ACTION REFERRAL MEMORANDUM

By electronic mail, the United States Department of Health and Human Services (HHS) notified EcoHealth Alliance, Inc. (EHA), in a May 15, 2024, Notice of Suspension and Proposed Debarment (Notice), and Action Referral Memorandum (ARM), and a December 11, 2024, Amended Notice and Amended ARM, that HHS had suspended and proposed EHA for debarment from participating in United States Federal Government procurement and nonprocurement programs. This action was initiated pursuant to the Nonprocurement Common Rule, found at 2 C.F.R. Part 180, which HHS adopted and gave regulatory effect to at 2 C.F.R. Subpart 376.10.

The suspension and proposed debarment actions were based on information from the following, indicating that EHA lacks the present responsibility to participate in United States Federal Government procurement and nonprocurement programs:

- October 18, 2024, Referral of Information (ROI), from the National Institutes of Health (NIH) to the HHS Suspension and Debarment Official (SDO), concerning EHA and Dr. Peter Daszak, former President and Chief Executive Officer of EHA, which included the following 13 attachments:
    - List of active NIH awards to EHA;
    - June 4, 2019, Closeout Notification letter to EHA;
    - October 20, 2021, Letter from NIH to EHA, requesting additional information;
    - October 26, 2021, Response from EHA to NIH's October 20, 2021, Letter;
    - Slide deck presented to OIG regarding RPPR analysis;
    - November 5, 2021, Letter from NIH to EHA;
    - November 18, 2021, Response from EHA to NIH's November 5, 2021, Letter;
    - January 6, 2022, Letter from NIH to EHA;
    - January 21, 2022, Response from EHA to NIH's January 6, 2022, Letter;
    - eRA Forensic Analysis of RPPR related activities for R01AI110964-05;
    - Select Subcommittee on the Coronavirus Pandemic (SSCP) Committee on Oversight & Accountability Interim Staff Report – "An Evaluation of the Evidence Surrounding EcoHealth Alliance, Inc.'s Research Activities" (May 1, 2024);
    - SSCP Democratic Staff Report – "EcoHealth Alliance Did Not Cause the COVID-19 Pandemic but Did Engage in Questionable Professional Conduct" (May 2024); and,
    - May 9, 2024, Email from EHA to NIH;
- SSCP Final Report – "After Action Review of the COVID-19 Pandemic: The Lessons Learned and a Path Forward" (December 4, 2024);
- SSCP Democrats' Final Report – "Partisan Probes Over Pandemic Prevention and Preparedness" (December 2024).
- October 1, 2013, National Institutes of Health Grants Policy Statement (NIH GPS) for

Fiscal Years 2013-2014;
- 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;
- May 28, 2016, letter from the NIAID to EHA;
- June 8, 2016, letter from EHA to the NIAID;
- July 7, 2016, letter from the NIAID to EHA;
- November 30, 2016, Revised NoA for Grant Number 5R01AI110964-03, awarded by the NIAID to EHA;
- May 26, 2017, NoA for Grant Number 5R01AI110964-04, awarded by the NIAID to EHA;
- HHS *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (HHS P3CO Framework), published on December 19, 2017;
- June 18, 2018, NoA for Grant Number 5R01AI110964-05, awarded by the NIAID to EHA;
- July 24, 2019, NoA for Grant Number 2R01AI110964-06, awarded by the NIAID to EHA;
- April 19, 2020, letter from the NIH to EHA;
- April 24, 2020, letter from the NIH to EHA;
- May 22, 2020, letter from the law firm of Tarter Krinsky & Droggin LLP, to the NIH;
- July 8, 2020, letter from the NIH to EHA;
- July 23, 2021, letter from the NIH to EHA;
- October 20, 2021, letter from the NIH to EHA;
- October 26, 2021, letter from EHA to the NIH;
- Year 4 Research Performance Progress Report (RPPR), for Grant Number 5R01AI110964-05;
- Year 5 Interim-Research Performance Progress Report (I-RPPR) for Grant Number R01AI110964-05;
- November 5, 2021, letter from the NIH to EHA;
- November 15, 2021, email from EHA to Wuhan Institute of Virology (WIV);
- November 18, 2021, letter from EHA to the NIH;
- January 6, 2022, letter from the NIH to EHA;
- January 21, 2022, letter from EHA to the NIH;
- August 19, 2022, letter from the NIH to EHA;
- 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;"
- July 17, 2023, HHS Notice and ARM for the Suspension and Proposed Debarment and of WIV;
- September 19, 2023, HHS Notice and ARM for the Debarment of WIV;
- May 6, 2024, NIH forensics summary report of the eRA Commons reporting system logs for RPPR related activities for R01AI110964-05;
- NIH RePORTER database documents for Grant Numbers 5U01AI151797-04, 5U01AI153420-04, and 5R01AI163118-02;

- May 15, 2024, HHS Notice and ARM for EHA;
- July 22, 2024, Response to the May 15, 2024, Notice and ARM from EHA and Dr. Daszak;
- September 19, 2024, Proposed Administrative Agreement from EHA and Dr. Daszak;
- December 11, 2024, Amended Notice and Amended ARM for EHA;
- January 13, 2025, Response to the December 11, 2024, Notice and ARM from EHA; and,
- January 15, 2025, Information from EHA for consideration by the HHS SDO, submitted subsequent to the January 15, 2025, Presentation of Matters in Opposition (PMIO) meeting conducted between HHS and EHA and its attorney representatives.

INFORMATION IN THE RECORD

A summary of the information in the record upon which the suspension and proposed debarment were 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 was the President and Chief Executive Officer of EHA from 2009 until his termination, effective January 6, 2025. Dr. Daszak was the Project Director (PD)/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 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 5R01AI110964-05[1], 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

[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.

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."

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 5R01AI110964-05, nearly 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 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 the original May 15, 2024, ARM, EHA had 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 showed that Grant Numbers 5U01AI151797-04, 5U01AI153420-04, and 5R01AI163118-02, were uniquely focused on either emerging infectious disease, highly transmissible pathogens, or novel viruses.

34. On October 18, 2024, the NIH submitted an ROI to the HHS SDO, recommending that EHA and Dr. Daszak be considered for suspension and debarment action.

