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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

August 24, 2021

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

Dear Dr. Collins,

We have significant concerns that the National Institutes of Health (NIH) has not been adequately meeting its oversight responsibilities over the National Institute of Allergy and Infectious Diseases (NIAID) grant R01AI110964, “Understanding the Risk of Bat Coronavirus Emergence.” The grant was awarded to the non-profit organization, EcoHealth Alliance, that funneled NIH funds to the Wuhan Institute of Virology (WIV) to conduct research on bat coronaviruses. In our July 21, 2021, letter to you, we requested that the NIH provide staff briefings with Dr. Ping Chen and Dr. Erik Stemmy, NIAID officials involved with this grant and responsibility for oversight of the WIV. Unfortunately, the NIH has ignored this request.

In addition to potentially inadequately assessing the inherent risks of the WIV research supported by NIH’s grant, we are also concerned that the NIH failed to oversee biosafety concerns at the WIV. The WIV is a complex of laboratories with various Biosafety Level (BSL) levels up to a BSL-4, the most secure biosafety level laboratory. However, under the R01AI110964 grant, the WIV researchers specifically reported performing coronavirus research in BSL-2 laboratories.¹ Yet, risky coronavirus research should have been conducted in a laboratory with higher safety measures.

The grant award R01AI110964 was subject to biosafety requirements as acknowledged by NIH in its the July 8, 2020, grant suspension letter to EcoHealth Alliance: “NIH grantees and subawardees must comply with the biosafety requirements set forth in the NIH Grants Policy

¹ Lei-Ping Zeng, Peter Daszak, Zheng-Li Shi, et al, *Bat Severe Acute Respiratory Syndrome-Like Coronavirus WIV1 Encodes an Extra Accessory Protein, ORFX, Involved in Modulation of the Host Immune Response*, ASM Journal of Virology (June 24, 2016) available at <https://journals.asm.org/doi/full/10.1128/JVI.03079-15>,

Statement (*see* NIH GPS, § 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)]’).

These requirements are especially relevant given the history of serious lab accidents in China.² In 1977, the H1N1 influenza virus escaped from a lab in China that caused a worldwide pandemic.³ Two lab escapes of the first SARS virus in China were reported in the spring of 2004.⁴ Most recently in November 2019, an outbreak of brucellosis occurred in two research centers in Lanzhou, China, infecting over 100 students and staff members.⁵ Chinese experts have also raised concerns about laboratory safety in their own country, lamenting that “lab trash can contain man-made viruses, bacteria or microbes” and that “some researchers discharge laboratory materials into the sewer after experiments without a specific biological disposal mechanism.”⁶

We would expect the NIH to know about this history of lab accidents, and to know that Chinese researchers were conducting bat coronavirus work in BSL-2 labs. For example, bat coronavirus expert Dr. Ralph Baric of the University of North Carolina observed that “Historically, the Chinese have done a lot of their bat coronavirus research under BSL-2 conditions. Obviously, the safety standards of BSL-2 are different than BSL-3, and lab-acquired infections occur much more frequently at BSL-2. There is also much less oversight at BSL-2.”⁷

There is evidence that WIV conducted other coronavirus propagation research in BSL-2 facilities. We would expect that the NIH would know this as well, since the evidence is in published literature and presumably in NIH grant progress reports. For example, in 2016, the WIV and EcoHealth Alliance published a study partially funded by the NIAID grant that noted the following:

The SL-CoV WIV1 strain (GenBank accession number KF367457) and other viruses were propagated as described previously (2). Sendai virus (SeV) strain Cantell (kindly provided by Hanzhong Wang) was propagated in 10-day-old embryonated chicken eggs at 37°C for 48 h (24). **All experiments using live virus was conducted under biosafety level 2 (BSL2) conditions.**⁸ (Emphasis added).

² Rossana Segreto and Yuri Deigin, The genetic structure of SARS-CoV-2 does not rule out a laboratory origin, Wiley Online Library (Nov. 17, 2020) available at <https://onlinelibrary.wiley.com/doi/full/10.1002/bies.202000240>.

³ *Id.*

⁴ *Id.*

⁵ *Id.*

⁶ Liu Caiyu and Leng Shumei, *Biosafety guideline issued to fix chronic management loopholes at virus labs*, Global Times (Feb. 16, 2020) available at <https://www.globaltimes.cn/content/1179747.shtml>.

⁷ Rowan Jacobsen, *We never created a supervirus* Ralph Baric explains gain-of-function research, MIT Tech Review (July 26, 2021) available at <https://www.technologyreview.com/2021/07/26/1030043/gain-of-function-research-coronavirus-ralph-baric-vaccines/>.

