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RANKING MEMBER

ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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WASHINGTON, DC 20515-6115
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February 2, 2023

Lawrence A. Tabak, D.D.S, Ph.D.
Senior Official Performing the Duties of the Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dr. Tabak:

Pursuant to Rules X and XI of the U.S. House of Representatives, we write to request information and documents from the National Institutes of Health (NIH) that could help support the Committee's potential legislative efforts to improve pandemic preparedness, strengthen NIH grant oversight, and enhance the biosafety of laboratory and field research.

The Committee is investigating management concerns related to EcoHealth Alliance's (EcoHealth) federal grants and proposals on bat coronaviruses. The management concerns include the adequacy of EcoHealth's monitoring of biosafety and research practices at the NIH grant subrecipient Wuhan Institute of Virology (WIV) [1] required under 45 C.F.R. § 75.101. The NIH suspended EcoHealth's grant R01AI110964 since July 8, 2020, stemming from concerns that could include information pertinent to the origins of the COVID-19 pandemic. As noted by the NIH and in our correspondence with you, EcoHealth failed to obtain laboratory notebooks and electronic files of transgenic mice experiment(s) conducted by the WIV as a research activity supported by the NIH grant. This material failure violated the NIH grant terms and conditions. There is no evidence that the work from the experiment(s) was ever published. There is no substantiation of the experiment(s) other than the WIV's assertions to EcoHealth that included inconsistent and incomplete data representations. Thus, there was no scientific work product produced for the American taxpayers who helped finance these efforts, and no useful information to support pandemic preparedness efforts. Further, EcoHealth's lack of monitoring of the WIV research in accordance with NIH grant terms presented additional biosafety risks, raising

[1] All references to the WIV include the former names of the Chinese establishment, that include the Wuhan Institute of Microbiology, the Wuhan Microbiology Research Laboratory, the Hubei Provincial Institute of Microbiology and the Chinese Academy of Sciences. Wuhan Institute of Virology, CAS, *About WIV* (last accessed January 21, 2023), *available at* http://english.whiov.cas.cn/About_Us2016/Brief_Introduction2016/.

questions about the possibility that WIV biosafety lapses could have contributed to the origins of the COVID-19 pandemic.

This letter builds on our previous oversight efforts from the 117th Congress related to COVID origins/EcoHealth grant R01AI110964. There are still significant questions and requests from our previous COVID origins inquiries that were left unanswered by NIH.[2] Thus, we are incorporating some of these unanswered questions or requests in this letter.

The COVID-19 pandemic is a catastrophic biological incident resulting so far in the deaths of more than a million Americans and more than 6 million people worldwide. The threat of similar pandemics is increasing. As the Government Accountability Office (GAO) noted, globalization, climate change, and urbanization has increased the probability, intensity, and frequency of catastrophic biological incidents.[3] A study in 2021 found a high probability of observing pandemics similar to COVID-19 (probability of experiencing it in one's lifetime is 38 percent), which may double in coming decades.[4] The global proliferation of high-containment laboratories has similarly increased the probability of a catastrophic biological incident caused by the escape of a pandemic pathogen.[5]

Given these extraordinary circumstances and the need to prepare for the growing risk of future pandemics, we want a productive working relationship with the NIH and seek the NIH's cooperation in this investigation.

In the spirit of comity and inter-branch accommodation, we expect the NIH to cooperate as much as possible with the Committee's oversight requests. If NIH has determined it will not voluntarily cooperate with the requests, please provide electronic written notice within two business days specifying which requests you are declining to cooperate with and the stated reasons for voluntary noncooperation.

To assist our efforts, please provide the following by February 16, 2023:

Basic grant documents

1. The complete grant file for EcoHealth grant R01AI110964.

2. Copies of completed Type 5 checklists for the EcoHealth grant R01AI110964.

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[2] *See* Letter from Committee Ranking Members (Full and Subcommittees, respectively) Cathy McMorris Rodgers, Brett Guthrie, Morgan Griffith to Lawrence A. Tabak, D.D.S., PhD., Senior Official Performing the Duties of the Director, NIH (November 30, 2022) (Following up on 12 unanswered or insufficiently addressed letters that requested information and were sent to NIH between March 12, 2021 and October 31, 2022).

