From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM)

Sent: 5/26/2020 2:11:45 PM

To: Jacobs, Anna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e76eeb11df9a4024b53864ffac4c4c56-jacobsal]

CC: Black, Jodi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=782921b9f08249b59a582e93f6963f5f-blackj]; Lankford, David (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4f29a9bef672409d967e3aa5fb36e96a-lankford]; Lauer, Michael (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]

Subject: Re: EcoHealth Alliance re Termination of NIH Research Grant R01 Al 110964

Attachments: Re: Partial Suspension-IMPORTANT; Partial Suspension-IMPORTANT; FW: Please read and acknowledge receipt --

Actions needed regarding 2R01AI110964-06

Hi again Anna – part 2 of background material.

Thanks, Mike

From: "Jacobs, Anna (NIH/OD) [E]" < (b) (6)

Date: Tuesday, May 26, 2020 at 9:22 AM

To: "Lauer, Michael (NIH/OD) [E]" < (b) (6)

Cc: "Black, Jodi (NIH/OD) [E]" < (b) (6) "Lankford, David (NIH/OD) [E]"

< (b) (6)

Subject: RE: EcoHealth Alliance re Termination of NIH Research Grant R01 Al 110964

Good morning, Mike,

Thanks for providing this information. I'd be glad to discuss, if you'd like, although my familiarity with the matter is a bit limited. I can reach out to Melanie to find time. I assume 15 minutes will suffice. If a conversation is no longer needed, just let me or Melanie know.

Thanks,

Anna L. Jacobs, J.D., M.S.

Senior Attorney

HHS Office of the General Counsel

Public Health Division, NIH Branch

31 Center Drive, Bldg. 31, Rm.2B-50

Bethesda, MD 20892

(b) (6) (phone)

301-402-1034 (fax)

(b) (6)

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From: Lauer, Michael (NIH/OD) [E] (b) (6)

Sent: Friday, May 22, 2020 6:04 PM

To: Jacobs, Anna (NIH/OD) [E] < (b) (6)

Cc: Lauer, Michael (NIH/OD) [E] < (b) (6) Black, Jodi (NIH/OD) [E] < (b) (6) Lankford,

David (NIH/OD) [E] < (b) (6)

Subject: FW: EcoHealth Alliance re Termination of NIH Research Grant R01 AI 110964

Importance: High

Hi Anna – at some point we should discuss this.

Many thanks, Mike

(b) (6) Aleksei Chmura Subject: EcoHealth Alliance re Termination of NIH Research Grant R01 Al 110964

Dr. Lauer:

Please see the attached letter from Andrew N. Krinsky on behalf of EcoHealth Alliance, Inc., pursuant to NIH Grants Policy Statement Section 8.7, regarding the decision by NIAID to terminate NIH Research Grant R01 Al 110964 on or about April 24, 2020.

Thank you.

Best, Matthew R. Torsiello



Matthew R.Torsiello | Associate
D: (b) (6) | F: 212-216-8001
(b) (6) | Bio

Tarter Krinsky & Drogin LLP 1350 Broadw ay | New York | NY | 10018 w ww.tarterkrinsky.com

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Тапет Малаку & Скодію І.Г.Р., Апограув-ві-Цачу.

From:

Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]

Sent:

4/19/2020 1:51:18 AM

To:

 $Lauer,\ Michael\ (NIH/OD)\ [E]\ [/o=ExchangeLabs/ou=Exchange\ Administrative\ Group]$

(FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]

Subject:

Re: Partial Suspension-IMPORTANT

Thanks Mike; yes, I think you need to send to both. Larry

From: "Lauer, Michael (NIH/OD) [E]" < (b) (6)

Date: Saturday, April 18, 2020 at 9:50 PM

To: "Tabak, Lawrence (NIH/OD) [E]" < (b) (6)

Cc: "Lauer, Michael (NIH/OD) [E]" <
Subject: Re: Partial Suspension-IMPORTANT

Hi Larry

It looks like EcoHealth Alliance is linked to Columbia University. I can send this to the VPR at EcoHealth Alliance (Kevin Olival), but also to research leadership at Columbia (whom we know well).

(b)(6)

Of note, the PI of the grant is the President of EcoHealth Alliance. He seems to have a Columbia affiliation.

Best, Mike

From: "Tabak, Lawrence (NIH/OD) [E]" < (b) (6)

Date: Saturday, April 18, 2020 at 9:37 PM

To: "Lauer, Michael (NIH/OD) [E]" < (b) (6)

Subject: Re: Partial Suspension-IMPORTANT

Please let me know once it is sent.

Thanks Larry

From: "Lauer, Michael (NIH/OD) [E]" < (b) (6)

Date: Saturday, April 18, 2020 at 9:33 PM

To: "Tabak, Lawrence (NIH/OD) [E]" < (b) (6) **Cc:** "Lauer, Michael (NIH/OD) [E]" < (b) (6)

Subject: FW: Partial Suspension-IMPORTANT

Hi Larry – it should come from me. I will get to the appropriate official tomorrow.

Thanks, Mike

From: "Tabak, Lawrence (NIH/OD) [E]" < (b) (6)

Date: Saturday, April 18, 2020 at 9:30 PM

To: "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Subject: Partial Suspension-IMPORTANT

Mike,

I have been directed to have this sent on Sunday. I presume you are the right person to send it? I will send if you prefer. Just let me know.

Thanks, Larry From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]

Sent: 4/19/2020 1:30:09 AM

To: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]

Subject: Partial Suspension-IMPORTANT
Attachments: Suspension of WIV_NIHB edits.docx

Mike,

I have been directed to have this sent on Sunday. I presume you are the right person to send it? I will send if you prefer. Just let me know.

Thanks,

Larry



From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: 4/19/2020 3:00:34 PM

To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]

CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Black, Jodi (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=782921b9f08249b59a582e93f6963f5f-blackj] FW: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06

Attachments: EcoHealth Alliancere Al grant 4 19 20.pdf

Labeled "High Priority"

Subject:

From: "Lauer, Michael (NIH/OD) [E]" < (b) (6)

Date: Sunday, April 19, 2020 at 10:59 AM

To: " (b) (6) < (b) (6) Naomi Schrag < (b) (6)

Cc: "Black, Jodi (NIH/OD) [E]" < (b) (6)

Subject: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06

Dear Dr. Olival and Ms. Schrag

Please see attached.

Many thanks, Mike

Michael S Lauer, MD NIH Deputy Director for Extramural Research 1 Center Drive, Building 1, Room 144 Bethesda, MD 20892

(b)(6)

Phone: (b) (6)

Date: April 19, 2020

From: Michael S Lauer, MD

NIH Deputy Director for Extramural Research

Lauer, Michael Digitally signed by Lauer, Michael (NIH/OD) [E] (NIH/OD) [E]

Date: 2020.04.19 10:47:40

To: Kevin Olival, PhD

Vice-President for Research

EcoHealth Alliance

(b) (6)

Naomi Schrag, JD

Vice-President for Research Compliance, Training, and Policy

Columbia University (b) (6)

Subject: Project Number 2R01AI110964-06

Dear Dr. Olival and Ms. Schrag:

EcoHealth Alliance, Inc. is the recipient, as grantee, of an NIH grant entitled "Understanding the Risk of Bat Coronavirus Emergence." It is our understanding that one of the sub-recipients of the grant funds is the Wuhan Institute of Virology ("WIV"). It is our understanding that WIV studies the interaction between corona viruses and bats. The scientific community believes that the coronavirus causing COVID-19 jumped from bats to humans likely in Wuhan where the COVID-19 pandemic began. There are now allegations that the current crisis was precipitated by the release from WIV of the coronavirus responsible for COVID-19. Given these concerns, we are pursuing suspension of WIV from participation in Federal programs.

While we review these allegations during the period of suspension, you are instructed to cease providing any funds from the above noted grant to the WIV. This temporary action is authorized by 45 C.F.R. § 75.371(d) ("Initiate suspension or debarment proceedings as authorized under 2 C.F.R. part 180"). The incorporated OMB provision provides that the funding agency may, through suspension, immediately and temporarily exclude from Federal programs persons who are not presently responsible where "immediate action is necessary to protect the public interest." 2 C.F.R. § 180.700(c). It is in the public interest that NIH ensure that a sub-recipient has taken all appropriate precautions to prevent the release of pathogens that it is studying. This suspension of the sub-recipient does not affect the remainder of your grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension.

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: 5/26/2020 9:58:16 AM

CC:

To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl] Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Allen-Gifford, Patrice

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-allengiffor]

Subject: FW: EcoHealth Alliance Incomings

Attachments: 1a Letter to Dr. Collins from The American Association of Immunologists. May 20, 2020.pdf; RE: Question about CBS

report of a terminated research grant; 1a IDSA-HIVMA-ASTMH-PIDS EcoHealth Alliancegrant_Final.pdf; 29

Organizations and over 300 scientists sign a letter demanding NIH re-fund EcoHealth Alliance; 1 Letter to Secretary

Azar.pdf; EcoHealth Response.doc; nobellettergrant.pdf

Hi Larry – I see that the Nobel letter is on the agenda for Exec Comm this morning. Patrice has picked up other letters along the same line.

Patrice also kindly drafted a response (second to last attachment) which I think makes sense.

Many thanks, Mike

From: "Lauer, Michael (NIH/OD) [E]" < (b) (6)

Date: Friday, May 22, 2020 at 11:39 AM

To: "Tabak, Lawrence (NIH/OD) [E]" < (b) (6)

Cc: "Lauer, Michael (NIH/OD) [E]" < (b) (6) "Allen-Gifford, Patrice (NIH/OD) [E]" < (b) (6) "Black, Jodi (NIH/OD) [E]" < (b) (6)

Subject: FW: EcoHealth Alliance Incomings

Hi Larry – with many thanks to Patrice, we are getting more letters about EcoHealth Alliance grant. I'll discuss with you at our 1:1 later today.

Best, Mike

From: "Allen-Gifford, Patrice (NIH/OD) [E]" < (b) (6)

Date: Friday, May 22, 2020 at 11:35 AM

To: "Lauer, Michael (NIH/OD) [E]" < (b) (6) (Cc: "Pollock, Rachel (NIH/OD) [E]" < (b) (6)

Subject: FW: EcoHealth Alliance Incomings

Hi Mike,

I just learned this morning that we have several letters on this, some from significant organizations (examples attached). I think I should share these with Larry – unless you prefer to do so in the course of your follow up conversation with him. Will you let us know please if after you talk with Larry, there are changes to the draft we received (attached) to clear?

Thank you,

Patrice

The AMERICAN ASSOCIATION of IMMUNOLOGISTS

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Jeremy M. Boss, Ph.D.

May 20, 2020

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Executive Director
M. Michele Hogan, Ph.D.

Francis S. Collins, M.D., Ph.D.

Director, National Institutes of Health 1 Center Drive, Building 1, Room 126

Bethesda, MD 20814

Dear Dr. Collins:

We are writing on behalf of The American Association of Immunologists (AAI), the nation's largest professional association of research scientists and clinicians who are dedicated to studying the immune system. As you know, many of our members are deeply immersed in research that may lead to needed vaccines and treatments for COVID-19. This research and development, while potentially lifesaving during this pandemic, will no doubt also help prepare our nation and the world for future pandemics.

We were concerned, therefore, to learn of a decision by the National Institutes of Health (NIH) to revoke grant funding for the EcoHealth Alliance project entitled, "Understanding the Risk of Bat Coronavirus Emergence." As scientists who support merit-based peer review, we believe it is important for NIH to explain why this grant — which appears to fund research of great relevance to the COVID-19 pandemic — was abruptly terminated. While we understand there could be legitimate reasons for this action, the NIH response has been unsatisfactory. According to NPR, the email NIH sent to EcoHealth Alliance President Peter Daszak, Ph.D., informed him that, "at this time NIH does not believe the current project outcomes align with the program goals and agency priorities." NIH subsequently refused to answer questions regarding this grant termination or whether NIH had taken similar actions previously. This response is both confusing and troubling. Your explanation could reinforce confidence in the NIH grant review system at a time when many are concerned that world and national events may be politicizing the science we need the most. We support the request made in a community letter organized by our colleagues at the American Society for Biochemistry and Molecular Biology (ASBMB) for a full explanation of the reasoning for this grant termination.

AAI greatly appreciates your ongoing leadership and support for the nation's medical researchers and remains ready to assist you in these most challenging times.

Sincerely,

Jeremy M. Boss, Ph.D.

President

Ross M. Kedl, Ph.D.

Chair, AAI Committee

on Public Affairs

M. Michele Hogan, Ph.D.

Executive Director

Dr. Greichele Hogan

From: Calin-Jageman, Robert [(b) (6

Sent: 5/12/20207:35:43 PM

To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]

Subject: RE: Question about CBS report of a terminated research grant

Director Collins,

I recently saw a CBS report claiming that an NIH research grant held by Dr. Peter Daszak and the Eco Health Alliance has been unexpectedly terminated (https://www.cbsnews.com/news/trump-administration-coronavirus-vaccine-researcher-covid-19-cure-60-minutes/).

I haven't been able to find an official NIH response or explanation related to this report. But did find in the NIH reporter a grant held by Dr. Daszak and the Eco Health Alliance that shows an unusual end date that is less than 1 year from the approval data (see bellw)

Could you direct me to the NIH's response or explanation for the situation? I'd like to know if this grant (or another held by these researchers) was terminated before the date initially specified in the award letter. And if so, I'd like to know more about the process that led to the early termination. If there's a better contact person, I'd be happy to be directed to them.

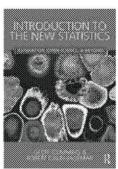
Thanks,

Bob



Robert Calin-Jageman Professor, Psychology Neuroscience Program Director Dominican University Parmer 210 7900 West Division River Forest, IL 60305

http://calin-jageman.net



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here: https://www.routledge.com/resources/deskcopy. Or, order on Amazon.







May 11, 2020

President Donald J. Trump The White House 1600 Pennsylvania Ave. NW Washington, DC 20500

Dear President Trump:

We write on behalf of the Infectious Diseases Society of America (IDSA), the HIV Medicine Association (HIVMA), American Society of Tropical Medicine and Hygiene (ASTMH), and the Pediatric Infectious Diseases Society of America (PIDS) to raise serious concerns regarding what appears to have been political interference in the scientific process with the termination of an EcoHealth Alliance grant that included a partnership with the Wuhan Institute of Virology (WIV).

Our organizations represent physicians, scientists and other healthcare professionals committed to infectious diseases, pediatric infectious diseases, tropical medicine, and global health. We were dismayed to learn about the termination of the National Institutes of Health (NIH) grant supporting an important international collaboration with WIV studying the transmission of coronaviruses from bats to humans, microbial genetics, and drug and vaccine development. Such studies are critical to understand the viruses, their transmission, and approaches for prevention and treatment of this dangerous illness. As of May 11, the current SARS-CoV-2 pandemic has resulted in more than 284,628 deaths globally, including more than 80,087 deaths in the U.S.

The grant from the NIH National Institute of Allergy and Infectious Diseases was in its sixth year and was renewed in 2019 for five years through the NIH peer review process, which is the gold standard for identifying and supporting the most promising biomedical research without bias. Basic research completed under the grant has been critical to the evaluation of remdesivir as a treatment for COVID-19, the first drug receiving FDA Emergency Use Authorization to treat hospitalized patients. The ongoing work of the Alliance has become more important than ever to help prevent future coronavirus pandemics. Furthermore, the NIH has not provided a legitimate cause for terminating the EcoHealth Alliance grant, which was given superb ratings in its renewal evaluation. There is no scientific evidence that SARS-CoV-2 originated at WIV or any other laboratory, and the NIH has not responded to inquiries asking for additional clarification and rationale.

An independent and impartial scientific process and robust support for global research collaborations have been indispensable in making the United States the world leader in biomedical research and establishing the NIH as the world's premier medical research enterprise. Continued independent and impartial processes are absolutely essential to the successful development of effective treatments, vaccines, and cures for many infectious diseases and the epidemics and pandemics they can cause. This includes SARS-CoV-2, the cause of severe COVID-19 disease.

We urge immediate reconsideration of the termination of the EcoHealth Alliance grant, with assurances that politics will not influence the scientific process. A failure to set strong boundaries between politics and science will set back future medical discoveries for years to come and leave the U.S. poorly prepared to respond to current and future pandemics. health crisis. If you have questions or require additional information, please do not hesitate to contact Amanda Jezek, IDSA Senior Vice President for Public Policy and Government Relations at (b) (6) or Andrea Weddle, HIVMA Executive Director at

Homas He

Sincerely,

Thomas M. File, Jr., MD, MSc

Lucina Bragatino

President, IDSA

Judith Feinberg, MD Chair, HIVMA

Karen a Gralisti

Kristina Bryant, MD, FPIDS President, PIDS

Karen A. Goraleski CEO, ASTMH

CC: Francis S. Collins, MD, PhD, Director, NIH Anthony S. Fauci, MD, Director, NIH's NIAID From: Joseph Osmundson [(b) (6

Sent: 5/11/2020 8:13:02 PM

To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]

Subject: 29 Organizations and over 300 scientists sign a letter demanding NIH re-fund EcoHealth Alliance

Attachments: Coronavirus Grant Cancelation Protest SIGN ON LETTER.pdf

Dr. Collins,

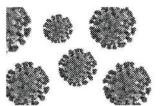
Today, the COVID-19 Working Group-NY (CWG-NY) is sending a letter, signed by 29 organizations, more than 300 scientists, physicians, and community health advocates, to Dr. Francis Collins, Director of the US National Institutes of Health (NIH), Dr. Anthony Fauci, Director of the National Institute for Allergy and Infectious Diseases (NIAID), and Alex Azar, Secretary of Health and Human Services, along with officials on the House Oversight Committee and the Senate Health Committee.

The letter expresses outrage at the canceling of a major R01 grant to the EcoHealth Alliance, an international collaboration that studies coronaviruses in bats to determine how they may evolve to transmit in human populations. We demand immediate reinstatement of the R01 to EcoHealth Alliance.

Signatories of the letter – which include scientists from many top research institutions across the US including Harvard, Yale, Stanford, University of Michigan, University of Pennsylvania, University of Wisconsin, University of Florida, University of California San Francisco, University of Washington, AstraZeneca, and Columbia University – called for immediate release of the NIH R01 funds to EcoHealth and for an investigation into the decision-making process that canceled the grant funding in the first place.

Best,

Joseph Osmundson COVID-19 Working Group NY





COVID-19 Working Group New York City

www.covid-19workinggroupnyc.org

The NIH must not cancel awarded grants for purely political reasons

On May 1, 2020, Science Magazine reported the cancelation of a major grant to the EcoHealth Alliance, an international collaboration studying how coronaviruses transmitting in bats can evolve to spread in human populations. Based on emails reviewed by Science, this decision appears to be directly related to the Trump administration's belief in the conspiracy theory that the SARS-CoV-2 virus, the cause of COVID-19, was purposefully or accidentally released from the Wuhan Institute of Virology. The Wuhan Institute of Virology was a participant in the EcoHealth Alliance grant that was canceled.

We ask for the immediate reinstatement of the grant to EcoHealth Alliance and for a congressional investigation into the decision making process at the NIH that canceled the funding in the first place. A vibrant community of independent scientists is crucial to a functioning democracy and will be the first line of defense against another crisis that costs as many lives as the COVID-19 pandemic.

To be clear, there is <u>no evidence of human engineering</u> of the SARS-CoV-2 virus nor of accidental release of a laboratory viral strain. <u>Phylogenetic analyses</u> clearly support the evolution of the SARS-CoV-2 virus from bats in the wild.

We write in strong condemnation of political interference in scientific grantmaking. The NIH has a long and well-established protocol for scoring and funding grants, including decisions on scientific merit, productivity, and the import of research by large panels of expert scientists. During the course of an NIH grant, alterations in funding are incredibly disruptive to ongoing research projects, many of which span years if not decades.

Cancelation of a grant mid-term will disrupt the progress of research in how coronaviruses can evolve to infect humans, the exact process that birthed SARS-CoV-2, leading to hundreds of thousands of deaths worldwide. This research was always critical given the possibility of a coronavirus pandemic; it is now absolutely essential to understand how this crisis originated and to avoid another pandemic in the

future. Bowing to conspiracy theories in this time of crisis to prevent necessary research may, therefore, be sowing the seeds of another crisis in the future.

In fact, the grant to EcoHealth Alliance <u>provided critical data</u> – <u>including</u> the <u>sequences</u> of closely related bat coronaviruses to <u>SARS-CoV-2</u> – that both helped <u>identify the origin</u> of COVID-19 and identified remdesivir as a potential drug for the disease, allowing it to be rapidly moved into clinical trials. It is absurd and horrifying that the Trump administration would shut down a research program that led to the first promising treatment for COVID-19.

Beyond the critical importance of the research the NIH defunded, political interference in grantmaking is a disturbing trend that would allow politicians to effectively squash research that does not align with their political desires. Industry influence in research, the silencing of climate science, and long term harm of American science in the global climate become increasingly likely if politicians can easily meddle in grantmaking. We must stand united as a community of clinicians, scientists, activists, and citizens to demand the best – most transparent – scientific decision making process in this moment of crisis, and always.

Signed:

Organizations Signed On:

COVID-19 Working Group, New York City The PrEP4All Collaboration AVAC – AIDS Vaccine Advocacy Coalition ICAP at Columbia University ACT-UP AIDS Foundation Chicago Universities Allied for Essential Medicines (UAEM) Center for Science in the Public Interest **Equity Forward** National Black Leadership Commission on Health Association of Nurses in AIDS Care **Progressive Doctors** Black AIDS Institute Latino Commission on AIDS Treatment Action Group AIDS Action Baltimore

TPAN - Test Positive Aware Network

HIV + Aging Research Project – Palm Springs

HealthxDesign

Georgia AIDS Coalition

Climate Health Now

National Working Positive Coalition

Prevention Access Campaign

The Well Project

Map Data Science

American Academy of HIV Medicine

GCCDC – Gowanus Canal Community Development Corporation

Bannon Consulting Services

Individuals Signed On:

David Ho, Director, Aaron Diamond AIDS Research Center of Columbia University

Vagelos College of Physicians and Surgeons

Gregg Gonsalves, Yale School of Public Health

Sten H. Vermund, Yale School of Public Health

Martin S. Hirsch, Harvard University

Seth Darst, The Rockefeller University

Anthony Eller, Yale AIDS Program

A. David Paltiel, Yale School of Public Health

Ted Cohen, Yale School of Public Health

Nathan Grubaugh, Yale School of Public Health

Robert Heimer, Yale School of Public Health

Taiga Christie, Yale School of Public Health

Eli Fenichel, Yale University

Samy Galvez, Yale University

David Vlahov, Yale University

Nathan Price, Yale University

Walther Mothes, Yale University

Nancy Stanwood, Yale University

Frederick L. Altice, Yale University School of Medicine

Akiko Iwasaki, Yale University School of Medicine

Angela L. Rasmussen, Columbia Mailman School of Public Health

Mady Hornig, Columbia University

Jacqueline Klopp, Columbia University

Sarah Lima, Columbia University Mailman School of Public Health

Maimuna S. Majumder, Boston Children's Hospital & Harvard Medical School

Donald Thea, Boston University School of Public Health

Jerry Avorn, Harvard Medical School

Julia Marcus, Harvard Medical School

Aaron Kesselheim, Harvard Medical School/Brigham and Women's Hospital

Ameet Sarpatwari, Brigham & Women's Hospital/Harvard Medical School

Robyn Lee, Harvard School of Public Health

Keletso Makofane, Harvard University

Bryan Terrazas, Harvard University

Grace Mosley, Icahn School of Medicine at Mount Sinai

Alice O Kamphorst, Icahn School of Medicine at Mount Sinai

AMIR HOROWITZ, Icahn School of Medicine at Mount Sinai

Miriam Merad, Icahn School of Medicine at Mount Sinai

Thomas Marron, Tisch Cancer Institute - Icahn School of Medicine at Mount Sinai

Duncan Maru, Icahn School of Medicine at Mount Sinai

Konstantina Alexandropoulos, Icahn School of Medicine at Mount Sinai

Stephen A Lauer, Johns Hopkins Bloomberg School of Public Health

David D Celentano, Johns Hopkins Bloomberg School of Public Health

Nicole Carter, Johns Hopkins School of Medicine

Sarah Horst, Johns Hopkins University

Edward Banigan, Massachusetts Institute of Technology

Mila González, Columbia University/ NewYork Presbyterian Hospital

Meredith Whittaker, Co-director, Al Now Institute at NYU

Joseph Osmundson, New York University

ENRIQUE R ROJAS, New York University

Brendan Parent, New York University

Michael Purugganan, New York University

Hayley Belli, New York University

ESTEBAN ORLANDO MAZZONI, New York University

Carol Shoshkes Reiss, New York University

Arthur L Caplan, NYU Grossman School of Medicine

Alison Bateman-House, NYU Grossman School of Medicine

Kelly Folkers, NYU Grossman School of Medicine

Aisha Langford, NYU Grossman School of Medicine

Jamie Webb, NYU Grossman School of Medicine Division of Medical Ethics

Tarlise Townsend, NYU Grossman School of Medicine, Department of Population Health

Christopher J. Morten, NYU School of Law

Bernardo S Reis, The Rockefeller University

Lisa Pomeranz, The Rockefeller University

Simin Liu, The Rockefeller University

Daniel Mucida, The Rockefeller University

Stefan Oliver, Stanford University

Kelsey Logas, Stanford University

Hannah Frank, Stanford University

Veronica Rogers Everett, UMass-Amherst

Diana Taft, UC Davis

Kishana Taylor, UC Davis

Steffanie Strathdee, UC San Diego

Carol L. Brosgart, MD, UCSF

Jennifer Thomas, UCSF

Cesar Augusto Lopez, UNC Chapel Hill

Catherine Eliza Kehl, UNC Chapel Hill

Joseph M McCune, Bill & Melinda Gates Foundation

Christopher Robertson, University of Arizona

Nina A Sokolov, University of California, Berkeley

BethAnn McLaughlin, Academic Decency League

Sarah Tuttle, University of Washington

Kathleen J Millen, University of Washington

Lauren Dunnington, University of Washington

Colm Atkins, Rutgers University

DANA WOELL, Rutgers University

Catherine M Herzog, Penn State University

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Marcello Graziano, Central Michigan University

M. Drew LaMar, College of William and Mary

Graham J McDougall Jr, Florida State University College of Nursing

Jeffrey Levi, George Washington University

Adam R. Ward, George Washington University, Milken Institute School of Public Health

Kristin Harper, Harper Health & Science Communications LLC

Simon Collins, HIV i-Base

Isaiah Sumner, James Madison University

Bruce Jennison, JENNISONFYI

Emmy Killett, Jet Propulsion Lab

Jennifer Chang, Kaiser Permanente at Los Angeles Medical Center

Tara C Smith, Kent State University

Kimberly Stone, Kimberly C Stone PA

Lorna B. Hall, La Cheim Behavioral Health

Stephan R. Glicken, Lehigh Valley Physician Group

Jeremy P. Kamil, LSU Health Sciences Center

Meredith Clement, LSU Health Sciences Center

Lydia Wills, Lydia Wills LLC

Amy H Fitzpatrick, Marine Institute

Tony Mistretta, Medical Management

Wendell Bell, Minnesota State Bar Assn.

Ellyse A. Vitiello, Morningside Monthly Meeting (Quakers)

Greta J. Quintin, Morristown Emergency Services

Navin Pokala, New York Institute of Technology (NYIT)

Mark Cutis, Nihon Phoenix Advisors

Leo Beletsky, Northeastern University

Katrina Kuh, Pace Law School

Aaron Steiner, Pace University

Michelle Fearon, University of Michigan

John Dennehy, Queens College CUNY

Jennifer C Fish, MD, Santa Rosa Community Health

Michael W. Busch, SETI Institute

Sofia P Singer, Seven Directions

Princess McLawrence-Manning, SMART, NYCWC

Sanjeev K Sriram, Social Security Works

Danielle N. Lee, Southern Illinois University Edwardsville

LIliana M Davalos, Stony Brook University

Stephen B Baines, Stony Brook University

Frances Ryan, Commission for Persons with disAbilities

Matt Sharp, The Reunion Project

Thomas St. Julien Lankiewicz, The University of California, Santa Barbara

Arthur R. James, Three Peas in a Pod

Amelia Gifford, Toxics Use Reduction Institute

Perry Mitchell, Truckee Meadows Community College

Lawrence Hunter, University of Colorado School of Medicine

Blair T. Johnson, University of Connecticut

Jennifer L. Hoffman, University of Denver

Patrick Kearns, University of Edinburgh Wellcome Lecturer & Harvard University Frank Knox Fellow

Michael Riley II, University of Florida

Adria LeBoeuf, University of Fribourg

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Kristina Elizabeth Atanasoff, University of Maryland, Baltimore County

Monique, University of Michigan

Chanda Prescod-Weinstein, University of New Hampshire

Matthew Martinez, University of Pennsylvania

Robert E. Marc, University of Utah School of Medicine

Emily Bruce, University of Vermont

Autumn Kent, University of Wisconsin

Kathryn Anderson, UW School of Medicine

Face Pickens, Virginia Commonwealth University

Stephanie Hart, Virginia Commonwealth University

Mary Loos, Virginia Commonwealth University

Zachary Pincus, Washington University in St. Louis

John Moore, Weill Cornell School of Medicine

Judith Feinberg, West Virginia University

Linda Grabill, Western Washington University

C. Virginia Fields

Holly H Balogh

Jean Webner

Charles Franchino

Saskia Popescu

Jennifer Taylor

Jere J Lepley

Lydia McKay

Brian Nord

Kim Wallace

Zoe Schroeder

Mingjane Wu

Sureka Gattu

Arthur Smith

Sara Bazaco

Tatiana Rodriguez

Susan Miller

Maureen E Hoatlin

Victor Janusz

Alexei L. Krasnoselsky

Peter Simonetti

Laura Diamondstone

Leslie Carroll

Dorthy Gordon

Leroy Nunez

Malaya Fletcher

Edwin Chen

Linda van der Wal

Angela Wagner

Joan Holup

Ben Spiker

Kelly Roth

Denise McIsaac

Alexandra Sundell

Minda Sarna

Suzanne Vogel

Tracy Wells

Amy Reese

Bella Berlly

Mike Berlly

Robert Goodwin

Michael Sheehy

Brianne Barker

Angela Diuble

Barbara Kolber

Nathan Myers

Eric Shattuck

Amy Gregg

Douglas Buchanan

Barbara J Casey

Mary Beth Bowerman

Nicolle Bruett Shanman

Iris Nathan

Jake Scott

Clifford Johnson

Dyan Traynor

Wendy Wifler

Peggy Hamilton

Tim Mackey

Joanne Baio

Leslie Sude

Nicola Chamberlain

Arthur Rourke

Tara Martinez

Ken Kidd

Carly Harrison

K Barrett

Val Barton

Elizabeth Eisen

Catherine Koebel

Victoria Sharp

Diane Tabellija

Kristen Boyle-Heimann

M. Maggie O'Meara

Laura Hanson

Lina Correa Cerro

Jennifer Thompson

Katie Love

Karen Smith-McCune

Tiffany Doherty

Robin Schwartz

Gabrielle Lopez

Danelle Forseth

Tina

Jess Seline

Nina Lee

Callie Preheim

Ysabel Beatrice Floresca

LIPI ROY

Elizabeth Spradley

Gregory G. Sarno

Eric Neumann

Anna Costello

Liz Kroboth

Carol Kessler

Karyn Pomerantz

Keshet Ronen

Danielle Francois

Jeff Sheehy

Rachel Barr

Ann Hartzler

Arturo Garcia Jr

Natan Vega Potler

Ben Stoner-Duncan

Daniel Lugassy

Kate Mastroianni

Pam Kolber zicca

John True

Murray Penner

John Howard

Hannah Forsberg

Zach Watson

Stephen Waldmann

Frances Cross

Alison Fitzgerald

Kurt Fleagle

Mariya Masyukov

Grant Leavins

Lark Jarvis

Joseph Gaschen

Krishna Stone

Robert Haas

PATRICK OLEARY

Racquel Kim Sherwood

Gláucia Furtado

Michael O'Quinn

Siobhan Cooke

Jaclyn Novatt

Jhilya Mayas

Caitlyn Passaretti

W. David Hardy

Amanda Ramsdell

Laura Raffield

Kimberleigh Smith

Barbara McCormack

Toph Allen (Christopher Allen)



May 12, 2020

The Honorable Alex Azar Secretary U.S. Department of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201

Dear Secretary Azar,

On behalf of Research! America, I am writing to request that you clarify the decision to end National Institutes of Health (NIH) grant funding for the EcoHealth Alliance project entitled "Understanding the Risk of Bat Coronavirus Emergence." We believe the American people, whose tax dollars enable federal grants for life-saving research and other national priorities, deserve more clarity on the basis of this decision than has thus far been provided.

The abrupt termination of this grant has generated concern, not only because of the relevance of this research to COVID-19 and future pandemics, but because the lack of transparency surrounding the termination creates uncertainty about the integrity of federal grant-making.

We certainly appreciate there may be facets of this decision that cannot be made public, but given the high degree of integrity expected of the NIH extramural grant program, we urge the Administration to bring as much information to light as possible surrounding this decision.

We respectfully request that you provide the American public with insight into the basis of the decision to end funding for the EcoHealth grant and how this decision conforms to the circumstances in which grant terminations are permitted under the United States Code of Federal Regulations.

We are grateful for your leadership during this profoundly challenging period in our nation's history, and appreciate your consideration of this request.

Sincerely,

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241 18th Street South Suite SC1 Arlington, VA 22202 P 703,739,2577 F 703.739.2372

E info@researchamerica.org

That M. Coatle Mary Woolley
Michael N. Castle Mary Woolley The Honorable Michael N. Castle Chair, Member of Congress 1993-2011







National Institutes of Health Bethesda, Maryland 20892

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77 US Nobel Laureates in Science

May 21, 2020

Secretary Azar and Director Collins:

The 77 signatories of this letter, American Nobel Laureates in Physiology or Medicine, Chemistry, and Physics, are gravely concerned about the recent cancellation of a grant from the National Institutes of Health (NIH) to Dr. Peter Daszak at the EcoHealth Alliance in New York. We believe that this action sets a dangerous precedent by interfering in the conduct of science and jeopardizes public trust in the process of awarding federal funds for research.

For many years, Dr. Daszak and his colleagues have been conducting highly regarded, NIH-supported research on coronaviruses and other infectious agents, focusing on the transmission of these viruses from animal hosts to human beings. Their work depends on productive collaborations with scientists in other countries, including scientists in Wuhan, China, where the current pandemic caused by a novel coronavirus arose. Now is precisely the time when we need to support this kind of research if we aim to control the pandemic and prevent subsequent ones.

As has now been widely reported, the grant to the EcoHealth Alliance was abruptly terminated by NIH on April 24, 2020, just a few days after President Trump responded to a question from a reporter who erroneously claimed that the grant awarded millions of dollars to investigators in Wuhan. Despite the misrepresentation of Dr. Daszak's grant, despite the high relevance of the studies to the current pandemic, and despite the very high priority score that his application for renewal had received during peer review, the NIH informed Dr. Daszak and his colleagues that the grant was being terminated because "NIH does not believe that the current project outcomes align with the program goals and agency priorities." Such explanations are preposterous under the circumstances.

We are scientists who have devoted our careers to research, both in medical and related scientific disciplines that bear on the overall health and well-being of society, as well as fundamental scientific research, much of it supported by NIH and other federal agencies. We take pride in our nation's widely admired system for allocating funds based on expert review and public health needs. The abrupt revoking of the award to Dr. Daszak contravenes these basic tenets and deprives the nation and the world of highly regarded science that could help control one of the greatest health crises in modern history and those that may arise in the future.

We ask that you act urgently to conduct and release a thorough review of the actions that led to the decision to terminate the grant, and that, following this review, you take appropriate steps to rectify the injustices that may have been committed in revoking it.

| Peter Agre | Chemistry | 2003 | James P. Allison | Medicine | 2018 |
|------------------------|-----------|------|-----------------------|-----------|------|
| Sidney Altman | Chemistry | 1989 | Frances H. Arnold | Chemistry | 2018 |
| David Baltimore | Medicine | 1975 | Barry Clark Barish | Physics | 2017 |
| Paul Berg | Chemistry | 1980 | J. Michael Bishop | Medicine | 1989 |
| Elizabeth H. Blackburn | Medicine | 2009 | Michael S. Brown | Medicine | 1985 |
| William C. Campbell | Medicine | 2015 | Mario R. Capecchi | Medicine | 2007 |
| Thomas R. Cech | Chemistry | 1989 | Martin Chalfie | Chemistry | 2008 |
| Steven Chu | Physics | 1997 | Elias James Corey | Chemistry | 1990 |
| Robert F. Curl Jr. | Chemistry | 1996 | Johann Deisenhofer | Chemistry | 1988 |
| Andrew Z. Fire | Medicine | 2006 | Edmond H. Fischer | Medicine | 1992 |
| Joachim Frank | Chemistry | 2017 | Jerome I. Friedman | Physics | 1990 |
| Walter Gilbert | Chemistry | 1980 | Sheldon Glashow | Physics | 1979 |
| Joseph L. Goldstein | Medicine | 1985 | Carol W. Greider | Medicine | 2009 |
| David J. Gross | Physics | 2004 | Roger Guillemin | Medicine | 1977 |
| Leland H. Hartwell | Medicine | 2001 | Dudley R. Herschbach | Chemistry | 1986 |
| Roald Hoffmann | Chemistry | 1981 | H. Robert Horvitz | Medicine | 2002 |
| Louis J. Ignarro | Medicine | 1998 | William G. Kaelin Jr. | Medicine | 2019 |
| Eric R. Kandel | Medicine | 2000 | Wolfgang Ketterle | Physics | 2001 |
| Brian K. Kobilka | Chemistry | 2012 | Roger D. Kornberg | Chemistry | 2006 |
| Robert J. Lefkowitz | Chemistry | 2012 | Anthony J. Leggett | Physics | 2003 |
| Michael Levitt | Chemistry | 2013 | Roderick MacKinnon | Chemistry | 2003 |
| John C. Mather | Physics | 2006 | Craig C. Mello | Medicine | 2006 |
| William E. Moerner | Chemistry | 2014 | Mario J. Molina | Chemistry | 1995 |
| Ferid Murad | Medicine | 1998 | Douglas D. Osheroff | Physics | 1996 |
| | | | | | |

| James Peebles | Physics | 2019 | Saul Perlmutter | Physics | 2011 |
|------------------------|-----------|------|-----------------------|----------|------|
| William D. Phillips | Physics | 1997 | H. David Politzer | Physics | 2004 |
| Sir Richard J. Roberts | Medicine | 1993 | Michael Rosbash | Medicine | 2017 |
| James E. Rothman | Medicine | 2013 | Randy W. Schekman | Medicine | 2013 |
| Richard R. Schrock | Chemistry | 2005 | Gregg L. Semenza | Medicine | 2019 |
| Phillip A. Sharp | Medicine | 1993 | Hamilton O. Smith | Medicine | 1978 |
| George P. Smith | Chemistry | 2018 | Horst L. Stormer | Physics | 1998 |
| Thomas C. Sudhof | Medicine | 2013 | Jack W. Szostak | Medicine | 2009 |
| Joseph H. Taylor Jr. | Physics | 1993 | Kip Stephen Thorne | Physics | 2017 |
| Susumu Tonegawa | Medicine | 1987 | Daniel C. Tsui | Physics | 1998 |
| Harold E. Varmus | Medicine | 1989 | Steve Weinberg | Physics | 1979 |
| Rainer Weiss | Physics | 2017 | Carl E. Wieman | Physics | 2001 |
| Eric F. Wieschaus | Medicine | 1995 | Torsten N. Wiesel | Medicine | 1981 |
| Frank Wilczek | Physics | 2004 | Robert Woodrow Wilson | Physics | 1978 |
| Michael W. Young | Medicine | 2017 | | | |
| | | | | | |

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: 5/22/2020 10:04:16 PM

To: Jacobs, Anna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e76eeb11df9a4024b53864ffac4c4c56-jacobsal]

CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Black, Jodi (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=782921b9f08249b59a582e93f6963f5f-blackj]; Lankford, David (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4f29a9bef672409d967e3aa5fb36e96a-lankford]

Subject: FW: EcoHealth Alliance re Termination of NIH Research Grant R01 Al 110964

Attachments: EcoHealth Alliance First-Level Appeal of NIH Grant Termination, dated May 22, 2020 (R01 Al 110964)

(02103179xA1AB5).PDF

Hi Anna – at some point we should discuss this.

Many thanks, Mike

(b)(6)From: "Matthew R.Torsiello" < Date: Friday, May 22, 2020 at 5:12 PM To: "Lauer, Michael (NIH/OD) [E]" < (b) (6) Cc: "Linde, Emily (NIH/NIAID) [E]" < (b) (6) "Stemmy, Erik (NIH/NIAID) [E]" (b) (6) "Nels T. Lippert" (b) (6) "Andrew N. Krinsky" < (b) (6) "Black, Jodi (NIH/OD) [E]" < < (b) (6) "Erbelding, Emily (NIH/NIAID) [E]" < (b) (6) "Bulls, Michelle G. (NIH/OD) [E]" < (b) (6) Peter Daszak (b) (6) Aleksei Chmura

Subject: EcoHealth Alliance re Termination of NIH Research Grant R01 Al 110964

Dr. Lauer:

Please see the attached letter from Andrew N. Krinsky on behalf of EcoHealth Alliance, Inc., pursuant to NIH Grants Policy Statement Section 8.7, regarding the decision by NIAID to terminate NIH Research Grant R01 Al 110964 on or about April 24, 2020.

Thank you.

Best,

Matthew R. Torsiello



Matthew R.Torsiello | Associate D: (b) (6) | F: 212-216-8001 (b) (6) | Bio

Tarter Krinsky & Drogin LLP 1350 Broadw ay | New York | NY | 10018 www.tarterkrinsky.com

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Tarter Krinsky & Drogin LLP 1350 Broadway New York, NY 10018 P 212.216.8000 F 212.216.8001 www.tarterkrinsky.com

Andrew N. Krinsky, Partner 212-216-8080, Direct Dial (b) (6)

May 22, 2020

Via Email, Certified Mail, & FedEx

(b) (6)

Michael S. Lauer, MD
NIH Deputy Director for Extramural Research
National Institutes of Health
National Institute of Allergy and Infectious Diseases
1 Center Drive, Building 1, Room 144
Bethesda, Maryland 20892

Re: Termination of NIH Grant 2R01 AI 110964-6

Dear Dr. Lauer:

This firm represents EcoHealth Alliance, Inc. ("EcoHealth Alliance") with regard to the post-award decision by the National Institute of Allergy and Infectious Diseases ("NIAID"), an Institute within the National Institute of Health ("NIH"), under the Department of Health and Human Services ("HHS"), to terminate the project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AI 110964, on April 24, 2020 (the "Termination").

This letter, pursuant to NIH Grants Policy Statement Section 8.7 and 42 CFR 50, Subpart D, constitutes EcoHealth Alliance's first-level appeal of the Termination, which was "for convenience." As set forth in more detail below, the Termination is not authorized under the NIH Grants Policy Statement, arbitrary and capricious and an indefensible attack on public health and welfare given that it undermines a pivotal 10-year research project involving the origins, spread and threat of emerging bat coronaviruses during the peak of an unprecedented worldwide coronavirus pandemic. Accordingly, EcoHealth Alliance hereby demands that grant 2R01 AI 110964-6 be reinstated immediately.

BACKGROUND

A. EcoHealth Alliance

EcoHealth Alliance is a prominent New York-based nonprofit institution dedicated to protecting the health of people, animals, and the environment from emerging zoonotic diseases. For more than a decade, EcoHealth Alliance has been conducting cutting edge scientific research to identify hundreds of new coronaviruses ("CoVs") in bats and to study the capacity of these viruses to infect human cells. The purpose of this research is to identify high risk populations so international actors can leverage their resources to address potential pandemics. In cooperation with a global network of over seventy partners, including academic institutions, intergovernmental

EcoHealth Alliance May 22, 2020 Page | 2

and governmental agencies, infectious disease surveillance laboratories, and other international and national organizations in over thirty countries, EcoHealth Alliance's work has led to numerous scientific papers published in high impact journals. These publications have been critical in raising awareness of the threat that CoVs pose to global health, the global economy, and U.S. National Security.

EcoHealth Alliance has a long history of successful cooperation with NIH including multiple Research Project Grant R01 awards. In particular, Peter Daszak, EcoHealth Alliance's President and Chief Scientist, has been the Principal Investigator on five multidisciplinary R01s. All of these projects used modeling, epidemiology, laboratory, and field science to test hypotheses on the emergence of wildlife-origin viral zoonoses, including SARS-CoV, the Nipah and Hendra viruses, Avian influenza, and other bat-origin viruses. EcoHealth Alliance, a 501(c)(3) organization, is unique in that it goes one step further by leveraging its research goals to create an alliance of international collaborators that can advocate for real-world changes to protect high risk populations.

Notably, in collaboration with virologists in China, EcoHealth Alliance isolated and characterized SARSr-CoVs from bats that use the same human host cell receptor (ACE2) as SARS-CoV. This work provided critical reagents and resources that have advanced scientific understanding of virus-host binding and contributed to vaccine development. For example, the genetic sequences of the bat viruses that EcoHealth Alliance discovered under its NIH research funding, which were published online (Genbank & GISAID), have been used to test the effectiveness of the drug Remdesivir against not only SARS-CoV, but also MERS, and other potentially zoonotic or pre-pandemic bat CoVs. Significantly, this type of testing can be performed without the need for viral cultures or shipping viruses internationally.

B. NIH Awards And Extends EcoHealth Alliance Research Grant R01 AI 110964

In 2014, NIH issued EcoHealth Alliance a five-year research award for the project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AI 110964 (the "Project"). EcoHealth Alliance received additional awards for the Project each year between 2015 and 2018. Between 2015 and 2019, the Project resulted in the publication of more than twenty papers.

In 2019, EcoHealth Alliance submitted a renewal application to NIH through NIAID to extend the Project period for an additional five years. Upon filing of its renewal application, the Project was ranked as an "extremely high priority" (in the top 3%) by NIAID during its external review process. In light of its success and the importance of EcoHealth Alliance's work, on July 24, 2019, NIH reauthorized grant R01 AI 110964 and increased EcoHealth Alliance's funding. EcoHealth Alliance was issued a notice of award in the amount of \$733,750.00 (the "2019 Award"). The notice of award also extended the Project period for an additional five years to 2024. A copy of the notice of award is attached hereto as Exhibit A.

C. EcoHealth Alliance Agrees Not To Fund The Wuhan Institute Of Virology

During the pendency of the Project, in December of 2019, China reported a cluster of cases of pneumonia in Wuhan, Hubei Province. It was later determined that the cause of this pneumonia

EcoHealth Alliance May 22, 2020 Page | 3

was a novel CoV, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), causing coronavirus disease (COVID-19). Thereafter, SARS-CoV-2 spread to nearly every country throughout the world. In response, EcoHealth Alliance has prioritized its efforts in conducting research that will be integral to developing an effective strategy to combat SARS-CoV-2.

On April 19, 2020, Michael S. Lauer, MD, NIH Deputy Director for Extramural Research, sent a letter to EcoHealth Alliance on behalf of NIH regarding a laboratory in China, the Wuhan Institute of Virology ("WIV"). WIV was a prior sub-recipient of a small portion of the R01 AI 110964 grant funds. The letter stated that, given allegations that COVID-19 "was precipitated by the release from WIV of the coronavirus responsible for COVID-19", NIH was pursuing suspension of WIV from participating in Federal programs. However, Mr. Lauer assured EcoHealth Alliance that "[t]his suspension of the sub-recipient does not affect the remainder of [EcoHealth Alliance's] grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension." A copy of the letter is attached hereto as Exhibit B.

On April 21, 2020, Dr. Daszak of EcoHealth Alliance responded by email to Dr. Lauer stating that he could "categorically state that no funds from [sic] 2R01 AI 110964-6 have been sent to Wuhan Institute of Virology, nor has any contract been signed." Dr. Daszak further represented that EcoHealth Alliance would comply with all NIAID requirements. Dr. Lauer acknowledged (1) that no monies from grant 2R01 AI 110964-6 had gone to WIV and no contract between EcoHealth Alliance and WIV had been signed and (2) EcoHealth Alliance's agreement that it would not provide any funds to WIV until and unless directed otherwise by NIH. A copy of the email correspondence between NIH and EcoHealth Alliance is attached hereto as Exhibit C.

D. NIH Abruptly Terminates Research Grant 2R01 AI 110964-6 "For Convenience"

Notwithstanding NIH's representation that suspension of WIV would not affect the remainder of EcoHealth Alliance's 2019 Award, on April 24, 2020, NIH notified EcoHealth Alliance by letter that, effective immediately, the 2019 Award had been terminated by NIAID. The stated grounds for the Termination were: (1) convenience; (2) NIH's discretion not to award a grant, or to award a grant at a particular funding level; and (3) NIH's belief that the Project outcomes did not align with the program goals and agency priorities. A copy of the Termination is attached hereto as Exhibit D.

ARGUMENT

A. NIH Research Grants Are Not Subject To Termination For Convenience

"Termination for convenience" refers to the exercise of the government's right to bring to an end the performance of all or part of the work provided for under a contract prior to the expiration of the contract "when it is in the Government's interest" to do so. Federal agencies typically incorporate clauses in their procurement contracts which give them the right to terminate for convenience. Here, there is no clause in the terms and conditions applicable to the 2019 Award, or in the NIH Grants Policy Statement, that permits NIAID or NIH to issue a post-award decision to terminate a NIH research grant award "for convenience."

EcoHealth Alliance May 22, 2020 Page | 4

Moreover, the unprecedented assertion by NIH that active research grants can be terminated "for convenience" during the subject budget period renders Section 8.5.2 of the NIH Grants Policy Statement meaningless. See, e.g., Li v. Eddy, 324 F.3d 1109, 1110 (9th Cir. 2003) (rejecting suggested statutory interpretation on the grounds that the interpretation ran squarely against the canon of construction that courts interpret statutes so as not to render any section meaningless). Section 8.5.2 of the NIH Grants Policy Statement governs, inter alia, modification or termination of an award for misconduct. If NIH grants were terminable for convenience, NIH could always choose to terminate for convenience to avoid (1) the "for cause" restriction on grant terminations and (2) the labor intensive task of enforcing compliance through disallowing costs, withholding further awards, or wholly suspending the grant, pending corrective action.

B. NIH's Discretion Not To Award A Grant, Or To Award a Grant At A Particular Funding Level, Does Not Authorize A Post-Award Decision To Terminate

NIH's discretion regarding the "decision not to award a grant, or to award a grant at a particular funding level" does not give NIH the authority to issue a post-award decision terminating a duly awarded grant during the budget period. This purported discretion, which is based on language in the last paragraph of NIH Grants Policy Statement Section 2.4.4, entitled *Disposition of Applications*, concerns NIH's authority to reject incomplete or otherwise undesirable grant applications in the first instance only. The provisions of Section 2, generally, have no bearing on post-award decisions affecting duly approved grants for which specified funds have already been allocated. As the 2019 Grant in the amount of \$733,750.00 was awarded to EcoHealth Alliance on July 24, 2019, NIH's authority to deny initial grant applications does not allow NIH to terminate the 2019 Grant.

C. The Research Goals Of EcoHealth Alliance And NIAID Are Virtually Identical

NIH's contention that the Project's outcomes do not align with the agency's priorities is demonstrably false. First, the Project was ranked as "extremely high priority" on external review by NIAID less than nine months ago, before the discovery of SARS-CoV-2. Since this discovery, NIH has promulgated new grants seeking applicants to conduct research on the same issues covered by the Project and the 2019 Award.

In addition, there is substantial overlap between the four strategic research priorities on page 1 of NIAID's Strategic Plan for COVID-19 Research, published April 22, 2020, and the three Specific Aims of the Project. Both NIAID and EcoHealth Alliance seek to: (1) improve fundamental knowledge of SARS-Cov-2; (2) develop methods to assess the rate of infection and disease incidence; (3) contribute to the development of an effective vaccine; and (4) increase public health preparedness. Copies of the Project's Specific Aims and the NIAID Strategic Plan's four strategic research priorities for COVID-19 research are attached hereto as Exhibit E.

