

EMPOWER OVERSIGHT

Whistleblowers & Research



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February 6, 2023

VIA ELECTRONIC TRANSMISSION: FOIA@OIG.HHS.GOV

Freedom of Information Officer
Office of the Inspector General
Department of Health and Human Services,
330 Independence Ave, S.W., Cohen Building, Suite 1062
Washington, D.C. 20201

RE: FOIA Request for Information Relating to NIH/NIAID’s Failure to Enforce a Grant Provision Requiring EcoHealth Alliance to Submit Annual Progress Reports With Respect to Grant R01A/110964, Which Is Entitled *Understanding the Risk of Bat Coronavirus Emergence*

Dear FOIA Officer:

INTRODUCTION

Empower Oversight Whistleblowers & Research (“Empower Oversight”) is a nonpartisan, nonprofit educational organization dedicated to enhancing independent oversight of government and corporate wrongdoing. We work to help insiders safely and legally report waste, fraud, abuse, corruption, and misconduct to the proper authorities, and seek to hold those authorities accountable to act on such reports by, among other means, publishing information concerning the same.

BACKGROUND

On or about January 25, 2023, the Office of Inspector General for the Department of Health and Human Services (“HHS-OIG”) issued Audit Report Number A-05-21-00025, which is entitled *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*.¹ In contrast to its antiseptic title and opening summary (*i.e.*, Report in Brief), the body of the report raises serious questions about the origin of the COVID-19 pandemic and failures by the National Institutes of Health (“NIH”) and the National Institute of Allergy and Infectious Diseases (“NIAID”) to enforce important grant requirements. The audit makes clear that NIH and NIAID failed to require EcoHealth Alliance (“EcoHealth”)—and EcoHealth failed to require the Wuhan Institute of Virology (“WIV”), a subrecipient—to comply with terms of the grant designed to ensure proper supervision, control, and oversight. It is crucial for the public to learn to what extent these failures impaired earlier warning and understanding of the emergence of the pandemic.

¹ A copy of the “Complete Report” is available for inspection at <https://oig.hhs.gov/oas/reports/region5/52100025.asp>.

Setting the Stage

Setting the stage for its findings, HHS-OIG reports that the Department of Health and Human Services (“HHS”)—and, thus, NOH and NIAID—grants are subject to HHS’s *Grants Policy Administration Manual* (“GPAM”), which establishes minimum policy requirements for the administration (including monitoring) of grants throughout their life cycles.² Among other things, GPAM requires HHS divisions to monitor (and document such monitoring of) the adequacy of their grant recipients’ performance and compliance, at least annually.³ Such monitoring must include an annual acknowledgement, review, assessment, and statement concerning each grantee’s annual progress report. Further, since HHS’s divisions do not have direct relationships with their grantees’ subrecipients, such grantees are responsible for monitoring their subrecipients’ activities and compliance with terms and conditions of the grant awards. *Id.*

Additionally, HHS-OIG reports that in October of 2014 a governmentwide funding pause on gain-of-function research was announced.⁴ The pause applied to projects that could be reasonably anticipated to confer attributes to influenza, Middle East Respiratory Syndrome, or Severe Acute Respiratory Syndrome viruses such that a virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route. *Id.* Then, in January of 2017, the White House issued guidance, *The Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight* (“P3CO”), which describes procedures that Federal agencies need to adopt in order to lift the funding pause. *Id.* Then, in December of 2017, HHS issued *The HHS Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (“HHS P3CO Framework”), to address the White House’s conditions for lifting the funding pause. *Id.* The HHS P3CO Framework controls HHS—and, thus, NIH and NIAID—funding decisions on research that is reasonably anticipated to create transfer, or use Enhanced Potential Pandemic Pathogens (“ePPPs”), which are understood to include bacteria, viruses, and other microorganisms that are highly transmissible, and capable of wide, uncontrollable spread in human populations, and highly virulent, making them likely to cause significant morbidity and/or mortality in humans.⁵

² See, Audit Report Number A-05-21-00025, which is entitled *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, at p. 3.