[3] GAO, *Trends Affecting Government and Society*, GAO-22-3SP, 10 (April 2022). https://www.gao.gov/assets/gao-22-3sp.pdf

[4] Marco Marani, Gabriel G. Katul, William K. Pan, and Anthony J. Parolari, *Intensity and frequency of extreme novel epidemics*, PNAS (August 23, 2021). https://www.pnas.org/doi/10.1073/pnas.2105482118

[5] Duprex, W., Fouchier, R., Imperiale, M. *et al.* Gain-of-function experiments: time for a real debate. *Nat Rev Microbiol* **13**, 58–64 (January 2015). https://doi.org/10.1038/nrmicro3405

3. All documents related to the Scientific Review Group (SRG) review of EcoHealth's renewal application for R01AI110964.

<u>Oversight of transgenic mice experiment(s)</u>

4. All documents related to the review(s) by the internal committee at the National Institute of Allergy and Infectious Diseases (NIAID) of EcoHealth's transgenic mice experiment proposed in 2016 both during the gain of function research pause and after the HHS P3CO framework went into effect.

5. When NIAID reviewed EcoHealth's research proposal to study pathogenesis of SARS-related viruses in humanized mice, did the NIAID approve only one experiment? Was EcoHealth authorized by NIH to conduct as many experiments as it wanted pursuant to the proposal submitted to NIH? Other than the viral growth policy, were there any other restrictions or conditions on EcoHealth's authority in conducting the humanized mice experiment?

6. If a grantee submits a research plan involving an animal experiment on pathogenicity for NIH's review, does the grantee need to specify how pathogenicity is evaluated? Or can the grantee evaluate pathogenicity through a survival study that could result in animal deaths without explicitly informing the NIH?

7. All documents related to submission(s) and/or resubmission(s) of the Year 4 and Year 5 progress reports for EcoHealth Alliance grant R01AI110964, including:

   - EcoHealth's original Year 4 progress report emailed to NIH on April 25, 2018;
   - EcoHealth's Year 4 progress report revised or updated on or around September 16, 2020;
   - Description of the source of the April 13, 2018, dated version of EcoHealth Year 4 progress report, since it must have been taken from somewhere other than the NIH grants system. Was this version stored as an electronic file or a hard copy? How can the provenance of that version be verified?
   - Is it common for the NIH to retain two different versions of a progress report? If so, what is the standard practice for how the NIH retains the version that is different from what is in the NIH grants system?
   - On December 30, 2021, NIH grants official Shaun Gratton offered an explanation that EcoHealth's Year 4 progress report had been revised accidentally after EcoHealth placed a phone call to the NIH's eRA service desk about updating grant inclusion enrollment data. All documents relating to EcoHealth's request to update the inclusion of enrollment data.
   - What was the NIH investigative process used to determine Shaun Gratton's explanation for the revision of the year-4 progress report that he provided?
   - Why did it take NIH more than two months finally to respond on December 30, 2021, to EcoHealth's October 22, 2021, inquiry about why EcoHealth's Year 4 progress report was revised in the NIH grant system?

- Examples of other submitted progress reports revised in the NIH grant system two years after original submission.
- What other documents are present in the location from which the September 16, 2020, dated Year 4 progress report was obtained?
- Is the April 13, 2018, dated version of EcoHealth's Year 4 progress report that was provided to the *The Intercept* and Congress identical to the original report submitted by EcoHealth on April 13, 2018? If so, how are you certain? If not, what else was changed?
- When and how did the NIH first learn that EcoHealth Year 5 progress report was missing?
- Why did the NIH not note EcoHealth's Year 5 progress report was missing until Dr. Michael Lauer's July 23, 2021, letter to EcoHealth?
- Was there an earlier version of EcoHealth's Year 5 progress report submitted prior to July 23, 2021? If so, please provide a copy of the report and explain why it was removed and replaced by the version submitted on August 3, 2021?
- All emails sent from era-notify@mail.nih.gov since January 1, 2019 related to the EcoHealth grant sent to or copied to: Erik Stemmy, Tseday Girma, Peter Daszak, and/or Alexei Chmura.
- All emails sent (including CC) to or from NIAID GM 12 Notifications related to the EcoHealth grant since January 1, 2019;
- All emails sent from era-notify@mail.nih.gov since January 1, 2019, that include any of the keywords: "R01AI110964" or "Daszak" or "EcoHealth."

8. When did NIAID first learn that EcoHealth had conducted the transgenic or humanized mice experiment proposed in 2016?

9. Why did NIAID conduct an HHS P3CO review of the EcoHealth research proposal if the experiment was already conducted?

10. Why were less risky alternative approaches to EcoHealth's proposed experiment not considered and discussed?

11. Please explain why NIAID concluded that the EcoHealth grant was not subject to the HHS P3CO framework.

12. Will NIH investigate how EcoHealth was able to report the transgenic or humanized mice experiment results in the Year 4 and Year 5 progress reports since (1) EcoHealth admitted it does not have copies of the laboratory notebooks and electronic files; and (2) EcoHealth did not create or retain these records? If not, why not? How does NIH know that the progress report discussion of the experiment results is reliable?

