



VIA ELECTRONIC MAIL AND CERTIFIED MAIL-RETURN RECEIPT REQUESTED

EcoHealth Alliance, Inc.
Attn: Dr. Peter Daszak, President
520 Eighth Avenue, Suite 1200
New York, NY 10018-4183
Email: daszak@ecohealthalliance.org

Re: Notice of Suspension and Proposed Debarment of EcoHealth Alliance, Inc.

Dear Dr. Daszak:

This is to provide notification that, on behalf of the United States Department of Health and Human Services (HHS), I have suspended and proposed for debarment EcoHealth Alliance, Inc. (EHA) from participating in United States Federal Government procurement and nonprocurement programs. This action is initiated pursuant to 2 C.F.R. Part 180. HHS adopted and gave regulatory effect to 2 C.F.R. Part 180 at 2 C.F.R. Subpart 376.10. Copies of the referenced regulations are enclosed. Also enclosed is a copy of an Action Referral Memorandum (ARM), dated May 15, 2024, which sets forth the basis for the suspension and proposed debarment. The information in the ARM indicates that EHA lacks the present responsibility to participate in federal procurement and nonprocurement programs

As indicated in the ARM, I base this suspension and proposed debarment on information from the following:

- 1) October 1, 2013, National Institutes of Health Grants Policy Statement (NIH GPS) for Fiscal Years 2013-2014;
- 2) a May 27, 2014, Notice of Award (NoA) for Grant Number 1R01AI110964-01, awarded by the NIH/National Institute of Allergy and Infectious Disease (NIAID) to EHA;
- 3) a May 28, 2016, letter from the NIAID to EHA;
- 4) a June 8, 2016, letter from EHA to the NIAID;
- 5) a July 7, 2016, letter from the NIAID to EHA;
- 6) a November 30, 2016, Revised NoA for Grant Number 5R01AI110964-03, awarded by the NIAID to EHA;
- 7) a May 26, 2017, NoA for Grant Number 5R01AI110964-04, awarded by the NIAID to EHA;
- 8) HHS *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (HHS P3CO Framework), published on December 19, 2017;
- 9) a June 18, 2018, NoA for Grant Number 5R01AI110964-05, awarded by the NIAID to EHA;
- 10) a July 24, 2019, NoA for Grant Number 2R01AI110964-06, awarded by the NIAID to EHA;

- 11) an April 19, 2020, letter from the NIH to EHA;
- 12) an April 24, 2020, letter from the NIH to EHA;
- 13) a May 22, 2020, letter from the law firm of Tarter Krinsky & Droggin LLP, to the NIH;
- 14) a July 8, 2020, letter from the NIH to EHA;
- 15) a July 23, 2021, letter from the NIH to EHA;
- 16) an October 20, 2021, letter from the NIH to EHA;
- 17) an October 26, 2021, letter from EHA to the NIH;
- 18) Year 4 Research Performance Progress Report (RPPR), for Grant Number 5R01AI110964-05;
- 19) Year 5 Interim-Research Performance Progress Report (I-RPPR) for Grant Number R01AI110964-05;
- 20) a November 5, 2021, letter from the NIH to EHA;
- 21) a November 15, 2021, email from EHA to Wuhan Institute of Virology (WIV);
- 22) a November 18, 2021, letter from EHA to the NIH;
- 23) a January 6, 2022, letter from the NIH to EHA;
- 24) a January 21, 2022, letter from EHA to the NIH;
- 25) an August 19, 2022, letter from the NIH to EHA;
- 26) a January 25, 2023, HHS Office Of Inspector General (OIG) Audit Report Number A-05-21-00025, titled, “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;”
- 27) a July 17, 2023, HHS Notice and ARM for the Suspension and Proposed Debarment and of WIV;
- 28) a September 19, 2023, HHS Notice and ARM for the Debarment of WIV;
- 29) a May 6, 2024, NIH forensics summary report of the eRA Commons reporting system logs for RPPR related activities for R01AI110964-05; and
- 30) NIH RePORTER database documents for Grant Numbers 5U01AI151797-04, 5U01AI153420-04, and 5R01AI163118-02.

