

EMPOWER OVERSIGHT

Whistleblowers & Research



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March 29, 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 Compliance with/Enforcement of Legal Requirements Applicable to 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 EcoHealth Alliance (“EcoHealth”), an NIH/NIAID grantee, glaringly failed to comply with several legal requirements applicable to Grant RO1A/110964, which is entitled *Understanding the Risk of Bat Coronavirus Emergence*, and that NIH/NIAID failed to enforce the applicable legal requirements. 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

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

Further, HHS-OIG credits NIH with establishing “policies and procedures to monitor awards consistent with Federal requirements.”⁴ Primarily, such “monitoring is accomplished through reviews of reports and correspondence from the recipient, independent audit reports, site visits, and reviews of other information.”⁵

Additionally, HHS-OIG notes that since October 1, 2010, the Federal Funding Accountability and Transparency Act (“FFATA”), as amended,⁶ has required that recipients of new Federal grants of at least \$25,000 must report information concerning their first-tier sub-recipients to a Federal database, the FFATA Subaward Reporting System (“FSRS”).⁷ (This requirement is made plain by Office of Management and Budget (“OMB”) guidance).⁸ Among other things, grant recipients must report their sub-recipients’ names and addresses, where sub-recipient work under the subaward will be performed, the amount of the subawards, and the descriptions of the projects to be performed by the sub-recipients.⁹

Similarly, OMB’s uniform guidance for the administration of Federal grants requires that grantees that expend in one year \$750,000 or more in Federal assistance “must have a single or program-specific audit conducted for that year,” and such audit must be conducted in accordance with OMB guidance.¹⁰ To accomplish this requirement, grantees must procure an audit; ensure that such audit is performed according to OMB guidance; prepare financial statements that include a Schedule of Expenditures of Federal Awards (“SEFA”) to facilitate the audit; take corrective action on audit findings; and provide their contract auditors with access to personnel, accounts, books, records, supporting documentation, and other information needed to perform the audit.¹¹ Regarding the SEFA, among other things, it must include the Federal agencies/programs that funded the applicable grants, the total amounts expended under each

² See 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.

³ *Id.* at p. 8.

⁴ *Id.*

⁵ *Id.* at pp. 8 – 9.

⁶ Pub. Law No. 109-282, as amended by Pub. Law No. 110-252.

⁷ 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. 15; see also Pub. Law No. 109-282, as amended by Pub. Law No. 110-252; 2 C.F.R. § 200.300(b); 45 C.F.R. § 75.300(b).

⁸ Memorandum to Senior Accountable Officials, from Jeffrey D. Zients, dated August 27, 2022, at App. A, pp. 7 – 8, available at https://www.fsr.gov/documents/OMB_Guidance_on_FFATA_Subaward_and_Executive_Compensation_Reporting_08272010.pdf; *Federal Funding Accountability and Transparency Act Subaward Reporting System (FSRS)* (Undated), available at <https://www.fsr.gov> (sub-recipient information that recipients report to the FFATA Subaward Reporting System is then publicly displayed at www.USASpending.gov).

⁹ Memorandum to Senior Accountable Officials, from Jeffrey D. Zients, dated August 27, 2022, at App. C, available at https://www.fsr.gov/documents/OMB_Guidance_on_FFATA_Subaward_and_Executive_Compensation_Reporting_08272010.pdf.

¹⁰ 2 C.F.R. § 200.501(a) (HHS adopted OMB’s uniform guidance for the administration of grants at 2 C.F.R. § 300.1); see also, 45 C.F.R. § 75.501(a).

¹¹ 2 C.F.R. § 200.508(a) (referencing 2 C.F.R. §§ 200.509 – 200.512); see also, 45 C.F.R. § 75.508(a) (referencing 45 C.F.R. §§ 75.509 – 75.512).

such agency program, and the total amounts of subawards made to sub-recipients under each such agency program.¹²

Moreover, by regulation, HHS requires that its grantees ensure that “every subaward” that they make clearly identifies the sub-recipient.¹³ Lest there be any confusion among grantees concerning what HHS deems clear identification to be, HHS’s regulation sets forth 13 data elements (e.g., the name of the sub-recipient, the grant identification number, the date of the grant, the total amount of grant funds provided to the sub-recipient, the name of the HHS division that made the underlying grant, and whether the subaward is to fund research and development) that must be included in the subaward document.¹⁴

Finding: EcoHealth Failed to Comply with Legal Requirements Applicable to Grant RO1A/110964, and NIH/NIAID Failed to Enforce Such Requirements

With respect to EcoHealth, HHS-OIG found that for multiple years EcoHealth did not report sub-recipient information—including information concerning EcoHealth’s subaward to the Wuhan Institute of Virology—on the FSRs website.¹⁵ According to HHS-OIG, EcoHealth had not complied with the FSRs reporting requirement with respect to any subawards that it had made under its NIH/NIAID grants until after July of 2020, when NIH informed it that it was not in compliance with the applicable reporting requirements.¹⁶ HHS-OIG attributed EcoHealth’s compliance failure to its insufficient policies and procedures.¹⁷

Additionally, HHS-OIG found that the SEFAs in EcoHealth’s financial statements for the years ended June 30, 2016, June 30, 2017, June 30, 2018, and June 30, 2019, did not include the proper amount of subawards funded under NIAID’s programs.¹⁸ EcoHealth stated that its independent accountants advised EcoHealth not to include that information on its SEFAs, according to HHS-OIG.¹⁹ Such accounting advice would have been contrary to Federal reporting requirements.²⁰

Moreover, HHS-OIG analyzed 11 subaward agreements created by EcoHealth.²¹ Of the 11 agreements, HHS-OIG found that each of them lacked at least 1 of the 13 data elements required by the applicable HHS regulation.²² All of them excluded at least 5 of the required elements, and 10 of them omitted 6 of the required elements.²³ HHS-OIG concluded that these remarkable results occurred because EcoHealth’s policies and procedures were defective.²⁴

¹² 2 C.F.R. § 200.510(b); see also, 45 C.F.R. § 75.510(b); 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 pp. 22 – 23.

