

EMPOWER OVERSIGHT

Whistleblowers & Research



January 5, 2022

VIA ELECTRONIC TRANSMISSION: NIHFOIA@MAIL.NIH.GOV

Chief FOIA Officer
National Institutes of Health
Building 31, Room 5B35
31 Center Drive, MSC 2107
Bethesda, MD 20892

RE: FOIA Request for Regarding EcoHealth Alliance

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

In response to a recent Freedom of Information Act (“FOIA”), the National Institutes of Health (“NIH”) released correspondence with EcoHealth Alliance. These documents were published by Sharon Lerner with *The Intercept*.¹ In a letter addressed to Dr. Michael Lauer, Deputy Director for Extramural Research, EcoHealth Alliance sent the NIH documentation of the assessment of the Wuhan Institute of Virology’s (“WIV”) compliance with terms of an NIH grant. This letter from EcoHealth Alliance is dated April 23, 2021.

The EcoHealth Alliance letter to the NIH references numerous attached documents. The letter states, in pertinent part:

As requested, we have supplied all EcoHealth Alliance-WIV subrecipient agreements, as well as documents pertaining to EHA's monitoring of WIV's compliance with the terms and conditions of award. The attached documents

¹ <https://www.documentcloud.org/documents/21169285-nih-ecohealth-communications-bat-coronavirus-grant-2021>

demonstrate that we have fulfilled all requirements in the CFR codes listed in your letter excerpted above.

The letter then lists six separate attachments. However, the NIH did not make these attachments public. The letter from EcoHealth Alliance also references a letter dated April 11, 2021, that it sent to the NIH.

The NIH responded to the EcoHealth Alliance letter on July 23, 2021. In response, NIH asked the EcoHealth Alliance to provide further documents. The NIH letter states, in pertinent part:

In closing, please be advised that EcoHealth Alliance, Inc. must satisfy the existing specific award condition for UO I All 51797 by 30 days from establishment and must provide the remaining documents and reports requested herein for all three grants (RO1AI110964, U01AI151797, U01AI153420) no later than August 27, 2021.

For ease in responding to this request, attached please find the letter from EcoHealth Alliance dated April 23, 2021, and the NIH letter dated July 23, 2021.

RECORDS REQUEST

To shed light on EcoHealth Alliance's compliance with NIH regulations regarding its "subrecipient," the WIV, we respectfully request, pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, copies of:

1. All attachments that the EcoHealth Alliance describes in its April 23, 2021, letter as: "EcoHealth Alliance 2016-2019 Subrecipient Monitoring Forms for WIV. EcoHealth Alliance began this formal subrecipient monitoring policy in 2016 as per OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR 200) ("Uniform Guidance"), specifically §200.331."
2. All attachments that the EcoHealth Alliance describes in its April 23, 2021, letter as: "2006-2018 WIV Annual Reports. In addition, NIH has full reports on the programmatic results that we filed annually."
3. All attachments that the EcoHealth Alliance describes in its April 23, 2021, letter as: "Wuhan Institute of Virology contracts and invoices for all 5 Years of Grant R01AI110964: 2014-2019."
4. All attachments that the EcoHealth Alliance describes in its April 23, 2021, letter as: "Federal Funding Accountability & Transparency Act Reports for WIV. From 2015 – 2019."
5. All attachments that the EcoHealth Alliance describes in its April 23, 2021, letter as: "Annual Independent Audit Reports from 2014-2019."
6. All attachments that the EcoHealth Alliance describes in its April 23, 2021, letter as: "Inter-Institutional Agreements from DHHS for WIV 2014 & 2019."

7. Any other attachments provided to the NIH in EcoHealth Alliance's letter dated April 23, 2021.
8. All internal communications at NIH regarding the EcoHealth Alliance letter with attachments dated April 23, 2021.
9. EcoHealth Alliance's letter to the NIH dated April 11, 2021, including any attachments.
10. Any response by EcoHealth Alliance to the NIH letter dated July 23, 2021, including any attachments.

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.

INSTRUCTIONS

The time period of the requested records is April 11, 2021, 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.

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”² 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.

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.

REQUEST FOR EXPEDITED PROCESSING

Although Empower Oversight fully expects the NIH to respond to this FOIA request within the 20 business days allotted by the FOIA, it requests expedited processing. The request is of widespread and exceptional media interest and the information sought involves questions about research integrity that affect public confidence in the activities and operations of the NIH. Empower Oversight is engaged in disseminating information to the public through its website and working with media.³ Accordingly, it is important that this request be processed and the results publicly disseminated as quickly as possible.

² 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. “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 (Sep 24, 2021), <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/>

³ “Mission,” Empower Oversight (<http://empowr.us/mission>).