As further explained in the ARM, the information from this record provides cause for the suspension under 2 C.F.R. § 180.700(b) and (c) for the debarment cause provided in 2 C.F.R. § 180.800(d) – “Any other cause of so serious or compelling a nature that it affects your present responsibility.” HHS believes there is adequate evidence in the record for this debarment cause and that immediate action is necessary to protect the public interest.

If EHA wishes to contest this action, EHA or EHA’s representative acting on its behalf, must either send, or make arrangements to appear and present information and argument to me, the HHS Suspension and Debarment Official (SDO), within 30 days after EHA receives this Notice and ARM. *See* 2 C.F.R. § 180.725(b) (addressing the time a respondent has to contest a suspension and when a Notice is considered to be “received”).

If EHA designates a representative to respond on its behalf, please send notification of the identity of the representative via electronic mail to the HHS Exclusion Mailbox at the following email address: exclusioninquiries@hhs.gov. The designation should specifically state the names, addresses, phone numbers, and email addresses of all individuals or companies the designee has the authority to represent in this matter.

Any response contesting this suspension action may include any information and argument in opposition to the suspension that EHA would like considered by the SDO and should provide information responsive to 2 C.F.R. § 180.730(a)(1)-(4). Additional information about contesting the suspension is available at 2 C.F.R. Part 180, Subparts F and G, generally, and specifically, 2 C.F.R. § 180.720 *et seq.*

Any response contesting this proposed debarment action may similarly include any information and argument in opposition to the suspension and proposed debarment that EHA would like considered by the SDO and should provide information responsive to 2 C.F.R. § 180.825(a)(1)-(4). Additional information about contesting the debarment is available at 2 C.F.R. Part 180, Subparts F and H, generally, and specifically, 2 C.F.R. § 180.815 *et seq.*

The suspension and proposed debarment are effective as of May 14, 2024. The suspension and debarment, if ultimately imposed, has the following consequences pursuant to the authorities of 2 C.F.R. § 180 and the Federal Acquisition Regulation (FAR) (under the reciprocal effect provision of 2 C.F.R. § 180.140).

1. The entity's name, EcoHealth Alliance, Inc., will be published in the General Services Administration's web-based System for Award Management (SAM), available at www.sam.gov. SAM contains the names of contractors debarred, suspended, proposed for debarment, or declared ineligible by any federal agency. Suspension and proposed debarment are effective throughout the executive branch of the United States Federal Government and apply to procurement and nonprocurement programs.
2. Offers will not be solicited from, contracts will not be awarded to, existing contracts will not be renewed or otherwise extended for, and subcontracts requiring United States Federal Government approval will not be approved for EHA by any agency in the executive branch of the United States Federal Government, unless the head of the agency taking the contracting action determines that there is a compelling reason for such action.
3. EHA may not conduct business with the United States Federal Government as an agent or representative of other contractors, or as an agent or representative of other participants in federal assistance programs, nor may EHA act as an individual surety to other United States Federal Government contractors.
4. No United States Federal Government contractor may award to EHA a subcontract equal to or in excess of \$35,000, except for certain subcontracts for commercially available off-the-shelf items, unless there is a compelling reason to do so and the contractor first notifies the contracting officer and further complies with the provisions of FAR 9.405-2(b).
5. EHA's affiliation with, or relationship to, any organization doing business with the United States Federal Government will be carefully examined to determine the impact of those ties on the responsibility of that organization to be a United States Federal Government contractor or subcontractor.
6. EHA is prohibited from acting as a participant in Federal agency transactions that are covered transactions unless an exception applies, and prohibited from acting as a principal of a participant in those covered transactions. *See* 2 C.F.R. §§ 180.130, 180.200,

and 180.980. Covered transactions include certain procurement and certain nonprocurement transactions. *See* 2 C.F.R. § 180.200. EHA is prohibited from participating in certain non-procurement transactions which include but are not limited to grants, cooperative agreements, scholarships, fellowships, contracts of assistance, loans, loan guarantees, subsidies, insurances, payments for specified uses, and donation agreements. *See* 2 C.F.R. § 180.970. No agency in the executive branch shall enter into, renew, or extend, primary or lower-tier covered transactions in which EHA is either a participant or principal, unless the head of the agency grants an exception in writing.

