



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

The Honorable Ron Estes
U.S. House of Representatives
Washington, DC 20515

Dear Representative Estes:

Thank you for your letter regarding my recent correspondence about my testimony before the Ways and Means Committee last year. I welcome the opportunity to further clarify my statements about a National Institutes of Health (NIH) grant to EcoHealth Alliance (EHA) and its subaward to the Wuhan Institute of Virology.

NIH assures me that neither NIH nor its National Institute of Allergy and Infectious Diseases have ever approved any grant that would have supported research on coronaviruses that would have increased their transmissibility or lethality for humans. It is also important to note that the ability of a virus to bind to a particular human cellular receptor in a laboratory study or in an animal model is not equivalent to the ability to cause infection in humans^{1,2}

Further, Dr. Tabak's October 20, 2021, correspondence did not assert that "research was conducted on a virus...capable of human transmission." In fact, Dr. Tabak's letter stated, "these bat coronaviruses had not been shown to infect humans." This point is critical to emphasize, as it relates to the definition of enhanced potential pandemic pathogen (ePPP) used by the U.S. Government (USG), including the Department of Health and Human Services (HHS).

*The Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO)*³ outlines USG policy guidance for the oversight of federally funded research that is anticipated to create, transfer, or use enhanced potential pandemic pathogens (ePPPs). A potential pandemic pathogen (PPP) is a pathogen that is likely highly transmissible and likely capable of wide and uncontrollable spread in human populations; and likely highly virulent and likely to cause significant morbidity and/or mortality in humans. An ePPP is a PPP resulting from the enhancement of a pathogen's transmissibility and/or virulence. In accordance with this policy guidance, HHS uses the USG definition of ePPPs when assessing the subset of research that entails risks that are potentially significant enough to warrant additional oversight.

The USG policy guidance described above was developed by the White House Office of Science and Technology Policy following a comprehensive and prolonged public, deliberative process with the explicit goal of developing a new federal policy framework to guide future investments in this area of research. The deliberative process was conducted in partnership with the life sciences community as well as additional stakeholders and featured multiple public meetings and

¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6083867/>

² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3246895/>

³ <https://www.phe.gov/s3/dualuse/documents/p3co-finalguidancestatement.pdf>

two commissioned independent studies, including a comprehensive assessment of the risks and benefits of this research.

NIH application of HHS P3CO Framework

In response to, and in accordance with the USG policy guidance described above, in 2017, HHS published the *U.S. Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (HHS P3CO Framework).⁴ The Framework guides HHS funding decisions for research that is reasonably anticipated to create, transfer, or use ePPPs.

NIH reviewed the research proposed by the grant referenced in your letter under the definitions in the USG policy guidance and HHS P3CO Framework. NIH determined that the experiments were not subject to the HHS P3CO Framework because the bat coronaviruses used in this research have not been shown to infect humans and the experiments were not reasonably anticipated to increase transmissibility or virulence in humans.

Progress Reports

NIH primarily conducted oversight of the EHA award through four progress reports submitted by EHA over the course of the grant and a competing renewal application that reported progress on the initial grant, as well as through published articles detailing the science conducted. Each report contains six categories of prescribed information, including scientific accomplishments, proposed modifications to scientific goals, an accounting of changes to key personnel or other support, and demographics of research subjects. The scientific accomplishments are the main subject and the source of much information into the activities of the sub-awardees.

Peer Review Process

The application process at NIH involves both the two-level peer review process to evaluate the merit and feasibility of the science and a robust administrative review to gain assurances that the applicant institution is aware of and intends to follow all relevant federal laws, regulations, and policies⁵ and evaluate the degree to which the proposal in the application holds to NIH's high standards of scientific integrity, ethical conduct, and financial stewardship.

The review of the initial application was completed in December 2013. Once a reviewer agrees to serve on a review committee, an entry is created for them by NIH staff to access the NIH eRA Commons system (<https://era.nih.gov/>). The eRA Commons has a 2-factor system for login. Reviewers can only access the review meeting where they are assigned as a reviewer. Before a reviewer can gain access to the applications, they must first certify they are not lobbyists and sign the confidentiality statement. Dr. Peter Daszak was not involved in the peer review process for this grant apart from submitting the formal grant application.

⁴ <https://www.phe.gov/s3/dualuse/documents/p3co.pdf>

⁵ <https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>

As touched upon in Dr. Tabak's October 20, 2021, correspondence, NIH is currently performing a grants compliance review to ensure recipient compliance with the terms and conditions of award.

NIH continually strives to provide clear and transparent information about the full scope of research we support. We hope the information provided is useful.

Sincerely,

Xavier Becerra