35. According to the October 18, 2024, NIH ROI, On October 20, 2021, the NIH sent a letter to EHA regarding recently received materials, including an interim Year 5 RPPR that was submitted nearly two years. The interim Year 5 RPPR included text and a figure (Figure 13) which described experiments in which certain viral chimeras led to substantially greater mortality rates and to more than a 1-log increase in viral activity. The NIH had previously imposed a term and condition of award stating that any experiment that led to a greater than 1-log increase in viral would need to be reported immediately to the agency, thus giving the agency an opportunity to consider possible safety concerns and possible need for additional oversight.

36. According to the October 18, 2024, NIH ROI states that on October 26, 2021, Dr. Daszak wrote to the NIH, stating that the experiment shown in Figure 13 of the Year 5 I-RPPR was the "same experiment" as one reported in April 2018 in Figure 35 of the Year 4 RPPR. He went on to write that "It is very important that these facts be acknowledged." NIH staff reviewed Dr. Daszak's October 26, 2021, letter, as well as the experiment description from the Year 4 RPPR and the Year 5 I-RPPR, and NIH staff noted a number of differences which suggested that contrary to Dr. Daszak's assertions, the two RPPRs were describing two distinct experiments, not "the same experiment."

37. According to the October 18, 2024, NIH ROI, the NIH's November 5, 2021, letter to EHA, requested "complete and dated copies of the original laboratory notebook entries and of the original electronic files 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 (e.g., the Year 5 I-RPPR text in which you stated that "rWIV1-SHC014 was detected at all time points and showed an increasing viral titer after infection…")." The NIH's letter reminded EHA of its regulatory obligations to honor the records request by citing 45 CFR 75.364, which implements 2 CFR 200.337, as well as the NIH GPS.

38. According to the October 18, 2024, NIH ROI, on November 18, 2021, Dr. Daszak's November 18, 2021, letter to NIH acknowledged the records request and admitted that EHA did not have the records supporting the experiments described in EHA's RPPRs and noting that the NIH request had been forwarded to WIV.

39. According to the October 18, 2024, NIH ROI, on January 6, 2022, the NIH again requested the records and again described in detail NIH's regulatory authority to make the records request and fully expect that EHA would honor the request.

40. According to the October 18, 2024, NIH ROI, on January 21, 2022, Dr. Daszak wrote to the NIH, indicating that EHA was unable to honor the records request at that time, ("We have not received any information from [WIV]. We will inform you if and when we receive a response.").

41. According to the October 18, 2024, NIH ROI, as of October 2024, nearly three years after the initial request, the NIH had yet to receive any records in response to the original safety-related records request of November 5, 2021.

42. According to the October 18, 2024, NIH ROI, at no time in 2021, 2022, or 2023, did EHA ever challenge the NIH's regulatory authority to make the safety-related records request of November 5, 2021, which it formally requested again on January 6, 2022.

43. According to the October 18, 2024, NIH ROI, in EHA's October 26, 2021, letter to the NIH, Dr. Daszak stated that EHA was unable to submit the Interim Year 5 RPPR in a timely manner because of a systems lockout.

44. According to the October 18, 2024, NIH ROI, NIH conducted a detailed forensic investigation indicating that Dr. Daszak and EHA were never locked out of the NIH eRA grants system after June 19, 2021, when the NIH notified EHA of required document submissions. To date, the NIH has not seen any documentation or phone logs indicating that EHA was complaining about a systems lockout.

45. According to the October 18, 2024, NIH ROI, EHA as an entity, and Dr. Daszak as an individual, failed to honor their regulatory requirements to respond appropriately to safety-related records request. The request was triggered by Dr. Daszak's claim that experiments described in two different RPPRs were the same along with Dr. Daszak's demand from NIH that, "It is very important that these facts be acknowledged." To address possible serious safety-related noncompliance concerns, NIH gave EHA and Dr. Daszak an opportunity to support his claims by submitting

original electronic files and lab notebook entries that informed their own progress reports.

46. According to the October 18, 2024, NIH ROI, it is undisputed that EHA did not provide the NIH with the requested records, and that EHA did not, at the time of the request, challenge the NIH's regulatory authority to make the request, which raised serious concerns for NIH about possible non-compliance with the "1 log rule," a safety-related term and condition of award, and, therefore, the NIH's concerns remain regarding EHA's ability to comply with grant award terms and conditions and adherence to safety requirements.

47. On December 2, 2024, the SSCP Final Report was issued, titled, "After Action Review of the COVID-19 Pandemic: The Lessons Learned and a Path Forward," which was officially submitted to the Congressional record on December 4, 2024. The SSCP Final Report was the conclusion of a two-year investigation into the COVID-19 pandemic.

48. According to the SSCP Final Report, EHA "could have chosen to submit its Year 5 RPPR and chose not to." The SSCP Final Report stated that for project years one through four, Dr. Daszak, in addition to submitting the annual report via the NIH online reporting system, would routinely also send it via e-mail to its NIAID program officer. However, when asked why he did not continue this pattern for the Year 5 Report, Dr. Daszak testified that he "wish[ed]" he did email the Year 5 Report to the NIH grants office but did not. According to its NIAID program officer, Dr. Daszak did not send an e-mail with the Year 5 Report until Dr. Daszak officially submitted it August 3, 2021. In Dr. Daszak's November 14, 2023, testimony, he testified that "the information from the Year 5 Report was in the resubmitted - - [year 6 competitive] renewal submission, in the first part of that renewal submission." However, after a review of the Year 6 competitive renewal, the SSCP stated that it did not believe the experiment in question in the Year 5 Report was in the renewal application. Regardless, the SSCP Final Report concluded that simply because there was a renewal application, it did not exempt EHA from following the terms of its grant and submitting its Year 5 Report on time. The SSCP Report cited that multiple NIH witnesses testified that the Year 5 Report was still due on time, regardless of the competitive renewal application.

49. According to the SSCP Final Report, Dr. Daszak's November 14, 2023, testimony that EHA was locked out of eRA Commons, "does not stand up to further scrutiny," citing the NIH's forensic audit across its systems to attempt to confirm Dr. Daszak's claim, and that the NIH was unable to verify the claim. The forensic analysis of the NIH reporting system concluded "[t]he user was never locked out of the system." Further, the analysis determined that EHA accessed the reporting system at least once a day for 72 days between July 24, 2019 and July 27, 2021. The analysis stated, "[e]ach of those times accessing Commons was an opportunity to route the RPPR so it could be submitted to NIH."