The determination to suspend and/or debar is discretionary and is being made on the basis of an administrative record. Any written information submitted by EHA will become a part of this administrative record, as will any information added to the record by the United States Federal Government. A copy of the administrative record will be furnished upon request.

As noted in the ARM, this suspension is a temporary action. Suspension is used where immediate action is necessary to protect the integrity of federal procurement and nonprocurement activities. The suspension is effective until the conclusion of debarment proceedings pursuant to 2 C.F.R. § 180.760(a). It is important to note that suspension and debarment actions are not punitive. Accordingly, I will consider any information EHA provides in response to this Notice.

Debarment is generally for a period not to exceed three years; however, regardless of whether EHA contests this action or responds to this Notice, I may impose debarment for a longer period or shorter period as the circumstances warrant. The length of debarment, if ultimately imposed, will be based on the seriousness of the cause for debarment, as provided by 2 C.F.R. § 180.865. I may also take into account any mitigating or aggravating factors that may apply, as provided by 2 C.F.R. § 180.860.

Any electronic communications regarding this matter should be addressed to the HHS Exclusion Mailbox at exclusioninquiries@hhs.gov. Written submissions should be addressed to the U.S. Department of Health and Human Services, Office of Acquisitions, Office of Recipient Integrity Coordination, 200 Independence Avenue, S.W., Room 519H, Washington, D.C. 20201.

Sincerely,

H. Katrina Brisbon
Suspension and Debarment Official and
Deputy Assistant Secretary for Acquisitions

Enclosures: Action Referral Memorandum
[Copy of 2 C.F.R. Part 180](#)
[Copy of 2 C.F.R. Part 376](#)



ACTION REFERRAL MEMORANDUM

On behalf of the United States Department of Health and Human Services (HHS), I hereby suspend and propose the debarment of EcoHealth Alliance, Inc. (EHA) from participating in United States Federal Government procurement and nonprocurement programs. This action is initiated pursuant to 2 C.F.R. Part 180. HHS adopted and gave regulatory effect to 2 C.F.R. Part 180 at 2 C.F.R. Subpart 376.10.

The suspension and proposed debarment for EHA is based on information from the following:

- 1) October 1, 2013, National Institutes of Health Grants Policy Statement (NIH GPS) for Fiscal Years 2013-2014;
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- 3) a May 28, 2016, letter from the NIAID to EHA;
- 4) a June 8, 2016, letter from EHA to the NIAID;
- 5) a July 7, 2016, letter from the NIAID to EHA;
- 6) a November 30, 2016, Revised NoA for Grant Number 5R01AI110964-03, awarded by the NIAID to EHA;
- 7) a May 26, 2017, NoA for Grant Number 5R01AI110964-04, awarded by the NIAID to EHA;
- 8) HHS *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (HHS P3CO Framework), published on December 19, 2017;
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- 10) a July 24, 2019, NoA for Grant Number 2R01AI110964-06, awarded by the NIAID to EHA;
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- 21) a November 15, 2021, email from EHA to Wuhan Institute of Virology (WIV);

- 22) a November 18, 2021, letter from EHA to the NIH;
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- 24) a January 21, 2022, letter from EHA to the NIH;
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- 30) NIH RePORTER database documents for Grant Numbers 5U01AI151797-04, 5U01AI153420-04, and 5R01AI163118-02.

The information summarized below indicates that EHA lacks the present responsibility to participate in United States Federal Government procurement and nonprocurement programs. The information from this record provides cause for the suspension under 2 C.F.R. § 180.700(b) and (c) for the debarment cause provided in 2 C.F.R. § 180.800(d) – "Any other cause of so serious or compelling a nature that it affects your present responsibility." HHS believes there is adequate evidence in the record for this debarment cause and that immediate action is necessary to protect the public interest.