D. There Is No Rational Basis To Terminate The 2019 Award For Cause

The grounds and procedures for suspension and termination of awards are specified in NIH Grants Policy Statement Section 8.5.2 and 45 CFR Parts 75.371 through 75.373. Notably, Section

EcoHealth Alliance May 22, 2020 Page | 5

8.5.2 provides, *inter alia*, that NIH will generally suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision. Through this lens, 45 CFR 75.372 provides that NIH may terminate a Federal award, in whole or in part, if: (1) the non-Federal entity fails to comply with the terms and conditions of the award; (2) for cause; (3) by the HHS awarding agency or pass-through entity with the consent of the non-Federal entity; or (4) by the non-Federal entity upon written notice to the HHS awarding agency setting forth the reasons for such termination, and other information. None of the foregoing predicate conditions exist here.

As of the date of the Termination, EcoHealth Alliance had not received any notice from NIH, NIAID, or HHS that it either failed to comply with any of the terms or conditions of the 2019 Award, or committed any misconduct in connection with the award. To the contrary, in email correspondence following EcoHealth Alliance's representation that it had not and would not give any funds from the 2019 Award to WIV, Aleksei Chmura, EcoHealth Alliance's Chief of Staff, memorialized the mutual agreement between NIH and EcoHealth Alliance that EcoHealth Alliance was in compliance with all requests. (Ex. C, #8). To be clear, EcoHealth Alliance clearly and unequivocally stated that it had not and will not distribute any funds from the 2019 Award to WIV.

In sum, there is no statutory, regulatory, or contractual basis for NIAID's termination of the Project, *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant 2R01 AI 110964-6. However, please note that this letter is not intended to provide an exhaustive list of all possible grounds for reversal of the Termination and may not reflect all arguments and claims that EcoHealth Alliance will assert in the event that a formal second-level appeal of the Termination is required.

Should you wish to present evidence in an effort to refute any of the factual assertions made in this letter and/or to engage in good faith negotiations regarding appropriate terms and conditions for the resumption of funding for grant 2R01 AI 110964-6, we are prepared to review such evidence and to participate in such negotiations.

We await your response to this letter.

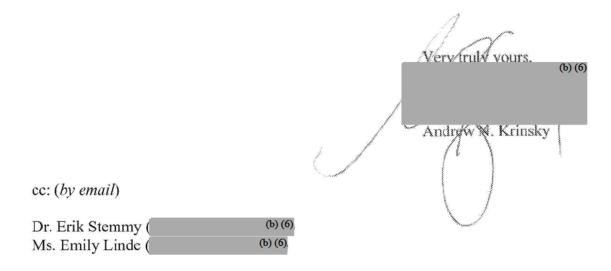


Exhibit A

Federal Award Date: 07/24/2019



NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 2R01Al110964-06 **FAIN:** R01Al110964

Principal Investigator(s): PETER DASZAK, PHD

Project Title: Understanding the Risk of Bat Coronavirus Emergence

Dr. Daszak, Peter PD/PI 460 West 34th Street Suite 1701 New York, NY 100012320

Award e-mailed to: (b) (6)

Period Of Performance:

Budget Period: 07/24/2019 – 06/30/2020 **Project Period:** 06/01/2014 – 06/30/2024

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$733,750 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to ECOHEALTH ALLIANCE, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI110964. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Tseday G Girma Grants Management Officer NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

SECTION I - AWARD DATA - 2R01AI110964-06





Approved Budget
Total Amount of Federal Funds Obligated (Federal Share)
TOTAL FEDERAL AWARD AMOUNT

\$733,750 \$733,750 \$733,750

AMOUNT OF THIS ACTION (FEDERAL SHARE)

\$733,750

| SUMMARY TOTALS FOR ALL YEARS | | | | |
|------------------------------|------------|-------------------|--|--|
| YR | THIS AWARD | CUMULATIVE TOTALS | | |
| 6 | \$733,750 | \$733,750 | | |
| 7 | \$709,750 | \$709,750 | | |
| 8 | \$709,750 | \$709,750 | | |
| 9 | \$709,750 | \$709,750 | | |
| 10 | \$709,750 | \$709,750 | | |

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name: Allergy and Infectious Diseases Research

CFDA Number: 93.855

EIN: 1311726494A1

Document Number: RAI110964B

PMS Account Type: P (Subaccount)

Fiscal Year: 2019

| IC | CAN | 2019 | 2020 | 2021 | 2022 | 2023 | |
|----|---------|-----------|-----------|-----------|-----------|-----------|--|
| AL | 8472364 | \$733,750 | \$709.750 | \$709.750 | \$709.750 | \$709.750 | |

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:

PCC: M51C B / OC: 414B / Released: (b) (6) 07/18/2019

Award Processed: 07/24/2019 12:03:26 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 2R01AI110964-06

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III - TERMS AND CONDITIONS - 2R01AI110964-06

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.

- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01Al110964. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

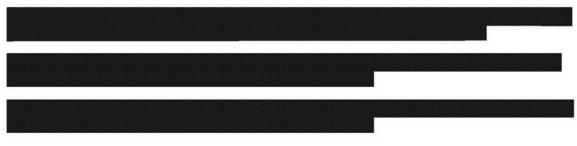
Treatment of Program Income:

Additional Costs

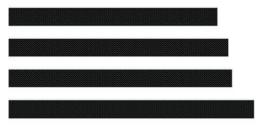
SECTION IV - AI Special Terms and Conditions - 2R01Al110964-06

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.



The Research Performance Progress Report (RPPR), Section G.9 (Foreign component), includes reporting requirements for all research performed outside of the United States. Research conducted at the following site(s) must be reported in your RPPR:



This award reflects current Federal policies regarding Facilities & Administrative (F&A) Costs for foreign grantees including foreign sub-awardees, and domestic awards with foreign sub-awardees. Please see: Chapter 16 Grants to Foreign Organizations, International Organizations, and Domestic Grants with Foreign Components, <u>Section 16.6 "Allowable and Unallowable Cost"</u> of the NIH Grants Policy.

This award may include collaborations with and/or between foreign organizations. Please be advised that short term travel visa expenses are an allowable expense on this grant, if justified as critical and necessary for the conduct of the project.

The budget period anniversary start date for future year(s) will be July 1.

Dissemination of study data will be in accord with the Recipient's accepted genomic data sharing plan as stated in the page(s) **203** of the application. Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIAID may result in Enforcement Actions as described in the NIH Grants Policy Statement.

This award is subject to the Clinical Terms of Award referenced in the NIH Guide for Grants and Contracts, July 8, 2002, NOT Al-02-032. These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address: https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Award.

Awardees who conduct research involving Select Agents (see 42 CFR 73 for the Select Agent list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens at http://www.selectagents.gov/Regulations.html) must complete registration with CDC (or APHIS, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.

Prior to conducting a restricted experiment with a Select Agent or Toxin, awardees must notify the NIAID and must request and receive approval from CDC or APHIS.

Select Agents:

Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:

NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)

(http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.

When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- o A list of the new and/or additional Agent(s) that will be studied;
- o A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- o The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Tseday G Girma

Email: (b) (6) Phone: (b) (6) Fax: 301-493-0597

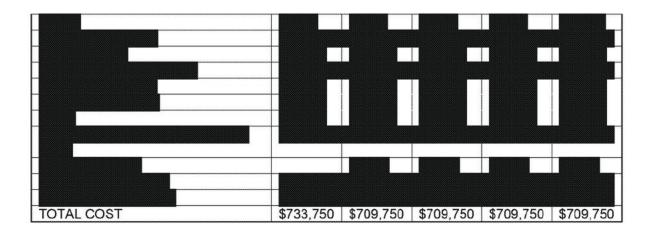
Program Official: Erik J. Stemmy

Email: (b) (6) Phone: (b) (6)

SPREADSHEET SUMMARY

GRANT NUMBER: 2R01Al1110964-06

INSTITUTION: ECOHEALTH ALLIANCE, INC.



| Facilities and Administrative Costs | Year 6 | Year 7 | Year 8 | Year 9 | Year 10 |
|-------------------------------------|-----------|-----------|-----------|-----------|-----------|
| F&A Cost Rate 1 | 32% | 32% | 32% | 32% | 32% |
| F&A Cost Base 1 | \$438,711 | \$363,711 | \$363,711 | \$363,711 | \$363,711 |
| F&A Costs 1 | \$140,388 | \$116,388 | \$116,388 | \$116,388 | \$116,388 |

Exhibit B

Date: April 19, 2020

From: Michael S Lauer, MD

NIH Deputy Director for Extramural Research

Lauer, Michael Digitally signed by Lauer, Michael (NIH/OD) [E] (NIH/OD) [E]

Date: 2020.04.19 10:47:40

To: Kevin Olival, PhD

Vice-President for Research

EcoHealth Alliance

Naomi Schrag, JD

Vice-President for Research Compliance, Training, and Policy

Columbia University

Subject: Project Number 2R01AI110964-06

Dear Dr. Olival and Ms. Schrag:

EcoHealth Alliance, Inc. is the recipient, as grantee, of an NIH grant entitled "Understanding the Risk of Bat Coronavirus Emergence." It is our understanding that one of the sub-recipients of the grant funds is the Wuhan Institute of Virology ("WIV"). It is our understanding that WIV studies the interaction between corona viruses and bats. The scientific community believes that the coronavirus causing COVID-19 jumped from bats to humans likely in Wuhan where the COVID-19 pandemic began. There are now allegations that the current crisis was precipitated by the release from WIV of the coronavirus responsible for COVID-19. Given these concerns, we are pursuing suspension of WIV from participation in Federal programs.

While we review these allegations during the period of suspension, you are instructed to cease providing any funds from the above noted grant to the WIV. This temporary action is authorized by 45 C.F.R. § 75.371(d) ("Initiate suspension or debarment proceedings as authorized under 2 C.F.R. part 180"). The incorporated OMB provision provides that the funding agency may, through suspension, immediately and temporarily exclude from Federal programs persons who are not presently responsible where "immediate action is necessary to protect the public interest." 2 C.F.R. § 180.700(c). It is in the public interest that NIH ensure that a sub-recipient has taken all appropriate precautions to prevent the release of pathogens that it is studying. This suspension of the sub-recipient does not affect the remainder of your grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension.

Exhibit C

1 Michael Lauer email 20 April 2020

From: Lauer, Michael (NIH/OD) [E] (b) (6) Sent: Sunday, April 19, 2020 11:00 AM ^{டு்டு}; Naomi Schrag (b)(6)To: Cc: Black, Jodi (NIH/OD) [E] Subject: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06 Importance: High Dear Dr. Olival and Ms. Schrag Please see attached. (Referring to Exhibit B) Many thanks, Mike Michael S Lauer, MD NIH Deputy Director for Extramural Research 1 Center Drive, Building 1, Room 144

Bethesda, MD 20892

(b)(6)

(b) (6)

Phone

Email:

2 Kevin Olival email on 20 April 2020

| Date : April 20, 2020 at 4:12:28 PM EDT To : "Lauer, Michael (NIH/OD) [E]" < | (b) (6) edge receipt Actions needed regarding a (b) (6) (r) (Black, Jodi (NIH/OD) [E]" | _ |
|---|--|--|
| Dear Mike, | | |
| I received the attached letter, however please | note: | |
| I am not the PI on this award. You should colleading this project for EcoHealth Alliance. Columbia University is not involved in this Pincluded. | ontact Dr. Peter Daszak NIH project, and it is not clear to me why Naomi a | who is the PI and and Columbia University were |
| Thank you, | | |

Kevin J. Olival, PhD

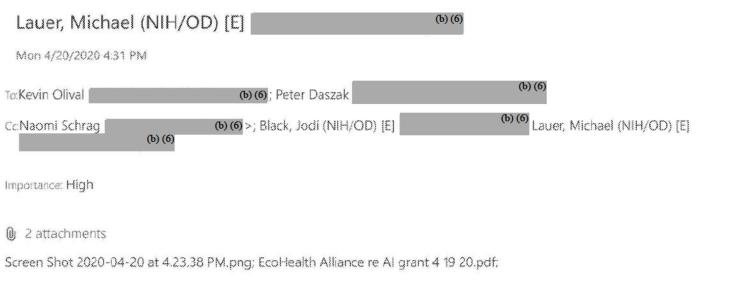
Kevin

Vice President for Research

EcoHealth Alliance 460 West 34th Street, Suite 1701 New York, NY 10001

(direct)
(mobile)
1.212.380.4465 (fax)
www.ecohealthalliance.org

Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06



Thank you Kevin

Best. Mike

- We need to work with a senior responsible business official usually PI's and senior business officials are different people.
- When I looked you up on the web, I see the Columbia logo (see attached screenshot). Specifically, it
 appears to be Columbia University > Ecology, Evolution, and Environmental Biology > EcoHealth
 Alliance (labeled as an "Affiliation/Department"). Thus the web profile makes it look to me as if
 EcoHealth Alliance is linked to Columbia University.
- In any case, I'm looping in Dr. Daszak.
- We need to know all sites in China that have been in any way linked to this award (Type 1 and Type
 We have data in NIH, but we want to make absolutely sure that we're of the same understanding.

We greatly appreciate your prompt attention to this matter.

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone:
(b) (6)
Email: (b) (6)

Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06 4 Michael Lauer email on 20 April 2020

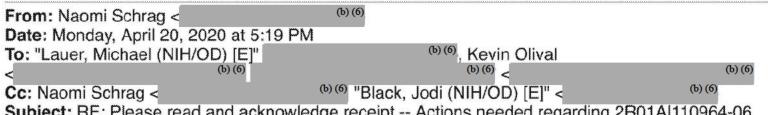
| Lauer, Michael (NIH/C | DD) [E] | (b) (6) | |
|----------------------------------|-------------------------|----------------------|---------|
| Mon 4/20/2020 6:34 PM | | | |
| To:Naomi Schrag | (6) (6) Kevin Olival | (b) (6) Peter Daszak | (b) (6) |
| CcBlack, Jodi (NIH/OD) [E] | (NIH | (b) (6) | |
| 1 attachment | | | |
| Screen Shot 2020-04-20 at 4.23.3 | 38 PM.ong: | | |

Thanks Naomi - not the impression an observer would get looking at the website (see screen shot), but we understand about the grant.

If they "are entirely separate entities" then why does Columbia identify EcoHealth Alliance as an "Affiliation/Department" on its website.

Maybe with the label "Affiliation/Department" you would have a clearly visible disclaimer that says, "EcoHealth Alliance is not affiliated with nor a department of Columbia"? - although even that is internally contradictory.

Best, Mike



Subject: RE: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06

Dear Dr. Lauer,

Columbia and EcoHealth Alliance are entirely separate entities. Some individuals affiliated with EcoHealth Alliance do have adjunct appointments in Columbia's Ecology, Evolution, and Environmental Biology ("E3B") department, but we are not aware of any Columbia involvement with the referenced grant, and have found no agreement or record in our grants system to the contrary.

We would be happy to answer any additional questions. Thank you. Sincerely, Naomi Schrag

Naomi J. Schrag

Vice President for Research Compliance, Training and Policy Office of Research Compliance and Training 475 Riverside Drive, Suite 840

New York, New York 10115

(b) (6)

www.researchcompliance.columbia.edu

RE: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06 5 Peter Daszak email on 21 April 2020

| | Peter Daszak | | | |
|-------|---|---------|------------------------|------------------------------|
| | Tue 4/21/2020 1:32 AM | | | |
| and a | c:Lauer, Michael (NIH/OD) [E] < <olival@ecohealthalliance.org>;</olival@ecohealthalliance.org> | ž. | (b) (6) Naomi Schrag < | (b) (б >; Kevin Oliva |
| (| teBlack, Jodi (NIH/OD) [E] ≺ | (b) (6) | | |

Dear Michael Lauer & Jodi Black — I now have your email and will deal with it directly with you and your staff. Naomi is correct that there is no involvement of Columbia University in this grant. I'm sure NIH has records to confirm that.

From this moment on, I will not cc any staff at Columbia as part of this discussion, and I hope you will also honor that. Respecfully, the discussion of whether or not EHA is an affiliate of CU is entirely irrelevant to the request that you contacted us about, and should remain a private matter between EcoHealth Alliance and Columbia University.

I'll look over your email and respond tomorrow.

Cheers.

Peter

Peter Daszak

President

EcoHealth Alliance 460 West 34th Street New York, NY 10001 USA

Tel.: + (b) (6)

Website: www.ecohealthalliance.org

Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

RE: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

6 Peter Daszak email on 21 April 2020

| Peter Daszak | | |
|---|------------------|---------|
| Tue 4/21/2020 7:03 PM | | |
| To:Lauer, Michael (NIH/OD) [E] < | (b) (6) | |
| CcBlack, Jodi (NIH/OD) (E) (b) (6) | ; Aleksei Chmura | (b) (6) |
| Stemmy, Erik (NIH/NIAID) [E] | | (b) (6) |
| Importance: High | | |
| 1 attachment | | |
| EcoHealth Alliance re Al grant 4 19 20.pdf; | | |

Dear Michael – Confirming receipt of your email. I'm also cc'ing the following people so they're aware of this request:

- 1. Our AOR Dr. Aleksei Chmura, who has access to all our records
- My Program Officer for this award, Dr. Erik Stemmy & the Division Director (DMID), Dr. Emily Erberding, so they are informed and aware of the request and our response.

That said we need some time to go through the request for information and will provide this as quickly as we can.

However, I can categorically state that no funds form 2R01Al110964-06 have been sent to Wuhan Institute of Virology, nor has any contract been signed. Furthermore, we will comply with NIAID requirements, of course.

Concerning the request for information on all of the sites linked to this award in China, you should be aware that these are documented in our progress reports over the course of the grant. As you can understand we are under enormous pressure to generate data related to the current pandemic, and we do not want to divert staff to this effort. We are hoping the previously filed reports will satisfy this request.

We are well aware of the political concerns over the origins of this outbreak. Our collaboration with Wuhan Institute of Virology has been scientific and we have been consistently impressed with the scientific capabilities of that laboratory and its research staff. Our joint work has led to a series of critical papers published in high impact journals that served to raise awareness of the future threat coronaviruses pose for global health and therefore US national security. Scientific insights with epidemiological significance have been jointly published and our relationship has always been open and transparent and with one concern only, scientific validity. We are concerned that current actions may jeopardize 15 years of fruitful collaboration with colleagues in Wuhan, who are working at the leading edge to design vaccines and drugs that could help us fight this new threat in future years. It is quite remarkable that of the 5 vaccine candidates listed by WHO that are already in human trials, 3 have been developed in China. That said, we of course will

do all we can to make sure any further questions from NIH or any Federal agency are addressed to our fullest knowledge.

Yours sincerely,

Peter Daszak

President

EcoHealth Alliance 460 West 34th Street New York, NY 10001 USA

Tel.: (b) (6)

Website: www.ecohealthalliance.org

Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

7 Michael Lauer email on 21 April 2020

| From: | Lauer, Michael (NIH/OD) [E] | (b) (6) | | |
|----------|--------------------------------|------------------------------------|--|---|
| Subject: | Re: Please read and acknowledg | ge receipt Actions needed regardin | g 2R01Al110964-06 | |
| Date: | April 21, 2020 at 19:28 | | | 8 |
| To: | Peter Daszak | (b) (6) | | |
| Co: | Black, Jodi (NIH/OD) [E] | (b) (6), Aleksei Chmura | (b) (б)g, Stemmy, Erik (NIH/NIAID) [E] | |
| | | , Emily (NIH/NIAID) [E] | (b) (6), Lauer, Michael (NIH/OD) [E] | |
| | (b) (6) | | | |

Many thanks Peter for your response.

We note that:

- No monies have gone to WIV on the Type 2 award and no contract has been signed.
- You agree that you will not provide any funds to WIV until and unless directed otherwise by NIH.
- All foreign sites for the Type 1 and Type 2 awards have been documented in the progress reports submitted to NIH.

We appreciate your working with us.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)

8 Aleksei Chmura email on 21 April 2020

From: Aleksei Chmura (b) (6)

Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06

Date: April 23, 2020 at 13:50

To: Lauer, Michael (NIH/OD) [E] (b) (6)

Cc: Peter Daszak (b) (6) 3, Black, Jodi (NIH/OD) [E] (b) (6) Erik Stemmy (b) (6),

Erbelding, Emily (NIH/NIAID) [E] (b) (6)

Dear Mike,

I read that we are in agreement and in compliance with all requests. Please let us know if anything further is required. We will continue in our usual close communication with our Program Officer Erik Stemmy.

Sincerely,

-Aleksei

Aleksei Chmura

Chief of Staff & Authorized Organizational Representative

EcoHealth Alliance 460 West 34th Street, Suite 1701 New York, NY 10001

(b) (6) (office) (mobile) www.ecohealthalliance.org

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation.



From: Lauer, Michael (NIH/OD) [E] michael.lauer@nih.gov

Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06

Date: April 23, 2020 at 13:59

To: Aleksei Chmura (b) (6)

Cc: Peter Daszak (b) (6) Black, Jodi (NIH/OD) [E] (b) (6) Stemmy, Erik (NIH/NIAID) [E]

(b) (6), Erbelding, Emily (NIH/NIAID) [E] (b) (6) Lauer, Michael (NIH/OD) [E]

(b) (6) Compliance Review (b)

Many thanks Aleksei.

9 Michael Lauer email on 21 April 2020

Best, Mike



From: Lauer, Michael (NIH/OD) [E] (b) (6)

Subject: PLEASE READ -- Re: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06

Date: April 24, 2020 at 16:47

To: Aleksei Chmura (b) (6), Peter Daszak (Ce: Black, Jodi (NIH/OD) [E] (b) (6), Stemmy, Erik (NIH/I

(b) (6), Stemmy, Erik (NIH/NIAID) [E] (b) (6),

Erbelding, Emily (NIH/NIAID) [E] (b) (6), Linde, Emily (NIH/NIAID) [E] (b) (6)

Lauer, Michael (NIH/OD) [E] (b) (6), Bulls, Michelle G. (NIH/OD) [E] (b)

10 Michael Lauer email on 24 April 2020

(b) (6)

Dear Dr. Chmura and Dr. Daszak

Please see attached. (Referring to Exhibit D)

Sincerely, Michael S Lauer, MD

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)

Email: (b) (6)



From: Aleksei Chmura (b) (6)

Subject: Re: PLEASE READ -- Re: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06

Date: April 27, 2020 at 23:57

To: Lauer, Michael (NIH/OD) [E] (b) (6)

Cc: Peter Daszak (b) (6) Black, Jodi (NIH/OD) [E] (b) (6), Erik Stemmy (b) (6) Emily Erbelding (b) (6), Linde, Emily (NIH/NIAID) [E] (b) (6), Bulls, Michelle G. (NIH/OD) [E]

(b) (6), Alison Andre (b) (6)

(F) (F) Fusions Fusion

Dear Michael,

Could Peter and I have a quick chat with you sometime tomorrow (Tuesday) about your email, below?

Sincerely,

11 Aleksei Chmura email on 27 April 2020

-Aleksei

Aleksei Chmura, PhD Chief of Staff

EcoHealth Alliance 460 West 34th Street, Suite 1701 New York, NY 10001

(b) (6) (office) (mobile) (www.ecohealthalliance.org

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation.

Exhibit D



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

24 April 2020

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

Re: Termination of NIH Grant R01 AI 110964

Dear Drs. Chmura and Daszak:

I am writing to notify you that the National Institute of Allergy and Infectious Diseases (NIAID), an Institute within the National Institutes of Health (NIH), under the Department of Health and Human Services (HHS) has elected to terminate the project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 Al110964, for convenience. This grant project was issued under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284). This grant was funded as a discretionary grant as outlined in the NIH Grants Policy Statement, which states that the decision not to award a grant, or to award a grant at a particular funding level, is at the discretion of the agency, in accordance with NIH's dual review system.

At this time, NIH does not believe that the current project outcomes align with the program goals and agency priorities. NIAID has determined there are no animal and human ethical considerations, as this project is not a clinical trial, but rather an observational study.

As a result of this termination, a total of \$369,819.56 will be remitted to NIAID and additional drawdowns will not be supported. The remaining funds have been restricted in the HHS Payment Management System, effective immediately.

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

Sincerely,

Lauer, Michael (NIH/OD) [E] Obj. (8) Ob

Michael S Lauer, MD

NIH Deputy Director for Extramural Research

Email: (b) (6)

cc: Dr. Erik Stemmy Ms. Emily Linde



Exhibit E

SPECIFIC AIMS

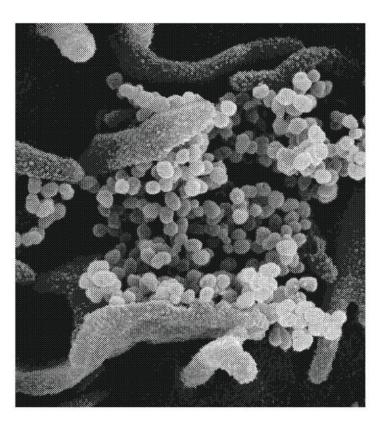
Zoonotic coronaviruses are a significant threat to global health, as demonstrated with the emergence of Severe Acute Respiratory Syndrome coronavirus (SARS-CoV) in 2002, and the continuing spread of Middle East Respiratory Syndrome (MERS-CoV). The wildlife reservoirs of SARS-CoV were identified by our group as bat species, and since then we have sequenced dozens of novel SARS-related CoV (SARSr-CoV) strains. Our previous R01 work demonstrates that bats in southern China harbor an extraordinary diversity of SARSr-CoVs, some of which are able to use human ACE2 to enter into human cells, can infect humanized mouse models to cause SARS-like illness, and evade available therapies or vaccines. We found that the bat hosts of SARSr-CoVs appear to no longer be traded in wildlife markets, and that people living close to bat habitats are the primary risk groups for spillover. At one of these sites, we found diverse SARSr-CoVs containing every genetic element of the wild-type SARS-CoV genome, and serological evidence of human exposure among people living nearby. Thus, there is significant potential for future spillover of SARSr-CoVs, and of public health impacts. Yet salient questions remain: Are there specific bat communities and sites that harbor CoV strains with higher risk for bat-to-human spillover? Which human behaviors drive risk of bat SARSr-CoV exposure that could lead to infection? Does human exposure to these viruses cause SARSlike or other illness? Can we characterize viral strain diversity, bat traits and human behaviors to assess risk of potential future CoV spillover? The proposed work in this renewal R01 builds on these findings to address these issues by conducting: 1) focused sampling of bats in southern China to identify viral strains with high predicted risk of spillover; 2) community-based, and clinic-based syndromic, sampling of people to identify spillover, and assess behavioral risk factors and evidence of illness; and 3) conduct in vitro and in vivo viral characterization and analyze epidemiological data to identify hotspots of future CoV spillover risk. This work will follow 3 specific aims:

<u>Aim 1:</u> Characterize the diversity and distribution of high spillover-risk SARSr-CoVs in bats in southern China. We will conduct targeted bat sampling at sites where we predict that undiscovered high risk SARSr-CoV strains exist. Bat sampling will be targeted geographically and by host species to test predictions about evolutionary diversity of SARSr-CoV. We will analyze RdRp and S protein sequences to test their capacity for spillover to people in Aim 3.

<u>Aim 2:</u> Community- and clinic-based surveillance to capture SARSr-CoV spillover, routes of exposure and potential public health consequences. We will conduct focused, targeted human surveys and <u>sampling to identify key risk factors for SARSr-CoV spillover and evidence of illness.</u> To maximize our opportunity of capturing human exposure to bat CoVs, we will conduct <u>community-based surveillance</u> in regions with high SARSr-CoV prevalence and diversity, and individuals having contact with bats. We will assess bat-CoV seropositive status against a small number of questions about human-wildlife contact and exposure. We will conduct <u>clinic-based syndromic surveillance</u> close to these sites to identify patients presenting with influenzalike illness and severe acute respiratory illness, assess their exposure to bats via a questionnaire, and test samples for PCR- and serological evidence of SARSr-CoV infection. We will conduct follow-up sampling to capture patients who had not yet seroconverted at the time of clinic visit.

<u>Aim 3</u>: *In vitro* and *in vivo* characterization of SARSr-CoV spillover risk, coupled with spatial and phylogenetic analyses to identify the regions and viruses of public health concern. We will characterize the propensity of novel SARSr-CoVs to infect people *in vitro* using primary human airway epithelial cells and *in vivo* using the transgenic hACE2 mouse model. We will use mAb and vaccine treatments to test our hypothesis that SARSr-CoVs with 10-25% divergence in S protein sequences from SARS-CoV are <u>likely able to infect human cells</u>, and to evade mAb therapeutics and vaccines. We will then map the geographic distribution of their bat hosts and other ecological risk factors to <u>identify the key 'hotspots' of risk for future spillover</u>.

Overall, our SARSr-CoV program serves as a model platform to integrate virologic, molecular and ecologic factors contributing to CoV emergence while informing high impact strategies to intervene and prevent future pandemics. This includes providing critical reagents, therapeutic interventions and recombinant viruses for future SARSr-CoV pandemic and public health preparedness.



This scanning electron microscope image shows SARS-CoV-2 (yellow), the virus that causes COVID-19, isolated from a patient in the United States, emerging from the surface of cells (pink) cultured in the lab. Credit: NIAID-RML

NIAID STRATEGIC PLAN FOR COVID-19 RESEARCH

FY2020 - FY2024 April 22, 2020





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Executive Summary

The National Institute of Allergy and Infectious Diseases (NIAID) at the United States (U.S.) National Institutes of Health (NIH) is committed to safeguarding the health of Americans and people around the world by accelerating research efforts to prevent, diagnose, and treat COVID-19 and characterize the causative agent of this disease, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This

NIAID Strategic Plan for COVID-19 Research builds on current trans-NIAID efforts to better understand SARS-CoV-2 pathogenesis, transmission, and mechanisms of protective immunity by expanding resources and activities that support rapid development of biomedical tools to more effectively combat this disease and pandemic. Given the urgency of the public health response, studies that inform efforts to control virus

Box 1 NIAID Strategic Plan for COVID-19 Research Mission

Conduct and support research on SARS-CoV-2 and COVID-19 to accelerate the development of safe and effective medical countermeasures that decrease disease incidence, mitigate morbidity and prevent mortality.

spread and mitigate morbidity and mortality, including therapeutic and vaccine development, are the priority. In addition, it is essential to develop rapid, accurate, point-of-care diagnostics—a critical asset to mitigating the spread of COVID-19.

The NIAID Strategic Plan for COVID-19 Research aligns with the priorities set by U.S. Government—wide task forces for the development of medical countermeasures. NIAID actively participates in COVID-19 task forces to identify opportunities, ensure open communication, encourage resource sharing, and avoid duplication of effort. The plan is structured around four strategic research priorities:

- Improve fundamental knowledge of SARS-CoV-2 and COVID-19, including studies to characterize
 the virus and how it is transmitted and understand the natural history, epidemiology, host
 immunity, disease immunopathogenesis, and the genetic, immunologic, and clinical associations
 with more severe disease outcomes. This includes accelerating the development of small and large
 animal models that replicate human disease.
- Support the development of diagnostics and assays, including point-of-care molecular and antigen-based diagnostics for identifying and isolating COVID-19 cases and serologic assays to better understand disease prevalence in the population. Diagnostics also will be essential for evaluating the effectiveness of candidate countermeasures.
- Characterize and test therapeutics, including identifying and evaluating repurposed drugs and novel broad-spectrum antivirals, virus-targeted antibody-based therapies (including plasma-derived intravenous immunoglobulin (IVIG) and monoclonal antibodies), and host-directed strategies to combat COVID-19.
- 4. Develop safe and effective vaccines against SARS-CoV-2, including support of clinical trial testing.

To accelerate research, NIAID will leverage current resources and global collaborations, including existing research programs and clinical trials networks. NIAID's research response to COVID-19 will build on experience with diseases caused by other zoonotic coronaviruses (CoVs), including severe acute

respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). NIAID will pursue public-private partnerships to facilitate the translation of research outcomes into life-saving public health interventions. Working with pharmaceutical companies, NIAID has already initiated Phase 1 clinical trials for candidate COVID-19 vaccines and therapeutics. A concerted effort will be made to include minority populations, as well as at-risk and vulnerable populations, in all aspects of NIAID-sponsored research to address health disparities between diverse groups. Characterization of the fundamental virology of SARS-CoV-2 and the immunological response to infection will inform future studies and facilitate the development of effective medical countermeasures. With collaboration from all agencies within the U.S. government and other key U.S. and global partners, NIAID will rapidly disseminate these results so that the information can be translated into clinical practice and public health interventions to combat the pandemic. As such, NIAID has already implemented open sharing of scientific data through publicly available websites and will continue to promote the prompt disclosure of SARS-CoV-2 and COVID-19 research data by the scientific community.

Research Plan

Priority 1: Improve fundamental knowledge of SARS-CoV-2 and COVID-19

Developing effective medical and public health countermeasures against a newly emergent virus like SARS-CoV-2 will require a better understanding of the complex molecular and immune mechanisms underlying infection and disease. Studies that delineate the viral lifecycle and host immune responses to infection can lead to the identification of novel targets for intervention against SARS-CoV-2 infection and COVID-19. Early studies suggest that the clinical manifestations of COVID-19 can vary significantly, and disease severity can range from mild to critical. Thus, a detailed understanding of the clinical course of disease, as well as the clinical, virologic, immunological, and genetic predictors of disease severity, are needed. Gaps also exist in our understanding of the dynamics of disease transmission in different populations over time, including the role of pediatric and elderly populations in viral spread, and the potential seasonality of viral circulation.

Objective 1.1: Characterize fundamental SARS-CoV-2 virology and immunological host response to infection

- Support the development and distribution of reagents and viral isolates to researchers. NIAID will
 continue to support both intramural and extramural researchers by developing reagents and assays
 for virus characterization and immunological analyses. NIAID will continue to accelerate SARS-CoV-2
 research by sourcing viral isolates and clinical specimens for the research community and placing
 them in repositories to help advance research and countermeasure development. In addition, NIAID
 - will place other critical reagents needed for assay development (e.g., pseudovirions and antigens) in publicly available repositories for distribution.
- Characterize virus biology and immunological responses to disease. A comprehensive understanding of the

Box 2

Priority 1: Improve fundamental knowledge of SARS-CoV-2 and COVID-19

Objective 1.1: Characterize fundamental SARS-CoV-2 virology and immunological host response to infection Objective 1.2: Evaluate disease dynamics through natural history, transmission, and surveillance studies

Objective 1.3: Develop animal models that recapitulate human disease

biological processes involved in SARS-CoV-2 infection and the pathogenesis of COVID-19 are paramount to developing new medical countermeasures to fight the spread of disease. Building on prior research related to MERS and SARS coronaviruses, early studies confirmed several critical features of SARS-CoV-2 infection, including the primary host receptor, angiotensin converting enzyme 2 (ACE-2), and the structure of the virus receptor-binding domain. Studies that delineate the viral lifecycle and host immune responses to infection can lead to the identification of novel targets for intervention against SARS-CoV-2 infection and COVID-19. Understanding the function of essential viral proteins will be necessary for improving diagnostic and immunological assays, *in vitro* and *in vivo* models, and other resources needed to advance safe and effective medical countermeasure development. In addition, evaluating the dynamics of host-pathogen interactions at the molecular and cellular levels will be critical to advancing our understanding of viral pathogenesis and immune responses that contribute to SARS-CoV-2 infection.

- Determine viral evolution and molecular epidemiology. With a newly emergent virus like SARS-CoV-2, studies to characterize genetic diversity, including those that assess the potential for the virus to evolve and escape host immunity, are pivotal for understanding disease progression and transmission dynamics and may have implications for countermeasure development. Viral genomic analysis matched with patient clinical data will be important to identify biomarkers of virulence and establish paradigms of sequence diversity. In addition, evaluating viral sequence associations with disease outcomes, immune status, and viral replication will provide crucial data to accelerate the development of effective medical countermeasures.
- Develop low-containment assays to study virus neutralization. Studies using non-infectious
 pseudovirions can be conducted in labs without BSL-3 capacity, making them an important tool to
 enhance understanding of SARS-CoV-2 infection. This capability would enable researchers without
 high-containment infrastructure to study the dynamics of virus neutralization in vitro.
- Research into optimal public health prevention and mitigation modalities. Clinical trials including
 family members of a COVID-19 positive individual can be devised to evaluate transmission,
 prevention, and other mitigation measures within the household.

Objective 1.2: Evaluate disease dynamics through natural history, transmission, and surveillance studies

• Characterize disease incidence through surveillance studies. Clinical manifestations of COVID-19 can vary greatly, ranging from asymptomatic or mildly symptomatic to the development of pneumonia, acute respiratory distress syndrome, and even death. The variation in clinical presentation of COVID-19, combined with the challenges in diagnostic capacity, have made accurate initial assessments of disease incidence a formidable challenge. However, rapid point-of-care and point-of-need molecular tests, which became available in March 2020, will enable hospitals and other healthcare facilities to make informed decisions regarding patient isolation and care. Studies that leverage existing high-throughput diagnostic capacity along with these rapid tests will advance our understanding of disease incidence across the nation and will be a critical component of strategies to implement effective medical countermeasures. Combining these studies with broad serosurveillance studies across existing surveillance networks, including blood bank studies, would

3

¹ Wu Z and McGoogan JM. JAMA 2020 Feb 24. Epub. PMID 32091533.

provide a more complete picture of the scope of disease and the dynamics of infection. Detailed knowledge of host genetics and the human responses to infection across the lifespan will not only provide insights into new approaches for diagnosis, treatment, and prevention, but also may elucidate why individuals respond to SARS-CoV-2 in different ways. Reports to date suggest that COVID-19 resolves in most cases, implying that the immune system can keep the infection from progressing to severe disease in many individuals. However, additional research is needed to better understand why some people progress to severe disease, which will lend critical insights to medical countermeasure development.

- Assess the dynamics of disease transmission. Our current understanding of COVID-19 transmission is limited. While recent studies have suggested timeframes for virus survival in aerosols and on surfaces,³ the contributions of different routes of transmission and the dynamics of animal-tohuman and human-to-human transmission remain unclear. The diverse clinical presentations of COVID-19, including a high prevalence of asymptomatic cases, add further complexity to understanding transmission dynamics. Providing a clearer picture of the natural history of viral shedding is a priority, both in acute cases and in asymptomatic infection. Given the challenges of accurately diagnosing asymptomatic individuals because they do not present for treatment, determining the role they play in transmission would provide valuable insights. Elucidating the role of pediatric cases in the spread of SARS-CoV-2 is particularly important. Although pediatric COVID-19 cases are generally asymptomatic or have less severe clinical manifestations than those of adults, the role that children play in spreading the virus is unknown. Additionally, studies to identify potential animal reservoirs and better understand transmission from animals to humans are a research priority, as these reservoirs may lead to future virus introductions and re-emergence of disease in humans. Virus transmission depends on a complex interplay of host, viral, and environmental factors that contribute to disease incidence and spread. Identifying the factors that maintain the disease transmission cycle is critical to developing effective medical countermeasures and public health interventions that will prevent future pandemics.
- Determine disease progression through natural history studies. Delineating the natural history of COVID-19 will inform immunopathogenesis, viral tropisms and length of shedding, immune phenotypes, and both protective immunity and host susceptibility. Disease assessment using longitudinal cohort studies, including among high-risk populations such as healthcare workers and the elderly, are important to better understand disease pathogenesis and immune responses to infection. Biomarkers identified from these studies may provide valuable insights into predictors of disease severity.

Objective 1.3: Develop animal models that recapitulate human disease

• Develop small and large animal models that replicate SARS-CoV-2 pathogenesis. Developing animal models that recapitulate human disease is a vital early step toward understanding disease pathogenesis and testing the efficacy of medical countermeasures. Small animal models enable rapid, scalable analyses that are particularly valuable for screening countermeasure candidates for efficacy and addressing issues concerning vaccine-induced immune enhancement. Among the small animal models being tested, transgenic mice expressing the human ACE-2 receptor are a promising candidate. In parallel, development and characterization of large animal models, including non-human primates (NHPs) that mimic human COVID-19, are a pivotal step to advance promising

. . .

² ibid.

³ van Doremalen *N et al. N Engl J Med* 2020 Mar 17. Epub. PMID 32182409.

countermeasure candidates. Previous experience with related coronavirus diseases such as MERS and SARS suggests that replicating human disease, particularly its more severe manifestations, in an animal model may be challenging. Fundamental research assessing animal models ranging from mice to NHPs is already underway. NIAID will continue to support the development of small and large animal model candidates to better understand this emerging infection and investigate optimal ways to treat and prevent COVID-19. NIAID also will ensure that validated animal models are made available to the scientific community for evaluating priority countermeasures.

Priority 2: Support the development of diagnostics and assays

Availability of rapid, accurate Food and Drug Administration (FDA)-cleared or authorized diagnostics will increase testing capacity and are critical for identifying and rapidly isolating cases, tracking spread of the virus, managing patient care, and supporting clinical trials. Molecular tests specifically designed to detect SARS-Cov-2 RNA in clinical samples are able to detect low levels of pathogen in clinical samples and offer robust specificity in differentiating SARS-CoV-2 from other related viruses. Continuing to improve the speed and accuracy of molecular and antigen-based diagnostics and making them available at point- of-care will be paramount to accelerating the ability to mitigate disease spread in the current outbreak and any future outbreaks. The development of serologic assays would further bolster surveillance efforts, including the ability to identify individuals who may have resolved prior infection with SARS-CoV-2.

Objective 2.1: Accelerate the development and evaluation of diagnostic platforms

Support the development, characterization and availability of reagents for diagnostic validation.

NIAID will support this effort through the development and testing of reagents for diagnostic validation that will be made available through NIAID-sponsored repositories.

Box 3

Priority 2: Support the development of diagnostics and assays

Objective 2.1: Accelerate the development and evaluation of diagnostic platforms

Objective 2.2: Develop assays to increase understanding of infection and disease incidence

- Support the development of new rapid diagnostics. NIAID will provide funding to support the development of new rapid diagnostics, including molecular tests and novel antigen detection tests with improved sensitivity, if deemed feasible based on natural history studies.
- Support the evaluation of promising diagnostics. In some cases, stakeholders that develop
 potential diagnostic tests do not have the infrastructure needed to rigorously validate those tests
 against clinical samples. NIAID will support the testing of promising diagnostics and provide the
 capacity for evaluating them with live virus samples using our biocontainment laboratories.

Objective 2.2: Develop assays to increase understanding of infection and disease incidence

Develop and validate SARS-CoV-2 serological assays. Serological tests, which detect host antibodies
to infectious agents, do not detect the presence of a pathogen directly but can be used as a
surrogate marker of infection. Developing more effective serologic tests would help provide
information on the extent of asymptomatic infections and cumulative disease incidence, for
example through serosurveillance studies. NIAID, with the Centers for Disease Control and

Prevention and the FDA, is developing tests that identify antibodies to SARS-CoV-2 proteins to determine seroprevalence rates and potentially help distinguish antibody responses in individuals receiving vaccines. NIAID will support the development and validation of additional serological assays for serosurveillance studies and as tools for testing the efficacy of promising vaccine or therapeutic candidates.

Priority 3: Characterize and test therapeutics

Currently, there are no FDA-approved or licensed therapeutics specific for coronaviruses. While traditional development pathways for therapeutics can take years, the urgency of the current outbreak underscores the need for rapid development and testing of promising therapeutics. Possible avenues for developing therapeutics include the evaluation of broad-spectrum antiviral agents (antivirals) that have shown promise for other coronaviruses and the identification of novel monoclonal antibodies (mAbs). For broad-spectrum antivirals, Phase 2/2b testing of the RNA polymerase inhibitor developed by Gilead, remdesivir, is already underway. Additional studies will be critical to identify promising therapeutic candidates and to advance them through clinical trial testing. To optimize findings during the pandemic, multiple clinical trials will be conducted in parallel among various populations, including both inpatient and outpatient studies.

Objective 3.1: Identify promising candidates with activity against SARS-CoV-2

- Screen protease inhibitor and nucleotide analogue class agents and other small molecules with documented activity against other coronaviruses SARS-CoV-2. Screening drugs that are already licensed by the FDA for other indications and might be efficacious against SARS-CoV-2 infection may provide a route to identifying a therapeutic for use in the current pandemic. Broad-spectrum antivirals that are already FDA approved or in clinical development for other indications—including those previously targeting SARS-CoV-1 and MERS CoV—can be evaluated for their potential activity against SARS-CoV-2 infections. Approved therapeutics for other infectious diseases also are being evaluated as possible treatments for COVID-19. By leveraging their existing efficacy, safety, and manufacturability data, the time to development and production can be reduced. NIAID also will continue working with partners to screen compound libraries for potential activity against SARS-CoV-2. For these studies, priority will be given to compounds based on in vitro screening data and
 - the existence of human safety data.

Identify viral targets for therapeutic development.

Advances in structural biology technology enable researchers to map key viral structures at an

Box 4

Priority 3: Characterize and test therapeutics

Objective 3.1: Identify promising candidates with activity against SARS-CoV-2

Objective 3.2: Conduct treatment studies to advance high-priority therapeutic candidates

unprecedented level. The Structural Genomics Centers for Infectious Diseases (SGCID) apply state-of-the-art, high-throughput technologies and methodologies, including computational modeling, x-ray crystallography, nuclear magnetic resonance imaging, and cryogenic electron microscopy, to experimentally characterize the three dimensional atomic structure of proteins that play an important biological role in human pathogens and infectious diseases. NIAID will continue to support use of this powerful technology to identify viral targets of SARS-CoV-2 for therapeutics or vaccines.

• Identify novel mAbs for use as therapy or prophylaxis. Data from early studies indicate that well-characterized convalescent plasma may provide a treatment benefit in COVID-19.⁴ Therefore, IVIG derived from convalescent plasma may also hold promise for treatment. Moreover, peripheral blood mononuclear cells and plasma are being used to identify novel neutralizing antibodies. Through collaborations with structural biologists, binding properties can be quickly assessed. Paired with assessment of neutralization activity, the most promising mAbs will be identified for further characterization in animal models and human trials.

Objective 3.2: Conduct treatment studies to advance high-priority therapeutic candidates

- Characterize and evaluate host-directed strategies for treatment of disease. Experience with other coronaviruses indicates that infection of the respiratory tract is rapid and damage is primarily mediated by the host inflammatory response. These conditions may make it difficult to modify COVID-19 with pathogen-directed therapeutics. Instead, host-directed strategies that target the immune response may exert a beneficial therapeutic effect. Host-directed strategies, including immune-modulating agents, will be investigated as potential therapeutic candidates.
- Conduct clinical trials to demonstrate safety and efficacy of lead therapeutic candidates. Many
 potential therapeutic candidates have been identified and are being tested in clinical trials.
 - o In March 2020, NIAID launched a multicenter, adaptive, randomized controlled clinical trial to evaluate the safety and efficacy of the investigational antiviral drug remdesivir (GS-5734) for the treatment of COVID-19 in hospitalized adults with laboratory-confirmed SARS-CoV-2 infection and evidence of lung involvement. The trial builds on recent studies by NIAID scientists showing that remdesivir can improve the disease course in rhesus macaques when administered promptly after viral challenge with the MERS CoV. The trial is also adaptive, allowing for additional arms should other therapeutics warrant assessment for efficacy.
 - NIAID is finalizing the protocol for the Big Effect Trial (BET), in which putative therapeutics that have existing human data and are readily available will be tested in patients hospitalized with lower respiratory tract disease. Each potential intervention will be given to approximately 75 patients and evaluated for mitigating disease symptoms. Candidate therapeutics that meet the criteria in this initial study will be further evaluated in larger clinical trials for which the infrastructure is already in place.
 - As mentioned above, identification of novel mAbs for therapy or prophylaxis is another strategic priority. These mAbs should be safe, highly effective, amenable to fast manufacturing, and easy to administer. They will be tested in clinical trials to develop immunotherapies for the prevention and early treatment of COVID-19, potentially in high-risk populations including healthcare workers.
- Conduct outpatient studies for mild COVID-19 cases. In cases of mild COVID-19 that do not require
 hospitalization, outpatient studies could be extremely valuable for testing promising, orally
 administered FDA-approved drugs that have existing safety data. The antiviral activity of
 hydroxychloroquine and azithromycin against SARS-CoV-2 has been the focus of many early

⁴ Roback JD and Guarner J. JAMA 2020 Mar 27. Epub. 32219429.

⁵ Newton AH et al. *Semin Immunopathol*. 2016;38(4):471-82. PMID 26965109.

⁶ de Wit E et al. *Proc Natl Acad Sci USA* 2020;117(12):6771-6. PMID 32054787.

therapeutic studies. ^{7,8,9} Testing of these and other candidates, including protease inhibitors and other molecules, in outpatient studies may provide critical efficacy data and could identify an existing drug or drug combination that is safe and effective against COVID-19.

Conduct outpatient studies in high-risk populations. High-risk populations, including health care
workers, the elderly or individuals with chronic conditions, are a critical target for the development
of therapeutics. Conducting studies in patients with mild cases of COVID-19 among these high-risk
groups would be of interest for identifying the benefits of early treatment strategies to mitigate the
impact of infection. Therapeutic candidates that have once a day dosing could also be considered for
pre-exposure prophylaxis (PrEP) in some of these populations.

Priority 4: Develop safe and effective vaccines against SARS-CoV-2

Developing a safe and effective SARS-CoV-2 vaccine is a priority for preventing future outbreaks of the virus. As vaccine candidates for MERS-CoV, SARS-CoV-1 and other coronaviruses have previously been developed, NIAID investigators and the scientific community are well poised to use similar approaches in the current pandemic. NIAID will leverage its broad intramural and extramural infrastructure to advance vaccine candidates through Phase 1 safety and dosing clinical trials, with considerations for Phase 2/2b clinical trials for the most promising candidates.

Objective 4.1: Advance promising vaccine candidates through clinical trial testing

- Conduct a Phase 1 clinical trial of (mRNA) platform candidate mRNA-1273. Given the urgency of
 the response effort to develop a safe and effective vaccine, NIAID is prioritizing promising vaccine
 candidates that can be rapidly produced and tested. NIAID, in collaboration with the biotechnology
 company Moderna, is conducting a Phase 1 clinical trial of a vaccine candidate that uses a
 messenger RNA (mRNA) vaccine platform expressing a NIAID-designed recombinant spike protein of
 SARS-CoV-2. The trial is being conducted at NIAID-funded clinical research sites, with the first
 enrolled individual receiving the vaccine on March 16, 2020.
- Prepare for a pivotal Phase 2/2b clinical trial of candidate mRNA-1273. Preparing for the likelihood of a seasonal recurrence of SARS-CoV-2 is imperative to the public health response. Given the theoretical risk of vaccine-enhanced respiratory disease, large Phase 2 trials are unlikely to launch until this possibility is evaluated in animal models. Planning for those animal studies is underway, and, assuming favorable results, a Phase 2/2b study could be launched later in 2020. This represents a historically fast timeline for the development and testing of a vaccine candidate. Additionally, these studies will provide information on correlates of immunity that will help accelerate the advancement of other vaccine candidates. If the mRNA-1273 vaccine candidate shows protection against SARS-CoV-2 infection in a Phase 2/2b trial, NIAID will work with government partners to ensure that the vaccine is manufactured in sufficient quantities to allow prompt distribution to those at highest risk of acquiring disease.

⁷ Gautret P et al. Int J Antimicrob Agents. 2020 Mar 20:105949. Epub. PMID 32205204.

⁸ Molina JM et al. 2020 Med Mal Infect. 2020 Mar 30. pii:S0399-077X(20)30085-8. Epub. PMID 32240719.

⁹ Chen Z et al. medRxiv 2020:2020.03.22.20040758. https://www.medrxiv.org/content/10.1101/2020.03.22.20040758v2

 Investigate additional candidates through NIAID vaccine programs. Although promising candidates may show efficacy in preclinical studies, many do not translate into effective vaccines in clinical trials. Therefore, it is crucial to support multiple promising

Box 5.

Priority 4: Develop safe and effective vaccines against SARS-CoV-2

Objective 4.1: Advance promising vaccine candidates through clinical trial testing

Objective 4.2: Advance vaccine development through assay and reagent development

Objective 4.3: Advance vaccine development through adjuvant characterization and development

preclinical candidates in the research and development pipeline. To that end, NIAID is advancing multiple additional SARS-CoV-2 vaccine candidates through its Rocky Mountain Laboratories (RML), including approaches that have shown promise against coronaviruses that cause SARS and MERS. Building on previous research to develop a MERS-CoV vaccine, scientists at RML are collaborating with Oxford University investigators to develop a SARS-CoV-2 vaccine that uses a chimpanzee adenovirus vector. RML investigators also are partnering with the biopharmaceutical company CureVac on an mRNA vaccine candidate and collaborating with the University of Washington on a universal coronavirus vaccine development. By leveraging its extensive expertise and research infrastructure, NIAID will continue working with partners and collaborators to advance promising SARS-CoV-2 vaccine candidates.

