



August 19, 2022

The Honorable James Comer
Ranking Member, Committee on Oversight and Reform
U.S. House of Representatives
Washington, DC 20515

Dear Representative Comer:

Thank you for your interest in the work of the National Institutes of Health (NIH). I write to you today in a continuing effort to be responsive to your inquiries about NIH oversight of awards to EcoHealth Alliance (EHA).

As you know, the National Institute of Allergy and Infectious Diseases (NIAID) awarded EHA grant R01AI110964 (“R01 award”) after the application received a meritorious score through the peer review process. This grant included three sub-awards, including one to the Wuhan Institute of Virology (WIV) and had a performance period starting on June 1, 2014. The renewal application for this grant underwent peer review, and the Notice of Award was issued on July 24, 2019. The research approved under this grant sought to understand how bat coronaviruses evolve naturally in the environment to become transmissible to the human population. This type of research is a critical component of pandemic preparedness. Identifying pathogens that have the potential to cause disease in humans allows the research community to prepare for how to respond if these pathogens do enter the human population.

NIH’s Office of Extramural Research (OER) suspended EHA grant R01AI110964 on July 8, 2020, due to grant administrative non-compliance concerns. Over time, NIH reviewed EHA’s compliance with requirements under the R01 award and requested information and documentation from EHA to enable NIH to conduct its review.

NIH also reviewed EHA’s compliance with requirements under two other NIH awards to EHA, the Research Project Cooperative Agreements (“U awards”). See Table 1 for a list of all current NIH awards to EHA.

Table 1: Current NIH Awards to EHA

Award Number	Grant Title	Performance Period
R01AI110964	Understanding the Risk of Bat Coronavirus Emergence	July 1, 2014-May 31, 2019; Renewal: June 1, 2019- May 31, 2024*

U01AI151797	Understanding Risk of Zoonotic Virus Emergence in Emerging Infectious Disease Hotspots of Southeast Asia	June 17, 2020-May 31, 2025**
U01AI153420	Study of Nipah Virus (NiV) Dynamics and Genetics in Bat Reservoirs and of Human Exposure to NiV Across Bangladesh to Understand Patterns of Human Outbreaks	September 15, 2020-June 30, 2025**

*This grant was suspended on July 8, 2020 and has remained suspended.

**Specific award conditions imposed on January 6, 2022 but was never suspended.

As NIH notified you on January 6, 2022, NIH sent a letter to EHA that day conveying the outcome of its detailed administrative review of compliance under the U awards. NIH identified a number of compliance issues, including inadequate oversight in monitoring the activities of its subawardees, failure to report subawards to the General Services Administration's Federal Subaward Reporting System, and errors in indirect rate charges. In cases of non-compliance, NIH's approach is generally to provide a grantee the opportunity to come into compliance in an effort to preserve the research, when possible. This approach is consistent with HHS grant regulations, which provide that in cases of non-compliance, a funding agency can impose specific award conditions; and if the agency determines that the non-compliance cannot be remedied by specific award conditions, then the agency may take more severe actions, such as terminating an award in whole or in part.

Our January 6, 2022 letter announced immediate imposition of specific award conditions on the U awards to allow NIH to monitor these awards more closely. The U awards were never suspended. In addition, the letter outlined areas where EHA needed to improve its administrative policies and practices. NIH requested EHA submit a Corrective Action Plan (CAP) to address these issues.

EHA provided a proposed CAP to NIH on February 4, 2022. The CAP outlined steps EHA would take to address the non-compliance NIH identified under the two U awards. Between February and April 2022, NIH approved EHA's CAP and EHA implemented the CAP. Pursuant to the CAP, EHA revised the U subaward agreements to include details on EHA's procedures for access to subawardees' records and financial statements, data-sharing and management of awards, and a correction of the Facilities and Administrative cost rate. EHA also provided NIH with new and updated EHA policies that describe how, for all EHA projects, EHA will comply with reporting requirements and other deficiencies identified by NIH.

