

EMPOWER OVERSIGHT

Whistleblowers & Research



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March 23, 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 Policies and Procedures for Reviewing Research for Enhanced Potential Pandemic Pathogens That Failed to Forewarn or Prevent the Generation of “Enhanced Growth” of One or More Viruses Under Grant RO1A/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 shows that in application policies and procedures of the Department of Health and Human Services (“HHS”), NIH, and NIAID that were intended to review research funded by their grants for creation or development of Enhanced Potential Pandemic Pathogens (“ePPPs”)² failed to

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

² 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.

prevent or timely detect the generation of enhanced growth of one or more viruses under Grant RO1A/110964, which is entitled *Understanding the Risk of Bat Coronavirus Emergence*. It is crucial for the public to learn to what extent these failures impaired earlier warning and understanding of the emergence of the pandemic.

Setting the Stage

Setting the stage for its findings, HHS-OIG reports that in October of 2014 a governmentwide funding pause on gain-of-function research was announced.³ 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.⁴ 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 waive the funding pause.⁵ 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 overcoming the funding pause.⁶ The HHS P3CO Framework controls HHS—and, thus, NIH and NIAID—funding decisions on research that is reasonably anticipated to create, transfer, or use ePPPs, which are understood to include bacteria, viruses, and other microorganisms that are highly transmissible (capable of wide, uncontrollable spread in human populations) and highly virulent (making them likely to cause significant morbidity and/or mortality in humans).⁷

According to HHS-OIG, NIAID’s standard operating procedures for implementing the HHS P3CO Framework include an instruction that staff, who review proposed research that may involve an ePPP, must “err on the side of inclusion” when determining whether such research should be referred to NIAID’s Dual Use Research Concern (“DURC”)/P3CO Committee for further review and possible referral to HHS for further review under the framework.⁸ The DURC/P3CO Committee is staffed by NIAID personnel “and leadership with broader infectious diseases and policy expertise who review research that could be subject to” the framework.⁹

Finding: NIH/NIAID Had Policies and Procedures to Review Research Funded by Grants for ePPPs, But in Application They Failed to Forewarn or Prevent the Generation of “Enhanced Growth” of One or More Viruses Under Grant RO1A/110964

HHS-OIG examined three NIH/NIAID grants made to EcoHealth Alliance (“EcoHealth”).¹⁰ With respect to a 2014 grant, RO1A/110964, which involved the Wuhan Institute of Virology (“WIV”),¹¹ it reports that, pursuant to NIH/NIAID procedures, a peer review of the research proposed to be funded by the grant was conducted

³ Audit Report Number A-05-21-00025, *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.

⁴ *Id.*

⁵ *Id.*

⁶ *Id.*

⁷ *Id.* at pp. 3 – 4.

⁸ *Id.* at pp. 4 and 11.

⁹ *Id.* at p. 4.

¹⁰ *Id.* at p. 6.

¹¹ *Id.*

before grant performance commenced.¹² The peer review noted that risks associated with the proposed research “were not fully addressed in the [grant] application.”¹³ However, HHS-OIG adds that, despite the peer review findings, NIAID approved the grant application with:

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.¹⁴

Subsequent to the commencement of performance under RO1A/110964—on May 28, 2016—NIAID notified EcoHealth that, based upon information in its progress report for the Second Year of RO1A/110964, NIAID had determined that the funded research could be gain-of-function and subject to the funding pause on certain gain-of-function research.¹⁵ NIAID added that, per the funding pause announcement, new funding would not be released for gain-of-function research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity or transmissibility in mammals via the respiratory route.¹⁶ Hence, NIAID requested from EcoHealth additional information about the research funded by the grant, including documentation demonstrating whether the research did or did not include work applicable to the gain-of-function funding pause.¹⁷

On June 8, 2016, EcoHealth responded to NIAID’s correspondence, supplying additional details describing the research funded by RO1A/110964.¹⁸ EcoHealth explained that the goal of the research was to understand the potential origins of MERS-Coronavirus (“CoV”) in bats by studying MERS-like CoVs in bats. EcoHealth assured NIAID that it was highly unlikely that the research would involve any pathogenic potential.¹⁹ Nonetheless, EcoHealth stated that should any of the viruses studied show evidence of enhanced growth, or grow more efficiently in human airway epithelial cells, it would immediately: (1) stop all experiments with such virus, (2) inform the NIAID of the occurrence, and (3) participate in decision-making trees to decide appropriate paths forward.²⁰

On July 7, 2016, NIAID replied to EcoHealth, advising that it had reviewed the original grant application and the documents and explanations provided by EcoHealth in response to NIAID’s May 28th questions.²¹ Despite the risk concerns raised by the peer review and its review of the Second Year progress report, NIAID concluded that the research funded by RO1A/110964 was not subject to the gain-of-function research funding pause because it was not reasonably anticipated to have enhanced pathogenicity or transmissibility in mammals via the

¹² *Id.* at p. 9.