• Leverage existing vaccine approaches to target SARS-CoV-2. NIAID is pursuing multiple strategies to develop a COVID-19 vaccine. Building on past research on emerging pathogens, especially MERS-CoV and SARS-CoV-1 (the virus that causes SARS), NIAID is using previously developed vaccine platforms to rapidly assess the potential of SARS-CoV-2 vaccine candidates. This approach has already resulted in several promising strategies that may be leveraged for SARS-CoV-2, including vaccination using recombinant spike protein, chimpanzee adenovirus vaccine vector, virus-like particles, and live attenuated virus. In addition, NIAID is funding the development of novel vaccine candidates that will be efficacious across the lifespan, including in the elderly.

Objective 4.2: Advance vaccine development through assay and reagent development

Develop critical reagents to support vaccine development. Appropriate tools are needed to identify
the most promising vaccine candidates and advance the development of lead candidates as rapidly
as possible. To accelerate the vaccine pipeline, NIAID is generating master and working SARS-CoV-2
virus stocks and other reagents critical for developing SARS-CoV-2 immune assays, developing
quantitative tests for characterizing SARS-CoV2 assay material, developing a quantitative SARS-CoV2-specific ELISA, developing virus-specific neutralization assays, and developing quantitative assays
for assessing SARS-CoV-2 viral load.

Objective 4.3: Advance vaccine development through adjuvant characterization and development

Provide adjuvants to support vaccine development. Adjuvants are vaccine components that
improve vaccine efficacy by inducing long-lived protective immunity. Selection of appropriate
adjuvants is crucial for developing safe and effective vaccines. NIAID is working with multiple
collaborators to provide adjuvants to the research community for use in SARS-CoV-2 vaccine
candidates. These adjuvants are at various stages of development and include compounds that

specifically improve vaccine efficacy in elderly individuals or modulate host immunity toward protective responses while limiting or preventing harmful inflammatory responses.

Conclusion

The sudden emergence and rapid global spread of the novel coronavirus SARS-CoV-2 has created a daunting public health challenge. To address this challenge, NIAID is focusing its considerable expertise and emerging infectious disease resources to facilitate the development of medical countermeasures including diagnostics, therapeutics, and vaccines. The resulting discoveries will not only help mitigate the current pandemic, but also inform prevention, diagnosis, and treatment of future emerging infectious diseases.

A comprehensive strategy requires a coordinated effort among governmental, academic, private, and community-based organizations. The NIAID Strategic Plan for COVID-19 Research defines the areas of COVID-19 research within the NIAID mission and outlines the institute's research priorities and goals. This strategic plan builds on many other national efforts and represents a commitment from multiple U.S. government agencies to improve coordination of COVID-19 research and discovery efforts and the development of medical countermeasures.

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: 6/4/2020 11:27:59 AM

To: Jacobs, Anna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e76eeb11df9a4024b53864ffac4c4c56-jacobsal]

CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Black, Jodi (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=782921b9f08249b59a582e93f6963f5f-blackj]

Subject: Draft letter

Attachments: Daszakletter June XX 2020.docx

Hi Anna – thanks for the phone call – here's a draft letter.

Best, Mike

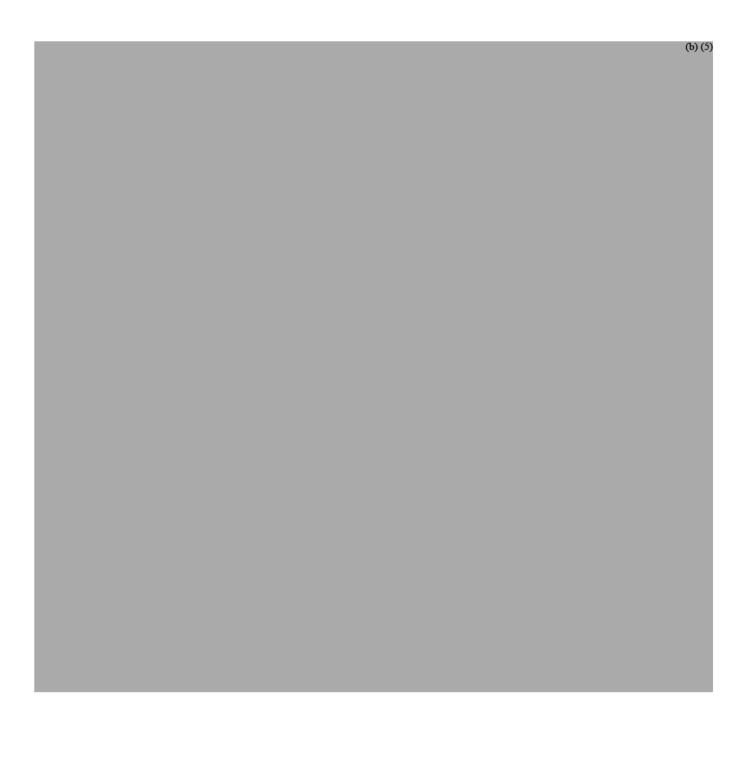


DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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





From: Fine, Amanda (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=61290B74AA9A44358954C45439FFDEB6-FINEAB]

Sent: 6/14/20202:59:31 PM

To: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Myles, Renate (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]

Subject: RE: Grant termination

Thanks Mike we can handle.

Hope you're having a good weekend! Amanda

From: Lauer, Michael (NIH/OD) [E] < (b) (6)

Sent: Sunday, June 14, 2020 9:35 AM

To: Myles, Renate (NIH/OD) [E] < (b) (6) Fine, Amanda (NIH/OD) [E] < (b) (6)

Cc: Lauer, Michael (NIH/OD) [E] < (b) (6)

Subject: FW: Grant termination

Hi Renate and Amanda – forwarding to you.

Thanks, Mike

From: "Rainey, Jim" < jim.rainey@latimes.com>

Date: Saturday, June 13, 2020 at 6:53 PM

To: "Lauer, Michael (NIH/OD) [E]" < (b) (6)

Subject: Grant termination

Dr. Lauer,

I am a reporter for the Los Angeles Times. I have written in the past about some of the work of the EcoHealth Alliance. As you know, the termination of the NIH grant (award renewal #2R01AI110964-06) to the EcoHealth Alliance for "Understanding the Risk of Bat Coronavirus Emergence" is a matter of considerable public interest.

I would like to talk to you as soon as possible about this award and why it was discontinued. You can reach me at this email or the attached phone numbers.

I am also available via **Signal**, the secure and encrypted messaging service. My contact number there is the same as **my cell number**, (b) (6). The source of all communications can be kept confidential, if necessary. That is a pledge I take very seriously.

I hope you will see fit to communicate with me.

With kind regards,

Jim

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM] Sent: 5/7/2020 2:29:36 AM Aguirre, Lisa (IOS/ONS) [/o=ExchangeLabs/ou=Exchange Administrative Group To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=148aca8632f14d2ca6227b9b5cde0947-Lisa.Aguirr]; Hudgens, Alisa (b) (6) Hollie, Les W (OIG/OI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a553c4e88894e6c9ff26cdcc9241fd7-Les.Hollie.] CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange AdministrativeGroup (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Muroff, Julie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f3fd404b36a4d4e8dda4a3dcb9a72c0-muroffj]; Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm] Subject: Re: Wuhan Lab Attachments: Wuhan Lab; NoA R01Al110964-01.pdf; NoA R01Al110964-06.pdf Also – as mentioned earlier today, the grantee (EcoHealth Alliance) failed to report as required the subawards to the Federal Subaward Reporting System (2 CFR 170). I've highlighted the relevant section of the NoA. Best, Mike From: "Lauer, Michael (NIH/OD) [E]" < (b)(6)Date: Wednesday, May 6, 2020 at 2:53 PM To: "Aguirre, Lisa (IOS/ONS)" < (b) (6) "Hudgens, Alisa (HHS/OS/ONS)" (b) (6) "Hollie, Les W (OIG/OI)" < Cc: "Lauer, Michael (NIH/OD) [E]" < (b) (6) "Tabak, Lawrence (NIH/OD) [E]" (b) (6) "Muroff, Julie (NIH/OD) [E]" < Subject: Wuhan Lab Hi Lisa, Alisa, and Les – as we discussed. Narrative below (scroll down to my note to Larry). Video (need to skip the political ads) Two letters (6th and 7th attachments) Our rationale: (b) (5) Background:

(b)(5)

| | | | | (b) (5) |
|---|---------|--------------------------------------|---------|----------------|
| Hope this helps, | | | | |
| Mike | | | | |
| Michael S Lauer, MD NIH Deputy Director for Extramural Research L Center Drive, Building 1, Room 144 Bethesda, MD 20892 Phone: (b) (6) Email: (b) (6) | | | | |
| From: "Lauer, Michael (NIH/OD) [E]" < | | (b) (6) | | |
| Date: Wednesday, April 22, 2020 at 9:56 AM To: "Tabak, Lawrence (NIH/OD) [E]" < | | (b) (6) | | |
| Cc: "Lauer, Michael (NIH/OD) [E]" < | (b) (6) | (b) (6) "Black, Jodi (NIH/OD) [E]" < | (| b) (6) |
| Subject: Wuhan Lab | | | | |
| Hi Larry — in follow-up to our 1:1 earlier today, | | | (b) (5) | |
| | | | | (b) (5) |

Many thanks,

Mike

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM)

Sent: 5/26/2020 2:11:44 PM

To: Jacobs, Anna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e76eeb11df9a4024b53864ffac4c4c56-jacobsal]

CC: Black, Jodi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=782921b9f08249b59a582e93f6963f5f-blackj]; Lankford, David (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4f29a9bef672409d967e3aa5fb36e96a-lankford]; Lauer, Michael (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]

Subject: Re: EcoHealth Alliance re Termination of NIH Research Grant R01 Al 110964

Attachments: Re: Wuhan Lab; EcoHealth Alliance First-Level Appeal of NIH Grant Termination, dated May 22, 2020 (R01 Al 110964)

(02103179xA1AB5).PDF

Excellent, Anna, I think we'rescheduled for 11. I'm attaching some background material.

Best, Mike

From: "Jacobs, Anna (NIH/OD) [E]" < (b) (6)

Date: Tuesday, May 26, 2020 at 9:22 AM

To: "Lauer, Michael (NIH/OD) [E]" < (b) (6)

Cc: "Black, Jodi (NIH/OD) [E]" < (b) (6) "Lankford, David (NIH/OD) [E]"

(b) (6)

Subject: RE: EcoHealth Alliance re Termination of NIH Research Grant R01 Al 110964

Good morning, Mike,

Thanks for providing this information. I'd be glad to discuss, if you'd like, although my familiarity with the matter is a bit limited. I can reach out to Melanie to find time. I assume 15 minutes will suffice. If a conversation is no longer needed, just let me or Melanie know.

Thanks,

Anna L. Jacobs, J.D., M.S.

Senior Attorney

HHS Office of the General Counsel

Public Health Division, NIH Branch

31 Center Drive, Bldg. 31, Rm.2B-50

Bethesda, MD 20892

(b) (6) (phone)

301-402-1034 (fax)

(b) (6

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From: Lauer, Michael (NIH/OD) [E] (b) (6)

Sent: Friday, May 22, 2020 6:04 PM

To: Jacobs, Anna (NIH/OD) [E] < (b) (6)

Cc: Lauer, Michael (NIH/OD) [E] < (b) (6) Black, Jodi (NIH/OD) [E] < (b) (6) Lankford,

David (NIH/OD) [E] < (b) (6)

Subject: FW: EcoHealth Alliance re Termination of NIH Research Grant R01 AI 110964

Importance: High

Hi Anna – at some point we should discuss this.

Many thanks, Mike

Subject: EcoHealth Alliance re Termination of NIH Research Grant R01 Al 110964

Dr. Lauer:

Please see the attached letter from Andrew N. Krinsky on behalf of EcoHealth Alliance, Inc., pursuant to NIH Grants Policy Statement Section 8.7, regarding the decision by NIAID to terminate NIH Research Grant R01 Al 110964 on or about April 24, 2020.

Thank you.

Best, Matthew R. Torsiello



Matthew R.Torsiello | Associate D: (b) (6) | F: 212-216-8001 (b) (6) | Bio

Tarter Krinsky & Drogin LLP 1350 Broadw ay | New York | NY | 10018 w ww.tarterkrinsky.com

Tarter Krinsky & Drogin is fully operational. All attorneys and staff have been and will continue to be working remotely and TKD has put measures in place to ensure our services continue uninsempted. However, because of anticipated delays in receiving regular mail and other deliveries, please e-mail copies of anything you send by regular mail or delivery, including issuing remittances electronically, until further notice. Please contact Kartrials Sources if reception@tarterkrinsky.com or by phone at 212-216-8000 with any questions. Thank you in advance for your courtesies during these unprecedented times.

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| Tarter Krinsky & Drogin LLP, Attorneys-at-Law. | |
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| From: | Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM] | |
|---|--|---------|
| Sent: | 5/7/2020 2:29:13 AM | |
| То: | Aguirre, Lisa (IOS/ONS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=148aca8632f14d2ca6227b9b5cde0947-Lisa.Aguirr]; Hudgens, Alisa (HHS/OS/ONS) [| |
| CC: | Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange AdministrativeGroup (FYDIBOHF23SPDLT]/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Muroff, Julie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange AdministrativeGroup (FYDIBOHF23SPDLT]/cn=Recipients/cn=8f3fd404b36a4d4e8dda4a3dcb9a72c0-muroffj]; Lauer, Michael (NIH/OD) [I [/o=ExchangeLabs/ou=Exchange AdministrativeGroup (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm] | Ε] |
| Subject: | Re: Wuhan Lab | |
| Attachments: | Wuhan Lab; NoA R01Al110964-01.pdf; NoA R01Al110964-06.pdf | |
| | ntioned earlier today, the grantee (EcoHealth Alliance) failed to report as required the subawards to the ward Reporting System (2 CFR 170). I've highlighted the relevant section of the NoA. | |
| Date: Wedn To: "Aguirre | er, Michael (NIH/OD) [E]" < | |
| Hi Lisa, Alisa, | and Les – as we discussed. | |
| Narra | ative below (scroll down to my note to Larry). | |
| *************************************** | o (need to skip the political ads) | |
| • Two | letters (6 th and 7 th attachments) | |
| Our rational | e: | |
| | | (b) (5) |
| Background: | | |
| | (b) (5) | 4 |

| | | (b) (5) |
|---|---|----------------|
| Hope this helps, | | |
| Mike | | |
| Michael S Lauer, MD NIH Deputy Director for Extramural Research I Center Drive, Building 1, Room 144 Bethesda, MD 20892 Phone: (b) (6) Email: (b) (6) | | |
| From: "Lauer, Michael (NIH/OD) [E]" < Date: Wednesday, April 22, 2020 at 9:56 AM To: "Tabak, Lawrence (NIH/OD) [E]" < Cc: "Lauer, Michael (NIH/OD) [E]" < "Schwetz, Tara (NIH/OD) [E]" < Subject: Wuhan Lab | (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) | (b) (6) |
| Hi Larry — in follow-up to our 1:1 earlier today, | (b) (5) | |
| | | (b) (5) |

Many thanks,

Mike

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: 5/31/20205:35:25 PM

To: Jacobs, Anna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e76eeb11df9a4024b53864ffac4c4c56-jacobsal)

CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]

Subject: FW: time for a short follow-up

Attachments: EcoHealth FACTS Year 1.pdf; EcoHealth FACTS Year 2.pdf; EcoHealth FACTS Year 3.pdf; EcoHealth FACTS Year 4.pdf;

EcoHealth FACTS Year 5.pdf; EcoHealth FACTS Year 6.pdf; EcoHealth NoA Year 6 April 27 2020.pdf; EcoHealth NoA Year 6.pdf; EcoHealth NoA Year 5.pdf; EcoHealth NoA Year 3.pdf; EcoHealth NoA Year 2.pdf; EcoHealth NoA Year 1.pdf; Re: Please read and acknowledge receipt -- Subaward concerns; EcoHealth

Alliance FedEx 20200531131626247.pdf

Hi Anna - I'm adding the letter sent to UC Irvine and the contents of the FedEx package.

Many thanks, Mike

From: "Lauer, Michael (NIH/OD) [E]" < (b) (6)

Date: Thursday, May 28, 2020 at 7:08 PM

To: "Jacobs, Anna (NIH/OD) [E]" < (b) (6) **Cc:** "Lauer, Michael (NIH/OD) [E]" < (b) (6)

Subject: Re: time for a short follow-up

Hi again Anna – here are the key documents that should answer the questions we discussed this morning.

Many thanks, Mike

From: "Lauer, Michael (NIH/OD) [E]" < (b) (6)

Date: Wednesday, May 27, 2020 at 5:20 PM

To: "Jacobs, Anna (NIH/OD) [E]" < (b) (6) "Showe, Melanie (NIH/OD) [E]"

<s (b) (6) h.gov>

Cc: "Lauer, Michael (NIH/OD) [E]" < (b) (6)

Subject: Re: time for a short follow-up

Hi Anna – yes, for sure.

Hi Melanie – appreciate your help with this. High priority.

Many thanks, Mike

From: "Jacobs, Anna (NIH/OD) [E]" < (b) (6)

Date: Wednesday, May 27, 2020 at 5:19 PM

To: "Lauer, Michael (NIH/OD) [E]" < (b) (6) "Showe, Melanie (NIH/OD) [E]"

<s (b) (б) h.gov>

Subject: time for a short follow-up

Mike, we had a preliminary discussion with Bob about the termination, and he had some factual questions that I wonder if you could look into. Would you have 10 minutes to talk tomorrow, and I can relay his questions?

Melanie, can you help us find 10 minutes tomorrow (Thursday)? I can make any time work, and I'd be glad to call Mike.

Thanks,

Anna L. Jacobs, J.D., M.S.
Senior Attorney
HHS Office of the General Counsel
Public Health Division, NIH Branch
31 Center Drive, Bldg. 31, Rm.2B-50
Bethesda, MD20892
(b) (6) (phone)
301-402-1034 (fax)

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QVR FACTS

FACTS Data Snapshot for: 1-R01-Al110964-01 (DASZAK, PETER) Understanding the Risk of Bat Coronavirus Emergence T CLOSE Appl Id: 867490

Launch the FACTS System: FRATTS

Hop to Country: Project Information BURMA CAMBODIA CHINA INDONESIA LAOS MALAYSIA THAILAND VIETNAM

| 1-R01-Al110964-01 (as reflected under competing project number 1-R01-Al110964-01 in FACTS) |
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| |
| DASZAK, PETER |
| ECOHEAITH ALLIANCE, INC. |
| Understanding the Risk of Bat Coronavirus Emergence |
| 2014 (Project Period from 2014-06-01 to 2019-05-31) |
| Awarded (05) |
| Domestic Application with Foreign Collaboration (2) |
| |

| BURMA | | | | | |
|--|-----------------------------------|----------------------------------|-----------|---|--|
| State Department Clearance Request (SDCR ID 212153) | | MIAID Contact | 5 | SOCR ACTIONS | ACTION DATES |
| Click the + to show the Research Objective listed on St | tate Department Clearance, | Bernabe, Gavie Phone: 301-451 | -1018 | Approved Auto Approvat Submit to State Department Send to Agency C Save | 2017-04-10 2017-04-10 2017-03-27 2017-03-25 2017-03-02 |
| Collaborator/Site (Site ID: 238626) | Site Flags | Budget Period | Budget Am | t Verified By | Verified Date |
| TOE, AUNG THAN SAN PYA CLINIC 20/256 Insein Road Yangon 11051 | Animals: Y FWA: Y Humans: N | | | | |

| State Department Clearance Request (SDCR ID 212148) | | NIAID Contact | SDCR | ACTIONS | ACTION DATES |
|---|-----------------------------------|---|-----------------------|---|--|
| Click the + to show the Research Objective listed on | State Department Clearance, | <u>Bernabe, Gayle</u> Phone: 301-451 | -1018 Auto A Submi | Approva: t to State Department o Agency | 2017-03-27 2017-03-27 2017-03-13 2017-03-13 2017-03-02 |
| Collaborator/Site (Site ID: 238614) | Site Flags | Budget Period | Budget Amt | Verified By | Verified Date |
| DUONG, VEASNA INSTITUT PASTEUR DU CAMBODGE No. 5 Moniveng Boutevand P.O. 80x 983 Phnom Penh | Animals: Y FWA: Y Humans: N | | | | |

| CHINA | | | | | |
|--|-----------------------------------|---------------|---|---|---|
| State Department Clearance Request (SDCR ID 211200) | NIAID Conta | ct | SDCR ACTIONS | ACTIO | ON DATES |
| Click the + to show the Research Objective listed on State Department Clearance. | Bernabe, Ga Phone: 301- | | Approved Approve Send to Agency Submit to State Departm IC Update IC Save | 2016- 2016- 2016- 2016- 2016- | ~11-29 11-29 10-24 10-24 10-20 10-12 |
| State Department Clearance Request (SDCR ID 202191) | NIAID Conta | ct. | SDCR ACTIONS | ACTIO | ON DATES |
| Click the + to show the Research Objective listed on State Department Clearance. | <u>Bernabe, Ga</u> Phone: 301- | | Approved Approve Send to Agency Submit to State Departm IC Update IC Save | 2016- 2016- ent 2016- 2016- | -03-11 11-29 10-24 10-24 10-20 10-12 |
| Collaborator/Site (Site ID: 211436) | Site Flags | Budget Period | Budget Amt | erified By | Verified Date |
| KE, CHANGWEN | Animals: Y | | | | |

Humans: Y

CENTER FOR DISEASE CONTROL AND PREVENTION OF GUANGDONG

176 Xigang Xilu Guangzhou 5103000

| | Site Elam | Rudaut t | Pariod | Rudnet Ame | | Marifind D. | 14 | facified Data |
|--|--|--|---|------------------------|--|--|---|---|
| Collaborator/Site (Site ID: 211435) ZHANG, SHUYI | Site Flags Animals: Y | Budget F | enou | Budget Amt S94.068 | | Verified By | , | erified Date |
| EAST CHINA NORMAL UNIVERSITY | FWA: N | 2 | | \$72,684 | | | | |
| 1663 Zhongshan Beitu Thanghai 200062 | Humans: Y | 3 | | \$54,117 \$42,300 | | | | |
| S on cross on it are said and time one time too time too to be true true trues and a | MENER AND EXCUSED AND | 5 | OR EMPLY COOP ESTIVOR | \$32,454 | N COCO DONNES COCO KON | ************************************** | | |
| ollaborator/Site (Site ID: 211433) | | Site Flags | Budget | Period | Budget Amt | Verified By | y | Verified Date |
| IHJ, GUANJIN BUANGDONG ENTOMOLOGICAL INSTITUTE (ECNU) | | Animals: Y FWA: N | | | | | | |
| Room 1707, Building 622 | | Humans: Y | | | | | | |
| 3663 Zhongshanisei Rd Shanghai, Putuo District 200026 | | | | | | | | |
| allaharatar/Siga (Siga (Siga (Siga (Siga)) | 3 45 100 4 3 100 3 100 100 100 | Siba Flase | Budent | Daried | Bridget Amb | Varidina R. | | Vasified Date |
| ollaborator/Site (Site ID: 235943) | | Site Flags | pucger | Period | Budget Amt | Verified By | y | Verified Date |
| LI, SHIYUE SCHOOL OF PUBLIC HEALTH, WUHAN UNIVERSITY | | Animats: N FWA: Y | | | | | | |
| 115 Donghu Road | | Humans: Y | | | | | | |
| Muchang Muhan, Hubel 430071 | | | | | | | | |
| ollaborator/Site (Site ID: 211434) | Site Flags | Budget Pe | eried | Budget Amt | | Verified By | | /erified Date |
| SHI, ZHENGLI | Animals: Y | 1 | | \$133,595 | | | | |
| WUHAN INSTITUTE OF VIROLOGY Xiao Hong Shan, No. 44 | FWA: N Humans: Y | 2 | | \$139,015 \$159,122 | | | | |
| Nuchang District | murans: T | 4 | | \$159,122 | | | | |
| Wuhan 430071 | | 5 | | \$159,122 | | | | |
| ollaborator/Site (Site ID: 211437) | | | Site Flags | Budget Perio | od Budget | t Amt Verif | fied By | Verified Da |
| ZHANG, YUN-ZHI | | | Animals: Y | | | | | |
| YUNNAN INSTITUTE OF ENDEMIC DISEASES CONTROL AND PREVENTION | | | FWA: N | | | | | |
| 33 Wenhua Road Dal: 650201 | | | Humans: Y | | | | | |
| NDONESIA tabe Department Clearance Request (SDCR ID 212150) | 100 PORTOR DOTOR PROPERTY | etiin statton etiin on tool en | NIAID Conta | and cover to cover | SOCR ACTIONS | S | ACTIO | N DATES |
| Click the + to show the Research Objective listed on State Department | t Clearance. | | Phone: 301- | | Auto Approva Send to Agend | | 2017-0 2017-0 2017-0 2017-0 | 3-27 3-13 3-13 |
| ollaborator/Site (Site ID: 238619) | | | Site Flags | Budget Period | Budget . | Amt Verifi | ed By | Verified Da |
| PAMUNGKAS, JOKO | | | Animals: Y | | | | | |
| PRIMATE RESEARCH CENTER AT BOGOR AGRICULTURAL UNIVERSITY JaianLodayaH/5 | | | FWA: Y Humans: N | | | | | |
| Bogor 16151 | | | 1131115115. 11 | | | | | |
| | | | | | | | | |
| AOS | | | | | | | | |
| and the second s | | | NIAID Conta | d | SDCR ACTION | 5 | ACTIO | N DATES |
| State Department Clearance Request (SDCR ID 212151) | THE RESIDENCE AND ADDRESS OF THE PARTY OF TH | CHICA STRUCKED STRUCK SCHOOLSE STRUCK | | ui e | Samuel Annual | | 2017- | |
| State Department Clearance Request (SDCR ID 212151) Click the + to show the Research Objective listed on State Department | : Clearance. | NOMES ADMINISTRAÇÃO ANTON MONTANCIA CONT. | Bernabe, Ga | 37.12 | Approved | 1 | 25 Jan 1 25 Jan | |
| max ano sina cama com sema camacena is anceitano ances ano samais ano sona cama com sema c | t Clearance. | THE REPORT AND ADDRESS AND | Bernabe, Ga Phone: 301- | 451-1018 | Auto Approva | | 2017-0 | 3.13 |
| nas ano ilito cama com sena mantenal is arrellano arres ano masis ano com cama com sena i | t Clearance. | THE PARTY AND A STATE OF THE PARTY AND A STATE | Bernabe, Ga Phone: 301- | 451-1018 | Auto Approval Submit to State Send to Agence | te Department | 2017-0 | 3-13 |
| Click the + to show the Research Objective listed on State Department | NO EMMA 6000 EMMA | te Flags | Phone: 301- | 451-1018 | Auto Approva Submit to Stat Send to Agend IC Save | te Department cy | 2017-0 2017-0 2017-0 | 3-13 3-02 |
| Click the + to show the Research Objective listed on State Department officers of the control of | Si | ite Flags | Bernabe, Gr Phone: 301- Budget Perio | 451-1018 | Auto Approval Submit to State Send to Agence | te Department | 2017-0 2017-0 2017-0 | 3-13 |
| Click the + to show the Research Objective listed on State Department officering the control of | Si A F | Animals: Y WA: Y | Phone: 301- | 451-1018 | Auto Approva Submit to Stat Send to Agend IC Save | te Department cy | 2017-0 2017-0 2017-0 | 3-13 3-02 |
| Click the + to show the Research Objective listed on State Department officering the state of th | Si A F | Animals: Y | Phone: 301- | 451-1018 | Auto Approva Submit to Stat Send to Agend IC Save | te Department cy | 2017-0 2017-0 2017-0 | 3-13 3-02 |
| Click the + to show the Research Objective listed on State Department officer of the state of th | Si A F | Animals: Y WA: Y | Phone: 301- | 451-1018 | Auto Approva Submit to Stat Send to Agend IC Save | te Department cy | 2017-0 2017-0 2017-0 | 3-13 3-02 |
| Click the + to show the Research Objective listed on State Department officering the state of th | Si A F | Animals: Y WA: Y | Phone: 301- | 451-1018 | Auto Approva Submit to Stat Send to Agend IC Save | te Department cy | 2017-0 2017-0 2017-0 | 3-13 3-02 |
| Click the + to show the Research Objective listed on State Department officering the state of th | Si A F | Animals: Y WA: Y | Phone: 301- | 451-1018 | Auto Approva Submit to Stat Send to Agend IC Save | te Department cy | 2017-0 2017-0 2017-0 | 3-13 3-02 |
| Click the + to show the Research Objective listed on State Department Collaborator/Site (Site ID: 238620) THE PRANCINA, WATTHANA NATIONAL ANIMAL HEALTH LABORATORY Department of Livestock and Fisheries Whinistry of Agriculture and Forestry Vientiane MALAYSIA | Si A F | Animals: Y WA: Y | Phone: 301- | d Bud | Auto Approva Submit to Stat Send to Agend IC Save | te Department cy Verified By | 2017-0 2017-0 2017-0 | 3-13 3-02 |
| | Si A | Animals: Y WA: Y | Phone: 301- Budget Perio NIAID Conta Bernabe, Gr | 451-1018 d Bud | Auto Approval Submit to State Send to Agenc IC Save get Amt SOCR ACTIONS Approved | te Department cy Verified By | 2017-0 2017-0 2017-0 ACTIO | 3-13 3-02 /erified Date N DATES 33-27 |
| Click the + to show the Research Objective listed on State Department Collaborator/Site (Site ID: 238620) THE PPANCINA, WAITHANA NATIONAL ANIMAL HEALTH LABORATORY Department of Livestock and Fisheries Ministry of Agriculture and Forestry Wentiane WALAYSIA State Department Clearance Request (SDCR ID 212152) | Si A | Animals: Y WA: Y | Phone: 301- Budget Perio | 451-1018 d Bud | Auto Approval Submit to State Send to Agent IC Save get Amt SOCR ACTIONS Approved Auto Approval | te Department cy Verified By | 2017-0 2017-0 2017-0 4CTIO 2017-0 2017-0 | 3-13 3-02 /erified Date N DATES 33-27 3-27 |
| Click the + to show the Research Objective listed on State Department Collaborator/Site (Site ID: 238620) ITEPPANGNA, VATTHANA NATIONAL ANIMAL HEALTH LABORATORY Department of Livestock and Fisheries Whistry of Agriculture and Forestry Vientiane MALAYSIA State Department Clearance Request (SDCR ID 212152) | Si A | Animals: Y WA: Y | Phone: 301- Budget Perio NIAID Conta Bernabe, Gr | 451-1018 d Bud | Auto Approval Submit to Stat Send to Agenc IC Save get Amt SDCR ACTION: Approved Auto Approval Send to Agenc Submit to Stat | te Department cy Verified By | ACTIO 2017-0 2017-0 2017-0 2017-0 2017-0 2017-0 | 3-13 3-02 /erified Date N DATES 03-27 3-27 3-13 3-13 |
| Click the + to show the Research Objective listed on State Department Collaborator/Site (Site ID: 238620) ITEPPANGNA, VATTHANA NATIONAL ANIMAL HEALTH LABORATORY Department of Livestock and Fisheries Whistry of Agriculture and Forestry Vientiane MALAYSIA State Department Clearance Request (SDCR ID 212152) | Si A | Animals: Y WA: Y | Phone: 301- Budget Perio NIAID Conta Bernabe, Gr | d Bud | Auto Approval Submit to Stat Send to Agenc IC Save get Amt SOCR ACTION: Approval Auto Approval Send to Agenc | te Department CY Verified By S | ACTIO 2017-0 2017-0 2017-0 2017-0 2017-0 2017-0 2017-0 2017-0 | 3-13 3-02 /erified Date N DATES 03-27 3-27 3-13 3-13 |

TOM, HUGHES CONSERVATION MEDICINE, LTD Suite 4A, Level 4, Main Office Tower Financial Park Complex Bandar Labuan, Federal Territory of Labuan

Animais: Y FWA: Y Humans: N

THAILAND

NIAID Contact SOCR ACTIONS ACTION DATES State Department Clearance Request (SDCR ID 212154)

Click the + to show the Research Objective listed on State Department Clearance.

Bernabe, Gayte Phone: 301-451-1018 2017-03-17 Approved 2017-03-17 Approve Submit to State Department 2017-03-13

Send to Agency IC Save 2017-03-13 2017-03-02

Collaborator/Site (Site ID: 238627) Site Flags **Budget Period** Budget Amt Verified By Verified Date

WACHARAPLUESADEE, SUPAPORN KING CHULALONGKORN MEMORIAL HOSPITAL Neuroscience Center for Research and Development Rama 4 Road

Animals: Y FWA: Y Humans: N

Bangkok, Patumwan 10330

VIETNAM

State Department Clearance Request (5DCR ID 212155) NIAID Contact SDCR ACTIONS ACTION DATES

Bernabe, Gavie Phone: 301-451-1018 Approved Click the + to show the Research Objective listed on State Department Clearance.

2017-03-27 Auto Approvat Send to Agency 2017-03-27 2017-03-13 Submit to State Department IC Save 2017-03-13 2017-03-02

Collaborator/Site (Site ID: 238629) Site Flags **Budget Period Budget Amt** Verified By Verified Date

NAM, NGUYEN HUU HANOI AGRICULTURAL UNIVERSITY Faculty of Animal and Veterinary Science Trauquy Hanoi, Gialam

OVR FACTS

| 5-R01-Alt10964-02 (as reflected under competing project number 1-R01-Alt10964-01 in FACYS) |
|--|
| DASZAK, PETER |
| ECOHEALTH ALLIANCE, INC. |
| Understanding the Risk of Bat Coronavirus Emergence |
| 2015 (Project Period from 2014-06-01 to 2019-05-31) |
| Awarded (05) |
| Domestic Application with Foreign Collaboration (2) |
| |

BURMA

FACTS Data Snapshot for: 5-R01-Al110964-02 (DASZAK, PETER)
Understanding the Risk of Bat Coronavirus Emergence

PRINT CLOSE

Appl Id: 88538:

Launch the FACTS System: PACTS

Hop to Country: Project Information BURMA CAMBODIA CHINA INDONESIA LAOS MALAYSIA THAILAND VIETNAM

TCE, AUNG THAN SAN PYA CLINIC 20/256 Insein Road Yangon 1 1051 Animals: Y FWA: Y

Humans: N

CAMBODIA

State Department Clearance Request (SDCR ID 212148)

Click the + to show the Research Objective listed on State Department Clearance.

Bernatie. Gavie Phone: 301-451-1018

Budget Period

Humans: Y

| Send to Agency | 2017-03-13 |
| IC Save | 2017-03-02 |
| Budset Amt | Verified By | Verified Date

Collaborator/Site (Site ID: 238614)

DUONG, VEASNA INSTITUT PASTEUR DU CAMBODGE

No. 5 Monivong Boulevand P.O. Box 983

Prinom Penh

Animals: Y FWA: Y Humans: N

Site Flags

CHINA State Department Clearance Request (SDCR ID 211200) NIAID Contact SDCR ACTIONS **ACTION DATES** 2016-11-29 Bernabe, Gayte Approved Click the + to show the Research Objective listed on State Department Clearance. Phone: 301-451-1018 Approve 2016-11-29 2016-10-24 Send to Agency Submit to State Department 2016-10-24 IC Update 2016-10-20 2016-10-12 IC Save State Department Clearance Request (SDCR ID 202191) MIAID Contact SDCR ACTIONS ACTION DATES 2014-03-11 Bernabe, Gavie Phone: 301-451-1018 Approved Click the + to show the Research Objective listed on State Department Clearance. Approve Send to Agency 2016-11-29 2016-10-24 Submit to State Department 2016-10-24 IC Update 2016-10-20 IC Save 2016-10-12 Site Flags **Budget Period Budget Amt** Verified By Verified Date

Collaborator/Site (Site ID: 211436)

KE, CHANGWEN

CENTER FOR DISEASE CONTROL AND PREVENTION OF GUANGDONG

Site Flags

Budget Period

Budget Amt

Verified By

Animals: Y

FWA: N

176 Xigang Xilu Guangzhou 5103000

Collaborator/Site (Site ID: 211435) Site Flags **Budget Period** Verified By Verified Date **Budget Amt** \$94,068 ZHANG, SHUYI Animais: Y EAST CHINA NORMAL UNIVERSITY FWA: N \$72,684 3663 Zhongshan Beilu Humans: Y \$54,117 Shanghai 200062 \$42,300 \$32,454

Site Flags Collaborator/Site (Site ID: 211433) **Budget Period** Verified By Verified Date **Budget Amt** ZHU, GUANJIN Animals: Y GUANGDONG ENTOMOLOGICAL INSTITUTE (ECNU) FWA: N Room 1707, Building 622. Humans: Y 3663 Zhongshanbei Rd Shanghai, Putuo District 200026 Collaborator/Site (Site ID: 235943) Site Flags **Budget Period Budget Amt** Verified By **Verified Date** Animais: N SCHOOL OF PUBLIC HEALTH, WUHAN UNIVERSITY 115 Donghu Road PWA: Y Humans: Y Wuchang Wuhan, Hubei 430071 Collaborator/Site (Site ID: 211434) Site Flags **Budget** Period **Budget Amt** Verified By Verified Date SHI, ZHENGLI Animals: Y \$133,595 WUHAN INSTITUTE OF VIROLOGY FWA: N \$139,015 Xiao Hong Shan, No. 44 Wuchang District Humans: Y 3 \$159,122 \$159,122 4 Wuhan 430071 5 \$159,122 Collaborator/Site (Site ID: 211437) Site Flags **Budget Period Budget Amt** Verified By Verified Date ZHANG, YUN-ZHI Animals: Y YUNNAN INSTITUTE OF ENDEMIC BISEASES CONTROL AND PREVENTION FWA: N 33 Wenhua Road Humans: Y Dall 650201 INDONESIA State Department Clearance Request (SDCR ID 212150) NIAID Contact SDCR ACTIONS **ACTION DATES** Bernabe, Gavie Phone: 301-451-1018 2017-03-27 Approved Click the + to show the Research Objective listed on State Department Clearance. 2017-03-27 Auto Approvat Send to Agency 2017-03-13 2017-03-13 Submit to State Department IC Save 2017-03-02 Collaborator/Site (Site ID: 238619) Site Flags **Budget Period Budget Amt** Verified By Verified Date PAMUNGKAS, JOKO Animals: Y PRIMATE RESEARCH CENTER AT BOGOR AGRICULTURAL UNIVERSITY FWA: Y Humans: N JalanLodavaH/5 Bogor 16151 LAOS MIAID Contact SDCR ACTIONS **ACTION DATES** State Department Clearance Request (SDCR ID 212151) 2017-03-27 Bernabe, Gavie Phone: 301-451-1018 Approved Click the + to show the Research Objective listed on State Department Clearance. Auto Approvat 2017-03-27 Submit to State Department 2017-03-13 2017-03-13 Send to Agency IC Save 2017-03-02 Collaborator/Site (Site ID: 238620) Site Flags **Budget Period Budget Amt** Verified By Verified Date THEPPANGNA, WATTHANA Animals: Y NATIONAL ANIMAL HEALTH LABORATORY FWA: Y Department of Livestock and Fisheries Humans: N Ministry of Agriculture and Forestry Vientiane MALAYSIA State Department Clearance Request (SDCR ID 212152) NIAID Contact SOCR ACTIONS ACTION DATES <u> 8ernabe, Gayle</u> Phone: 301-451-1018 2017-03-27 Approved Click the + to show the Research Objective listed on State Department Clearance. Auto Approval Send to Agency 2017-03-27 2017-03-13 Submit to State Department 2017-03-13 IC Save 2017-03-02 Collaborator/Site (Site ID: 238622) Site Flags **Budget Period Budget Amt** Verified By Verified Date TOM, HUGHES Animais: Y CONSERVATION MEDICINE, LTD FWA: Y Suite 4A, Level 4, Main Office Tower Financial Park Complex Humans: N Bandar Labuan, Federal Territory of Labuan

| State Department Clearance Request (SDCR ID 212154) | | NIAID Contact | SDCR ACTIONS | | ACTION DATES |
|--|-----------------------------------|---|--|---------------------------|--|
| Click the + to show the Research Objective listed on State Department Clearance. | | <u>Bernabe, Gayle</u> Phone: 301-451-1018 | Approved Approve Submit to State Send to Agency IC Save | Department | 2017-03-17 2017-03-17 2017-03-13 2017-03-13 2017-03-02 |
| Collaborator/Site (Site ID: 238627) | Site Flags | Budget Period | Budget Amt | Verified By | / Verified Date |
| WACHARAPLUESADEE, SUPAPORN KING CHULALONGKORN MEMORIAL HOSPITAL Neuroscience Center for Research and Development Rama 4 Road Bangkok, Patumwan 10330 | Animats: Y FWA: Y Humans: N | | 3 800 531 003 00183 003 53853 | | |
| | | | | | |
| VIETNAM | | | | | |
| VIETNAM State Department Clearance Request (SDCR ID 212155) | | PHAID Contact | SDCR ACTIONS | | ACTION DATES |
| | | MIAID Contact <u>Bernabe, Gavie</u> Phone: 301-451-1018 | SDCR ACTIONS Approved Auto Approvai Send to Agency Submit to State IC Save | Department | ACTION DATES 2017-03-27 2017-03-27 2017-03-13 2017-03-13 2017-03-02 |
| State Department Clearance Request (SDCR ID 212155) Click the + to show the Research Objective listed on State Department Clearance. | Site Flags | Bernabe, Gavle | Approved Auto Approvai Send to Agency Submit to State IC Save | Department Verified By | 2017-03-27 2017-03-27 2017-03-13 2017-03-13 |

QVR FACTS

FACTS Data Snapshot for: 5-R01-Al110964-03 (DASZAK, PETER) Understanding the Risk of Bat Coronavirus Emergence T CLOSE Appl Id: 908628

Launch the FACTS System: FRATTS

Hop to Country: Project Information BURMA CAMBODIA CHINA INDONESIA LAGS MALAYSIA THAILAND VIETNAM

| 5-R01-Al110964-03 (as reflected under competing project number 1-R01-Al110964-01 in FACTS) |
|--|
| DASZAK, PETER |
| ECOHEALTH ALLIANCE, INC. |
| Understanding the Risk of Bat Coronavirus Emergence |
| 2016 (Project Period from 2014-06-01 to 2019-05-31) |
| Awarded (05) |
| Domestic Application with Foreign Collaboration (2) |
| |

| BURMA | | | | | |
|---|---|-------------------------------------|-----------|--|--|
| State Department Clearance Request (SDCR ID 212153) | e Department Clearance Request (SDCR ID 212153) | | | SDCR ACTIONS | ACTION DATES |
| Click the + to show the Research Objective listed on S | tate Department Clearance, | Bernabe, Gavie Phone; 301-451-10 | 18 | Approved Auto Approvat Submit to State Department Send to Agency IC Save | 2017-04-10 2017-04-10 2017-03-27 2017-03-25 2017-03-02 |
| Collaborator/Site (Site ID: 238626) | Site Flags | Budget Period | Budget Am | nt Verified By | Verified Date |
| TOE, AUNG THAN SAN PYA CLINIC 20/256 Insein Road Yangon 1 1051 | Animals: Y FWA: Y Humans: N | | | | |

| State Department Clearance Request (SDCR ID 212148) | | NIAID Contact | SDCR / | ACTIONS | ACTION DATES | |
|---|-----------------------------------|---|------------------------|--|--|--|
| Click the + to show the Research Objective listed on | State Department Clearance, | <u>Bernabe, Gayle</u> Phone: 301-451 | -1018 Auto A Submit | pprovai t to State Department o Agency | 2017-03-27 2017-03-27 2017-03-13 2017-03-13 2017-03-02 | |
| Collaborator/Site (Site ID: 238614) | Site Flags | Budget Period | Budget Amt | Verified By | Verified Date | |
| DUONG, VEASNA INSTITUT PASTEUR DU CAMBODGE No. 5 Moniveng Boulevand P.O. Box 983 Phnom Penh | Animals: Y FWA: Y Humans: N | | | | | |

| CHINA | | | |
|--|--|---|--|
| State Department Clearance Request (SDCR ID 211200) | NIAID Contact | SDCR ACTIONS | ACTION DATES |
| Click the + to show the Research Objective listed on State Department Clearance. | Bernabe, Gavie Phone: 301-451-1018 | Approved Approve Send to Agency Submit to State Department IC Update IC Save | 2016-11-29 2016-11-29 2016-10-24 2016-10-24 2016-10-20 2016-10-12 |
| State Department Clearance Request (SDCR ID 202191) | NIAID Contact | SDCR ACTIONS | ACTION DATES |
| Click the + to show the Research Objective listed on State Department Clearance. | <u>Bernabe, Gavie</u> Phone: 301-451-1018 | Approved Approve Send to Agency Submit to State Department IC Update IC Save | 2014-03-11 2016-11-29 2016-10-24 2016-10-24 2016-10-20 2016-10-12 |
| Collaborator/Site (Site ID: 211436) | Site Flags Budget Peri | od Budget Amt Verif | ied By Verified Date |
| the annual and the second | I | | |

RE, CHANGWEN
CENTER FOR DISEASE CONTROL AND PREVENTION OF GUANGDONG
176 Xigang Xilu
Guangzhou 5103009

Animals: Y FWA: N Humans: Y

| Collaborator/Site (Site ID: 211435) ZHANG, SHUYI EAST CHINA NORMAL UNIVERSITY 3663 Zhongshan Berlu Shanghai 200062 | Site Flags Animals: Y FWA: N Humans: Y | Budget P 1 2 3 4 5 | eriod | Sudget Amt \$94,068 \$72,684 \$54,117 \$42,300 \$32,454 | | Verified By | Ver | ified Date |
|---|---|---|---|---|--|-------------------------|---|----------------------------|
| Collaborator/Site (Site ID: 211433) ZHJ, GUANJIN GUANGDONG ENTOMOLOGICAL INSTITUTE (ECNU) Room 1707, Building 622 3663 Zhongshanbel Rd Shanghal, Putuo District 200026 | | Site Flags Animals: Y FWA: N Humans: Y | Budget | t Period | Budget Amt | Verified B | y Ve | prified Date |
| Collaborator/Site (Site ID: 235943) LI, SHIYUE SCHOOL OF PUBLIC HEALTH, WUHAN UNIVERSITY 115 Donghu Road Wuchang Wuhan, Hubei 430071 | | Site Flags Animats: N FWA: Y Humans: Y | Budget | t Period | Budget Amt | Verified B | y Ve | erified Date |
| Collaborator/Site (Site ID: 211434) SHI, ZHENGLI WUHAN INSTITUTE OF VIROLOGY Xiao Hong Shan, No. 44 Wuchang District Wuhan 430071 | Site Flags Animals: Y FWA: N Humans: Y | Budget Ps 1 2 3 4 5 | ried | 8udget Amt \$133,595 \$139,015 \$159,422 \$159,422 \$159,122 | | Verified By | Ver | ified Date |
| Collaborator/Site (Site ID: 211437) ZHANG, YUH-ZHI YUNNAN INSTITUTE OF ENDEMIC DISEASES CONTROL AND PREVENTION 33 Wershua Road Dali 658201 | O MICHEL BACK CHO 100 | 1003 KIN 1003 KINSKI 1003 K | Site Flags Animals: Y FWA: N Humans: Y | Budget Per | iod Budg | et Amt Veri | fied By | Verified Dat |
| INDONESIA State Department Clearance Request (SDCR ID 212150) | | | NIAID Conte | act | SOCR ACTIO | NS | ACTION D | ATES |
| Click the + to show the Research Objective listed on State Department | t Clearance. | | Bernabe, G Phone: 301- | | Approved Auto Approved Send to Age Submit to S IC Save | | 2017-03-2 2017-03-2 2017-03-1 2017-03-1 2017-03-0 | 7 3 3 |
| Collaborator/Site (Site ID: 238619) PAMUNGKAS, JOKO PRIMATE RESEARCH CENTER AT BOGOR AGRICULTURAL UNIVERSITY JaianLodayall/5 Bogor 16151 | | | Site Flags Animals: Y FWA: Y Humans: N | Budget Perio | | t Amt Verif | ied By | Verified Dat |
| LAOS | | | | | | | | |
| State Department Clearance Request (SDCR ID 212151) Click the + to show the Research Objective listed on State Department | t Clearance. | DECEMBER OF STREET | NIAID Conta Bernabe, G Phone: 301 | avle | Approved Auto Approv Submit to S Send to Age IC Save | rai. tate Department | ACTION D 2017-03-2 2017-03-1 2017-03-1 2017-03-6 | 27 27 3 |
| Collaborator/Site (Site ID: 238620) THEPPANGNA, WATTHANA NATIONAL ANIMAL HEALTH LABORATORY Department of Livestock and Fisheries Manistry of Agriculture and Forestry Vientiane | A F | ite Flags Introdus: Y WA: Y furnans: N | Budget Perio | d Bu | dget Amt | Verified By | MINO EMINO CO | ified Date |
| MALAYSIA | | | | | **** | | | 34073140734073407340734071 |
| State Department Clearance Request (SDCR ID 212152) | | CHO KIMION CHO IN HOL | NIAID Conta | act | SOCR ACTIO | NS | ACTION D | ATES |
| Click the + to show the Research Objective listed on State Department | t Clearance. | | <u>Bernabe, G</u> Phone: 301 | | Approved Auto Approv Send to Age Submit to S IC Save | | 2017-03- 2017-03-2 2017-03-1 2017-03-0 | 17 13 13 |
| Collaborator/Site (Site ID: 238622) | | Site Flags | Budget Per | iod B | udget Amt | Verified By | Vei | rified Date |

TOM, HUGHES CONSERVATION MEDICINE, LTD Suite 4A, Level 4, Main Office Tower Financial Park Complex Bandar Labuan, Federal Territory of Labuan

Animais: Y FWA: Y Humans: N

THAILAND

NIAID Contact SOCR ACTIONS ACTION DATES State Department Clearance Request (SDCR ID 212154)

Click the + to show the Research Objective listed on State Department Clearance.