For ease of administration and to conserve resources, we ask that documents be produced in a readily accessible electronic format. In the event our requests for a fee waiver and/or expedited processing are denied, or if you have any questions about this request, please contact us immediately. Thank you for your prompt attention to this matter.

Cordially,

/Jason Foster/

Jason Foster
Founder & President

Attachments



Dr. Michael Lauer
Deputy Director for Extramural Research,
NIH, Bethesda, MD.

Re: R01AI110964 and 2R01AI110964
"Understanding the Risk of Bat Coronavirus Emergence"

April 23rd 2021

Dear Dr. Lauer,

I am responding your letter of 4/13/21 regarding our response to conditions placed on the suspended NIH grant 2R01AI110964 "*Understanding the Risk of Bat Coronavirus Emergence*". In particular, this letter addresses your request for documentation on our assessment of WIV's compliance with terms of our subcontracts from the initial (now expired) 5-year award:

"...copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any and all other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award NIH must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. § 75.364); and must have "timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents" (id.). These requirements flow down to subawards to subrecipients. 45 C.F.R. § 75.101. "Non-Federal entities must comply with requirements in [45 C.F.R. Part 75] regardless of whether the non-Federal entity is a recipient or subrecipient of a Federal award." 45 C.F.R. 75.101. As the grantee, EcoHealth was required to have in place, "A requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part." 45 C.F.R. § 75.352(a)(5)..."

As requested, we have supplied all EcoHealth Alliance-WIV subrecipient agreements, as well as documents pertaining to EHA's monitoring of WIV's compliance with the terms and conditions of award. The attached documents demonstrate that we have fulfilled all requirements in the CFR codes listed in your letter excerpted above. These documents include:

1. EcoHealth Alliance 2016-2019 Subrecipient Monitoring Forms for WIV. EcoHealth Alliance began this formal subrecipient monitoring policy in 2016 as per OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR 200) ("Uniform Guidance"), specifically §200.331.
2. 2006-2018 WIV Annual Reports. In addition, NIH has full reports on the programmatic results that we filed annually.
3. Wuhan Institute of Virology contracts and invoices for all 5 Years of Grant R01AI110964: 2014-2019
4. Federal Funding Accountability & Transparency Act Reports for WIV. From 2015 – 2019
5. Annual Independent Audit Reports from 2014-2019
6. Inter-Institutional Agreements from DHHS for WIV 2014 & 2019

We hope these documents satisfy your request by demonstrating that EcoHealth Alliance maintained detailed records of our appropriate monitoring of WIV's performance against the conditions of our initial (now expired) R01 grant and our contracts with them.

We also would like draw your attention to our letter dated 4.11.2021 regarding plans for biosafety monitoring for the renewal R01, under which we had not yet set up a subcontract with WIV, specifically:

"8. Provide copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award, including with respect to biosafety.

As we related in response to your letter of 4/19/2020 that asked us to suspend work with WIV, we had not yet set up a subcontract with WIV for the period of this award, therefore no such subrecipient agreements exist. Our plan was to monitor WIV's compliance as we had in the 5 years prior, by means of semi-annual meetings with the lead investigator and assessments of compliance against all conditions of the award. Additionally, following the NIH's termination, then reinstatement and suspension of our funding, we have contracted with a leading lab biosafety contractor based in Southeast Asia (b) (4), (b) (6) (b) (4), (b) (6) who has extensive experience commissioning, accrediting and auditing BSL-2, -3, and -4 labs, and has worked for over a decade at the BSL-4 (b) (4). We will be using their services where appropriate for foreign lab subcontractees to assess lab biosafety procedures and conduct audits, including following the full reinstatement of 2R01AI110964. Finally, we have appointed a Senior Field Veterinarian who will oversee all EcoHealth Alliance fieldwork in the region and ensure continued compliance with biosafety when conducting animal capture, sampling and sample handling. We have done this at EcoHealth Alliance's own expense, despite our unblemished record on biosafety, to pre-empt calls for further sanctions against our work given the continued attacks against EcoHealth Alliance in the press after the termination of our NIH grant."

We believe the attached documents lay out details of how we had previously monitored compliance according to the federal codes you cite, and the above response lays out an appropriate plan for biosafety monitoring. Together, we believe they appropriately and fully addresses your condition #8 for full reinstatement with access to funding for the renewal phase of the R01.