³ See, Audit Report Number A-05-21-00025, which is entitled *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, at p. 8.

⁴ See, Audit Report Number A-05-21-00025, which is entitled *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, at p. 3.

⁵ See, Audit Report Number A-05-21-00025, which is entitled *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, at pp. 3 – 4.

HHS-OIG uses “gain-of-function” and “ePPP” interchangeably in its report. See, Audit Report Number A-05-21-00025, which is entitled *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, at p. 4, fn. 7.

Finding: NIH Did Not Ensure a Progress Report Was Submitted in a Timely Manner for One of EcoHealth's Grant Awards

HHS-OIG examined three NIH/NIAID grants made to EcoHealth.⁶ One grant, RO1A/110964, is entitled *Understanding the Risk of Bat Coronavirus Emergence* and involved WIV as a subrecipient.⁷

With respect to RO1A/110964, HHS-OIG reports that, pursuant to NIH/NIAID procedures, a peer review of the research proposed to be funded by the grant was conducted before grant performance commenced.⁸ The peer review noted that risks associated with the proposed research “were not fully addressed in the [grant] application,” and:

To minimize risk associated with the award, NIAID added restrictions to the Notice of Award that no human subjects may be involved in any project supported by the award until all requirements set forth by NIH for human subjects research had been met and approved by NIH, and that no funds for research involving human subjects may be drawn down until NIAID had notified EcoHealth that the issues had been resolved and the restriction removed. NIH was responsible for oversight to ensure compliance with these additional restrictions added to the Notice of Award. *Id.*

Despite the risks posed by EcoHealth's proposed research, and the normal monitoring requirements applicable to RO1A/110964, HHS-OIG found:

Contrary to GPAM requirements, NIH did not follow up in a timely manner with EcoHealth after it failed to submit a progress report due September 2019. EcoHealth's failure to submit a progress report in a timely manner and NIH's failure to follow up on a missing progress report limited NIH's ability to effectively monitor its grant award to EcoHealth and evaluate whether the special terms and conditions were met. This oversight failure is particularly concerning because NIH had previously raised concerns with EcoHealth about the nature of the research being performed.⁹

HHS-OIG went on to explain that NIH/NIAID grantees complete their annual progress reports online as part of a multistep process.¹⁰ The principal investigator identified by the grant, or a delegate initiates the progress report, and then the processing of the report continues with edits, and is ultimately submitted to NIH. *Id.* Until the progress report is ultimately submitted to NIH, the online system marks the report status as “draft” and the submission date space is left blank. *Id.* EcoHealth initiated the progress report for the Fifth Year of RO1A/110964 in July 2019, but, according to HHS-OIG, it was not until after NIH expressly requested the progress report in July 2021 that EcoHealth submitted it on August 3, 2021. *Id.*

⁶ See, Audit Report Number A-05-21-00025, which is entitled *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, at p. 6.

⁷ See, Audit Report Number A-05-21-00025, which is entitled *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, at p. 6.

⁸ See, Audit Report Number A-05-21-00025, which is entitled *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, at p. 9.

⁹ See, Audit Report Number A-05-21-00025, which is entitled *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, at p. 14.

¹⁰ See, Audit Report Number A-05-21-00025, which is entitled *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, at p. 14.

In other words, the report was submitted **nearly 2 years late**, well into the course of the COVID-19 pandemic.

Although HHS-OIG determined that EcoHealth bears responsibility for the late progress report, it found no evidence that NIH informed EcoHealth of the late progress report from the time EcoHealth initiated the report in NIH's online system until July 2021.¹¹ Hence, HHS-OIG concluded that—in addition to botching its monitoring responsibility—NIH failed to comply with a GPAM requirement that it follow-up with its grantees regarding late reports “no later than 30 days after the[ir] established due date.” *Id.*