13. Why did NIAID not seek details on the kind of pathogenicity study that EcoHealth wanted to pursue with the WIV?

14. Has NIAID ever funded research involving the insertion of a furin cleavage site into a sarbecovirus? If so, please provide the grant number, the name of the Principal Investigator and affiliation, and any citation to the published research.

15. Has the NIAID ever received an award application for research involving the insertion of a furin cleavage site into a sarbecovirus that ultimately was not funded? If so, please provide all documents related to this submission.

Oversight of EcoHealth compliance issues

16. All documents related to compliance concerns with EcoHealth Alliance grant R01AI110964 since July 8, 2020, including all documents between the NIH Office of Extramural Research and EcoHealth on and since July 8, 2020.

17. All documents related to NIH draft responses to Congressional requests related to COVID origins and/or EcoHealth grant R01AI110964 since March 18, 2021.

18. All documents related to NIH discussion on how to respond to Congressional requests related to COVID origins and/or EcoHealth Alliance grant R01AI110964.

19. All documents related to the origins of the COVID-19 pandemic from the following: Dr. Francis Collins, Dr. Anthony Fauci, Dr. Hugh Auchincloss, Dr. Clifford Lane, Dr. Emily Erbelding, and Dr. David Morens.

NIH Discussions with external scientists during the early phase of the pandemic

20. The fully unredacted version of the documents provided to Jimmy Tobias and/or Jason Leopold in response to Freedom of Information Act requests for production of early NIH communications concerning the origins of COVID-19.

21. NIH leaders worked with scientists external to the NIH to discuss the origins of the COVID-19 pandemic in January/February 2020. Some of these scientists may have had pending grant applications or were subject to compliance oversight with NIH at the time. There are conflict-of-interest risks that may be presented in consultation arrangements with scientists external to NIH.[6] Federal ethical principles are

[6] *See* GAO, *Response to Heparin Contamination Helped Protect Public Health; Controls That Were Needed for Working With External Entities Were Recently Added*, GAO-11-95 (October 2010). https://www.gao.gov/assets/gao-11-95.pdf (FDA did not have processes in place to ensure that it considered or applied ethical guidance when it accepted assistance from external entities with ties to heparin firms on a voluntary basis during the heparin crisis. Not adequately addressing these risks could have affected the public's confidence in FDA's response efforts and in its other activities related to the regulation of heparin products and also left FDA open to claims for payment for services that these external entities provided to FDA).

applicable even to informal arrangements.[7] Not addressing these risks could affect public trust in the NIH.[8] What are the NIH ethical guidances or regulations for this situation? What steps did NIH take to consider whether these relationships exposed the agency to the conflict-of-interest risks described in its guidance or to address conflict-of-interest risks before engaging them?

Vetting for other EcoHealth grants or other funding

22. How does NIH avoid not awarding unapproved duplicate grants for the same or similar research already funded by other agencies, to EcoHealth or other NIH grant recipients? For all NIH awards to EcoHealth, please provide accounting information for EcoHealth subawards to recipients in China.

23. How does NIH audit the financial reports submitted to the IRS by its 501(c)(3) non-profit organization grant award recipients to ensure NIH awards are accurately reported? How does NIH ensure its grantees do not act as a pass-through or money laundering provider to send U.S. research funding to China?

24. Please explain NIH's policy for ensuring its awardees accurately report the actual place of research performance. For all NIH-funded research, please provide all China site locations where EcoHealth's work was performed.

25. Please explain if EcoHealth reported its other funding or in-kind support, including awards from other federal agencies, to NIH. Please explain if EcoHealth reported any support from organizations in China.

26. How did NIH assess the conflicts of interest in EcoHealth's research involving its anonymous financial source and the private financial sources[9]?

27. Did EcoHealth disclose the private donations to NIH? If not, what actions will NIH take to obtain this reporting? If yes, how did NIH assess the conflicts of interest?

28. Will NIH investigate whether EcoHealth's research funded by NIH was also funded by USAID? If not, why not?

29. Did the NIH confer with any other federal agency about EcoHealth before making the most recent award? If so, please identify the agencies, the date of contact, and the issues discussed.