Yours sincerely,



Dr. Peter Daszak, President

(t) (b) (6) (e) (b) (6)



National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

23 July 2021

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: R01AI110964, U01AI151797, U01AI153420

Dear Drs. Chmura and Daszak:

Thank you for your correspondence of April 11, 2021 and April 23, 2021 regarding R01AI110964. We are in the process of conducting detailed analyses of your answers to our questions and well as of the documents you sent, and we have the following additional requests:

1. Records

For us to continue our analyses, we will need to receive and review WIV's records validating expenditures specific to R01AI110964 as well as any and all monitoring, safety, and financial reports specific to R01AI110964 that WIV submitted to you. As a reminder, subawardees are required to have a financial management system that includes records that identify adequately the source and application of funds for federally-funded activities. These records must contain information pertaining to Federal awards, authorizations, obligations, unobligated balances, assets, expenditures, income and interest and be supported by source documentation. 45 C.F.R. §§ 75.101 and 75.302.

As a term and condition of award, NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. 75.364). This right of access applies not only to awardee records, but also to subawardee records. Awardees indicate their acceptance of an NIH award and its associated terms and conditions as they draw down the NIH grant funds to support the scientific project (see NIHGPS [Section 5](#)).



We will also need to see subaward agreements, subawardee audit reports, subawardee safety monitoring documents, subawardee progress reports submitted to you, and subawardee financial and accounting records for two other NIH EcoHealth Alliance grants. Specifically, please send us all responsive documents for:

- U01AI151797 (Daszak): subawardees Chulalongkorn Hospital, Chulalongkorn University, Duke-National Singapore University, and University of North Carolina at Chapel Hill
- U01AI153420 (Epstein): subawardees International Center for Diarrhoeal Disease Research of Bangladesh, Institute of Epidemiology Disease Control and Research of Bangladesh.

We remind you that the Notice of Award for U01AI151797 already contains the following specific award conditions that must still be satisfied by 30 days from establishment.

Subaward Agreement Requirements: The ECOHEALTH ALLIANCE, INC. must provide NIAID with copies of all (existing and newly established) subaward agreements established under this award, including descriptions of the biosafety monitoring plans, within 30 days of establishment.

Federal Funding Accountability and Transparency Subaward Reporting System (FSRS) Requirements: This award is subject to the Transparency Act subaward reporting requirement of 2 CFR Part 170, which must be reported through the Federal Funding Accountability and Transparency Subaward Reporting System (FSRS). The ECOHEALTH ALLIANCE, INC. must provide NIAID with proof of documentation of timely entries of subaward information into the FSRS within 30 days of submitting to FSRS.

2. Reports

We are also writing to notify you that a review of our records for R01AI110964 indicates that EcoHealth Alliance, Inc. is out of compliance with requirements to submit the following reports that are outlined in the NIHGPS: the Federal Financial Report (FFR, see [8.4.1.2.3](#) Modified Financial Reporting Requirements) and the Interim Research Performance Progress Report (I-RPPR, see NIHGPS [8.4.1.4](#) Final Research Performance Progress Report).

R01AI110964 was issued under the Streamlined Noncompeting Award Process (SNAP). For awards under SNAP, an FFR must be submitted within 120 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment.

Additionally, NIH requires that organizations submit an Interim-RPPR while their Type 2 application is under consideration. In the event that the Type 2 is funded, NIH treats the Interim-RPPR as the annual performance report for the final year of the previous competitive segment.

The FFR and I-RPPR for R01AI110964 were due within 120 days after the end of the project period. In this case, the competitive segment ended on May 31, 2019, and reports were due September 30, 2019. To date, NIH has still not received these reports. Compliance with [Section 8, Administrative Requirements](#) within the NIH Grants Policy Statement (NIHGPS) is a standard term and condition of award that applies to all NIH recipients.

A recipient's failure to comply with the terms and conditions of award, may cause NIH to take one or more actions on the award, depending on the severity and duration of the non-compliance. Additionally, a history of non-compliance related to R01AI110964, including reporting non-compliance, may impact other projects where EcoHealth serves as the primary grant recipient. When a recipient has a history of failure to comply with the general or specific terms and conditions of a previous Federal award, NIH may impose specific award conditions on other awards of the recipient, including withholding authority to proceed to the next phase of a project until receipt of evidence of acceptable performance (see NIHGPS [Section 8.5](#), Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support).

In closing, please be advised that EcoHealth Alliance, Inc. must satisfy the existing specific award condition for U01AI151797 by 30 days from establishment and must provide the remaining documents and reports requested herein for all three grants (R01AI110964, U01AI151797, U01AI153420) no later than August 27, 2021.

Please let me know if you have any questions concerning the information in this letter.

Sincerely,

Lauer, Michael (NIH/
OD) [E]

Digitally signed by Lauer,
Michael (NIH/OD) [E]
Date: 2021.07.23 17:24:01 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research

(b) (6)

cc: Ms. Emily Linde
Dr. Erik Stemmy