I write today to update you on EHA's implementation of the CAP under the U awards, the conclusion of NIH's review of compliance under the R01 award, and the next steps NIH will take with EHA. At this time, EHA has successfully implemented the NIH-approved CAP for its active U awards, which includes rewriting subaward agreements, and improving monitoring and reporting conflicts of interest by its subawardees. Accordingly, NIH has determined that EHA was able to resolve the problems identified with those awards. For the R01 award, NIH identified the same issues that were present with the U awards (including inadequate oversight in monitoring the activities of its subawardees, failure to report subawards to the General Services Administration's Federal Subaward Reporting System, and errors in indirect rate charges), as

well as reporting delinquencies, such as the late submission of the fifth year progress report. NIH has determined that these problems can be remedied by imposing specific award conditions, because EHA demonstrated that it could resolve these same problems under the U awards with the successful implementation of a CAP.

However, NIH also identified one non-compliance under the R01 award that cannot be remedied with specific award conditions. NIH has requested on two occasions that EHA provide NIH the laboratory notebooks and original electronic files from the research conducted at WIV. To date, WIV has not provided these records. Under 45 CFR 75.371, “If a non-federal entity fails to comply with federal statutes, regulations, or the terms and conditions of a federal award, the HHS awarding agency or pass-through entity may impose additional conditions, as described in § 75.207. If the HHS awarding agency or pass-through entity determines that non-compliance cannot be remedied by imposing additional conditions, the HHS awarding agency or pass-through entity may take one or more [enforcement] actions, as appropriate in the circumstances[.]” 45 CFR 75.371. Such actions may include partly terminating the federal award. Id. at 75.371(c).

Today, NIH has informed EHA that since WIV is unable to fulfill its duties for the subaward under grant R01AI110964, the WIV subaward is terminated for failure to meet award terms and conditions requiring provision of records to NIH upon request.

In light of the cooperation from EHA and the subsequent substantial improvements in administrative processes that EHA demonstrated with the two U awards, NIAID will begin to engage with EHA to renegotiate the specific aims and objectives of the R01 grant without the involvement of WIV. If an agreement is made, the revised grant will be reviewed again in its entirety to ensure all applicable policy and guideline requirements are met including the HHS Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens (P3CO) and other relevant policies and guidelines. A revised Notice of Award will be issued, subject to specific award conditions and any additional precautions that may be appropriate for inclusion, and the suspension on the grant will be lifted. If revisions to the grant’s aims and objectives cannot be revised to stay within the original peer reviewed, scientific scope of the project, NIH reserves the right to request a bilateral termination of the remainder of the award.

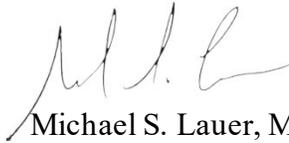
As specific award conditions, NIH will maintain a higher level of oversight over all EHA awards for a minimum of three years, including a doubling of the frequency for the required scientific progress and financial reports, and a requirement that EHA submit additional documents illustrating their subaward monitoring activity. In addition, EHA will be required to conduct onsite inspections of all of its subawardees every six months to confirm that all terms of subaward agreements are being fully and appropriately executed. EHA will also be required to submit updated subaward agreements under the revised R01 award that address the deficiencies identified by NIH.

NIH takes its oversight of grants very seriously and always considers what further measures can be taken to strengthen routine oversight of grants at NIH. In light of this compliance case, NIH has taken additional steps. NIH has incorporated additional automated systems of controls for

the timely receipt of progress reports to ensure that the most recent information is received and accepted by program officers. NIH has implemented program scripts in the NIH grants system (eRA) that send additional reminders to grant recipients and NIH staff of delinquencies if progress reports are either delayed or not fully reviewed and accepted. Should this happen, the system establishes a “red bar” to funding of the next non-competing renewal, which would prevent the award from being processed until the “red bar” is resolved. NIH believes that these new measures will further strengthen our oversight of grantees while continuing the life-saving work done by NIH grantees.

NIH is committed to ensuring responsible stewardship and accurate reporting of the use of federal funds. In a continued effort to be transparent, NIH has attached to this letter the communications between NIH and EHA regarding the implementation of the CAP. I hope this information is helpful to you.

Sincerely,



Michael S. Lauer, M.D.

Deputy Director for Extramural Research
National Institutes of Health

Enclosures:

First letter from NIH to EHA on January 6, 2022

Second letter from NIH to EHA on January 6, 2022

CAP proposed by EHA (in 2 parts)

NIH response to EHA's CAP

Follow-up CAP documents submitted by EHA (in 5 parts)

Letter from NIH to EHA on August 19, 2022