



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health  
National Institute of Allergy  
and Infectious Diseases  
Bethesda, Maryland 20892

July 05, 2018

Mr. Aleksei Chmura  
EcoHealth Alliance  
460 W. 34th Street – 17th Floor  
New York, NY 10001

RE: 5R01AI110964-05

Dear Mr. Chmura:

On December 19, 2017, the U.S. Department of Health and Human Services (DHHS) issued the *Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (HHS P3CO Framework) (<https://www.phe.gov/s3/dualuse/Documents/P3CO.pdf>). The HHS P3CO Framework is responsive to and in accordance with the *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight* (Recommended Policy Guidance) (<https://www.phe.gov/s3/dualuse/Documents/P3CO-FinalGuidanceStatement.pdf>) issued by the White House Office of Science and Technology Policy on January 9, 2017. Additionally, and as noted in the Recommended Policy Guidance, adoption of the HHS P3CO Framework satisfies the requirement for lifting the Research Funding Pause on certain gain-of-function (GoF) research.

The HHS P3CO Framework guides DHHS funding decisions on research that is reasonably anticipated to create, transfer, or use enhanced potential pandemic pathogens (PPPs). A PPP is a pathogen that satisfies both of the following:

- It is likely highly transmissible and likely capable of wide and uncontrollable spread in human populations; and
- It is likely highly virulent and likely to cause significant morbidity and/or mortality in humans.

In accordance with the HHS P3CO Framework, research involving an enhanced PPP is subject to additional HHS department-level review. NIAID re-reviewed the grant application and other information provided by you, and made the following assessment:

The experiments to generate MERS-like or SARS-like chimeric coronaviruses, are not subject to the HHS P3CO Framework. The terms and conditions of the award have been revised to indicate that should 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 and that further research involving the resulting virus(es) may require review by the DHHS in accordance with the HHS P3CO Framework.

Please remember that the institution must comply in full with all terms and conditions placed on this grant.

Please let us know if you have any questions, or if you require additional information.

Sincerely,

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Adam Graham  
Grants Management Specialist  
NIAID/NIH/DHHS

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Erik J. Stemmy, Ph.D.  
Program Officer  
Respiratory Diseases Branch  
Division of Microbiology and Infectious Diseases  
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CC: Dr. Peter Daszak  
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