



6 January 2022

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: R01AI110964

Dear Drs. Chmura and Daszak:

Thank you for your correspondence of November 18, 2021. We are following up on your response to our request for Institutional Animal Care and Use Committee (IACUC) approval for the field work, and your response to our request for laboratory notebook entries and electronic files related to the experiments described in the Year 4 RPPR and Year 5 I-RPPR.

IACUC Approval

As we noted before and as required by the NIH Grants Policy Statement (GPS), [4.1.1.2](#), NIH requires verification of IACUC approval of those sections of the grant application that involve use of vertebrate animals. As noted by the NIH Office of Laboratory Animal Welfare (OLAW) cover letter accompanying your Interinstitutional Agreement for the WIV animal work, “under your approved Assurance with the Wuhan Institute of Virology, their Institutional Animal Care and Use Committee (IACUC) is authorized to carry out subsequent reviews of this project.” In the final Vertebrate Animal Section of EcoHealth’s Just-in-Time materials submitted on May 16, 2014 for 1 R01 AI110964-01, you stated that “all animal work to be done at Wuhan has been approved by the Wuhan IRB (IACUC) #WIVA05201402. Animals will be housed in a BSL-3 facility and will be under the care of a full-time veterinarian.”

In my November 5, 2021, letter I requested documentation from the *WIV IACUC* regarding approval for *field work* (e.g., work in caves to collect materials from live bats) supported by R01AI110964. In your November 18, 2021, letter you indicated that no such *WIV IACUC* documentation exists. You stated, “the fieldwork in China that we conducted under our R01 is covered by the Inter-institutional agreement we cited in our letter of October 26th, and by our relevant US institutional IACUC approval.”

Through our own search, we have confirmed that the field work was indeed approved by an IACUC. We understand that one of your co-investigators, Dr. Jonathan Epstein, submitted the field work proposal to the Tufts University IACUC; the Tufts University IACUC provided approval; and NIAID accepted the use of the Tufts University IACUC. However, in response to our requests for documentation of IACUC approval, you did not identify who the US institutional IACUC was, nor did you provide us with the Tufts University IACUC approval documentation. We had to obtain the documentation directly from Tufts University. While we are satisfied that the field work was approved by an IACUC, EcoHealth’s inability or unwillingness to



6 January 2022

provide the Tufts University IACUC documentation to us upon request raises questions about the quality and rigor of EcoHealth's record-keeping.

Laboratory Notebooks and Electronic Files

In my letter of November 5, 2021, I asked you to send us by no later than Friday, November 19, 2021, 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..."). On November 18, 2021, you responded: "We do not have copies of these, which were created by and retained by the WIV. Nonetheless, I have forwarded your letter to the WIV, and will let you know their response as soon as WIV replies to our request." We are following up to confirm whether you received a response from WIV and whether the materials are forthcoming.

As a reminder, it is critical to note that our request for the original laboratory notebook entries and the original electronic files underlying the Year 4 RPPR Figure 35 and the Year 5 I-RPPR Figure 13 is consistent with the term and condition of award which provides that NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. 75.364). It is also consistent with the term and condition of award that "The Federal Government has the right to obtain...the data produced under a Federal award." (45 C.F.R. 75.322(d)). Moreover, as a term and condition of award, unless extended by the Federal awarding agency, all "records pertinent to a Federal award must be retained for a period of three years from the date of submission of the final expenditure report or, for Federal awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, respectively, as reported to the HHS awarding agency or pass-through entity in the case of a subrecipient." (45 C.F.R. 75.361). NIH's rights of access "are not limited to the required retention period but last as long as the records are retained." (45 C.F.R. 75.364(c)). These rights and requirements apply not only to EcoHealth's records and data, but also to WIV's records and data, regardless of whether WIV is an active subawardee of EcoHealth at this time. Awardees indicate their acceptance of an NIH award and its associated terms and conditions as they draw down the NIH grant funds to support the scientific project (see NIHGPS [Section 5](#)). If an awardee fails to comply with the terms and conditions of award, and NIH determines that noncompliance cannot be remedied with specific award conditions, the NIH may take one or more enforcement actions, including terminating the award in whole or in part, disallowing all or part of the cost of the activity or action not in compliance, and withholding further federal awards for the project. (45 C.F.R. 75.371).

Upon receipt of this letter, please confirm whether you have received a response from WIV and whether the materials are forthcoming. If the materials are forthcoming, we request that they be provided to us no later than close-of-business on January 14, 2022.

Please let me know if you have any questions concerning the information in this letter.

Sincerely,

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Michael.Lauer@nih.gov

cc: Ms. Emily Linde
Dr. Erik Stemmy