Bernabe, Gayte Phone: 301-451-1018 2017-03-17 Approved 2017-03-17 Approve Submit to State Department 2017-03-13

Send to Agency IC Save 2017-03-13 2017-03-02

Collaborator/Site (Site ID: 238627) Site Flags **Budget Period** Budget Amt Verified By Verified Date

Animals: Y

FWA: Y Humans: N

WACHARAPLUESADEE, SUPAPORN KING CHULALONGKORN MEMORIAL HOSPITAL Neuroscience Center for Research and Development Rama 4 Road

Bangkok, Patumwan 10330

VIETNAM

State Department Clearance Request (5DCR ID 212155) NIAID Contact SDCR ACTIONS ACTION DATES

Bernabe, Gavie Phone: 301-451-1018 Approved 2017-03-27 Click the + to show the Research Objective listed on State Department Clearance. Auto Approvat Send to Agency 2017-03-27 2017-03-13

Submit to State Department IC Save 2017-03-13 2017-03-02

Collaborator/Site (Site ID: 238629) Site Flags **Budget Period Budget Amt** Verified By Verified Date Animais: Y

FWA: Y

Humans: N

NAM, NGUYEN HUU HANOI AGRICULTURAL UNIVERSITY Faculty of Animal and Veterinary Science Trauquy

Hanoi, Gialam

QVR FACTS

FACTS Data Snapshot for: 5-R01-Al110964-04 (DASZAK, PETER) Understanding the Risk of Bat Coronavirus Emergence NT CLOSE Appl ld: 932074

Launch the FACTS System: FRATTS

Hop to Country: Project Information BURMA CAMBODIA CHINA INDONESIA LAGS MALAYSIA THAILAND VIETNAM

| 5-R01-Al110964-04 (as reflected under competing project number 1-R01-Al110964-01 in FACTS) |
|--|
| DASZAK, PETER |
| ECOHEAITH ALLIANCE, INC. |
| Understanding the Risk of Bat Coronavirus Emergence |
| 2017 (Project Period from 2014-06-01 to 2019-05-31) |
| Awarded (05) |
| Domestic Application with Foreign Collaboration (2) |
| |

| BURMA | | | | | |
|--|-----------------------------------|-------------------------------------|-----------|---|--|
| State Department Clearance Request (SDCR ID 212153) | | MIAID Contact | 5 | DCR ACTIONS | ACTION DATES |
| Click the + to show the Research Objective listed on S | tate Department Clearance, | Bernabe, Gavie Phone: 301-451-1(| 018 A | approved Auto Approval Jubmit to State Department Jend to Agency C Save | 2617-04-10 2017-04-10 2017-03-27 2017-03-25 2017-03-02 |
| Collaborator/Site (Site ID: 238626) | Site Flags | Budget Period | Budget Am | t Verified By | Verified Date |
| TOE, AUNG THAN SAN PYA CLINIC 20/256 Insein Road Yangon 11054 | Animals: Y FWA: Y Humans: N | | | | |

| State Department Clearance Request (SDCR ID 212148) | | NIAID Contact | SDCR | ACTIONS | ACTION DATES | |
|---|-----------------------------------|---|------------|---|--|--|
| Click the + to show the Research Objective listed on | State Department Clearance. | <u>Bernabe, Gayis</u> Phone: 301-451 | -1018 Auto | Approva: it to State Department to Agency | 2017-03-27 2017-03-27 2017-03-13 2017-03-13 2017-03-02 | |
| Collaborator/Site (Site ID: 238614) | Site Flags | Budget Period | Budget Amt | Verified By | Verified Date | |
| DUONG, YEASNA INSTITUT PASTEUR DU CAMBODGE No. 5 Montveng Boutevand P.O. Box 983 Phnom Penh | Animals: Y FWA: Y Humans: N | | | | | |

| CHINA | | | | | |
|--|-----------------------------------|---------------|---|--------------------------------------|---|
| State Department Clearance Request (SDCR ID 211200) | NIAID Conta | ct | SDCR ACTIONS | ACTIO | ON DATES |
| Click the + to show the Research Objective listed on State Department Clearance. | Phone: 301-451-1018 | | | | ~11-29 11-29 10-24 10-24 10-20 10-12 |
| State Department Clearance Request (SDCR ID 202191) | NIAID Conta | ct. | SDCR ACTIONS | ACTIO | ON DATES |
| Click the + to show the Research Objective listed on State Department Clearance. | <u>Bernabe, Ga</u> Phone: 301- | | Approved Approve Send to Agency Submit to State Departm IC Update IC Save | 2016- 2016- ent 2016- 2016- | -03-11 11-29 10-24 10-24 10-20 10-12 |
| Collaborator/Site (Site ID: 211436) | Site Flags | Budget Period | Budget Amt | erified By | Verified Date |
| KE, CHANGWEN | Animals: Y | | | | |

Humans: Y

CENTER FOR DISEASE CONTROL AND PREVENTION OF GUANGDONG

176 Xigang Xilu Guangzhou 5103000

| Collaborator/Site (Site ID: 211435) | | D | Davind | Budent 4 | | Marisia J D. | Ma - 262 - 1 | Det- |
|--|---------------------------|---|--|-----------------------------|---|--|---|--------------|
| 7UANC CLUIVI | Site Flags | Budget F | тепоа | Budget Amt | | Verified By | Verified | nace |
| PHANG, SHUYI EAST CHINA NORMAL UNIVERSITY | Animais: Y FWA: N | 1 2 | | \$94,068 \$72,684 | | | | |
| 3663 Zhongshan Beilu | Humans: Y | 3 | | \$54,117 | | | | |
| Shanghai 200062 | | 4 5 | | \$42,300 \$32,454 | | | | |
| ollaborator/Site (Site ID: 211433) | | Site Flags | Budget | : Period | Budget Amt | Verified By | y Verifie | d Dati |
| IFU, GUANJIN | | Animals: Y | | | | | | |
| GUANGDONG ENTOMOLOGICAL INSTITUTE (ECNU) Boom 1707, Building 622 | | FWA: N Humans: Y | | | | | | |
| 1663 Zhongshanbel Rd Hanghai, Putuo District 200026 | O MOTHER ACK DESCRIPTION | | etkonnon konnenkonnon on | | | | | CONTRACT TOO |
| ollaborator/Site (Site ID: 235943) | | Site Flags | Budget | Period | Budget Amt | Verified By | y Verifie | d Date |
| u, shiyue | | Animats: N | | | | | | |
| SCHOOL OF PUBLIC HEALTH, WUHAN UNIVERSITY 115 Dooghu Road | | FWA: Y Humans: Y | | | | | | |
| Muchang Muhan, Huber 430071 | | | | | | | | |
| ollaborator/Site (Site ID: 211434) | Site Flags | Budget Pi | pried | Budget Amt | | Verified By | Verified | Date |
| SH, ZHENGLI | Animals: Y | i sauger r | | 5133,595 | | months by | e est in est C | |
| WUHAN INSTITUTE OF VIROLOGY | FWA: N | 2 | | \$139,015 | | | | |
| Kiao Hong Shan, No. 44 Wuchang District | Humans: Y | 3 4 | | \$159,422 \$159,422 | | | | |
| Wilhari 430071 | | 5 | | \$159,122 | | | | |
| ollaborator/Site (Site ID: 211437) | | | Site Flags | Budget Peri | od Budge | t Amt Verif | fied By Veri | ified [|
| ZHANG, YUH-ZHI | | | Animals: Y | | | | | |
| YUNNAN INSTITUTE OF ENDEMIC DISEASES CONTROL AND PREVENTION 33 Wenhua Road | | | FWA: N Humans: Y | | | | | |
| Dal: 650201 | CF RESCRICT RESCRICTOR NO | 0.000 CH 0.001 000001 0.001 C | NORSE SOCIOSES O | SOCK OKCOSES AN DESCRIPTION | DOX DONOCK DANGEDONICA CO | ************************************** | SOCIET SOCIE POSICIONOSOCIO | onecu co |
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| NDONESIA tabe Department Clearance Request (SDCR ID 212150) | | | NIAID Conta | act | SOCR ACTION | s | ACTION DATES | |
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| and the course of the company of the confidence of the course of the cou | 4 4.112 011 011 1111 1 | | Phone: 301- | 451-1018 | Auto Approva Send to Agent | | 2017-03-27 | |
| | | | | | | | 2017-03-13 | |
| | | | | | Submit to Sta | te Department | 2017-03-13 2017-03-13 2017-03-02 | |
| ollaborator/Site (Site ID: 238619) | | | Site Flags | Budget Perio | Submit to Sta IC Save | te Department | 2017-03-13 2017-03-02 | fied D |
| | | | | Budget Perior | Submit to Sta IC Save | te Department | 2017-03-13 2017-03-02 | fied D |
| ollaborator/Site (Site ID: 238619) PAMUNGKAS, JOKO PRIMATE RESEARCH CENTER AT BOGOR AGRICULTURAL UNIVERSITY | | | Animals: Y FWA: Y | Budget Perior | Submit to Sta IC Save | te Department | 2017-03-13 2017-03-02 | fied D |
| PAMUNGKAS, JOKO PRIMATE RESEARCH CENTER AT BOGOR AGRICULTURAL UNIVERSITY JalanLodayaH/5 | | | Animals: Y | Budget Perior | Submit to Sta IC Save | te Department | 2017-03-13 2017-03-02 | fied D |
| MAMUNGKAS, JOKO PRIMATE RESEARCH CENTER AT BOGOR AGRICULTURAL UNIVERSITY IslanLodayall/5 | | \$1 \$10 \$100 \$10 \$1 \$10 \$10 \$10 \$10 \$10 \$ | Animals: Y FWA: Y | Budget Period | Submit to Sta IC Save | te Department | 2017-03-13 2017-03-02 | fied D |
| MMUNGKAS, JOKO PRIMATE RESEARCH CENTER AT BOGOR AGRICULTURAL UNIVERSITY BIANLOGAYAH/S | | 10 504 508 50 504 504 504 508 508 508 508 508 508 508 508 509 509 509 509 509 509 509 509 509 509 | Animals: Y FWA: Y | Budget Perior | Submit to Sta IC Save | te Department | 2017-03-13 2017-03-02 | fled D |
| MMUNGKAS, JOKO PRIMATE RESEARCH CENTER AT BOGOR AGRICULTURAL UNIVERSITY ialanLodayaH/5 logor 16151 | | | Animals: Y FWA: Y Humans: N | C. O SO CS COO SO CO. | Submit to Sta IC Save d Budget | te Department | 2017-03-13 2017-03-02 ied By Verif | |
| PAMUNGKAS, JOKO PRIMATE RESEARCH CENTER AT BOGOR AGRICULTURAL UNIVERSITY ialanLodayaH/5 logor 16151 | 0.000 0.000 0.000 | | Animals: Y FWA: Y Humans: N | d | Submit to Sta IC Save d Budget | te Department | 2017-03-13 2017-03-02 led By Veril ACTION DATES | |
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| AMUNGKAS, JOKO PRIMATE RESEARCH CENTER AT BOGOR AGRICULTURAL UNIVERSITY islanLodayall/5 logor 16151 AOS istate Department Clearance Request (SDCR ID 212151) | t Clearance. | | Animals: Y FWA: Y Humans: N | ect | Submit to Sta IC Save d Budget SDCR ACTION Approved Auto Approved Auto Approves Submit to Sta | te Department Amt Verifi S L te Department | 2017-03-13 2017-03-02 led By Veril ACTION DATES 2017-03-27 2017-03-27 2017-03-13 | |
| PAMUNGKAS, JOKO PRIMATE RESEARCH CENTER AT BOGOR AGRICULTURAL UNIVERSITY islanLodayaH/5 Bogor 16151 LAOS State Department Clearance Request (SDCR ID 212151) | t Clearance. | | Animals: Y FWA: Y Humans: N NIAID Conta Bernabe, Gr | ect | Submit to Stail C Save d Budget SDCR ACTION Approved Auto Approve Submit to Sta Send to Agen | te Department Amt Verifi S L te Department | 2017-03-13 2017-03-02 led By Veril ACTION DATES 2017-03-27 2017-03-27 | |
| AMUNGKAS, JOKO PRIMATE RESEARCH CENTER AT BOGOR AGRICULTURAL UNIVERSITY islanLodayaH/5 Regor 16151 AOS State Department Clearance Request (SDCR ID 212151) Click the + to show the Research Objective listed on State Department | 10 EURA 1110 EURA | ite Flags | Animals: Y FWA: Y Humans: N NIAID Conta Bernabe, Gr | ict nyle 491-1018 | Submit to Sta IC Save d Budget SDCR ACTION Approved Auto Approved Auto Approves Submit to Sta | te Department Amt Verifi S L te Department | 2017-03-13 2017-03-02 led By Verif ACTION DATES 2017-03-27 2017-03-13 2017-03-13 | |
| PAMIUNGKAS, JOKO PRIMATE RESEARCH CENTER AT BOGOR AGRICULTURAL UNIVERSITY islanLodayall/5 Bogor 16151 LAOS State Department Clearance Request (SDCR ID 212151) Click the + to show the Research Objective listed on State Department offaborator/Site (Site ID: 238620) | S. | ite Flags | Animals: Y FWA: Y Humans: N NIAID Conta Bernabe, G Phone: 301- | ict nyle 491-1018 | Submit to Stail C Save d Budget SDCR ACTION Approved Auto Approved Submit to Stail Send to Agent IC Save | te Department S te Department Cy | 2017-03-13 2017-03-02 led By Veril ACTION DATES 2017-03-27 2017-03-27 2017-03-13 2017-03-02 | |
| PAMIUNGKAS, JOKO PRIMATE RESEARCH CENTER AT BOGGR AGRICULTURAL UNIVERSITY JAIALLOGAYAH/S Boggr 16151 LAOS State Department Clearance Request (SDCR ID 212151) Click the + to show the Research Objective listed on State Department Cliaborator/Site (Site ID: 238620) THE PRINCIPAL ANIMAL HEALTH LABORATORY | S: | Animals: Y FWA: Y | Animals: Y FWA: Y Humans: N NIAID Conta Bernabe, G Phone: 301- | ict nyle 491-1018 | Submit to Stail C Save d Budget SDCR ACTION Approved Auto Approved Submit to Stail Send to Agent IC Save | te Department S te Department Cy | 2017-03-13 2017-03-02 led By Veril ACTION DATES 2017-03-27 2017-03-27 2017-03-13 2017-03-02 | |
| PAMIUNGKAS, JOKO PRIMATE RESEARCH CENTER AT BOGGR AGRICULTURAL UNIVERSITY islanLodayaH/5 Boggr 16151 LAOS State Department Clearance Request (SDCR ID 212151) Click the + to show the Research Objective listed on State Department offisborator/Site (Site ID: 238620) THE PPANGNA, WATTHANA NATIONAL ANIMAL HEALTH LABORATORY Papartment of Livestock and Fisheries | S: | Animals: Y | Animals: Y FWA: Y Humans: N NIAID Conta Bernabe, G Phone: 301- | ict nyle 491-1018 | Submit to Stail C Save d Budget SDCR ACTION Approved Auto Approved Submit to Stail Send to Agent IC Save | te Department S te Department Cy | 2017-03-13 2017-03-02 led By Veril ACTION DATES 2017-03-27 2017-03-27 2017-03-13 2017-03-02 | |
| AMUNGKAS, JOKO REMATE RESEARCH CENTER AT BOGOR AGRICULTURAL UNIVERSITY alanLodayali/5 ogor 16151 AOS tate Department Clearance Request (SDCR ID 212151) Click the + to show the Research Objective listed on State Department officers of the Communication of the | S: | Animals: Y FWA: Y | Animals: Y FWA: Y Humans: N NIAID Conta Bernabe, G Phone: 301- | ict nyle 491-1018 | Submit to Stail C Save d Budget SDCR ACTION Approved Auto Approved Submit to Stail Send to Agent IC Save | te Department S te Department Cy | 2017-03-13 2017-03-02 led By Veril ACTION DATES 2017-03-27 2017-03-27 2017-03-13 2017-03-02 | |
| AMUNGKAS, JOKO RIMATE RESEARCH CENTER AT BOGGR AGRICULTURAL UNIVERSITY alanLodayali/5 logor 16151 AOS AOS Click the + to show the Research Objective listed on State Department officerorial officero | S: | Animals: Y FWA: Y | Animals: Y FWA: Y Humans: N NIAID Conta Bernabe, G Phone: 301- | ict nyle 491-1018 | Submit to Stail C Save d Budget SDCR ACTION Approved Auto Approved Submit to Stail Send to Agent IC Save | te Department S te Department Cy | 2017-03-13 2017-03-02 led By Veril ACTION DATES 2017-03-27 2017-03-27 2017-03-13 2017-03-02 | |
| AMMUNGKAS, JOKO PRIMATE RESEARCH CENTER AT BOGGR AGRICULTURAL UNIVERSITY alanLodayali/5 logor 16151 AOS State Department Clearance Request (SDCR ID 212151) Click the + to show the Research Objective listed on State Department of laborator/Site (Site ID: 238620) THE PPANGNA, WATTHANA IATIONAL ANIMAL HEALTH LABORATORY Department of Livestock and Fisheries finistry of Agriculture and Forestry fientiance | S: | Animals: Y FWA: Y | Animals: Y FWA: Y Humans: N NIAID Conta Bernabe, Gi Phone: 301- | d Bud | Submit to Stail C Save d Budget SDCR ACTION Approved Auto Approve Submit to Stail Send to Agent IC Save | te Department Amt Verifi S It te Department Cy Verified By | 2017-03-13 2017-03-02 led By Verifi ACTION DATES 2017-03-27 2017-03-13 2017-03-13 2017-03-02 Verified | |
| PAMIUNGKAS, JOKO PRIMATE RESEARCH CENTER AT BOGGR AGRICULTURAL UNIVERSITY islanLodayall/5 Rogor 16151 LAOS State Department Clearance Request (SDCR ID 212151) Click the + to show the Research Objective listed on State Department collaborator/Site (Site ID: 238620) ITEPPANGNA, WAITHANA | S: | Animals: Y FWA: Y | Animals: Y FWA: Y Humans: N NIAID Conta Bernabe, Gi Phone: 301- Budget Perio | ect avie 451-1018 d Bud | Submit to Sta IC Save d Budget SDCR ACTION Approved Auto Approve Submit to Sta Send to Agent IC Save Iget Amt | te Department Amt Verifi S It te Department Cy Verified By | 2017-03-13 2017-03-02 led By Verifi ACTION DATES 2017-03-27 2017-03-13 2017-03-13 2017-03-02 Verified | |
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TOM, HUGHES CONSERVATION MEDICINE, LTD Suite 4A, Level 4, Main Office Tower Financial Park Complex Bandar Labuan, Federal Territory of Labuan

Animais: Y FWA: Y Humans: N

THAILAND

NIAID Contact SOCR ACTIONS ACTION DATES State Department Clearance Request (SDCR ID 212154)

Click the + to show the Research Objective listed on State Department Clearance.

Bernabe, Gayte Phone: 301-451-1018 2017-03-17 Approved 2017-03-17 Approve Submit to State Department 2017-03-13

Send to Agency IC Save 2017-03-13 2017-03-02

Collaborator/Site (Site ID: 238627) Site Flags **Budget Period** Budget Amt Verified By Verified Date

WACHARAPLUESADEE, SUPAPORN KING CHULALONGKORN MEMORIAL HOSPITAL Neuroscience Center for Research and Development

Animals: Y FWA: Y Humans: N

Rama 4 Road

Bangkok, Patumwan 10330

VIETNAM

State Department Clearance Request (5DCR ID 212155) NIAID Contact SDCR ACTIONS ACTION DATES

Bernabe, Gavie Phone: 301-451-1018 Approved 2017-03-27 Click the + to show the Research Objective listed on State Department Clearance. Auto Approvat Send to Agency 2017-03-27 2017-03-13

Submit to State Department IC Save 2017-03-13 2017-03-02

Collaborator/Site (Site ID: 238629) Site Flags **Budget Period Budget Amt** Verified By Verified Date

NAM, NGUYEN HUU HANOI AGRICULTURAL UNIVERSITY Faculty of Animal and Veterinary Science Trauquy Hanoi, Gialam

Animais: Y FWA: Y Humans: N

QVR FACTS

FACTS Data Snapshot for: 5-R01-Al110964-05 (DASZAK, PETER) Understanding the Risk of Bat Coronavirus Emergence NT CLOSE Appl ld: 94916;

Launch the FACTS System: FRATTS

Hop to Country: Project Information BURMA CAMBODIA CHINA INDONESIA LAOS MALAYSIA THAILAND VIETNAM

| 5-RC1-Al110964-05 (as reflected under competing project number 1-R01-Al110964-01 in FACTS) |
|--|
| DASZAK, PETER |
| ECOHEALTH ALLIANCE, INC. |
| Understanding the Risk of Bat Coronavirus Emergence |
| 2018 (Project Period from 2014-06-01 to 2019-05-31) |
| Awarded (05) |
| Demestic Application with Foreign Collaboration (2) |
| |

| BURMA | | | | | |
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| State Department Clearance Request (SDCR ID 212153) | Department Clearance Request (SDCR ID 212153) | | S | DCR ACTIONS | ACTION DATES |
| Click the + to show the Research Objective listed on St | ate Department Clearance. | Bernabe, Gavie Phone; 301-451-10 | 18 A 5 2 | pproved Litto Approval ubmit to State Department end to Agency C Save | 2017-04-10 2017-04-10 2017-03-27 2017-03-25 2017-03-02 |
| Collaborator/Site (Site ID: 238626) | Site Flags | Budget Period | Budget Amt | Verified By | Verified Date |
| TOE, AUNG THAN SAN PYA CLINIC 20/236 Insein Road Yangon 1 1051 | Animals: Y FWA: Y Humans: N | | | | |

| State Department Clearance Request (SDCR ID 212148) | | NIAID Contact | SDCR | ACTIONS | ACTION DATES |
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| Click the + to show the Research Objective listed on | State Department Clearance, | <u>Bernabe, Gayle</u> Phone: 301-451 | -1018 Auto A Submi Send t | Approved Auto Approva: Submit to State Department Send to Agency IC Save | |
| Collaborator/Site (Site ID: 238614) | Site Flags | Budget Period | Budget Amt | Verified By | Verified Date |
| DUONG, VEASNA INSTITUT PASTEUR DU CAMBODGE No. 5 Moniveng Boutevand P.O. 80x 983 Phnom Penh | Animals: Y FWA: Y Humans: N | | | | |

| CHINA | | | |
|--|--|---|--|
| State Department Clearance Request (SDCR ID 211200) | MAID Contact | SDCR ACTIONS | ACTION DATES |
| Click the + to show the Research Objective listed on State Department Clearance. | Bernabe, Gavie Phone: 301-451-1018 | Approved Approve Send to Agency Submit to State Department IC Update IC Save | 2016-11-29 2016-11-29 2016-10-24 2016-10-24 2016-10-20 2016-10-12 |
| State Department Clearance Request (SDCR ID 202191) | NIAID Contact | SDCR ACTIONS | ACTION DATES |
| Click the + to show the Research Objective listed on State Department Clearance. | <u>Bernabe, Gavie</u> Phone: 301-451-1018 | Approved Approve Send to Agency Submit to State Department IC Update IC Save | 2014-03-11 2016-11-29 2016-10-24 2016-10-24 2016-10-20 2016-10-12 |
| Collaborator/Site (Site ID: 211436) | Site Flags Budget Period | Budget Amt Verif | ied By Verified Date |
| | | | |

RE, CHANGWEN
CENTER FOR DISEASE CONTROL AND PREVENTION OF GUANGDONG
176 Xigang Xilu
Guangzhou 5103009

Animals: Y FWA: N Humans: Y

| Collaborator/Site (Site ID: 211435) ZHANG, SHUYI EAST CHINA NORMAL UNIVERSITY 3663 Zhongshan Berlu Shanghai 200062 | Site Flags Animals: Y FWA: N Humans: Y | Budget P 1 2 3 4 5 | eriod | Sudget Amt \$94,068 \$72,684 \$54,117 \$42,300 \$32,454 | DE TOTAL ROBBINS CONTO | Verified By | | Verified Date |
|--|---|---|---|---|---|-------------------------|--|-----------------------|
| Collaborator/Site (Site ID: 211433) ZHU, GUANJIN GUANGDONG ENTOMOLOGICAL INSTITUTE (ECNU) Room 1707, Building 622 3663 Zhongshanbel Rd Shanghai, Putuo District 2000726 | MUNICO ES MONTANONIO | Site Flags Animals: Y FWA: N Humans: Y | Budget | Period | Budget Amt | Verified B | у | Verified Date |
| Collaborator/Site (Site ID: 235943) LI, SHIYUE SCHOOL OF PUBLIC HEALTH, WUHAN UNIVERSITY 115 Donghu Road Wuchang Wuhan, Hubel 430071 | | Site Flags Animats: N FWA: Y Humans: Y | Budget | Period | Budget Amt | Verified B | y | Verified Date |
| Collaborator/Site (Site ID: 211434) SML ZHENGLI WUHAN INSTITUTE OF VIROLOGY Xiao Hong Shan, No. 44 Wuchang District Wuhan 430071 | Site Flags Animals: Y FWA: N Humans: Y | Budget Ps 1 2 3 4 5 | eriod | 8udget Amt \$133,595 \$139,015 \$159,122 \$159,122 \$159,122 | | Verified By | , | Verified Date |
| Collaborator/Site (Site ID: 211437) ZHANG, YUH-ZHI YUNNAN INSTITUTE OF ENDEMIC DISEASES CONTROL AND PREVENTION 33 Werflua Road Dali 650201 | NOON 1000 CTO 100 | NOR TO THE RESERVE THE PERSON NAMED TO | Site Flags Animals: Y FWA: N Humans: Y | Budget Peri | od Budg | get Amt Veri | fied By | Verified Date |
| NDONESIA | | | NIED Conto | | 6000 4000 | MIC | ACTIO | . Dure |
| State Department Clearance Request (SDCR ID 212150) Click the + to show the Research Objective listed on State Department | Clearance. | | Sernabe, G Phone: 301- | RYIE | Approved Auto Appro Send to Age Submit to S IC Save | yai | 2017-0 2017-0 2017-0 2017-0 2017-0 | 3-27 3-13 3-13 |
| oliaborator/Site (Site ID: 238619) PAMUNGKAS, JOKO PRIMATE RESEARCH CENTER AT BOGOR AGRICULTURAL UNIVERSITY JalanLodayaH/5 Bogor 16151 | | | Site Flags Animals: Y FWA: Y Humans: N | Budget Perioc | | et Amt Verif | ied By | Verified Date |
| LAOS | | | | | | | | |
| State Department Clearance Request (SDCR ID 212151) Click the + to show the Research Objective listed on State Department | Clearance. | NO ENTER STOR STORES ENTER | NIAID Conta Bernabe, Gr Phone: 301- | avie | Approved Auto Appro Submit to S Send to Age IC Save | val Itate Department | 2017-0 2017-0 2017-0 2017-0 2017-0 | 3-27 3-13 3-13 |
| Collaborator/Site (Site ID: 238620) THEPPSHIGNA, WATTHANA NATIONAL ANIMAL HEALTH LABORATORY Department of Livestock and Fisheries Ministry of Agriculture and Forestry Vientiane | A | te Flags nimals: Y WA: Y umans: N | Budget Perio | d Bud | iget Amt | Verified By | H-100 EH100 | /erified Date |
| MALAYSIA | | | | | | | | |
| State Department Clearance Request (SDCR ID 212152) Click the + to show the Research Objective listed on State Department | Clearance. | CHANGE CHANGE OF THE CO. | NIAID Conta Bernabe, G Phone: 301- | ayie | | yai | 2017-0 2017-0 2017-0 2017-0 | 3-27 3-13 3-13 |
| Collaborator/Site (Site ID: 238622) | | Site Flags | Budget Per | iod Bu | IC Save | Verified By | 2017-0 | 3-02 Verified Date |

TOM, HUGHES CONSERVATION MEDICINE, LTD Suite 4A, Level 4, Main Office Tower Financial Park Complex Bandar Labuan, Federal Territory of Labuan

Animais: Y FWA: Y Humans: N

THAILAND

NIAID Contact SOCR ACTIONS State Department Clearance Request (SDCR ID 212154)

Click the + to show the Research Objective listed on State Department Clearance.

Bernabe, Gayte Phone: 301-451-1018 Approved Approve

Budget Period

2017-03-17 2017-03-17 Submit to State Department 2017-03-13 Send to Agency IC Save 2017-03-13 2017-03-02

ACTION DATES

Budget Amt Verified By Verified Date

Collaborator/Site (Site ID: 238627) WACHARAPLUESADEE, SUPAPORN KING CHULALONGKORN MEMORIAL HOSPITAL Neuroscience Center for Research and Development

Rama 4 Road Bangkok, Patumwan 10330 Animals: Y FWA: Y Humans: N

Site Flags

VIETNAM

State Department Clearance Request (5DCR ID 212155) NIAID Contact SDCR ACTIONS ACTION DATES

Click the + to show the Research Objective listed on State Department Clearance.

Bernabe, Gavie Phone: 301-451-1018 Approved 2017-03-27 Auto Approvat Send to Agency 2017-03-27 2017-03-13 Submit to State Department IC Save 2017-03-13 2017-03-02

Collaborator/Site (Site ID: 238629) Site Flags **Budget Period Budget Amt** Verified By Verified Date

NAM, NGUYEN HUU HANOI AGRICULTURAL UNIVERSITY Faculty of Animal and Veterinary Science Trauquy

Hanoi, Gialam

2-R01-Al110964-06 (as reflected under competing project number 2-R01-Al110964-06 in FACTS)

QVR FACTS

Project Info Project Number

FACTS Data Snapshot for: 2-R01-Al110964-06 (DASZAK, PETER) Understanding the Risk of Bat Coronavirus Emergence

Launch the FACTS System: FRATTS

Hop to Country: Project Information CHINA SINGAPORE

PRINT CLOSE Appl Id: 981930

| PI Hame | DASZAK, PETER | | | | | |
|--|--|---|---|---|--|--|
| Org Hame | ECOHEALTH ALLIANCE, INC. | | | | | |
| Project Title | Understanding the Risk of Bat Cor | onavirus Emergence | | | | |
| FY/Project Dates | 2019 (Project Period from 2014-06 | 5-01 to 2020-04-24) | | | | |
| Project Status | Awarded (05) | | | | | |
| Foreign Appl Flag | Domestic Application with Foreign | Collaboration (2) | | | | |
| CHINA | *************************************** | *************************************** | | | | 0.0000000000000000000000000000000000000 |
| State Department Clearano | e Request (SDCR ID 219890) | | NIAID Contact | SDCR AC | TIONS | ACTION DATES |
| Click the + to show th | e Research Objective listed on State Dep | partment Clearance, | <u>Bernabe, Gavie</u> Phone: 301-451-1 | | o State Department Agency | 2019-05-30 2019-05-30 2019-05-29 2019-05-28 2019-05-24 2019-05-10 |
| Collaborator/Site (Site ID: 2) | 62256) | Site Flags | Budget Period | Budget Amt | Verified By | Verified Date |
| ZHU, GUANGJIAN EAST CHINA NORMAL UNIVE School of Life Science, 8327 Science building, 3663 Zhong Shanghat 200062 | | Antmals: Y FWA: Humans: N | | | | |
| Collaborator/Site (Site ID: 2: | 62253} | Site Flags | Budget Period | Budget Amt | Verified By | Verified Date |
| GUO, LI INSTITUTE OF PATHOGEN BI Dong Dan San Tiao, No. 9 Dongcheng District Beljing 100730 | OLOGY | Animals: N PWA: Y Humans: Y | | | | |
| Collaborator/Site (Site ID: 2) | 62252) | Site Flags | Budget Period | Budget Amt | Verified By | Verified Date |
| REN, LILI INSTITUTE OF PATHOGEN BI Dong Dan San Tiao, No. 9 Dongcheng District Beijing 100730 | OLOGY | Animals; N FWA: Y Humans: Y | | | 0 - 40 - 40 - 40 - 40 - 40 - 40 - 40 - | *************************************** |
| Collaborator/Site (Site ID: 2: | 62251) | Site Flags | Budget Period | Budget Amt | Verified By | Verified Date |
| HU, BEN WUHAN INSTITUTE OF VIRO Xiao Hong Shan, No. 44 Wuchang District Wuhan 430071 | LOGY | Ammals: Y FWA: Humans: N | 1000E11000 100 E7 000 E00E7 000 E | NO. 1 COLUMN 1 TO THE PARTY OF | | |
| Collaborator/Site (Site ID: 2 | 61948) | Site Flags | Budget Period | Budget Amt | Verified By | Verified Date |
| SHI, ZHENG LI WUHAN INSTITUTE OF VIRO Xiao Hong Shan, No. 44 Wuchang District Wuhan 430071 | LOGY | Animals: Y FVA: Humans: N | | | | |
| Collaborator/Site (Site ID: 2 | 62250) | Site Flags | Budget Period | Budget Amt | Verified By | Verified Date |
| ZHOU, PENG WUHAN INSTITUTE OF VIRO Xiao Hong SHan, No. 44 Wuchang District Wuhan 430071 | LOGY | Animals: Y FWA: Humans: N | | | | |

| Click the + to show the Research Objective listed on | State Department Clearance. | <u>Bernabe, Gavie</u> Phone: 301-451 | -1018 Auto Ap Send to | oproval Agency to State Department | 2019-05-20 2019-05-20 2019-05-06 2019-05-06 2019-05-01 |
|--|---------------------------------|---|--------------------------|--|--|
| Collaborator/Site (Site ID: 262258) | Site Flags | Budget Period | Budget Amt | Verified By | Verified Date |
| WANG, LINFA DUKE-RUS MEDICAL SCHOOL 8 College Road Singapore 169857 | Arimais: N FWA: Humans: N | | | | |

Federal Award Date: 08/05/2019



NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 2R01Al110964-06 REVISED

FAIN: R01Al110964

Principal Investigator(s): PETER DASZAK, PHD

Project Title: Understanding the Risk of Bat Coronavirus Emergence

Dr. Daszak, Peter PD/PI 460 West 34th Street Suite 1701 New York, NY 100012320

Award e-mailed to: (b) (6)

Period Of Performance:

Budget Period: 07/24/2019 – 06/30/2020 **Project Period:** 06/01/2014 – 06/30/2024

Dear Business Official:

The National Institutes of Health hereby revises this award to reflect a decrease in the amount of \$71,770 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to ECOHEALTH ALLIANCE, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI110964. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Tseday G Girma
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

SECTION I - AWARD DATA - 2R01AI110964-06 REVISED

| Award Calculation (U.S. Dollars) | |
|---|-------------|
| Salaries and Wages | \$170,123 |
| Fringe Benefits | \$53,590 |
| Personnel Costs (Subtotal) | \$223,713 |
| Consultant Services | \$49,750 |
| Materials & Supplies | \$20,850 |
| Travel | \$15,027 |
| Subawards/Consortium/Contractual Costs | \$229,651 |
| | |
| Federal Direct Costs | \$538,991 |
| Federal F&A Costs | \$122,989 |
| Approved Budget | \$661,980 |
| Total Amount of Federal Funds Obligated (Federal Share) | \$661,980 |
| TOTAL FEDERAL AWARD AMOUNT | \$661,980 |
| AMOUNT OF THIS ACTION (FEDERAL SHARE) | (\$-71,770) |

| SUMMARY TOTALS FOR ALL YEARS | | | | |
|------------------------------|------------|-------------------|--|--|
| YR | THIS AWARD | CUMULATIVE TOTALS | | |
| 6 | \$661,980 | \$661,980 | | |
| 7 | \$637,980 | \$637,980 | | |
| 8 | \$637,980 | \$637,980 | | |
| 9 | \$637,980 | \$637,980 | | |
| 10 | \$637,980 | \$637,980 | | |

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name: Allergy and Infectious Diseases Research

CFDA Number: 93.855

EIN: 1311726494A1

Document Number: RAI110964B

PMS Account Type: P (Subaccount)

Fiscal Year: 2019

| IC | CAN | 2019 | 2020 | 2021 | 2022 | 2023 |
|----|---------|-----------|-----------|-----------|-----------|-----------|
| Al | 8472364 | \$661,980 | \$637,980 | \$637,980 | \$637,980 | \$637,980 |

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:

PCC: M51C B / OC: 414B / Released: (b) (6) 08/02/2019

Award Processed: 08/05/2019 12:01:51 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 2R01AI110964-06 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III - TERMS AND CONDITIONS - 2R01AI110964-06 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.

- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01Al110964. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV - AI Special Terms and Conditions - 2R01Al110964-06 REVISED

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISED AWARD: This award is revised to adjust the budget in accordance with the letter from Aleksei Chmura/ECOHealth Alliance.

Supersedes previous Notice of Award dated 07/24/2019.

This Notice of Award (NoA) includes funds for activity with **The University of North Carolina at Chapel Hill** in the amount of \$77,750 (\$50,000 direct costs + \$27,750F&A costs).

This Notice of Award (NoA) includes funds for activity with **Wuhan Institute of Virology** in the amount of \$76,301 (\$70,649 direct costs + \$5,652 F&A costs).

This Notice of Award (NoA) includes funds for activity with **Institute of Pathogen Biology** in the amount of \$75,600 (\$70,000 direct costs + \$5,600 F&A costs).

The Research Performance Progress Report (RPPR), Section G.9 (Foreign component), includes reporting requirements for all research performed outside of the United States. Research conducted at the following site(s) must be reported in your RPPR:

Wuhan Institute of Virology, CHINA

Institute of Pathogen Biology, CHINA

East China Normal University, CHINA

Duke-NUS Medical School, SINGAPORE

This award reflects current Federal policies regarding Facilities & Administrative (F&A) Costs for foreign grantees including foreign sub-awardees, and domestic awards with foreign sub-awardees. Please see: Chapter 16 Grants to Foreign Organizations, International Organizations, and Domestic Grants with Foreign Components, <u>Section 16.6 "Allowable and Unallowable Cost"</u> of the NIH Grants Policy.

This award may include collaborations with and/or between foreign organizations. Please be advised that short term travel visa expenses are an allowable expense on this grant, if justified as critical and necessary for the conduct of the project.

The budget period anniversary start date for future year(s) will be July 1.

Dissemination of study data will be in accord with the Recipient's accepted genomic data sharing plan as stated in the page(s) **203** of the application. Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIAID may result in Enforcement Actions as described in the NIH Grants Policy Statement.

This award is subject to the Clinical Terms of Award referenced in the NIH Guide for Grants and Contracts, July 8, 2002, NOT Al-02-032. These terms and conditions are hereby incorporated by

reference, and can be accessed via the following World Wide Web address: https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Award.

Awardees who conduct research involving Select Agents (see 42 CFR 73 for the Select Agent list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens at http://www.selectagents.gov/Regulations.html) must complete registration with CDC (or APHIS, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.

Prior to conducting a restricted experiment with a Select Agent or Toxin, awardees must notify the NIAID and must request and receive approval from CDC or APHIS.

Select Agents:

Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:

NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)

(http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.

When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- o A list of the new and/or additional Agent(s) that will be studied;
- o A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- o The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Tseday G Girma

Email: (b) (6) Phone: (b) (6) Fax: 301-493-0597

Program Official: Erik J. Stemmy

Email: (b) (6) Phone: (b) (6)

SPREADSHEET SUMMARY

GRANT NUMBER: 2R01AI110964-06 REVISED

INSTITUTION: ECOHEALTH ALLIANCE, INC.

| Budget | Year 6 | Year 7 | Year 8 | Year 9 | Year 10 |
|--|-----------|-----------|-----------|-----------|-----------|
| Salaries and Wages | \$170,123 | \$170,123 | \$170,123 | \$170,123 | \$170,123 |
| Fringe Benefits | \$53,590 | \$53,590 | \$53,590 | \$53,590 | \$53,590 |
| Personnel Costs (Subtotal) | \$223,713 | \$223,713 | \$223,713 | \$223,713 | \$223,713 |
| Consultant Services | \$49,750 | \$49,750 | \$49,750 | \$49,750 | \$49,750 |
| Materials & Supplies | \$20,850 | \$14,850 | \$14,850 | \$14,850 | \$14,850 |
| Travel | \$15,027 | \$15,027 | \$15,027 | \$15,027 | \$15,027 |
| Subawards/Consortium/Contractual Costs | \$229,651 | \$229,651 | \$229,651 | \$229,651 | \$229,651 |
| Publication Costs | | \$6,000 | \$6,000 | \$6,000 | \$6,000 |
| TOTAL FEDERAL DC | \$538,991 | \$538,991 | \$538,991 | \$538,991 | \$538,991 |
| TOTAL FEDERAL F&A | \$122,989 | \$98,989 | \$98,989 | \$98,989 | \$98,989 |
| TOTAL COST | \$661,980 | \$637,980 | \$637,980 | \$637,980 | \$637,980 |

| Facilities and Administrative Costs | Year 6 | Year 7 | Year 8 | Year 9 | Year 10 |
|-------------------------------------|-----------|-----------|-----------|-----------|-----------|
| F&A Cost Rate 1 | 32% | 32% | 32% | 32% | 32% |
| F&A Cost Base 1 | \$384,340 | \$309,340 | \$309,340 | \$309,340 | \$309,340 |
| F&A Costs 1 | \$122,989 | \$98,989 | \$98,989 | \$98,989 | \$98,989 |

Federal Award Date: 04/27/2020



NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 2R01Al110964-06 REVISED

FAIN: R01Al110964

Principal Investigator(s): PETER DASZAK, PHD

Project Title: Understanding the Risk of Bat Coronavirus Emergence

Dr. Daszak, Peter PD/PI 460 West 34th Street Suite 1701 New York, NY 100012320

Award e-mailed to: (b) (6)

Period Of Performance:

Budget Period: 07/24/2019 – 04/24/2020 **Project Period:** 06/01/2014 – 04/24/2020

Dear Business Official:

The National Institutes of Health hereby revises this award to reflect a decrease in the amount of \$369,819 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to ECOHEALTH ALLIANCE, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI110964. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Emily Linde Grants Management Officer NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

SECTION I - AWARD DATA - 2R01AI110964-06 REVISED

| Award Calculation (U.S. Dollars) | |
|--|-----------|
| Salaries and Wages | \$83,190 |
| Fringe Benefits | \$26,206 |
| Personnel Costs (Subtotal) | \$109,396 |
| Consultant Services | \$24,328 |
| Materials & Supplies | \$9,491 |
| Travel | \$7,348 |
| Subawards/Consortium/Contractual Costs | \$112,299 |
| Federal Direct Costs | \$262,862 |
| Federal F&A Costs | \$29,299 |

| AMOUNT OF THIS ACTION (FEDERAL SHARE) | (\$-369,819) |
|---------------------------------------|--------------|
|---------------------------------------|--------------|

\$292,161

\$292,161

\$292,161

| SUMMARY TOTALS FOR ALL YEARS | | | | |
|------------------------------|------------|-------------------|--|--|
| YR | THIS AWARD | CUMULATIVE TOTALS | | |
| 6 | \$292,161 | \$292,161 | | |

Fiscal Information:

Approved Budget

CFDA Name: Allergy and Infectious Diseases Research

Total Amount of Federal Funds Obligated (Federal Share)

CFDA Number: 93.855

EIN: 1311726494A1

Document Number: RAI110964B

PMS Account Type: P (Subaccount)

TOTAL FEDERAL AWARD AMOUNT

Fiscal Year: 2019

| IC | CAN | 2019 |
|----|---------|-----------|
| Al | 8472364 | \$292,161 |

NIH Administrative Data:

PCC: M51C B / OC: 41022 / Released: (b) (6) 04/27/2020

Award Processed: 04/27/2020 07:00:27 PM

SECTION II - PAYMENT/HOTLINE INFORMATION - 2R01AI110964-06 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III - TERMS AND CONDITIONS - 2R01AI110964-06 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01Al110964. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports,

http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr instruction guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV - AI Special Terms and Conditions - 2R01Al110964-06 REVISED

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISED AWARD: Pursuant to the letter to EcoHealth Alliance, Inc. dated April 24, 2020, this award has been terminated for convenience at the Agency's discretion.

Supersedes previous Notice of Award dated 08/05/2019. All other terms and conditions still apply to this award.

REVISED AWARD: This award is revised to adjust the budget in accordance with the letter from Aleksei Chmura/ECOHealth Alliance.

Supersedes previous Notice of Award dated 07/24/2019.

This Notice of Award (NoA) includes funds for activity with **The University of North Carolina at Chapel Hill** in the amount of \$77,750 (\$50,000 direct costs + \$27,750F&A costs).

This Notice of Award (NoA) includes funds for activity with **Wuhan Institute of Virology** in the amount of **\$76,301** (**\$70,649** direct costs + **\$5,652** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Institute of Pathogen Biology** in the amount of \$75,600 (\$70,000 direct costs + \$5,600 F&A costs).

The Research Performance Progress Report (RPPR), Section G.9 (Foreign component), includes reporting requirements for all research performed outside of the United States. Research conducted at the following site(s) must be reported in your RPPR:

Wuhan Institute of Virology, CHINA

Institute of Pathogen Biology, CHINA

East China Normal University, CHINA

Duke-NUS Medical School, SINGAPORE

This award reflects current Federal policies regarding Facilities & Administrative (F&A) Costs for foreign grantees including foreign sub-awardees, and domestic awards with foreign sub-awardees. Please see: Chapter 16 Grants to Foreign Organizations, International Organizations, and Domestic Grants with Foreign Components, <u>Section 16.6 "Allowable and Unallowable Cost"</u> of the NIH Grants Policy.

This award may include collaborations with and/or between foreign organizations. Please be advised that short term travel visa expenses are an allowable expense on this grant, if justified as critical and necessary for the conduct of the project.

The budget period anniversary start date for future year(s) will be July 1.

Dissemination of study data will be in accord with the Recipient's accepted genomic data sharing plan as stated in the page(s) **203** of the application. Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIAID may result in Enforcement Actions as described in the NIH Grants Policy Statement.

This award is subject to the Clinical Terms of Award referenced in the NIH Guide for Grants and Contracts, July 8, 2002, NOT Al-02-032. These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address: https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award All submissions required by

the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Award.

Awardees who conduct research involving Select Agents (see 42 CFR 73 for the Select Agent list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens at http://www.selectagents.gov/Regulations.html) must complete registration with CDC (or APHIS, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.

Prior to conducting a restricted experiment with a Select Agent or Toxin, awardees must notify the NIAID and must request and receive approval from CDC or APHIS.

Select Agents:

Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:

NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)

(http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.

When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- o A list of the new and/or additional Agent(s) that will be studied;
- o A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- o The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Shaun W Gratton

Email: (b) (6) Phone: (b) (6) Fax: 301-493-0597

Program Official: Erik J. Stemmy

Email: (b) (6) Phone: (b) (6)

SPREADSHEET SUMMARY

GRANT NUMBER: 2R01AI110964-06 REVISED

INSTITUTION: ECOHEALTH ALLIANCE, INC.

| Budget | Year 6 |
|--|-----------|
| Salaries and Wages | \$83,190 |
| Fringe Benefits | \$26,206 |
| Personnel Costs (Subtotal) | \$109,396 |
| Consultant Services | \$24,328 |
| Materials & Supplies | \$9,491 |
| Travel | \$7,348 |
| Subawards/Consortium/Contractual Costs | \$112,299 |
| TOTAL FEDERAL DC | \$262,862 |
| TOTAL FEDERAL F&A | \$29,299 |
| TOTAL COST | \$292,161 |

| Facilities and Administrative Costs | Year 6 |
|-------------------------------------|----------|
| F&A Cost Rate 1 | 32% |
| F&A Cost Base 1 | \$91,559 |
| F&A Costs 1 | \$29,299 |

Federal Award Date: 06/18/2018



NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 5R01Al110964-05 **FAIN:** R01Al110964

Principal Investigator(s): PETER DASZAK, PHD

Project Title: Understanding the Risk of Bat Coronavirus Emergence

Aleksei Chmura President 460 West 34th Street 17th Floor New York, NY 100012317

Award e-mailed to: (b) (6)

Period Of Performance:

Budget Period: 06/01/2018 – 05/31/2019 **Project Period:** 06/01/2014 – 05/31/2019

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$581,646 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to ECOHEALTH ALLIANCE, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI110964. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Tseday G Girma Grants Management Officer NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

SECTION I - AWARD DATA - 5R01AI110964-05

| Award Calculation (U.S. I | Dollars) |
|---------------------------|----------|
|---------------------------|----------|

| Salaries and Wages | \$167,708 |
|--|-----------|
| Fringe Benefits | \$54,168 |
| Personnel Costs (Subtotal) | \$221,876 |
| Materials & Supplies | \$3,500 |
| Travel | \$35,918 |
| Other | \$9,400 |
| Subawards/Consortium/Contractual Costs | \$191,576 |

| Federal Direct Costs | \$462,270 |
|---|-----------|
| Federal F&A Costs | \$119,376 |
| Approved Budget | \$581,646 |
| Total Amount of Federal Funds Obligated (Federal Share) | \$581,646 |
| TOTAL FEDERAL AWARD AMOUNT | \$581,646 |

AMOUNT OF THIS ACTION (FEDERAL SHARE) \$581,646

| | SUMMARY TOTALS FOR | ALL YEARS |
|----|--------------------|-------------------|
| YR | THIS AWARD | CUMULATIVE TOTALS |
| 5 | \$581,646 | \$581,646 |

Fiscal Information:

CFDA Name: Allergy and Infectious Diseases Research

CFDA Number: 93.855

EIN: 1311726494A1

Document Number: RAI110964A

PMS Account Type: P (Subaccount)

Fiscal Year: 2018

| IC | CAN | 2018 |
|----|---------|-----------|
| Al | 8472350 | \$581,646 |

NIH Administrative Data:

PCC: M51C / OC: 414E / Released: (b) (6) 06/15/2018

Award Processed: 06/18/2018 12:02:35 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 5R01AI110964-05

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III - TERMS AND CONDITIONS - 5R01AI110964-05

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- a. The grant program legislation and program regulation cited in this Notice of Award.
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- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

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Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01Al110964. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports,

http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

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Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

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National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV - AI Special Terms and Conditions - 5R01Al110964-05

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

If any experiments proposed in this award result in a virus with enhanced growth by more than 1 log compared to wild type strains, you must notify your NIAID Program Officer and Grants Management Specialist immediately. Further research involving the resulting virus(es) may require review by the Department of Health and Human Services in accordance with the Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens (https://www.phe.gov/s3/dualuse/Documents/P3CO.pdf).

The Research Performance Progress Report (RPPR), Section G.9 (Foreign component), includes reporting requirements for all research performed outside of the United States. Research conducted at the following site(s) must be reported in your RPPR:

San Pya Clinic, BURMA
Institut Pasteur du Cambodge, CAMBODIA
Primate Research Center at Bogor Agricultural University, INDONESIA
Conservation Medicine, Ltd, MALAYSIA
King Chulalongkorn Memorial Hospital, THAILAND
Hanoi Agricultural University, VIETNAM
National Animal Health Laboratory, LAOS

This Notice of Award (NoA) includes collaboration with **Wuhan University School of Public Health, CHINA**.

This Notice of Award (NoA) includes funds for activity with Wuhan Institute of Virology, CHINA.

This Notice of Award (NoA) includes funds for activity with **East China Normal University**.

This award may include collaborations with and/or between foreign organizations. Please be advised that short term travel visa expenses are an allowable expense on this grant, if justified as critical and necessary for the conduct of the project.

This award is subject to the Clinical Terms of Award included in Monitoring of Clinical Trials and Studies - NIAID (see NIH Guide for Grants and Contracts, July 8, 2002, NOT AI-02-032). These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address: https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Award.

Select Agents:

Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:

NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)

(http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.

When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- o A list of the new and/or additional Agent(s) that will be studied;
- o A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- o The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

| Grants | Management Special | ist: Adam | Graham | |
|--------|---------------------------|-----------|---------|-------------------|
| Email: | (b) (6) | Phone: | (b) (6) | Fax: 301-493-0597 |
| Progra | m Official: Erik J. Sten | nmy | | |
| Email: | (b) (6) | Phone: | (b) (6) | |

SPREADSHEET SUMMARY

GRANT NUMBER: 5R01Al110964-05

INSTITUTION: ECOHEALTH ALLIANCE, INC.

| Budget | Year 5 |
|--|-----------|
| Salaries and Wages | \$167,708 |
| Fringe Benefits | \$54,168 |
| Personnel Costs (Subtotal) | \$221,876 |
| Materials & Supplies | \$3,500 |
| Travel | \$35,918 |
| Other | \$9,400 |
| Subawards/Consortium/Contractual Costs | \$191,576 |
| TOTAL FEDERAL DC | \$462,270 |
| TOTAL FEDERAL F&A | \$119,376 |
| TOTAL COST | \$581,646 |

| Facilities and Administrative Costs | Year 5 |
|-------------------------------------|-----------|
| F&A Cost Rate 1 | 44.1% |
| F&A Cost Base 1 | \$270,694 |

| F&A Costs 1 | \$119,376 |
|-------------|-----------|
| | |

Federal Award Date: 05/26/2017



NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 5R01Al110964-04 **FAIN:** R01Al110964

Principal Investigator(s): PETER DASZAK, PHD

Project Title: Understanding the Risk of Bat Coronavirus Emergence

Aleksei Chmura President 460 West 34th Street 17th Floor New York, NY 100012317

Award e-mailed to: (b) (6)

Period Of Performance:

Budget Period: 06/01/2017 – 05/31/2018 **Project Period:** 06/01/2014 – 05/31/2019

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$597,112 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to ECOHEALTH ALLIANCE, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI110964. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Laura A. Pone Grants Management Officer NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

SECTION I - AWARD DATA - 5R01AI110964-04

| Award Calculation (U.S. Dollars) | |
|----------------------------------|-----------|
| Salaries and Wages | \$167,708 |
| Fringe Benefits | \$54,168 |
| Personnel Costs (Subtotal) | \$221,876 |
| Materials & Supplies | \$7,000 |
| Travel | \$35,918 |

Other \$9,800 Subawards/Consortium/Contractual Costs \$201,422

| Federal Direct Costs | \$476,016 |
|---|-----------|
| Federal F&A Costs | \$121,096 |
| Approved Budget | \$597,112 |
| Total Amount of Federal Funds Obligated (Federal Share) | \$597,112 |
| TOTAL FEDERAL AWARD AMOUNT | \$597,112 |

AMOUNT OF THIS ACTION (FEDERAL SHARE) \$597,112

| | SUMMARY TOTALS FOR | SUMMARY TOTALS FOR ALL YEARS | |
|-------------------------|--------------------|------------------------------|--|
| YR THIS AWARD CUMULATIV | | CUMULATIVE TOTALS | |
| 4 | \$597,112 | \$597,112 | |
| 5 | \$581,646 | \$581,646 | |

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name: Allergy and Infectious Diseases Research

CFDA Number: 93.855

EIN: 1311726494A1

Document Number: RAI110964A

PMS Account Type: P (Subaccount)

Fiscal Year: 2017

| IC | CAN | 2017 | 2018 | |
|----|---------|-----------|-----------|--|
| Al | 8472350 | \$597,112 | \$581,646 | |

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:

PCC: M51C / OC: 414E / Released: (b) (6) 05/25/2017

Award Processed: 05/26/2017 12:05:11 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 5R01AI110964-04

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III - TERMS AND CONDITIONS - 5R01AI110964-04

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget

- period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01Al110964. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

The Research Performance Progress Report (RPPR), Section G.9 (Foreign component), includes reporting requirements for all research performed outside of the United States. Research conducted at the following site(s) must be reported in your RPPR:

San Pya Clinic, BURMA
Institut Pasteur du Cambodge, CAMBODIA
Primate Research Center at Bogor Agricultural University, INDONESIA
Conservation Medicine, Ltd, MALAYSIA
King Chulalongkorn Memorial Hospital, THAILAND
Hanoi Agricultural University, VIETNAM
National Animal Health Laboratory, LAOS

This Notice of Award (NoA) includes collaboration with **Wuhan University School of Public Health, CHINA.**

This Notice of Award (NoA) includes funds for activity with Wuhan Institute of Virology, CHINA.