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[7] *Id.*
[8] *Id.*
[9] *See* Letter from Committee Ranking Members (Full and Subcommittees, respectively) Cathy McMorris Rodgers, Brett Guthrie, Morgan Griffith to Lawrence A. Tabak, D.D.S., PhD., Acting Director of NIH (February 24, 2022).

Security concerns

30. Did NIH perform a biodefense risk analysis for coronavirus research conducted at the WIV as research with potential for dual use of research concern, pandemic pathogen, or bioweapon development, as outlined in HHS P3CO framework? Please describe NIH's coordination procedures with the U.S. Intelligence Community that are completed before NIH funds research projects in foreign countries with existing biodefense programs.

31. All documents to and from Dr. Ping Chen of NIAID related to the WIV since January 1, 2018.

32. Does the NIH intend to enter the EcoHealth suspension into the www.SAM.gov database that is intended for agency reporting of temporary or permanent suspensions? If yes, when? If no, why not?

33. We are troubled that research sponsored by NIH must first be reviewed and approved by an institution in China before NIH receives the data. Is this process a special arrangement NIH authorized for EcoHealth? When did NIH become aware that a foreign institution was intervening in the contractual relationship between NIH and an NIH grant recipient? Before sponsoring research to be conducted in a foreign country, does the NIH evaluate the likelihood that the government of such country will prohibit the NIH from obtaining any materials or data related to such research?

34. Can NIH determine if EcoHealth provided the WIV with access to the NIH eraCommons system for grantees? If so, did EcoHealth provide the WIV with such access?

NIH letter October 20, 2021, letter to Representative Cathy McMorris Rodgers

On October 20, 2021, the Principal Deputy Director on behalf of the NIH sent a letter to Representative Rodgers and others in Congress regarding COVID origins and the transgenic mice experiment supported by the EcoHealth grant. Several statements in the letter prompt follow-up questions:

35. The letter stated: "The **limited experiment** described in the final progress report provided by EcoHealth Alliance was testing if spike proteins from naturally occurring bat coronaviruses circulating in China were capable of binding to the human ACE2 receptor in a mouse model." (Bolded for emphasis). Thus, NIH referred to the experiment in the singular. However, in a November 18, 2022, briefing with bipartisan committee staff, an NIAID official said that he did not know how many transgenic mice experiments were actually conducted pursuant to the EcoHealth grant despite EcoHealth's public statement that there was only a single experiment. Given the NIAID official's uncertainty about the actual number of experiments, does the

NIH still stand by this statement of a single experiment? If so, what is the basis? If not, what new information did NIH learn to change its conclusion, and why did NIH not follow-up with Congress to clarify or supplement the letter?

36. The letter stated: "All other aspects of the mice, including the immune system, remained unchanged. In this limited experiment, laboratory mice infected with the SHC014 WIV1 bat coronavirus became sicker than those infected with the WIV1 bat coronavirus." EcoHealth's Year 5 progress report submitted nearly two years late to the NIH in August 2021 indicated that the experiment resulted in mice deaths, including a 75 percent death rate in the mice group infected with SHC014, and a 50 percent death rate in two other groups infected with other chimeras. Those infected with the WIV1 bat coronavirus had a 25 percent death rate. Why didn't NIH acknowledge the mice deaths and the lethality rates in the letter to Congress?

37. The letter stated: "As sometimes occurs in science, this was an unexpected result of the research, as opposed to something that the researchers set out to do." Why would NIH conclude this was an unexpected result since it was already known from a 2015 study[10] that one of the strains (SHC014) was a potential threat to human health? Was the purpose of the EcoHealth grant not intentionally to pursue coronaviruses that could cause pandemics? Given the 2015 paper and the avowed grant purpose, would evidence of infection in human cells in transgenic mice and their deaths not be an expected result in a research project aimed at finding potential pandemic threats?

38. The letter stated: "Regardless, the viruses being studied under this grant were genetically very distant from SARS-CoV-2." Does the NIH know what viruses were being studied under this grant during 2019 at the WIV? If so, what information does the NIH have on these viruses? In its renewal application, EcoHealth notified the NIH that it planned to study SARS-related coronaviruses that were 10-25 percent divergent from SARS. The SARS CoV-2 virus genome is about 24 percent divergent from SARS. How does NIH know that SARS CoV-2 or its progenitor was not studied under the EcoHealth grant?

