From:	Lauer, Michael (NIH/OD) [E]
To:	Aleksei Chmura; Peter Daszak
Cc:	Black, Jodi (NIH/OD) [E]; Stemmy, Erik (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Linde, Emily (NIH/NIAID) [E]; Bulls, Michelle G. (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]; Compliance Review
Subject:	PLEASE READ -- Re: Please read and acknowledge receipt -- update regarding 2R01AI110964-06
Date:	Wednesday, July 8, 2020 9:50:49 PM
Attachments:	Daszak 7 8 20.pdf

Dear Dr. Chmura and Dr. Daszak

Please see attached.

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)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

8 July 2020

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

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

In follow-up to my previous letter of April 24, 2020, 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Institute within the National Institutes of Health (NIH), under the Department of Health and Human Services (HHS), has withdrawn its termination of grant R01AI110964, which supports the project *Understanding the Risk of Bat Coronavirus Emergence*. Accordingly, the grant is reinstated.

However, as you are aware, the NIH has received reports that the Wuhan Institute of Virology (WIV), a subrecipient of EcoHealth Alliance under R01AI110964, has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, create health and welfare threats to the public in China and other countries, including the United States. Grant award R01AI110964 is subject to biosafety requirements set forth in the NIH Grants Policy Statement (e.g., NIH GPS, Section 4.1.24 "Public Health Security") and the Notice of Award (e.g., requiring that "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]."). Moreover, NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients. 45 C.F.R. § 75.101.

As the grantee, EcoHealth Alliance was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). We have concerns that WIV has not satisfied safety requirements under the award, and that EcoHealth Alliance has not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance.

Moreover, as we have informed you through prior Notices of Award, this award is subject to the Transparency Act subaward and executive compensation reporting requirement of 2 C.F.R. Part

170. To date you have not reported any subawards in the Federal Subaward Reporting System.

Therefore, effective the date of this letter, July 8, 2020, NIH is suspending all activities related to R01AI110964, until such time as these concerns have been addressed to NIH's satisfaction. This suspension is taken in accordance with 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. This action is not appealable in accordance with 42 C.F.R. § 50.404 and the NIH GPS Section 8.7, Grant Appeals Procedures. However, EcoHealth Alliance has the opportunity to provide information and documentation demonstrating that WIV and EcoHealth Alliance have satisfied the above-mentioned requirements.

Specifically, to address the NIH's concerns, EcoHealth must provide the NIH with the following information and materials, which must be complete and accurate:

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.
2. Explain the apparent disappearance of Huang Yanling, a scientist / technician who worked in the WIV lab but whose lab web presence has been deleted.
3. Provide the NIH with WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns.
4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.
5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.
6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.
7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System

During this period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further asses compliance by EcoHealth Alliance and WIV, including compliance with other terms and conditions of award that may be implicated. Additionally, during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the

recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. Once the original award is reinstated, NIH will take additional steps to restrict all funding in the HHS Payment Management System in the amount of $369,819. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 CFR Part 75, including, but not limited to, terminating the grant award. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

.

Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2020.07.08 21:43:41 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

From: Park, Eun-Chung (NIH/NIAID) [E]
To: Strickler-Dinglasan, Patricia (NIH/NIAID) [F]; NIAID VARB
Cc: DMID GrantOps
Subject: RE: ACTION: Please confirm ARRA Responsiveness for Administrative Supplement Requests in NPARS
Date: Wednesday, April 29, 2009 10:54:23 AM

M34A and 32D corrected.

Best,
Eunchung

Eun-Chung Park, PhD, MPA
Virology Branch, DMID, NIAID, NIH
6610 Rockledge Dr., Rm 1209
Bethesda, MD 20892-7630
(Zip for Express Mail Only: 20817)

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NIAID, National Institutes of Health, DHHS

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****

From: Strickler-Dinglasan, Patricia (NIH/NIAID) [F]
Sent: Wednesday, April 29, 2009 9:58 AM
To: NIAID VARB
Cc: DMID GrantOps
Subject: ACTION: Please confirm ARRA Responsiveness for Administrative Supplement Requests in NPARS

Dear VB Program Staff,

The administrative supplement requests listed below are not designated as "ARRA" in NPARS. If a request is ARRA-responsive, please select "ARRA" from the Discretionary Pool pull-down menu. If a request is to come from a different funding pool, please let me know.

