ACTION REFERRAL MEMORANDUM

On behalf of the United States Department of Health and Human Services (HHS), I hereby suspend and propose the debarment of Wuhan Institute of Virology, Chinese Academy of Sciences Capital Construction ("WIV") 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 WIV is based on information from the following:

1) a September 29, 2022, Referral of Information (ROI), from the National Institutes of Health (NIH), Office of Policy for Extramural Research Administration (OPERA) concerning WIV;
2) the October 1, 2013, NIH Grants Policy Statement (NIH GPS) for Fiscal Years 2013-2014;
3) a May 27, 2014, Notice of Award (NoA) for Grant Number 1R01AI110964-01, awarded by the NIH's National Institute of Allergy and Infectious Disease (NIAID) to EcoHealth Alliance, Inc. ("EcoHealth")
4) a May 28, 2016, letter from NIAID to EcoHealth;
5) a June 8, 2016, letter from EcoHealth to NIAID;
6) a July 7, 2016, letter from NIAID to EcoHealth;
7) a November 30, 2016, Revised NoA for Grant Number 5R01AI110964-03, awarded by NIAID to EcoHealth;
8) a May 26, 2017, NoA for Grant Number 5R01AI110964-04, awarded by NIAID to EcoHealth;
9) HHS *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (HHS P3CO Framework), published on December 19, 2017;
10) a June 18, 2018, NoA for Grant Number 5R01AI110964-05, awarded by NIAID to EcoHealth;
11) a July 24, 2019, NoA for Grant Number 2R01AI110964-06, awarded by NIAID to EcoHealth;
12) an April 19, 2020, letter from the NIH to EcoHealth;
13) an April 24, 2020, letter from the NIH to EcoHealth;
14) a May 22, 2020, letter from the law firm of [redacted], to the NIH;
15) a July 8, 2020, letter from the NIH to EcoHealth;
16) a July 23, 2021, letter from the NIH to EcoHealth;
17) an October 20, 2021, letter from the NIH to EcoHealth;
18) an October 26, 2021, letter from EcoHealth to the NIH;
19) Year 4 Research Performance Progress Report (RPPR), for Grant Number 5R01AI110964-05;

20) Year 5 Interim-Research Performance Progress Report (I-RPPR) for Grant Number R01AI110964-05;
21) a November 5, 2021, letter from the NIH to EcoHealth;
22) a November 18, 2021, letter from EcoHealth to the NIH;
23) a January 6, 2022, letter from the NIH to EcoHealth;
24) a January 21, 2022, letter from EcoHealth to the NIH;
25) an August 19, 2022, letter from the NIH to EcoHealth; and
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."

The information summarized below indicates that WIV 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 EcoHealth, with a project period from June 1, 2014 through May 31, 2019.

2. EcoHealth 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 EcoHealth is protecting people, animals, and the environment from emerging infectious diseases.

3. WIV, located in Wuhan, China, was listed as a consortium participant in the NoA for Grant Number 1R01AI110964-01.

4. 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).

5. 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)/Principal Investigator (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.

6. Grant Number 1R01AI110964-01 involved the study of highly pathogenic agents, which required the grant prime awardee's (EcoHealth'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)])."

7. 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.

8. In a letter dated May 28, 2016, NIAID contacted EcoHealth concerning possible GoF research based on information submitted in its most recent Year 2 RPPR. NIAID notified EcoHealth 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, NIAID requested that EcoHealth provide a determination within 15 days of the date of the letter as to whether EcoHealth's research under Grant Number 5R01AI110964-03 did or did not include GoF work subject to the funding pause.

9. In a letter dated June 8, 2016, EcoHealth provided a response to NIAID's May 28, 2016 letter. EcoHealth 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. EcoHealth 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, EcoHealth 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.

10. Based on the information provided by EcoHealth, NIAID concluded that the proposed work was not subject to the GoF research pause. In a letter dated July 7, 2016, however, NIAID informed EcoHealth 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, EcoHealth must stop all experiments with these viruses and provide NIAID Program Officer and Grants Management Specialist, and WIV Institutional Biosafety Committee, with the relevant data and information related to these unanticipated outcomes.

11. This issue formed the basis for the special term and condition that was included in Section IV of the revised R01AI110964-03, issued on November 30, 2016, to remind EcoHealth 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 EcoHealth Alliance, 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."

12. 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).

13. 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

[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.

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.

14. On November 5, 2018, the NIH received a renewal application from EcoHealth (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 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 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.

15. In a letter dated April 19, 2020, the NIH notified EcoHealth 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 EcoHealth to cease providing any funds from Grant Number R01AI110964 to WIV.