This Notice of Award (NoA) includes funds for activity with (East China Normal University.

This award may include collaborations with and/or between foreign organizations. Please be advised that short term travel visa expenses are an allowable expense on this grant, if justified as critical and necessary for the conduct of the project.

This award is subject to the Clinical Terms of Award included in Monitoring of Clinical Trials and Studies - NIAID (see NIH Guide for Grants and Contracts, July 8, 2002, NOT AI-02-032). These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address: https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Award.

Select Agents:

Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:

NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)

(http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.

When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- o A list of the new and/or additional Agent(s) that will be studied;
- o A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- o The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

| Grante | Management | Specialist. | Carina | Mormil |
|--------|------------|-------------|--------|---------|
| Grants | Manauement | Specialist. | Carrie | NOTHIII |

Email: (b) (6) Phone: (b) (6) Fax: 301-493-0597

Program Official: Erik J. Stemmy

Email: (b) (6) Phone: (b) (6)

SPREADSHEET SUMMARY

GRANT NUMBER: 5R01Al110964-04

INSTITUTION: ECOHEALTH ALLIANCE, INC.

| Budget | Year 4 | Year 5 |
|--|-----------|-----------|
| Salaries and Wages | \$167,708 | \$167,708 |
| Fringe Benefits | \$54,168 | \$54,168 |
| Personnel Costs (Subtotal) | \$221,876 | \$221,876 |
| Materials & Supplies | \$7,000 | \$3,500 |
| Travel | \$35,918 | \$35,918 |
| Other | \$9,800 | \$9,400 |
| Subawards/Consortium/Contractual Costs | \$201,422 | \$191,576 |
| TOTAL FEDERAL DC | \$476,016 | \$462,270 |
| TOTAL FEDERAL F&A | \$121,096 | \$119,376 |
| TOTAL COST | \$597,112 | \$581,646 |

| Facilities and Administrative Costs | Year 4 | Year 5 |
|-------------------------------------|-----------|-----------|
| F&A Cost Rate 1 | 44.1% | 44.1% |
| F&A Cost Base 1 | \$274,594 | \$270,694 |
| F&A Costs 1 | \$121,096 | \$119,376 |

Federal Award Date: 05/05/2017



NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 5R01Al110964-03 REVISED

FAIN: R01Al110964

Principal Investigator(s): PETER DASZAK, PHD

Project Title: Understanding the Risk of Bat Coronavirus Emergence

Aleksei Chmura President 460 West 34th Street 17th Floor New York, NY 100012317

Award e-mailed to: (b) (6)

Period Of Performance:

Budget Period: 06/01/2016 – 05/31/2017 **Project Period:** 06/01/2014 – 05/31/2019

Dear Business Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to ECOHEALTH ALLIANCE, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI110964. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Philip E. Smith
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

SECTION I - AWARD DATA - 5R01AI110964-03 REVISED

| Award Calculation (U.S | . Dollars) |
|------------------------|------------|
|------------------------|------------|

| Salaries and Wages | \$167,708 |
|--|-----------|
| Fringe Benefits | \$54,168 |
| Personnel Costs (Subtotal) | \$221,876 |
| Materials & Supplies | \$7,250 |
| Travel | \$35,918 |
| Other | \$11,050 |
| Subawards/Consortium/Contractual Costs | \$213,239 |

| Federal Direct Costs | \$489,333 |
|---|-----------|
| Federal F&A Costs | \$121,757 |
| Approved Budget | \$611,090 |
| Total Amount of Federal Funds Obligated (Federal Share) | \$611,090 |
| TOTAL FEDERAL AWARD AMOUNT | \$611,090 |

AMOUNT OF THIS ACTION (FEDERAL SHARE)

\$0

| | SUMMARY TOTALS FOR ALL YEARS | | | |
|--------------------------------|------------------------------|-----------|--|--|
| YR THIS AWARD CUMULATIVE TOTAL | | | | |
| 3 | \$611,090 | \$611,090 | | |
| 4 | \$597,112 | \$597,112 | | |
| 5 | \$581,646 | \$581,646 | | |

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name: Allergy and Infectious Diseases Research

CFDA Number: 93.855

EIN: 1311726494A1

Document Number: RAI110964A

PMS Account Type: P (Subaccount)

Fiscal Year: 2016

| IC | CAN | 2016 | 2017 | 2018 | |
|----|---------|-----------|-----------|-----------|--|
| Al | 8472350 | \$611,090 | \$597,112 | \$581,646 | |

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:

PCC: M51C / OC: 414E / Released: (b) (6) 05/05/2017

Award Processed: 05/05/2017 07:00:56 PM

SECTION II - PAYMENT/HOTLINE INFORMATION - 5R01AI110964-03 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III - TERMS AND CONDITIONS - 5R01AI110964-03 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants

- Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01Al110964. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV - AI Special Terms and Conditions - 5R01Al110964-03 REVISED

The Research Performance Progress Report (RPPR), Section G.9 (Foreign component), includes reporting requirements for all research performed outside of the United States. Research conducted at the following site(s) must be reported in your RPPR:

San Pya Clinic, BURMA
Institut Pasteur du Cambodge, CAMBODIA
Primate Research Center at Bogor Agricultural University, INDONESIA
Conservation Medicine, Ltd, MALAYSIA
King Chulalongkorn Memorial Hospital, THAILAND
Hanoi Agricultural University, VIETNAM

REVISED AWARD: This Notice of Award is revised to provide approval for collaboration with the **Wuhan University School of Public Health (CHINA)** in accordance with the request submitted by Aleksei Chmura, Ecohealth Alliance, Inc. on October 6, 2016.

Supersedes previous Notice of Award dated 7/26/2016.

REVISED AWARD: This Notice of Award is revised to provide approval for collaboration with the **Wuhan University School of Public Health (CHINA)** in accordance with the request submitted by Aleksei Chmura, Ecohealth Alliance, Inc. on October 6, 2016.

Supersedes previous Notice of Award dated 7/26/2016.

No funds are provided and no funds can be used to support gain-of-function research covered under the October 17, 2014 White House Announcement (NIH Guide Notice NOT-OD-15-011).

Per the letter dated July 7, 2016 to Mr. Aleksei Chmura at EcoHealth Alliance, should any of the MERS-like or SARS-like chimeras generated under this grant show evidence of enhanced virus growth greater than 1 log over the parental backbone strain you must stop all experiments with these viruses and provide the NIAID Program Officer and Grants Management Specialist, and Wuhan Institute of Virology Institutional Biosafety Committee with the relevant data and information related to these unanticipated outcomes.

This Notice of Award (NoA) includes funds for consortium activity with:

- Wuhan Institute of Virology CHINA awarded in the Total Costs amount of \$159,122 (\$147,335 Direct Costs + \$11,787 F&A Costs). Future year commitments are as follows: Year 4 Total Costs: \$159,122 and Year 5 Total Costs: \$159,122
- East China Normal University CHINA awarded in the Total Costs amount of \$54,117 (\$50,108 Direct Costs + \$4,009 F&A Costs). Future year commitments are as follows: Year 4 Total Costs: \$42,300 and Year 5 Total Costs: \$32,454

Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at http://grants.nih.gov/grants/policy/nihgps_2013/nihgps_ch15.htm# Toc271265264.

The written agreement with the consortium must address the negotiated arrangements for meeting the scientific, administrative, financial and reporting requirements for this grant.

No foreign performance site may be added to this project without prior approval of the National Institute of Allergy and Infectious Diseases.

Although a specific amount has been awarded for each consortium, the grantee retains standard rebudgeting authorities.

This award may include collaborations with and/or between foreign organizations. Please be advised that short term travel visa expenses are an allowable expense on this grant, if justified as critical and necessary for the conduct of the project.

Select Agents:

Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:

NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a

must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.

When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- o A list of the new and/or additional Agent(s) that will be studied;
- o A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- o The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These

individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Jenny L. Greer

Email: (b) (6) Phone: (b) (6) Fax: 301-493-0597

Program Official: Erik J. Stemmy

Email: (b) (6) Phone: (b) (6)

SPREADSHEET SUMMARY

GRANT NUMBER: 5R01AI110964-03 REVISED

INSTITUTION: ECOHEALTH ALLIANCE, INC.

| Budget | Year 3 | Year 4 | Year 5 |
|--|-----------|-----------|-----------|
| Salaries and Wages | \$167,708 | \$167,708 | \$167,708 |
| Fringe Benefits | \$54,168 | \$54,168 | \$54,168 |
| Personnel Costs (Subtotal) | \$221,876 | \$221,876 | \$221,876 |
| Materials & Supplies | \$7,250 | \$7,000 | \$3,500 |
| Travel | \$35,918 | \$35,918 | \$35,918 |
| Other | \$11,050 | \$9,800 | \$9,400 |
| Subawards/Consortium/Contractual Costs | \$213,239 | \$201,422 | \$191,576 |
| TOTAL FEDERAL DC | \$489,333 | \$476,016 | \$462,270 |
| TOTAL FEDERAL F&A | \$121,757 | \$121,096 | \$119,376 |
| TOTAL COST | \$611,090 | \$597,112 | \$581,646 |

| Facilities and Administrative Costs | Year 3 | Year 4 | Year 5 |
|-------------------------------------|-----------|-----------|-----------|
| F&A Cost Rate 1 | 44.1% | 44.1% | 44.1% |
| F&A Cost Base 1 | \$276,094 | \$274,594 | \$270,694 |
| F&A Costs 1 | \$121,757 | \$121,096 | \$119,376 |

Notice of Award



RESEARCH Federal Aw
Department of Health and Human Services

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Federal Award Date: 06/10/2015



Grant Number: 5R01Al110964-02 **FAIN:** R01Al110964

Principal Investigator(s): PETER DASZAK, PHD

National Institutes of Health

Project Title: Understanding the Risk of Bat Coronavirus Emergence

Aleksei Chmura President 460 West 34th Street 17th Floor New York, NY 100012317

Award e-mailed to: (b) (6)

Period Of Performance:

Budget Period: 06/01/2015 – 05/31/2016 **Project Period:** 06/01/2014 – 05/31/2019

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$630,445 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to ECOHEALTH ALLIANCE, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI110964. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Laura A. Pone Grants Management Officer NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

SECTION I - AWARD DATA - 5R01AI110964-02

Award Calculation (U.S. Dollars)

| Federal Direct Costs | \$502,293 |
|---|-----------|
| Federal F&A Costs | \$128,152 |
| Approved Budget | \$630,445 |
| Total Amount of Federal Funds Obligated (Federal Share) | \$630,445 |
| TOTAL FEDERAL AWARD AMOUNT | \$630,445 |
| AMOUNT OF THIS ACTION (FEDERAL SHARE) | \$630,445 |

| SUMMARY TOTALS FOR ALL YEARS | | | | |
|------------------------------|------------|-------------------|--|--|
| YR | THIS AWARD | CUMULATIVE TOTALS | | |
| 2 | \$630,445 | \$630,445 | | |
| 3 | \$611,090 | \$611,090 | | |
| 4 | \$597,112 | \$597,112 | | |
| 5 | \$581,646 | \$581,646 | | |

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name: Allergy, Immunology and Transplantation Research

CFDA Number: 93.855

EIN: 1311726494A1

Document Number: RAI110964A

PMS Account Type: P (Subaccount)

Fiscal Year: 2015

| IC | CAN | 2015 | 2016 | 2017 | 2018 |
|----|---------|-----------|-----------|-----------|-----------|
| Al | 8472350 | \$630,445 | \$611,090 | \$597,112 | \$581,646 |

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:

PCC: M51C / OC: 414E / Released: (b) (6) 06/09/2015

Award Processed: 03/23/2015 01:36:12 PM

SECTION II - PAYMENT/HOTLINE INFORMATION - 5R01AI110964-02

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III - TERMS AND CONDITIONS - 5R01AI110964-02

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain

references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the Central Contractor Registration. Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See

http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01Al110964. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Treatment of Program Income:

Additional Costs

SECTION IV - AI Special Terms and Conditions - 5R01Al110964-02

This Notice of Award (NoA) includes funds for consortium activity with **Wuhan Institute of Virology - CHINA** awarded in the Total Costs amount of \$139,015 (\$128,718 Direct Costs + \$10,297 F&A Costs).

Future year commitments are as follows:

Year 3 Total Costs: \$159,122 Year 4 Total Costs: \$159,122 Year 5 Total Costs: \$159,122

This Notice of Award (NoA) includes funds for consortium activity with **East China Normal University - CHINA** awarded in the Total Costs amount of \$72,684 (\$67,300 Direct Costs + \$5,384 F&A Costs).

Future year commitments are as follows:

Year 3 Total Costs: \$54,117 Year 4 Total Costs: \$42,300 Year 5 Total Costs: \$32,454

Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at http://grants.nih.gov/grants/policy/nihgps_2013/nihgps_ch15.htm#_Toc271265264.

The written agreement with the consortium must address the negotiated arrangements for meeting the scientific, administrative, financial and reporting requirements for this grant.

No foreign performance site may be added to this project without prior approval of the National Institute of Allergy and Infectious Diseases.

Although a specific amount has been awarded for each consortium, the grantee retains standard rebudgeting authorities.

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# Select Agents:

Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

#### Highly Pathogenic Agent:

NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)

(<a href="http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm">http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm</a>). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.

When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- o The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

#### STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Laura A. Pone

Email: (b) (6) Phone: (b) (6) Fax: 301-493-0597

Program Official: Erik J. Stemmy

Email: (b) (6) Phone: (b) (6)

SPREADSHEET SUMMARY

**GRANT NUMBER: 5R01AI110964-02** 

INSTITUTION: ECOHEALTH ALLIANCE, INC.

| Facilities and Administrative Costs | Year 2    | Year 3    | Year 4    | Year 5    |
|-------------------------------------|-----------|-----------|-----------|-----------|
| F&A Cost Rate 1                     | 44.1%     | 44.1%     | 44.1%     | 44.1%     |
| F&A Cost Base 1                     | \$290,594 | \$276,094 | \$274,594 | \$270,694 |
| F&A Costs 1                         | \$128,152 | \$121,757 | \$121,096 | \$119,376 |

#### Notice of Award

Issue Date: 05/27/2014



RESEARCH
Department of Health and Human Services
National Institutes of Health





**Grant Number:** 1R01Al110964-01 **FAIN:** R01Al110964

Principal Investigator(s): PETER DASZAK, PHD

Project Title: Understanding the Risk of Bat Coronavirus Emergence

Aleksei President 460 West 34th Street 17th Floor New York, NY 100012317

Award e-mailed to: (b) (6)

**Budget Period:** 06/01/2014 – 05/31/2015 **Project Period:** 06/01/2014 – 05/31/2019

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$666,442 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to ECOHEALTH ALLIANCE, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI110964. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <a href="http://grants.nih.gov/grants/policy/coi/">http://grants.nih.gov/grants/policy/coi/</a> for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Laura A. Pone Grants Management Officer NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

#### SECTION I - AWARD DATA - 1R01AI110964-01

| Award Calculation (U.S. Dollars) Salaries and Wages | \$167,708 |
|-----------------------------------------------------|-----------|
| Fringe Benefits                                     | \$54,168  |
| Supplies                                            | \$21,400  |
| Travel Costs                                        | \$35,918  |
| Other Costs                                         | \$10,000  |
| Consortium/Contractual Cost                         | \$227,663 |
| Federal Direct Costs                                | \$516,857 |
| Federal F&A Costs                                   | \$149,585 |
| Approved Budget                                     | \$666,442 |
| Federal Share                                       | \$666,442 |
| TOTAL FEDERAL AWARD AMOUNT                          | \$666,442 |
| AMOUNT OF THIS ACTION (FEDERAL SHARE)               | \$666,442 |

| SUMMARY TOTALS FOR ALL YEARS |            |                   |  |  |  |
|------------------------------|------------|-------------------|--|--|--|
| YR                           | THIS AWARD | CUMULATIVE TOTALS |  |  |  |
| 1                            | \$666,442  | \$666,442         |  |  |  |
| 2                            | \$630,445  | \$630,445         |  |  |  |
| 3                            | \$611,090  | \$611,090         |  |  |  |
| 4                            | \$597,112  | \$597,112         |  |  |  |
| 5                            | \$581,646  | \$581,646         |  |  |  |

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

#### Fiscal Information:

 CFDA Number:
 93.855

 EIN:
 1311726494A1

 Document Number:
 RAI110964A

PMS Account Type: P (Subaccount)
Fiscal Year: 2014

| IC | CAN     | 2014      | 2015      | 2016      | 2017      | 2018      |
|----|---------|-----------|-----------|-----------|-----------|-----------|
| Al | 8472350 | \$666,442 | \$630,445 | \$611,090 | \$597,112 | \$581,646 |

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

#### NIH Administrative Data:

PCC: M51C / OC: 414A / Released: (b) (6) 05/20/2014

Award Processed: 05/08/2014 01:52:21 PM

### SECTION II - PAYMENT/HOTLINE INFORMATION - 1R01AI110964-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <a href="http://grants.nih.gov/grants/policy/awardconditions.htm">http://grants.nih.gov/grants/policy/awardconditions.htm</a>

#### SECTION III - TERMS AND CONDITIONS - 1R01AI110964-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.

- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
- d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <a href="http://grants.nih.gov/grants/policy/awardconditions.htm">http://grants.nih.gov/grants/policy/awardconditions.htm</a> for certain references cited above.)

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the Central Contractor Registration. Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See

http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01Al110964. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <a href="http://grants.nih.gov/grants/policy/awardconditions.htm">http://grants.nih.gov/grants/policy/awardconditions.htm</a> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <a href="http://publicaccess.nih.gov/">http://publicaccess.nih.gov/</a>.

# Treatment of Program Income:

Additional Costs

#### SECTION IV - AI Special Terms and Conditions - 1R01Al110964-01

THIS AWARD CONTAINS GRANT SPECIFIC RESTRICTIONS. THESE RESTRICTIONS MAY ONLY BE LIFTED BY A REVISED NOTICE OF AWARD.

RESTRICTION: This award is issued with the knowledge that subjects may be involved within the period of support, but definite plans were not set forth in the application as per 45 CFR 46.118. No human subjects may be involved in any project supported by this award until all requirements for Human Subjects research as identified in the PHS398/SF424 Instructions have been provided to and approved by NIH.

RESTRICTION: The present award is being made without a currently valid certification of IRB approval for this project with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects may be conducted pending the NIAID's acceptance of the certification of IRB review and approval.

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for any research involving human subjects prior to the NIAID's notification to the grantee that the identified issues have been resolved and this restriction removed.

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This award includes funds for subcontract/consortium activity with Wuhan Institute of Virology, CHINA and is budgeted as follows:

| -Y r | 1 - | Yr 2 | -Yr 3 | -Yr 4 | -Yr 5 |
|----------------------|-----------|-----------|-----------|-----------|-----------|
| Total Direct Costs | \$123,699 | \$128,718 | \$147,335 | \$147,335 | \$147,335 |
| F&A Costs @ 8%(MTDC) | \$9,896 | \$10,297 | \$11,787 | \$11,787 | \$11,787 |
| TOTAL COSTS | \$133,595 | \$139,015 | \$159,122 | \$159,122 | \$159,122 |

Consortiums are to be established and administered as described in the NIH Grants Policy Statement. This written agreement with the consortium must address the negotiated arrangements for meeting the scientific, administrative, financial, and reporting requirements for this grant.

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This award includes funds for subcontract/consortium activity with <u>East China Normal University</u>, <u>CHINA</u> and is budgeted as follows:

| -Yr                  | 1        | -Yr 2    | -Yr 3    | -Yr 4    | -Yr 5    |
|----------------------|----------|----------|----------|----------|----------|
| Total Direct Costs   | \$87,100 | \$67,300 | \$50,108 | \$39,167 | \$14,850 |
| F&A Costs @ 8%(MTDC) | \$6,968  | \$5,384  | \$4,009  | \$3,133  | \$2,404  |
| TOTAL COSTS          | \$94,068 | \$72,684 | \$54,117 | \$42,300 | \$32,454 |

Consortiums are to be established and administered as described in the NIH Grants Policy Statement. This written agreement with the consortium must address the negotiated arrangements for meeting the scientific, administrative, financial, and reporting requirements for this grant.

~~~~~~

Select Agents:

Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:

NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)

(http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.

When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- o A list of the new and/or additional Agent(s) that will be studied;
- o A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- o The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Laura A. Pone

Email: (b) (6) Phone: (b) (6) Fax: 301-493-0597

Program Official: Erik J. Stemmy

Email: (b) (6) Phone: (b) (6)

SPREADSHEET SUMMARY

GRANT NUMBER: 1R01AI110964-01

INSTITUTION: ECOHEALTH ALLIANCE, INC.

| Budget | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|-----------------------------|-----------|-----------|-----------|-----------|-----------|
| Salaries and Wages | \$167,708 | \$167,708 | \$167,708 | \$167,708 | \$167,708 |
| Fringe Benefits | \$54,168 | \$54,168 | \$54,168 | \$54,168 | \$54,168 |
| Supplies | \$21,400 | \$19,250 | \$7,250 | \$7,000 | \$3,500 |
| Travel Costs | \$35,918 | \$35,918 | \$35,918 | \$35,918 | \$35,918 |
| Other Costs | \$10,000 | \$13,550 | \$11,050 | \$9,800 | \$9,400 |
| Consortium/Contractual Cost | \$227,663 | \$211,699 | \$213,239 | \$201,422 | \$191,576 |
| TOTAL FEDERAL DC | \$516,857 | \$502,293 | \$489,333 | \$476,016 | \$462,270 |
| TOTAL FEDERAL F&A | \$149,585 | \$128,152 | \$121,757 | \$121,096 | \$119,376 |
| TOTAL COST | \$666,442 | \$630,445 | \$611,090 | \$597,112 | \$581,646 |

| Facilities and Administrative | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|-------------------------------|-----------|-----------|-----------|-----------|-----------|
| Costs | | | | | |
| F&A Cost Rate 1 | 44.1% | 44.1% | 44.1% | 44.1% | 44.1% |
| F&A Cost Base 1 | \$339,194 | \$290,594 | \$276,094 | \$274,594 | \$270,694 |
| F&A Costs 1 | \$149,585 | \$128,152 | \$121,757 | \$121,096 | \$119,376 |

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: 5/20/2020 10:19:00 AM

To: (b) (6); (b) (6)

CC: Black, Jodi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=c78548de622942b2a9019fff403ff89e-ComplianceR]; Lauer, Michael

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange AdministrativeGroup

(FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]

Subject: Re: Please read and acknowledge receipt -- Subaward concerns

Attachments: NIH letter to UCI re Wuhan Institute of Virology 5-20-2020 msl [2].pdf; Automatic reply: Please read and

acknowledge receipt -- Subaward concerns

Dear Dr. Khargonekar

Please see attached.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)

Phone: (b) (6) Email: (b) (6)

From: "Lauer, Michael (NIH/OD) [E]" < (b) (6)

Date: Wednesday, May 20, 2020 at 6:14 AM

To: '(b) (6) < (b) (6)

Cc: "Lauer, Michael (NIH/OD) [E]" < (b) (6) "Black, Jodi (NIH/OD) [E]" < (b) (6)

Compliance Review < (b) (6)

Subject: Please read and acknowledge receipt -- Subaward concerns

Dear Mr. Bourbonnais

Please see attached.

Many thanks, Mike

Michael S Lauer, MD NIH Deputy Director for Extramural Research 1 Center Drive, Building 1, Room 144 Bethesda, MD 20892

Phone: (b) (6) Email: (b) (6)



Public Health Service

National Institutes of Health Bethesda, Maryland 20892

May 20, 2020

Mr. Mark Bourbonnais Director Research Support Services School of Medicine University of California, Irvine (b) (6)

Dear Mr. Bourbonnais:

I am writing to inform you that the National Institutes of Health (NIH) has been made aware of reports that Wuhan Institute of Virology (WIV) has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, health and welfare threats to the public, both in China and other countries, including the United States. The University of California, Irvine (UCI) has an NIH grant award that supports Wuhan Institute of Virology as a subrecipient consortium.

It is the NIH mission to protect public health and welfare from a serious deficiency such as unsafe laboratory practices. Therefore, effective the date of this letter, May 20, 2020, NIH is suspending all activities related to RF1 MH120020-01, Genetically engineered anterograde monosynaptic viral tracers for multi-species neural circuit analysis, Dr. Xiangmin Xu (Contact PI), for which the Wuhan Institute of Virology is a subaward participant, awarded by the National Institute of Mental Health (NIMH).

This action is taken in accordance with the NIH Grants Policy Statement (GPS), a term and condition all NIH grant awards, <u>Section 8.5.2</u>, Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support, which implements our governing regulations <u>45 CFR Part 75.371</u>, Remedies for Noncompliance. This section states that NIH may take immediate action to terminate a grant when necessary to protect the public health and welfare. However, in this case NIH has chosen to suspend the sub-contractual activities directly supporting WIV, while the safety measures outlined in the NIH GPS <u>Section 4.1.12</u> Health and Safety Regulations and Guidelines, are reviewed. This action is not appealable in accordance with the NIH GPS <u>Section 8.7</u>, Grant Appeals Procedures.

During the period of suspension, UCI may not allow research under this project to be conducted by WIV. Further, no funds may be provided to or expended by WIV; all such charges are unallowable. Other grant funding for this project will remain available for the conduct of research that is not subject to this suspension action. It is UCI's responsibility as the recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by WIV. UCI must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms must be immediately reported to NIH. NIH has taken additional steps to restrict funding in the HHS Payment Management System in the amount of \$660,054, the total costs awarded for the research that is being conducted at WIV. UCI will receive a revised Notice of Award from NIMH indicating the suspension of these research activates and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from imposing additional special award conditions, corrective actions, or enforcement actions pursuant to 45 CFR including, but not limited to, terminating the grant award.

Please let me know if you have any questions concerning the information in this letter. My complete contact information follows my signature below.

Sincerely,

Lauer, Michael (NIH/OD) [E] Digitally signed by Lauer, Michael (NIH/OD) [E]
Date: 2020.05.20 06:09:28 -04'00'

Michael S. Lauer, M.D.
Deputy Director Extramural Research
1 Center Drive, Room 144
Bethesda, MD 20892

(b) (6) (b) (6) From: Bourbonnais, Mark (6) (6)

Sent: 5/20/2020 10:14:04 AM

To: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]

Subject: Automatic reply: Please read and acknowledge receipt -- Subaward concerns

The Mark Bourbonnais inbox is no longer active. Please direct your inquires and requests to the contacts listed below.

Grants & contracts related matters: SOMproposalreqs@hs.uci.edu Clinical Research related matters: UCIclinicaltrials@hs.uci.edu

*If oncology related, please also include: Rilesh Desai, Clinical Research Business Manager,

(b) (6)

(b) (6)

All other inquiries: Tara Massimino, Interim Director Contracts & Grants,

(b) (6)

(b) (6)

This message may contain confidential information and is for the sole use of the intended recipient (s). If you are not the intended recipient, do not use, distribute, or copy this e-mail. Please notify the UC Irvine Health — Compliance and Privacy Office via email at hacompliance @uci educity phone 888-456-7000 immediately if you have received this e-mail inerior. E-mail transmission cannot be guaranteed to be secure or error-free as information could be intercepted, complete, lost, destroyed, errive tate or incomplete, or contain virusee. The sender therefore does not accept liability for any errors or omissions in the contents of this message, which arise as a result of e-mail transmission.



Tarter Krinsky & Drogin LLP 1350 Broadway New York, NY 10018 P 212.216.8000 F 212.216.8001 www.tarterkrinsky.com

Andrew N. Krinsky, Partner 212-216-8080, Direct Dial (b) (6)

May 22, 2020

Via Email, Certified Mail, & FedEx

Michael S. Lauer, MD
NIH Deputy Director for Extramural Research
National Institutes of Health
National Institute of Allergy and Infectious Diseases
1 Center Drive, Building 1, Room 144
Bethesda, Maryland 20892

Re: Termination of NIH Grant 2R01 AI 110964-6

Dear Dr. Lauer:

This firm represents EcoHealth Alliance, Inc. ("EcoHealth Alliance") with regard to the post-award decision by the National Institute of Allergy and Infectious Diseases ("NIAID"), an Institute within the National Institute of Health ("NIH"), under the Department of Health and Human Services ("HHS"), to terminate the project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AI 110964, on April 24, 2020 (the "Termination").

This letter, pursuant to NIH Grants Policy Statement Section 8.7 and 42 CFR 50, Subpart D, constitutes EcoHealth Alliance's first-level appeal of the Termination, which was "for convenience." As set forth in more detail below, the Termination is not authorized under the NIH Grants Policy Statement, arbitrary and capricious and an indefensible attack on public health and welfare given that it undermines a pivotal 10-year research project involving the origins, spread and threat of emerging bat coronaviruses during the peak of an unprecedented worldwide coronavirus pandemic. Accordingly, EcoHealth Alliance hereby demands that grant 2R01 AI 110964-6 be reinstated immediately.

BACKGROUND

A. EcoHealth Alliance

EcoHealth Alliance is a prominent New York-based nonprofit institution dedicated to protecting the health of people, animals, and the environment from emerging zoonotic diseases. For more than a decade, EcoHealth Alliance has been conducting cutting edge scientific research to identify hundreds of new coronaviruses ("CoVs") in bats and to study the capacity of these viruses to infect human cells. The purpose of this research is to identify high risk populations so international actors can leverage their resources to address potential pandemics. In cooperation with a global network of over seventy partners, including academic institutions, intergovernmental

and governmental agencies, infectious disease surveillance laboratories, and other international and national organizations in over thirty countries, EcoHealth Alliance's work has led to numerous scientific papers published in high impact journals. These publications have been critical in raising awareness of the threat that CoVs pose to global health, the global economy, and U.S. National Security.

EcoHealth Alliance has a long history of successful cooperation with NIH including multiple Research Project Grant R01 awards. In particular, Peter Daszak, EcoHealth Alliance's President and Chief Scientist, has been the Principal Investigator on five multidisciplinary R01s. All of these projects used modeling, epidemiology, laboratory, and field science to test hypotheses on the emergence of wildlife-origin viral zoonoses, including SARS-CoV, the Nipah and Hendra viruses, Avian influenza, and other bat-origin viruses. EcoHealth Alliance, a 501(c)(3) organization, is unique in that it goes one step further by leveraging its research goals to create an alliance of international collaborators that can advocate for real-world changes to protect high risk populations.

Notably, in collaboration with virologists in China, EcoHealth Alliance isolated and characterized SARSr-CoVs from bats that use the same human host cell receptor (ACE2) as SARS-CoV. This work provided critical reagents and resources that have advanced scientific understanding of virus-host binding and contributed to vaccine development. For example, the genetic sequences of the bat viruses that EcoHealth Alliance discovered under its NIH research funding, which were published online (Genbank & GISAID), have been used to test the effectiveness of the drug Remdesivir against not only SARS-CoV, but also MERS, and other potentially zoonotic or pre-pandemic bat CoVs. Significantly, this type of testing can be performed without the need for viral cultures or shipping viruses internationally.

B. NIH Awards And Extends EcoHealth Alliance Research Grant R01 AI 110964

In 2014, NIH issued EcoHealth Alliance a five-year research award for the project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AI 110964 (the "Project"). EcoHealth Alliance received additional awards for the Project each year between 2015 and 2018. Between 2015 and 2019, the Project resulted in the publication of more than twenty papers.

In 2019, EcoHealth Alliance submitted a renewal application to NIH through NIAID to extend the Project period for an additional five years. Upon filing of its renewal application, the Project was ranked as an "extremely high priority" (in the top 3%) by NIAID during its external review process. In light of its success and the importance of EcoHealth Alliance's work, on July 24, 2019, NIH reauthorized grant R01 AI 110964 and increased EcoHealth Alliance's funding. EcoHealth Alliance was issued a notice of award in the amount of \$733,750.00 (the "2019 Award"). The notice of award also extended the Project period for an additional five years to 2024. A copy of the notice of award is attached hereto as Exhibit A.

C. EcoHealth Alliance Agrees Not To Fund The Wuhan Institute Of Virology

During the pendency of the Project, in December of 2019, China reported a cluster of cases of pneumonia in Wuhan, Hubei Province. It was later determined that the cause of this pneumonia

was a novel CoV, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), causing coronavirus disease (COVID-19). Thereafter, SARS-CoV-2 spread to nearly every country throughout the world. In response, EcoHealth Alliance has prioritized its efforts in conducting research that will be integral to developing an effective strategy to combat SARS-CoV-2.

On April 19, 2020, Michael S. Lauer, MD, NIH Deputy Director for Extramural Research, sent a letter to EcoHealth Alliance on behalf of NIH regarding a laboratory in China, the Wuhan Institute of Virology ("WIV"). WIV was a prior sub-recipient of a small portion of the R01 AI 110964 grant funds. The letter stated that, given allegations that COVID-19 "was precipitated by the release from WIV of the coronavirus responsible for COVID-19", NIH was pursuing suspension of WIV from participating in Federal programs. However, Mr. Lauer assured EcoHealth Alliance that "[t]his suspension of the sub-recipient does not affect the remainder of [EcoHealth Alliance's] grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension." A copy of the letter is attached hereto as Exhibit B.

On April 21, 2020, Dr. Daszak of EcoHealth Alliance responded by email to Dr. Lauer stating that he could "categorically state that no funds from [sic] 2R01 AI 110964-6 have been sent to Wuhan Institute of Virology, nor has any contract been signed." Dr. Daszak further represented that EcoHealth Alliance would comply with all NIAID requirements. Dr. Lauer acknowledged (1) that no monies from grant 2R01 AI 110964-6 had gone to WIV and no contract between EcoHealth Alliance and WIV had been signed and (2) EcoHealth Alliance's agreement that it would not provide any funds to WIV until and unless directed otherwise by NIH. A copy of the email correspondence between NIH and EcoHealth Alliance is attached hereto as Exhibit C.

D. NIH Abruptly Terminates Research Grant 2R01 AI 110964-6 "For Convenience"

Notwithstanding NIH's representation that suspension of WIV would not affect the remainder of EcoHealth Alliance's 2019 Award, on April 24, 2020, NIH notified EcoHealth Alliance by letter that, effective immediately, the 2019 Award had been terminated by NIAID. The stated grounds for the Termination were: (1) convenience; (2) NIH's discretion not to award a grant, or to award a grant at a particular funding level; and (3) NIH's belief that the Project outcomes did not align with the program goals and agency priorities. A copy of the Termination is attached hereto as Exhibit D.

ARGUMENT

A. NIH Research Grants Are Not Subject To Termination For Convenience

"Termination for convenience" refers to the exercise of the government's right to bring to an end the performance of all or part of the work provided for under a contract prior to the expiration of the contract "when it is in the Government's interest" to do so. Federal agencies typically incorporate clauses in their procurement contracts which give them the right to terminate for convenience. Here, there is no clause in the terms and conditions applicable to the 2019 Award, or in the NIH Grants Policy Statement, that permits NIAID or NIH to issue a post-award decision to terminate a NIH research grant award "for convenience."

Moreover, the unprecedented assertion by NIH that active research grants can be terminated "for convenience" during the subject budget period renders Section 8.5.2 of the NIH Grants Policy Statement meaningless. See, e.g., Li v. Eddy, 324 F.3d 1109, 1110 (9th Cir. 2003) (rejecting suggested statutory interpretation on the grounds that the interpretation ran squarely against the canon of construction that courts interpret statutes so as not to render any section meaningless). Section 8.5.2 of the NIH Grants Policy Statement governs, inter alia, modification or termination of an award for misconduct. If NIH grants were terminable for convenience, NIH could always choose to terminate for convenience to avoid (1) the "for cause" restriction on grant terminations and (2) the labor intensive task of enforcing compliance through disallowing costs, withholding further awards, or wholly suspending the grant, pending corrective action.

B. NIH's Discretion Not To Award A Grant, Or To Award a Grant At A Particular Funding Level, Does Not Authorize A Post-Award Decision To Terminate

NIH's discretion regarding the "decision not to award a grant, or to award a grant at a particular funding level" does not give NIH the authority to issue a post-award decision terminating a duly awarded grant during the budget period. This purported discretion, which is based on language in the last paragraph of NIH Grants Policy Statement Section 2.4.4, entitled *Disposition of Applications*, concerns NIH's authority to reject incomplete or otherwise undesirable grant applications in the first instance only. The provisions of Section 2, generally, have no bearing on post-award decisions affecting duly approved grants for which specified funds have already been allocated. As the 2019 Grant in the amount of \$733,750.00 was awarded to EcoHealth Alliance on July 24, 2019, NIH's authority to deny initial grant applications does not allow NIH to terminate the 2019 Grant.

C. The Research Goals Of EcoHealth Alliance And NIAID Are Virtually Identical

NIH's contention that the Project's outcomes do not align with the agency's priorities is demonstrably false. First, the Project was ranked as "extremely high priority" on external review by NIAID less than nine months ago, before the discovery of SARS-CoV-2. Since this discovery, NIH has promulgated new grants seeking applicants to conduct research on the same issues covered by the Project and the 2019 Award.

In addition, there is substantial overlap between the four strategic research priorities on page 1 of NIAID's Strategic Plan for COVID-19 Research, published April 22, 2020, and the three Specific Aims of the Project. Both NIAID and EcoHealth Alliance seek to: (1) improve fundamental knowledge of SARS-Cov-2; (2) develop methods to assess the rate of infection and disease incidence; (3) contribute to the development of an effective vaccine; and (4) increase public health preparedness. Copies of the Project's Specific Aims and the NIAID Strategic Plan's four strategic research priorities for COVID-19 research are attached hereto as Exhibit E.

D. There Is No Rational Basis To Terminate The 2019 Award For Cause

The grounds and procedures for suspension and termination of awards are specified in NIH Grants Policy Statement Section 8.5.2 and 45 CFR Parts 75.371 through 75.373. Notably, Section

8.5.2 provides, *inter alia*, that NIH will generally suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision. Through this lens, 45 CFR 75.372 provides that NIH may terminate a Federal award, in whole or in part, if: (1) the non-Federal entity fails to comply with the terms and conditions of the award; (2) for cause; (3) by the HHS awarding agency or pass-through entity with the consent of the non-Federal entity; or (4) by the non-Federal entity upon written notice to the HHS awarding agency setting forth the reasons for such termination, and other information. None of the foregoing predicate conditions exist here.

As of the date of the Termination, EcoHealth Alliance had not received any notice from NIH, NIAID, or HHS that it either failed to comply with any of the terms or conditions of the 2019 Award, or committed any misconduct in connection with the award. To the contrary, in email correspondence following EcoHealth Alliance's representation that it had not and would not give any funds from the 2019 Award to WIV, Aleksei Chmura, EcoHealth Alliance's Chief of Staff, memorialized the mutual agreement between NIH and EcoHealth Alliance that EcoHealth Alliance was in compliance with all requests. (Ex. C, #8). To be clear, EcoHealth Alliance clearly and unequivocally stated that it had not and will not distribute any funds from the 2019 Award to WIV.

In sum, there is no statutory, regulatory, or contractual basis for NIAID's termination of the Project, *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant 2R01 AI 110964-6. However, please note that this letter is not intended to provide an exhaustive list of all possible grounds for reversal of the Termination and may not reflect all arguments and claims that EcoHealth Alliance will assert in the event that a formal second-level appeal of the Termination is required.

Should you wish to present evidence in an effort to refute any of the factual assertions made in this letter and/or to engage in good faith negotiations regarding appropriate terms and conditions for the resumption of funding for grant 2R01 AI 110964-6, we are prepared to review such evidence and to participate in such negotiations.

Verviruly yours,

Andrew M. Krinsky

We await your response to this letter.

cc: (by email)

Dr. Erik Stemmy (e
Ms. Emily Linde (l. (b) (6)

5

Exhibit A

Notice of Award



Department of Health and Human Services
National Institutes of Health

Federal Award Date: 07/24/2019



NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 2R01Al110964-06 **FAIN:** R01Al110964

Principal Investigator(s): PETER DASZAK, PHD

Project Title: Understanding the Risk of Bat Coronavirus Emergence

Dr. Daszak, Peter PD/PI 460 West 34th Street Suite 1701 New York, NY 100012320

Award e-mailed to: (b) (6)

Period Of Performance:

Budget Period: 07/24/2019 – 06/30/2020 **Project Period:** 06/01/2014 – 06/30/2024

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$733,750 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to ECOHEALTH ALLIANCE, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01Al110964. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website

http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

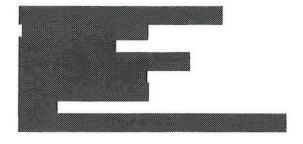
If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Tseday G Girma Grants Management Officer NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

SECTION I - AWARD DATA - 2R01Al110964-06





Approved Budget

Total Amount of Federal Funds Obligated (Federal Share)
TOTAL FEDERAL AWARD AMOUNT

\$733,750 \$733,750 \$733,750

AMOUNT OF THIS ACTION (FEDERAL SHARE)

\$733,750

| SUMMARY TOTALS FOR ALL YEARS | | | | | | |
|------------------------------|------------|-------------------|--|--|--|--|
| YR | THIS AWARD | CUMULATIVE TOTALS | | | | |
| 6 | \$733,750 | \$733,750 | | | | |
| 7 | \$709,750 | \$709,750 | | | | |
| 8 | \$709,750 | \$709,750 | | | | |
| 9 | \$709,750 | \$709,750 | | | | |
| 10 | \$709,750 | \$709,750 | | | | |

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name: Allergy and Infectious Diseases Research

CFDA Number: 93.855

EIN: 1311726494A1

Document Number: RAI110964B

PMS Account Type: P (Subaccount)

Fiscal Year: 2019

| IC | CAN | 2019 | 2020 | 2021 | 2022 | 2023 |
|----|---------|-----------|-----------|-----------|-----------|-----------|
| Al | 8472364 | \$733,750 | \$709,750 | \$709,750 | \$709,750 | \$709,750 |

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:

PCC: M51C B / OC: 414B / Released: (b) (6) 07/18/2019

Award Processed: 07/24/2019 12:03:26 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 2R01AI110964-06

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III - TERMS AND CONDITIONS - 2R01AI110964-06

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.

- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

this requirement and other additional information.

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing

This award has been assigned the Federal Award Identification Number (FAIN) R01Al110964. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

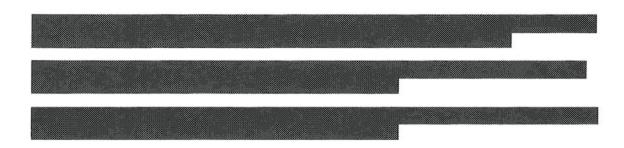
Treatment of Program Income:

Additional Costs

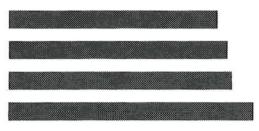
SECTION IV - AI Special Terms and Conditions - 2R01AI110964-06

Clinical Trial Indicator: No.

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.



The Research Performance Progress Report (RPPR), Section G.9 (Foreign component), includes reporting requirements for all research performed outside of the United States. Research conducted at the following site(s) must be reported in your RPPR:



This award reflects current Federal policies regarding Facilities & Administrative (F&A) Costs for foreign grantees including foreign sub-awardees, and domestic awards with foreign sub-awardees. Please see: Chapter 16 Grants to Foreign Organizations, International Organizations, and Domestic Grants with Foreign Components, Section 16.6 "Allowable and Unallowable Cost" of the NIH Grants Policy.

This award may include collaborations with and/or between foreign organizations. Please be advised that short term travel visa expenses are an allowable expense on this grant, if justified as critical and necessary for the conduct of the project.

The budget period anniversary start date for future year(s) will be July 1.

Dissemination of study data will be in accord with the Recipient's accepted genomic data sharing plan as stated in the page(s) **203** of the application. Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIAID may result in Enforcement Actions as described in the NIH Grants Policy Statement.

This award is subject to the Clinical Terms of Award referenced in the NIH Guide for Grants and Contracts, July 8, 2002, NOT Al-02-032. These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address:

https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Award.

Awardees who conduct research involving Select Agents (see 42 CFR 73 for the Select Agent list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens at http://www.selectagents.gov/Regulations.html) must complete registration with CDC (or APHIS, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.

Prior to conducting a restricted experiment with a Select Agent or Toxin, awardees must notify the NIAID and must request and receive approval from CDC or APHIS.

Select Agents:

Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagenis.gov/Regulations.html).

Highly Pathogenic Agent:

NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)

(http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.

When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- o The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Tseday G Girma

Email: (b) (6) Phone: (b) (6) Fax: 301-493-0597

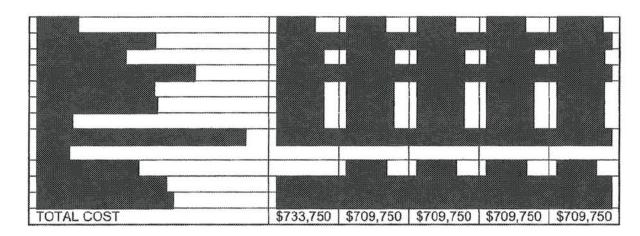
Program Official: Erik J. Stemmy

Email: (b) (6) Phone: (b) (6)

SPREADSHEET SUMMARY

GRANT NUMBER: 2R01Al110964-06

INSTITUTION: ECOHEALTH ALLIANCE, INC.



| Facilities and Administrative Costs | Year 6 | Year 7 | Year 8 | Year 9 | Year 10 |
|-------------------------------------|-----------|-----------|-----------|-----------|-----------|
| F&A Cost Rate 1 | 32% | 32% | 32% | 32% | 32% |
| F&A Cost Base 1 | \$438,711 | \$363,711 | \$363,711 | \$363,711 | \$363,711 |
| F&A Costs 1 | \$140,388 | \$116,388 | \$116,388 | \$116,388 | \$116,388 |

Exhibit B

Date:

April 19, 2020

From:

Michael S Lauer, MD

NIH Deputy Director for Extramural Research

Lauer, Michael Digitally signed by Lauer, Michael (NIH/OD) [6] (NIH/OD) [E]

Date: 2020.04.19 10:47:40

To:

Kevin Olival, PhD

Vice-President for Research

EcoHealth Alliance

(b) (6)

Naomi Schrag, JD

Vice-President for Research Compliance, Training, and Policy

Columbia University
(b) (6)

Subject:

Project Number 2R01A1110964-06

Dear Dr. Olival and Ms. Schrag:

EcoHealth Alliance, Inc. is the recipient, as grantee, of an NIH grant entitled "Understanding the Risk of Bat Coronavirus Emergence." It is our understanding that one of the sub-recipients of the grant funds is the Wuhan Institute of Virology ("WIV"). It is our understanding that WIV studies the interaction between corona viruses and bats. The scientific community believes that the coronavirus causing COVID-19 jumped from bats to humans likely in Wuhan where the COVID-19 pandemic began. There are now allegations that the current crisis was precipitated by the release from WIV of the coronavirus responsible for COVID-19. Given these concerns, we are pursuing suspension of WIV from participation in Federal programs.

While we review these allegations during the period of suspension, you are instructed to cease providing any funds from the above noted grant to the WIV. This temporary action is authorized by 45 C.F.R. § 75.371(d) ("Initiate suspension or debarment proceedings as authorized under 2 C.F.R. part 180"). The incorporated OMB provision provides that the funding agency may, through suspension, immediately and temporarily exclude from Federal programs persons who are not presently responsible where "immediate action is necessary to protect the public interest." 2 C.F.R. § 180.700(c). It is in the public interest that NIH ensure that a sub-recipient has taken all appropriate precautions to prevent the release of pathogens that it is studying. This suspension of the sub-recipient does not affect the remainder of your grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension.

Exhibit C

1 Michael Lauer email 20 April 2020

| From: Lauer, Michael (NIH/OD) [E] Sent: Sunday, April 19, 2020 11:00 AM To: Office Naomi Schrag Oc: Black, Jodi (NIH/OD) [E] Subject: Please read and acknowledge receipt — Actions needed regarding 2R01Al110964-06 Importance: High | |
|---|--|
| Dear Dr. Olival and Ms. Schrag | |
| Please see attached. (Referring to Exhibit B) | |
| Many thanks, Mike | |
| Michael S Lauer, MD NIH Deputy Director for Extramural Research 1 Center Drive, Building 1, Room 144 Bethesda, MD 20892 Phone: (b) (6) Email: | |

2 Kevin Olival email on 20 April 2020

| From: Kevin Olival | (b) (6) | |
|------------------------------------|------------------------------------|-------------------------------|
| Subject: Re: Please read and | acknowledge receipt Actions need | ded regarding 2R01Al110964-06 |
| Date: April 20, 2020 at 4:12:28 PI | M EDT | |
| To: "Lauer, Michael (NIH/OD) [E]" | (b) (6) | |
| Cc: Naomi Schrag | (b) (6) "Black, Jodi (NIH/OD) [E]" | (b) (6) |
| | | |

Dear Mike,

I received the attached letter, however please note:

- 1. I am not the PI on this award. You should contact Dr. Peter Daszak ்கர் கர்கள் கரும் கரும் கரும் கரும் இரும் பார்கள் கரும் கரும்
- 2. Columbia University is not involved in this NIH project, and it is not clear to me why Naomi and Columbia University were included.

Thank you, Kevin

Kevin J. Olival, PhD

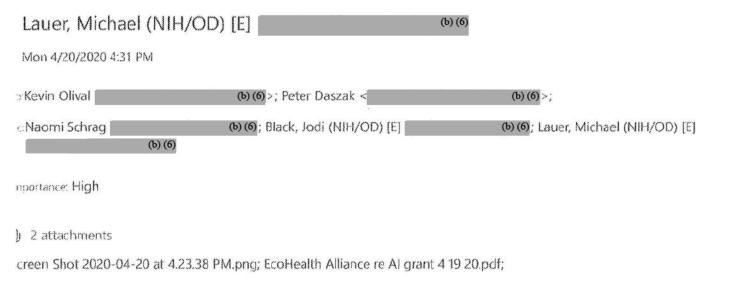
Vice President for Research

EcoHealth Alliance 460 West 34th Street, Suite 1701 New York, NY 10001

(direct) (mobile) 1.212.380.4465 (fax)

www.ecohealthalliance.org

Re: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06



hank you Kevin

3est, Mike

- We need to work with a senior responsible business official usually PI's and senior business officials are different people.
- When I looked you up on the web, I see the Columbia logo (see attached screenshot). Specifically, it
 appears to be Columbia University > Ecology, Evolution, and Environmental Biology > EcoHealth
 Alliance (labeled as an "Affiliation/Department"). Thus the web profile makes it look to me as if
 EcoHealth Alliance is linked to Columbia University.
- In any case, I'm looping in Dr. Daszak.
- We need to know all sites in China that have been in any way linked to this award (Type 1 and Type
 We have data in NIH, but we want to make absolutely sure that we're of the same understanding.

Ve greatly appreciate your prompt attention to this matter.

lichael S Lauer, MD
IIH Deputy Director for Extramural Research
Center Drive, Building 1, Room 144
lethesda, MD 20892
'hone: (b) (6)
:mail: (b) (6)

Re: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06 4 Michael Lauer email on 20 April 2020

| Lauer, Michael (NIH/OD) Mon 4/20/2020 6:34 PM | (b) | 6) | |
|--|--|-----------------------|----------|
| To:Naomi Schrag Cc:Black, Jodi (NIH/OD) [E] | (b) (6); Kevin Olival (b) (6); Lauer, Michael (NIH/OD) [E] | (b) (6); Peter Daszak | (b) (6); |
| ① 1 attachment Screen Shot 2020-04-20 at 4.23.38 Pt | M.png; | | |

Thanks Naomi – not the impression an observer would get looking at the website (see screen shot), but we understand about the grant.

If they "are entirely separate entities" then why does Columbia identify EcoHealth Alliance as an "Affiliation/Department" on its website.

Maybe with the label "Affiliation/Department" you would have a clearly visible disclaimer that says, "EcoHealth Alliance is not affiliated with nor a department of Columbia"? – although even that is internally contradictory.

Best, Mike

From: Naomi Schrag

Date: Monday, April 20, 2020 at 5:19 PM

To: "Lauer, Michael (NIH/OD) [E]"

Cc: Naomi Schrag

(b) (6)
(b) (7)
(b) (7)
(c) (NIH/OD) [E]"

Subject: RE: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06

Dear Dr. Lauer,

Columbia and EcoHealth Alliance are entirely separate entities. Some individuals affiliated with EcoHealth Alliance do have adjunct appointments in Columbia's Ecology, Evolution, and Environmental Biology ("E3B") department, but we are not aware of any Columbia involvement with the referenced grant, and have found no agreement or record in our grants system to the contrary.

We would be happy to answer any additional questions. Thank you. Sincerely,
Naomi Schrag

Naomi J. Schrag

Vice President for Research Compliance, Training and Policy Office of Research Compliance and Training 475 Riverside Drive, Suite 840
New York, New York 10115

(b) (6)

www.researchcompliance.columbia.edu

RE: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06 5 Peter Daszak email on 21 April 2020

Peter Daszak

Tue 4/21/2020 1:32 AM

| To:Lauer, Michael (NIH/OD) [E] (b) (6) | (b) (6) ; Naomi Schrag | (b) (б) ; Kevin Olival |
|--|-------------------------------|-------------------------------|
| CcBlack, Jodi (NIH/OD) [E] | (b) (6) | |

Dear Michael Lauer & Jodi Black — I now have your email and will deal with it directly with you and your staff. Naomi is correct that there is no involvement of Columbia University in this grant. I'm sure NIH has records to confirm that.

From this moment on, I will not co any staff at Columbia as part of this discussion, and I hope you will also honor that. Respectfully, the discussion of whether or not EHA is an affiliate of CU is entirely irrelevant to the request that you contacted us about, and should remain a private matter between EcoHealth Alliance and Columbia University.

I'll look over your email and respond tomorrow.

Cheers,

Peter

Peter Daszak

President

EcoHealth Alliance 460 West 34th Street New York, NY 10001 USA

Tel,: (b) (6

Website: www.ecohealthalliance.org

Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

RE: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06

6 Peter Daszak email on 21 April 2020

| Peter Daszak | | |
|---|-------------------------|---------|
| Tue 4/21/2020 7:03 PM | | |
| To:Lauer, Michael (NIH/OD) [E] | (b) (6); | |
| Cc.Black, Jodi (NIH/OD) [E] | (b) (б); Aleksei Chmura | (b) (6) |
| Stemmy, Erik (NIH/NIAID) [E] | (b) (6) ¿ | (b) (6) |
| Importance: High | | |
| 1 attachment | | |
| EcoHealth Alliance re Al grant 4 19 20.pdf; | | |

Dear Michael – Confirming receipt of your email. I'm also cc'ing the following people so they're aware of this request:

- Our AOR Dr. Aleksei Chmura, who has access to all our records
- My Program Officer for this award, Dr. Erik Stemmy & the Division Director (DMID), Dr. Emily Erberding, so they are informed and aware of the request and our response.

That said we need some time to go through the request for information and will provide this as quickly as we can

However, I can categorically state that no funds form 2R01Al110964-06 have been sent to Wuhan Institute of Virology, nor has any contract been signed. Furthermore, we will comply with NIAID requirements, of course.

Concerning the request for information on all of the sites linked to this award in China, you should be aware that these are documented in our progress reports over the course of the grant. As you can understand we are under enormous pressure to generate data related to the current pandemic, and we do not want to divert staff to this effort. We are hoping the previously filed reports will satisfy this request.

We are well aware of the political concerns over the origins of this outbreak. Our collaboration with Wuhan Institute of Virology has been scientific and we have been consistently impressed with the scientific capabilities of that laboratory and its research staff. Our joint work has led to a series of critical papers published in high impact journals that served to raise awareness of the future threat coronaviruses pose for global health and therefore US national security. Scientific insights with epidemiological significance have been jointly published and our relationship has always been open and transparent and with one concern only, scientific validity. We are concerned that current actions may jeopardize 15 years of fruitful collaboration with colleagues in Wuhan, who are working at the leading edge to design vaccines and drugs that could help us fight this new threat in future years. It is quite remarkable that of the 5 vaccine candidates listed by WHO that are already in human trials, 3 have been developed in China. That said, we of course will

do all we can to make sure any further questions from NIH or any Federal agency are addressed to our fullest knowledge.

Yours sincerely,

Peter Daszak President

EcoHealth Alliance 460 West 34th Street New York, NY 10001 USA

Tel.: (b) (6

Website: www.ecohealthalliance.org

Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

7 Michael Lauer email on 21 April 2020

From: Lauer, Michael (NiH/OD) [E]

Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06

Date: April 21, 2020 at 19:28

To: Peter Daszak

(b) (6)

Cc: Black, Jodi (NIH/OD) [E]

(b) (6) Aleksei Chmura

(b) (6) Stemmy, Erik (NIH/NIAID) [E]

(b) (6) Erbelding, Emily (NIH/NIAID) [E]

Many thanks Peter for your response.

We note that:

- No monies have gone to WIV on the Type 2 award and no contract has been signed.
- You agree that you will not provide any funds to WIV until and unless directed otherwise by NIH.
- All foreign sites for the Type 1 and Type 2 awards have been documented in the progress reports submitted to NIH.

We appreciate your working with us.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (6) (6)

Email: (b) (6)

8 Aleksei Chmura email on 21 April 2020

From: Aleksei Chmura (b) (6)

Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06

Date: April 23, 2020 at 13:50

To: Lauer, Michael (NIH/OD) [E] (b) (c)

Cc: Peter Daszak (b) (6) Black, Jodi (NIH/OD) [E] (b) (6), Erik Stemmy (b) (6)

Erbelding, Emily (NIH/NIAID) [E] (b)

(b) (6)

Dear Mike,

I read that we are in agreement and in compliance with all requests. Please let us know if anything further is required. We will continue in our usual close communication with our Program Officer Erik Stemmy.

Sincerely,

-Aleksei

Aleksei Chmura

Chief of Staff & Authorized Organizational Representative

EcoHealth Alliance 460 West 34th Street, Suite 1701 New York, NY 10001

> (b) (6) office) mobile)

www.ecohealthafliance.org

Ecoficalth Alliance develops science-based solutions to prevent pandemics and promote conservation.



From: Lauer, Michael (NIH/OD) [E]

Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06

Date: April 23, 2020 at 13:59

To: Aleksei Chmura

(b) (6) Cc: Peter Daszak

(b) (6) Black, Jodi (NIH/OD) [E] (b) (6), Stemmy, Erik (NIH/NIAID) [E]

(b) (6) Erbelding, Emily (NIH/NIAID) [E] (b) (6), Lauer, Michael (NIH/OD) [E]

(b) (6), Compliance Review Compliance Review@mail.nih.gov

(b)(6)

Many thanks Aleksei.

9 Michael Lauer email on 21 April 2020

Best, Mike



From: Lauer, Michael (NIH/OD) [E] (b) (6)

Subject: PLEASE READ -- Re: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06

Date: April 24, 2020 at 16:47

To: Aleksei Chmura (b) (6), Peter Daszak (b) (6)

Cc: Black, Jodi (NIH/OD) [E] (b) (6), Stemmy, Erik (NIH/NIAID) [E] (b) (6),

Erbelding, Emily (NIH/NIAID) [E] (b) (6), Linde, Emily (NIH/NIAID) [E] (b) (6) Lauer, Michael (NIH/OD) [E] (b) (6), Bulls, Michelle G. (NIH/OD) [E] (b)(6)

10 Michael Lauer email on 24 April 2020

Dear Dr. Chmura and Dr. Daszak

Please see attached. (Referring to Exhibit D)

Sincerely, Michael S Lauer, MD

Michael S Lauer, MD NIH Deputy Director for Extramural Research 1 Center Drive, Building 1, Room 144 Bethesda, MD 20892

Phone: (b)(6)

(b) (6) Email:



| Subject: | Aleksei Chmura Re: PLEASE REA April 27, 2020 at 2 | | (b) (6) and acknowledge | receipt Actions r | needed regarding 2R01Al110964-06 | |
|----------|---|-----------------------|---|--------------------|--|-------------------------|
| | Lauer, Michael (N | | (b) (6) | | | *** |
| | Peter Daszak Emily Erbelding | | (b) (б), Black, Jod (б), Linde, Emily (f | | (b) (6), Erik Stemmy (b) (6) Bulls, Michelle G. (| (b) (б) (NIH/OD) [E] |
| | | (b) (6), Alison Andre | | (b) (6) | | |
| | | | | | 1 200 | |
| D | ear Michael, | | | | | |
| C | ould Peter and I ha | ave a quick chat with | you sometime tom | orrow (Tuesday) al | bout your email, below? | |
| S | incerely, | | | 11 Aleksei | Chmura email on 27 April 2020 | |

Aleksei Chmura, PhD Chief of Staff

-Aleksei

EcoHealth Alliance 460 West 34th Street, Suite 1701 New York, NY 10001

(b) (6) (office) (mobile) www.ecohealthalliance.org

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation.

Exhibit D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service



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

24 April 2020

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

Re: Termination of NIH Grant R01 AI 110964

Dear Drs. Chmura and Daszak:

I am writing to notify you that the National Institute of Allergy and Infectious Diseases (NIAID), an Institute within the National Institutes of Health (NIH), under the Department of Health and Human Services (HHS) has elected to terminate the project Understanding the Risk of Bat Coronavirus Emergence, funded under grant R01 A1110964, for convenience. This grant project was issued under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284). This grant was funded as a discretionary grant as outlined in the NIH Grants Policy Statement, which states that the decision not to award a grant, or to award a grant at a particular funding level, is at the discretion of the agency, in accordance with NIH's dual review system.

At this time, NIH does not believe that the current project outcomes align with the program goals and agency priorities, NIAID has determined there are no animal and human ethical considerations, as this project is not a clinical trial, but rather an observational study.

As a result of this termination, a total of \$369,819.56 will be remitted to NIAID and additional drawdowns will not be supported. The remaining funds have been restricted in the HHS Payment Management System, effective immediately.

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

Sincerely,

Lauer, Michael (NIH/OD) [E] ODI III OD Digitally signed by Lauer, Michael (NIM/

Michael S Lauer, MD

NIH Deputy Director for Extramural Research

Email:

(b)(6)

cc: Dr. Erik Stemmy Ms. Emily Linde



Exhibit E

SPECIFIC AIMS

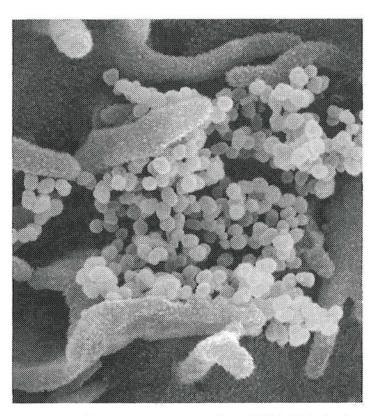
Zoonotic coronaviruses are a significant threat to global health, as demonstrated with the emergence of Severe Acute Respiratory Syndrome coronavirus (SARS-CoV) in 2002, and the continuing spread of Middle East Respiratory Syndrome (MERS-CoV). The wildlife reservoirs of SARS-CoV were identified by our group as bat species, and since then we have sequenced dozens of novel SARS-related CoV (SARSr-CoV) strains. Our previous R01 work demonstrates that bats in southern China harbor an extraordinary diversity of SARSr-CoVs, some of which are able to use human ACE2 to enter into human cells, can infect humanized mouse models to cause SARS-like illness, and evade available therapies or vaccines. We found that the bat hosts of SARSr-CoVs appear to no longer be traded in wildlife markets, and that people living close to bat habitats are the primary risk groups for spillover. At one of these sites, we found diverse SARSr-CoVs containing every genetic element of the wild-type SARS-CoV genome, and serological evidence of human exposure among people living nearby. Thus, there is significant potential for future spillover of SARSr-CoVs, and of public health impacts. Yet salient questions remain: Are there specific bat communities and sites that harbor CoV strains with higher risk for bat-to-human spillover? Which human behaviors drive risk of bat SARSr-CoV exposure that could lead to infection? Does human exposure to these viruses cause SARSlike or other illness? Can we characterize viral strain diversity, bat traits and human behaviors to assess risk of potential future CoV spillover? The proposed work in this renewal R01 builds on these findings to address these issues by conducting: 1) focused sampling of bats in southern China to identify viral strains with high predicted risk of spillover; 2) community-based, and clinic-based syndromic, sampling of people to identify spillover, and assess behavioral risk factors and evidence of illness; and 3) conduct in vitro and in vivo viral characterization and analyze epidemiological data to identify hotspots of future CoV spillover risk. This work will follow 3 specific aims:

<u>Aim 1:</u> Characterize the diversity and distribution of high spillover-risk SARSr-CoVs in bats in southern China. We will conduct targeted bat sampling at sites where we predict that undiscovered high risk SARSr-CoV strains exist. Bat sampling will be targeted geographically and by host species to test predictions about evolutionary diversity of SARSr-CoV. We will analyze RdRp and S protein sequences to test their capacity for spillover to people in Aim 3.

Aim 2: Community- and clinic-based surveillance to capture SARSr-CoV spillover, routes of exposure and potential public health consequences. We will conduct focused, targeted human surveys and sampling to identify key risk factors for SARSr-CoV spillover and evidence of illness. To maximize our opportunity of capturing human exposure to bat CoVs, we will conduct community-based surveillance in regions with high SARSr-CoV prevalence and diversity, and individuals having contact with bats. We will assess bat-CoV seropositive status against a small number of questions about human-wildlife contact and exposure. We will conduct clinic-based syndromic surveillance close to these sites to identify patients presenting with influenzalike illness and severe acute respiratory illness, assess their exposure to bats via a questionnaire, and test samples for PCR- and serological evidence of SARSr-CoV infection. We will conduct follow-up sampling to capture patients who had not yet seroconverted at the time of clinic visit.

<u>Aim 3</u>: In vitro and in vivo characterization of SARSr-CoV spillover risk, coupled with spatial and phylogenetic analyses to identify the regions and viruses of public health concern. We will characterize the propensity of novel SARSr-CoVs to infect people in vitro using primary human airway epithelial cells and in vivo using the transgenic hACE2 mouse model. We will use mAb and vaccine treatments to test our hypothesis that SARSr-CoVs with 10-25% divergence in S protein sequences from SARS-CoV are likely able to infect human cells, and to evade mAb therapeutics and vaccines. We will then map the geographic distribution of their bat hosts and other ecological risk factors to identify the key 'hotspots' of risk for future spillover.

Overall, our SARSr-CoV program serves as a model platform to integrate virologic, molecular and ecologic factors contributing to CoV emergence while informing high impact strategies to intervene and prevent future pandemics. This includes providing critical reagents, therapeutic interventions and recombinant viruses for future SARSr-CoV pandemic and public health preparedness.



This scanning electron microscope image shows SARS-CoV-2 (yellow), the virus that causes COVID-19, isolated from a patient in the United States, emerging from the surface of cells (pink) cultured in the lab. Credit: NIAID-RML

NIAID
STRATEGIC
PLAN FOR
COVID-19
RESEARCH

FY2020 - FY2024 April 22, 2020





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Executive Summary

The National Institute of Allergy and Infectious Diseases (NIAID) at the United States (U.S.) National Institutes of Health (NIH) is committed to safeguarding the health of Americans and people around the world by accelerating research efforts to prevent, diagnose, and treat COVID-19 and characterize the causative agent of this disease, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This

NIAID Strategic Plan for COVID-19 Research builds on current trans-NIAID efforts to better understand SARS-CoV-2 pathogenesis, transmission, and mechanisms of protective immunity by expanding resources and activities that support rapid development of biomedical tools to more effectively combat this disease and pandemic. Given the urgency of the public health response, studies that inform efforts to control virus

Box 1 NIAID Strategic Plan for COVID-19 Research Mission

Conduct and support research on SARS-CoV-2 and COVID-19 to accelerate the development of safe and effective medical countermeasures that decrease disease incidence, mitigate morbidity and prevent mortality.

spread and mitigate morbidity and mortality, including therapeutic and vaccine development, are the priority. In addition, it is essential to develop rapid, accurate, point-of-care diagnostics—a critical asset to mitigating the spread of COVID-19.

The NIAID Strategic Plan for COVID-19 Research aligns with the priorities set by U.S. Government—wide task forces for the development of medical countermeasures. NIAID actively participates in COVID-19 task forces to identify opportunities, ensure open communication, encourage resource sharing, and avoid duplication of effort. The plan is structured around four strategic research priorities:

- Improve fundamental knowledge of SARS-CoV-2 and COVID-19, including studies to characterize
 the virus and how it is transmitted and understand the natural history, epidemiology, host
 immunity, disease immunopathogenesis, and the genetic, immunologic, and clinical associations
 with more severe disease outcomes. This includes accelerating the development of small and large
 animal models that replicate human disease.
- Support the development of diagnostics and assays, including point-of-care molecular and
 antigen-based diagnostics for identifying and isolating COVID-19 cases and serologic assays to
 better understand disease prevalence in the population. Diagnostics also will be essential for
 evaluating the effectiveness of candidate countermeasures.
- Characterize and test therapeutics, including identifying and evaluating repurposed drugs and
 novel broad-spectrum antivirals, virus-targeted antibody-based therapies (including plasma-derived
 intravenous immunoglobulin (IVIG) and monoclonal antibodies), and host-directed strategies to
 combat COVID-19.
- 4. Develop safe and effective vaccines against SARS-CoV-2, including support of clinical trial testing.

To accelerate research, NIAID will leverage current resources and global collaborations, including existing research programs and clinical trials networks. NIAID's research response to COVID-19 will build on experience with diseases caused by other zoonotic coronaviruses (CoVs), including severe acute

respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). NIAID will pursue public-private partnerships to facilitate the translation of research outcomes into life-saving public health interventions. Working with pharmaceutical companies, NIAID has already initiated Phase 1 clinical trials for candidate COVID-19 vaccines and therapeutics. A concerted effort will be made to include minority populations, as well as at-risk and vulnerable populations, in all aspects of NIAID-sponsored research to address health disparities between diverse groups. Characterization of the fundamental virology of SARS-CoV-2 and the immunological response to infection will inform future studies and facilitate the development of effective medical countermeasures. With collaboration from all agencies within the U.S. government and other key U.S. and global partners, NIAID will rapidly disseminate these results so that the information can be translated into clinical practice and public health interventions to combat the pandemic. As such, NIAID has already implemented open sharing of scientific data through publicly available websites and will continue to promote the prompt disclosure of SARS-CoV-2 and COVID-19 research data by the scientific community.

Research Plan

Priority 1: Improve fundamental knowledge of SARS-CoV-2 and COVID-19

Developing effective medical and public health countermeasures against a newly emergent virus like SARS-CoV-2 will require a better understanding of the complex molecular and immune mechanisms underlying infection and disease. Studies that delineate the viral lifecycle and host immune responses to infection can lead to the identification of novel targets for intervention against SARS-CoV-2 infection and COVID-19. Early studies suggest that the clinical manifestations of COVID-19 can vary significantly, and disease severity can range from mild to critical. Thus, a detailed understanding of the clinical course of disease, as well as the clinical, virologic, immunological, and genetic predictors of disease severity, are needed. Gaps also exist in our understanding of the dynamics of disease transmission in different populations over time, including the role of pediatric and elderly populations in viral spread, and the potential seasonality of viral circulation.

Objective 1.1: Characterize fundamental SARS-CoV-2 virology and immunological host response to infection

- Support the development and distribution of reagents and viral isolates to researchers. NIAID will
 continue to support both intramural and extramural researchers by developing reagents and assays
 for virus characterization and immunological analyses. NIAID will continue to accelerate SARS-CoV-2
 research by sourcing viral isolates and clinical specimens for the research community and placing
 them in repositories to help advance research and countermeasure development. In addition, NIAID
 - will place other critical reagents needed for assay development (e.g., pseudovirions and antigens) in publicly available repositories for distribution.
- Characterize virus biology and immunological responses to disease. A comprehensive understanding of the

Box 2

Priority 1: Improve fundamental knowledge of SARS-CoV-2 and COVID-19

Objective 1.1: Characterize fundamental SARS-CoV-2 virology and immunological host response to infection

Objective 1.2: Evaluate disease dynamics through natural history, transmission, and surveillance studies

Objective 1.3: Develop animal models that recapitulate human disease

biological processes involved in SARS-CoV-2 infection and the pathogenesis of COVID-19 are paramount to developing new medical countermeasures to fight the spread of disease. Building on prior research related to MERS and SARS coronaviruses, early studies confirmed several critical features of SARS-CoV-2 infection, including the primary host receptor, angiotensin converting enzyme 2 (ACE-2), and the structure of the virus receptor-binding domain. Studies that delineate the viral lifecycle and host immune responses to infection can lead to the identification of novel targets for intervention against SARS-CoV-2 infection and COVID-19. Understanding the function of essential viral proteins will be necessary for improving diagnostic and immunological assays, *in vitro* and *in vivo* models, and other resources needed to advance safe and effective medical countermeasure development. In addition, evaluating the dynamics of host-pathogen interactions at the molecular and cellular levels will be critical to advancing our understanding of viral pathogenesis and immune responses that contribute to SARS-CoV-2 infection.

- Determine viral evolution and molecular epidemiology. With a newly emergent virus like SARS-CoV-2, studies to characterize genetic diversity, including those that assess the potential for the virus to evolve and escape host immunity, are pivotal for understanding disease progression and transmission dynamics and may have implications for countermeasure development. Viral genomic analysis matched with patient clinical data will be important to identify biomarkers of virulence and establish paradigms of sequence diversity. In addition, evaluating viral sequence associations with disease outcomes, immune status, and viral replication will provide crucial data to accelerate the development of effective medical countermeasures.
- Develop low-containment assays to study virus neutralization. Studies using non-infectious
 pseudovirions can be conducted in labs without BSL-3 capacity, making them an important tool to
 enhance understanding of SARS-CoV-2 infection. This capability would enable researchers without
 high-containment infrastructure to study the dynamics of virus neutralization in vitro.
- Research into optimal public health prevention and mitigation modalities. Clinical trials including family members of a COVID-19 positive individual can be devised to evaluate transmission, prevention, and other mitigation measures within the household.

Objective 1.2: Evaluate disease dynamics through natural history, transmission, and surveillance studies

• Characterize disease incidence through surveillance studies. Clinical manifestations of COVID-19 can vary greatly, ranging from asymptomatic or mildly symptomatic to the development of pneumonia, acute respiratory distress syndrome, and even death. The variation in clinical presentation of COVID-19, combined with the challenges in diagnostic capacity, have made accurate initial assessments of disease incidence a formidable challenge. However, rapid point-of-care and point-of-need molecular tests, which became available in March 2020, will enable hospitals and other healthcare facilities to make informed decisions regarding patient isolation and care. Studies that leverage existing high-throughput diagnostic capacity along with these rapid tests will advance our understanding of disease incidence across the nation and will be a critical component of strategies to implement effective medical countermeasures. Combining these studies with broad serosurveillance studies across existing surveillance networks, including blood bank studies, would

Wu Z and McGoogan JM. JAMA 2020 Feb 24. Epub. PMID 32091533.

provide a more complete picture of the scope of disease and the dynamics of infection. Detailed knowledge of host genetics and the human responses to infection across the lifespan will not only provide insights into new approaches for diagnosis, treatment, and prevention, but also may elucidate why individuals respond to SARS-CoV-2 in different ways. Reports to date suggest that COVID-19 resolves in most cases, 2 implying that the immune system can keep the infection from progressing to severe disease in many individuals. However, additional research is needed to better understand why some people progress to severe disease, which will lend critical insights to medical countermeasure development.

- Assess the dynamics of disease transmission. Our current understanding of COVID-19 transmission is limited. While recent studies have suggested timeframes for virus survival in aerosols and on surfaces,3 the contributions of different routes of transmission and the dynamics of animal-tohuman and human-to-human transmission remain unclear. The diverse clinical presentations of COVID-19, including a high prevalence of asymptomatic cases, add further complexity to understanding transmission dynamics. Providing a clearer picture of the natural history of viral shedding is a priority, both in acute cases and in asymptomatic infection. Given the challenges of accurately diagnosing asymptomatic individuals because they do not present for treatment, determining the role they play in transmission would provide valuable insights. Elucidating the role of pediatric cases in the spread of SARS-CoV-2 is particularly important. Although pediatric COVID-19 cases are generally asymptomatic or have less severe clinical manifestations than those of adults, the role that children play in spreading the virus is unknown. Additionally, studies to identify potential animal reservoirs and better understand transmission from animals to humans are a research priority, as these reservoirs may lead to future virus introductions and re-emergence of disease in humans. Virus transmission depends on a complex interplay of host, viral, and environmental factors that contribute to disease incidence and spread. Identifying the factors that maintain the disease transmission cycle is critical to developing effective medical countermeasures and public health interventions that will prevent future pandemics.
- Determine disease progression through natural history studies. Delineating the natural history of COVID-19 will inform immunopathogenesis, viral tropisms and length of shedding, immune phenotypes, and both protective immunity and host susceptibility. Disease assessment using longitudinal cohort studies, including among high-risk populations such as healthcare workers and the elderly, are important to better understand disease pathogenesis and immune responses to infection. Biomarkers identified from these studies may provide valuable insights into predictors of disease severity.

Objective 1.3: Develop animal models that recapitulate human disease

Develop small and large animal models that replicate SARS-CoV-2 pathogenesis. Developing animal models that recapitulate human disease is a vital early step toward understanding disease pathogenesis and testing the efficacy of medical countermeasures. Small animal models enable rapid, scalable analyses that are particularly valuable for screening countermeasure candidates for efficacy and addressing issues concerning vaccine-induced immune enhancement. Among the small animal models being tested, transgenic mice expressing the human ACE-2 receptor are a promising candidate. In parallel, development and characterization of large animal models, including nonhuman primates (NHPs) that mimic human COVID-19, are a pivotal step to advance promising

² ibid.

³ van Doremalen N et al. N Engl J Med 2020 Mar 17. Epub. PMID 32182409.

countermeasure candidates. Previous experience with related coronavirus diseases such as MERS and SARS suggests that replicating human disease, particularly its more severe manifestations, in an animal model may be challenging. Fundamental research assessing animal models ranging from mice to NHPs is already underway. NIAID will continue to support the development of small and large animal model candidates to better understand this emerging infection and investigate optimal ways to treat and prevent COVID-19. NIAID also will ensure that validated animal models are made available to the scientific community for evaluating priority countermeasures.

Priority 2: Support the development of diagnostics and assays

Availability of rapid, accurate Food and Drug Administration (FDA)-cleared or authorized diagnostics will increase testing capacity and are critical for identifying and rapidly isolating cases, tracking spread of the virus, managing patient care, and supporting clinical trials. Molecular tests specifically designed to detect SARS-Cov-2 RNA in clinical samples are able to detect low levels of pathogen in clinical samples and offer robust specificity in differentiating SARS-CoV-2 from other related viruses. Continuing to improve the speed and accuracy of molecular and antigen-based diagnostics and making them available at point- of-care will be paramount to accelerating the ability to mitigate disease spread in the current outbreak and any future outbreaks. The development of serologic assays would further bolster surveillance efforts, including the ability to identify individuals who may have resolved prior infection with SARS-CoV-2.

Objective 2.1: Accelerate the development and evaluation of diagnostic platforms

Support the development, characterization and availability of reagents for diagnostic validation.

NIAID will support this effort through the development and testing of reagents for diagnostic validation that will be made available through NIAID-sponsored repositories.

Вох 3

Priority 2: Support the development of diagnostics and assays

Objective 2.1: Accelerate the development and evaluation of diagnostic platforms
Objective 2.2: Develop assays to increase understanding of infection and disease incidence

- Support the development of new rapid diagnostics. NIAID will provide funding to support the development of new rapid diagnostics, including molecular tests and novel antigen detection tests with improved sensitivity, if deemed feasible based on natural history studies.
- Support the evaluation of promising diagnostics. In some cases, stakeholders that develop
 potential diagnostic tests do not have the infrastructure needed to rigorously validate those tests
 against clinical samples. NIAID will support the testing of promising diagnostics and provide the
 capacity for evaluating them with live virus samples using our biocontainment laboratories.

Objective 2.2: Develop assays to increase understanding of infection and disease incidence

Develop and validate SARS-CoV-2 serological assays. Serological tests, which detect host antibodies
to infectious agents, do not detect the presence of a pathogen directly but can be used as a
surrogate marker of infection. Developing more effective serologic tests would help provide
information on the extent of asymptomatic infections and cumulative disease incidence, for
example through serosurveillance studies. NIAID, with the Centers for Disease Control and

Prevention and the FDA, is developing tests that identify antibodies to SARS-CoV-2 proteins to determine seroprevalence rates and potentially help distinguish antibody responses in individuals receiving vaccines. NIAID will support the development and validation of additional serological assays for serosurveillance studies and as tools for testing the efficacy of promising vaccine or therapeutic candidates.

Priority 3: Characterize and test therapeutics

Currently, there are no FDA-approved or licensed therapeutics specific for coronaviruses. While traditional development pathways for therapeutics can take years, the urgency of the current outbreak underscores the need for rapid development and testing of promising therapeutics. Possible avenues for developing therapeutics include the evaluation of broad-spectrum antiviral agents (antivirals) that have shown promise for other coronaviruses and the identification of novel monoclonal antibodies (mAbs). For broad-spectrum antivirals, Phase 2/2b testing of the RNA polymerase inhibitor developed by Gilead, remdesivir, is already underway. Additional studies will be critical to identify promising therapeutic candidates and to advance them through clinical trial testing. To optimize findings during the pandemic, multiple clinical trials will be conducted in parallel among various populations, including both inpatient and outpatient studies.

Objective 3.1: Identify promising candidates with activity against SARS-CoV-2

- Screen protease inhibitor and nucleotide analogue class agents and other small molecules with documented activity against other coronaviruses SARS-CoV-2. Screening drugs that are already licensed by the FDA for other indications and might be efficacious against SARS-CoV-2 infection may provide a route to identifying a therapeutic for use in the current pandemic. Broad-spectrum antivirals that are already FDA approved or in clinical development for other indications—including those previously targeting SARS-CoV-1 and MERS CoV—can be evaluated for their potential activity against SARS-CoV-2 infections. Approved therapeutics for other infectious diseases also are being evaluated as possible treatments for COVID-19. By leveraging their existing efficacy, safety, and manufacturability data, the time to development and production can be reduced. NIAID also will continue working with partners to screen compound libraries for potential activity against SARS-CoV-2. For these studies, priority will be given to compounds based on *in vitro* screening data and
 - the existence of human safety data.

 Identify viral targets for therapeutic development.
 Advances in structural biology technology enable researchers to map key viral structures at an

Box 4

Priority 3: Characterize and test therapeutics

Objective 3.1: Identify promising candidates with activity against SARS-CoV-2

Objective 3.2: Conduct treatment studies to advance high-priority therapeutic candidates

unprecedented level. The Structural Genomics Centers for Infectious Diseases (SGCID) apply state-of-the-art, high-throughput technologies and methodologies, including computational modeling, x-ray crystallography, nuclear magnetic resonance imaging, and cryogenic electron microscopy, to experimentally characterize the three dimensional atomic structure of proteins that play an important biological role in human pathogens and infectious diseases. NIAID will continue to support use of this powerful technology to identify viral targets of SARS-CoV-2 for therapeutics or vaccines.

• Identify novel mAbs for use as therapy or prophylaxis. Data from early studies indicate that well-characterized convalescent plasma may provide a treatment benefit in COVID-19.⁴ Therefore, IVIG derived from convalescent plasma may also hold promise for treatment. Moreover, peripheral blood mononuclear cells and plasma are being used to identify novel neutralizing antibodies. Through collaborations with structural biologists, binding properties can be quickly assessed. Paired with assessment of neutralization activity, the most promising mAbs will be identified for further characterization in animal models and human trials.