39. The letter stated: "However, out of an abundance of caution and as an additional layer of oversight, language was included in the terms and conditions of the grant award to EcoHealth that outlined criteria for a secondary review, such as a requirement that the grantee report immediately a one log increase in growth. These measures would prompt a secondary review to determine whether the research aims should be reevaluated or new biosafety measures should be enacted. EcoHealth failed to report

[10] Menachery, V. et al, A SARS-like cluster of circulating bat coronaviruses shows potential for human emergence, Nature Medicine (Nov.20, 2015) *available at* https://www.nature.com/articles/nm.3985.pdf. ("We consider viruses with the SHC014 spike a potential threat owing to their ability to replicate in primary human airway cultures, the best available model for human disease. In addition, the observed pathogenesis in mice indicates a capacity for SHC014-containing viruses to cause disease in mammalian models, without RBD adaptation.").

this finding right away, as was required by the terms of the grant." NIH has maintained that EcoHealth was not in compliance with this policy during Year 5 of the grant. However, the graphs in the Year 4 progress report indicated more than one log increase in virus growth in the transgenic mice experiment. There is no evidence that the WIV notified EcoHealth and that EcoHealth in turn notified the NIAID. There is no evidence that the experiment was stopped. Was EcoHealth in compliance with the NIAID's virus growth policy it agreed to in 2016 during Year 4?

Continuing to fund EcoHealth despite compliance issues

40. What is the NIH precedent for resuming funding to suspended grantees under these circumstances? Please provide details on specific examples.

41. How much was EcoHealth paid under the grant to oversee the laboratory work of the WIV during Year 4 and Year 5 of the R01 award?

42. Did EcoHealth's drawdown of grant funds constitute a claim that EcoHealth would monitor its sub-grantee in compliance with the terms of the grant? What certifications did EcoHealth make to the NIH? Could the NIH require grantees affirmatively to certify in writing to complying with the terms of the grant? If no, why not? If so, will NIH require such certifications for future grant awards?

43. Did EcoHealth comply with the requirements to monitor the WIV? If so, what is the basis for this conclusion? If not, what is the basis for this conclusion?

44. Why has NIH continued to provide funding for EcoHealth Alliance's international research activities?

45. How will NIH validate the information regarding EcoHealth Alliance's oversight and compliance activities for its subawardees?

46. It is unclear how the additional terms and conditions that NIH has described will ensure that future issues with obtaining laboratory notebooks and data resulting from NIH funded activities will not reoccur. How will NIH make sure that EcoHealth will comply with these additional terms and conditions?

47. Did the NIH ever ask EcoHealth why it failed to include the terms and conditions required in Federal awards in WIV's subaward agreement to ensure access to any documents, papers, or other records of the non-Federal entity (WIV) pertinent to the Federal award? If so, what was EcoHealth's rationale? Did EcoHealth ever attempt to include such terms and conditions? Did the WIV refuse to agree to the inclusion of the terms and conditions? Did EcoHealth proceed with the subaward despite such a refusal if it occurred? If the NIH did not ask EcoHealth about the rationale for not including these terms and conditions, why did the NIH not ask?

In addition, the Committee believes testimony from NIH officials and employees about these, and related matters will be necessary. Please contact Committee staff to identify appropriate personnel and schedule videotaped, transcribed interviews.

Finally, this letter serves as a renewal of our previous formal request sent by letter on November 30, 2022, to preserve all existing and future records and materials in NIH's possession relating to the topics addressed in this letter. You should construe this preservation notice as an instruction to take all reasonable steps to prevent the destruction or alteration, whether intentionally or negligently, of all documents, communications, and other information, including electronic information and metadata, that are or may be responsive to this congressional inquiry. This instruction includes all electronic messages sent using official and personal accounts or devices, including records created using text messages, phone-based message applications, or encryption software.

An attachment to this letter provides additional instructions for responding to the committee's request.

Your assistance is appreciated. If you have any questions, please contact Alan Slobodin and John Strom of the Majority Committee staff at (202) 225-3641.

Sincerely,

Cathy McMorris Rodgers
Chair
House Committee on Energy and Commerce

Brett Guthrie
Chairman
Subcommittee on Health

H. Morgan Griffith
Chairman
Subcommittee on Oversight and Investigations

Attachment

CC: The Honorable Frank Pallone, Ranking Member

The Honorable Anna G. Eshoo, Ranking Member, Subcommittee on Health

The Honorable Kathy Castor, Ranking Member, Subcommittee on Oversight and Investigations

The Honorable Brad Wenstrup, D.P.M., Chair, Select Subcommittee on Coronavirus Pandemic

The Honorable Raul Ruiz, M.D., Ranking Member, Select Subcommittee on Coronavirus Pandemic