INFORMATION IN THE RECORD

A summary of the information in the record upon which the suspension and proposed debarment is based appears below:

1. In a NoA dated May 27, 2014, the NIH/NIAID awarded Grant Number 1R01AI110964-01, "Understanding the Risk of Bat Coronavirus Emergence," to EHA, with a project period from June 1, 2014 through May 31, 2019.
2. EHA is a United States-based nonprofit organization that focuses on research that aims to prevent pandemics and promote conservation in hotspot regions worldwide. The stated mission of EHA is protecting people, animals, and the environment from emerging infectious diseases.
3. Dr. Peter Daszak is the President of EHA and the Principal Investigator (PI) for Grant Number 1R01AI110964-01.
4. WIV, located in Wuhan, China, was listed as a consortium participant in the NoA for Grant Number 1R01AI110964-01.
5. As stated in the NIH GPS, the prime recipient is accountable to the NIH for the performance of the project, the appropriate expenditure of grant funds by all parties, applicable reporting requirements, and all other obligations of the recipient. In

- addition, the terms and conditions flow down to subrecipients in accordance with 2 C.F.R. Part 200.101(b)(2).
6. The NIH GPS defines a consortium agreement as a formalized agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. Under the agreement, the grantee must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties. These agreements typically involve a specific level of effort from the consortium organization's Project Director (PD)/PI and a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including F&A costs. The relationship between the recipient and the collaborating organizations is considered a subaward relationship.
 7. Grant Number 1R01AI110964-01 involved the study of highly pathogenic agents, which required the grant prime awardee's (EHA's) and subrecipient's (WIV's) adherence to specific biocontainment safety (biosafety) requirements; this was a term of the award. This grant was subject to biosafety requirements set forth in the NIH GPS, a term and condition of every NIH grant award, Section 4.1.24 "Public Health Security" and the Notice of Award, Section IV (e.g., requiring that "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)].")
 8. On October 17, 2014, the White House announced that the United States Federal Government was instituting a governmentwide funding pause on gain-of-function (GoF) research projects that may be reasonably anticipated to confer attributes to influenza, Middle East respiratory syndrome (MERS), or severe acute respiratory syndrome (SARS) viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.
 9. In a letter dated May 28, 2016, the NIAID contacted EHA concerning possible GoF research based on information submitted in its most recent Year 2 RPPR. The NIAID notified EHA that GoF research conducted under Grant Number 5R01AI110964-03 would be subject to the October 17, 2014, United States Federal Government funding pause, and that per the funding pause announcement, new United States Federal Government funding would not be released for GoF research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route. In the letter, the NIAID requested that EHA provide a determination within 15 days of the date of the letter as to whether EHA's research under Grant Number 5R01AI110964-03 did or did not include GoF work subject to the funding pause.
 10. In a letter dated June 8, 2016, EHA provided a response to the NIAID's May 28, 2016 letter. EHA explained that the goal of its proposed work was to construct MERS and MERS-like chimeric CoVs in order to understand the potential origins of MERS-CoV in bats by studying bat MERS-like CoVs in detail. EHA stated that it believed it was highly unlikely that the proposed work would have any pathogenic potential, but

- that should any of these recombinants show evidence of enhanced virus growth greater than certain specified benchmarks involving log growth increases, or grow more efficiently in human airway epithelial cells, EHA would immediately: (1) stop all experiments with the mutant, (2) inform the NIAID Program Officer of these results, and (3) participate in decision-making trees to decide appropriate paths forward.
11. Based on the information provided by EHA, the NIAID concluded that the proposed work was not subject to the GoF research pause. In a letter dated July 7, 2016, however, the NIAID informed EHA that should any of the MERS-like or SARS-like chimeras generated under the grant show evidence of enhanced virus growth greater than 1 log over the parental backbone strain, EHA must stop all experiments with these viruses and provide the NIAID Program Officer and Grants Management Specialist, and WIV Institutional Biosafety Committee, with the relevant data and information related to these unanticipated outcomes.
 12. This issue formed the basis for the special term and condition that was included in Section IV of the revised NoA for R01AI110964-03, issued on November 30, 2016, to remind EHA that it was prohibited from using funds to support GoF research. The full text of the special term and condition was included in Section IV of the NoA, as follows:

No funds are provided and no funds can be used to support gain-of-function research covered under the October 17, 2014 White House Announcement (NIH Guide Notice NOT-OD-15-011). Per the letter dated July 7, 2016 to [Senior Coordinator of Operations] at EHA, should any of the MERS-like or SARS-like chimeras generated under this grant show evidence of enhanced virus growth greater than 1 log over the parental backbone strain you must stop all experiments with these viruses and provide the NIAID Program Officer and Grants Management Specialist, and WIV Institutional Biosafety Committee with the relevant data and information related to these unanticipated outcomes.
 13. On January 9, 2017, the White House issued *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight* (P3CO), which described procedures for United States Federal agencies to adopt in order to lift the funding pause. The HHS *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (HHS P3CO Framework), which was published on December 19, 2017, satisfied the January 9, 2017, White House guidance to address certain gain-of-function research and to lift the requirement for the research funding pause. The HHS P3CO Framework is intended to guide HHS funding decisions on research that is reasonably anticipated to create, transfer, or use enhanced potential pandemic pathogens (ePPPs).

14. In the June 18, 2018, NoA non-competing grant renewal for 5R01AI110964-05¹, the language of the Section IV Special Award Condition was revised as follows: “If any experiments proposed in this award result in a virus with enhanced growth by more than 1 log compared to wild type strains, you must notify your NIAID Program Officer and Grants Management Specialist immediately. Further research involving the resulting virus(es) may require review by the Department of Health and Human Services in accordance with the Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens . . .”. The project was renewed with this version of the special term and condition, included in Section IV of the NoA, for the period covering from June 1, 2014 through May 31, 2019.
15. On November 5, 2018, the NIH received a renewal application from EHA (Type 2), and on April 23, 2019, the NIH approved the application for funding. On July 24, 2019, a NoA was issued for Grant Number 2R01AI110964-06, with a project period from June 1, 2014 through June 30, 2024. The proposed work in the renewal application for Grant Number 2R01AI110964-06 was to investigate more divergent animal viruses, and the NIAID determined that the HHS P3CO policies did not apply to the work proposed under the competitive renewal application. As such, the NoA for Grant Number 2R01AI110964-06 did not include the special term and condition in Section IV. Although the NIAID determined that the work under 2R01AI110964-06 was ultimately not subject to either to the GoF pause or the HHS P3CO policies, the special term and condition was included for the remainder of the original competitive segment of the award, which was from June 1, 2014 through May 31, 2019. Accordingly, the special term and condition cited to above in paragraph 11 was applicable to the grant as revised in R01AI110964-03 through the grant renewal period corresponding to 5R01AI110964-05. After processing the grant renewal 2R01AI110964-06, the NIH performed routine grant administration activities and monitoring.
16. In a letter dated April 19, 2020, the NIH notified EHA that it was reviewing allegations that WIV released the coronavirus that was responsible for the COVID-19 global pandemic. While it reviewed the allegations, the NIH instructed EHA to cease providing any funds from Grant Number R01AI110964 to WIV.
17. In a letter dated April 24, 2020, the NIH notified EHA that it had elected to terminate Grant Number R01AI110964, for convenience. The NIH stated that in accordance with the NIH GPS, “the decision not to award a grant, or to award a grant at a particular funding level, is at the discretion of the agency, in accordance with NIH’s dual review system.”

¹ The NoA for grant renewal 5R01AI110964-04, issued on May 26, 2017, inadvertently omitted the special term and condition from Section IV special term and condition. In an effort to ensure the terms was clear, it was correctly added to the subsequent year NoA, 5R01AI110964-05. At this time, all terms have been updated by NIH to ensure that all terms are accurate.