Objective 3.2: Conduct treatment studies to advance high-priority therapeutic candidates

- Characterize and evaluate host-directed strategies for treatment of disease. Experience with other coronaviruses indicates that infection of the respiratory tract is rapid and damage is primarily mediated by the host inflammatory response. These conditions may make it difficult to modify COVID-19 with pathogen-directed therapeutics. Instead, host-directed strategies that target the immune response may exert a beneficial therapeutic effect. Host-directed strategies, including immune-modulating agents, will be investigated as potential therapeutic candidates.
- Conduct clinical trials to demonstrate safety and efficacy of lead therapeutic candidates. Many
 potential therapeutic candidates have been identified and are being tested in clinical trials.
 - o In March 2020, NIAID launched a multicenter, adaptive, randomized controlled clinical trial to evaluate the safety and efficacy of the investigational antiviral drug remdesivir (GS-5734) for the treatment of COVID-19 in hospitalized adults with laboratory-confirmed SARS-CoV-2 infection and evidence of lung involvement. The trial builds on recent studies by NIAID scientists showing that remdesivir can improve the disease course in rhesus macaques when administered promptly after viral challenge with the MERS CoV.⁶ The trial is also adaptive, allowing for additional arms should other therapeutics warrant assessment for efficacy.
 - NIAID is finalizing the protocol for the Big Effect Trial (BET), in which putative therapeutics that have existing human data and are readily available will be tested in patients hospitalized with lower respiratory tract disease. Each potential intervention will be given to approximately 75 patients and evaluated for mitigating disease symptoms. Candidate therapeutics that meet the criteria in this initial study will be further evaluated in larger clinical trials for which the infrastructure is already in place.
 - As mentioned above, identification of novel mAbs for therapy or prophylaxis is another strategic priority. These mAbs should be safe, highly effective, amenable to fast manufacturing, and easy to administer. They will be tested in clinical trials to develop immunotherapies for the prevention and early treatment of COVID-19, potentially in high-risk populations including healthcare workers.
- Conduct outpatient studies for mild COVID-19 cases. In cases of mild COVID-19 that do not require
 hospitalization, outpatient studies could be extremely valuable for testing promising, orally
 administered FDA-approved drugs that have existing safety data. The antiviral activity of
 hydroxychloroquine and azithromycin against SARS-CoV-2 has been the focus of many early

⁴ Roback JD and Guarner J. JAMA 2020 Mar 27. Epub. 32219429.

⁵ Newton AH et al. Semin Immunopathol. 2016;38(4):471-82. PMID 26965109.

⁶ de Wit E et al. Proc Natl Acad Sci USA 2020;117(12):6771-6. PMID 32054787.

therapeutic studies.^{7,8,9} Testing of these and other candidates, including protease inhibitors and other molecules, in outpatient studies may provide critical efficacy data and could identify an existing drug or drug combination that is safe and effective against COVID-19.

• Conduct outpatient studies in high-risk populations. High-risk populations, including health care workers, the elderly or individuals with chronic conditions, are a critical target for the development of therapeutics. Conducting studies in patients with mild cases of COVID-19 among these high-risk groups would be of interest for identifying the benefits of early treatment strategies to mitigate the impact of infection. Therapeutic candidates that have once a day dosing could also be considered for pre-exposure prophylaxis (PrEP) in some of these populations.

Priority 4: Develop safe and effective vaccines against SARS-CoV-2

Developing a safe and effective SARS-CoV-2 vaccine is a priority for preventing future outbreaks of the virus. As vaccine candidates for MERS-CoV, SARS-CoV-1 and other coronaviruses have previously been developed, NIAID investigators and the scientific community are well poised to use similar approaches in the current pandemic. NIAID will leverage its broad intramural and extramural infrastructure to advance vaccine candidates through Phase 1 safety and dosing clinical trials, with considerations for Phase 2/2b clinical trials for the most promising candidates.

Objective 4.1: Advance promising vaccine candidates through clinical trial testing

- Conduct a Phase 1 clinical trial of (mRNA) platform candidate mRNA-1273. Given the urgency of the response effort to develop a safe and effective vaccine, NIAID is prioritizing promising vaccine candidates that can be rapidly produced and tested. NIAID, in collaboration with the biotechnology company Moderna, is conducting a Phase 1 clinical trial of a vaccine candidate that uses a messenger RNA (mRNA) vaccine platform expressing a NIAID-designed recombinant spike protein of SARS-CoV-2. The trial is being conducted at NIAID-funded clinical research sites, with the first enrolled individual receiving the vaccine on March 16, 2020.
- Prepare for a pivotal Phase 2/2b clinical trial of candidate mRNA-1273. Preparing for the likelihood of a seasonal recurrence of SARS-CoV-2 is imperative to the public health response. Given the theoretical risk of vaccine-enhanced respiratory disease, large Phase 2 trials are unlikely to launch until this possibility is evaluated in animal models. Planning for those animal studies is underway, and, assuming favorable results, a Phase 2/2b study could be launched later in 2020. This represents a historically fast timeline for the development and testing of a vaccine candidate. Additionally, these studies will provide information on correlates of immunity that will help accelerate the advancement of other vaccine candidates. If the mRNA-1273 vaccine candidate shows protection against SARS-CoV-2 infection in a Phase 2/2b trial, NIAID will work with government partners to ensure that the vaccine is manufactured in sufficient quantities to allow prompt distribution to those at highest risk of acquiring disease.

⁷ Gautret P et al. Int J Antimicrob Agents. 2020 Mar 20:105949. Epub. PMID 32205204.

⁸ Molina JM et al. 2020 Med Mai Infect. 2020 Mar 30. pii:S0399-077X(20)30085-8. Epub. PMID 32240719.

⁹ Chen Z et al. medRxiv 2020:2020.03.22.20040758.

 Investigate additional candidates through NIAID vaccine programs. Although promising candidates may show efficacy in preclinical studies, many do not translate into effective vaccines in clinical trials. Therefore, it is crucial to support multiple promising

Box 5.

Priority 4: Develop safe and effective vaccines against SARS-CoV-2

Objective 4.1: Advance promising vaccine candidates through clinical trial testing

Objective 4.2: Advance vaccine development through assay and reagent development

Objective 4.3: Advance vaccine development through adjuvant characterization and development

preclinical candidates in the research and development pipeline. To that end, NIAID is advancing multiple additional SARS-CoV-2 vaccine candidates through its Rocky Mountain Laboratories (RML), including approaches that have shown promise against coronaviruses that cause SARS and MERS. Building on previous research to develop a MERS-CoV vaccine, scientists at RML are collaborating with Oxford University investigators to develop a SARS-CoV-2 vaccine that uses a chimpanzee adenovirus vector. RML investigators also are partnering with the biopharmaceutical company CureVac on an mRNA vaccine candidate and collaborating with the University of Washington on a universal coronavirus vaccine development. By leveraging its extensive expertise and research infrastructure, NIAID will continue working with partners and collaborators to advance promising SARS-CoV-2 vaccine candidates.

• Leverage existing vaccine approaches to target SARS-CoV-2. NIAID is pursuing multiple strategies to develop a COVID-19 vaccine. Building on past research on emerging pathogens, especially MERS-CoV and SARS-CoV-1 (the virus that causes SARS), NIAID is using previously developed vaccine platforms to rapidly assess the potential of SARS-CoV-2 vaccine candidates. This approach has already resulted in several promising strategies that may be leveraged for SARS-CoV-2, including vaccination using recombinant spike protein, chimpanzee adenovirus vaccine vector, virus-like particles, and live attenuated virus. In addition, NIAID is funding the development of novel vaccine candidates that will be efficacious across the lifespan, including in the elderly.

Objective 4.2: Advance vaccine development through assay and reagent development

Develop critical reagents to support vaccine development. Appropriate tools are needed to identify
the most promising vaccine candidates and advance the development of lead candidates as rapidly
as possible. To accelerate the vaccine pipeline, NIAID is generating master and working SARS-CoV-2
virus stocks and other reagents critical for developing SARS-CoV-2 immune assays, developing
quantitative tests for characterizing SARS-CoV2 assay material, developing a quantitative SARS-CoV2-specific ELISA, developing virus-specific neutralization assays, and developing quantitative assays
for assessing SARS-CoV-2 viral load.

Objective 4.3: Advance vaccine development through adjuvant characterization and development

Provide adjuvants to support vaccine development. Adjuvants are vaccine components that
improve vaccine efficacy by inducing long-lived protective immunity. Selection of appropriate
adjuvants is crucial for developing safe and effective vaccines. NIAID is working with multiple
collaborators to provide adjuvants to the research community for use in SARS-CoV-2 vaccine
candidates. These adjuvants are at various stages of development and include compounds that

specifically improve vaccine efficacy in elderly individuals or modulate host immunity toward protective responses while limiting or preventing harmful inflammatory responses.

Conclusion

The sudden emergence and rapid global spread of the novel coronavirus SARS-CoV-2 has created a daunting public health challenge. To address this challenge, NIAID is focusing its considerable expertise and emerging infectious disease resources to facilitate the development of medical countermeasures including diagnostics, therapeutics, and vaccines. The resulting discoveries will not only help mitigate the current pandemic, but also inform prevention, diagnosis, and treatment of future emerging infectious diseases.

A comprehensive strategy requires a coordinated effort among governmental, academic, private, and community-based organizations. The NIAID Strategic Plan for COVID-19 Research defines the areas of COVID-19 research within the NIAID mission and outlines the institute's research priorities and goals. This strategic plan builds on many other national efforts and represents a commitment from multiple U.S. government agencies to improve coordination of COVID-19 research and discovery efforts and the development of medical countermeasures.

| From: | Garcia-Malene, Gorka (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C4DA0F5E0A0480AAD2A86924CABA7B7-GARCIAMALEN] |
|---|--|
| Sent: | 7/2/2020 6:27:08 PM |
| To: | Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm] |
| Subject: | FW: American Oversight Requests Related to Ongoing Investigation |
| Attachments: | FOIA Request (HHS-NIAID-20-1666); FOIA Request (HHS-20-1663); FOIA Request (HHS-20-1661); FOIA Request (HHS-20-1662) |
| Hi Mike, | |
| l should add t leadership. | that we received the same requests as those I just forwarded, but these are meant for OD / OER (b) (5) |
| Let me know | if you think we might proceed differently. |
| I look forward | d to any insights you can share. |
| Gorka | |
| Sent: Thursda To: Garcia-M | e, Roger (NIH/OD) [E] < (b) (6) ay, July 2, 2020 2:12 PM alene, Gorka (NIH/OD) [E] < (b) (6) American Oversight Requests Related to Ongoing Investigation |
| Hi Gorka, | |
| OD also rece of NIAID's. | eived 4 requests from Am. Oversight. that asked for the same records just from OD/OER leadership instead |
| Just FYI. | |
| - Roge | r |
| From: Schofic | eld, Robin (NIH/NIAID) [E] (b) (6) |
| Sent: Thursda | ay, July 2, 2020 12:42 PM |
| | alene, Gorka (NIH/OD) [E] (b) (6) |
| | Roger (NIH/OD) [E] 6) 6) Moore, Marg (NIH/NIAID) [E] 6) 6) rican Oversight Requests Related to Ongoing Investigation |
| Hi Gorka, | |
| | 4 new requests from American Oversight related to the NIAID grant that was cancelled by NIH on orders te House. Kindly let me know (b) (5) |
| | (b) (5) |
| Thank you! | |
| Robin | |

From: FOIA [foia@americanoversight.org]

Sent: 7/2/2020 4:36:05 PM

To: FOIA-7 [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=fb7dd35bf17146a5bd0bfe8a9c62c6af-FOIA-7]

Subject: FOIA Request (HHS-NIAID-20-1666)

Attachments: HHS-NIAID-20-1666.pdf

Dear FOIA Officer:

Please find attached a request for records under the Freedom of Information Act.

Sincerely,

Vibha Kannan
Paralegal
American Oversight
foia@americanoversight.org
www.americanoversight.org | @weareoversight

FOIA: HHS-NIAID-20-1666



July 2, 2020

VIA EMAIL

Robert Schofield National Institute of Allergy and Infectious Diseases Room 6G51 5601 Fishers Lane Rockville, MD 20857 foia@niaid.nih.gov

Re: Freedom of Information Act Request

Dear FOIA officer:

Pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and the implementing regulations of your agency, 45 C.F.R. Part 5, American Oversight makes the following request for records.

In late April, the National Institute of Health (NIH) cancelled a grant previously awarded to EcoHealth Alliance, purportedly on the grounds that "NIH does not believe the current project outcomes align with the program goals and agency priorities." This action, apparently at the direction of the White House, came after news reports suggested that the group was funding the Wuhan Institute of Virology. Prior to the funding cancellation, however, the president of EcoHealth Alliance had confirmed to NIH that none of its current funding had been sent to the Institute, that it had not entered into a contract with the Institute, and that it would comply with any federal requirements. The EcoHealth Alliance's focus—studying coronaviruses in bats—is also consistent with the NIH's strategic plan for studying novel coronaviruses. Leading scientists and scientific societies

⁴ Owermohle, *supra* note 1; *see* Media Advisory, NIH, NIAID Strategic Plan Details COVID-19 Research Priorities, Apr. 23, 2020, https://www.nih.gov/news-events/news-releases/niaid-strategic-plan-details-covid-19-research-priorities.



¹ Sarah Owermohle, *Trump Cuts U.S. Research on Bat-Human Virus Transmission over China Ties*, Politico (Apr. 27, 2020, 7:02 PM), https://www.politico.com/news/2020/04/27/trump-cuts-research-bat-human-virus-china-213076.

² David Lim & Brianna Ehley, Fauci Says White House Told NIH to Cancel Funding for Bat Virus Study, Politico (July 23, 2020, 5:41 PM),

https://www.politico.com/news/2020/06/23/fauci-nih-white-house-bat-study-336452.

³ Partial Transcript of Email Exchanges in Which NIH Cuts off Grant Funding to EcoHealth Alliance, Science,

https://www.sciencemag.org/sites/default/files/Lauer.Daszak.NIH%20grant%20killed.partial%20email%20transcripts.April%202020.pdf.

have since asked for NIH to review its decision to cut funding, expressing concern about the politicization of science.⁵

American Oversight seeks records that may shed light on the cancellation of the EcoHealth Alliance's grant.

Requested Records

American Oversight requests that your agency produce the following records within twenty business days:

All electronic communications (including email messages, complete email chains, calendar invitations, Jabber instant messages, text messages and similar electronic messaging applications (such as Signal, WhatsApp, Twitter DMs), etc., and any attachments thereto) of the following officials *regarding* the Wuhan Institute of Virology and/or the EcoHealth Alliance project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AI110964.

- a. Director Anthony Fauci
- b. Principal Deputy Director Hugh Auchincloss
- c. Director, Division of Extramural Activities, Matthew J. Fenton

American Oversight believes that a search for responsive record should include custodial inquiries to determine where and in what form responsive records may reside. Additionally, in the event that an electronic search is conducted to ensure all responsive records are located, American Oversight believes that records containing the terms below are likely to be responsive records. Accordingly, American Oversight requests that your agency, at a minimum, employ these search terms to identify responsive records:

- i. "Wuhan Institute"
- ii. "Virology Institute"
- iii. WIV
- iv. "Wuhan laboratory"
- v. "Wuhan lab"
- vi. "Shi Zhengli"
- vii. EcoHealth
- viii. "ecohealthalliance.org"
- ix. Daszak
- x. Olival

⁵ Nobel Laureates and Science Groups Demand NIH Review Decision to Kill Coronavirus Grant, Science (May 21, 2020, 6:40 PM),

https://www.sciencemag.org/news/2020/05/preposterous-77-nobel-laureates-blast-nih-decision-cancel-coronavirus-grant-demand.

xi. "Bat coronavirus"

xii. Bats

xiii. AI110964

Please provide all responsive records from April 10, 2020, through April 30, 2020.

Fee Waiver Request

In accordance with 5 U.S.C. § 552(a) (4) (A) (iii) and your agency's regulations, American Oversight requests a waiver of fees associated with processing this request for records. The subject of this request concerns the operations of the federal government, and the disclosures will likely contribute to a better understanding of relevant government procedures by the general public in a significant way. Moreover, the request is primarily and fundamentally for non-commercial purposes.

American Oversight requests a waiver of fees because disclosure of the requested information is "in the public interest because it is likely to contribute significantly to public understanding of operations or activities of the government." The public has a significant interest in the federal government's support of research that could help combat the current coronavirus outbreak and prevent similar outbreaks in the future. Records with the potential to shed light on this matter would contribute significantly to public understanding of operations of the federal government, including whether and to what extent research funding has become politicized. American Oversight is committed to transparency and makes the responses agencies provide to FOIA requests publicly available, and the public's understanding of the government's activities would be enhanced through American Oversight's analysis and publication of these records.

This request is primarily and fundamentally for non-commercial purposes. As a 501(c)(3) nonprofit, American Oversight does not have a commercial purpose and the release of the information requested is not in American Oversight's financial interest. American Oversight's mission is to promote transparency in government, to educate the public about government activities, and to ensure the accountability of government officials. American Oversight uses the information gathered, and its analysis of it, to educate the public through reports, press releases, or other media. American Oversight also makes materials it gathers available on its public website and promotes their availability on social media platforms, such as Facebook and Twitter. Oversight also makes

⁶ 5 U.S.C. § 552(a) (4) (A) (iii).

⁷ See Media Advisory, supra note 4.

⁸ See Science, supra note 5.

⁹ See 5 U.S.C. § 552(a) (4) (A) (iii).

 $^{^{10}}$ American Oversight currently has approximately 15,600 page likes on Facebook and 104,000 followers on Twitter. American Oversight, FACEBOOK,

https://www.facebook.com/weareoversight/ (last visited June 25, 2020); American

American Oversight has also demonstrated its commitment to the public disclosure of documents and creation of editorial content through numerous substantive analyses posted to its website.¹¹ Examples reflecting this commitment to the public disclosure of documents and the creation of editorial content include the posting of records related to an ethics waiver received by a senior Department of Justice attorney and an analysis of what those records demonstrated regarding the Department's process for issuing such waivers;¹² posting records received as part of American Oversight's "Audit the Wall" project to gather and analyze information related to the administration's proposed construction of a barrier along the U.S.-Mexico border, and analyses of what those records reveal;¹³ posting records regarding potential self-dealing at the Department of Housing & Urban Development and related analysis; 14 posting records and analysis relating to the federal government's efforts to sell nuclear technology to Saudi Arabia; ¹⁵ and posting records and analysis regarding the Department of Justice's decision in response to demands from Congress to direct a U.S. Attorney to undertake a wide-ranging review and make recommendations regarding criminal investigations relating to the President's political opponents and allegations of misconduct by the Department of Justice itself and the Federal Bureau of Investigation.16

Accordingly, American Oversight qualifies for a fee waiver.

Oversight (@weareoversight), TWITTER, https://twitter.com/weareoversight (last visited June 25, 2020).

¹¹ News, American Oversight, https://www.americanoversight.org/blog.

¹² DOJ Records Relating to Solicitor General Noel Francisco's Recusal, AMERICAN OVERSIGHT, https://www.americanoversight.org/document/doj-civil-division-response-noel-francisco-compliance; Francisco & the Travel Ban: What We Learned from the DOJ Documents, AMERICAN OVERSIGHT, https://www.americanoversight.org/francisco-the-travel-ban-what-we-learned-from-the-doj-documents.

¹³ See generally Audit the Wall, AMERICAN OVERSIGHT,
https://www.americanoversight.org/investigation/audit-the-wall; see, e.g., Border Wall
Investigation Report: No Plans, No Funding, No Timeline, No Wall, AMERICAN OVERSIGHT,
https://www.americanoversight.org/border-wall-investigation-report-no-plans-nofunding-no-timeline-no-wall.

¹⁴ Documents Reveal Ben Carson Jr.'s Attempts to Use His Influence at HUD to Help His Business, AMERICAN OVERSIGHT, https://www.americanoversight.org/documents-reveal-ben-carson-ir-s-attempts-to-use-his-influence-at-hud-to-help-his-business.

¹⁵ Investigating the Trump Administration's Efforts to Sell Nuclear Technology to Saudi Arabia, AMERICAN OVERSIGHT, https://www.americanoversight.org/investigating-the-trump-administrations-efforts-to-sell-nuclear-technology-to-saudi-arabia.

¹⁶ Sessions' Letter Shows DOJ Acted on Trump's Authoritarian Demand to Investigate Clinton, AMERICAN OVERSIGHT, https://www.americanoversight.org/sessions-letter.

Guidance Regarding the Search & Processing of Requested Records

In connection with its request for records, American Oversight provides the following guidance regarding the scope of the records sought and the search and processing of records:

- Please search all locations and systems likely to have responsive records, regardless of format, medium, or physical characteristics.
- Our request for records includes any attachments to those records or other
 materials enclosed with those records when they were previously transmitted. To
 the extent that an email is responsive to our request, our request includes all prior
 messages sent or received in that email chain, as well as any attachments to the
 email.
- Please search all relevant records or systems containing records regarding agency business. Do not exclude records regarding agency business contained in files, email accounts, or devices in the personal custody of your officials, such as personal email accounts or text messages. Records of official business conducted using unofficial systems or stored outside of official files are subject to the Federal Records Act and FOIA.¹⁷ It is not adequate to rely on policies and procedures that require officials to move such information to official systems within a certain period of time; American Oversight has a right to records contained in those files even if material has not yet been moved to official systems or if officials have, by intent or through negligence, failed to meet their obligations.¹⁸
- Please use all tools available to your agency to conduct a complete and efficient search for potentially responsive records. Agencies are subject to government-wide requirements to manage agency information electronically,¹⁹ and many agencies have adopted the National Archives and Records Administration (NARA) Capstone program, or similar policies. These systems provide options for searching emails and other electronic records in a manner that is reasonably likely to be more complete than just searching individual custodian files. For example, a

See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, 827 F.3d 145, 149–50
 (D.C. Cir. 2016); cf. Judicial Watch, Inc. v. Kerry, 844 F.3d 952, 955–56 (D.C. Cir. 2016).

¹⁸ See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).

¹⁹ Presidential Memorandum—Managing Government Records, 76 Fed. Reg. 75,423 (Nov. 28, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/11/28/presidential-memorandum-managing-government-records; Office of Mgmt. & Budget, Exec. Office of the President, Memorandum for the Heads of Executive Departments & Independent Agencies, "Managing Government Records Directive," M-12-18 (Aug. 24, 2012), https://www.archives.gov/files/records-mgmt/m-12-18.pdf.

custodian may have deleted a responsive email from his or her email program, but your agency's archiving tools may capture that email under Capstone. At the same time, custodian searches are still necessary; agencies may not have direct access to files stored in .PST files, outside of network drives, in paper format, or in personal email accounts.

- In the event some portions of the requested records are properly exempt from
 disclosure, please disclose any reasonably segregable non-exempt portions of the
 requested records. If a request is denied in whole, please state specifically why it is
 not reasonable to segregate portions of the record for release.
- Please take appropriate steps to ensure that records responsive to this request are not deleted by the agency before the completion of processing for this request. If records potentially responsive to this request are likely to be located on systems where they are subject to potential deletion, including on a scheduled basis, please take steps to prevent that deletion, including, as appropriate, by instituting a litigation hold on those records.

Conclusion

If you have any questions regarding how to construe this request for records or believe that further discussions regarding search and processing would facilitate a more efficient production of records of interest to American Oversight, please do not hesitate to contact American Oversight to discuss this request. American Oversight welcomes an opportunity to discuss its request with you before you undertake your search or incur search or duplication costs. By working together at the outset, American Oversight and your agency can decrease the likelihood of costly and time-consuming litigation in the future.

Where possible, please provide responsive material in an electronic format by email. Alternatively, please provide responsive material in native format or in PDF format on a USB drive. Please send any responsive material being sent by mail to American Oversight, 1030 15th Street NW, Suite B255, Washington, DC 20005. If it will accelerate release of responsive records to American Oversight, please also provide responsive material on a rolling basis.

We share a common mission to promote transparency in government. American Oversight looks forward to working with your agency on this request. If you do not understand any part of this request, please contact Christine H. Monahan at foia@americanoversight.org

or 202-869-5244. Also, if American Oversight's request for a fee waiver is not granted in full, please contact us immediately upon making such a determination.



From: FOIA [foia@americanoversight.org]

Sent: 7/2/2020 4:33:38 PM

To: FOIA-7 [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=fb7dd35bf17146a5bd0bfe8a9c62c6af-FOIA-7]; OS FOIA Request (HHS/ASPA)

[FOIARequest@hhs.gov]

Subject: FOIA Request (HHS-20-1663)

Attachments: HHS-20-1663.pdf

Dear FOIA Officer:

Please find attached a request for records under the Freedom of Information Act.

Sincerely,

Vibha Kannan
Paralegal
American Oversight
foia@americanoversight.org
www.americanoversight.org | @weareoversight

FOIA: HHS-20-1663



July 2, 2020

VIA EMAIL/ ONLINE PORTAL

Gorka Garcia-Malene NIH FOIA Office Building 31 Room 5B35 31 Center Drive, MSC 2107 Bethesda, MD 20892 https://foiaportal.nih.gov/

Robert Schofield National Institute of Allergy and Infectious Diseases Room 6G51 5601 Fishers Lane Rockville, MD 20857 foia@niaid.nih.gov

Brandon Gaylord
Freedom of Information Officer
Department of Health and Human Services
Hubert H. Humphrey Building
Room 729H
200 Independence Avenue SW
Washington, DC 20201
FOIARequest@hhs.gov

Re: Freedom of Information Act Request

Dear FOIA officer:

Pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and the implementing regulations of your agency, 45 C.F.R. Part 5, American Oversight makes the following request for records.

In late April, the National Institute of Health (NIH) cancelled a grant previously awarded to EcoHealth Alliance, purportedly on the grounds that "NIH does not believe the current project outcomes align with the program goals and agency priorities." This action, apparently at the direction of the White House, came after news reports suggested that

¹ Sarah Owermohle, *Trump Cuts U.S. Research on Bat-Human Virus Transmission over China Ties*, Politico (Apr. 27, 2020, 7:02 PM), https://www.politico.com/news/2020/04/27/trump-cuts-research-bat-human-virus-china-213076.



the group was funding the Wuhan Institute of Virology.² Prior to the funding cancellation, however, the president of EcoHealth Alliance had confirmed to NIH that none of its current funding had been sent to the Institute, that it had not entered into a contract with the Institute, and that it would comply with any federal requirements.³ The EcoHealth Alliance's focus—studying coronaviruses in bats—is also consistent with the NIH's strategic plan for studying novel coronaviruses.⁴ Leading scientists and scientific societies have since asked for NIH to review its decision to cut funding, expressing concern about the politicization of science.⁵

American Oversight seeks records that may shed light on the cancellation of the EcoHealth Alliance's grant.

Requested Records

American Oversight requests that your agency produce the following records within twenty business days:

Any directive or guidance from the White House (including coronavirus task force, led by Vice President Pence, or any other senior White House officials) to terminate funding for the EcoHealth Alliance, and/or any NIH grantee that, in the past or present, had a financial relationship with the Wuhan Institute of Virology.

Please search for responsive records from April 10, 2020, through April 30, 2020.

Given that this request seeks a specific, recent, readily identifiable document, American Oversight expects that this request can be processes on the Simple processing track in a prompt manner.

https://www.politico.com/news/2020/06/23/fauci-nih-white-house-bat-study-336452.

² David Lim & Brianna Ehley, Fauci Says White House Told NIH to Cancel Funding for Bat Virus Study, Politico (July 23, 2020, 5:41 PM),

³ Partial Transcript of Email Exchanges in Which NIH Cuts off Grant Funding to EcoHealth Alliance, Science,

https://www.sciencemag.org/sites/default/files/Lauer.Daszak.NIH%20grant%20killed.partial%20email%20transcripts.April%202020.pdf.

⁴ Owermohle, *supra* note 1; *see* Media Advisory, NIH, NIAID Strategic Plan Details COVID-19 Research Priorities, Apr. 23, 2020, https://www.nih.gov/news-events/news-releases/niaid-strategic-plan-details-covid-19-research-priorities.

⁵ Nobel Laureates and Science Groups Demand NIH Review Decision to Kill Coronavirus Grant, Science (May 21, 2020, 6:40 PM),

https://www.sciencemag.org/news/2020/05/preposterous-77-nobel-laureates-blast-nih-decision-cancel-coronavirus-grant-demand.

Fee Waiver Request

In accordance with 5 U.S.C. § 552(a)(4)(A)(iii) and your agency's regulations, American Oversight requests a waiver of fees associated with processing this request for records. The subject of this request concerns the operations of the federal government, and the disclosures will likely contribute to a better understanding of relevant government procedures by the general public in a significant way. Moreover, the request is primarily and fundamentally for non-commercial purposes.

American Oversight requests a waiver of fees because disclosure of the requested information is "in the public interest because it is likely to contribute significantly to public understanding of operations or activities of the government." The public has a significant interest in the federal government's support of research that could help combat the current coronavirus outbreak and prevent similar outbreaks in the future. Records with the potential to shed light on this matter would contribute significantly to public understanding of operations of the federal government, including whether and to what extent research funding has become politicized. American Oversight is committed to transparency and makes the responses agencies provide to FOIA requests publicly available, and the public's understanding of the government's activities would be enhanced through American Oversight's analysis and publication of these records.

This request is primarily and fundamentally for non-commercial purposes. As a 501(c)(3) nonprofit, American Oversight does not have a commercial purpose and the release of the information requested is not in American Oversight's financial interest. American Oversight's mission is to promote transparency in government, to educate the public about government activities, and to ensure the accountability of government officials. American Oversight uses the information gathered, and its analysis of it, to educate the public through reports, press releases, or other media. American Oversight also makes materials it gathers available on its public website and promotes their availability on social media platforms, such as Facebook and Twitter. Oversight and Decided to the public of the public of the public of the public website and promotes their availability on social media platforms, such as Facebook and Twitter.

American Oversight has also demonstrated its commitment to the public disclosure of documents and creation of editorial content through numerous substantive analyses posted to its website. ¹¹ Examples reflecting this commitment to the public disclosure of

⁶ 5 U.S.C. § 552(a) (4) (A) (iii).

⁷ See Media Advisory, supra note 4.

⁸ See Science, supra note 5.

⁹ See 5 U.S.C. § 552(a) (4) (A) (iii).

¹⁰ American Oversight currently has approximately 15,600 page likes on Facebook and 104,000 followers on Twitter. American Oversight, FACEBOOK, https://www.facebook.com/weareoversight/ (last visited June 25, 2020); American Oversight (@weareoversight), TWITTER, https://twitter.com/weareoversight (last visited June 25, 2020).

¹¹ News, AMERICAN OVERSIGHT, https://www.americanoversight.org/blog.

documents and the creation of editorial content include the posting of records related to an ethics waiver received by a senior Department of Justice attorney and an analysis of what those records demonstrated regarding the Department's process for issuing such waivers; ¹² posting records received as part of American Oversight's "Audit the Wall" project to gather and analyze information related to the administration's proposed construction of a barrier along the U.S.-Mexico border, and analyses of what those records reveal; ¹³ posting records regarding potential self-dealing at the Department of Housing & Urban Development and related analysis; ¹⁴ posting records and analysis relating to the federal government's efforts to sell nuclear technology to Saudi Arabia; ¹⁵ and posting records and analysis regarding the Department of Justice's decision in response to demands from Congress to direct a U.S. Attorney to undertake a wide-ranging review and make recommendations regarding criminal investigations relating to the President's political opponents and allegations of misconduct by the Department of Justice itself and the Federal Bureau of Investigation. ¹⁶

Accordingly, American Oversight qualifies for a fee waiver.

Guidance Regarding the Search & Processing of Requested Records

In connection with its request for records, American Oversight provides the following guidance regarding the scope of the records sought and the search and processing of records:

 Please search all locations and systems likely to have responsive records, regardless of format, medium, or physical characteristics.

¹² DOJ Records Relating to Solicitor General Noel Francisco's Recusal, AMERICAN OVERSIGHT, https://www.americanoversight.org/document/doj-civil-division-response-noel-francisco-compliance; Francisco & the Travel Ban: What We Learned from the DOJ Documents, AMERICAN OVERSIGHT, https://www.americanoversight.org/francisco-the-travel-ban-what-we-learned-from-the-doj-documents.

¹³ See generally Audit the Wall, AMERICAN OVERSIGHT, https://www.americanoversight.org/investigation/audit-the-wall; see, e.g., Border Wall Investigation Report: No Plans, No Funding, No Timeline, No Wall, AMERICAN OVERSIGHT, https://www.americanoversight.org/border-wall-investigation-report-no-plans-no-funding-no-timeline-no-wall.

¹⁴ Documents Reveal Ben Carson Jr.'s Attempts to Use His Influence at HUD to Help His Business, AMERICAN OVERSIGHT, https://www.americanoversight.org/documents-reveal-ben-carson-jr-s-attempts-to-use-his-influence-at-hud-to-help-his-business.

¹⁵ Investigating the Trump Administration's Efforts to Sell Nuclear Technology to Saudi Arabia, American Oversight, https://www.americanoversight.org/investigating-the-trump-administrations-efforts-to-sell-nuclear-technology-to-saudi-arabia.

¹⁶ Sessions' Letter Shows DOJ Acted on Trump's Authoritarian Demand to Investigate Clinton, AMERICAN OVERSIGHT, https://www.americanoversight.org/sessions-letter.

- Our request for records includes any attachments to those records or other
 materials enclosed with those records when they were previously transmitted. To
 the extent that an email is responsive to our request, our request includes all prior
 messages sent or received in that email chain, as well as any attachments to the
 email.
- Please search all relevant records or systems containing records regarding agency business. Do not exclude records regarding agency business contained in files, email accounts, or devices in the personal custody of your officials, such as personal email accounts or text messages. Records of official business conducted using unofficial systems or stored outside of official files are subject to the Federal Records Act and FOIA.¹⁷ It is not adequate to rely on policies and procedures that require officials to move such information to official systems within a certain period of time; American Oversight has a right to records contained in those files even if material has not yet been moved to official systems or if officials have, by intent or through negligence, failed to meet their obligations.¹⁸
- Please use all tools available to your agency to conduct a complete and efficient search for potentially responsive records. Agencies are subject to government-wide requirements to manage agency information electronically, 19 and many agencies have adopted the National Archives and Records Administration (NARA) Capstone program, or similar policies. These systems provide options for searching emails and other electronic records in a manner that is reasonably likely to be more complete than just searching individual custodian files. For example, a custodian may have deleted a responsive email from his or her email program, but your agency's archiving tools may capture that email under Capstone. At the same time, custodian searches are still necessary; agencies may not have direct access to files stored in .PST files, outside of network drives, in paper format, or in personal email accounts.
- In the event some portions of the requested records are properly exempt from disclosure, please disclose any reasonably segregable non-exempt portions of the

See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, 827 F.3d 145, 149–50
 (D.C. Cir. 2016); cf. Judicial Watch, Inc. v. Kerry, 844 F.3d 952, 955–56 (D.C. Cir. 2016).

¹⁸ See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).

¹⁹ Presidential Memorandum—Managing Government Records, 76 Fed. Reg. 75,423 (Nov. 28, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/11/28/presidential-memorandum-managing-government-records; Office of Mgmt. & Budget, Exec. Office of the President, Memorandum for the Heads of Executive Departments & Independent Agencies, "Managing Government Records Directive," M-12-18 (Aug. 24, 2012), https://www.archives.gov/files/records-mgmt/m-12-18.pdf.

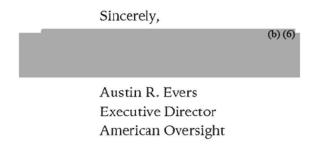
- requested records. If a request is denied in whole, please state specifically why it is not reasonable to segregate portions of the record for release.
- Please take appropriate steps to ensure that records responsive to this request are not deleted by the agency before the completion of processing for this request. If records potentially responsive to this request are likely to be located on systems where they are subject to potential deletion, including on a scheduled basis, please take steps to prevent that deletion, including, as appropriate, by instituting a litigation hold on those records.

Conclusion

If you have any questions regarding how to construe this request for records or believe that further discussions regarding search and processing would facilitate a more efficient production of records of interest to American Oversight, please do not hesitate to contact American Oversight to discuss this request. American Oversight welcomes an opportunity to discuss its request with you before you undertake your search or incur search or duplication costs. By working together at the outset, American Oversight and your agency can decrease the likelihood of costly and time-consuming litigation in the future.

Where possible, please provide responsive material in an electronic format by email. Alternatively, please provide responsive material in native format or in PDF format on a USB drive. Please send any responsive material being sent by mail to American Oversight, 1030 15th Street NW, Suite B255, Washington, DC 20005. If it will accelerate release of responsive records to American Oversight, please also provide responsive material on a rolling basis.

We share a common mission to promote transparency in government. American Oversight looks forward to working with your agency on this request. If you do not understand any part of this request, please contact Christine H. Monahan at foia@americanoversight.org or 202-869-5244. Also, if American Oversight's request for a fee waiver is not granted in full, please contact us immediately upon making such a determination.



From: FOIA [foia@americanoversight.org]

Sent: 7/2/2020 4:30:31 PM

To: FOIA-7 [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=fb7dd35bf17146a5bd0bfe8a9c62c6af-FOIA-7]; OS FOIA Request (HHS/ASPA)

[FOIARequest@hhs.gov]

Subject: FOIA Request (HHS-20-1661)

Attachments: HHS-20-1661.pdf

Dear FOIA Officer:

Please find attached a request for records under the Freedom of Information Act.

Sincerely,

Vibha Kannan
Paralegal
American Oversight
foia@americanoversight.org
www.americanoversight.org | @weareoversight

FOIA: HHS-20-1661



July 2, 2020

VIA EMAIL/ ONLINE PORTAL

Gorka Garcia-Malene NIH FOIA Office Building 31 Room 5B35 31 Center Drive, MSC 2107 Bethesda, MD 20892 https://foiaportal.nih.gov/

Robert Schofield National Institute of Allergy and Infectious Diseases Room 6G51 5601 Fishers Lane Rockville, MD 20857 foia@niaid.nih.gov

Brandon Gaylord
Freedom of Information Officer
Department of Health and Human Services
Hubert H. Humphrey Building
Room 729H
200 Independence Avenue SW
Washington, DC 20201
FOIARequest@hhs.gov

Re: Freedom of Information Act Request

Dear FOIA officer:

Pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and the implementing regulations of your agency, 45 C.F.R. Part 5, American Oversight makes the following request for records.

In late April, the National Institute of Health (NIH) cancelled a grant previously awarded to EcoHealth Alliance, purportedly on the grounds that "NIH does not believe the current project outcomes align with the program goals and agency priorities." This action, apparently at the direction of the White House, came after news reports suggested that

¹ Sarah Owermohle, *Trump Cuts U.S. Research on Bat-Human Virus Transmission over China Ties*, Politico (Apr. 27, 2020, 7:02 PM), https://www.politico.com/news/2020/04/27/trump-cuts-research-bat-human-virus-china-213076.



the group was funding the Wuhan Institute of Virology.² Prior to the funding cancellation, however, the president of EcoHealth Alliance had confirmed to NIH that none of its current funding had been sent to the Institute, that it had not entered into a contract with the Institute, and that it would comply with any federal requirements.³ The EcoHealth Alliance's focus—studying coronaviruses in bats—is also consistent with the NIH's strategic plan for studying novel coronaviruses.⁴ Leading scientists and scientific societies have since asked for NIH to review its decision to cut funding, expressing concern about the politicization of science.⁵

American Oversight seeks records that may shed light on the cancellation of the EcoHealth Alliance's grant.

Requested Records

American Oversight requests that your agency produce the following records within twenty business days:

The final decision memoranda or other records memorializing the basis, justification, or rationale for terminating the EcoHealth Alliance project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AII 10964.

Please search for responsive records from April 10, 2020, through April 30, 2020.

Given that this request seeks a specific, recent, readily identifiable document, American Oversight expects that this request can be processes on the Simple processing track in a prompt manner.

https://www.politico.com/news/2020/06/23/fauci-nih-white-house-bat-study-336452.

² David Lim & Brianna Ehley, Fauci Says White House Told NIH to Cancel Funding for Bat Virus Study, Politico (July 23, 2020, 5:41 PM),

³ Partial Transcript of Email Exchanges in Which NIH Cuts off Grant Funding to EcoHealth Alliance, Science,

https://www.sciencemag.org/sites/default/files/Lauer.Daszak.NIH%20grant%20killed.partial%20email%20transcripts.April%202020.pdf.

⁴ Owermohle, *supra* note 1; *see* Media Advisory, NIH, NIAID Strategic Plan Details COVID-19 Research Priorities, Apr. 23, 2020, https://www.nih.gov/news-events/news-releases/niaid-strategic-plan-details-covid-19-research-priorities.

⁵ Nobel Laureates and Science Groups Demand NIH Review Decision to Kill Coronavirus Grant, Science (May 21, 2020, 6:40 PM),

https://www.sciencemag.org/news/2020/05/preposterous-77-nobel-laureates-blast-nih-decision-cancel-coronavirus-grant-demand.

Fee Waiver Request

In accordance with 5 U.S.C. § 552(a) (4) (A) (iii) and your agency's regulations, American Oversight requests a waiver of fees associated with processing this request for records. The subject of this request concerns the operations of the federal government, and the disclosures will likely contribute to a better understanding of relevant government procedures by the general public in a significant way. Moreover, the request is primarily and fundamentally for non-commercial purposes.

American Oversight requests a waiver of fees because disclosure of the requested information is "in the public interest because it is likely to contribute significantly to public understanding of operations or activities of the government." The public has a significant interest in the federal government's support of research that could help combat the current coronavirus outbreak and prevent similar outbreaks in the future. Records with the potential to shed light on this matter would contribute significantly to public understanding of operations of the federal government, including whether and to what extent research funding has become politicized. American Oversight is committed to transparency and makes the responses agencies provide to FOIA requests publicly available, and the public's understanding of the government's activities would be enhanced through American Oversight's analysis and publication of these records.

This request is primarily and fundamentally for non-commercial purposes. As a 501(c)(3) nonprofit, American Oversight does not have a commercial purpose and the release of the information requested is not in American Oversight's financial interest. American Oversight's mission is to promote transparency in government, to educate the public about government activities, and to ensure the accountability of government officials. American Oversight uses the information gathered, and its analysis of it, to educate the public through reports, press releases, or other media. American Oversight also makes materials it gathers available on its public website and promotes their availability on social media platforms, such as Facebook and Twitter. Oversight and Twitter.

American Oversight has also demonstrated its commitment to the public disclosure of documents and creation of editorial content through numerous substantive analyses posted to its website. ¹¹ Examples reflecting this commitment to the public disclosure of

⁶ 5 U.S.C. § 552(a) (4) (A) (iii).

⁷ See Media Advisory, supra note 4.

⁸ See Science, supra note 5.

⁹ See 5 U.S.C. § 552(a) (4) (A) (iii).

¹⁰ American Oversight currently has approximately 15,600 page likes on Facebook and 104,000 followers on Twitter. American Oversight, FACEBOOK, https://www.facebook.com/weareoversight/ (last visited June 25, 2020); American Oversight (@weareoversight), TWITTER, https://twitter.com/weareoversight (last visited June 25, 2020).

¹¹ News, AMERICAN OVERSIGHT, https://www.americanoversight.org/blog.

documents and the creation of editorial content include the posting of records related to an ethics waiver received by a senior Department of Justice attorney and an analysis of what those records demonstrated regarding the Department's process for issuing such waivers; ¹² posting records received as part of American Oversight's "Audit the Wall" project to gather and analyze information related to the administration's proposed construction of a barrier along the U.S.-Mexico border, and analyses of what those records reveal; ¹³ posting records regarding potential self-dealing at the Department of Housing & Urban Development and related analysis; ¹⁴ posting records and analysis relating to the federal government's efforts to sell nuclear technology to Saudi Arabia; ¹⁵ and posting records and analysis regarding the Department of Justice's decision in response to demands from Congress to direct a U.S. Attorney to undertake a wide-ranging review and make recommendations regarding criminal investigations relating to the President's political opponents and allegations of misconduct by the Department of Justice itself and the Federal Bureau of Investigation. ¹⁶

Accordingly, American Oversight qualifies for a fee waiver.

Guidance Regarding the Search & Processing of Requested Records

In connection with its request for records, American Oversight provides the following guidance regarding the scope of the records sought and the search and processing of records:

 Please search all locations and systems likely to have responsive records, regardless of format, medium, or physical characteristics.

¹² DOJ Records Relating to Solicitor General Noel Francisco's Recusal, AMERICAN OVERSIGHT, https://www.americanoversight.org/document/doj-civil-division-response-noel-francisco-compliance; Francisco & the Travel Ban: What We Learned from the DOJ Documents, AMERICAN OVERSIGHT, https://www.americanoversight.org/francisco-the-travel-ban-what-we-learned-from-the-doj-documents.

¹³ See generally Audit the Wall, AMERICAN OVERSIGHT, https://www.americanoversight.org/investigation/audit-the-wall; see, e.g., Border Wall Investigation Report: No Plans, No Funding, No Timeline, No Wall, AMERICAN OVERSIGHT, https://www.americanoversight.org/border-wall-investigation-report-no-plans-no-funding-no-timeline-no-wall.

¹⁴ Documents Reveal Ben Carson Jr.'s Attempts to Use His Influence at HUD to Help His Business, AMERICAN OVERSIGHT, https://www.americanoversight.org/documents-reveal-ben-carson-ir-s-attempts-to-use-his-influence-at-hud-to-help-his-business.

¹⁵ Investigating the Trump Administration's Efforts to Sell Nuclear Technology to Saudi Arabia, American Oversight, https://www.americanoversight.org/investigating-the-trump-administrations-efforts-to-sell-nuclear-technology-to-saudi-arabia.

¹⁶ Sessions' Letter Shows DOJ Acted on Trump's Authoritarian Demand to Investigate Clinton, AMERICAN OVERSIGHT, https://www.americanoversight.org/sessions-letter.

- Our request for records includes any attachments to those records or other
 materials enclosed with those records when they were previously transmitted. To
 the extent that an email is responsive to our request, our request includes all prior
 messages sent or received in that email chain, as well as any attachments to the
 email.
- Please search all relevant records or systems containing records regarding agency business. Do not exclude records regarding agency business contained in files, email accounts, or devices in the personal custody of your officials, such as personal email accounts or text messages. Records of official business conducted using unofficial systems or stored outside of official files are subject to the Federal Records Act and FOIA.¹⁷ It is not adequate to rely on policies and procedures that require officials to move such information to official systems within a certain period of time; American Oversight has a right to records contained in those files even if material has not yet been moved to official systems or if officials have, by intent or through negligence, failed to meet their obligations.¹⁸
- Please use all tools available to your agency to conduct a complete and efficient search for potentially responsive records. Agencies are subject to government-wide requirements to manage agency information electronically, 19 and many agencies have adopted the National Archives and Records Administration (NARA) Capstone program, or similar policies. These systems provide options for searching emails and other electronic records in a manner that is reasonably likely to be more complete than just searching individual custodian files. For example, a custodian may have deleted a responsive email from his or her email program, but your agency's archiving tools may capture that email under Capstone. At the same time, custodian searches are still necessary; agencies may not have direct access to files stored in .PST files, outside of network drives, in paper format, or in personal email accounts.
- In the event some portions of the requested records are properly exempt from disclosure, please disclose any reasonably segregable non-exempt portions of the

See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, 827 F.3d 145, 149–50
 (D.C. Cir. 2016); cf. Judicial Watch, Inc. v. Kerry, 844 F.3d 952, 955–56 (D.C. Cir. 2016).

¹⁸ See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).

¹⁹ Presidential Memorandum—Managing Government Records, 76 Fed. Reg. 75,423 (Nov. 28, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/11/28/presidential-memorandum-managing-government-records; Office of Mgmt. & Budget, Exec. Office of the President, Memorandum for the Heads of Executive Departments & Independent Agencies, "Managing Government Records Directive," M-12-18 (Aug. 24, 2012), https://www.archives.gov/files/records-mgmt/m-12-18.pdf.

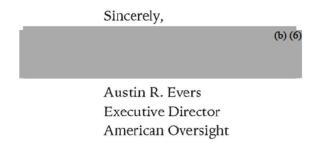
- requested records. If a request is denied in whole, please state specifically why it is not reasonable to segregate portions of the record for release.
- Please take appropriate steps to ensure that records responsive to this request are not deleted by the agency before the completion of processing for this request. If records potentially responsive to this request are likely to be located on systems where they are subject to potential deletion, including on a scheduled basis, please take steps to prevent that deletion, including, as appropriate, by instituting a litigation hold on those records.

Conclusion

If you have any questions regarding how to construe this request for records or believe that further discussions regarding search and processing would facilitate a more efficient production of records of interest to American Oversight, please do not hesitate to contact American Oversight to discuss this request. American Oversight welcomes an opportunity to discuss its request with you before you undertake your search or incur search or duplication costs. By working together at the outset, American Oversight and your agency can decrease the likelihood of costly and time-consuming litigation in the future.

Where possible, please provide responsive material in an electronic format by email. Alternatively, please provide responsive material in native format or in PDF format on a USB drive. Please send any responsive material being sent by mail to American Oversight, 1030 15th Street NW, Suite B255, Washington, DC 20005. If it will accelerate release of responsive records to American Oversight, please also provide responsive material on a rolling basis.

We share a common mission to promote transparency in government. American Oversight looks forward to working with your agency on this request. If you do not understand any part of this request, please contact Christine H. Monahan at foia@americanoversight.org or 202-869-5244. Also, if American Oversight's request for a fee waiver is not granted in full, please contact us immediately upon making such a determination.



From: FOIA [foia@americanoversight.org]

Sent: 7/2/2020 4:31:57 PM

To: FOIA-7 [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=fb7dd35bf17146a5bd0bfe8a9c62c6af-FOIA-7]; OS FOIA Request (HHS/ASPA)

[FOIARequest@hhs.gov]

Subject: FOIA Request (HHS-20-1662)

Attachments: HHS-20-1662.pdf

Dear FOIA Officer:

Please find attached a request for records under the Freedom of Information Act.

Sincerely,

Vibha Kannan
Paralegal
American Oversight
foia@americanoversight.org
www.americanoversight.org | @weareoversight

FOIA: HHS-20-1662



July 2, 2020

VIA EMAIL/ ONLINE PORTAL

Gorka Garcia-Malene NIH FOIA Office Building 31 Room 5B35 31 Center Drive, MSC 2107 Bethesda, MD 20892 https://foiaportal.nih.gov/

Robert Schofield National Institute of Allergy and Infectious Diseases Room 6G51 5601 Fishers Lane Rockville, MD 20857 foia@niaid.nih.gov

Brandon Gaylord
Freedom of Information Officer
Department of Health and Human Services
Hubert H. Humphrey Building
Room 729H
200 Independence Avenue SW
Washington, DC 20201
FOIARequest@hhs.gov

Re: Freedom of Information Act Request

Dear FOIA officer:

Pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and the implementing regulations of your agency, 45 C.F.R. Part 5, American Oversight makes the following request for records.

In late April, the National Institute of Health (NIH) cancelled a grant previously awarded to EcoHealth Alliance, purportedly on the grounds that "NIH does not believe the current project outcomes align with the program goals and agency priorities." This action, apparently at the direction of the White House, came after news reports suggested that

¹ Sarah Owermohle, *Trump Cuts U.S. Research on Bat-Human Virus Transmission over China Ties*, Politico (Apr. 27, 2020, 7:02 PM), https://www.politico.com/news/2020/04/27/trump-cuts-research-bat-human-virus-china-213076.



the group was funding the Wuhan Institute of Virology.² Prior to the funding cancellation, however, the president of EcoHealth Alliance had confirmed to NIH that none of its current funding had been sent to the Institute, that it had not entered into a contract with the Institute, and that it would comply with any federal requirements.³ The EcoHealth Alliance's focus—studying coronaviruses in bats—is also consistent with the NIH's strategic plan for studying novel coronaviruses.⁴ Leading scientists and scientific societies have since asked for NIH to review its decision to cut funding, expressing concern about the politicization of science.⁵

American Oversight seeks records that may shed light on the cancellation of the EcoHealth Alliance's grant.

Requested Records

American Oversight requests that your agency produce the following records within twenty business days:

Any final assessments or analyses (including formal memoranda, final talking points and associated background materials, or other written products) regarding the implications of terminating the EcoHealth Alliance project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AI110964, including but not limited to implications on research into the natural history of the novel coronavirus SARS-CoV-2 and the development of vaccines and treatments for the virus and the disease it causes, COVID-19.

American Oversight believes that your agencies are best positioned to determine where responsive records may reside. However, at a minimum, we believe a search for responsive records should include the following:

² David Lim & Brianna Ehley, Fauci Says White House Told NIH to Cancel Funding for Bat Virus Study, Politico (July 23, 2020, 5:41 PM),

https://www.politico.com/news/2020/06/23/fauci-nih-white-house-bat-study-336452.

³ Partial Transcript of Email Exchanges in Which NIH Cuts off Grant Funding to EcoHealth Alliance, Science.

https://www.sciencemag.org/sites/default/files/Lauer.Daszak.NIH%20grant%20killed.partial%20email%20transcripts.April%202020.pdf.

⁴ Owermohle, *supra* note 1; *see* Media Advisory, NIH, NIAID Strategic Plan Details COVID-19 Research Priorities, Apr. 23, 2020, https://www.nih.gov/news-events/news-releases/niaid-strategic-plan-details-covid-19-research-priorities.

⁵ Nobel Laureates and Science Groups Demand NIH Review Decision to Kill Coronavirus Grant, Science (May 21, 2020, 6:40 PM),

https://www.sciencemag.org/news/2020/05/preposterous-77-nobel-laureates-blast-nih-decision-cancel-coronavirus-grant-demand.

- Within HHS, the immediate offices of the Secretary and the Assistant Secretary for Preparedness and Response, and the headquarters staff of the Office of Intergovernmental and External Affairs (IEA).
- Within NIH, the immediate office of the Director, and the Office of Extramural Research (including but not limited to the files of Deputy Director Michael Lauer).
- Within the National Institute of Allergy and Infectious Diseases (NIAID), the immediate office of the Director, and the Division of Extramural Activities.

Please provide all responsive records from April 10, 2020, through the date the search is conducted.

Fee Waiver Request

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⁶ 5 U.S.C. § 552(a)(4)(A)(iii).

⁷ See Media Advisory, supra note 4.

⁸ See Science, supra note 5.

⁹ See 5 U.S.C. § 552(a) (4) (A) (iii).

public through reports, press releases, or other media. American Oversight also makes materials it gathers available on its public website and promotes their availability on social media platforms, such as Facebook and Twitter. 10

American Oversight has also demonstrated its commitment to the public disclosure of documents and creation of editorial content through numerous substantive analyses posted to its website. Examples reflecting this commitment to the public disclosure of documents and the creation of editorial content include the posting of records related to an ethics waiver received by a senior Department of Justice attorney and an analysis of what those records demonstrated regarding the Department's process for issuing such waivers; posting records received as part of American Oversight's "Audit the Wall" project to gather and analyze information related to the administration's proposed construction of a barrier along the U.S.-Mexico border, and analyses of what those records reveal; posting records regarding potential self-dealing at the Department of Housing & Urban Development and related analysis; posting records and analysis relating to the federal government's efforts to sell nuclear technology to Saudi Arabia; and posting records and analysis regarding the Department of Justice's decision in response to demands from Congress to direct a U.S. Attorney to undertake a wide-ranging review and make recommendations regarding criminal investigations relating to the President's

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¹¹ News, AMERICAN OVERSIGHT, https://www.americanoversight.org/blog.

¹² DOJ Records Relating to Solicitor General Noel Francisco's Recusal, AMERICAN OVERSIGHT, https://www.americanoversight.org/document/doj-civil-division-response-noel-francisco-compliance; Francisco & the Travel Ban: What We Learned from the DOJ Documents, AMERICAN OVERSIGHT, https://www.americanoversight.org/francisco-the-travel-ban-what-we-learned-from-the-doj-documents.

¹³ See generally Audit the Wall, AMERICAN OVERSIGHT, https://www.americanoversight.org/investigation/audit-the-wall; see, e.g., Border Wall Investigation Report: No Plans, No Funding, No Timeline, No Wall, AMERICAN OVERSIGHT, https://www.americanoversight.org/border-wall-investigation-report-no-plans-no-funding-no-timeline-no-wall.

¹⁴ Documents Reveal Ben Carson Jr.'s Attempts to Use His Influence at HUD to Help His Business, AMERICAN OVERSIGHT, https://www.americanoversight.org/documents-reveal-ben-carson-jr-s-attempts-to-use-his-influence-at-hud-to-help-his-business.

¹⁵ Investigating the Trump Administration's Efforts to Sell Nuclear Technology to Saudi Arabia, AMERICAN OVERSIGHT, https://www.americanoversight.org/investigating-the-trump-administrations-efforts-to-sell-nuclear-technology-to-saudi-arabia.

political opponents and allegations of misconduct by the Department of Justice itself and the Federal Bureau of Investigation.¹⁶

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- Our request for records includes any attachments to those records or other
 materials enclosed with those records when they were previously transmitted. To
 the extent that an email is responsive to our request, our request includes all prior
 messages sent or received in that email chain, as well as any attachments to the
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- Please search all relevant records or systems containing records regarding agency business. Do not exclude records regarding agency business contained in files, email accounts, or devices in the personal custody of your officials, such as personal email accounts or text messages. Records of official business conducted using unofficial systems or stored outside of official files are subject to the Federal Records Act and FOIA.¹⁷ It is not adequate to rely on policies and procedures that require officials to move such information to official systems within a certain period of time; American Oversight has a right to records contained in those files even if material has not yet been moved to official systems or if officials have, by intent or through negligence, failed to meet their obligations.¹⁸
- Please use all tools available to your agency to conduct a complete and efficient search for potentially responsive records. Agencies are subject to government-wide requirements to manage agency information electronically,¹⁹ and many agencies

¹⁶ Sessions' Letter Shows DOJ Acted on Trump's Authoritarian Demand to Investigate Clinton, AMERICAN OVERSIGHT, https://www.americanoversight.org/sessions-letter.

See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, 827 F.3d 145, 149–50
 (D.C. Cir. 2016); cf. Judicial Watch, Inc. v. Kerry, 844 F.3d 952, 955–56 (D.C. Cir. 2016).

¹⁸ See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).

¹⁹ Presidential Memorandum—Managing Government Records, 76 Fed. Reg. 75,423 (Nov. 28, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/11/28/presidential-memorandum-managing-government-records; Office of Mgmt. & Budget, Exec. Office of the President, Memorandum for the Heads of Executive

have adopted the National Archives and Records Administration (NARA) Capstone program, or similar policies. These systems provide options for searching emails and other electronic records in a manner that is reasonably likely to be more complete than just searching individual custodian files. For example, a custodian may have deleted a responsive email from his or her email program, but your agency's archiving tools may capture that email under Capstone. At the same time, custodian searches are still necessary; agencies may not have direct access to files stored in .PST files, outside of network drives, in paper format, or in personal email accounts.

- In the event some portions of the requested records are properly exempt from disclosure, please disclose any reasonably segregable non-exempt portions of the requested records. If a request is denied in whole, please state specifically why it is not reasonable to segregate portions of the record for release.
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Conclusion

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Departments & Independent Agencies, "Managing Government Records Directive," M-12-18 (Aug. 24, 2012), https://www.archives.gov/files/records-mgmt/m-12-18.pdf.

or 202-869-5244. Also, if American Oversight's request for a fee waiver is not granted in full, please contact us immediately upon making such a determination.



From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: 7/2/2020 2:33:44 PM

To: Jacobs, Anna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e76eeb11df9a4024b53864ffac4c4c56-jacobsal]

CC: Lankford, David (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4f29a9bef672409d967e3aa5fb36e96a-lankford]; Lauer, Michael (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]

Subject: Re: Suspension of Grant_Daszak letter June XX 2020_final clean RPC Comments

Attachments: Suspension of Grant_Daszak letter June XX 2020_final clean RPC Comments mgbedits[1].docx

Thanks Anna – let's stick with what we have. We have a letter cleared by downtown (including downtown OGC), and we'll use it.

(b)(6)

Best, Mike

From: "Jacobs, Anna (NIH/OD) [E]" (b) (6)

Date: Thursday, July 2, 2020 at 10:24 AM

To: "Lauer, Michael (NIH/OD) [E]"

Cc: "Lankford, David (NIH/OD) [E]" (b) (6

Subject: FW: Suspension of Grant_Daszak letter June XX 2020_final clean RPC Comments

Mike, thank you again for the discussion this morning. I spoke with David about the additional edits,

-so just let us know how you'd like

(b)(5)

for us to proceed.

Best,

Anna L. Jacobs, J.D., M.S.

Senior Attorney

HHS Office of the General Counsel

Public Health Division, NIH Branch

31 Center Drive, Bldg. 31, Rm.2B-50

Bethesda, MD 20892

(b) (6) (phone)

301-402-1034 (fax)