Click here to go to NPARS to review below listed applications:

Specialist	Grant No	PCC	PI	Title	TC Yr1	Pctile/Score	Disc Type
Wright, Artisha	5 U01AI065654-05	M32D B	Libraty, Daniel	A Study of Protective Immunity Against Dengue in Infants	$0	(b) (5)	
Anderson-Garlic, Mary Ann	5 R01AI063513-04	M34A	Davey, Robert	Receptor Trafficking in Entry of Murine Leukemia Viruses	$0		
Anderson-Garlic, Mary Ann	5 R01AI050237-07	M34A	Lloyd, Richard	Translation Regulation by Enterovirus Proteinase	$0		
Anderson-Garlic, Mary Ann	1 R21AI078307-01	M34A	Marriott, Susan	Transforming Potential of Emerging Human Retroviruses	$0		
Anderson-Garlic, Mary Ann	5 R01AI074668-02	M34A	Pfeiffer, Julie	The influence of host barriers on viral quasispecies diversity	$0		

						(b) (5)
				and pathogenesis		
Boggs, Leslie	5 R01AI072176-02	M34A	Samulski, Richard	Rational and combinatorial engineering of AAV vectors	$0	
Bumbray-Quarles, Devon	5 R01AI065972-03	M34A	Kirkegaard, Karla	The cell biology of Theiler's virus persistence in CNS	$0	
Bumbray-Quarles, Devon	5 R01AI068978-04	M34A	Wang, Pin	Targeting lentiviruses to infect chosen cells	$0	
Bumbray-Quarles, Devon	1 R01AI074967-01A2	M34A	Weitzman, Matthew	Mechanisms of APOBEC3A Inhibition	$0	
Bumbray-Quarles, Devon	5 R01AI072645-03	M34A	Young, John	Cellular factors in gammaretrovirus replication	$0	
Carlisle, Tina	1 R21AI081673-01A2	M34A	Mansky, Louis	HTLV Gag trafficking in living cells	$0	
Eisenman, Laura	1 R21AI082496-01	M34A	Bohm, A	T-antigen Binding to the Merkel Cell Carcinoma Virus Origin	$0	
England, Howard	1 R01AI079231-01	M34A	Daszak, Peter	Risk of Viral Emergence from Bats	$0	
England, Howard	5 R01AI074825-02	M34A	Casjens, Sherwood	DNA packaging and delivery by dsDNA viruses	$0	
Fato, Michael	5 R01AI046458-08	M34A	Pintel, David	Parvovirus RNA Processing	$0	
Fields, Cassandra	2 R01AI026109-21A1	M34A	Tattersall, Peter	Molecular Genetics of Parvoviral DNA Replication	$0	
Jarosik, Theresa	5 R01AI075219-02	M34A	Wimmer, Eckard	Synthetic Viral Genome Design for Rapid Vaccine Development	$0	
Johnson, Jackie	5 R01AI015539-28	M34A	Flanegan, James	Molecular Biology of Poliovirus RNA Replication	$0	
Leake, Christy	2 R01AI011676-33	M34A	Black, Lindsay	Phage T4 Head Assembly and Initiation of Infection	$0	
Leake, Christy	5 R01AI022470-24	M34A	White, Judith	Molecular Mechanisms of Viral Membrane Fusion Proteins	$0	
Mercogliano, Theresa	2 R01AI053531-06A1	M34A	Cameron, Craig	Picornavirus Genome Replication	$0	
Mercogliano, Theresa	1 R21AI079694-01	M34A	Craven, Rebecca	Structural Basis for Long-Range Genetic Interactions in Retroviral CA Assembly	$0	
Mercogliano, Theresa	5 R01AI057988-03	M34A	Meyers, Craig	Genetic Analysis of Papillomavirus Virion Morphogenesis	$0	
Mercogliano, Theresa	2 R01AI060021-19A1	M34A	Weiss, Susan	Molecular biology of coronavirus induced demyelination	$0	
Mercogliano, Theresa	5 R01AI077460-02	M34A	White, Martyn	Cytokine regulation of JC virus latency and reactivation	$0	
Qualls, Mildred	1 R21AI082430-01	M34A	Wiethoff, Christopher	Inflammasome activation by a respiratory virus	$0	
Robinson, Shadetra	5 R01AI028385-17	M34A	Parrish, Colin	Mechanisms of Parvovirus Infection	$0	