18. In a letter dated May 22, 2020, Tarter Krinsky & Droggin LLP, the law firm representing EHA, notified the NIH that it was appealing the termination of Grant Number R01AI110964.
19. In a letter dated July 8, 2020, the NIH notified EHA that it withdrew its termination of Grant Number R01AI110964, and reinstated the grant. However, the NIH informed EHA that all activities related to R01AI110964 were programmatically suspended in accordance with 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. The NIH stated that it had received reports that WIV had been conducting research at its facilities in China that posed serious biosafety concerns and, as a result, created health and welfare threats to the public in China and other countries, including the United States. The letter stated that during the period of programmatic suspension, the NIH would continue to review the activities under the grant, taking into consideration information provided by EHA to further assess compliance by EHA and WIV. Among the information and materials requested by the NIH from EHA, NIH also directed EHA to arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019.
20. In a letter dated July 23, 2021, the NIH requested that EHA provide 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 EHA, in order to analyze EHA's and WIV's compliance with the terms and conditions of the grant. The NIH noted that as a term and condition of award and in accordance with 45 C.F.R. § 75.364, the awarding agency 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, and that this right of access applies to both awardee and subawardee records. *See* 45 C.F.R. § 75.364(a). The NIH also informed EHA that it was delinquent in the submission of the Year 5 I-RPPR, for the reporting period from June 1, 2018 to May 31, 2019. The report was due to be submitted within 120 days after the end of the project period, which was September 30, 2019. The NIH requested that EHA provide the remaining documents and outstanding reports by August 27, 2021.
21. On August 3, 2021, EHA submitted the Year 5 I-RPPR for Grant Number 5R01AI110964-05ys, more than two years after the report due date. The NIH's review of the Year 5 I-RPPR determined that an experiment, shown in Figure 13 of the report, had possibly yielded a greater than 1 log increase in viral activity. However, there were no facts to show that EHA notified the NIAID Program Officer and Grants Management Specialist, as required by the NoA, Section IV special term and condition of the grant, identified above in paragraph 13.
22. In a letter dated October 20, 2021, the NIH informed EHA that in order to continue its analysis of the Year 5 I-RPPR, the NIH required verification that WIV received

- approval from the Institutional Animal Care & Use Committee (IACUC), for field work (e.g., work in caves to collect materials from live bats) supported by R01AI110964, as required by the NIH GPS, Section 4.1.1.2. As such, the NIH requested WIV provide documentation verifying IACUC approval. The NIH also requested that EHA provide all unpublished data supported by the grant that had not already reported in its RPPRs. The NIH requested that the materials be provided by no later than October 27, 2021.
23. In a letter dated October 26, 2021, EHA challenged the NIH's assertion that the experiment reported in the Year 5 I-RPPR had possibly yielded a greater than 1 log increase in viral activity. EHA stated that Figure 13 of Year 5 I-RPPR and Figure 35 of the Year 4 RPPR for Grant Number 5R01AI110964-05, which covered the reporting period from June 1, 2017 through May 31, 2018, were taken from the same experiment. EHA asked that "these facts be acknowledged." Experts from the NIH, however, reviewed the corresponding figures and text and concluded that it was more likely than not that the Year 5 I-RPPR was describing a different experiment than was described in the Year 4 RPPR.
 24. In a letter dated November 5, 2021, the NIH requested that EHA provide WIV's original laboratory notebook entries and original electronic files to support the information that was reported in the Year 4 RPPR Figure 35 and the Year 5 I-RPPR Figure 13 for Grant Number 5R01AI110964-05. The NIH requested the laboratory notebooks in order to examine and analyze critical data supporting EHA's claim that the experiment shown in Figure 13 of the I-RPPR was in fact the same experiment shown in Figure 35 of the Year 4 RPPR. The NIH requested that the documentation be provided by November 19, 2021.
 25. In a letter dated November 18, 2021, EHA informed the NIH that it did not have copies of the requested laboratory notebooks and electronic files, which were created by WIV. EHA stated that it forwarded the NIH's November 5, 2021, letter to WIV and would provide the NIH with WIV's response upon receipt.
 26. In a letter dated January 6, 2022, the NIH again requested that EHA provide WIV's complete and dated original laboratory notebook entries and original electronic files for Grant Number R01AI110964. The requested records were not provided to the NIH.
 27. In a letter dated January 21, 2022, EHA informed the NIH that it had forwarded its January 6, 2022, letter to WIV, but that no further information had been received. EHA stated that it would inform the NIH when and if WIV provided a response.
 28. In a letter dated August 19, 2022, the NIH notified EHA that it was terminating the subaward from EHA to WIV under Grant Number R01AI110964 due to material non-compliance with terms and conditions of award that cannot be remedied by specific award conditions. The NIH stated that this would be accomplished as a partial termination of the award to EHA under 45 C.F.R. § 75.371(c). In making this decision, the NIH noted that to date it had still not received the materials requested in

