEIJING
Action: WASHDC, SECSTATE *ROUTINE*
E.O.: 13526
TAGS: SHLH, ETRD, ECON, PGOV, CN
Captions: SENSITIVE
Reference: 17 WUHAN 48
Subject: China Opens First Bio Safety Level 4 Laboratory

1. (SBU) **Summary and Comment:** The Chinese Academy of Sciences (CAS) has recently established what is reportedly China's first Biosafety Level 4 (BSL-4) laboratory in Wuhan. This state-of-the-art facility is designed for prevention and control research on diseases that require the highest level of biosafety and biosecurity containment. Ultimately, scientists hope the lab will contribute to the development of new antiviral drugs and vaccines, but its current productivity is limited by a shortage of the highly trained technicians and investigators required to safely operate a BSL-4 laboratory and a lack of clarity in related Chinese government policies and guidelines. (b)(5)

(b)(5)

(b)(5)

End Summary and Comment.China Investing in Infectious Disease Control

2. (U) Between November 2002 and July 2003, China faced an outbreak of Severe Acute Respiratory Syndrome (SARS), which, according to the World Health Organization, resulting in 8,098 cases and leading to 774 deaths reported in 37 countries. A majority of cases occurred in China, where the fatality rate was 9.6%. This incident convinced China to prioritize international cooperation for infectious disease control. An aspect of this prioritization was China's work with the Jean Merieux BSL-4 Laboratory in Lyon, France, to build China's first high containment laboratory at Wuhan's Institute of Virology (WIV), an institute under the auspices of the Chinese Academy of Sciences (CAS). Construction took 11 years and \$44 million USD, and construction on the facility was completed on January 31, 2015. Following

two years of effort, which is not unusual for such facilities, the WIV lab was accredited in February 2017 by the China National Accreditation Service for Conformity Assessment. It occupies four floors and consists of over 32,000 square feet. WIV leadership now considers the lab operational and ready for research on class-four pathogens (P4), among which are the most virulent viruses that pose a high risk of aerosolized person-to-person transmission.

Unclear Guidelines on Virus Access and a Lack of Trained Talent Impede Research

3. (SBU) In addition to accreditation, the lab must also receive permission from the National Health and Family Planning Commission (NHFPC) to initiate research on specific highly contagious pathogens. According to some WIV scientists, it is unclear how NHFPC determines what viruses can or cannot be studied in the new laboratory. To date, WIV has obtained permission for research on three viruses: Ebola virus, Nipah virus, and Xinjiang hemorrhagic fever virus (a strain of Crimean Congo hemorrhagic fever found in China's Xinjiang Province). Despite this permission, however, the Chinese government has not allowed the WIV to import Ebola viruses for study in the BSL-4 lab. Therefore, WIV scientists are frustrated and have pointed out that they won't be able to conduct research project with Ebola viruses at the new BSL-4 lab despite of the permission.

(b)(6)

(b)(6)

Thus, while the BSL-4 lab is ostensibly fully accredited, its utilization is limited by lack of access to specific organisms and by opaque government review and approval processes. As long as this situation continues, Beijing's commitment to prioritizing infectious disease control - on the regional and international level, especially in relation to highly pathogenic viruses, remains in doubt.

(b)(6)

(b)(6) noted that the new lab has a serious shortage of appropriately trained technicians and investigators needed to safely operate this high-containment laboratory. University of Texas Medical Branch in Galveston (UTMB), which has one of several well-established BSL-4 labs in the United States (supported by the National Institute of Allergy and Infectious Diseases (NIAID of NIH)), has scientific collaborations with WIV, which may help alleviate this talent gap over time. Reportedly, researchers from GTMB are helping train technicians who work in the WIV BSL-4 lab. Despite this, (b)(6) they would welcome more help from U.S. and international organizations as they establish "gold standard" operating procedures and training courses for the first time in China. As China is building more BSL-4 labs, including one in Harbin Veterinary Research Institute subordinated to the Chinese Academy of Agricultural Sciences (CAAS) for veterinary research use (b)(6) the training for technicians and investigators working on dangerous pathogens will certainly be in demand.

Despite Limitations, WIV Researchers Produce SARS Discoveries

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6. (SBU) The ability of WIV scientists to undertake productive research despite limitations on the use of the new BSL-4 facility is demonstrated by a recent publication on the origins of SARS. Over a five-year study, (b)(6) (and their research team) widely sampled bats in Yunnan province with funding support from NIAID/NIH, USAID, and several Chinese funding agencies. The study results were published in PLoS Pathogens online on Nov. 30, 2017 (1), and it demonstrated that a SARS-like coronavirus isolated from horseshoe bats in a single cave contain all the building blocks of the pandemic SARS-coronavirus genome that caused the human outbreak. These results strongly suggest that the highly pathogenic SARS-coronavirus originated in this bat population. Most importantly, the researchers also showed that various SARS-like coronaviruses can interact with ACE2, the human receptor identified for SARS-coronavirus. This finding strongly suggests that SARS-like coronaviruses from bats can be transmitted to humans to cause SARS-like disease. From a public health perspective, this makes the continued surveillance of SARS-like coronaviruses in bats and study of the animal-human interface critical to future emerging coronavirus outbreak prediction and prevention. (b)(5) (b)(5) WIV scientists are allowed to study the SARS-like coronaviruses isolated from bats while they are precluded from studying human-disease causing SARS coronavirus in their new BSL-4 lab until permission for such work is granted by the NHFCP.

1. Hu B, Zeng L-P, Yang X-L, Ge X-Y, Zhang W, Li B, et al. (2017) Discovery of a rich gene pool of bat SARS-related coronaviruses provides new insights into the origin of SARS coronavirus. PLoS Pathog 13(11): e1006698. <https://doi.org/10.1371/journal.ppat.1006698>

Signature: BRANSTAD

Drafted By: (b)(6)
Cleared By:
Approved By:
Released By:
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Dissemination Rule: Archive Copy

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SBU

We await your response at the earliest opportunity.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'P. Daszak', with a long horizontal line extending from the end of the signature.

Dr. Peter Daszak
President

(t) +1 212-380-4462; (e) [REDACTED] (b) (6)
cc. Dr. Aleksei A. Chmura (Chief-of-Staff)



National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

23 October 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:

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:

	-Yr 1	-Yr 2	-Yr 3	-Yr 4	-Yr 5
Total Direct Costs	\$123,699	\$128,718	\$147,335	\$147,335	\$147,335
F&A Costs @ 8%	\$9,896	\$10,297	\$11,787	\$11,787	\$11,787
TOTAL COSTS	\$133,595	\$139,015	\$159,122	\$159,122	\$159,122

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, MD
NIH Deputy Director for Extramural Research
Email: [REDACTED] (b) (6)

cc: Dr. Erik Stemmy (NIAID)
Ms. Emily Linde (NIAID)



National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

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
Email: [REDACTED] (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde