**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Freedom of Information Office
5601 Fishers Lane, Suite 6G50
Bethesda, Maryland 20892
Tel (301) 451-5109
Fax (301) 480-0904/ Email foia@niaid.nih.gov

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

November 13, 2014

Jocelyn Kaiser
Writer, Science Magazine
1200 New York Avenue, NW
Washington, DC 20005

Re: FOI Case No. 43088

Dear Ms. Kaiser:

This is a final response to your November 4, 2014 Freedom of Information Act (FOIA) request emailed to the National Institute of Allergy and Infectious Diseases FOIA Office. Your requested a "list of the roughly 20 projects stopped as a result of the 'pause' on funding certain gain-of-function virology studies that was announced by the Office of Science and Technology and the Department of Health and Human Services in October 2014." In a November 4, 2014 email to me you amended your request to "copies of any letters sent to investigators (or their institutions) asking them to comply with the funding pause."

We searched the files of the Division of Extramural Activities and the Division of Intramural Research, National Institute of Allergy and Infectious Diseases (NIAID) for records. That search produced 72 pages responsive to your request. Enclosed please find the following 72 electronic pages:

1. Letters to Dr. James Downing (St. Jude) regarding Contract HHSN272201400006C:
   A. October 21, 2014 - Notice of Partial Stop Work Order, [3 pages]
   B. October 30, 2014 - Clarification of Notice of Stop Work Order, Contract [4 pages]
2. Letters to Dr. Michael J. King (Mt. Sinai) regarding Contract HHSN272201400008C:
   A. October 21, 2014 - Notice of Partial Stop Work Order [4 pages]
   B. October 30, 2014 - Clarification of Notice of Stop Work Order [4 pages]
3. Letters to Dr. Michael Amey (Johns Hopkins) regarding Contract HHSN272201400007C:
   A. October 21, 2014 - Notice of Partial Stop Work Order [3 pages]
   B. October 30, 2014 - Clarification of Notice of Stop Work Order [4 pages]
4. Letters to Dr. Edward Puzas (Rochester Medical Center) regarding Contract HHSN272201400005C:
   A. October 21, 2014 - Notice of Partial Stop Work Order [3 pages]
   B. October 30, 2014 - Clarification of Notice of Stop Work Order [4 pages]

5. Letters to Ms. Una Sweeten (Utah State) regarding Contract HHSN272201000039I:
   A. October 21, 2014 – Notice of Partial Stop Work Order [3 pages]
   B. October 30, 2014 – Clarification of Notice of Stop Work Order [3 pages]
6. Letters to Ms. Jessica Moise (Mount Sinai) regarding Contract HHSN272201000019I:
   A. October 21, 2014 – Notice of Partial Stop Work Order [3 pages]
   B. October 30, 2014 – Clarification of Notice of Stop Work Order Memo [3 pages]
7. Letters to Dr. David Wynes (Emory) regarding Contract HHSN272201400004C:
   A. October 21, 2014 – Notice of Partial Stop Work Order [3 pages]
   B. October 30, 2014 – Clarification of Notice of Stop Work Order [4 pages]
8. Letter dated November 7, 2014 to Ms. Jenny Dahlberg (University of Wisconsin-Madison) regarding Grant #5U19AI067772-02 [2 pages]
9. Letter dated October 21, 2014 to Ms. Teri Medley (Washington University) regarding Grant #5R01AI080672-04 [2 pages]
10. Letter dated October 21, 2014 to Ms. Connie Barton (University of Texas) regarding Grant #1R21AI113206-01 [2 pages]
11. Letter dated October 21, 2014 to Ms. Monika Lagaard (University of Chicago) regarding Grant #5R00AI095320-03 [2 pages]
12. Letter dated October 21, 2014 to Ms. Jennifer Lassner (University of Iowa) regarding Grant #5P01AI060699-09 [2 pages]
13. Letter dated October 21, 2014 to Ms. Joy Floyd (Emory University) regarding Grant #5R01AI099000-03 [2 pages]
14. Letter dated October 21, 2014 to Ms. Sherrie Settle (University of North Carolina, Chapel Hill) regarding Grant #5U19AI107810-02 [2 pages]
15. Letter dated October 21, 2014 to Ms. Venzula Harris (University of Maryland) regarding Grant #5R01AI095569-04 [2 pages]
16. Letter dated October 21, 2014 to Ms. Lisa Au (Vanderbilt University) regarding Grant #5R01AI108197-02 [2 pages]
17. Letter dated October 21, 2014 to Ms. Jenny Dahlberg (University of Wisconsin-Madison) regarding Grant #5R01AI080598-05 [2 pages]
18. Letter dated October 21, 2014 to Ms. Jenny Dahlberg (University of Wisconsin-Madison) regarding Grant #5R01AI069274-07 [2 pages]
19. Email dated October 18, 2014 from Dr. Kathryn Zoon (Director, Division of Intramural Research [DIR]) notifying DIR Principal Investigators of the White House announcement on the Gain of Function Research Pause [2 pages].

No information was removed from the enclosed records.

In certain circumstances provisions of the FOIA and Department of Health and Human Services FOIA Regulations allow us to recover part of the cost of responding to your request. Because the cost is below the $25 minimum, there is no charge for the enclosed materials.

Sincerely,

Margaret Moore
Freedom of Information Office
National Institute of Allergy and Infectious Diseases

Enclosures: 72 electronic pages

**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Phone: 301-496-0612
Fax: 301-402-0972
http://www.niaid.nih.gov/

National Institutes of Health (NIH)
National Institute of Allergy and Infectious Diseases (NIAID)
DEA, Office of Acquisitions
6700B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

October 21, 2014

Transmitted via e-mail to:
james.downing@stjude.org

Dr. James Downing
Office of Scientific Director
262 Danny Thomas Place, MS 7333
Memphis, TN

Subject: **NOTICE OF PARTIAL STOP WORK ORDER,** Contract HHSN272201400006C
"NIAID Centers of Excellence for Influenza Research and Surveillance"

Dear Dr. Downing:

On October 17, 2014, the US Government issued a Research Funding Pause on selected gain-of-function research on influenza, MERS and SARS viruses (http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf). The scope of this Research Funding Pause has been defined to include any gain-of-function experiments that may be reasonably anticipated to confer attributes to any influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route. NIAID has interpreted this Research Funding Pause to also include any experiments utilizing influenza viruses previously generated that exhibit enhanced transmissibility in mammals via the respiratory route. The Research Funding Pause does not apply to characterization or testing of naturally occurring influenza viruses, unless the experiments are reasonably anticipated to increase transmissibility and/or pathogenicity.

Contracts are used by the US Government to acquire goods and services for its direct benefit. While this Research Funding Pause is in place, goods and services tied to gain-of-function research on influenza, MERS and SARS are no longer a government requirement. Thus, experiments that fall under the scope of this Research Funding Pause will not be conducted under any NIAID contract. This action is being taken in accordance with FAR 52. 242-15 [Stop Work Order (August 1989) with Alternative I (April 1984)] incorporated under Article F.4. of the subject contract.

NIAID has determined that the following projects in your contract, HHSN272201400006C, may contain gain-of-function experiments that fall under the Research Funding Pause.

Project 1: Wild Birds in the Americas
SPECIFIC AIMS POTENTIALLY IMPACTED:
*Aim 3* – Pathogenesis of highly pathogenic avian influenza virus H7N3 in wild birds

Project 2: Swine Influenza in the Americas
SPECIFIC AIMS POTENTIALLY IMPACTED:

*Aim 1* – Ecology of influenza in swine in the Americas

Project 3: Ecology of avian influenza viruses in live animal markets in Colombia
SPECIFIC AIMS POTENTIALLY IMPACTED:

*Aim 1* - Determine if infection in domestic birds in the live animal market is due to "spillover" events from wild birds.

Project 4: Antiviral characterization and impact of mutations on transmission
SPECIFIC AIMS POTENTIALLY IMPACTED:
*Aim 4* – Role of drug-resistant mutations in virulence and transmissibility of influenza B viruses (interpandemic strains).

Project 5: Influenza in High Risk Populations: Impact on Virus and Host
SPECIFIC AIMS POTENTIALLY IMPACTED:
*Aim 2*: Determine the impact of obesity on influenza virus evolution
*Aim 2.1*: Understand how the obesigenic lung environment influences viral evolution between hosts.

Project 6: Transmission of influenza viruses at the swine-human interface
SPECIFIC AIMS POTENTIALLY IMPACTED
*Aim 1*: Virologic Factors Governing Influenza Virus Transmission
*Aim 1.1*: Determine how the HA activation pH controls host range and transmission
*Aim 1.2*: Identify molecular changes acquired by avian influenza viruses through adaptations in the swine host
*Aim 1.3*: Discovery of novel molecular markers of transmission

If these projects contain any work as described under the Research Funding Pause, it must stop effective immediately upon receipt of this Notice. In addition, should any other applicable research that is being conducted with NIAID contract funding fall under the Research Funding Pause it too must stop immediately. Within 14 days of the date of this letter please respond to this partial stop work notice with a detailed list of the projects and experiments that you have halted. You should contact your COR to discuss re-direction of the research that has been stopped. This partial stop work order will remain in effect for ninety (90) calendar days from the date of this letter or until you are otherwise notified.

You shall take the following steps related to cessation of work:

1) Evaluate all projects for experiments in question; stop all identified gain-of-function experiments that can enhance pathogenicity and transmissibility of any influenza virus; within 14 days of receipt of this Notice provide a detailed list of projects and experiments that have been halted, and contact COR to discuss redirection of contract activities.

2) Keep adequate records of your compliance with #1), above, showing the:

   (a) Effective date of the Partial Stop Work Order;
   (b) Evaluation of projects for GOF experiments

3) Furnish notice of stop work to each immediate subcontractor, consultant and supplier that will be affected by this Partial Stop Work Order. In this notice:

(a) Specify your Government contract number;
(b) State that the contract is under a Partial Stop Work Order;
(c) State the effective date of the Partial Stop Work Order;
(d) Provide instructions to stop work required;
(e) Request that similar notices and instructions be given to its immediate subcontractors.

Matters not covered by this notice should be brought to the attention of the undersigned.

bijan.mansoury@nih.gov

Digitally signed by bijan.mansoury@nih.gov
DN: cn=bijan.mansoury@nih.gov
Date: 2014.10.21 16:25:45 -04'00'

On behalf of Michael C. Finn
Contracting Officer, MID Research Contracts Branch-B
Office of Acquisitions, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892-7612

cc: Dr. Diane Post, CEIRS COR, RDB, DMID, NIAID
Dr. Irene Glowinski, Deputy Director, DMID, NIAID
Charles W. Grewe, C.C.O., Office of Acquisitions, DEA, NIAID
Dr. Richard Webby, St. Jude Children's Research Hospital
Dr. Stacey Schultz-Cherry, St. Jude Children's Research Hospital
Dr. Jeurgen Richt, Kansas State University
Dr. Jorge Osorio, University of Wisconsin
Dr. Elena Govorkova, St. Jude Children's Research Hospital
Dr. Charlie Russell, St. Jude Children's Research Hospital
Dr. Malik Peiris, University of Hong Kong

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Please acknowledge receipt of this notice as provided below:

ACKNOWLEDGEMENT OF NOTICE

The undersigned acknowledges receipt of a signed copy of this notice on _____. A signed, scanned and emailed copy of this notice is returned to Michael Finn.

_____
Signature

_____
Position / Title

National Institutes of Health

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National Institutes of Health (NIH)
National Institute of Allergy and Infectious Diseases (NIAID)
Division of Extramural Activities (DEA)
**Office of Acquisitions (OA)**
5601 Fishers Lane
Rockville, MD 20852

October 30, 2014

Transmitted via e-mail to:
james.downing@stjude.org

Dr. James Downing
Office of Scientific Director
262 Danny Thomas Place, MS 7333
Memphis, TN

Subject: **Clarification of Notice of Stop Work Order from NIAID,** Contract HHSN272201400006C "NIAID Centers of Excellence for Influenza Research and Surveillance"

Dear Dr. Downing:

On October 21st 2014, you received a Stop Work Order from NIAID temporarily suspending a portion of the activities under your contract. The Order was in follow-up to the October 17th, 2014 announcement by the U.S. Government regarding a research funding pause on select gain-of-function (GoF) experiments involving influenza, SARS, and MERS viruses. This follow-up letter provides some context and additional clarifications to that Order.

First, as background, the U.S. government is undertaking a deliberative process to assess the risks and benefits of certain GoF experiments. This will inform the development of a government-wide policy framework that will guide future federal investments in GoF studies. During this deliberative process, there will be a pause on the release of federal funds for studies that meet the stated definition (see www.phe.gov/s3/dualuse). NIAID will be adhering to this funding pause until the robust and broad deliberative process– including consultation with the National Science Advisory Board for Biosecurity and public input from forums hosted by the National Academies – is completed.

NIAID's intention is to exercise the funding pause to the full extent of its authority. Where NIAID does not have specific authority to pause funding, the Agency is encouraging researchers to pause voluntarily the specific experiments described in the Federal government's announcement of a funding pause. Under the contract mechanism, NIAID has the authority, and hence obligation as stewards of government funds, to implement this pause immediately for the contract work involving such studies. NIAID staff will work with you to determine what work may be conducted during the funding pause and what may not.

Second, the funding pause only applies to prescribed experiments – those 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. Such projects must be evaluated by investigators, working with the NIAID Contracting Officer's Representative (COR), to determine whether they meet the scope of the experiments described in the announcement. The research funding pause would not apply to characterization or testing of naturally occurring influenza, MERS, and SARS viruses, unless the tests are reasonably anticipated to increase transmissibility and/or pathogenicity. This pause was not intended to stop surveillance work, nor to apply to the routine characterization or testing of naturally occurring influenza, MERS, and SARS viruses, such as occurs during surveillance efforts, unless the experiments are reasonably anticipated to enhance transmissibility or pathogenicity of the naturally occurring isolates obtained through surveillance efforts. For example, if you have a surveillance project that involves reverse genetic experiments to understand pathogenesis and transmission, then those specific aspects of the work may fall under the funding pause. But again, this will need to be determined on a case-by-case basis with your NIAID COR.

The specific aims listed in the Stop Work Order that NIAID staff determined may be covered by the funding pause are based on the information staff currently have about your projects. If there are specific aims identified in your Order that you think are not covered by the funding pause, please send the COR and Contracting Officer (CO) a summary of that work and your rationale in your official response to the Stop Work Order.

As you know, NIAID staff do not have the exact details of each experiment you are planning to conduct. Therefore, at this time NIAID expects that you will evaluate the remaining projects and associated specific aims (those not identified in the letter) to assess if there are additional experiments that may fall under the funding pause. If you identify an experiment that you think meets the scope of experiments described in the announcement, then those experiments must stop immediately and you must notify the COR and CO. If you are unclear as to whether or not additional experiments fall under the funding pause, please send a summary of the experiments in question to the COR and include why you think they do or do not fall under the pause. NIAID staff will review those and then the CO provide you with further guidance.

Third, when the funding pause was announced, it was noted that an exception from the research pause may be obtained if the head of the US government funding agency determines that the research is urgently necessary to protect the public health or national security. If you feel that this exception may be applicable to your work that was stopped under the Order, please let the COR and CO know and the CO will provide further instructions. NIH will review exemption requests in as timely a manner as is possible.

The federal government intends for the deliberative process to occur as expeditiously and transparently as possible, and therefore has structured a one-year process that will facilitate the kind of deep and rigorous discussion such a complex topic demands. NIAID urges you to actively engage in the gain-of-function deliberative process and share your experience and perspective. Your engagement in this effort will help ensure that the product of the process is a robust and durable framework to guide future federal investments in this area of research.

Michael C. Finn
Contracting Officer, MID Research Contracts Branch-B
Office of Acquisitions, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892-7612

David Spiro, Ph.D.
Section Chief
Respiratory Diseases Branch
DMID/NIAID/NIH/DHHS

cc: Dr. Diane Post, CEIRS COR, RDB, DMID, NIAID
Dr. Irene Glowinski, Deputy Director, DMID, NIAID
Charles W. Grewe, C.C.O., Office of Acquisitions, DEA, NIAID
Dr. Richard Webby, St. Jude Children's Research Hospital
Dr. Stacey Schultz-Cherry, St. Jude Children's Research Hospital
Dr. Jeurgen Richt, Kansas State University
Dr. Jorge Osorio, University of Wisconsin
Dr. Elena Govorkova, St. Jude Children's Research Hospital
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Dr. Malik Peiris, University of Hong Kong

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ACKNOWLEDGEMENT OF NOTICE

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_____
Signature

_____
Position / Title

**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Phone: 301-496-0612
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National Institutes of Health (NIH)
National Institute of Allergy and Infectious Diseases (NIAID)
DEA, Office of Acquisitions
6700B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

October 21, 2014

Transmitted via e-mail to:
michael.king@mssm.edu

Dr. Michael J. King
Director, Grants and Contracts Office
Icahn School of Medicine at Mt. Sinai
One Gustave L. Place, Box 3500
New York, NY 10029

Subject: **NOTICE OF PARTIAL STOP WORK ORDER,** Contract HHSN272201400008C
"NIAID Centers of Excellence for Influenza Research and Surveillance"

Dear Dr. King:

On October 17, 2014, the US Government issued a Research Funding Pause on selected gain-of-function research on influenza, MERS and SARS viruses (http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf). The scope of this Research Funding Pause has been defined to include any gain-of-function experiments that may be reasonably anticipated to confer attributes to any influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route. NIAID has interpreted this Research Funding Pause to also include any experiments utilizing influenza viruses previously generated that exhibit enhanced transmissibility in mammals via the respiratory route. The Research Funding Pause does not apply to characterization or testing of naturally occurring influenza viruses, unless the experiments are reasonably anticipated to increase transmissibility and/or pathogenicity.

Contracts are used by the US Government to acquire goods and services for its direct benefit. While this Research Funding Pause is in place, goods and services tied to gain-of-function research on influenza, MERS and SARS are no longer a government requirement. Thus, experiments that fall under the scope of this Research Funding Pause will not be conducted under any NIAID contract. This action is being taken in accordance with FAR 52. 242-15 [Stop Work Order (August 1989) with Alternative I (April 1984)] incorporated under Article F.4. of the subject contract.

NIAID has determined that the following projects in your contract, HHSN272201400008C, may contain gain-of-function experiments that fall under the Research Funding Pause.

Project 1: MIT Surveillance and Surveillance-Related Research
SPECIFIC AIMS POTENTIALLY IMPACTED:
*Aim 1.* How does reassortment in LPAI impact their pandemic potential?
*Aim 2*: How does variation in receptor binding affect host specificity?

Project 2: Avian, swine and human H5N1 influenza virus surveillance activities in Asia and the Middle East
SPECIFIC AIMS POTENTIALLY IMPACTED:
*Aim:* Identification of novel virulence determinants.

Project 3: Phenotypic Characterization of Influenza Viruses
SPECIFIC AIMS POTENTIALLY IMPACTED:
*Aim.* Reverse genetics assays

Project 4: Host Factors and Disease Outcome
SPECIFIC AIMS POTENTIALLY IMPACTED:
*Aim 2.* To assess the antiviral mechanism(s) of Mx proteins
*Aim 2.3*: Selection of influenza viruses with increased resistance to MxA or Mx1 by introduction of random mutations.

Project 5: Host Factors and Virus Tropism
SPECIFIC AIMS POTENTIALLY IMPACTED:
*Aim 1:* Host specific inhibition of innate immunity by NS1.
*Aim 1.3.* Impact on virus replication, pathogenesis and host tropism
*Aim 2:* Host specific interactions of NEP.
*Aim 2.1:* Species-specific interactions of the NEP:
*Aim 2.3:* Impact on virus replication, pathogenesis and host tropism
*Aim 3:* Host adaptive polymerase mutations
*Aim 3.1:* Identify and characterize polymerase mutations that emerged during H5N1 passaging in ferrets:
*Aim 3.3:* Examine new polymerase polymorphisms and their role in promoting virus replication through interaction with essential human host factors.
*Aim 4:* Virus specific interactions with myeloid cells.
*Aim 4.3:* NS1 mediated inhibition of DCs and macrophages.

Project 6: HA Determinants of Virus Phenotype: Antigenicity, Virulence, and Transmission
SPECIFIC AIMS POTENTIALLY IMPACTED:
*Aim 1.* To identify molecular determinants of antigenic properties in HA
*Aim 2.* To identify molecular determinants of virulence in HA
*Aim 3.* To identify airborne transmission determinants of H5 HA
*Aim 4.* To identify airborne transmission determinants of H1 HA
*Aim 5.* To identify host determinants of transmission in guinea pigs and ferrets.

Project 7: Mechanisms of Interspecies Transmission of H9 and H7 Viruses
SPECIFIC AIMS POTENTIALLY IMPACTED:
*Aim 1.* Determine the tissue tropism, receptor binding preference, and growth kinetics of parental and transmissible viruses in ex vivo tissue explants (EXTE).
*Aim 2*: Quantify differences in viral shedding, determine mutation frequencies in virus populations, and determine the Aerosol Infectious Dose50 (AID50) of the H9 and H7 parental viruses and the respiratory transmissible viruses in ferrets.
*Aim 3*: Define the phenotypes of changes in each gene from transmissible H9 and H7 viruses, and test their pathogenesis and spread in animals,.
*Aim 4*: Determine if the molecular changes required for respiratory transmission can be transferred to influenza isolates from the same subtype

If these projects contain any work as described under the Research Funding Pause, it must stop effective immediately upon receipt of this Notice. In addition, should any other applicable research that is being conducted with NIAID contract funding fall under the Research Funding Pause it too must stop immediately. Within 14 days of the date of this letter please respond to this partial stop work notice with a detailed list of the projects and experiments that you have halted. You should contact your COR to discuss re-direction of the research that has been stopped. This partial stop work order will remain in effect for ninety (90) calendar days from the date of this letter or until you are otherwise notified.

You shall take the following steps related to cessation of work:

1) Evaluate all projects for experiments in question; stop all identified gain-of-function experiments that can enhance pathogenicity and transmissibility of any influenza virus; within 14 days of receipt of this Notice provide a detailed list of projects and experiments that have been halted, and contact COR to discuss redirection of contract activities.

2) Keep adequate records of your compliance with #1), above, showing the:

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   (b) Evaluation of projects for GOF experiments

3) Furnish notice of stop work to each immediate subcontractor, consultant and supplier that will be affected by this Partial Stop Work Order. In this notice:

   (a) Specify your Government contract number;
   (b) State that the contract is under a Partial Stop Work Order;
   (c) State the effective date of the Partial Stop Work Order;
   (d) Provide instructions to stop work required;
   (e) Request that similar notices and instructions be given to its immediate subcontractors.

Matters not covered by this notice should be brought to the attention of the undersigned.

bijan.mansoury@nih.gov Digitally signed by bijan.mansoury@nih.gov
DN: cn=bijan.mansoury@nih.gov
Date: 2014.10.21 16:29:36 -04'00'

On behalf of Michael C. Finn
Contracting Officer, MID Research Contracts Branch-B
Office of Acquisitions, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892-7612

cc: Dr. Diane Post, CEIRS COR, RDB, DMID, NIAID
Dr. Irene Glowinski, Deputy Director, DMID, NIAID
Charles W. Grewe, C.C.O., Office of Acquisitions, DEA, NIAID
Dr. Adolfo Garcia-Sastre, Icahn School of Medicine at Mt. Sinai
Dr. Jon Runstadler, MIT
Dr. Yoshi Kawaoka, University of Wisconsin
Dr. Randy Albrecht, Icahn School of Medicine at Mt. Sinai

Dr. Ana Sesma-Fernandez, Icahn School of Medicine at Mt. Sinai
Dr. Meghan Shaw, Icahn School of Medicine at Mt. Sinai
Dr. Ron Fouchier, Erasmus Medical Center
Dr. Nicole Bouvier, Icahn School of Medicine at Mt. Sinai
Dr. Daniel Perez, University of Maryland

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_____
Signature

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National Institutes of Health

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Fax: 301-480-4675
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National Institutes of Health (NIH)
National Institute of Allergy and Infectious Diseases (NIAID)
Division of Extramural Activities (DEA)
**Office of Acquisitions (OA)**
5601 Fishers Lane
Rockville, MD 20852

October 30, 2014

Transmitted via e-mail to:
michael.king@mssm.edu

Dr. Michael J. King
Director, Grants and Contracts Office
Icahn School of Medicine at Mt. Sinai
One Gustave L. Place, Box 3500
New York, NY 10029

Subject: **Clarification of Notice of Stop Work Order from NIAID,** Contract HHSN272201400008C "NIAID Centers of Excellence for Influenza Research and Surveillance"

Dear Dr. King:

On October 21st 2014, you received a Stop Work Order from NIAID temporarily suspending a portion of the activities under your contract. The Order was in follow-up to the October 17th, 2014 announcement by the U.S. Government regarding a research funding pause on select gain-of-function (GoF) experiments involving influenza, SARS, and MERS viruses. This follow-up letter provides some context and additional clarifications to that Order.

First, as background, the U.S. government is undertaking a deliberative process to assess the risks and benefits of certain GoF experiments. This will inform the development of a government-wide policy framework that will guide future federal investments in GoF studies. During this deliberative process, there will be a pause on the release of federal funds for studies that meet the stated definition (see www.phe.gov/s3/dualuse). NIAID will be adhering to this funding pause until the robust and broad deliberative process– including consultation with the National Science Advisory Board for Biosecurity and public input from forums hosted by the National Academies – is completed.

NIAID's intention is to exercise the funding pause to the full extent of its authority. Where NIAID does not have specific authority to pause funding, the Agency is encouraging researchers to pause voluntarily the specific experiments described in the Federal government's announcement of a funding pause. Under the contract mechanism, NIAID has the authority, and hence obligation as stewards of government funds, to implement this pause immediately for the contract work involving such studies. NIAID staff will work with you to determine what work may be conducted during the funding pause and what may not.

Second, the funding pause only applies to prescribed experiments – those 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. Such projects must be evaluated by investigators, working with the NIAID Contracting Officer's Representative (COR), to determine whether they meet the scope of the experiments described in the announcement. The research funding pause would not apply to characterization or testing of naturally occurring influenza, MERS, and SARS viruses, unless the tests are reasonably anticipated to increase transmissibility and/or pathogenicity. This pause was not intended to stop surveillance work, nor to apply to the routine characterization or testing of naturally occurring influenza, MERS, and SARS viruses, such as occurs during surveillance efforts, unless the experiments are reasonably anticipated to enhance transmissibility or pathogenicity of the naturally occurring isolates obtained through surveillance efforts. For example, if you have a surveillance project that involves reverse genetic experiments to understand pathogenesis and transmission, then those specific aspects of the work may fall under the funding pause. But again, this will need to be determined on a case-by-case basis with your NIAID COR.

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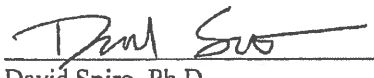
Michael C. Finn
Contracting Officer, MID Research Contracts Branch-B
Office of Acquisitions, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892-7612



David Spiro, Ph.D.
Section Chief
Respiratory Diseases Branch
DMID/NIAID/NIH/DHHS

cc: Dr. Diane Post, COR, RDB, DMID/NIAID
Dr. Irene Glowinski, Deputy Director, DMID, NIAID
Charles W. Grewe, C.C.O., Office of Acquisitions, DEA, NIAID
Dr. Adolfo Garcia-Sastre, Icahn School of Medicine at Mt. Sinai
Dr. Jon Runstadler, MIT
Dr. Yoshi Kawaoka, University of Wisconsin
Dr. Randy Albrecht, Icahn School of Medicine at Mt. Sinai
Dr. Ana Sesma-Fernandez, Icahn School of Medicine at Mt. Sinai
Dr. Meghan Shaw, Icahn School of Medicine at Mt. Sinai
Dr. Ron Fouchier, Erasmus Medical Center
Dr. Nicole Bouvier, Icahn School of Medicine at Mt. Sinai
Dr. Daniel Perez, University of Maryland

---

Please acknowledge receipt of this notice as provided below:

ACKNOWLEDGEMENT OF NOTICE

The undersigned acknowledges receipt of a signed copy of this notice on _____. A signed, scanned and emailed copy of this notice is returned to Michael Finn.

_____
Signature

_____
Position / Title

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Phone: 301-496-0612
Fax: 301-402-0972
http://www.niaid.nih.gov/

National Institutes of Health (NIH)
National Institute of Allergy and Infectious Diseases (NIAID)
DEA, Office of Acquisitions
6700B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

October 21, 2014

Transmitted via e-mail to:
mamey@jhmi.edu

Dr. Michael B. Amey
Associate Dean
Research Administration
Johns Hopkins University

Subject: **NOTICE OF PARTIAL STOP WORK ORDER,** Contract HHSN272201400007C
"NIAID Centers of Excellence for Influenza Research and Surveillance"

Dear Dr. Amey:

On October 17, 2014, the US Government issued a Research Funding Pause on selected gain-of-function research on influenza, MERS and SARS viruses (http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf). The scope of this Research Funding Pause has been defined to include any gain-of-function experiments that may be reasonably anticipated to confer attributes to any influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route. NIAID has interpreted this Research Funding Pause to also include any experiments utilizing influenza viruses previously generated that exhibit enhanced transmissibility in mammals via the respiratory route. The Research Funding Pause does not apply to characterization or testing of naturally occurring influenza viruses, unless the experiments are reasonably anticipated to increase transmissibility and/or pathogenicity.

Contracts are used by the US Government to acquire goods and services for its direct benefit. While this Research Funding Pause is in place, goods and services tied to gain-of-function research on influenza, MERS and SARS are no longer a government requirement. Thus, experiments that fall under the scope of this Research Funding Pause will not be conducted under any NIAID contract. This action is being taken in accordance with FAR 52. 242-15 [Stop Work Order (August 1989) with Alternative I (April 1984)] incorporated under Article F.4. of the subject contract.

NIAID has determined that the following projects in your contract, HHSN272201400007C, may contain gain-of-function experiments that fall under the Research Funding Pause.

Project 1: Virus Epithelial Cell Interactions
SPECIFIC AIMS POTENTIALLY IMPACTED:

*Aim 1.* Determine the affect of altering influenza A virus receptor recognition on virus replication and the induced innate immune responses in primary differentiated hNEC cultures.
*Aim 2.* Determine the affect of altering influenza A virus receptor recognition on virus replication and the induced innate immune responses in primary undifferentiated hNEC

Project 2: Pandemic Public Health Research Response Plan and Risk Assessment
SPECIFIC AIMS POTENTIALLY IMPACTED:
*Aim:* Predicting escape viruses by ultrahigh throughput, microfluidics-based serial passaging

If these projects contain any work as described under the Research Funding Pause, it must stop effective immediately upon receipt of this Notice. In addition, should any other applicable research that is being conducted with NIAID contract funding fall under the Research Funding Pause it too must stop immediately. Within 14 days of the date of this letter please respond to this partial stop work notice with a detailed list of the projects and experiments that you have halted. You should contact your COR to discuss re-direction of the research that has been stopped. This partial stop work order will remain in effect for ninety (90) calendar days from the date of this letter or until you are otherwise notified.

You shall take the following steps related to cessation of work:

1) Evaluate all projects for experiments in question; stop all identified gain-of-function experiments that can enhance pathogenicity and transmissibility of any influenza virus; within 14 days of receipt of this Notice provide a detailed list of projects and experiments that have been halted, and contact COR to discuss redirection of contract activities.

2) Keep adequate records of your compliance with #1), above, showing the:

   (a) Effective date of the Partial Stop Work Order;
   (b) Evaluation of projects for GOF experiments

3) Furnish notice of stop work to each immediate subcontractor, consultant and supplier that will be affected by this Partial Stop Work Order. In this notice:

   (a) Specify your Government contract number;
   (b) State that the contract is under a Partial Stop Work Order;
   (c) State the effective date of the Partial Stop Work Order;
   (d) Provide instructions to stop work required;
   (e) Request that similar notices and instructions be given to its immediate subcontractors.

Matters not covered by this notice should be brought to the attention of the undersigned.

bijan.mansoury@nih.gov Digitally signed by bijan.mansoury@nih.gov
DN: cn=bijan.mansoury@nih.gov
Date: 2014.10.21 16:30:46 -04'00'

On behalf of Michael C. Finn
Contracting Officer, MID Research Contracts Branch-B
Office of Acquisitions, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892-7612

cc: Dr. Diane Post, CEIRS COR, RDB, DMID, NIAID
Dr. Irene Glowinski, Deputy Director, DMID, NIAID
Charles W. Grewe, C.C.O., Office of Acquisitions, DEA, NIAID
Dr. Richard Rothman, Johns Hopkins University
Dr. Andrew Pekosz, Johns Hopkins University

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ACKNOWLEDGEMENT OF NOTICE

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_____
Signature

_____
Position / Title

National Institutes of Health

Phone: 301-496-0612
Fax: 301-480-4675
www.niaid.nih.gov

National Institutes of Health (NIH)
National Institute of Allergy and Infectious Diseases (NIAID)
Division of Extramural Activities (DEA)
**Office of Acquisitions (OA)**
5601 Fishers Lane
Rockville, MD 20852

October 30, 2014

Transmitted via e-mail to:
mamey@jhmi.edu

Dr. Michael B. Amey
Associate Dean
Research Administration
Johns Hopkins University

Subject: **Clarification of Notice of Stop Work Order from NIAID,** Contract HHSN272201400007C "NIAID Centers of Excellence for Influenza Research and Surveillance"

Dear Dr. Amey:

On October 21st 2014, you received a Stop Work Order from NIAID temporarily suspending a portion of the activities under your contract. The Order was in follow-up to the October 17th, 2014 announcement by the U.S. Government regarding a research funding pause on select gain-of-function (GoF) experiments involving influenza, SARS, and MERS viruses. This follow-up letter provides some context and additional clarifications to that Order.

First, as background, the U.S. government is undertaking a deliberative process to assess the risks and benefits of certain GoF experiments. This will inform the development of a government-wide policy framework that will guide future federal investments in GoF studies. During this deliberative process, there will be a pause on the release of federal funds for studies that meet the stated definition (see www.phe.gov/s3/dualuse). NIAID will be adhering to this funding pause until the robust and broad deliberative process– including consultation with the National Science Advisory Board for Biosecurity and public input from forums hosted by the National Academies – is completed.

NIAID's intention is to exercise the funding pause to the full extent of its authority. Where NIAID does not have specific authority to pause funding, the Agency is encouraging researchers to pause voluntarily the specific experiments described in the Federal government's announcement of a funding pause. Under the contract mechanism, NIAID has the authority, and hence obligation as stewards of government funds, to implement this pause immediately for the contract work involving such studies. NIAID staff will work with you to determine what work may be conducted during the funding pause and what may not.

Second, the funding pause only applies to prescribed experiments – those 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. Such projects must be evaluated by investigators, working with the NIAID Contracting Officer's Representative (COR), to determine whether they meet the scope of the experiments described in the announcement. The research funding pause would not apply to characterization or testing of naturally occurring influenza, MERS, and SARS viruses, unless the tests are reasonably anticipated to increase transmissibility and/or pathogenicity. This pause was not intended to stop surveillance work, nor to apply to the routine characterization or testing of naturally occurring influenza, MERS, and SARS viruses, such as occurs during surveillance efforts, unless the experiments are reasonably anticipated to enhance transmissibility or pathogenicity of the naturally occurring isolates obtained through surveillance efforts. For example, if you have a surveillance project that involves reverse genetic experiments to understand pathogenesis and transmission, then those specific aspects of the work may fall under the funding pause. But again, this will need to be determined on a case-by-case basis with your NIAID COR.

The specific aims listed in the Stop Work Order that NIAID staff determined may be covered by the funding pause are based on the information staff currently have about your projects. If there are specific aims identified in your Order that you think are not covered by the funding pause, please send the COR and Contracting Officer (CO) a summary of that work and your rationale in your official response to the Stop Work Order.

As you know, NIAID staff do not have the exact details of each experiment you are planning to conduct. Therefore, at this time NIAID expects that you will evaluate the remaining projects and associated specific aims (those not identified in the letter) to assess if there are additional experiments that may fall under the funding pause. If you identify an experiment that you think meets the scope of experiments described in the announcement, then those experiments must stop immediately and you must notify the COR and CO. If you are unclear as to whether or not additional experiments fall under the funding pause, please send a summary of the experiments in question to the COR and include why you think they do or do not fall under the pause. NIAID staff will review those and then the CO provide you with further guidance.

Third, when the funding pause was announced, it was noted that an exception from the research pause may be obtained if the head of the US government funding agency determines that the research is urgently necessary to protect the public health or national security. If you feel that this exception may be applicable to your work that was stopped under the Order, please let the COR and CO know and the CO will provide further instructions. NIH will review exemption requests in as timely a manner as is possible.

The federal government intends for the deliberative process to occur as expeditiously and transparently as possible, and therefore has structured a one-year process that will facilitate the kind of deep and rigorous discussion such a complex topic demands. NIAID urges you to actively engage in the gain-of-function deliberative process and share your experience and perspective. Your engagement in this effort will help ensure that the product of the process is a robust and durable framework to guide future federal investments in this area of research.

Michael C. Finn
Contracting Officer, MID Research Contracts Branch-B
Office of Acquisitions, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892-7612

David Spiro, Ph.D.
Section Chief
Respiratory Diseases Branch
DMID/NIAID/NIH/DHHS

cc: Dr. Diane Post, CEIRS COR, RDB, DMID, NIAID
Dr. Irene Glowinski, Deputy Director, DMID, NIAID
Charles W. Grewe, C.C.O., Office of Acquisitions, DEA, NIAID
Dr. Richard Rothman, Johns Hopkins University
Dr. Andrew Pekosz, Johns Hopkins University
Dr. Andrew Feldman, Johns Hopkins Applied Physics Lab

Please acknowledge receipt of this notice as provided below:

ACKNOWLEDGEMENT OF NOTICE

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_____
Signature

_____
Position / Title

**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Phone: 301-496-0612
Fax: 301-402-0972
http://www.niaid.nih.gov/

National Institutes of Health (NIH)
National Institute of Allergy and Infectious Diseases (NIAID)
DEA, Office of Acquisitions
6700B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

October 21, 2014

Transmitted via e-mail to:
Edward_Puzas@urmc.rochester.edu

J. Edward Puzas, Ph.D.
Senior Associate Dean for Research
University of Rochester Medical Center
601 Elmwood Avenue
Rochester, NY 14642

Subject: **NOTICE OF PARTIAL STOP WORK ORDER,** Contract HHSN272201400005C
"NIAID Centers of Excellence for Influenza Research and Surveillance"

Dear Dr. Puzas:

On October 17, 2014, the US Government issued a Research Funding Pause on selected gain-of-function research on influenza, MERS and SARS viruses (http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf). The scope of this Research Funding Pause has been defined to include any gain-of-function experiments that may be reasonably anticipated to confer attributes to any influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route. NIAID has interpreted this Research Funding Pause to also include any experiments utilizing influenza viruses previously generated that exhibit enhanced transmissibility in mammals via the respiratory route. The Research Funding Pause does not apply to characterization or testing of naturally occurring influenza viruses, unless the experiments are reasonably anticipated to increase transmissibility and/or pathogenicity.

Contracts are used by the US Government to acquire goods and services for its direct benefit. While this Research Funding Pause is in place, goods and services tied to gain-of-function research on influenza, MERS and SARS are no longer a government requirement. Thus, experiments that fall under the scope of this Research Funding Pause will not be conducted under any NIAID contract. This action is being taken in accordance with FAR 52. 242-15 [Stop Work Order (August 1989) with Alternative I (April 1984)] incorporated under Article F.4. of the subject contract.

NIAID has determined that the following projects in your contract, HHSN272201400005C, may contain gain-of-function experiments that fall under the Research Funding Pause.

Project 1: Cleavage activation of HA
SPECIFIC AIMS POTENTIALLY IMPACTED:
*Aim 1.* Characterization of circulating influenza viruses with modified HA cleavage sites

If this project contains any work as described under the Research Funding Pause, it must stop effective

immediately upon receipt of this Notice. In addition, should any other applicable research that is being conducted with NIAID contract funding fall under the Research Funding Pause it too must stop immediately. Within 14 days of the date of this letter please respond to this partial stop work notice with a detailed list of the projects and experiments that you have halted. You should contact your COR to discuss re-direction of the research that has been stopped. This partial stop work order will remain in effect for ninety (90) calendar days from the date of this letter or until you are otherwise notified.

You shall take the following steps related to cessation of work:

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bijan.mansoury@nih.gov

Digitally signed by bijan.mansoury@nih.gov
DN: cn=bijan.mansoury@nih.gov
Date: 2014.10.21 16:28:16 -04'00'

On behalf of Michael C. Finn
Contracting Officer, MID Research Contracts Branch-B
Office of Acquisitions, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892-7612

cc: Dr. Diane Post, CEIRS COR, RDB, DMID, NIAID
Dr. Irene Glowinski, Deputy Director, DMID, NIAID
Charles W. Grewe, C.C.O., Office of Acquisitions, DEA, NIAID
Dr. John Treanor, University of Rochester
Dr. David Topham, University of Rochester
Dr. Gary Whittaker, Cornell University

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_____
Signature

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Position / Title

National Institutes of Health

Phone: 301-496-0612
Fax: 301-480-4675
www.niaid.nih.gov

National Institutes of Health (NIH)
National Institute of Allergy and Infectious Diseases (NIAID)
Division of Extramural Activities (DEA)
**Office of Acquisitions (OA)**
5601 Fishers Lane
Rockville, MD 20852

October 30, 2014

Transmitted via e-mail to:
Edward_Puzas@urmc.rochester.edu

J. Edward Puzas, Ph.D.
Senior Associate Dean for Research
University of Rochester Medical Center
601 Elmwood Avenue
Rochester, NY 14642

Subject: **Clarification of Notice of Stop Work Order from NIAID,** Contract HHSN272201400005C "NIAID Centers of Excellence for Influenza Research and Surveillance"

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Michael C. Finn
Contracting Officer, MID Research Contracts Branch-B
Office of Acquisitions, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892-7612

David Spiro, Ph.D.
Section Chief
Respiratory Diseases Branch
DMID/NIAID/NIH/DHHS

cc: Dr. Diane Post, CEIRS COR, RDB, DMID, NIAID
Dr. Irene Glowinski, Deputy Director, DMID, NIAID
Charles W. Grewe, C.C.O., Office of Acquisitions, DEA, NIAID
Dr. John Treanor, University of Rochester
Dr. David Topham, University of Rochester
Dr. Gary Whittaker, Cornell University

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ACKNOWLEDGEMENT OF NOTICE

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_____
Signature

_____
Position / Title

**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Phone: 301-496-0612
Fax: 301-402-0972
http://www.niaid.nih.gov/

National Institutes of Health (NIH)
National Institute of Allergy and Infectious Diseases (NIAID)
DEA, Office of Acquisitions
6700B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

October 21, 2014

Transmitted via e-mail to:
Una.sweeten@usu.edu

Una Sweeten
Contract Administrator, Sponsored Programs
1415 Old Main Hill
Logan, UT 84322-1415

Subject: **NOTICE OF PARTIAL STOP WORK ORDER,** Contract HHSN272201000039I Task Order No. HHSN27200010 (A57) "Mouse Model for Evaluation of Medical Countermeasures Against Middle East Respiratory Syndrome (MERS-CoV)

Dear Ms. Sweeten:

On October 17, 2014, the US Government issued a Research Funding Pause on selected gain-of-function research on influenza, MERS and SARS viruses (http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf). The scope of this Research Funding Pause has been defined to include any gain-of-function experiments that may be reasonably anticipated to confer attributes to any influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route. NIAID has interpreted this Research Funding Pause to include efforts to mouse-adapt MERS-CoV to increase pathogenesis in mouse models. The Research Funding Pause does not apply to other work supporting the development of MERS animal models (such as breeding of transgenic mouse lines or characterization of these lines), nor does it apply to the use of naturally occurring MERS-CoV strains in mouse models, unless the experiments are reasonably anticipated to increase transmissibility and/or pathogenicity of the virus.

Contracts are used by the US Government to acquire goods and services for its direct benefit. While this Research Funding Pause is in place, goods and services tied to gain-of-function research on influenza, MERS and SARS are no longer a government requirement. Thus, experiments that fall under the scope of this Research Funding Pause will not be conducted under any NIAID contract.

This action is being taken in accordance with FAR 52. 242-15 [Stop Work Order (August 1989 with Alternative I (April 1984)] incorporated under Article F.3. of the subject contract.

NIAID has determined that the following projects in your contract, HHSN272201000039I Task Order No. HHSN272000010 (A57), may contain gain-of-function experiments that fall under the Research Funding Pause.

> Experiments to serially passage (or otherwise adapt) wild type MERS-CoV strains to increase pathogenesis in the mouse model.

If these projects contain any work as described under the Research Funding Pause, you are hereby notified that you are to stop work that work must stop effective immediately upon receipt of this Notice. In addition, should any other applicable research that is being conducted with NIAID contract funding fall under the Research Funding Pause it too must stop immediately. Within 14 days of the date of this letter please respond to this partial stop work notice with a detailed list of the projects and experiments that you have halted.

You shall take the following steps related to cessation of work:

1) Evaluate all projects for experiments in question; stop all identified gain-of-function experiments that can enhance pathogenicity and transmissibility of any MERS-CoV strain; within 14 days of receipt of this Notice provide a detailed list of projects and experiments that have been halted.

2) Keep adequate records of your compliance with #1), above, showing the:

   (a) Effective date of the Partial Stop Work Order;
   (b) Evaluation of projects for GOF experiments

3) Furnish notice of stop work to each immediate subcontractor, consultant and supplier that will be affected by this Partial Stop Work Order. In this notice:

   (a) Specify your Government contract number;
   (b) State that the contract is under a Partial Stop Work Order;
   (c) State the effective date of the Partial Stop Work Order;
   (d) Provide instructions to stop work required;
   (e) Request that similar notices and instructions be given to its immediate subcontractors.

This stop-work order shall remain in effect for 90 calendar days, unless we mutually agree to a further period. As provided by Stop Work Order clause, you are to take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the order during the period of work stoppage.

Should the issuance of this stop-work order result in an increase in either the time or your cost of performing work under the contract when work resumes, you will be entitled to an equitable adjustment in the delivery schedule or contract price, or both. For this reason, you should maintain detailed records of any costs incurred in complying with this order.

Matters not covered by this notice should be brought to the attention of the undersigned.

Charles H. Jackson -S

Digitally signed by Charles H. Jackson -S
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010130910, cn=Charles H. Jackson -S
Date: 2014.10.21 14:51:53 -04'00'

Charles H. Jackson Jr.
Contracting Officer, MID Research Contracts Branch-A
Office of Acquisitions, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3156, MSC 7612
Bethesda, Maryland 20892-7612

cc: Dr. John Morrey, Contract PI, Utah State University
Dr. Erik Stemmy, Contract COR, RDB, DMID, NIAID
Dr. Joseph Campbell, Contract CPO, OBRRTR, DMID, NIAID
Dr. Irene Glowinski, Deputy Director, DMID, NIAID
Charles W. Grewe, C.C.O., Office of Acquisitions, DEA, NIAID
Richard L. Hartmann, Chief, MIDRCB-A, OA, DEA, NIAID
Anna Wong, Contract Specialist, OA, DEA, NIAID, NIH

---

Please acknowledge receipt of this notice as provided below:

ACKNOWLEDGEMENT OF NOTICE

The undersigned acknowledges receipt of a signed copy of this notice on 10/21/2014. A signed, scanned and emailed copy of this notice is returned to the Contracting Officer.

Signature

EXECUTIVE DIRECTOR
SPONSORED PROGRAMS
Position / Title

National Institutes of Health

Phone: 301-496-0612
Fax: 301-480-4675
www.niaid.nih.gov

National Institutes of Health (NIH)
National Institute of Allergy and Infectious Diseases (NIAID)
Division of Extramural Activities (DEA)
**Office of Acquisitions (OA)**
5601 Fishers Lane
Rockville, MD 20852

October 30, 2014

Transmitted via e-mail to:
Una.sweeten@usu.edu

Una Sweeten
Contract Administrator, Sponsored Programs
1415 Old Main Hill
Logan, UT 84322-1415

Subject: **Clarification of Notice of Stop Work Order,** Contract HHSN272201000039I
Task Order No. HHSN27200010 (A57) "Mouse Model for Evaluation of Medical Countermeasures Against Middle East Respiratory Syndrome (MERS-CoV)

Dear Ms. Sweeten:

On October 21st 2014, you received a Stop Work Order from NIAID temporarily suspending a portion of the activities under your contract. The Order was in follow-up to the October 17th, 2014 announcement by the U.S. Government regarding a research funding pause on select gain-of-function (GoF) experiments involving influenza, SARS, and MERS viruses. This follow-up letter provides some context and additional clarifications to that Order.

First, as background, the U.S. government is undertaking a deliberative process to assess the risks and benefits of certain GoF experiments. This will inform the development of a government-wide policy framework that will guide future federal investments in GoF studies. During this deliberative process, there will be a pause on the release of federal funds for studies that meet the stated definition (see www.phe.gov/s3/dualuse). NIAID will be adhering to this funding pause until the robust and broad deliberative process– including consultation with the National Science Advisory Board for Biosecurity and public input from forums hosted by the National Academies – is completed.

NIAID's intention is to exercise the funding pause to the full extent of its authority. Where NIAID does not have specific authority to pause funding, the Agency is encouraging researchers to pause voluntarily the specific experiments described in the Federal government's announcement of a funding pause. Under the contract mechanism, NIAID has the authority, and hence obligation as stewards of government funds, to implement this pause immediately for the contract work involving such studies. NIAID staff will work with you to determine what work may be conducted during the funding pause and what may not.

Second, the funding pause only applies to prescribed experiments – those 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. Such projects must be evaluated by investigators, working with the NIAID Contracting Officer's Representative (COR), to determine whether they meet the scope of experiments described in the announcement. The research funding pause would not apply to characterization or testing of naturally occurring influenza, MERS, and SARS viruses, unless the tests are reasonably anticipated to increase transmissibility and/or pathogenicity. This pause was not intended to stop surveillance work, nor to apply to the routine characterization or testing of naturally occurring influenza, MERS, and SARS viruses, such as occurs during surveillance efforts, unless the experiments are reasonably anticipated to enhance transmissibility or pathogenicity of the naturally occurring isolates obtained through surveillance efforts. For example, if you have a surveillance project that involves reverse genetic experiments to understand pathogenesis and transmission, then those specific aspects of the work may fall under the funding pause. But again, this will need to be determined on a case-by-case basis with your NIAID COR.

The specific aims listed in the Stop Work Order that NIAID staff determined may be covered by the funding pause are based on the information staff currently have about your projects. If there are specific aims identified in your Order that you think are not covered by the funding pause, please send the COR and Contracting Officer (CO)a summary of that work and your rationale in your official response to the Stop Work Order.

As you know, NIAID staff do not have the exact details of each experiment you are planning to conduct. Therefore, at this time NIAID expects that you will evaluate the remaining projects and associated specific aims (those not identified in the letter) to assess if there are additional experiments that may fall under the funding pause. If you identify an experiment that you think meets the scope of experiments described in the announcement, then those experiments must stop immediately and you must notify the COR and CO. If you are unclear as to whether or not additional experiments fall under the funding pause, please send a summary of the experiments in question to the COR and include why you think they do or do not fall under the pause. NIAID staff will review those and then the CO provide you with further guidance.

Third, when the funding pause was announced, it was noted that an exception from the research pause may be obtained if the head of the US government funding agency determines that the research is urgently necessary to protect the public health or national security. If you feel that this exception may be applicable to your work that was stopped under the Order, please let the COR and CO know and the CO will provide further instructions. NIH will review exemption requests in as timely a manner as is possible.

The federal government intends for the deliberative process to occur as expeditiously and transparently as possible, and therefore has structured a one-year process that will facilitate the kind of deep and rigorous discussion such a complex topic demands. NIAID urges you to actively engage in the gain-of-function deliberative process and share your experience and perspective. Your engagement in this effort will help ensure that the product of the process is a robust and durable framework to guide future federal investments in this area of research.

Charles H. Jackson Jr.
Contracting Officer, MID
Research Contracts Branch-A
Office of Acquisitions, DEA, NIAID, NIH
5601 Fishers Lane, Room 3D41, MSC 9821
Rockville, Maryland 20852-9821

Dr. Erik Stemmy
Contracting Officer Representative
RDB, DMID, NIAID
5601 Fishers Lane, Room 8E18
Rockville, Maryland 20852-9825

cc: Dr. John Morrey, Contract PI, Utah State University
Dr. Erik Stemmy, Contract COR, RDB, DMID, NIAID
Dr. Joseph Campbell, Contract CPO, OBRRTR, DMID, NIAID
Dr. Irene Glowinski, Deputy Director, DMID, NIAID
Charles W. Grewe, C.C.O., Office of Acquisitions, DEA, NIAID
Richard L. Hartmann, Chief, MIDRCB-A, OA, DEA, NIAID
Anna Wong, Contract Specialist, OA, DEA, NIAID, NIH

**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Phone: 301-496-0612
Fax: 301-402-0972
http://www.niaid.nih.gov/

National Institutes of Health (NIH)
National Institute of Allergy and Infectious Diseases (NIAID)
DEA, Office of Acquisitions
6700B Rockledge Drive, Room 2209, MSC 7612
Bethesda, MD 20892-7612

October 21, 2014

Transmitted via e-mail to:
Jessica.moise@mssm.edu

Jessica Moise
Grants and Contracts Officer
Mount Sinai School of Medicine
One Gustave L. Levy Place, Box 1075
New York, NY 10029

Subject: **NOTICE OF PARTIAL STOP WORK ORDER,** Contract HHSN272201000019I Task Order No. HHSN27200003 (A57) "Mouse Model for Evaluation of Medical Countermeasures against Middle East Respiratory Syndrome" (MERS-CoV)

Dear Ms. Moise:

On October 17, 2014, the US Government issued a Research Funding Pause on selected gain-of-function research on influenza, MERS and SARS viruses (http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf). The scope of this Research Funding Pause has been defined to include any gain-of-function experiments that may be reasonably anticipated to confer attributes to any influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route. NIAID has interpreted this Research Funding Pause to include efforts to mouse-adapt MERS-CoV to increase pathogenesis in mouse models. The Research Funding Pause does not apply to other work supporting the development of MERS animal models (such as breeding of transgenic mouse lines or characterization of these lines), nor does it apply to the use of naturally occurring MERS-CoV strains in mouse models, unless the experiments are reasonably anticipated to increase transmissibility and/or pathogenicity of the virus.

Contracts are used by the US Government to acquire goods and services for its direct benefit. While this Research Funding Pause is in place, goods and services tied to gain-of-function research on influenza, MERS and SARS are no longer a government requirement. Thus, experiments that fall under the scope of this Research Funding Pause will not be conducted under any NIAID contract. This action is being taken in accordance with FAR 52. 242-15 [Stop Work Order (August 1989 with Alternative I (April 1984) incorporated under Article F.3. of the subject contract.

NIAID has determined that the following projects in your contract, HHSN272201000019I Task Order No. HHSN27200003 (A57), may contain gain-of-function experiments that fall under the Research Funding Pause.

> Experiments to serially passage (or otherwise adapt) wild type MERS-CoV strains to increase pathogenesis in the mouse model.

If these projects contain any work as described under the Research Funding Pause, it must stop effective immediately upon receipt of this Notice. In addition, should any other applicable research that is being conducted with NIAID contract funding fall under the Research Funding Pause it too must

stop immediately. Within 14 days of the date of this letter please respond to this partial stop work notice with a detailed list of the projects and experiments that you have halted.

You shall take the following steps related to cessation of work:

1) Evaluate all projects for experiments in question; stop all identified gain-of-function experiments that can enhance pathogenicity and transmissibility of any MERS-CoV strain; within 14 days of receipt of this Notice provide a detailed list of projects and experiments that have been halted.

2) Keep adequate records of your compliance with #1), above, showing the:

   (a) Effective date of the Partial Stop Work Order;
   (b) Evaluation of projects for GOF experiments

3) Furnish notice of stop work to each immediate subcontractor, consultant and supplier that will be affected by this Partial Stop Work Order. In this notice:

   (a) Specify your Government contract number;
   (b) State that the contract is under a Partial Stop Work Order;
   (c) State the effective date of the Partial Stop Work Order;
   (d) Provide instructions to stop work required;
   (e) Request that similar notices and instructions be given to its immediate subcontractors.

This stop-work order shall remain in effect for 90 calendar days, unless we mutually agree to a further period. As provided by Stop Work Order clause, you are to take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the order during the period of work stoppage.

Should the issuance of this stop-work order result in an increase in either the time or your cost of performing work under the contract when work resumes, you will be entitled to an equitable adjustment in the delivery schedule or contract price, or both. For this reason, you should maintain detailed records of any costs incurred in complying with this order.

Matters not covered by this notice should be brought to the attention of the undersigned.

Stanley A. Knight, Sr.

Digitally signed by Stanley A. Knight, Sr.
DN: cn=Stanley A. Knight, Sr., o=Office of Acquisitions, ou=DEA, email=stanley.knight@nih.gov, c=US
Date: 2014.10.21 11:06:17 -04'00'

Stanley A. Knight, Sr.
Contracting Officer, MID Research Contracts Branch-A
Office of Acquisitions, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 2209, MSC 7612
Bethesda, Maryland 20892-7612

cc: Dr. Peter Palese, Contract PI, Mount Sinai School of Medicine
Dr. Erik Stemmy, Contract COR, RDB, DMID, NIAID
Dr. Judy Hewitt, Contract CPO, OBRRTR, DMID, NIAID
Dr. Irene Glowinski, Deputy Director, DMID, NIAID
Charles W. Grewe, C.C.O., Office of Acquisitions, DEA, NIAID

Richard L. Hartmann, Chief, MIDRCB-A, OA, DEA, NIAID
Miranda Adams, Contract Specialist, OA, DEA, NIAID, NIH

---

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ACKNOWLEDGEMENT OF NOTICE

The undersigned acknowledges receipt of a signed copy of this notice on _____. A signed, scanned and emailed copy of this notice is returned to the Contracting Officer.

_____
Signature

_____
Position / Title

National Institutes of Health

Phone: 240-669-5159
Fax: 301-402-0972

National Institutes of Health (NIH)
National Institutes of Allergies and Infectious Diseases (NIAID)
Division of Extramural Activities (DEA)
**Office of Acquisitions (OA)**
5601 Fishers Lane
Rockville, MD 20852

***MEMORANDUM***

***Transmitted via email to:***
Jessica.moise@mssm.edu

DATE: October 30, 2014

TO: Jessica Moise, Grants and Contracts Officer
Mount Sinai School of Medicine
One Gustave L. Levy Place, Box 1075
New York, NY 10029

FROM: Stanley A. Knight, Sr., Contracting Officer, NIAID

SUBJECT: Clarification of Notice of Stop Work Order from NIAID

Dear Ms. Moise:

On October 21st 2014, you received a Stop Work Order from NIAID temporarily suspending a portion of the activities under your contract. The Order was in follow-up to the October 17th, 2014 announcement by the U.S. Government regarding a research funding pause on select gain-of-function (GoF) experiments involving influenza, SARS, and MERS viruses. This follow-up letter provides some context and additional clarifications to that Order.

First, as background, the U.S. government is undertaking a deliberative process to assess the risks and benefits of certain GoF experiments. This will inform the development of a government-wide policy framework that will guide future federal investments in GoF studies. During this deliberative process, there will be a pause on the release of federal funds for studies that meet the stated definition (see www.phe.gov/s3/dualuse). NIAID will be adhering to this funding pause until the robust and broad deliberative process– including consultation with the National Science Advisory Board for Biosecurity and public input from forums hosted by the National Academies – is completed.

NIAID's intention is to exercise the funding pause to the full extent of its authority. Where NIAID does not have specific authority to pause funding, the Agency is encouraging researchers to pause voluntarily the specific experiments described in the Federal government's announcement of a funding pause. Under the contract mechanism, NIAID has the authority, and hence obligation as stewards of government funds, to implement this pause immediately for the

contract work involving such studies. NIAID staff will work with you to determine what work may be conducted during the funding pause and what may not.

Second, the funding pause only applies to prescribed experiments – those 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. Such projects must be evaluated by investigators, working with the NIAID Contracting Officer's Representative (COR), to determine whether they meet the scope of experiments described in the announcement. The research funding pause would not apply to characterization or testing of naturally occurring influenza, MERS, and SARS viruses, unless the tests are reasonably anticipated to increase transmissibility and/or pathogenicity. This pause was not intended to stop surveillance work, nor to apply to the routine characterization or testing of naturally occurring influenza, MERS, and SARS viruses, such as occurs during surveillance efforts, unless the experiments are reasonably anticipated to enhance transmissibility or pathogenicity of the naturally occurring isolates obtained through surveillance efforts. For example, if you have a surveillance project that involves reverse genetic experiments to understand pathogenesis and transmission, then those specific aspects of the work may fall under the funding pause. But again, this will need to be determined on a case-by-case basis with your NIAID COR.

The specific aims listed in the Stop Work Order that NIAID staff determined may be covered by the funding pause are based on the information staff currently have about your projects. If there are specific aims identified in your Order that you think are not covered by the funding pause, please send the COR and Contracting Officer (CO)a summary of that work and your rationale in your official response to the Stop Work Order.

As you know, NIAID staff do not have the exact details of each experiment you are planning to conduct. Therefore, at this time NIAID expects that you will evaluate the remaining projects and associated specific aims (those not identified in the letter) to assess if there are additional experiments that may fall under the funding pause. If you identify an experiment that you think meets the scope of experiments described in the announcement, then those experiments must stop immediately and you must notify the COR and CO. If you are unclear as to whether or not additional experiments fall under the funding pause, please send a summary of the experiments in question to the COR and include why you think they do or do not fall under the pause. NIAID staff will review those and then the CO provide you with further guidance.

Third, when the funding pause was announced, it was noted that an exception from the research pause may be obtained if the head of the US government funding agency determines that the research is urgently necessary to protect the public health or national security. If you feel that

this exception may be applicable to your work that was stopped under the Order, please let the COR and CO know and the CO will provide further instructions. NIH will review exemption requests in as timely a manner as is possible.

The federal government intends for the deliberative process to occur as expeditiously and transparently as possible, and therefore has structured a one-year process that will facilitate the kind of deep and rigorous discussion such a complex topic demands. NIAID urges you to actively engage in the gain-of-function deliberative process and share your experience and perspective. Your engagement in this effort will help ensure that the product of the process is a robust and durable framework to guide future federal investments in this area of research.

Stanley A. Knight -S

Digitally signed by Stanley A. Knight -S
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0011868212, cn=Stanley A. Knight -S
Date: 2014.10.30 15:09:31 -04'00'

Stanley A. Knight, Sr.
Contracting Officer, MID
Research Contracts Branch-A
Office of Acquisitions, DEA, NIAID, NIH
5601 Fishers Lane, Room 3D50, MSC 9821
Rockville, Maryland 20852-9821

Digitally signed by erik.stemmy@niaid.nih.gov
Date: 2014.10.30 15:21:45 -04'00'

Dr. Erik Stemmy
Contracting Officer Representative
RDB, DMID, NIAID
5601 Fishers Lane, Room 8E18
Rockville, Maryland 20852-9825

cc: Dr. Peter Palese, Contract PI, Mount Sinai School of Medicine
Dr. Mark Heise, Subcontract Co-PI, University of North Carolina at Chapel Hill
Dr. Erik Stemmy, Contract COR, RDB, DMID, NIAID
Dr. Joseph Campbell, Contract CPO, OBRRTR, DMID, NIAID
Dr. Irene Glowinski, Deputy Director, DMID, NIAID
Charles W. Grewe, C.C.O., Office of Acquisitions, DEA, NIAID
Richard L. Hartmann, Chief, MIDRCB-A, OA, DEA, NIAID
Miranda Adams, Contract Specialist, OA, DEA, NIAID, NIH

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Phone: 301-496-0612
Fax: 301-402-0972
http://www.niaid.nih.gov/

National Institutes of Health (NIH)
National Institute of Allergy and Infectious Diseases (NIAID)
DEA, Office of Acquisitions
6700B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

October 21, 2014

Transmitted via e-mail to:
david.wynes@emory.edu

David Wynes, Ph.D.
Vice President for Research Administration
Emory University
Mailstop 1599/001/1BE
1599 Clifton Road, NE, 4th Floor
Atlanta, GA 30322

Subject: **NOTICE OF PARTIAL STOP WORK ORDER,** Contract HHSN272201400004C
"NIAID Centers of Excellence for Influenza Research and Surveillance"

Dear Dr. Wynes:

On October 17, 2014, the US Government issued a Research Funding Pause on selected gain-of-function research on influenza, MERS and SARS viruses (http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf). The scope of this Research Funding Pause has been defined to include any gain-of-function experiments that may be reasonably anticipated to confer attributes to any influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route. NIAID has interpreted this Research Funding Pause to also include any experiments utilizing influenza viruses previously generated that exhibit enhanced transmissibility in mammals via the respiratory route. The Research Funding Pause does not apply to characterization or testing of naturally occurring influenza viruses, unless the experiments are reasonably anticipated to increase transmissibility and/or pathogenicity.

Contracts are used by the US Government to acquire goods and services for its direct benefit. While this Research Funding Pause is in place, goods and services tied to gain-of-function research on influenza, MERS and SARS are no longer a government requirement. Thus, experiments that fall under the scope of this Research Funding Pause will not be conducted under any NIAID contract. This action is being taken in accordance with FAR 52. 242-15 [Stop Work Order (August 1989) with Alternative I (April 1984)] incorporated under Article F.4. of the subject contract.

NIAID has determined that the following projects in your contract, HHSN272201400004C, may contain gain-of-function experiments that fall under the Research Funding Pause.

Project 1: Influenza glycoprotein functions as determinants of host range, transmission, pathogenicity, and pandemic potential
SPECIFIC AIMS POTENTIALLY IMPACTED:

*Aim 2*. Develop novel assays for influenza NA properties to investigate the evolution of HA-NA functional interplay during antigenic drift, and the compatibility of glycoprotein from currently circulating swine and human isolates.

*Aim 2.4* Examine the effects of matched and mis-matched NA pairs on incorporation into virions and virus replication phenotypes, and transmission.

*Aim 3*. Define the spectrum of inhibition and mechanisms of neutralization by anti-HA stem antibodies, and evaluate potential for resistance to "universal vaccines" based on anti-HA stem antibodies.

*Aim 3.3* We will examine the effects of fusion pH mutants and antibody binding site mutants on the inhibitory effects of stem antibodies.

Project 2: Interplay among host adaptation, reassortment and transmission of influenza viruses at the animal-human interface

SPECIFIC AIMS POTENTIALLY IMPACTED:

*Aim 1* Evaluate reassortment of North American swine influenza viruses of the TRIG lineage with human strains derived from the 2009 pandemic.

*Aim 2* Identify and characterize low fitness intermediates in the evolution of Eurasian swine influenza viruses.

*Aim 3* Evaluate the impact of adaptation of avian influenza viruses to human tracheo- bronchial epithelial (HTBE) cells on the potential for reassortment with human viruses and transmission among mammals.

If these projects contain any work as described under the Research Funding Pause, it must stop effective immediately upon receipt of this Notice. In addition, should any other applicable research that is being conducted with NIAID contract funding fall under the Research Funding Pause it too must stop immediately. Within 14 days of the date of this letter please respond to this partial stop work notice with a detailed list of the projects and experiments that you have halted. You should contact your COR to discuss re-direction of the research that has been stopped. This partial stop work order will remain in effect for ninety (90) calendar days from the date of this letter or until you are otherwise notified.

You shall take the following steps related to cessation of work:

1) Evaluate all projects for experiments in question; stop all identified gain-of-function experiments that can enhance pathogenicity and transmissibility of any influenza virus; within 14 days of receipt of this Notice provide a detailed list of projects and experiments that have been halted, and contact COR to discuss redirection of contract activities.

2) Keep adequate records of your compliance with #1), above, showing the:

   (a) Effective date of the Partial Stop Work Order;
   (b) Evaluation of projects for GOF experiments

3) Furnish notice of stop work to each immediate subcontractor, consultant and supplier that will be affected by this Partial Stop Work Order. In this notice:

   (a) Specify your Government contract number;
   (b) State that the contract is under a Partial Stop Work Order;
   (c) State the effective date of the Partial Stop Work Order;
   (d) Provide instructions to stop work required;
   (e) Request that similar notices and instructions be given to its immediate subcontractors.

Matters not covered by this notice should be brought to the attention of the undersigned.

bijan.mansoury@nih.gov Digitally signed by bijan.mansoury@nih.gov
DN: cn=bijan.mansoury@nih.gov
Date: 2014.10.21 16:26:59 -04'00'

On behalf of Michael C. Finn
Contracting Officer, MID Research Contracts Branch-B
Office of Acquisitions, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892-7612

cc: Dr. Diane Post, CEIRS COR, RDB, DMID, NIAID
Dr. Irene Glowinski, Deputy Director, DMID, NIAID
Charles W. Grewe, C.C.O., Office of Acquisitions, DEA, NIAID
Dr. Walt Orenstein, Emory University
Dr. Richard Compans, Emory University
Dr. David Steinhauer, Emory University
Dr. Anice Lowen, Emory University
Dr. John Steel, Emory University

---

Please acknowledge receipt of this notice as provided below:

ACKNOWLEDGEMENT OF NOTICE

The undersigned acknowledges receipt of a signed copy of this notice on _____. A signed, scanned and emailed copy of this notice is returned to Michael Finn.

_____
Signature

_____
Position / Title

National Institutes of Health

Phone: 301-496-0612
Fax: 301-480-4675
www.niaid.nih.gov

National Institutes of Health (NIH)
National Institute of Allergy and Infectious Diseases (NIAID)
Division of Extramural Activities (DEA)
**Office of Acquisitions (OA)**
5601 Fishers Lane
Rockville, MD 20852

October 30, 2014

Transmitted via e-mail to:
david.wynes@emory.edu

David Wynes, Ph.D.
Vice President for Research Administration
Emory University
Mailstop 1599/001/1BE
1599 Clifton Road, NE, 4th Floor
Atlanta, GA 30322

Subject: **Clarification of Notice of Stop Work Order from NIAID,** Contract HHSN272201400004C "NIAID Centers of Excellence for Influenza Research and Surveillance"

Dear Dr. Wynes:

On October 21st 2014, you received a Stop Work Order from NIAID temporarily suspending a portion of the activities under your contract. The Order was in follow-up to the October 17th, 2014 announcement by the U.S. Government regarding a research funding pause on select gain-of-function (GoF) experiments involving influenza, SARS, and MERS viruses. This follow-up letter provides some context and additional clarifications to that Order.

First, as background, the U.S. government is undertaking a deliberative process to assess the risks and benefits of certain GoF experiments. This will inform the development of a government-wide policy framework that will guide future federal investments in GoF studies. During this deliberative process, there will be a pause on the release of federal funds for studies that meet the stated definition (see www.phe.gov/s3/dualuse). NIAID will be adhering to this funding pause until the robust and broad deliberative process– including consultation with the National Science Advisory Board for Biosecurity and public input from forums hosted by the National Academies – is completed.

NIAID's intention is to exercise the funding pause to the full extent of its authority. Where NIAID does not have specific authority to pause funding, the Agency is encouraging researchers to pause voluntarily the specific experiments described in the Federal government's announcement of a funding pause. Under the contract mechanism, NIAID has the authority, and hence obligation as stewards of government funds, to implement this pause immediately for the

contract work involving such studies. NIAID staff will work with you to determine what work may be conducted during the funding pause and what may not.

Second, the funding pause only applies to prescribed experiments – those 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. Such projects must be evaluated by investigators, working with the NIAID Contracting Officer's Representative (COR), to determine whether they meet the scope of the experiments described in the announcement. The research funding pause would not apply to characterization or testing of naturally occurring influenza, MERS, and SARS viruses, unless the tests are reasonably anticipated to increase transmissibility and/or pathogenicity. This pause was not intended to stop surveillance work, nor to apply to the routine characterization or testing of naturally occurring influenza, MERS, and SARS viruses, such as occurs during surveillance efforts, unless the experiments are reasonably anticipated to enhance transmissibility or pathogenicity of the naturally occurring isolates obtained through surveillance efforts. For example, if you have a surveillance project that involves reverse genetic experiments to understand pathogenesis and transmission, then those specific aspects of the work may fall under the funding pause. But again, this will need to be determined on a case-by-case basis with your NIAID COR.

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As you know, NIAID staff do not have the exact details of each experiment you are planning to conduct. Therefore, at this time NIAID expects that you will evaluate the remaining projects and associated specific aims (those not identified in the letter) to assess if there are additional experiments that may fall under the funding pause. If you identify an experiment that you think meets the scope of experiments described in the announcement, then those experiments must stop immediately and you must notify the COR and CO. If you are unclear as to whether or not additional experiments fall under the funding pause, please send a summary of the experiments in question to the COR and include why you think they do or do not fall under the pause. NIAID staff will review those and then the CO provide you with further guidance.

Third, when the funding pause was announced, it was noted that an exception from the research pause may be obtained if the head of the US government funding agency determines that the research is urgently necessary to protect the public health or national security. If you feel that this exception may be applicable to your work that was stopped under the Order, please let the COR and CO know and the CO will provide further instructions. NIH will review exemption requests in as timely a manner as is possible.

The federal government intends for the deliberative process to occur as expeditiously and transparently as possible, and therefore has structured a one-year process that will facilitate the kind of deep and rigorous discussion such a complex topic demands. NIAID urges you to actively engage in the gain-of-function deliberative process and share your experience and perspective.

Your engagement in this effort will help ensure that the product of the process is a robust and durable framework to guide future federal investments in this area of research.

Michael C. Finn
Contracting Officer, MID Research Contracts Branch-B
Office of Acquisitions, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892-7612

David Spiro, Ph.D.
Section Chief
Respiratory Diseases Branch
DMID/NIAID/NIH/DHHS

cc: Dr. Diane Post, CEIRS COR, RDB, DMID, NIAID
Dr. Irene Glowinski, Deputy Director, DMID, NIAID
Charles W. Grewe, C.C.O., Office of Acquisitions, DEA, NIAID
Dr. Walt Orenstein, Emory University
Dr. Richard Compans, Emory University
Dr. David Steinhauer, Emory University
Dr. Anice Lowen, Emory University
Dr. John Steel, Emory University

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ACKNOWLEDGEMENT OF NOTICE

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_____
Signature

_____
Position / Title

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

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

November 7, 2014

Ms. Jenny M. Dahlberg
University of Wisconsin-Madison
2015 Linden Drive
Madison, WI 53706

RE: 5U19 AI106772-02

Dear Ms. Dahlberg:

NIAID has determined that the above referenced grant may include Gain of Function (GoF) research that is subject to the recently-announced U.S. Government funding pause (http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf), issued on October 17, 2014. The following research projects appear to involve research covered under the pause:

- Research Project 1: Systems biology analysis of influenza A virus and Ebola virus to reveal host regulators of viral pathogenicity - Yoshihiro Kawaoka, DVM, PhD - Project Leader
- Supplement to Research Project 1 : Systems biology analysis of influenza A H7N9 viruses - Yoshihiro Kawaoka, DVM, PhD - Project Leader
- Supplemental Research Project: Systems biology analysis of Middle Eastern Respiratory Syndrome Coronaviruses - Ralph S. Baric, PhD- Project Leader
- Pilot Research Project: Epigenetic regulation of interferon-stimulated genes following MERS-CoV and influenza A virus infections - Amy Sims, PhD - Project Leader
- Supplemental Research Project: Systems biology approaches for the identification of combination therapies for treatment of influenza A virus infections - Yoshihiro Kawaoka, DVM, PhD - Project Leader

As your grant is currently funded, this pause is voluntary. Organizations conducting GoF research supported by the NIH have an opportunity to transition the applicable research to research that is not covered by the funding pause; halt the applicable GoF research until the outcome of the deliberative process is known; or continue to conduct the applicable GoF research until the end of the currently active budget period.

NIAID requests information on University of Wisconsin-Madison's plans for the research outlined above within 90 days of the date of this letter.

- **If you determine that the above research does NOT include GoF work subject to the funding pause**, please provide a detailed explanation of the research being conducted and why it is not covered by the pause. NIAID will review this information and make the final determination.
- **If the ongoing research includes GoF work subject to the funding pause and the grantee proposes to transition it to areas of research not covered by the pause,** please provide the transition plan. It should identify the research to be transitioned, a detailed description of the new planned specific aims (in most cases this will require NIAID pre-approval), and a timeline for the proposed transition.
- **If the grantee plans to voluntarily halt the research subject to the funding pause,** please identify the research that will be halted and the proposed date by which the applicable research will be stopped. Please provide a confirmation that the research has been halted.
- **If the ongoing research includes GoF work and the grantee plans on continuing the research until the end of the currently active budget period,** please provide a detailed description of the GoF research to be conducted.

These plans are for the currently active budget period. Please be advised that while the funding pause is in effect, NIAID will not support GoF research identified in the pause after the end of the current grant budget period. Neither competing nor non-competing renewal applications will be funded to support applicable GoF research.

If you have any questions about this matter please do not hesitate to contact the NIAID program and/or grants management contact listed below.

Sincerely,

Dhana Khurana
Grants Management Specialist
NIAID/NIH/DHHS

Vivien Dugan, Ph.D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Yoshihiro Kawaoka
Ms. Mary Kirker
Dr. Irene Glowinski

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 21, 2014

Ms. Teri Medley
Washington University
660 South Euclid Avenue
Campus Box 8018
St. Louis, MO 63110

RE: 5 R01 AI080672-04

Dear Ms. Medley:

NIAID has determined that the above referenced grant may include Gain of Function (GoF) research that is subject to the recently-announced U.S. Government funding pause (http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf), issued on October 17, 2014. The following specific aim appears to involve research covered under the pause:

> Aim 2. Determine whether conjugation of ISG15 to target proteins is required for resistance to influenza virus infection

As your grant is currently funded, this pause is voluntary. Organizations conducting GoF research supported by the NIH have an opportunity to transition the applicable research to research that is not covered by the funding pause; halt the applicable GoF research until the outcome of the deliberative process is known; or continue to conduct the applicable GoF research until the end of the currently active budget period.

NIAID requests information on Washington University's plans for the research outlined above within 90 days of the date of this letter.

- **If you determine that the above research does NOT include GoF work subject to the funding pause**, please provide a detailed explanation of the research being conducted and why it is not covered by the pause. NIAID will review this information and make the final determination.
- **If the ongoing research includes GoF work subject to the funding pause and the grantee proposes to transition it to areas of research not covered by the pause,** please provide the transition plan. It should identify the research to be transitioned, a detailed description of the

new planned specific aims (in most cases this will require NIAID pre-approval), and a timeline for the proposed transition.

- **If the grantee plans to voluntarily halt the research subject to the funding pause**, please identify the research that will be halted and the proposed date by which the applicable research will be stopped. Please provide a confirmation that the research has been halted.
- **If the ongoing research includes GoF work and the grantee plans on continuing the research until the end of the currently active budget period**, please provide a detailed description of the GoF research to be conducted.

These plans are for the currently active budget period. Please be advised that while the funding pause is in effect, NIAID will not support GoF research identified in the pause after the end of the current grant budget period. Neither competing nor non-competing renewal applications will be funded to support applicable GoF research.

If you have any questions about this matter please do not hesitate to contact the NIAID program and/or grants management contact listed below.

Sincerely,

Dhana Khurana
Grants Management Specialist
NIAID/NIH/DHHS

Teresa M. Hauguel, Ph.D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Deborah Lenschow
Ms. Mary Kirker
Dr. Irene Glowinski

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

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

October 21, 2014

Ms. Connie Barton
University of Texas Medical Branch
301 University Boulevard
Galveston, TX 77551-0156

RE: 1 R21AI113206-01

Dear Ms. Barton:

NIAID has determined that the above referenced grant may include Gain of Function (GoF) research that is subject to the recently-announced 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:

> Section 4 of the application (Potential Problems and Alternative Strategies) includes the alternative approach of mouse-adapting MERS-CoV to increase disease in the mouse model.

As your grant is currently funded, this pause is voluntary. Organizations conducting GoF research supported by the NIH have an opportunity to transition the applicable research to research that is not covered by the funding pause; halt the applicable GoF research until the outcome of the deliberative process is known; or continue to conduct the applicable GoF research until the end of the currently active budget period.

NIAID requests information on University of Texas Medical Branch's plans for the research outlined above within 90 days of the date of this letter.

- **If you determine that the above research does NOT include GoF work subject to the funding pause,** please provide a detailed explanation of the research being conducted and why it is not covered by the pause. NIAID will review this information and make the final determination.
- **If the ongoing research includes GoF work subject to the funding pause and the grantee proposes to transition it to areas of research not covered by the pause,** please provide the transition plan. It should identify the research to be transitioned, a detailed description of the

new planned specific aims (in most cases this will require NIAID pre-approval), and a timeline for the proposed transition.

- **If the grantee plans to voluntarily halt the research subject to the funding pause,** please identify the research that will be halted and the proposed date by which the applicable research will be stopped. Please provide a confirmation that the research has been halted.
- **If the ongoing research includes GoF work and the grantee plans on continuing the research until the end of the currently active budget period,** please provide a detailed description of the GoF research to be conducted.

These plans are for the currently active budget period. Please be advised that while the funding pause is in effect, NIAID will not support GoF research identified in the pause after the end of the current grant budget period. Neither competing nor non-competing renewal applications will be funded to support applicable GoF research.

If you have any questions about this matter please do not hesitate to contact the NIAID program and/or grants management contact listed below.

Sincerely,

Mike Fato

Mike Fato
Grants Management Specialist
NIAID/NIH/DHHS

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

CC: Dr. Chien-Te Tseng
Ms. Mary Kirker
Dr. Irene Glowinski

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

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

October 21, 2014

Ms. Monika Hailey Lagaard
University of Chicago
6030 South Ellis Avenue
Chicago, IL 60637

RE: 5 R00 AI095320-03

Dear Ms. Lagaard:

NIAID has determined that the above referenced grant may include Gain of Function (GoF) research that is subject to the recently-announced U.S. Government funding pause (http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf), issued on October 17, 2014. The following specific aim appears to involve research covered under the pause:

Aim 2. To investigate how the NS1 protein antagonizes innate immune responses *in vivo*

As your grant is currently funded, this pause is voluntary. Organizations conducting GoF research supported by the NIH have an opportunity to transition the applicable research to research that is not covered by the funding pause; halt the applicable GoF research until the outcome of the deliberative process is known; or continue to conduct the applicable GoF research until the end of the currently active budget period.

NIAID requests information on University of Chicago's plans for the research outlined above within 90 days of the date of this letter.

- **If you determine that the above research does NOT include GoF work subject to the funding pause,** please provide a detailed explanation of the research being conducted and why it is not covered by the pause. NIAID will review this information and make the final determination.
- **If the ongoing research includes GoF work subject to the funding pause and the grantee proposes to transition it to areas of research not covered by the pause,** please provide the transition plan. It should identify the research to be transitioned, a detailed description of the new planned specific aims (in most cases this will require NIAID pre-approval), and a timeline for the proposed transition.

- **If the grantee plans to voluntarily halt the research subject to the funding pause**, please identify the research that will be halted and the proposed date by which the applicable research will be stopped. Please provide a confirmation that the research has been halted.
- **If the ongoing research includes GoF work and the grantee plans on continuing the research until the end of the currently active budget period,** please provide a detailed description of the GoF research to be conducted.

These plans are for the currently active budget period. Please be advised that while the funding pause is in effect, NIAID will not support GoF research identified in the pause after the end of the current grant budget period. Neither competing nor non-competing renewal applications will be funded to support applicable GoF research.

If you have any questions about this matter please do not hesitate to contact the NIAID program and/or grants management contact listed below.

Sincerely,

Greg Smith
Grants Management Specialist
NIAID/NIH/DHHS

Teresa M. Hauguel, Ph.D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Balaji Manicassamy
Ms. Mary Kirker
Dr. Irene Glowinski

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 21, 2014

Ms. Jennifer Lassner
Asst. Vice President for Research
Division of Sponsored Programs
University of Iowa
2 Gilmore Hall
Iowa City, IA 52242-1320

RE: 5 P01 AI060699-09

Dear Ms. Lassner:

NIAID has determined that the above referenced grant may include Gain of Function (GoF) research that is subject to the recently-announced 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:

> Projects 1 and 3 of the award include the potential of mouse-adapting MERS-CoV to increase disease in mouse models of MERS-CoV infection.

As your grant is currently funded, this pause is voluntary. Organizations conducting GoF research supported by the NIH have an opportunity to transition the applicable research to research that is not covered by the funding pause; halt the applicable GoF research until the outcome of the deliberative process is known; or continue to conduct the applicable GoF research until the end of the currently active budget period.

NIAID requests information on University of Iowa's plans for the research outlined above within 90 days of the date of this letter.

- **If you determine that the above research does NOT include GoF work subject to the funding pause,** please provide a detailed explanation of the research being conducted and why it is not covered by the pause. NIAID will review this information and make the final determination.
- **If the ongoing research includes GoF work subject to the funding pause and the grantee proposes to transition it to areas of research not covered by the pause,** please provide the

transition plan. It should identify the research to be transitioned, a detailed description of the new planned specific aims (in most cases this will require NIAID pre-approval), and a timeline for the proposed transition.

- **If the grantee plans to voluntarily halt the research subject to the funding pause**, please identify the research that will be halted and the proposed date by which the applicable research will be stopped. Please provide a confirmation that the research has been halted.
- **If the ongoing research includes GoF work and the grantee plans on continuing the research until the end of the currently active budget period,** please provide a detailed description of the GoF research to be conducted.

These plans are for the currently active budget period. Please be advised that while the funding pause is in effect, NIAID will not support GoF research identified in the pause after the end of the current grant budget period. Neither competing nor non-competing renewal applications will be funded to support applicable GoF research.

If you have any questions about this matter please do not hesitate to contact the NIAID program and/or grants management contact listed below.

Sincerely,

Julie Bergerud

Julie Bergerud
Grants Management Specialist
NIAID/NIH/DHHS

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

CC: Dr. Stanley Perlman
Ms. Mary Kirker
Dr. Irene Glowinski

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

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

October 21, 2014

Ms. Joy Floyd
Office of Sponsored Programs
Emory University
1599 Clifton Road NE, 4th Floor
Atlanta, GA 30322

RE: 5 R01 AI099000-03

Dear Ms. Floyd:

NIAID has determined that the above referenced grant may include Gain of Function (GoF) research that is subject to the recently-announced U.S. Government funding pause (http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf), issued on October 17, 2014. The following specific aim appears to involve research covered under the pause:

Aim 2. Identify factors that affect reassortment frequency in a co-infected host

As your grant is currently funded, this pause is voluntary. Organizations conducting GoF research supported by the NIH have an opportunity to transition the applicable research to research that is not covered by the funding pause; halt the applicable GoF research until the outcome of the deliberative process is known; or continue to conduct the applicable GoF research until the end of the currently active budget period.

NIAID requests information on Emory University's plans for the research outlined above within 90 days of the date of this letter.

- **If you determine that the above research does NOT include GoF work subject to the funding pause**, please provide a detailed explanation of the research being conducted and why it is not covered by the pause. NIAID will review this information and make the final determination.
- **If the ongoing research includes GoF work subject to the funding pause and the grantee proposes to transition it to areas of research not covered by the pause,** please provide the transition plan. It should identify the research to be transitioned, a detailed description of the new planned specific aims (in most cases this will require NIAID pre-approval), and a timeline for the proposed transition.

- **If the grantee plans to voluntarily halt the research subject to the funding pause**, please identify the research that will be halted and the proposed date by which the applicable research will be stopped. Please provide a confirmation that the research has been halted.
- **If the ongoing research includes GoF work and the grantee plans on continuing the research until the end of the currently active budget period**, please provide a detailed description of the GoF research to be conducted.

These plans are for the currently active budget period. Please be advised that while the funding pause is in effect, NIAID will not support GoF research identified in the pause after the end of the current grant budget period. Neither competing nor non-competing renewal applications will be funded to support applicable GoF research.

If you have any questions about this matter please do not hesitate to contact the NIAID program and/or grants management contact listed below.

Sincerely,

Laura Pone

Laura Pone
Grants Management Specialist
NIAID/NIH/DHHS

Teresa M. Hauguel

Teresa M. Hauguel, Ph D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Anice Lowen
Ms. Mary Kirker
Dr. Irene Glowinski

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

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

October 21, 2014

Ms. Sherrie Settle
Director, Proposal Management
University of North Carolina at Chapel Hill
Office of Sponsored Research
Administrative Office Bldg, Suite 2200
104 Airport Drive #1350
Chapel Hill, NC 27599-1350

RE: 5U19 AI107810-02

Dear Ms. Settle:

NIAID has determined that the above referenced grant may include Gain of Function (GoF) research that is subject to the recently-announced 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:

Project 1: Role of Uncharacterized Genes in High Pathogenic Human Coronavirus Infection - Ralph S. Baric, PhD- Project Leader

- Specific Aim 2. Novel functions in virus replication in vitro.
- Specific Aim 3. Novel functions in virus pathogenesis in vivo.

Project 2: Determining the functions of novel genes for Influenza A and Ebola viruses (EBOV) - Yoshihiro Kawaoka, PhD- Project Leader

- Specific Aim 2. To determine the significance of uncharacterized IAV and EBOV genes in viral replication.
- Specific Aim 3. To determine the significance of uncharacterized IAV and EBOV genes in virus pathogenicity.

As your grant is currently funded, this pause is voluntary. Organizations conducting GoF research supported by the NIH have an opportunity to transition the applicable research to research that is not covered by the funding pause; halt the applicable GoF research until the outcome of the deliberative process is known; or continue to conduct the applicable GoF research until the end of the currently active budget period.

NIAID requests information on University of North Carolina at Chapel Hill's plans for the research outlined above within 90 days of the date of this letter.

- **If you determine that the above research does <u>NOT</u> include GoF work subject to the funding pause**, please provide a detailed explanation of the research being conducted and why it is not covered by the pause. NIAID will review this information and make the final determination.
- **If the ongoing research includes GoF work subject to the funding pause and the grantee proposes to transition it to areas of research not covered by the pause,** please provide the transition plan. It should identify the research to be transitioned, a detailed description of the new planned specific aims (in most cases this will require NIAID pre-approval), and a timeline for the proposed transition.
- **If the grantee plans to voluntarily halt the research subject to the funding pause**, please identify the research that will be halted and the proposed date by which the applicable research will be stopped. Please provide a confirmation that the research has been halted.
- **If the ongoing research includes GoF work and the grantee plans on continuing the research until the end of the currently active budget period,** please provide a detailed description of the GoF research to be conducted.

These plans are for the currently active budget period. Please be advised that while the funding pause is in effect, NIAID will not support GoF research identified in the pause after the end of the current grant budget period. Neither competing nor non-competing renewal applications will be funded to support applicable GoF research.

If you have any questions about this matter please do not hesitate to contact the NIAID program and/or grants management contact listed below.

Sincerely,

Chernay Mason
Grants Management Specialist
NIAID/NIH/DHHS

Vivien Dugan, Ph.D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Ralph Baric
Ms. Mary Kirker
Dr. Irene Glowinski

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

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

October 21, 2014

Ms. Venzula Harris
University of Maryland School of Medicine
660 West Redwood Street
Room 021
Baltimore, MD 21201

RE: 5 R01 AI095569-04

Dear Ms. Harris:

NIAID has determined that the above referenced grant may include Gain of Function (GoF) research that is subject to the recently-announced 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:

> An administrative supplement made to the award in FY2014 included the potential of mouse-adapting MERS-CoV to increase disease in mouse models of MERS-CoV infection.

As your grant is currently funded, this pause is voluntary. Organizations conducting GoF research supported by the NIH have an opportunity to transition the applicable research to research that is not covered by the funding pause; halt the applicable GoF research until the outcome of the deliberative process is known; or continue to conduct the applicable GoF research until the end of the currently active budget period.

NIAID requests information on University of Maryland School of Medicine's plans for the research outlined above within 90 days of the date of this letter.

- **If you determine that the above research does NOT include GoF work subject to the funding pause**, please provide a detailed explanation of the research being conducted and why it is not covered by the pause. NIAID will review this information and make the final determination.
- **If the ongoing research includes GoF work subject to the funding pause and the grantee proposes to transition it to areas of research not covered by the pause,** please provide the transition plan. It should identify the research to be transitioned, a detailed description of the

new planned specific aims (in most cases this will require NIAID pre-approval), and a timeline for the proposed transition.

- **If the grantee plans to voluntarily halt the research subject to the funding pause**, please identify the research that will be halted and the proposed date by which the applicable research will be stopped. Please provide a confirmation that the research has been halted.
- **If the ongoing research includes GoF work and the grantee plans on continuing the research until the end of the currently active budget period,** please provide a detailed description of the GoF research to be conducted.

These plans are for the currently active budget period. Please be advised that while the funding pause is in effect, NIAID will not support GoF research identified in the pause after the end of the current grant budget period. Neither competing nor non-competing renewal applications will be funded to support applicable GoF research.

If you have any questions about this matter please do not hesitate to contact the NIAID program and/or grants management contact listed below.

Sincerely,

Sam Tempchin
Grants Management Specialist
NIAID/NIH/DHHS

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

CC: Dr. Matthew Frieman
Ms. Mary Kirker
Dr. Irene Glowinski

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

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

October 21, 2014

Ms. Lisa Au
Vanderbilt University
Office of Sponsored Programs
1400 18th Avenue South
Nashville, TN 37212-2809

RE: 5 R01 AI108197-02

Dear Ms. Au:

NIAID has determined that the above referenced grant may include Gain of Function (GoF) research that is subject to the recently-announced 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**: To determine the effect of altered fidelity on *in vivo* replication and pathogenesis.

As your grant is currently funded, this pause is voluntary. Organizations conducting GoF research supported by the NIH have an opportunity to transition the applicable research to research that is not covered by the funding pause; halt the applicable GoF research until the outcome of the deliberative process is known; or continue to conduct the applicable GoF research until the end of the currently active budget period.

NIAID requests information on Vanderbilt University's plans for the research outlined above within 90 days of the date of this letter.

- **If you determine that the above research does NOT include GoF work subject to the funding pause,** please provide a detailed explanation of the research being conducted and why it is not covered by the pause. NIAID will review this information and make the final determination.
- **If the ongoing research includes GoF work subject to the funding pause and the grantee proposes to transition it to areas of research not covered by the pause,** please provide the transition plan. It should identify the research to be transitioned, a detailed description of the

new planned specific aims (in most cases this will require NIAID pre-approval), and a timeline for the proposed transition.

- **If the grantee plans to voluntarily halt the research subject to the funding pause**, please identify the research that will be halted and the proposed date by which the applicable research will be stopped. Please provide a confirmation that the research has been halted.
- **If the ongoing research includes GoF work and the grantee plans on continuing the research until the end of the currently active budget period,** please provide a detailed description of the GoF research to be conducted.

These plans are for the currently active budget period. Please be advised that while the funding pause is in effect, NIAID will not support GoF research identified in the pause after the end of the current grant budget period. Neither competing nor non-competing renewal applications will be funded to support applicable GoF research.

If you have any questions about this matter please do not hesitate to contact the NIAID program and/or grants management contact listed below.

Sincerely,

Shellie Wilburn
Grants Management Specialist
NIAID/NIH/DHHS

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

CC: Dr. Mark Dennison
Ms. Mary Kirker
Dr. Irene Glowinski

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

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

October 21, 2014

Ms. Jenny M. Dahlberg
University of Wisconsin-Madison
2015 Linden Drive
Madison, WI 53706

RE: 5 R01 AI080598-05

Dear Ms. Dahlberg:

NIAID has determined that the above referenced grant may include Gain of Function (GoF) research that is subject to the recently-announced 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 1. To assess the risk of emergence of 1918 virus-like pandemic influenza viruses
Aim 2. To assess the molecular features of HA that support the high virulence of the 1918 virus
Aim 3. To assess the role of the 1918 virus replication complex in severe viral infection

As your grant is currently funded, this pause is voluntary. Organizations conducting GoF research supported by the NIH have an opportunity to transition the applicable research to research that is not covered by the funding pause; halt the applicable GoF research until the outcome of the deliberative process is known; or continue to conduct the applicable GoF research until the end of the currently active budget period.

NIAID requests information on University of Wisconsin-Madison's plans for the research outlined above within 90 days of the date of this letter.

- **If you determine that the above research does NOT include GoF work subject to the funding pause**, please provide a detailed explanation of the research being conducted and why it is not covered by the pause. NIAID will review this information and make the final determination.
- **If the ongoing research includes GoF work subject to the funding pause and the grantee proposes to transition it to areas of research not covered by the pause**, please provide the transition plan. It should identify the research to be transitioned, a detailed description of the

new planned specific aims (in most cases this will require NIAID pre-approval), and a timeline for the proposed transition.

- **If the grantee plans to voluntarily halt the research subject to the funding pause,** please identify the research that will be halted and the proposed date by which the applicable research will be stopped. Please provide a confirmation that the research has been halted.
- **If the ongoing research includes GoF work and the grantee plans on continuing the research until the end of the currently active budget period,** please provide a detailed description of the GoF research to be conducted.

These plans are for the currently active budget period. Please be advised that while the funding pause is in effect, NIAID will not support GoF research identified in the pause after the end of the current grant budget period. Neither competing nor non-competing renewal applications will be funded to support applicable GoF research.

If you have any questions about this matter please do not hesitate to contact the NIAID program and/or grants management contact listed below.

Sincerely,

Victoria P. Connors for

Tina Carlisle
Grants Management Specialist
NIAID/NIH/DHHS

Teresa M. Hauguel

Teresa M. Hauguel, Ph.D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Yoshi Kawaoka
Ms. Mary Kirker
Dr. Irene Glowinski

**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

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

October 21, 2014

Ms. Jenny M. Dahlberg
University of Wisconsin-Madison
2015 Linden Drive
Madison, WI 53706

RE: 5 R01 AI069274-07

Dear Ms. Dahlberg:

NIAID has determined that the above referenced grant may include Gain of Function (GoF) research that is subject to the recently-announced 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 1. To identify the mechanisms that control H5N1 virus transmissibility in mammals
Aim 2. To characterize the contribution of viral genes other than HA to H5N1 virus transmissibility

As your grant is currently funded, this pause is voluntary. Organizations conducting GoF research supported by the NIH have an opportunity to transition the applicable research to research that is not covered by the funding pause; halt the applicable GoF research until the outcome of the deliberative process is known; or continue to conduct the applicable GoF research until the end of the currently active budget period.

NIAID requests information on University of Wisconsin-Madison's plans for the research outlined above within 90 days of the date of this letter.

- **If you determine that the above research does NOT include GoF work subject to the funding pause**, please provide a detailed explanation of the research being conducted and why it is not covered by the pause. NIAID will review this information and make the final determination.
- **If the ongoing research includes GoF work subject to the funding pause and the grantee proposes to transition it to areas of research not covered by the pause,** please provide the transition plan. It should identify the research to be transitioned, a detailed description of the

new planned specific aims (in most cases this will require NIAID pre-approval), and a timeline for the proposed transition.

- **If the grantee plans to voluntarily halt the research subject to the funding pause,** please identify the research that will be halted and the proposed date by which the applicable research will be stopped. Please provide a confirmation that the research has been halted.
- **If the ongoing research includes GoF work and the grantee plans on continuing the research until the end of the currently active budget period,** please provide a detailed description of the GoF research to be conducted.

These plans are for the currently active budget period. Please be advised that while the funding pause is in effect, NIAID will not support GoF research identified in the pause after the end of the current grant budget period. Neither competing nor non-competing renewal applications will be funded to support applicable GoF research.

If you have any questions about this matter please do not hesitate to contact the NIAID program and/or grants management contact listed below.

Sincerely,

Victoria P. Connors for

Tina Carlisle
Grants Management Specialist
NIAID/NIH/DHHS

Teresa M. Hauguel

Teresa M. Hauguel, Ph.D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Yoshi Kawaoka
Ms. Mary Kirker
Dr. Irene Glowinski

## Moore, Marg (NIH/NIAID) [E]

**From:** Schmidt, Beth (NIH/NIAID) [E] on behalf of Zoon, Kathryn (NIH/NIAID) [E]
**Sent:** Thursday, November 13, 2014 10:50 AM
**To:** Moore, Marg (NIH/NIAID) [E]
**Subject:** FW: White House announcement: Gain of Function Research Pause

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**From:** Zoon, Kathryn (NIH/NIAID) [E]
**Sent:** Saturday, October 18, 2014 12:53 PM
**To:** NIAID DIR Principal Investigators
**Subject:** Fw: White House announcement: Gain of Function Research Pause

Fyi

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Sent from my BlackBerry Wireless Handheld

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**From**: Heilman, Carole (NIH/NIAID) [E]
**Sent**: Friday, October 17, 2014 05:19 PM Eastern Standard Time
**To**: Rotrosen, Daniel (NIH/NIAID) [E]; Dieffenbach, Carl (NIH/NIAID) [E]; Zoon, Kathryn (NIH/NIAID) [E]; Mascola, John (NIH/VRC) [E]; Lane, Cliff (NIH/NIAID) [E]
**Cc**: Auchincloss, Hugh (NIH/NIAID) [E]; Fenton, Matthew (NIH/NIAID) [E]
**Subject**: FW: White House announcement: Gain of Function Research Pause

Dear All

Today the White House announced a U.S. Government-wide pause on certain gain-of-function experiments involving influenza, SARS, and MERS viruses. Under this pause, the U.S. Government will not release new funding for gain-of-function research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the resulting virus has enhanced pathogenicity and/or transmissibility (via the respiratory route) in mammals. The USG encourages those currently conducting this type of work – whether federally funded or not – to voluntarily pause their research while risks and benefits are being reassessed.

The pause will **not apply** to characterizing or testing naturally occurring influenza, MERS, and SARS viruses, unless these tests are reasonably anticipated to increase their transmissibility or pathogenicity.

While most of the affected research is under DMID and DIR's purview, you may be contacted by investigators concerning research projects that are within your portfolio or have questions about ongoing research within your intramural laboratories. If you receive an inquiry or have a question about an ongoing effort that may be included in the pause, please talk with me and with the help of my staff we may be able to guide you as to how to handle the situation. Please also note that if you have contracts, or are actively working in the lab in these areas --- The OD has decided to pause these effort now, and not at the next funding cycle.

**White House Blog announcement:**
http://www.whitehouse.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research
**Blog from Dr. Collins:** http://www.nih.gov/about/director/10172014_statement_gof.htm
**Additional information:**
http://www.phe.gov/s3/dualuse/Pages/default.aspx

http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf

Carole