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.* at p. 11.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.* at pp. 11 – 12.

²¹ *Id.* at p. 12.

respiratory route.²² However, NIAID instructed EcoHealth that if any of the viruses involved in the research showed evidence of enhanced growth, EcoHealth would have to immediately stop all experiments with the virus(es) in question and provide NIAID with the relevant data and information related to the occurrence.²³

Following the issuance the HHS P3CO Framework, NIAID re-reviewed the grant application for R01A/110964 and other information provided by EcoHealth.²⁴ Based upon its review, NIAID determined that the research funded by the grant was not subject to the framework.²⁵ Nonetheless, NIAID revised the terms and conditions of the award for the Fifth Year funding under the grant to indicate that should experiments included in the research result in a virus with “enhanced growth,” EcoHealth must notify NIAID immediately and subsequent research could require a secondary review according to the framework.²⁶

In contrast to NIH/NIAID’s determinations, which EcoHealth had encouraged, that the 2014 funding pause and the HHS P3CO Framework were not applicable to the research funded by R01A/110964 because it was not anticipated to involve viruses with enhanced pathogenicity or transmissibility in mammals, when it reviewed EcoHealth’s progress report for the Fifth Year of the grant—a progress report that EcoHealth submitted nearly two years late and well into the course of the COVID-19 pandemic (i.e., in 2021)—it determined that the research had resulted in one or more virus(es) with enhanced growth.²⁷ Specifically, HHS-OIG explains that according to NIH’s eventual evaluation of EcoHealth’s progress report for the Fifth Year of R01A/110964, NIH determined 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.²⁸

Despite the obvious, unexplained inconsistencies among NIH/NIAID’s peer review (finding unaccounted for risks), review of the Second Year progress report (finding that the funded research potentially invoked the gain-of-function funding pause), 2016 funding pause determination (finding that the funding pause was inapplicable to the funded research), 2018 HHS P3CO Framework decision (finding that the funded research was not subject to the framework), and review of the Fifth Year progress report (finding that the research had generated precisely what the gain of function funding pause and the HHS P3CO Framework were intended to protect against: ePPP), HHS-OIG states:

Our audit did not review the basis of NIH’s determinations, which is a scientific issue beyond our scope and expertise, and we do not make any conclusions about NIH’s determinations about gain-of-function research or the necessity of a departmental review under the HHS P3CO Framework.²⁹

RECORDS REQUEST

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.* at p. 14.

²⁸ *Id.* at p. 15.

²⁹ *Id.* at p. 11.

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. All communications and documents relative to HHS-OIG's decision to not review the basis of NIH/NIAID's "scientific" determinations and to define the scope of its audit not to include consideration of the support for and validity of such determinations.
2. All communications and documents (including agendas, minutes, and pre-meeting background materials) related to NIAID's June 17, 2016, DURC/Gain-of-Function meeting, which was scheduled to include a discussion of Grant R01A/110964, and is referenced at footnote 12 of Audit Report Number A-05-21-00025.
3. All communications and documents (including agendas, minutes, and pre-meeting background materials) related to any NIAID DURC/ P3CO Committee meeting that include a discussion of Grant R01A/110964.
4. The membership of NIAID's DURC/ P3CO Committee(s) for:
 - a. 2016,
 - b. 2017, and
 - c. 2018.
5. All communications and documents pertaining to NIAID's 2016 review of the application of the gain-of-function funding pause to Grant R01A/110964.
6. All communications and documents bearing upon NIAID's 2018 review of the application of the HHS P3CO Framework to Grant R01A/110964.
7. All communications and documents concerning NIH/NIAID's analysis of EcoHealth's tardy Fifth Year progress report for 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 me by e-mail at tleavitt@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”³⁰ 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*.

³⁰ 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,

[/Tristan Leavitt/](#)
Tristan Leavitt
President