As a consequence of NIH/NIAID's monitoring and follow-up failures, HHS-OIG found “Once NIH received and reviewed the late progress report, NIH concluded the research resulted in a virus with enhanced growth.”¹² Such “enhanced growth” of a virus triggered a special grant provision applicable to the Fifth Year award of RO1A/110964 that required EcoHealth immediately to notify its NIAID Program Officer and Grants Management Specialist of any virus with an enhanced growth of more than one log compared to wild-type strains.¹³ The Notice of Award also stated that research involving such resulting virus(es) could require additional review under the HHS P3CO Framework. *Id.*

HHS-OIG explained that according to NIH's eventual/tardy evaluation of EcoHealth's progress report for the Fifth Year of RO1A/110964, NIH believed there was evidence that the research conducted by EcoHealth's subrecipient, WIV, resulted in enhanced growth of an unnamed virus by more than one log, thus triggering immediate notification of NIAID and potentially requiring the research to undergo further review under the HHS P3CO Framework.¹⁴ A one log increase in virus growth had been used as a criteria for initiating a secondary review under the HHS P3CO Framework; such secondary review is intended to determine whether the research aims should be re-evaluated or new biosafety measures should be enacted. *Id.*

HHS-OIG concluded that “NIH's failure to follow[-]up with EcoHealth about the late progress report limited its ability to understand the nature of the research conducted during Year 5 of the award on a timely basis.”¹⁵ As grave as this conclusion sounds—considering the timing and location of the enhanced growth: 2019 and WIV—NIH nevertheless insisted it “does not believe that either experiment” associated with the enhanced growth “is associated with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) or the COVID-19 pandemic.”¹⁶ Yet, HHS-OIG adds that “scientific documentation” that NIH explicitly sought from EcoHealth in order to “gain insights into the nature of the experiments that [WIV] performed” during the term in question were not made available to NIH.¹⁷

¹¹ See, Audit Report Number A-05-21-00025, which is entitled *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, at p. 14.

¹² See, Audit Report Number A-05-21-00025, which is entitled *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, at p. 14.

¹³ See, Audit Report Number A-05-21-00025, which is entitled *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, at p. 15.

¹⁴ See, Audit Report Number A-05-21-00025, which is entitled *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, at p. 15.

¹⁵ See, Audit Report Number A-05-21-00025, which is entitled *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, at p. 14.

¹⁶ See, Audit Report Number A-05-21-00025, which is entitled *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, at p. 15, fn. 17.

¹⁷ See, Audit Report Number A-05-21-00025, which is entitled *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*, at pp. 21 – 22.

RECORDS REQUEST

To shed light on NIH/NIAID's administration of grants supporting research related to actual or potential ePPP, and in particular Grant R01A/110964, pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, Empower Oversight hereby requests:

1. The pre-performance peer review associated with Grant R01A/110964.
2. All communications regarding the pre-performance peer review associated with Grant R01A/110964, including NIH/NIAID's rationale for proceeding with the grant in spite of the recognized risks.
3. All communications regarding EcoHealth's Fifth Year progress report for Grant R01A/110964.
4. All communications between NIH/NIAID and EcoHealth pertaining to Grant R01A/110964, during the period June 1, 2019, through October 30, 2019.
5. All communications between (or including both) Anthony Fauci and Peter Daszak during the period June 1, 2019, and October 30, 2019.
6. NIH/NIAID's analysis of EcoHealth's tardy Fifth Year progress report for Grant R01A/110964.
7. All communications between NIH/NIAID and EcoHealth regarding NIH/NIAID's November 5, 2021, request for "scientific documentation" associated with WIV's "substantiating research" covering experiments performed in connection with the Fourth and Fifth years of Grant R01A/110964.

DEFINITIONS

"COMMUNICATION(S)" means every manner or method of disclosure, exchange of information, statement, or discussion between or among two or more persons, including but not limited to, face-to-face and telephone conversations, correspondence, memoranda, telegrams, telexes, email messages, voice-mail messages, text messages, Slack messages, meeting minutes, discussions, releases, statements, reports, publications, and any recordings or reproductions thereof.