(b) (6)

NOTICE: The contents of this message and any attachments may be privileged and confidential. Please do not disseminate without the approval of the Office of the General Counsel. If you are not an intended recipient, or have received this message in error, please delete it without reading it and please do not print, copy, forward, disseminate, or otherwise use this information. Also, please notify the sender that you have received this communication in error. Your receipt of this message is not intended to waive any applicable privilege.

From: Lauer, Michael (NIH/OD) [E] (b) (6)

Sent: Thursday, July 2, 2020 8:38 AM

To: Jacobs, Anna (NIH/OD) [E] (b) (6)
Cc: Lauer, Michael (NIH/OD) [E] (b) (6)

Subject: FW: Suspension of Grant_Daszak letter June XX 2020_final clean RPC Comments

From: "Bulls, Michelle G. (NIH/OD) [E]" (b) (6)

Date: Tuesday, June 30, 2020 at 4:03 PM

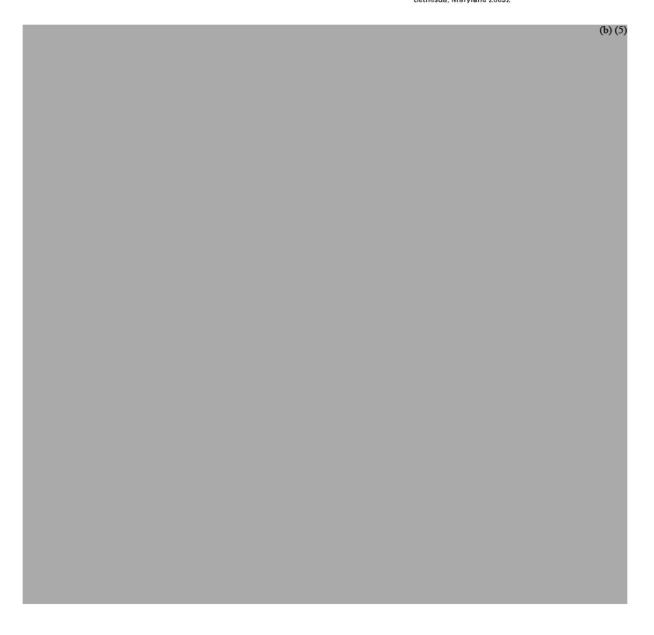
To: "Lauer, Michael (NIH/OD) [E]" (b) (6), "Black, Jodi (NIH/OD) [E]" (b) (6)

Subject: Suspension of Grant_Daszak letter June XX 2020_final clean RPC Comments



Public Health Service

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







From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: 7/2/2020 6:26:31 PM

To: Garcia-Malene, Gorka (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4c4da0f5e0a0480aad2a86924caba7b7-garciamalen]

CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]

Subject: FW: American Oversight Requests Related to Ongoing Investigation

Attachments: FOIA Request (HHS-NIAID-20-1666); FOIA Request (HHS-20-1663); FOIA Request (HHS-20-1661); FOIA Request (HHS-20-1663); FOIA Reques

20-1662)

Hi Gorka – yes, all of these would be part of an ongoing investigation. We referred this matter to OIG / ONS.

Many thanks, Mike

From: "Garcia-Malene, Gorka (NIH/OD) [E]" (b) (6)

Date: Thursday, July 2, 2020 at 2:17 PM

To: "Lauer, Michael (NIH/OD) [E]" (b) (6)

Subject: FW: American Oversight Requests Related to Ongoing Investigation

Good afternoon, Mike -

Please see attached and below: American Oversight has filed requests seeking records relating to the EcoHealth Alliance project. They have gone to NIAID, and they wonder whether these records would be denied pursuant to an ongoing investigation. For convenience, I summarize the requested records below.

Do you have a sense as to whether all records responsive to these requests would be part of the ongoing investigation?

We are already in litigation with the requester, AO, on related matters

(b) (5)

(b)(5)

(b) (5)

...-1666

All communications of the following officials regarding the Wuhan Institute of Virology and/or the EcoHealth Alliance project Understanding the Risk of Bat Coronavirus Emergence, funded under grant R01 AI110964.

- a. Director Anthony Fauci
- b. Principal Deputy Director Hugh Auchincloss
 - c. Director, Division of Extramural Activities, Matthew J. Fenton

...-1663

Any directive or guidance from the White House (including coronavirus task force, led by Vice President Pence, or any other senior White House officials) to terminate funding for the EcoHealth Alliance, and/or any NIH grantee that, in the past or present, had a financial relationship with the Wuhan Institute of Virology.

...-1661

The final decision memoranda or other records memorializing the basis, justification, or rationale for terminating the EcoHealth Alliance project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AI110964.

...-1662

Any final assessments or analyses regarding the implications of terminating the EcoHealth Alliance project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AI110964, including implications on research into the natural

history of the novel coronavirus SARS-CoV-2 and the development of vaccines and treatments for the virus and the disease it causes, COVID-19.

Let me know if there are any questions.

Gorka

From: Schofield, Robin (NIH/NIAID) [E] (b) (6)

Sent: Thursday, July 2, 2020 12:42 PM

To: Garcia-Malene, Gorka (NIH/OD) [E] (b) (6)

Cc: Bordine, Roger (NIH/OD) [E] (b) (6) Moore, Marg (NIH/NIAID) [E] (b) (6)

Subject: American Oversight Requests Related to Ongoing Investigation

Hi Gorka,

Attached are 4 new requests from American Oversight related to the NIAID grant that was cancelled by NIH on orders from the White House. Kindly let me know (b) (5) (b) (5)

Thank you!

Robin

From: FOIA [foia@americanoversight.org]

Sent: 7/2/2020 4:36:05 PM

To: FOIA-7 [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=fb7dd35bf17146a5bd0bfe8a9c62c6af-FOIA-7]

Subject: FOIA Request (HHS-NIAID-20-1666)

Attachments: HHS-NIAID-20-1666.pdf

Dear FOIA Officer:

Please find attached a request for records under the Freedom of Information Act.

Sincerely,

Vibha Kannan
Paralegal
American Oversight
foia@americanoversight.org
www.americanoversight.org | @weareoversight

FOIA: HHS-NIAID-20-1666



July 2, 2020

VIA EMAIL

Robert Schofield National Institute of Allergy and Infectious Diseases Room 6G51 5601 Fishers Lane Rockville, MD 20857 foia@niaid.nih.gov

Re: Freedom of Information Act Request

Dear FOIA officer:

Pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and the implementing regulations of your agency, 45 C.F.R. Part 5, American Oversight makes the following request for records.

In late April, the National Institute of Health (NIH) cancelled a grant previously awarded to EcoHealth Alliance, purportedly on the grounds that "NIH does not believe the current project outcomes align with the program goals and agency priorities." This action, apparently at the direction of the White House, came after news reports suggested that the group was funding the Wuhan Institute of Virology. Prior to the funding cancellation, however, the president of EcoHealth Alliance had confirmed to NIH that none of its current funding had been sent to the Institute, that it had not entered into a contract with the Institute, and that it would comply with any federal requirements. The EcoHealth Alliance's focus—studying coronaviruses in bats—is also consistent with the NIH's strategic plan for studying novel coronaviruses. Leading scientists and scientific societies

⁴ Owermohle, *supra* note 1; *see* Media Advisory, NIH, NIAID Strategic Plan Details COVID-19 Research Priorities, Apr. 23, 2020, https://www.nih.gov/news-events/news-releases/niaid-strategic-plan-details-covid-19-research-priorities.



¹ Sarah Owermohle, *Trump Cuts U.S. Research on Bat-Human Virus Transmission over China Ties*, Politico (Apr. 27, 2020, 7:02 PM), https://www.politico.com/news/2020/04/27/trump-cuts-research-bat-human-virus-china-213076.

² David Lim & Brianna Ehley, Fauci Says White House Told NIH to Cancel Funding for Bat Virus Study, Politico (July 23, 2020, 5:41 PM),

https://www.politico.com/news/2020/06/23/fauci-nih-white-house-bat-study-336452.

³ Partial Transcript of Email Exchanges in Which NIH Cuts off Grant Funding to EcoHealth Alliance, Science,

https://www.sciencemag.org/sites/default/files/Lauer.Daszak.NIH%20grant%20killed.partial%20email%20transcripts.April%202020.pdf.

have since asked for NIH to review its decision to cut funding, expressing concern about the politicization of science.⁵

American Oversight seeks records that may shed light on the cancellation of the EcoHealth Alliance's grant.

Requested Records

American Oversight requests that your agency produce the following records within twenty business days:

All electronic communications (including email messages, complete email chains, calendar invitations, Jabber instant messages, text messages and similar electronic messaging applications (such as Signal, WhatsApp, Twitter DMs), etc., and any attachments thereto) of the following officials *regarding* the Wuhan Institute of Virology and/or the EcoHealth Alliance project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AI110964.

- a. Director Anthony Fauci
- b. Principal Deputy Director Hugh Auchincloss
- c. Director, Division of Extramural Activities, Matthew J. Fenton

American Oversight believes that a search for responsive record should include custodial inquiries to determine where and in what form responsive records may reside. Additionally, in the event that an electronic search is conducted to ensure all responsive records are located, American Oversight believes that records containing the terms below are likely to be responsive records. Accordingly, American Oversight requests that your agency, at a minimum, employ these search terms to identify responsive records:

- i. "Wuhan Institute"
- ii. "Virology Institute"
- iii. WIV
- iv. "Wuhan laboratory"
- v. "Wuhan lab"
- vi. "Shi Zhengli"
- vii. EcoHealth
- viii. "ecohealthalliance.org"
- ix. Daszak
- x. Olival

https://www.sciencemag.org/news/2020/05/preposterous-77-nobel-laureates-blast-nih-decision-cancel-coronavirus-grant-demand.

⁵ Nobel Laureates and Science Groups Demand NIH Review Decision to Kill Coronavirus Grant, Science (May 21, 2020, 6:40 PM),

xi. "Bat coronavirus"

xii. Bats

xiii. AI110964

Please provide all responsive records from April 10, 2020, through April 30, 2020.

Fee Waiver Request

In accordance with 5 U.S.C. § 552(a) (4) (A) (iii) and your agency's regulations, American Oversight requests a waiver of fees associated with processing this request for records. The subject of this request concerns the operations of the federal government, and the disclosures will likely contribute to a better understanding of relevant government procedures by the general public in a significant way. Moreover, the request is primarily and fundamentally for non-commercial purposes.

American Oversight requests a waiver of fees because disclosure of the requested information is "in the public interest because it is likely to contribute significantly to public understanding of operations or activities of the government." The public has a significant interest in the federal government's support of research that could help combat the current coronavirus outbreak and prevent similar outbreaks in the future. Records with the potential to shed light on this matter would contribute significantly to public understanding of operations of the federal government, including whether and to what extent research funding has become politicized. American Oversight is committed to transparency and makes the responses agencies provide to FOIA requests publicly available, and the public's understanding of the government's activities would be enhanced through American Oversight's analysis and publication of these records.

This request is primarily and fundamentally for non-commercial purposes. As a 501(c)(3) nonprofit, American Oversight does not have a commercial purpose and the release of the information requested is not in American Oversight's financial interest. American Oversight's mission is to promote transparency in government, to educate the public about government activities, and to ensure the accountability of government officials. American Oversight uses the information gathered, and its analysis of it, to educate the public through reports, press releases, or other media. American Oversight also makes materials it gathers available on its public website and promotes their availability on social media platforms, such as Facebook and Twitter.

⁶ 5 U.S.C. § 552(a)(4)(A)(iii).

⁷ See Media Advisory, supra note 4.

⁸ See Science, supra note 5.

⁹ See 5 U.S.C. § 552(a) (4) (A) (iii).

 $^{^{10}}$ American Oversight currently has approximately 15,600 page likes on Facebook and 104,000 followers on Twitter. American Oversight, FACEBOOK,

https://www.facebook.com/weareoversight/ (last visited June 25, 2020); American

American Oversight has also demonstrated its commitment to the public disclosure of documents and creation of editorial content through numerous substantive analyses posted to its website.¹¹ Examples reflecting this commitment to the public disclosure of documents and the creation of editorial content include the posting of records related to an ethics waiver received by a senior Department of Justice attorney and an analysis of what those records demonstrated regarding the Department's process for issuing such waivers;12 posting records received as part of American Oversight's "Audit the Wall" project to gather and analyze information related to the administration's proposed construction of a barrier along the U.S.-Mexico border, and analyses of what those records reveal;¹³ posting records regarding potential self-dealing at the Department of Housing & Urban Development and related analysis; 14 posting records and analysis relating to the federal government's efforts to sell nuclear technology to Saudi Arabia;15 and posting records and analysis regarding the Department of Justice's decision in response to demands from Congress to direct a U.S. Attorney to undertake a wide-ranging review and make recommendations regarding criminal investigations relating to the President's political opponents and allegations of misconduct by the Department of Justice itself and the Federal Bureau of Investigation.16

Accordingly, American Oversight qualifies for a fee waiver.

-

Oversight (@weareoversight), TWITTER, https://twitter.com/weareoversight (last visited June 25, 2020).

¹¹ News, AMERICAN OVERSIGHT, https://www.americanoversight.org/blog.

¹² DOJ Records Relating to Solicitor General Noel Francisco's Recusal, AMERICAN OVERSIGHT, https://www.americanoversight.org/document/doj-civil-division-response-noel-francisco-compliance; Francisco & the Travel Ban: What We Learned from the DOJ Documents, AMERICAN OVERSIGHT, https://www.americanoversight.org/francisco-the-travel-ban-what-welearned-from-the-doj-documents.

¹³ See generally Audit the Wall, AMERICAN OVERSIGHT, https://www.americanoversight.org/investigation/audit-the-wall; see, e.g., Border Wall Investigation Report: No Plans, No Funding, No Timeline, No Wall, AMERICAN OVERSIGHT, https://www.americanoversight.org/border-wall-investigation-report-no-plans-no-funding-no-timeline-no-wall.

¹⁴ Documents Reveal Ben Carson Jr.'s Attempts to Use His Influence at HUD to Help His Business, AMERICAN OVERSIGHT, https://www.americanoversight.org/documents-reveal-ben-carson-jr-s-attempts-to-use-his-influence-at-hud-to-help-his-business.

¹⁵ Investigating the Trump Administration's Efforts to Sell Nuclear Technology to Saudi Arabia, AMERICAN OVERSIGHT, https://www.americanoversight.org/investigating-the-trump-administrations-efforts-to-sell-nuclear-technology-to-saudi-arabia.

¹⁶ Sessions' Letter Shows DOJ Acted on Trump's Authoritarian Demand to Investigate Clinton, AMERICAN OVERSIGHT, https://www.americanoversight.org/sessions-letter.

Guidance Regarding the Search & Processing of Requested Records

In connection with its request for records, American Oversight provides the following guidance regarding the scope of the records sought and the search and processing of records:

- Please search all locations and systems likely to have responsive records, regardless of format, medium, or physical characteristics.
- Our request for records includes any attachments to those records or other
 materials enclosed with those records when they were previously transmitted. To
 the extent that an email is responsive to our request, our request includes all prior
 messages sent or received in that email chain, as well as any attachments to the
 email.
- Please search all relevant records or systems containing records regarding agency business. Do not exclude records regarding agency business contained in files, email accounts, or devices in the personal custody of your officials, such as personal email accounts or text messages. Records of official business conducted using unofficial systems or stored outside of official files are subject to the Federal Records Act and FOIA.¹⁷ It is not adequate to rely on policies and procedures that require officials to move such information to official systems within a certain period of time; American Oversight has a right to records contained in those files even if material has not yet been moved to official systems or if officials have, by intent or through negligence, failed to meet their obligations.¹⁸
- Please use all tools available to your agency to conduct a complete and efficient search for potentially responsive records. Agencies are subject to government-wide requirements to manage agency information electronically, 19 and many agencies have adopted the National Archives and Records Administration (NARA) Capstone program, or similar policies. These systems provide options for searching emails and other electronic records in a manner that is reasonably likely to be more complete than just searching individual custodian files. For example, a

See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, 827 F.3d 145, 149–50
 (D.C. Cir. 2016); cf. Judicial Watch, Inc. v. Kerry, 844 F.3d 952, 955–56 (D.C. Cir. 2016).

¹⁸ See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).

¹⁹ Presidential Memorandum—Managing Government Records, 76 Fed. Reg. 75,423 (Nov. 28, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/11/28/presidential-memorandum-managing-government-records; Office of Mgmt. & Budget, Exec. Office of the President, Memorandum for the Heads of Executive Departments & Independent Agencies, "Managing Government Records Directive," M-12-18 (Aug. 24, 2012), https://www.archives.gov/files/records-mgmt/m-12-18.pdf.

custodian may have deleted a responsive email from his or her email program, but your agency's archiving tools may capture that email under Capstone. At the same time, custodian searches are still necessary; agencies may not have direct access to files stored in .PST files, outside of network drives, in paper format, or in personal email accounts.

- In the event some portions of the requested records are properly exempt from
 disclosure, please disclose any reasonably segregable non-exempt portions of the
 requested records. If a request is denied in whole, please state specifically why it is
 not reasonable to segregate portions of the record for release.
- Please take appropriate steps to ensure that records responsive to this request are not deleted by the agency before the completion of processing for this request. If records potentially responsive to this request are likely to be located on systems where they are subject to potential deletion, including on a scheduled basis, please take steps to prevent that deletion, including, as appropriate, by instituting a litigation hold on those records.

Conclusion

If you have any questions regarding how to construe this request for records or believe that further discussions regarding search and processing would facilitate a more efficient production of records of interest to American Oversight, please do not hesitate to contact American Oversight to discuss this request. American Oversight welcomes an opportunity to discuss its request with you before you undertake your search or incur search or duplication costs. By working together at the outset, American Oversight and your agency can decrease the likelihood of costly and time-consuming litigation in the future.

Where possible, please provide responsive material in an electronic format by email. Alternatively, please provide responsive material in native format or in PDF format on a USB drive. Please send any responsive material being sent by mail to American Oversight, 1030 15th Street NW, Suite B255, Washington, DC 20005. If it will accelerate release of responsive records to American Oversight, please also provide responsive material on a rolling basis.

We share a common mission to promote transparency in government. American Oversight looks forward to working with your agency on this request. If you do not understand any part of this request, please contact Christine H. Monahan at foia@americanoversight.org

or 202-869-5244. Also, if American Oversight's request for a fee waiver is not granted in full, please contact us immediately upon making such a determination.



From: FOIA [foia@americanoversight.org]

Sent: 7/2/2020 4:33:38 PM

To: FOIA-7 [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=fb7dd35bf17146a5bd0bfe8a9c62c6af-FOIA-7]; OS FOIA Request (HHS/ASPA)

[FOIARequest@hhs.gov]

Subject: FOIA Request (HHS-20-1663)

Attachments: HHS-20-1663.pdf

Dear FOIA Officer:

Please find attached a request for records under the Freedom of Information Act.

Sincerely,

Vibha Kannan
Paralegal
American Oversight
foia@americanoversight.org
www.americanoversight.org | @weareoversight

FOIA: HHS-20-1663



July 2, 2020

VIA EMAIL/ ONLINE PORTAL

Gorka Garcia-Malene NIH FOIA Office Building 31 Room 5B35 31 Center Drive, MSC 2107 Bethesda, MD 20892 https://foiaportal.nih.gov/

Robert Schofield National Institute of Allergy and Infectious Diseases Room 6G51 5601 Fishers Lane Rockville, MD 20857 foia@niaid.nih.gov

Brandon Gaylord
Freedom of Information Officer
Department of Health and Human Services
Hubert H. Humphrey Building
Room 729H
200 Independence Avenue SW
Washington, DC 20201
FOIARequest@hhs.gov

Re: Freedom of Information Act Request

Dear FOIA officer:

Pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and the implementing regulations of your agency, 45 C.F.R. Part 5, American Oversight makes the following request for records.

In late April, the National Institute of Health (NIH) cancelled a grant previously awarded to EcoHealth Alliance, purportedly on the grounds that "NIH does not believe the current project outcomes align with the program goals and agency priorities." This action, apparently at the direction of the White House, came after news reports suggested that

¹ Sarah Owermohle, *Trump Cuts U.S. Research on Bat-Human Virus Transmission over China Ties*, Politico (Apr. 27, 2020, 7:02 PM), https://www.politico.com/news/2020/04/27/trump-cuts-research-bat-human-virus-china-213076.



the group was funding the Wuhan Institute of Virology.² Prior to the funding cancellation, however, the president of EcoHealth Alliance had confirmed to NIH that none of its current funding had been sent to the Institute, that it had not entered into a contract with the Institute, and that it would comply with any federal requirements.³ The EcoHealth Alliance's focus—studying coronaviruses in bats—is also consistent with the NIH's strategic plan for studying novel coronaviruses.⁴ Leading scientists and scientific societies have since asked for NIH to review its decision to cut funding, expressing concern about the politicization of science.⁵

American Oversight seeks records that may shed light on the cancellation of the EcoHealth Alliance's grant.

Requested Records

American Oversight requests that your agency produce the following records within twenty business days:

Any directive or guidance from the White House (including coronavirus task force, led by Vice President Pence, or any other senior White House officials) to terminate funding for the EcoHealth Alliance, and/or any NIH grantee that, in the past or present, had a financial relationship with the Wuhan Institute of Virology.

Please search for responsive records from April 10, 2020, through April 30, 2020.

Given that this request seeks a specific, recent, readily identifiable document, American Oversight expects that this request can be processes on the Simple processing track in a prompt manner.

https://www.politico.com/news/2020/06/23/fauci-nih-white-house-bat-study-336452.

² David Lim & Brianna Ehley, Fauci Says White House Told NIH to Cancel Funding for Bat Virus Study, Politico (July 23, 2020, 5:41 PM),

³ Partial Transcript of Email Exchanges in Which NIH Cuts off Grant Funding to EcoHealth Alliance, Science,

https://www.sciencemag.org/sites/default/files/Lauer.Daszak.NIH%20grant%20killed.partial%20email%20transcripts.April%202020.pdf.

⁴ Owermohle, *supra* note 1; *see* Media Advisory, NIH, NIAID Strategic Plan Details COVID-19 Research Priorities, Apr. 23, 2020, https://www.nih.gov/news-events/news-releases/niaid-strategic-plan-details-covid-19-research-priorities.

⁵ Nobel Laureates and Science Groups Demand NIH Review Decision to Kill Coronavirus Grant, Science (May 21, 2020, 6:40 PM),

https://www.sciencemag.org/news/2020/05/preposterous-77-nobel-laureates-blast-nih-decision-cancel-coronavirus-grant-demand.

Fee Waiver Request

In accordance with 5 U.S.C. § 552(a)(4)(A)(iii) and your agency's regulations, American Oversight requests a waiver of fees associated with processing this request for records. The subject of this request concerns the operations of the federal government, and the disclosures will likely contribute to a better understanding of relevant government procedures by the general public in a significant way. Moreover, the request is primarily and fundamentally for non-commercial purposes.

American Oversight requests a waiver of fees because disclosure of the requested information is "in the public interest because it is likely to contribute significantly to public understanding of operations or activities of the government." The public has a significant interest in the federal government's support of research that could help combat the current coronavirus outbreak and prevent similar outbreaks in the future. Records with the potential to shed light on this matter would contribute significantly to public understanding of operations of the federal government, including whether and to what extent research funding has become politicized. American Oversight is committed to transparency and makes the responses agencies provide to FOIA requests publicly available, and the public's understanding of the government's activities would be enhanced through American Oversight's analysis and publication of these records.

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⁶ 5 U.S.C. § 552(a) (4) (A) (iii).

⁷ See Media Advisory, supra note 4.

⁸ See Science, supra note 5.

⁹ See 5 U.S.C. § 552(a) (4) (A) (iii).

¹⁰ American Oversight currently has approximately 15,600 page likes on Facebook and 104,000 followers on Twitter. American Oversight, FACEBOOK, https://www.facebook.com/weareoversight/ (last visited June 25, 2020); American Oversight (@weareoversight), TWITTER, https://twitter.com/weareoversight (last visited June 25, 2020).

¹¹ News, AMERICAN OVERSIGHT, https://www.americanoversight.org/blog.

documents and the creation of editorial content include the posting of records related to an ethics waiver received by a senior Department of Justice attorney and an analysis of what those records demonstrated regarding the Department's process for issuing such waivers; ¹² posting records received as part of American Oversight's "Audit the Wall" project to gather and analyze information related to the administration's proposed construction of a barrier along the U.S.-Mexico border, and analyses of what those records reveal; ¹³ posting records regarding potential self-dealing at the Department of Housing & Urban Development and related analysis; ¹⁴ posting records and analysis relating to the federal government's efforts to sell nuclear technology to Saudi Arabia; ¹⁵ and posting records and analysis regarding the Department of Justice's decision in response to demands from Congress to direct a U.S. Attorney to undertake a wide-ranging review and make recommendations regarding criminal investigations relating to the President's political opponents and allegations of misconduct by the Department of Justice itself and the Federal Bureau of Investigation. ¹⁶

Accordingly, American Oversight qualifies for a fee waiver.

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¹² DOJ Records Relating to Solicitor General Noel Francisco's Recusal, AMERICAN OVERSIGHT, https://www.americanoversight.org/document/doj-civil-division-response-noel-francisco-compliance; Francisco & the Travel Ban: What We Learned from the DOJ Documents, AMERICAN OVERSIGHT, https://www.americanoversight.org/francisco-the-travel-ban-what-we-learned-from-the-doj-documents.

¹³ See generally Audit the Wall, AMERICAN OVERSIGHT, https://www.americanoversight.org/investigation/audit-the-wall; see, e.g., Border Wall Investigation Report: No Plans, No Funding, No Timeline, No Wall, AMERICAN OVERSIGHT, https://www.americanoversight.org/border-wall-investigation-report-no-plans-no-funding-no-timeline-no-wall.

¹⁴ Documents Reveal Ben Carson Jr.'s Attempts to Use His Influence at HUD to Help His Business, AMERICAN OVERSIGHT, https://www.americanoversight.org/documents-reveal-ben-carson-jr-s-attempts-to-use-his-influence-at-hud-to-help-his-business.

¹⁵ Investigating the Trump Administration's Efforts to Sell Nuclear Technology to Saudi Arabia, American Oversight, https://www.americanoversight.org/investigating-the-trump-administrations-efforts-to-sell-nuclear-technology-to-saudi-arabia.

¹⁶ Sessions' Letter Shows DOJ Acted on Trump's Authoritarian Demand to Investigate Clinton, AMERICAN OVERSIGHT, https://www.americanoversight.org/sessions-letter.

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 materials enclosed with those records when they were previously transmitted. To
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- Please search all relevant records or systems containing records regarding agency business. Do not exclude records regarding agency business contained in files, email accounts, or devices in the personal custody of your officials, such as personal email accounts or text messages. Records of official business conducted using unofficial systems or stored outside of official files are subject to the Federal Records Act and FOIA.¹⁷ It is not adequate to rely on policies and procedures that require officials to move such information to official systems within a certain period of time; American Oversight has a right to records contained in those files even if material has not yet been moved to official systems or if officials have, by intent or through negligence, failed to meet their obligations.¹⁸
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- In the event some portions of the requested records are properly exempt from disclosure, please disclose any reasonably segregable non-exempt portions of the

¹⁷ See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, 827 F.3d 145, 149–50 (D.C. Cir. 2016); cf. Judicial Watch, Inc. v. Kerry, 844 F.3d 952, 955–56 (D.C. Cir. 2016).

¹⁸ See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).

¹⁹ Presidential Memorandum—Managing Government Records, 76 Fed. Reg. 75,423 (Nov. 28, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/11/28/presidential-memorandum-managing-government-records; Office of Mgmt. & Budget, Exec. Office of the President, Memorandum for the Heads of Executive Departments & Independent Agencies, "Managing Government Records Directive," M-12-18 (Aug. 24, 2012), https://www.archives.gov/files/records-mgmt/m-12-18.pdf.

- requested records. If a request is denied in whole, please state specifically why it is not reasonable to segregate portions of the record for release.
- Please take appropriate steps to ensure that records responsive to this request are not deleted by the agency before the completion of processing for this request. If records potentially responsive to this request are likely to be located on systems where they are subject to potential deletion, including on a scheduled basis, please take steps to prevent that deletion, including, as appropriate, by instituting a litigation hold on those records.

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Where possible, please provide responsive material in an electronic format by email. Alternatively, please provide responsive material in native format or in PDF format on a USB drive. Please send any responsive material being sent by mail to American Oversight, 1030 15th Street NW, Suite B255, Washington, DC 20005. If it will accelerate release of responsive records to American Oversight, please also provide responsive material on a rolling basis.

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Sent: 7/2/2020 4:30:31 PM

To: FOIA-7 [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=fb7dd35bf17146a5bd0bfe8a9c62c6af-FOIA-7]; OS FOIA Request (HHS/ASPA)

[FOIARequest@hhs.gov]

Subject: FOIA Request (HHS-20-1661)

Attachments: HHS-20-1661.pdf

Dear FOIA Officer:

Please find attached a request for records under the Freedom of Information Act.

Sincerely,

Vibha Kannan
Paralegal
American Oversight
foia@americanoversight.org
www.americanoversight.org | @weareoversight

FOIA: HHS-20-1661



July 2, 2020

VIA EMAIL/ ONLINE PORTAL

Gorka Garcia-Malene NIH FOIA Office Building 31 Room 5B35 31 Center Drive, MSC 2107 Bethesda, MD 20892 https://foiaportal.nih.gov/

Robert Schofield National Institute of Allergy and Infectious Diseases Room 6G51 5601 Fishers Lane Rockville, MD 20857 foia@niaid.nih.gov

Brandon Gaylord
Freedom of Information Officer
Department of Health and Human Services
Hubert H. Humphrey Building
Room 729H
200 Independence Avenue SW
Washington, DC 20201
FOIARequest@hhs.gov

Re: Freedom of Information Act Request

Dear FOIA officer:

Pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and the implementing regulations of your agency, 45 C.F.R. Part 5, American Oversight makes the following request for records.

In late April, the National Institute of Health (NIH) cancelled a grant previously awarded to EcoHealth Alliance, purportedly on the grounds that "NIH does not believe the current project outcomes align with the program goals and agency priorities." This action, apparently at the direction of the White House, came after news reports suggested that

¹ Sarah Owermohle, *Trump Cuts U.S. Research on Bat-Human Virus Transmission over China Ties*, Politico (Apr. 27, 2020, 7:02 PM), https://www.politico.com/news/2020/04/27/trump-cuts-research-bat-human-virus-china-213076.



the group was funding the Wuhan Institute of Virology.² Prior to the funding cancellation, however, the president of EcoHealth Alliance had confirmed to NIH that none of its current funding had been sent to the Institute, that it had not entered into a contract with the Institute, and that it would comply with any federal requirements.³ The EcoHealth Alliance's focus—studying coronaviruses in bats—is also consistent with the NIH's strategic plan for studying novel coronaviruses.⁴ Leading scientists and scientific societies have since asked for NIH to review its decision to cut funding, expressing concern about the politicization of science.⁵

American Oversight seeks records that may shed light on the cancellation of the EcoHealth Alliance's grant.

Requested Records

American Oversight requests that your agency produce the following records within twenty business days:

The final decision memoranda or other records memorializing the basis, justification, or rationale for terminating the EcoHealth Alliance project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AII 10964.

Please search for responsive records from April 10, 2020, through April 30, 2020.

Given that this request seeks a specific, recent, readily identifiable document, American Oversight expects that this request can be processes on the Simple processing track in a prompt manner.

https://www.politico.com/news/2020/06/23/fauci-nih-white-house-bat-study-336452.

² David Lim & Brianna Ehley, Fauci Says White House Told NIH to Cancel Funding for Bat Virus Study, Politico (July 23, 2020, 5:41 PM),

³ Partial Transcript of Email Exchanges in Which NIH Cuts off Grant Funding to EcoHealth Alliance, Science,

https://www.sciencemag.org/sites/default/files/Lauer.Daszak.NIH%20grant%20killed.partial%20email%20transcripts.April%202020.pdf.

⁴ Owermohle, *supra* note 1; *see* Media Advisory, NIH, NIAID Strategic Plan Details COVID-19 Research Priorities, Apr. 23, 2020, https://www.nih.gov/news-events/news-releases/niaid-strategic-plan-details-covid-19-research-priorities.

⁵ Nobel Laureates and Science Groups Demand NIH Review Decision to Kill Coronavirus Grant, Science (May 21, 2020, 6:40 PM),

https://www.sciencemag.org/news/2020/05/preposterous-77-nobel-laureates-blast-nih-decision-cancel-coronavirus-grant-demand.

Fee Waiver Request

In accordance with 5 U.S.C. § 552(a) (4) (A) (iii) and your agency's regulations, American Oversight requests a waiver of fees associated with processing this request for records. The subject of this request concerns the operations of the federal government, and the disclosures will likely contribute to a better understanding of relevant government procedures by the general public in a significant way. Moreover, the request is primarily and fundamentally for non-commercial purposes.

American Oversight requests a waiver of fees because disclosure of the requested information is "in the public interest because it is likely to contribute significantly to public understanding of operations or activities of the government." The public has a significant interest in the federal government's support of research that could help combat the current coronavirus outbreak and prevent similar outbreaks in the future. Records with the potential to shed light on this matter would contribute significantly to public understanding of operations of the federal government, including whether and to what extent research funding has become politicized. American Oversight is committed to transparency and makes the responses agencies provide to FOIA requests publicly available, and the public's understanding of the government's activities would be enhanced through American Oversight's analysis and publication of these records.

This request is primarily and fundamentally for non-commercial purposes. As a 501(c)(3) nonprofit, American Oversight does not have a commercial purpose and the release of the information requested is not in American Oversight's financial interest. American Oversight's mission is to promote transparency in government, to educate the public about government activities, and to ensure the accountability of government officials. American Oversight uses the information gathered, and its analysis of it, to educate the public through reports, press releases, or other media. American Oversight also makes materials it gathers available on its public website and promotes their availability on social media platforms, such as Facebook and Twitter. Oversight and Twitter.

American Oversight has also demonstrated its commitment to the public disclosure of documents and creation of editorial content through numerous substantive analyses posted to its website. ¹¹ Examples reflecting this commitment to the public disclosure of

⁶ 5 U.S.C. § 552(a) (4) (A) (iii).

⁷ See Media Advisory, supra note 4.

⁸ See Science, supra note 5.

⁹ See 5 U.S.C. § 552(a) (4) (A) (iii).

¹⁰ American Oversight currently has approximately 15,600 page likes on Facebook and 104,000 followers on Twitter. American Oversight, FACEBOOK, https://www.facebook.com/weareoversight/ (last visited June 25, 2020); American Oversight (@weareoversight), TWITTER, https://twitter.com/weareoversight (last visited June 25, 2020).

¹¹ News, AMERICAN OVERSIGHT, https://www.americanoversight.org/blog.

documents and the creation of editorial content include the posting of records related to an ethics waiver received by a senior Department of Justice attorney and an analysis of what those records demonstrated regarding the Department's process for issuing such waivers; ¹² posting records received as part of American Oversight's "Audit the Wall" project to gather and analyze information related to the administration's proposed construction of a barrier along the U.S.-Mexico border, and analyses of what those records reveal; ¹³ posting records regarding potential self-dealing at the Department of Housing & Urban Development and related analysis; ¹⁴ posting records and analysis relating to the federal government's efforts to sell nuclear technology to Saudi Arabia; ¹⁵ and posting records and analysis regarding the Department of Justice's decision in response to demands from Congress to direct a U.S. Attorney to undertake a wide-ranging review and make recommendations regarding criminal investigations relating to the President's political opponents and allegations of misconduct by the Department of Justice itself and the Federal Bureau of Investigation. ¹⁶

Accordingly, American Oversight qualifies for a fee waiver.

Guidance Regarding the Search & Processing of Requested Records

In connection with its request for records, American Oversight provides the following guidance regarding the scope of the records sought and the search and processing of records:

 Please search all locations and systems likely to have responsive records, regardless of format, medium, or physical characteristics.

¹² DOJ Records Relating to Solicitor General Noel Francisco's Recusal, AMERICAN OVERSIGHT, https://www.americanoversight.org/document/doj-civil-division-response-noel-francisco-compliance; Francisco & the Travel Ban: What We Learned from the DOJ Documents, AMERICAN OVERSIGHT, https://www.americanoversight.org/francisco-the-travel-ban-what-we-learned-from-the-doj-documents.

¹³ See generally Audit the Wall, AMERICAN OVERSIGHT, https://www.americanoversight.org/investigation/audit-the-wall; see, e.g., Border Wall Investigation Report: No Plans, No Funding, No Timeline, No Wall, AMERICAN OVERSIGHT, https://www.americanoversight.org/border-wall-investigation-report-no-plans-no-funding-no-timeline-no-wall.

¹⁴ Documents Reveal Ben Carson Jr.'s Attempts to Use His Influence at HUD to Help His Business, AMERICAN OVERSIGHT, https://www.americanoversight.org/documents-reveal-ben-carson-ir-s-attempts-to-use-his-influence-at-hud-to-help-his-business.

¹⁵ Investigating the Trump Administration's Efforts to Sell Nuclear Technology to Saudi Arabia, American Oversight, https://www.americanoversight.org/investigating-the-trump-administrations-efforts-to-sell-nuclear-technology-to-saudi-arabia.

¹⁶ Sessions' Letter Shows DOJ Acted on Trump's Authoritarian Demand to Investigate Clinton, AMERICAN OVERSIGHT, https://www.americanoversight.org/sessions-letter.

- Our request for records includes any attachments to those records or other
 materials enclosed with those records when they were previously transmitted. To
 the extent that an email is responsive to our request, our request includes all prior
 messages sent or received in that email chain, as well as any attachments to the
 email.
- Please search all relevant records or systems containing records regarding agency business. Do not exclude records regarding agency business contained in files, email accounts, or devices in the personal custody of your officials, such as personal email accounts or text messages. Records of official business conducted using unofficial systems or stored outside of official files are subject to the Federal Records Act and FOIA.¹⁷ It is not adequate to rely on policies and procedures that require officials to move such information to official systems within a certain period of time; American Oversight has a right to records contained in those files even if material has not yet been moved to official systems or if officials have, by intent or through negligence, failed to meet their obligations.¹⁸
- Please use all tools available to your agency to conduct a complete and efficient search for potentially responsive records. Agencies are subject to government-wide requirements to manage agency information electronically, 19 and many agencies have adopted the National Archives and Records Administration (NARA) Capstone program, or similar policies. These systems provide options for searching emails and other electronic records in a manner that is reasonably likely to be more complete than just searching individual custodian files. For example, a custodian may have deleted a responsive email from his or her email program, but your agency's archiving tools may capture that email under Capstone. At the same time, custodian searches are still necessary; agencies may not have direct access to files stored in .PST files, outside of network drives, in paper format, or in personal email accounts.
- In the event some portions of the requested records are properly exempt from disclosure, please disclose any reasonably segregable non-exempt portions of the

¹⁷ See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, 827 F.3d 145, 149–50 (D.C. Cir. 2016); cf. Judicial Watch, Inc. v. Kerry, 844 F.3d 952, 955–56 (D.C. Cir. 2016).

¹⁸ See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).

¹⁹ Presidential Memorandum—Managing Government Records, 76 Fed. Reg. 75,423 (Nov. 28, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/11/28/presidential-memorandum-managing-government-records; Office of Mgmt. & Budget, Exec. Office of the President, Memorandum for the Heads of Executive Departments & Independent Agencies, "Managing Government Records Directive," M-12-18 (Aug. 24, 2012), https://www.archives.gov/files/records-mgmt/m-12-18.pdf.

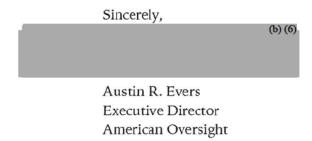
- requested records. If a request is denied in whole, please state specifically why it is not reasonable to segregate portions of the record for release.
- Please take appropriate steps to ensure that records responsive to this request are not deleted by the agency before the completion of processing for this request. If records potentially responsive to this request are likely to be located on systems where they are subject to potential deletion, including on a scheduled basis, please take steps to prevent that deletion, including, as appropriate, by instituting a litigation hold on those records.

Conclusion

If you have any questions regarding how to construe this request for records or believe that further discussions regarding search and processing would facilitate a more efficient production of records of interest to American Oversight, please do not hesitate to contact American Oversight to discuss this request. American Oversight welcomes an opportunity to discuss its request with you before you undertake your search or incur search or duplication costs. By working together at the outset, American Oversight and your agency can decrease the likelihood of costly and time-consuming litigation in the future.

Where possible, please provide responsive material in an electronic format by email. Alternatively, please provide responsive material in native format or in PDF format on a USB drive. Please send any responsive material being sent by mail to American Oversight, 1030 15th Street NW, Suite B255, Washington, DC 20005. If it will accelerate release of responsive records to American Oversight, please also provide responsive material on a rolling basis.

We share a common mission to promote transparency in government. American Oversight looks forward to working with your agency on this request. If you do not understand any part of this request, please contact Christine H. Monahan at foia@americanoversight.org or 202-869-5244. Also, if American Oversight's request for a fee waiver is not granted in full, please contact us immediately upon making such a determination.



From: FOIA [foia@americanoversight.org]

Sent: 7/2/2020 4:31:57 PM

To: FOIA-7 [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=fb7dd35bf17146a5bd0bfe8a9c62c6af-FOIA-7]; OS FOIA Request (HHS/ASPA)

[FOIARequest@hhs.gov]

Subject: FOIA Request (HHS-20-1662)

Attachments: HHS-20-1662.pdf

Dear FOIA Officer:

Please find attached a request for records under the Freedom of Information Act.

Sincerely,

Vibha Kannan
Paralegal
American Oversight
foia@americanoversight.org
www.americanoversight.org | @weareoversight

FOIA: HHS-20-1662



July 2, 2020

VIA EMAIL/ ONLINE PORTAL

Gorka Garcia-Malene NIH FOIA Office Building 31 Room 5B35 31 Center Drive, MSC 2107 Bethesda, MD 20892 https://foiaportal.nih.gov/

Robert Schofield National Institute of Allergy and Infectious Diseases Room 6G51 5601 Fishers Lane Rockville, MD 20857 foia@niaid.nih.gov

Brandon Gaylord
Freedom of Information Officer
Department of Health and Human Services
Hubert H. Humphrey Building
Room 729H
200 Independence Avenue SW
Washington, DC 20201
FOIARequest@hhs.gov

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Dear FOIA officer:

Pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and the implementing regulations of your agency, 45 C.F.R. Part 5, American Oversight makes the following request for records.

In late April, the National Institute of Health (NIH) cancelled a grant previously awarded to EcoHealth Alliance, purportedly on the grounds that "NIH does not believe the current project outcomes align with the program goals and agency priorities." This action, apparently at the direction of the White House, came after news reports suggested that

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the group was funding the Wuhan Institute of Virology.² Prior to the funding cancellation, however, the president of EcoHealth Alliance had confirmed to NIH that none of its current funding had been sent to the Institute, that it had not entered into a contract with the Institute, and that it would comply with any federal requirements.³ The EcoHealth Alliance's focus—studying coronaviruses in bats—is also consistent with the NIH's strategic plan for studying novel coronaviruses.⁴ Leading scientists and scientific societies have since asked for NIH to review its decision to cut funding, expressing concern about the politicization of science.⁵

American Oversight seeks records that may shed light on the cancellation of the EcoHealth Alliance's grant.

Requested Records

American Oversight requests that your agency produce the following records within twenty business days:

Any final assessments or analyses (including formal memoranda, final talking points and associated background materials, or other written products) regarding the implications of terminating the EcoHealth Alliance project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AI110964, including but not limited to implications on research into the natural history of the novel coronavirus SARS-CoV-2 and the development of vaccines and treatments for the virus and the disease it causes, COVID-19.

American Oversight believes that your agencies are best positioned to determine where responsive records may reside. However, at a minimum, we believe a search for responsive records should include the following:

² David Lim & Brianna Ehley, Fauci Says White House Told NIH to Cancel Funding for Bat Virus Study, Politico (July 23, 2020, 5:41 PM),

https://www.politico.com/news/2020/06/23/fauci-nih-white-house-bat-study-336452.

³ Partial Transcript of Email Exchanges in Which NIH Cuts off Grant Funding to EcoHealth Alliance, Science.

https://www.sciencemag.org/sites/default/files/Lauer.Daszak.NIH%20grant%20killed.partial%20email%20transcripts.April%202020.pdf.

⁴ Owermohle, *supra* note 1; *see* Media Advisory, NIH, NIAID Strategic Plan Details COVID-19 Research Priorities, Apr. 23, 2020, https://www.nih.gov/news-events/news-releases/niaid-strategic-plan-details-covid-19-research-priorities.

⁵ Nobel Laureates and Science Groups Demand NIH Review Decision to Kill Coronavirus Grant, Science (May 21, 2020, 6:40 PM),

https://www.sciencemag.org/news/2020/05/preposterous-77-nobel-laureates-blast-nih-decision-cancel-coronavirus-grant-demand.

- Within HHS, the immediate offices of the Secretary and the Assistant Secretary for Preparedness and Response, and the headquarters staff of the Office of Intergovernmental and External Affairs (IEA).
- Within NIH, the immediate office of the Director, and the Office of Extramural Research (including but not limited to the files of Deputy Director Michael Lauer).
- Within the National Institute of Allergy and Infectious Diseases (NIAID), the immediate office of the Director, and the Division of Extramural Activities.

Please provide all responsive records from April 10, 2020, through the date the search is conducted.

Fee Waiver Request

In accordance with 5 U.S.C. § 552(a)(4)(A)(iii) and your agency's regulations, American Oversight requests a waiver of fees associated with processing this request for records. The subject of this request concerns the operations of the federal government, and the disclosures will likely contribute to a better understanding of relevant government procedures by the general public in a significant way. Moreover, the request is primarily and fundamentally for non-commercial purposes.

American Oversight requests a waiver of fees because disclosure of the requested information is "in the public interest because it is likely to contribute significantly to public understanding of operations or activities of the government." The public has a significant interest in the federal government's support of research that could help combat the current coronavirus outbreak and prevent similar outbreaks in the future. Records with the potential to shed light on this matter would contribute significantly to public understanding of operations of the federal government, including whether and to what extent research funding has become politicized. American Oversight is committed to transparency and makes the responses agencies provide to FOIA requests publicly available, and the public's understanding of the government's activities would be enhanced through American Oversight's analysis and publication of these records.

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⁶ 5 U.S.C. § 552(a)(4)(A)(iii).

⁷ See Media Advisory, supra note 4.

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public through reports, press releases, or other media. American Oversight also makes materials it gathers available on its public website and promotes their availability on social media platforms, such as Facebook and Twitter. 10

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¹¹ News, AMERICAN OVERSIGHT, https://www.americanoversight.org/blog.

¹² DOJ Records Relating to Solicitor General Noel Francisco's Recusal, AMERICAN OVERSIGHT, https://www.americanoversight.org/document/doj-civil-division-response-noel-francisco-compliance; Francisco & the Travel Ban: What We Learned from the DOJ Documents, AMERICAN OVERSIGHT, https://www.americanoversight.org/francisco-the-travel-ban-what-we-learned-from-the-doj-documents.

¹³ See generally Audit the Wall, AMERICAN OVERSIGHT, https://www.americanoversight.org/investigation/audit-the-wall; see, e.g., Border Wall Investigation Report: No Plans, No Funding, No Timeline, No Wall, AMERICAN OVERSIGHT, https://www.americanoversight.org/border-wall-investigation-report-no-plans-no-funding-no-timeline-no-wall.

¹⁴ Documents Reveal Ben Carson Jr.'s Attempts to Use His Influence at HUD to Help His Business, AMERICAN OVERSIGHT, https://www.americanoversight.org/documents-reveal-ben-carson-jr-s-attempts-to-use-his-influence-at-hud-to-help-his-business.

¹⁵ Investigating the Trump Administration's Efforts to Sell Nuclear Technology to Saudi Arabia, AMERICAN OVERSIGHT, https://www.americanoversight.org/investigating-the-trump-administrations-efforts-to-sell-nuclear-technology-to-saudi-arabia.

political opponents and allegations of misconduct by the Department of Justice itself and the Federal Bureau of Investigation.¹⁶

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In connection with its request for records, American Oversight provides the following guidance regarding the scope of the records sought and the search and processing of records:

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 materials enclosed with those records when they were previously transmitted. To
 the extent that an email is responsive to our request, our request includes all prior
 messages sent or received in that email chain, as well as any attachments to the
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- Please search all relevant records or systems containing records regarding agency business. Do not exclude records regarding agency business contained in files, email accounts, or devices in the personal custody of your officials, such as personal email accounts or text messages. Records of official business conducted using unofficial systems or stored outside of official files are subject to the Federal Records Act and FOIA.¹⁷ It is not adequate to rely on policies and procedures that require officials to move such information to official systems within a certain period of time; American Oversight has a right to records contained in those files even if material has not yet been moved to official systems or if officials have, by intent or through negligence, failed to meet their obligations.¹⁸
- Please use all tools available to your agency to conduct a complete and efficient search for potentially responsive records. Agencies are subject to government-wide requirements to manage agency information electronically,¹⁹ and many agencies

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See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, 827 F.3d 145, 149–50
 (D.C. Cir. 2016); cf. Judicial Watch, Inc. v. Kerry, 844 F.3d 952, 955–56 (D.C. Cir. 2016).

¹⁸ See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).

¹⁹ Presidential Memorandum—Managing Government Records, 76 Fed. Reg. 75,423 (Nov. 28, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/11/28/presidential-memorandum-managing-government-records; Office of Mgmt. & Budget, Exec. Office of the President, Memorandum for the Heads of Executive

have adopted the National Archives and Records Administration (NARA) Capstone program, or similar policies. These systems provide options for searching emails and other electronic records in a manner that is reasonably likely to be more complete than just searching individual custodian files. For example, a custodian may have deleted a responsive email from his or her email program, but your agency's archiving tools may capture that email under Capstone. At the same time, custodian searches are still necessary; agencies may not have direct access to files stored in .PST files, outside of network drives, in paper format, or in personal email accounts.

- In the event some portions of the requested records are properly exempt from disclosure, please disclose any reasonably segregable non-exempt portions of the requested records. If a request is denied in whole, please state specifically why it is not reasonable to segregate portions of the record for release.
- Please take appropriate steps to ensure that records responsive to this request are not deleted by the agency before the completion of processing for this request. If records potentially responsive to this request are likely to be located on systems where they are subject to potential deletion, including on a scheduled basis, please take steps to prevent that deletion, including, as appropriate, by instituting a litigation hold on those records.

Conclusion

If you have any questions regarding how to construe this request for records or believe that further discussions regarding search and processing would facilitate a more efficient production of records of interest to American Oversight, please do not hesitate to contact American Oversight to discuss this request. American Oversight welcomes an opportunity to discuss its request with you before you undertake your search or incur search or duplication costs. By working together at the outset, American Oversight and your agency can decrease the likelihood of costly and time-consuming litigation in the future.

Where possible, please provide responsive material in an electronic format by email. Alternatively, please provide responsive material in native format or in PDF format on a USB drive. Please send any responsive material being sent by mail to American Oversight, 1030 15th Street NW, Suite B255, Washington, DC 20005. If it will accelerate release of responsive records to American Oversight, please also provide responsive material on a rolling basis.

We share a common mission to promote transparency in government. American Oversight looks forward to working with your agency on this request. If you do not understand any part of this request, please contact Christine H. Monahan at foia@americanoversight.org

Departments & Independent Agencies, "Managing Government Records Directive," M-12-18 (Aug. 24, 2012), https://www.archives.gov/files/records-mgmt/m-12-18.pdf.

or 202-869-5244. Also, if American Oversight's request for a fee waiver is not granted in full, please contact us immediately upon making such a determination.



Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM) 7/27/2020 10:02:16 PM Sent: To: Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange AdministrativeGroup (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl] CC: Lohmann, Larry (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93f4206cbb2c4d82adbc1eda15e035c4-lohmannII]; LaMontagne, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3399bdbada594ee0913948b8ca6fb50b-lamontagnek]; Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Black, Jodi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=782921b9f08249b59a582e93f6963f5f-blackj] Subject: Re: EcoHealth oversight response Attachments: EcoHealth Alliance narrative 7-27-20[2].docx; 06.26.20 SST EC Letter to HHS[1].pdf; EcoHealth Alliance narrative 7-27-20 Option 1a msl.docx; EcoHealth Alliancenarrative 7-27-20 Option 1b msl.docx; EcoHealth Alliance narrative 7-27-20 Option 1c msl.docx Thanks Adrienne – taking FC off. The edits look great. I'm attaching options 1a, 1b, and 1c (b)(5)Best, Mike From: "Hallett, Adrienne (NIH/OD) [E]" (b) (6) Date: Monday, July 27, 2020 at 3:58 PM To: "Lauer, Michael (NIH/OD) [E]" (b) (6), "Collins, Francis (NIH/OD) [E]" (b) (6), "Tabak, Lawrence (NIH/OD) [E]" (b)(6)Cc: "Lohmann, Larry (NIH/OD) [E]" (b) (6), "LaMontagne, Karen (NIH/OD) [E]" Subject: Re: EcoHealth oversight response Attached is the incoming EcoHealth Alliance letter plus Mike's draft of the response, with some edits and additions from me. A few issues to note: (b)(5)

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| Date: Wednesday, July 22, 2020 at 6:29 AM | | |
| To: Adrienne Hallett | (b) (6), Francis Collins | டு 6) (6), Lawrence Tabak |
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| Cc: "Lohmann, Larry (NIH/OD) [E]' | (b) (6) Karen LaMontagne | |
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| Date: Tuesday, July 21, 2020 at 1:50 PM | | |
| To: "Collins, Francis (NIH/OD) [E]" | 6) டு, "Lauer, Michael (NIH/OI | ח/ ובויי |
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| Sent: Tuesday, July 21, 2020 12:59 PM | (-) (-) | |
| To: Collins, Francis (NIH/OD) [E] | (b) (6); Lauer, Michael (NIH/OD) [E] | (b) (б); Tabak, |
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| Cc: Lohmann, Larry (NIH/OD) [E] | (চ) (চ); LaMontagne, Karen (NIH/OL | D) [E] |
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Mike, can you help with the draft?

Thanks! Adrienne

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Congress of the United States Trouse of Representatives Washington, DC 20515

June 26, 2020

The Honorable Alex M. Azar II Secretary U.S. Department of Health and Human Services 200 Independence Avenue SW Washington, DC 20201

Dear Secretary Azar,

We write with strong concerns surrounding the Administration's termination of the National Institutes of Health (NIH) grant to EcoHealth Alliance on April 24, 2020. In the letter communicating the grant's termination, NIH Deputy Director for Extramural Research, Dr. Michael Lauer, wrote that "At this time, NIH does not believe the current project outcomes align with the program goals and agency priorities." However, press reports indicate that the grant was canceled because a small portion of the funding was to be given to the Wuhan Institute of Virology for on-the-ground sample collection and analysis. Given the potential for this study to inform our knowledge of coronavirus disease 2019 (COVID-19) transmission, it is deeply concerning that it may have been canceled for political reasons in the midst of the current pandemic.

It is always important that federal research priorities are driven by science-based decisions. This is especially true in a time that requires unparalleled investment in research that may help bring an end to this public health crisis. It is therefore troubling that this abrupt grant cancellation came just a week after President Trump announced that the Administration was looking into "grants going to that area" and continued that "we will end that grant very quickly." This was in response to a reporter referencing false claims that COVID-19 "likely

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⁴ Clip of President Trump with Coronavirus Task Force Briefing, *CSPAN*, April 17, 2020, accessed here: https://www.c-span.org/video/?c4869590/user-clip-us-2015-grant-wuhan-lab-question

came from a Level 4 lab in Wuhan."⁵ The Administration has been pushing this theory⁶ despite scientific experts saying this path of transmission would be virtually impossible given what is known about the virus and lab safety protocols. This theory is the basis for the grant termination, it would be an egregious example of the Administration politicizing scientific decision making in order to further a politically convenient narrative.

EcoHealth Alliance's grant was renewed in 2019 after an initial five-year grant on the same topic. The grant it received was extremely competitive – only 22 percent of proposals were funded in 2019. The July 2019 project proposal was titled, "Understanding the Risk of Bat Coronavirus Emergence." In the midst of the COVID-19 pandemic that has taken over 115,000 American lives, it is inconceivable that this project would no longer "align with the program goals and agency priorities" of NIH. Any termination of a grant that has gone through NIH's rigorous scientific review process must be adequately justified on a scientific basis – particularly a grant which would appear to be so relevant to understanding our current health crisis.

As the Committees of jurisdiction over public health and science, we need to better understand the decision to terminate EcoHealth Alliance's NIH grant. We are especially concerned given Dr. Anthony Fauci's, Director of NIH's National Institute of Allergy and Infectious Diseases, assertion at a Committee on Energy and Commerce hearing on June 23 that "the grant was canceled because NIH was told to cancel it." In order to understand how this decision was reached, we request a briefing to be delivered by July 15, 2020. At this briefing, we ask that you be prepared to address the following questions:

- 1. When the decision was made to terminate the grant to EcoHealth Alliance;
- 2. Who at HHS was involved in the decision to terminate the grant;
- 3. Whether entities outside HHS, including but not limited to the White House, the State Department, the National Security Council, and intelligence agencies, were involved in this decision;

⁶ Mark Mazzetti, Julian E. Barnes, Edward Wong, and Adam Goldman, "Trump Officials Are Said to Press Spies to Link Virus and Wuhan Labs," *New York Times*, April 30, 2020, accessed here: https://www.nytimes.com/2020/04/30/us/politics/trump-administration-intelligence-coronavirus-china.html

https://projectreporter.nih.gov/project_info_description.cfm?aid=9819304&icde=49752569

⁵ *Id*.

⁷ Geoff Brumfel and Emily Kwong, "Virus Researchers Cast Doubt On Theory Of Coronavirus Lab Accident," *NPR*, April 23, 2020, accessed here: https://www.npr.org/sections/goatsandsoda/2020/04/23/841729646/virus-researchers-cast-doubt-on-theory-of-coronavirus-lab-accident

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¹⁰ House Committee on Energy and Commerce, Testimony of Anthony S. Fauci, M.D., Director, National Institute for Allergy and Infectious Diseases, *Oversight of the Trump Administration's Response to the COVID-19 Pandemic*, 116th Cong. (Jun. 23, 2020).

- 4. The analysis conducted to determine that the EcoHealth Alliance grant's project outcomes did not align with program goals and NIH priorities;
- 5. Any analysis conducted to determine EcoHealth Alliance's alleged improper disbursal of NIH funds to the Wuhan Institute of Virology;
- 6. Any other decision NIH has made to terminate grants since January 1, 2020; and
- 7. Any further action NIH is considering taking regarding EcoHealth Alliance or any other grant holder regarding alleged relationships with international laboratories.

In addition to the briefing, we request the following materials be provided to the Committees no later than July 10, 2020. Please provide these materials in a searchable electronic format.

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- All documentation of audits or other analyses conducted to determine improper disbursement of federal grant money from grant-holding institutions to other entities; and
- 4. The criteria that NIH used to assess the EcoHealth Alliance grant and determine that such grant merited cancelation, and documentation thereof.

Any decision to terminate a research grant should be conducted in a deliberative and transparent process that adheres to the highest standards of scientific integrity. Especially in this unprecedented time, it is important that our public health and science agencies remain free from political pressure and be allowed to pursue federally-funded research based on scientific merit.

Thank you for your attention to this matter. We look forward to speaking with you and reviewing the relevant materials.

Sincerely,

Eddie Bernice Johnson

Chairwoman

Committee on Science, Space,

Eddie Bernice Johnson

and Technology

Frank Pallone, Jr.

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Chairman

Committee on Energy and Commerce

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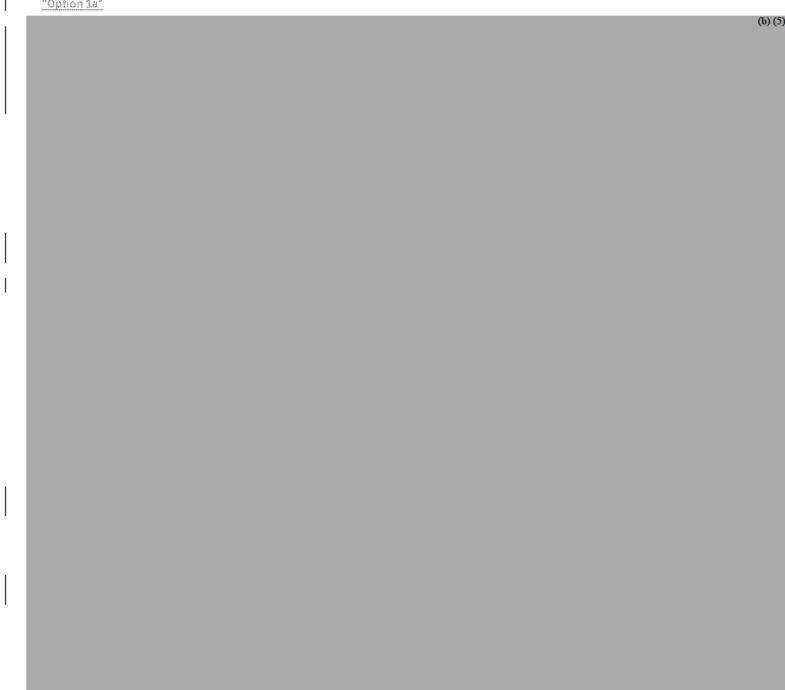
Bill Foster Chairman Subcommittee on Investigations and Oversight Diena Deslette

Chair

Subcommittee on Oversight and

Investigations

EcoHealth Alliance narrative Mike Lauer (OER) July 273, 2020 "Option 1a"



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EcoHealth Alliance narrative Mike Lauer (OER) July 273, 2020 "Option 1b"



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EcoHealth Alliance narrative Mike Lauer (OER) July 273, 2020 "Option 1c"



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From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM] Sent: 7/28/20208:53:24 PM To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf] Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group CC: (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa] Subject: FW: EcoHealth oversight response Attachments: 06.26.20 SST EC Letter to HHS[1].pdf; EcoHealth Alliance narrative 7-27-20 Option 1c msl clean.docx Hi Francis – we have discussed this (b)(5)I'm attaching the incoming letter and proposed our draft response. Many thanks, Mike From: "Hallett, Adrienne (NIH/OD) [E]" (b) (6) Date: Monday, July 27, 2020 at 3:58 PM (b) (6) "Collins, Francis (NIH/OD) [E]" To: "Lauer, Michael (NIH/OD) [E]" (b) (6), "Tabak, Lawrence (NIH/OD) [E]" Cc: "Lohmann, Larry (NIH/OD) [E]" (b) (6), "LaMontagne, Karen (NIH/OD) [E]" Subject: Re: EcoHealth oversight response Attached is the incoming EcoHealth Alliance letter plus Mike's draft of the response, with some edits and additions from me. A few issues to note: (b)(5)

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Date: Wednesday, July 22, 2020 at 6:29 AM

| | To: Adrienne Hallett | (b) (6), Francis Coll | ins | (b) (б), Lawrence | |
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| | From: "Hallett, Adrienne (NIH/OD) [E]" | | (b) (6) | | |
| | Date: Tuesday, July 21, 2020 at 1:50 PM | | | | |
| | To: "Collins, Francis (NIH/OD) [E]" | (b) (6), "Laı | uer, Michael (NIH/O | D) [E]" | |
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Congress of the United States Trouse of Representatives Washington, DC 20515

June 26, 2020

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⁵ *Id*.

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