50. According to the SSCP Final Report, Dr. Daszak, himself, publicly and via e-mail appeared to contradict his own claims that he was "locked out" from submitting the Year 5 Report on time. On October 1, 2021, Dr. Daszak wrote in an email regarding the late Year 5 Report, "[f]or your interest, here's the truth behind the mystery: We got our report ready to file for yr5 of the grant, but when it was re-funded, we assumed we didn't need to…eventually NIH wrote to us and told us to file, so we did."

51. According to the SSCP Final Report, EHA failed to timely report a potentially dangerous experiment to the NIH, due to the fact that the experiment published in EHA's Year 5 Report exhibited greater than one log growth and should have been reported to NIAID, but was not. EHA argued that if an experiment did violate the one log notification requirement, it was previously reported in its Year 4 Report, which is an argument that was contested by the NIH. The SSCP Final Report found that, regardless, the grant term required "immediate notification," and that simply adding the experiment to an annual report does not satisfy that requirement.

52. According to the SSCP Final Report, to support Dr. Daszak's claim that the Year 4 and 5 experiments were the same, he called Dr. Zhengli Shi, his collaborator at WIV, who assured him they were the same. The NIH stated that calling Dr. Shi to "verify" when the experiment occurred is not sufficient and that production of the underlying data and original lab notebooks was necessary and required. The SSCP cited that in Dr. Daszak's November 14, 2023, testimony he stated that he was not required to have access to or produce WIV's underlying original lab notebooks. While Dr. Daszak forwarded the NIH's request for the original lab notebooks to WIV, he never explicitly requested the notebooks from the WIV, but instead simply informed it of the request from NIH. As such, the SSCP Final Report concluded that Dr. Daszak's claim that the Year 4 and 5 experiments conducted by WIV were the same, without verifiable evidence, "lacks credibility."

53. On December 3, 2024, the SSCP Democrats' Final Report was issued titled, "Partisan Probes Over Pandemic Prevention and Preparedness." According to the SSCP Democrats' final report, several of the allegations in HHS's original suspension and proposed debarment action of EHA mirrored the SSCP's bipartisan findings. The report states that it identified information that draws into question EHA's professional conduct as a grantee and recipient of federal taxpayer funding, including that Dr. Daszak and EHA may have misled the Federal Government about their work and participated in other questionable conduct. The report found that as a grantee, EHA's questionable conduct spanned administrative issues, such as annual reporting requirements, and substantive scientific issues, such as representations of its work in communications with NIAID staff. Dr. Daszak also engaged in conduct outside the scope of EHA's grant that raises reasonable questions regarding his professional integrity.

54. According to the SSCP Democrats' Final Report, during Dr. Daszak's November 14, 2023, SSCP interview, and again during his May 1, 2024, SSCP hearing, Dr. Daszak

testified that EHA was not required to have access to or produce WIV's underlying original lab notebooks. According to the SSCP Final Report, it appears that Dr. Daszak never explicitly requested the original lab notebooks from WIV in writing, and did nothing further to respond to the NIH's requests for the notebooks after passively forwarding the NIH's November 15, 2021, email to WIV.

55. According to the SSCP Democrats' Final Report, questions were raised regarding EHA's truthfulness, citing EHA's assertion that it attempted an early upload of the Year 5 RPPR in July 2019 but claimed to be locked out, and the NIH's electronic forensic investigation, which found no evidence supporting EHA's claim of being locked out. The SSCP Democratic Staff Final Report also noted that the HHS OIG was unable to validate EHA's assertions. The SSCP Democrats' Final Report stated that EHA staff have consistently maintained that they uploaded the Year 5 RPPR in July 2019, but that when they tried to officially submit the report, they were locked out of NIH's electronic filing system. EHA claims that NIH never responded to outreach or asked for the report, which EHA took to mean that its submission was not required. The report states that he documentary evidence available to the SSCP appears to be inconsistent with a July 2019 upload and system lockout, and that the SSCP received no records or communication to corroborate a late July 2019 upload or a system lockout.

56. According to the SSCP Democrats' Final Report, at Dr. Daszak's November 14, 2023, transcribed interview, he suggested that the absence of documentary evidence was consistent with EHA's later unsuccessful efforts to communicate with the grants officer exclusively by phone. The SSCP Democrat's Final Report stated that given that EHA had emailed the grants officer regarding the report at least twice in the final two weeks of July 2019, it was difficult to conceive that EHA would shift and persist in a different pattern of communication despite their unsuccessful efforts. The SSCP Democrats' Final Report found that EHA's claimed reliance on a resolution over phone is particularly questionable considering Dr. Daszak had emailed copies of EHA's RPPRs to grants or program officers in previous years, and, on occasion, ahead of official submission.

57. According to the SSCP Democrats' Final Report, based on the available evidence, EHA did not adequately monitor virus growth WIV's experiments and WIV's compliance (and thus, its own compliance) with the 1 log rule. Moreover, virus growth presented in EHA's Year 4 RPPR and Year 5 I-RPPR arguably show enhanced virus growth greater than 1 log, notwithstanding EHA's arguments to the contrary.

RESPONDENT'S RESPONSE TO MAY 15, 2024, NOTICE AND ARM

The May 15, 2024, Notice and ARM, for EHA were transmitted to Dr. Peter Daszak, EHA's President and Chief Executive Officer at that time, via electronic mail to his email address of record at that time, daszak@ecohealthalliance.org. The May 15, 2024, Notice and ARM provided Dr. Daszak with the opportunity to submit information and argument in

opposition to the suspension and proposed debarment actions within 30 days of receipt of the documents. On June 3, 2024, Dr. Daszak's and, at that time, EHA's designated attorney representative in this matter, Paul Hurst, Partner at Steptoe LLP, requested an extension to provide a response by July 22,2024, which was granted by the HHS SDO.

On July 22, 2024, on behalf of EHA and Dr. Daszak, Mr. Hurst submitted a response to the suspension and proposed actions, which were added to the administrative record for this matter. In addition, on September 19, 2024, Mr. Hurst submitted a proposed Administrative Agreement on behalf of EHA and Dr. Daszak to resolve the suspension and debarment proceedings, which was also added to the administrative record for this matter.

