DEPARTMENT OF HEALTH & HUMAN SERVICES





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).





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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.

<u>Subaward Agreement Requirements</u>: 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 <u>8.4.1.2.3</u> Modified Financial Reporting Requirements) and the Interim Research Performance Progress Report (I-RPPR, see NIHGPS <u>8.4.1.4</u> 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.

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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/ Digitally signed by Lauer, Michael (NIH/OD) [E]

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