⁸ Lei-Ping Zeng, *et al.*, *Bat Severe Acute Respiratory Syndrome-Like Coronavirus WIV1 Encodes an Extra Accessory Protein, ORFA, Involved in Modulation of the Host Immune Response*, Journal of Virology, (Jul. 15, 2016) available at <https://archive.ph/dQRTH#selection-1225.0-1245.93>

We would also expect that the NIH would recognize that the NIAID grant was supporting deficient and potentially dangerous biosafety practices. We note that Dr. Baric stated all his research studies on bat coronaviruses are conducted in BSL-3 plus conditions, and that he would not conduct the WIV's experiments in BSL-2 labs. Dr. Baric said: "There's definitely some risk associated with these and other SARS-like bat viruses that can enter human cells."⁹

Further, the "Biosafety in Microbiological and Biomedical Laboratories" (BMBL) manual, co-authored by the NIH explains:

Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents **that may cause serious or potentially lethal disease through the inhalation route of exposure**. [Emphasis added] Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents, and must be supervised by scientists competent in handling infectious agents and associated procedures.¹⁰

For this reason, the Centers for Disease Control and Prevention required that live virus samples of SARS CoV2 could only be shipped to BSL-3 labs.¹¹

NIH has admitted awareness of biosafety concerns at the WIV. In its July 8, 2020, letter to EcoHealth Alliance, NIH acknowledged receiving reports of serious biosafety concerns at the WIV:

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.

NIH expressed its concerns that EcoHealth Alliance and the WIV had not satisfied safety requirements as recipients of NIH grant funds. NIH further acknowledged in the July 8, 2020, letter: "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." Specifically, former U.S. Deputy Assistant Secretary of State, David Feith, stated that he had uncovered safety issues at the WIV: "There was work with very dangerous viruses carried out at Biosafety Level 2, which has been compared to the safety level roughly of a dentist's office."¹²

⁹ Rowan Jacobsen, *We never created a supervirus* Ralph Baric explains gain-of-function research, MIT Tech Review (July 26, 2021) available at <https://www.technologyreview.com/2021/07/26/1030043/gain-of-function-research-coronavirus-ralph-baric-vaccines/>.

¹⁰ Lei-Ping Zeng, *Bat Severe Acute Respiratory Syndrome-Like Coronavirus WIV1 Encodes an Extra Accessory Protein, ORFX, Involved in Modulation of the Host Immune Response*, (Jun 24, 2016) available at <https://www.cdc.gov/labs/pdf/CDC-BiosafetymicrobiologicalBiomedicalLaboratories-2009-P.pdf>.

¹¹ Glenn Rockman, *To accelerate innovation, the CDC should ease limits on which labs can handle the coronavirus*, STAT (Apr. 14, 2020) available at <https://www.statnews.com/2020/04/14/allow-bsl-2-labs-handle-novel-coronavirus/>.

¹² CBS News, *GOP seeks records on possible U.S. funding of research at Chinese lab before pandemic* (July 22, 2021) available at <https://www.cbsnews.com/news/gop-pressing-for-records-on-possible-us-funding-research-chinese-lab-before-pandemic/>.

Though the NIH wrote in its July 8, 2020, letter to EcoHealth Alliance that U.S. State Department cables in 2018 raised safety concerns about the WIV, the NIH failed to acknowledge how its own scientist stationed in Beijing, Dr. Ping Chen of NIAID, personally visited the WIV in 2017 and co-wrote one of the 2018 U.S. State Department warning cables. The information about NIH's awareness of the WIV safety concerns and its part in supplying that information to the U.S. State Department, only became publicly known from recently released NIH emails in response to Freedom of Information Act requests. Although a representative from the NIAID played a critical role in the 2018 State Department cables raising concerns about the WIV, there is no record of NIH taking any oversight action regarding the EcoHealth Alliance grant until after April 14, 2020, when these Department cables were publicly revealed in a Washington Post column.

There is no apparent justification for NIH officials to permit the NIAID grant to support BSL-3 research at the BSL-2 level. When propagating a coronavirus and the risks of the research are unknown, work must be done in a BSL-3 lab until it is verified and confirmed that propagating a virus does not raise a public health concern. Only after such confirmation can the research be moved to BSL-2. The NIH, in accordance with its own policies and BMBL, should have required EcoHealth Alliance to ensure that all SARS CoV research by its sub-grantee was done in a BSL-3 lab. Even if the research did not meet a technical definition of gain-of-function research, we have concerns that NIH failed to address the potential risks associated with virus propagation research in a BSL-2 lab with pathogens like SARS CoV that has of Dual Use of Research Concern (DURC) potential, a research category of which gain-of-function research is a subset. Further, NIH's belated oversight interest in this grant in 2020 has been completely ineffective, and NIH has shown no interest or capability in getting compliance from its grantee EcoHealth Alliance.

EcoHealth Alliance's grant remains suspended in-house with NIH, though the NIH through the Department of Health and Human Services has failed to report publicly the grant suspension on the www.SAM.gov database, which provides a reporting mechanism that can alert other U.S. Government agencies of risky non-compliant behavior of grant recipients. For over a year, EcoHealth Alliance has not complied with the terms of the NIH award. In the June 28, 2021, virtual meeting with Committee staff, NIH gave no indication of any interest in taking further action against EcoHealth Alliance for award noncompliance. In fact, when asked if they would further pursue information gathering from EcoHealth Alliance, NIH stated that all of EcoHealth's research had been published. In order for NIH to be convinced they should take action to obtain NIH-funded data from EcoHealth Alliance, NIH put the burden on the Minority committee staff to supply documented statements from EcoHealth Alliance indicating that EcoHealth Alliance represented that they are in possession of unpublished bat coronavirus sequences. Despite the Minority staff supplying such statements, there is still no indication from NIH that they will do anything on this front.