As stated in the December 11, 2024, Amended Notice and Amended ARM, I reviewed the July 22, 2024, response and found that it did not sufficiently address the following concerns regarding EHA and Dr. Daszak, identified in the information in the record: 1) ongoing safety concerns regarding a lack of technical oversight of high-risk virology research being conducted through EHA's grant awards; 2) questions about EHA's and Dr. Daszak's professional integrity due to providing inaccurate and misleading information; and 3) EHA's ongoing administrative management issues of its active grant awards and subawards. Also, as stated in the December 11, 2024, Notice and ARM, I found that the September 19, 2024, proposed Administrative Agreement stated that EHA represented that all written materials and other information supplied to HHS by its authorized representatives during the course of discussion with HHS preceding the proposed Administrative Agreement were true and accurate in all material respects, to the best of EHA's information and belief. However, as stated in the December 11, 2024, Amended Notice and Amended ARM, I found that the information in the proposed Administrative Agreement was inconsistent with the information in the record, as further indicated in the October 18, 2024, NIH ROI and the SSCP Final Reports. In addition, I found that the proposed Administrative Agreement did not provide adequate detail regarding internal controls and policies and procedures that EHA had implemented/would implement, to ensure compliance with its grant awards related to allowable costs, reporting, subaward agreements, etc.

RESPONDENT'S RESPONSE TO THE DECEMBER 11, 2024, AMENDED NOTICE AND AMENDED ARM

The December 11, 2024, Amended Notice and Amended ARM for EHA, which amended the May 15, 2024, Notice and ARM, were sent by electronic mail to Mr. Hurst, at phurst@steptoe.com, on December 12, 2024. On January 7, 2025, EHA notified HHS that it was no longer being represented by Steptoe LLP in this matter, and that EHA had retained the law firm of Arnold & Porter Kaye Scholer LLP as its representation in this matter. EHA also informed HHS that, effective January 6, 2025, Dr. Peter Daszak was no longer employed by EHA.

On January 13, 2025, Alex Sirio and Charles Blanchard from Arnold & Porter submitted a response to the December 11, 2024, Amended Notice and Amended ARM, on behalf of EHA, which included a proposed Administrative Agreement. On January 15, 2025, a PMIO meeting was conducted between HHS and EHA and its attorney representatives. Following the meeting,

Mr. Blanchard submitted additional information, on behalf of EHA, all of which has been added to the administrative record and has been taken into consideration in my final decision.

The January 13, 2025, and January 15, 2025, responses stated the following:

- EHA believes that it has demonstrated its present responsibility with the remedial actions that the organization has already undertaken, including the closure of a number of federal audits of EcoHealth Alliance and the reduction of some special conditions imposed by NIH, along with the following undertakings: (1) the termination of Dr. Peter Daszak as President and Chief Executive Officer, effective January 6, 2025; (2) the appointment of an experienced interim leadership team dedicated to enhancing the organization's ethics, compliance, and monitoring policies and practices; (3) the appointment of an independent monitor; (4) the emplacement of new leadership at the Board of Directors level; and (5) a commitment to focus on One Health-principled research.
- EHA will return to its focus on One Health principles, including understanding the conservation and health impacts of ecological disruption on human and animal populations. The organization commits not to directly conduct nor directly fund nor financially support any recombinant virus research. EcoHealth Alliance scientists will strictly adhere to best biosafety practices while conducting research and ensure that all field and laboratory work is conducted at appropriate biosafety levels in compliance with—or exceeding—U.S. federal regulations.
- EHA takes its legal and ethical obligations as a federal grant recipient very seriously. The organization is committed to operating with the highest standards of integrity and transparency and, in that vein, has implemented a number of corrective actions specifically designed to ensure that both EcoHealth Alliance and its subrecipients maintain full compliance with federal grant laws and regulations.
- EHA understands that fostering a culture of compliance, integrity, and transparency begins at the top: the organization's executive leadership must exemplify and reinforce the fundamental importance of these values at all times and in all respects. EcoHealth Alliance is therefore dedicated to selecting a management team of individuals whose credentials and accomplishments demonstrate a strong commitment to those core values.
- On January 2, 2025, EcoHealth Alliance's Board of Directors voted to terminate Dr. Daszak as President and CEO of the organization. The Board took this action because it no longer had confidence in Dr. Daszak's leadership. Dr. Daszak's termination became effective on January 6, 2025. Going forward, Dr. Daszak will not have any involvement in the operation or management of EcoHealth Alliance.
- Effective January 6, 2025, EHA's Board appointed Dr. Kevin Olival, EHA's Vice President for Research, and Dr. Jonathan Epstein, EHA's Vice President for Science and Outreach, who have been with EHA for over thirty-seven years between them, were appointed by the Board to co-lead the EHA's interim leadership team. Drs. Olival and Epstein are in the process of developing plans and procedures to enhance EHA's compliance policies and procedures and to implement a search guided by both external experts and stakeholders as well as the Board for a new President/CEO. Joseph Riccardi will continue in his role as Chief Financial Officer. The EHA Board recently signed an agreement with Dr. William Karesh, under which Dr. Karesh will serve as the organization's Special Consultant for Interim Management Affairs. On August 2, 2024,

Stephen Shapiro was named interim EHA Board Chair. Mr. Shapiro is Managing Partner of BSR Investments and the Benjamin Shapiro Realty LLC.