"DOCUMENT(S)" or "RECORD(S)" mean any kind of written, graphic, or recorded matter, however produced or reproduced, of any kind or description, whether sent, received, or neither, including drafts, originals, non-identical copies, and information stored magnetically, electronically, photographically or otherwise. As used herein, the terms "DOCUMENT(S)" or "RECORD(S)" include, but are not limited to, studies, papers, books, accounts, letters, diagrams, pictures, drawings, photographs, correspondence, telegrams, cables, text messages, emails, memoranda, notes, notations, work papers, intra-office and inter-office communications, communications to, between and among employees, contracts, financial agreements, grants, proposals, transcripts, minutes, orders, reports, recordings, or other documentation of telephone or other conversations, interviews, affidavits, slides, statement summaries, opinions, indices, analyses, publications, questionnaires, answers to questionnaires, statistical records, ledgers, journals, lists, logs, tabulations, charts, graphs, maps, surveys, sound recordings, data sheets, computer printouts, tapes, discs, microfilm, and all other records kept, regardless of the title, author, or origin.

“PERSON” means individuals, entities, firms, organizations, groups, committees, regulatory agencies, governmental entities, business entities, corporations, partnerships, trusts, and estates.

“REFERS,” “REFERRING TO,” “REGARDS,” “REGARDING,” “RELATES,” “RELATING TO,” “CONCERNS,” “BEARS UPON,” or “PERTAINS TO” mean containing, alluding to, responding to, commenting upon, discussing, showing, disclosing, explaining, mentioning, analyzing, constituting, comprising, evidencing, setting forth, summarizing, or characterizing, either directly or indirectly, in whole or in part.

“INCLUDING” means comprising part of, but not being limited to, the whole.

INSTRUCTIONS

The time period of the requested records is August 31, 2019, through the present.

The words “and” and “or” shall be construed in the conjunctive or disjunctive, whichever is most inclusive.

The singular form shall include the plural form and vice versa.

The present tense shall include the past tense and vice versa.

In producing the records described above, you shall segregate them by reference to each of the numbered items of this FOIA request.

For ease of administration and to conserve resources, we ask that documents be produced in a readily accessible electronic format.

If you have any questions about this request, please contact Bryan Saddler by e-mail at bsaddler@empowr.us.

FEE WAIVER REQUEST

Empower Oversight agrees to pay up to \$25.00 in applicable fees, but notes that it qualifies as a “representative of the news media”¹⁸ and requests a waiver of any fees that may be associated with processing this request, in keeping with 5 U.S.C. § 552 (a)(4)(A)(iii).

Empower Oversight is a non-profit educational organization as defined under Section 501(c)(3) of the Internal Revenue Code, which helps insiders safely and legally report waste, fraud, abuse, corruption, and misconduct to the proper authorities, and seeks to hold those authorities accountable to act on such reports by, among other means, publishing information concerning the same. Empower Oversight has no commercial interest in making this request.

Further, the information that Empower Oversight seeks is in the public interest because it is likely to contribute significantly to the public understanding of NIH/NIAID’s administration of grants supporting research related to actual or potential ePPP, and in particular Grant R01A/110964, which is entitled *Understanding the Risk of Bat Coronavirus Emergence*.

¹⁸ On September 23, 2021, the Securities Exchange Commission conceded that Empower Oversight qualifies as a news media requester for purposes of fees assessed pursuant to the FOIA. See “Empower Oversight Wins Appeal of Erroneous SEC Fee Decision: Must be treated as a “media requestor” in seeking ethics records of senior officials,” Empower Oversight Press Release (September 24, 2021), available at <https://empowr.us/empower-oversight-wins-appeal-of-erroneous-sec-fee-decision-must-be-treated-as-a-media-requestor-in-seeking-ethics-records-of-senior-officials/>. Thereafter, numerous other agencies recognized Empower Oversight as a media requester.

Empower Oversight is committed to government accountability, public integrity, and transparency. In the latter regard, the information that that Empower Oversight receives that tends to explain the subject matter of this FOIA request will be disclosed publicly via its website, and copies will be shared with other news media for public dissemination.

Thank you for your time and consideration. Please don't hesitate to contact me with any questions.

Cordially,

[/Jason Foster/](#)

Jason Foster
Founder & President