¹³ 45 C.F.R. § 75.352(a)(1).

¹⁴ *Id.*

¹⁵ 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. 22.

¹⁶ *Id.* at p. 23.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.* at p. 20.

²² *Id.*

²³ *Id.* at p. 51 (Appx. H).

²⁴ *Id.* at p. 20.

HHS-OIG concluded that EcoHealth's failures to report sub-recipient information, to properly report subaward funding, and to comply with regulatory requirements applicable to making subawards limited NIH/NIAID's access to accurate information to use in its monitoring process, and impaired the general public's visibility into, and transparency of, how NIH/NIAID's grant funds were used.²⁵

In regard to NIH/NIAID's monitoring of EcoHealth, HHS-OIG found that it did not discover EcoHealth's noncompliance with reporting requirements for more than 5 years, which HHS-OIG claims demonstrates that their monitoring policies and procedures were not effective.²⁶ (Alternatively, it seems reasonably possible that the policies and procedures could have been highly effective, but were not followed by NIH/NIAID personnel.)

Prior to July 2020, EcoHealth had not complied with the sub-recipient reporting requirement for at least 5 years.²⁷ HHS-OIG notes that, given that the first subaward under Grant R01A/110964 covered the period June 1, 2014, through May 31, 2015, it believes that NIH/NIAID's monitoring of EcoHealth's grants should have revealed EcoHealth's failure to comply with reporting requirements as early as 2016 during the third year renewal process for the grant.²⁸ Nonetheless, although EcoHealth was not in compliance with the disclosure requirements, HHS-OIG reports that it was not evident that NIH/NIAID was aware of this failure until July 2020, when compliance with the disclosure requirements was expressly added as a condition of the grant.²⁹

Moreover, as part of its monitoring, NIH/NIAID had access to EcoHealth's audit reports and financial statements.³⁰ Based on HHS-OIG's review of such audit reports, it noted that EcoHealth's SEFAs for the years ended June 30, 2016, June 30, 2017, June 30, 2018, and June 30, 2019, did not include the proper amounts of subaward funding for NIAID's Federal programs.³¹ HHS-OIG states that it reasonably would have expected NIH/NIAID's monitoring activities to have detected EcoHealth's repeated reporting omissions (as HHS-OIG's review detected them), and then to have advised EcoHealth to modify its SEFAs.³²

Finally, although all 11 of EcoHealth's subawards that HHS-OIG reviewed included at least one example of noncompliance with the applicable HHS regulation, and most of them included multiple examples, HHS-OIG did not comment on NIH/NIAID's failure discover such noncompliance and to enforce the regulation.³³

²⁵ *Id.* at pp. 16, 20, and 23.

²⁶ *Id.* at p. 15.

²⁷ *Id.* at p. 16.

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² *Id.*

³³ Interestingly, despite HHS-OIG's silence concerning NIH/NIAID's failure to discover and remedy EcoHealth's multiple instances of non-compliance, NIH's response to HHS-OIG's audit findings and recommendations provides that by letter dated August 19, 2022, it directed EcoHealth to update its subaward agreements associated with Grant R01A/110964 to correct the deficiencies noted by HHS-OIG. 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. 53 (Appx. I).

RECORDS REQUEST

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

1. With respect to Grant R01A/110964, all communications and documents (including audit working papers), supporting HHS-OIG's conclusion that NIH/NIAID's policies and procedures for monitoring grantee compliance with the FFATA and Transparency Act and regulations implementing it (*e.g.*, 2 C.F.R. § 200.300(b); 45 C.F.R. § 75.300(b)) "were not always effective."
2. With respect to Grant R01A/110964, all communications and documents (including audit working papers), supporting HHS-OIG's conclusion that NIH/NIAID's policies and procedures for monitoring grantee compliance with uniform guidance for the administration of Federal grants and/or 45 C.F.R. §§ 75.501 – 75.512 "were not always effective."
3. With respect to Grant R01A/110964, all communications and documents (including audit working papers) bearing upon NIH/NIAID's examinations/reviews of EcoHealth's reporting on first-tier sub-recipients under the grant.
4. With respect to Grant R01A/110964, all communications and documents (including audit working papers) bearing upon NIH/NIAID's examinations/reviews of EcoHealth's SEFAs for the years ended June 30, 2016, June 30, 2017, June 30, 2018, and June 30, 2019.
5. With respect to Grants R01A/110964, U01A/151797, and U01A/153420, all communications and documents (including audit working papers) bearing upon NIH/NIAID's examinations/reviews of subaward agreements that EcoHealth made under the grants.

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, audit working papers, 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 tl@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”³⁴ 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 made to EcoHealth Alliance, and in particular Grant R01A/110964, which is entitled *Understanding the Risk of Bat Coronavirus Emergence*.

³⁴ 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