- EHA has updated its Policy on Subaward Contracts and Monitoring, which applies to all subawards issued by EHA under federally and privately sponsored programs.
- EHA has updated its NIH Subaward Agreement Template, which applies to all subawards entered into by EHA with outside organizations to perform NIH grant-supported research activities.
- EHA has updated its Guidance on Foreign Subrecipient Risk Mitigation, to acknowledge EHA's responsibility for monitoring subrecipients to ensure compliance with federal regulations and grant terms and conditions.
- EHA has updated its Employee Handbook, which implements an organization-wide standard of conduct for all employees and requires employees to comply with applicable laws, regulations, and policies.
- EHA has developed a Policy on Principal Investigator Eligibility that establishes key responsibilities for all Principal Investigators, including timely reporting to the project sponsor as required by the terms of the award, completing required trainings, including training on subrecipient monitoring, animal biosafety requirements, and research security.
- EHA is in the process of developing Guidelines for Field Biosafety to ensure that field research is being conducted in accordance with the highest safety standards, which will address hazard identification, risk management, risk mitigation (including elimination and substitution control protocols, engineering control protocols, administrative control protocols, and personal protective equipment control protocols), pathogen exposure and response, biosecurity during animal activities, field biosafety levels, and the organization's prohibition on any recombinant virus research.
- EHA is in the process of developing a Research Security Program, designed to be consistent with National Security Presidential Memorandum–33, that will enhance EHA's ability to safeguard against improper or illicit activity, including misuse of federal funds, and alleviate the risks and concerns presented by the global landscape for research institutions.
- EHA is creating a Business Ethics and Conduct Code which will, among other things, provide notice to all employees that the highest standard of business ethics is expected and will also address key ethics and compliance risks associated with EHA's federal grants.
- EHA is in the process of creating an Employee Ethics "Hotline" through which employees may report anonymously any ethics or compliance concerns, including suspected violations
- All EHA Principal Investigators/Project Directors and responsible personnel (including Finance, Operations, and Program Management Teams) at EHA will engage in additional training related to federal grants and will be subject to the oversight of a new committee managed by, and reporting to, EHA's Board of Directors.
- EHA has updated its policy to specify procedures and timelines for preparing any federal award report and implemented internal review controls and deadlines.
- EHA has updated its policy and all subaward contracts to require that subaward reporting is due no later than one month prior to any EcoHealth Alliance reporting deadline to a funder, to allow time for information synthesis and inclusion.

- EHA has expanded its Funding Action Board to include those with roles in Research Administration who have responsibility to help prepare and track reports, and meets weekly and serves as a forum for tracking deadlines and other compliance items on active awards.
- EHA has implemented grant management software, which allows EHA to configure automated reminders to Principal Investigators and Research Administrators at repeated, specified amounts of time prior to any deadline.
- EHA now requires review and any necessary revision of its policies at least annually, but more frequently as necessary to remain current with federal regulations.
- EHA has installed checks and balances to ensure the least possible risk of compliance failure.
- The EHA Executive Team, which includes the Vice President for Grant Compliance and Policy, meets regularly (at least once per week).
- The proposed Administrative Agreement submitted for the SDO's consideration stated the following:
    - EHA shall have a values-based Ethics and Compliance Program with the following components: Policy on Subaward Contracts and Monitoring; EHA-NIH Subaward Agreement Template; Policy and Procedure for Reporting on Federal Awards; Semi-Annual Reporting Addendum; Guidance on Foreign Subrecipient Risk Mitigation; Guidelines for Field Biosafety; Employee Handbook; Research Security Program; Malign Foreign Talent Recruitment Program (MFTRP) Policy; and Policy on Principal Investigator Eligibility.
    - EHA shall adopt a separate Code of Business Ethics and Conduct.
    - EHA will create a "hotline" for reporting potential violations of federal laws and EHA's policies and procedures, which must be available to receive information 24 hours a day, 7 days a week.
    - EHA will develop and Ethics and Compliance Training Program.
    - EHA's Board of Directors will continue to take a more active role in overseeing the organization's compliance enhancements.
    - EcoHealth Alliance will maintain a Funding Action Board to oversee active awards issued to EHA and to tracks reporting deadlines.
    - EHA will appoint an Independent Monitor to oversee and review its compliance with the proposed Administrative Agreement.
    - EHA will not directly conduct nor directly fund nor financially support any recombinant virus research.

DISCUSSION

The Nonprocurement Common Rule at 2 C.F.R. § 180.860 lists a number of mitigating and aggravating factors a debarring official may consider in determining whether to debar an entity or individual in determining the length of the debarment period. The appropriateness of the mitigating and aggravating factors provided in 2 C.F.R. §180.860 are evaluated in the context of the seriousness of the cause(s) and conditions that gave rise to the suspension and proposed debarment. As the HHS SDO, I may also consider other factors, as appropriate, in light of the circumstances of a particular case. The following aggravating and mitigating factors were taken into consideration for this matter to determine that a five-year debarment for EHA is appropriate:

- *2 C.F.R § 180.860(a) – The actual or potential harm or impact that results or may result from the wrongdoing.*

EHA failed to comply with safety-related reporting requirements and records request. Safety is a consideration in all biomedical research. The kind of research conducted by EHA in particular poses biosafety and public health concerns. These stem from interactions with infected wildlife, handling of specimens that may contain novel or dangerous viruses and increased viral activity following recombinant manipulations. To assure the government that research will be conducted safely, and that public health will not be endangered, it is essential that the work is conducted within an organizational culture of safety and follows sponsored project's reporting requirements.

Failure to do so as observed in this matter significantly poses a threat to public safety and public health. In an organizational culture of safety, concerns are addressed quickly, seriously, and with the highest degrees of integrity. In this matter, EHA's failure to adhere to the 1-log immediate reporting requirement, failure to submit a progress report on time, inaccurate claim that experiments described in the Year 4 and Year 5 progress reports were the same, failure to take robust active steps to obtain records from WIV to address the safety concerns, and claim that the delay in submitting the Year 5 progress report was due to a computer system lockout – are all reflective of a culture in which safety is not valued. A research organization lacking a culture of safety and integrity is one that constitutes a threat to public safety and public health.

I find that EHA's past wrongdoing continues to present harm. EHA only appeared to recognize the seriousness of HHS' and the NIH's concerns upon being suspended and proposed for debarment in May 2024, despite the numerous written letters and emails from NIH to EHA documenting concerns going back several years. This leads to questions regarding whether EHA's statements claiming to recognize the seriousness of the concerns identified are genuine. Though I initially took exclusion action against EHA in May of 2024, and through Amended Notice and Amended ARM in December of 2024, it was not until January 6, 2025, and days thereafter, that I received notice of Dr. Daszak's termination, and was presented with a proposed Administrative Agreement shortly thereafter. In both instances of the Notice and Amended Notice, opportunities were provided to present a meaningful Administrative Agreement. EHA did not take advantage of these opportunities that were given to present a meaningful agreement until it was clear that HHS had lost confidence in its ability to manage any federal award. In short, EHA's changes came too late, so I do not believe in their authenticity. Therefore, based on the information in the record, I find this to be an applicable aggravating factor for consideration in this case.