- its previous correspondence, dated November 5, 2021, and January 6, 2022, complete and dated copies of the original laboratory notebook entries and of the original electronic files from WIV that led to the generation of the Year 4 RPPR Figure 35 and the Year 5 I-RPPR Figure 13, along with all their accompanying texts. The NIH also stated that its examination of the subaward agreement from EHA to WIV found that the agreement did not include “a requirement that the subrecipient [WIV] permit the pass-through entity [EHA] 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,” as required under 45 C.F.R. § 75.352. The subaward agreement also did not include “all requirements imposed by the pass-through entity on the subrecipient so that the [United States] Federal [Government] award is used in accordance with United States Federal Government statutes, regulations and the terms and conditions of the [United States] Federal [Government] award[.]” *See* 45 C.F.R. § 75.352.
29. On January 25, 2023, the HHS-OIG issued Audit Report Number A-05-21-00025, titled, “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.” The HHS-OIG recommended that the NIH consider whether it was appropriate to refer WIV to the HHS Suspension and Debarment Official (SDO) for potential administrative actions, based on information provided in the audit and any other information available to the NIH. The HHS-OIG also recommended that EHA submit progress reports by the required due date, comply with immediate notification requirements, ensure access to all subrecipient records, properly account for subawards, and refund to the Federal Government \$89,171 in unallowable costs. In written comments, EHA disagreed with the HHS-OIG’s findings regarding the timeliness of the submission of the Year 5 I-RPPR and claimed that the report could not be submitted due to EHA being locked out of the NIH reporting system. In response to EHA’s comments, the HHS-OIG stated, “We acknowledge in our report that [EHA’s] Year 5 progress report was initiated on NIH’s online portal in July 2019; however, we have no evidence that the progress report was fully uploaded to the online portal at that time. Furthermore, we have no evidence that there was any correspondence between [EHA] and NIH describing technical difficulties with uploading the progress report on time.”
30. In a July 17, 2023, Notice of Suspension and Proposed Debarment and ARM, HHS suspended WIV and proposed WIV for debarment from participating in United States Federal Government procurement and nonprocurement programs. The suspension was pursuant to 2 C.F.R. § 180.700(b) and (c) and the proposed debarment was pursuant to 2 C.F.R. 180.800(d) – “Any other cause of so serious or compelling nature that it affects your present responsibility.” WIV failed to send or make arrangements to appear and present information and argument in opposition to the Notice of Suspension and Proposed Debarment within 30 days after the receipt of the Notice of Suspension and Proposed Debarment. Accordingly, on September 19, 2023, HHS debarred WIV for a period of ten years.

31. On May 5, 2024, the NIH provided the HHS SDO with a forensics summary report of the eRA Commons reporting system logs for RPPR related activities for R01AI110964-05, documenting that EHA was never locked out of the system, as EHA claimed in written comments in HHS-OIG Audit Report Number A-05-21-00025. The logs show that on July 24, 2019, the PI initiated the Year 5 I-RPPR through the link provided but did not route it to the Signing Official (SO). On May 26, 2020, the PI accessed the Year 5 I-RPPR to upload a document and to enter data. On July 26, 2021, the PI linked their account to Login.gov. On July 27, 2021, the PI unsuccessfully attempted to change their eRA Commons password; the password was locked, but the PI continued accessing eRA using Login.gov. On July 27, 2021, the PI routed the Year 5 I-RPPR to the SO. On August 2, 2021, the SO uploaded documents for Year 5 I-RPPR. On August 3, 2021, the SO submitted the Year 5 I-RPPR to the NIH.
32. As of the date of this ARM, EHA has the following three active NIH-funded grant awards:
- 5U01AI151797-04, “Understanding Risk of Zoonotic Virus Emergence in Emerging Infectious Diseases (EID) Hotspots of Southeast Asia;”
 - 5U01AI153420-04, “Study of Nipah virus (NiV) dynamics and genetics in its bat reservoir and of human exposure to NiV across Bangladesh to understand patterns of human outbreaks;” and
 - 5R01AI163118-02, “Analyzing the potential for future bat coronavirus emergence in Myanmar, Laos, and Vietnam.”
33. A review of the abstract text from the NIH RePORTER database documents that Grant Numbers 5U01AI151797-04, 5U01AI153420-04, and 5R01AI163118-02, are uniquely focused on either emerging infectious disease, highly transmissible pathogens, or novel viruses.

