DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 28, 2016

Mr. Aleksei Chmura
Senior Coordinator of Operations
EcoHealth Alliance
460 West 34th Street – 17th Floor
New York, NY 10001

RE: 5R01AI110964-03

Dear Mr. Chmura:

Based upon information in the most recent progress report, NIAID has determined that the above referenced grant may include Gain of Function (GoF) research that is subject to the U.S. Government funding pause (http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf), issued on October 17, 2014. The following specific aims appear to involve research covered under the pause:

Aim 3: Testing predictions of CoV inter-species transmission

As per the funding pause announcement, new USG funding will 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. Therefore, the next non-competing segment of the award that starts June 1, 2016 cannot be released until a determination is reached based on the receipt and review of the information requested below. The research funding pause would not apply to characterization or testing of naturally occurring influenza, MERS, or SARS viruses, unless the tests are reasonably anticipated to increase transmissibility and/or pathogenicity.

NIAID requests that you provide the following information within 15 days of the date of this letter:

- **Determination as to whether the above research does or does not include GoF work subject to the funding pause**. Please provide a detailed explanation for this determination, including, but not limited to, descriptions of the MERS and MERS-like chimeric CoVs that you propose to create, and detailed descriptions of the experiments you plan to conduct. Your determination should also include whether each chimeric virus is reasonably anticipated to exhibit enhanced pathogenicity and/or transmissibility in mammals via the respiratory route compared to wild type MERS-CoV.

- **In addition, your progress report makes reference to two chimeric bat SARS-like CoVs constructed on a WIV-1 backbone.** NIAID requests additional information on these strains of SARS-like CoVs, including: the dates the strains were created; whether the chimeric viruses exhibit enhanced pathogenicity and/or transmissibility in mammals via the respiratory route compared to wild type SARS-CoV; and what research plans you have for these chimeric viruses.
- **If it is determined that the above research <u>DOES</u> include GoF work subject to the funding pause, provide detailed information on what research will remain viable with the removal of the GoF work and appropriate budget adjustments. Options include:**
    - For the specific aims that propose GoF work, provide a detailed description of changes that can be made to remove the GoF work but maintain the specific aim(s); or
    - Remove the specific aims and experiments that are subject to the pause from the Research Plan and request to have the award budget renegotiated.

If you have any questions about this matter please do not hesitate to contact the NIAID Program Officer.

Sincerely,

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Jenny Greer
Grants Management Specialist
NIAID/NIH/DHHS

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Erik J. Stemmy, Ph.D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Peter Daszak
Ms. Mary Kirker
Dr. Irene Glowinski
Dr. Andrew Ford