Therefore, I have determined that EHA's noncompliance with Government award regulations, and failure to acknowledge and failed attempts to correct this violation, is an aggravating factor for consideration that additionally supports my decision to debar EHA for a period of five years.

- *2 C.F.R. § 180.860 (b) – The frequency of incidents and/or duration of the wrongdoing.*

  As established in the information in the record, EHA submitted the Year 5 I-RPPR for Grant Number 5R01AI110964-05, on August 3, 2021, nearly two years after the report due date. In addition, the NIH first formally requested that EHA provide WIV's laboratory notebooks on November 18, 2021, and again on January 6, 2022. To date, WIV's laboratory notebooks have not been provided. I find the duration of the two occurrences of wrongdoing to be substantial and significant since they inhibited the NIH's ability to thoroughly assess the research being conducted under NIH-funded grant awards.

  Also as previously stated, EHA only appeared to recognize the seriousness of HHS' and the NIH's concerns upon being suspended and proposed for debarment in May 2024, despite the numerous written letters and emails from NIH to EHA documenting concerns going back several years. This leads to questions regarding whether EHA's statements claiming to recognize the seriousness of the concerns identified are genuine. Though I initially took exclusion action against EHA in May of 2024, and through Amended Notice and Amended ARM in December of 2024, it was not until January 6, 2025, and days thereafter, that I received notice of Dr. Daszak's termination, and was presented with a proposed Administrative Agreement shortly thereafter. In both instances of the Notice and Amended Notice, opportunities were provided to present a meaningful Administrative Agreement. EHA did not take advantage of these opportunities that were given to present a meaningful agreement until it was clear that HHS had lost confidence in its ability to manage any federal award. In short, EHA's changes came too late, so I do not believe in their authenticity. Further, there has not been enough time to assess the efficacy of the EHA's updates.

  Therefore, I have determined that EHA's noncompliance with Government award regulations, and failure to acknowledge and failed attempts to correct this violation, is an aggravating factor for consideration that additionally supports my decision to debar EHA for a period of five years.

- *2 C.F.R. § 180.860 (c) – Whether there is a pattern or prior history of wrongdoing. For example, if you have been found by another Federal agency or a State agency to have engaged in wrongdoing similar to that found in the debarment action, the existence of this fact may be used by the debarring official in determining that you have a pattern or prior history of wrongdoing.*

  Based on the information in the record, I find that there is not enough information to assess the applicability of this factor to the circumstances of this case.

- *2 C.F.R. § 180.860 (d) – Whether you are or have been excluded or disqualified by an agency of the Federal Government or have not been allowed to participate in State or local contracts or assistance agreements on a basis of conduct similar to one or more of the causes for debarment specified in this part.*

I note that Congress has limited the use of Department of Defense funds for certain work performed by EcoHealth Alliance. See, e.g., the Further Consolidated Appropriations Act of 2024 (P.L. 118-47), Division A (Department of Defense Appropriations Act, 2024), Sec. 8143: "None of the funds made available by [Division A] may be used to fund any work to be performed by EcoHealth Alliance, Inc. in China on research supported by the government of China unless the Secretary of Defense determines that a waiver to such prohibition is in the national security interests of the United States…" (applicable to FY 2025 through continuing resolution, P.L. 118-158, Dec. 21, 2024).

Therefore, I have determined that EHA's noncompliance with Government award regulations, and failure to acknowledge and failed attempts to correct this violation, is an aggravating factor for consideration that additionally supports my decision to debar EHA for a period of five years.

- *2 C.F.R. § 180.860 (e) – Whether you have entered into an administrative agreement with a Federal agency or a State or local government that is not governmentwide but is based on conduct similar to one or more of the causes for debarment specified in this part.*

Based on the information in the record, I find that there is not enough information to assess the applicability of this factor to the circumstances of this case.

- *2 C.F.R. § 180.860 (f) – Whether and to what extent you planned, initiated, or carried out the wrongdoing.*

Based on the information in the record, I find that there is not enough information to assess the applicability of this factor to the circumstances of this case.

- *2 C.F.R. § 180.860 (g) – Whether you have accepted responsibility for the wrongdoing and recognize the seriousness of the misconduct that led to the cause for debarment.*

According to the January 15, 2025, response, "EHA believes that it has demonstrated its present responsibility with the remedial actions that the organization has already undertaken, including the closure of a number of federal audits of EcoHealth Alliance and the reduction of some special conditions imposed by NIH, along with the following undertakings: (1) the termination of Dr. Peter Daszak as President and Chief Executive Officer, effective January 6, 2025; (2) the appointment of an experienced interim leadership team dedicated to enhancing the organization's ethics, compliance, and monitoring policies and practices; (3) the appointment of an independent monitor; (4) the emplacement of new leadership at the Board of Directors level; and (5) a commitment to focus on One Health-principled research."

While I acknowledge receiving EHA's statement that it has accepted responsibility, I do not believe the information in the record adequately demonstrates that EHA has fully accepted responsibility for its role in the wrongdoing. For instance, to date, EHA still claims that it did not submit its Year 5 I-RPPR on time due to being

locked out of eRA Commons, despite the forensic evidence presented by the NIH, and the findings presented in the two final Congressional Staff reports.

In addition, as previously stated, the changes made by EHA are not sufficient for consideration in EHA's acceptance of responsibility. EHA only appeared to recognize the seriousness of HHS' and the NIH's concerns upon being suspended and proposed for debarment in May 2024, despite the numerous written letters and emails from NIH to EHA documenting concerns going back several years. This leads to questions regarding whether EHA's statements claiming to recognize the seriousness of the concerns identified are genuine. Though I initially took exclusion action against EHA in May of 2024, and through Amended Notice and Amended ARM in December of 2024, it was not until January 6, 2025, and days thereafter, that I received notice of Dr. Daszak's termination, and was presented with a proposed Administrative Agreement shortly thereafter. In both instances of the Notice and Amended Notice, opportunities were provided to present a meaningful Administrative Agreement. EHA did not take advantage of these opportunities that were given to present a meaningful agreement until it was clear that HHS had lost confidence in its ability to manage any federal award. In short, EHA's changes came too late, so I do not believe in their authenticity.

Therefore, I have determined that EHA's noncompliance with Government award regulations, and failure to acknowledge and failed attempts to correct this violation, is an aggravating factor for consideration that additionally supports my decision to debar EHA for a period of five years.