BASIS FOR THE SUSPENSION AND PROPOSED DEBARMENT

Based on the information in the record identified above, I have determined that there is adequate evidence which provides cause for the suspension and proposed debarment of EHA, pursuant to the Nonprocurement Common Rule, found at 2 C.F.R. § 180. Pursuant to 2 C.F.R. § 180.700, a suspending and debaring official may immediately suspend an individual or entity when “there exists adequate evidence to suspect any other cause for debarment listed under § 180.800(b)-(d)” and “immediate action is necessary to protect the public interest.” *See* 2 C.F.R. §§ 180.700; 180.800. It is important to note that suspension is a temporary action, used where immediate action is necessary to protect the integrity of United States Federal Government procurement and nonprocurement activities.

I find that the information in the record constitutes adequate evidence to demonstrate that the immediate suspension of EHA is necessary to protect the public interest. *See* 2 C.F.R. §180.700(c). Pursuant to 45 C.F.R. § 75.352, grantees that function as pass-through entities must

monitor the activities of subrecipients, including foreign subrecipients, to ensure that subawards are used for authorized purposes in compliance with relevant laws and the terms and conditions of the subaward. Furthermore, in accordance with the NIH GPS, prime award recipients are required to perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to its subrecipient by providing appropriate oversight of all scientific, programmatic, financial, and administrative matters related to the grant. As established in the record, the NIH's review of the Year 5 I-RPPR submitted by EHA, more than two years late, determined that an experiment by WIV, shown in Figure 13 of the report, had possibly yielded a greater than 1 log increase in viral activity, in violation of the terms of the grant. The NIH gave EHA and WIV several opportunities to disprove this finding, but EHA and WIV failed to do so. Due to EHA's and WIV's failure to adequately respond to the NIH's requests that the required materials to support WIV's research reported in the grant RPPRs and I-RPPRs be provided, the NIH's conclusion that WIV research likely violated protocols of the NIH regarding biosafety is undisputed. As a prime grantee administrator, EHA's role is to provide adequate oversight of the activities of its subawardees, including reporting requirements back to NIH (and other Federal Government agencies), to ensure compliance with all grant terms and conditions and federal regulations. The information in the record establishes EHA did not adequately monitor WIV's compliance, and, therefore, its own compliance, with the terms and conditions of its grant award. Therefore, given the issues regarding the management of EHA's grant awards and subawards, I have determined that the immediate suspension of EHA is necessary to protect the public interest.

I also find that the information in the record constitutes adequate evidence to demonstrate that the suspension and proposed debarment of EHA is necessary due to a cause of so serious or compelling a nature that it affects EHA's present responsibility. *See* 2 C.F.R. 180.800(d). As previously mentioned, 45 C.F.R. § 75.364(a) requires that the HHS awarding agency, Inspectors General, the Comptroller General of the United States, and the pass-through entity, or any of their authorized representatives, 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. The information in the record establishes that the NIH requested materials be provided by EHA and WIV to support WIV's research on at least two documented occasions, November 5, 2021, and January 6, 2022. To date, the NIH has not received the requested materials from EHA, as the prime awardee and pass-through entity on behalf of WIV, or from WIV. In addition, the available evidence shows that EHA submitted its Year 5 I-RPPR more than two years after its due date, without sufficient justification for the delayed submission. Therefore, I have determined that there is adequate evidence to document that EHA has not been compliant with federal regulations and grant terms and conditions, which affects EHA's present responsibility.

For the reasons set forth, I have determined that the immediate suspension of EHA is necessary to protect the public interest and due to a cause of so serious or compelling a nature that it affects EHA's present responsibility, including EHA's failure to adequately monitor the virus growth in WIV's experiments; EHA's failure to notify the NIH that the WIV viruses appeared to grow beyond permissible thresholds under the grant's terms and conditions; EHA's failure to provide the requested information to support WIV's research reported in the grant RPPRs and I-RPPRs; and EHA's failure to comply with the timely submission of its Year 5 I-RPPR.

DECISION

Pursuant to 2 C.F.R. Part 180, which was adopted and given regulatory effect by HHS at 2 C.F.R. § 376.10, EHA is hereby suspended and proposed for debarment, effective May 15, 2024. The suspension is effective until the conclusion of debarment proceedings, pursuant to 2 C.F.R. §180.760(a).

H. Katrina Brisbon
Suspension and Debarment Official and
Deputy Assistant Secretary for Acquisitions