16. In a letter dated April 24, 2020, the NIH notified EcoHealth that it had elected to terminate Grant Number R01AI110964, for convenience. 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."

17. In a letter dated May 22, 2020, [redacted], the law firm representing EcoHealth, notified the NIH that it was appealing the termination of Grant Number R01AI110964.

18. In a letter dated July 8, 2020, the NIH notified EcoHealth that it withdrew its termination of Grant Number R01AI110964, and reinstated the grant. However, the NIH informed EcoHealth 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 EcoHealth to further assess compliance by EcoHealth and WIV. Among the information and materials requested by NIH from EcoHealth, NIH also directed EcoHealth 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.

19. In a letter dated July 23, 2021, the NIH requested that EcoHealth 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 EcoHealth, in order to analyze EcoHealth'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 EcoHealth 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 EcoHealth provide the remaining documents and outstanding reports by August 27, 2021.

20. On August 3, 2021, EcoHealth submitted the Year 5 I-RPPR for Grant Number 5R01AI110964-05. 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 EcoHealth 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.

21. In a letter dated October 20, 2021, the NIH informed EcoHealth 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 Grants Policy Statement, 4.1.1.2. As such, the NIH requested WIV provide documentation verifying IACUC approval. The NIH also requested that EcoHealth 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.

22. In a letter dated October 26, 2021, EcoHealth 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. EcoHealth 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. EcoHealth 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.

23. In a letter dated November 5, 2021, the NIH requested that EcoHealth 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 EcoHealth'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.

24. In a letter dated November 18, 2021, EcoHealth informed the NIH that it did not have copies of the requested laboratory notebooks and electronic files, which were created by WIV. EcoHealth stated that it forwarded the NIH's November 5, 2021, letter to WIV and would provide the NIH with WIV's response upon receipt.

25. In a letter dated January 6, 2022, the NIH again requested that EcoHealth 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.

26. In a letter dated January 21, 2022, EcoHealth informed the NIH that it had forwarded its January 6, 2022, letter to WIV, but that no further information had been received. EcoHealth stated that it would inform the NIH when and if WIV provided a response.

27. In a letter dated August 19, 2022, the NIH notified EcoHealth that it was terminating the subaward from EcoHealth 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 EcoHealth 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 EcoHealth 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.

28. 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 report 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.

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 WIV, pursuant to the Nonprocurement Common Rule, found at 2 C.F.R. § 180. Pursuant to 2 C.F.R. § 180.700, a suspending and debarring 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 WIV is necessary to protect the public interest. See 2 C.F.R. §180.700(c). The NIH's review of the Year 5 I-RPPR 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. NIH has given WIV several opportunities to disprove this finding, but WIV has failed to do so. Due to WIV's disregard of the NIH's requests that WIV provide the required materials to support its research reported in the grant RPPRs and I-RPPRs, the NIH's conclusion that WIV research likely violated protocols of the NIH regarding biosafety is undisputed. As such, there is risk that WIV not only previously violated, but is currently violating, and will continue to violate, protocols of the NIH on biosafety, as set forth in the NIH GPS, Section 4.1.24 "Public Health Security," and the terms and conditions of the NoA for Grant Number R01AI110964 (e.g., requiring that "Research funded under this grant must adhere to the [Centers for Disease Control (CDC)/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)])." Therefore, I have determined that the immediate suspension of WIV is necessary to mitigate any potential public health risk.

Furthermore, I find that the information in the record constitutes adequate evidence to demonstrate that the suspension and proposed debarment of WIV is necessary due to a cause of so serious or compelling a nature that it affects WIV's present responsibility. *See* 2 C.F.R. 180.800(d). As previously stated, 45 C.F.R. § 75.364(a) requires non-United States Federal

Government entities (non-Federal entities) to grant access to any documents, papers, or other records of the non-Federal entity that are pertinent to the Federal award, and 45 C.F.R. § 75.352 requires that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity. The information in the record establishes that the NIH requested materials be provided 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 WIV or EcoHealth (as the pass-through entity on behalf of WIV). For the reasons set forth, it appears that WIV's failure to respond to NIH's request, which was necessary to review allegations that WIV has not satisfied biosafety requirements under the grant, reflect that WIV is not compliant with federal regulations and is not presently responsible.

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, WIV is hereby suspended and proposed for debarment, effective July 17, 2023. The suspension is effective until the conclusion of debarment proceedings, pursuant to 2 C.F.R. §180.760(a).

[redacted] Digitally signed by [redacted]
Date: 2023.07.17 14:10:50 -04'00'

[redacted]
Suspension and Debarment Official and
Deputy Assistant Secretary for Acquisition