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- *2 C.F.R. § 180.860 (h) – Whether you have paid or agreed to pay all criminal, civil and administrative liabilities for the improper activity, including any investigative or administrative costs incurred by the government, and have made or agreed to make full restitution.*

Based on the information in the record, I find that there is not enough information to assess the applicability of this factor to the circumstances of this case.

- *2 C.F.R. § 180.860 (i) – Whether you have cooperated fully with the government agencies during the investigation and any court or administrative action. In determining the extent of cooperation, the debarring official may consider when the cooperation began and whether you disclosed all pertinent information known to you.*

The October 18, 2024, ROI submitted by NIH raised serious concerns of doubt in EHA's cooperation in responding truthfully to questions to fully assess EHA's compliance practices with NIH grant awards. Full cooperation in compliance assessments

require disclosure of all pertinent information requested. Specifically, there were three instances that demonstrated a lack of full cooperation:

1. The claim that the experiments in the Year 4 and Year 5 progress report were the same.
2. The claim that the delay in submitting the Year 5 progress report was due to a computer system lockout.
3. The failure to make any reasonable effort to obtain records from a subrecipient in response to NIH's multiple safety-related requests.

I find that EHA's conduct in each of these three instances represents a failure on the part of EHA to cooperate fully with the NIH as it was conducting its compliance review.

Therefore, I have determined that EHA's noncompliance with Government award regulations, and failure to acknowledge and failed attempts to correct this violation, is an aggravating factor for consideration that additionally supports my decision to debar EHA for a period of five years.

- *2 C.F.R. § 180.860 (j) – Whether the wrongdoing was pervasive within the organization.*

Based on the information in the record, I find that there is not enough information for me to assess the applicability of this factor to the circumstances of this case.

- *2 C.F.R. § 180.860 (k) – The kind of positions held by the individuals involved in the wrongdoing.*

As established in the information in the record, Dr. Daszak was the President and Chief Executive Officer of EHA from 2009 until his termination, effective January 6, 2025. Dr. Daszak was also the PD/PI for Grant Number R01AI110964. The NIH PD/PI has overall responsibility for the design, conduct, reporting and scientific integrity of the research. As a PD/PI, Dr. Daszak was responsible for ensuring full compliance with applicable HHS and NIH regulations and guidelines, and the terms and conditions of the grant awards.

Therefore, I have determined that EHA's noncompliance with Government award regulations, and failure to acknowledge and failed attempts to correct this violation, is an aggravating factor for consideration that additionally supports my decision to debar EHA for a period of five years.

- *2 C.F.R. § 180.860 (l) – Whether the organization took appropriate corrective action or remedial measures, such as establishing ethics training and implementing programs to prevent recurrence.*

Also as previously stated, EHA only appeared to recognize the seriousness of HHS' and the NIH's concerns upon being suspended and proposed for debarment in May 2024, despite the numerous written letters and emails from NIH to EHA documenting

concerns going back several years. This leads to questions regarding whether EHA's statements claiming to recognize the seriousness of the concerns identified are genuine. Though I initially took exclusion action against EHA in May of 2024, and through Amended Notice and Amended ARM in December of 2024, it was not until January 6, 2025, and days thereafter, that I received notice of Dr. Daszak's termination, and was presented with a proposed Administrative Agreement shortly thereafter. In both instances of the Notice and Amended Notice, opportunities were provided to present a meaningful Administrative Agreement. EHA did not take advantage of these opportunities that were given to present a meaningful agreement until it was clear that HHS had lost confidence in its ability to manage any federal award. In short, EHA's changes came too late, so I do not believe in their authenticity. Further, there has not been enough time to assess the efficacy of the EHA's updates.

Therefore, I have determined that EHA's noncompliance with Government award regulations, and failure to acknowledge and failed attempts to correct this violation, is an aggravating factor for consideration that additionally supports my decision to debar EHA for a period of five years.

- *2 C.F.R. § 180.860 (m) – Whether the principals tolerated the offense.*

Based on the information in the record, I find that there is not enough information to assess the applicability of this factor to the circumstances of this case.

- *2 C.F.R. § 180.860 (n) – Whether the activity cited as a basis for the debarment was brought to the attention of the appropriate government agency in a timely manner.*

Based on the information in the record, I find that there is not enough information to assess the applicability of this factor to the circumstances of this case.

- *2 C.F.R. § 180.860 (o) – Whether the circumstances surrounding the cause for debarment have been fully investigated and, if so, the results of the investigation have been made available to the debarring official.*

Based on the information in the record, I find that there is not enough information to assess the applicability of this factor to the circumstances of this case.

- *2 C.F.R. § 180.860 (p) – Whether there were effective standards of conduct and internal control systems in place at the time the questioned conduct occurred.*

As established in the record and by EHA's and Dr. Daszak's own admissions, EHA had significant failings in its internal control systems and policies and procedures at the time the questioned conduct and wrongdoing occurred. Therefore, I have determined that EHA's noncompliance with Government award regulations, and failure to acknowledge and failed attempts to correct this violation, is an aggravating factor for consideration that additionally supports my decision to debar EHA for a period of five years.

- *2 C.F.R. § 180.860 (q) – Whether appropriate disciplinary action has been taken against the individuals responsible for the activity which constitutes the cause for debarment.*

As previously noted, Dr. Daszak was terminated by EHA, effective January 6, 2025. I acknowledge EHA's action to terminate Dr. Daszak demonstrates that EHA holds him largely responsible for the misconduct and activity that constitutes the cause for debarment in this case, as he was the President of EHA at the time the misconduct occurred, and the PD/PI for Grant Number RO1AI110964. However, despite ongoing exchanges between EHA and NIH over safety concerns related to inadequate oversight of high-risk virology research funded through EHA's grants—concerns that spanned several years—EHA failed to take disciplinary action until after the issuance of the Amended Proposal for Debarment by HHS on December 11, 2024. This delayed response highlights a lack of accountability within EHA and reflects an organizational culture that deprioritizes biosafety in high-risk research.

Furthermore, Select Subcommittee reports made public in May 2024 raised significant questions about the professional integrity of both EHA and Dr. Daszak. Yet, EHA did not act until January 6, 2025, to terminate Dr. Daszak, and even now, EHA can only point to ongoing policy changes without clear evidence of a cultural shift that prioritizes biosafety or integrity. This inaction underscores a concerning lack of present responsibility for managing federal awards.