As indicated by the NIH's July 8, 2020, letter suspending EcoHealth Alliance's grant, the NIH and the grantee are not absolved from ensuring sound biosafety practices regardless of the merits of the research. After first notifying EcoHealth Alliance in April 2020 that it must provide information to NIH to be in compliance with the terms of its grant for project number R01AI110964, NIAID separately awarded a \$3 million cooperative agreement in June 2020 to EcoHealth Alliance, followed by another cooperative agreement award to EcoHealth Alliance in September 2020 for \$1.15 million.¹³ After notifying EcoHealth Alliance that their funding would stop until they complied with NIH's requests for information, providing additional funding to EcoHealth Alliance in \$4.5 million in NIAID cooperative agreements thereby undercut NIH's ability to get EcoHealth Alliance to comply with NIH's requests for information on biosafety practices and other issues at the WIV. The new funding to EcoHealth Alliance suggests that the NIH is not serious about oversight of NIH grants and, more specifically, its compliance requests of EcoHealth Alliance in its July 8, 2020, letter.

NIH's conduct in this case raises serious doubts about NIH's competent stewardship of research funds. If the NIH continues down this path, the NIH risks losing substantial public support and risks undermining public health efforts that are based on trust in NIH.

We urge you to be transparent and produce all documents and information related to the NIAID grant and to provide in writing the NIH's complete understanding of the NIH-supported research conducted at the WIV by September 7, 2021. Please immediately make arrangements to schedule the staff briefings with Dr. Ping Chen and Dr. Erik Stemmy. Finally, in light of our concerns, please respond to the following:

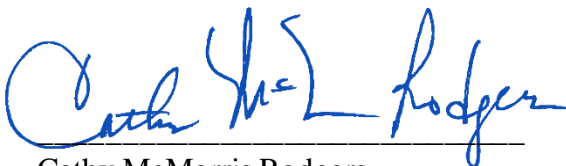
1. In recent testimony before the Senate Committee on Health, Education, Labor and Pensions, Dr. Anthony Fauci, Director of NIAID, testified that the WIV research in question "was judged by qualified staff up and down the chain as not being gain of function."
 - a. Please provide names and positions of the staff involved. Please provide details on the scope of the review and the process for how the review was conducted. Please identify all documents used in the review and submit these documents.
 - b. Did the staff review the biosafety practices and BSL level of labs that were involved with the WIV research? If so, what were their findings?
 - c. Did the staff know how many novel coronaviruses were being studied at the WIV? If so, please provide the information.
 - d. Were staff aware of the WIV's standard operating procedures for working with a novel coronavirus? If so, please provide the information.

¹³ USA Spending.gov, *EcoHealthAlliance*, Advanced Recipient Search (Aug. 2, 2021) available at <https://www.usaspending.gov/search/?hash=b2b11ac84d498190e8e69a33c04cdd99>.

- e. Were staff aware of how the WIV collected virus samples? If so, please provide the information.
 - f. Were staff aware of the standard operating procedures at the WIV for propagating or culturing viruses? If so, please provide the information.
 - g. Did the staff have information on the biosafety procedures at the WIV designed to prevent potential exposure events? If so, please provide the information.
 - h. Did the staff know what cell lines were used at the WIV? If so, please provide the information.
 - i. Did the staff know what safety measures were used at the WIV to prevent cross-contamination? If so, please provide the information.
 - j. Did the staff have information on the training records of the staff? If so, please provide the information.¹⁴
2. Since EcoHealth Alliance still has its NIAID grant suspended due to lack of cooperation with the NIH, why is NIAID continuing to fund EcoHealth Alliance through other cooperative agreements?
3. When did the NIH first recognize biosafety concerns at the WIV? What actions were taken?

If you have any questions, please contact Alan Slobodin or Diane Cutler of the Minority Committee staff.

Sincerely,

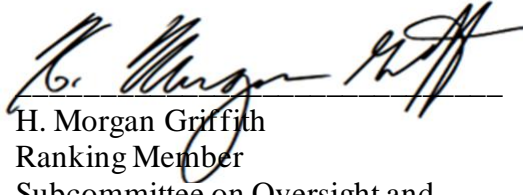


Cathy McMorris Rodgers
Ranking Member
Committee on Energy and Commerce



Brett Guthrie
Ranking Member
Subcommittee on Health

¹⁴ Sub-questions (g), and (j) were suggested by Dr. Ralph Baric to MIT Tech Review, note 9.

A handwritten signature in black ink, appearing to read "H. Morgan Griffith", is written over a horizontal line.

H. Morgan Griffith
Ranking Member
Subcommittee on Oversight and
Investigations

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