Therefore, while this is a mitigating factor, I am giving less weight to this because of the timing and my ongoing concerns about EHA's organizational culture.

- *2 C.F.R. § 180.860 (r) – Whether there has been adequate time to eliminate the circumstances within the organization that led to the cause for the debarment.*

As previously state, EHA submitted the Year 5 I-RPPR for Grant Number 5R01AI110964-05, on August 3, 2021, nearly two years after the report due date. In addition, the NIH first formally requested that EHA provide WIV's laboratory notebooks on November 18, 2021, and again on January 6, 2022. To date, WIV's laboratory notebooks have not been provided. I find the duration of the two occurrences of wrongdoing to be substantial and significant since they inhibited the NIH's ability to thoroughly assess the research being conducted under NIH-funded grant awards.

Also as previously stated, EHA only appeared to recognize the seriousness of HHS' and the NIH's concerns upon being suspended and proposed for debarment in May 2024, despite the numerous written letters and emails from NIH to EHA documenting concerns going back several years. This leads to questions regarding whether EHA's statements claiming to recognize the seriousness of the concerns identified are genuine. Though I initially took exclusion action against EHA in May of 2024, and through Amended Notice and Amended ARM in December of 2024, it was not until January 6, 2025, and days thereafter, that I received notice of Dr. Daszak's termination, and was presented with a proposed Administrative Agreement shortly thereafter. In both instances of the Notice and Amended Notice, opportunities were provided to present a meaningful

Administrative Agreement. EHA did not take advantage of these opportunities that were given to present a meaningful agreement until it was clear that HHS had lost confidence in its ability to manage any federal award. In short, EHA's changes came too late, so I do not believe in their authenticity. Further, there has not been enough time to assess the efficacy of the EHA's updates. Considering the length of time that lapsed during EHA's performance as a grant recipient, the potential health consequences and repercussions stemming from their violations, represents that there is continued potential harm and health risks caused by EHA.

Therefore, I have determined that EHA's noncompliance with Government award regulations, and failure to acknowledge and failed attempts to correct this violation, is an aggravating factor for consideration that additionally supports my decision to debar EHA for a period of five years.

- *2 C.F.R. § 180.860 (s) – Whether any business, technical, or professional license(s) has been suspended, terminated, or revoked.*

Based on the information in the record, I find this to be inapplicable to the circumstances in this case.

- *2 C.F.R. § 180.860 (t) – Other factors that are appropriate to the circumstances of a particular case.*

Pursuant to *45 C.F.R 75.303(a)*, Federal grant recipients are required by law to "establish and maintain effective internal control over the Federal award that provides reasonable assurance that the non-Federal entity is managing the Federal award in compliance with Federal statutes, regulations, and the terms and conditions of the Federal award". NIH's interactions with Dr. Daszak in his capacity as President and Chief Executive Officer at EHA, as well as numerous other examples cited in the Republican and Democratic House Committee reports, indicate that the "Tone at the Top" of EHA did not demonstrate present responsibility with Dr. Daszak as the leader. While it is true that as of January 6, 2025, EHA has terminated Dr. Daszak, this only came after a long delay. Furthermore, the culture that Dr. Daszak has established over his many years of leading EHA (since 2009) is one that cannot be transformed overnight.

Therefore, I have determined that EHA's noncompliance with Government award regulations, and failure to acknowledge and failed attempts to correct this violation, is an aggravating factor for consideration that additionally supports my decision to debar EHA for a period of five years.

FINDINGS

As stated in the May 15, 2024, Notice and ARM, and December 11, 2024, Amended Notice and Amended ARM, pursuant to 2 C.F.R. § 180.800, a federal agency may debar an entity or individual for "any other cause of so serious or compelling a nature that it affects their present responsibility." *See* 2 C.F.R. § 180.800(d). I find the serious and egregious nature of the

misconduct committed by EHA indicates a lack of business integrity and business honesty, thereby directly affecting its present responsibility, and provides cause for the debarment of EHA, pursuant to 2 C.F.R. § 180.800(d).

DECISION

Pursuant to 2 C.F.R. §180.865, if the suspending and debarring official determines that a period of debarment is necessary, the length of the period of debarment will be based on the seriousness of the cause(s) upon which the respondent's debarment is based. While the typical debarment period should not exceed three years, if circumstances warrant, the suspending and debarring official may impose a longer period of debarment. In these types of cases, the suspending and debarring official considers the seriousness of the conduct ("acts or omissions") and its effect on the respondent's present responsibility and any mitigating or aggravating factors identified in the record. *See* 2 C.F.R. § 180.845(a).

Based on the information presented in the administrative record and the aggravating and mitigating factors set forth in this document, including EHA's aforementioned responses to the suspension and proposed debarment actions, I have determined that a five-year debarment period for EHA is necessary to protect the United States Federal Government's interests. I acknowledge and understand that debarment is an administrative remedy that is serious in nature and is not an action to be taken lightly. However, given the seriousness of the misconduct, as presented in the administrative record, the Federal Government's interests must be protected accordingly. In making this determination, I reviewed the totality of the information in the administrative record, including all information submitted by EHA in response to the suspension and debarment actions, and determined that EHA has not demonstrated, to my satisfaction, that it is presently responsible to be a steward of federal funds. Therefore, I have determined that a debarment period is necessary to protect the Federal Government's interests.

Pursuant to 2 C.F.R. Part 180, which was adopted and given regulatory effect by HHS at 2 C.F.R. Subpart 376.10, and based upon the administrative record and the findings herein, EHA is hereby debarred for a period of five years. The debarment is effective from the date of this ARM and the accompanying Notice. The period of ineligibility during EHA's suspension and proposed debarment, which was effective May 15, 2024, will be included in the period of debarment. Therefore, under the five-year period of debarment, EHA will remain ineligible through May 14, 2029. The debarment is effective for covered transactions subject to the prohibitions of 2 C.F.R. §180 and contracts that are subject to the Federal Acquisition Regulation (48 C.F.R. chapter 1), throughout the executive branch of the United States Federal Government, unless an agency head or an authorized designee grants an exception in writing.

Suspension & Debarment Official and
Deputy Assistant Secretary for Acquisitions