						(b) (5)
				and Host Range		
Robinson, Shadetra	5 R01AI072345-02	M34A	Stenlund, Arne	Biochemical analysis of papillomavirus replication	$0	
Shea, Mollie	1 R03AI070193-01A2	M34A	Milavetz, Barry	HISTONE HYPERACETYLATION IN REPLICATING SV40 CHROMOSOMES	$0	
Smith, Gregory	1 R01AI080791-01	M34A	Hagan, Michael	Multiscale modeling of mechanisms for viral capsid assembly and polymorphism	$0	
Sullivan, Donna	1 R01AI078229-01	M34A	Jones-Engel, Lisa	Evolution and Emergence of Simian Retroviruses in South Asia	$0	
Twilley, Jennifer	1 R01AI081307-01A2	M34A	Dougherty, Joseph	Gene regulation using novel drugs modulating premature translational termination	$0	
Waugh, Julie	5 R37AI011219-37	M34A	Rossmann, Michael	Structure and function of icosahedral viruses	$0	
Wolcott, Roberta	5 R01AI064296-03	M34A	Tsai, Billy	Transport of polyomavirus across the ER membrane	$0	
Chatman, Kimberly	5 R01AI060739-04	M34A S	Saif, Linda	Porcine Respiratory Coronavirus as a SARS Model	$0	
Amidon, Laura	1 R43AI079937-01	M52A B	Hruby, Dennis	Novel small molecule inhibitors of dengue replication	$0	
Fields, Cassandra	5 U01AI070343-03	M52A B	Fikrig, Erol	Immunotherapeutics for Treatment of Flavivirus Infection	$0	
Rais-Danai, Sahar	5 R01AI070791-03	M52A B	Padmanabhan, Radhakrishnan	Identification and Analysis of Flavivirus Protease and RNA Helicase Inhibitors	$0	
Scott-Morring, Lisa	5 U01AI061441-05	M52A B	Block, Timothy	Imino sugars for flavivirus infections of bioterror	$0	
Sullivan, Donna	5 U01AI075549-02	M52A B	Chen, Qiang	Plant-derived MAb therapeutics for west nile virus	$0	
Wright, Michael	5 R01AI064738-04	M52A B	Andino, Raul	RNAi as an Intercellular Antiviral Defense Mechanism	$0	

Thank you!

Trish
Patricia M. Strickler-Dinglasan, PhD
AAAS Science and Technology Policy Fellow 2007-2009
Office of Scientific Coordination and Program Operations
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
6610 Rockledge Drive, **Room 4107A**
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Phone: (b) (6)
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From: Bateman, Karen (NIH/NIAID) [E]
To: Park, Eun-Chung (NIH/NIAID) [E]
Subject: RE: AI79231 Daszak---can you ask Ann Devine about this
Date: Tuesday, April 1, 2008 4:08:43 PM

Hi,

I don't think we want to ask that question. Realistically, GMP can just point to the SS, (b) (5) "… It's in the summary statement resume and is therefore Gospel, as far as NIAID GMP is concerned. My suggestion is to either:

(b) (5)

OR

(b) (5)

To try to do both, (b) (5) , as I think you are suggesting, is going to be a tough one to justify scientifically. I don't think we have a chance with that, but I'm willing to listen, if you can present a strong rationale.

Send me something, or stop by tomorrow AM.

Karen

From: Park, Eun-Chung (NIH/NIAID) [E]
Sent: Tuesday, April 01, 2008 3:28 PM
To: Bateman, Karen (NIH/NIAID) [E]
Subject: RE: AI79231 Daszak---can you ask Ann Devine about this

I am sure you would, but could you also find out what "suggest" instead of "recommend" means for (b) (5) Thanks.

From: Bateman, Karen (NIH/NIAID) [E]

Sent: Tuesday, April 01, 2008 3:27 PM

To: Park, Eun-Chung (NIH/NIAID) [E]

Subject: RE: AI79231 Daszak---can you ask Ann Devine about this

Sure. We meet tomorrow. My gut says they will not allow, and Irene agreed, but I can approach GMP for you.

From: Park, Eun-Chung (NIH/NIAID) [E]
Sent: Tuesday, April 01, 2008 2:52 PM
To: Bateman, Karen (NIH/NIAID) [E]
Subject: FW: AI79231 Daszak---can you ask Ann Devine about this

Karen,

I have not heard from Jackie yet, re: (b) (5) --this came in response to PA_07-246.. I am enclosing the summary statement for this application. Thank you.

<< File: R01AI079231-01.PDF >>

Best,
Eunchung

Eun-Chung Park, PhD, MPA
Virology Branch, DMID, NIAID, NIH
6610 Rockledge Dr., Rm 4103
Bethesda, MD 20892-7630
(Zip for Express Mail Only: 20817)

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NIAID, National Institutes of Health, DHHS

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From: Park, Eun-Chung (NIH/NIAID) [E]

Sent: Monday, March 31, 2008 11:30 AM

To: Johnson, Jackie (NIH/NIAID) [E]

Cc: Bateman, Karen (NIH/NIAID) [E]

Subject: AI79231 Daszak

Jackie,

I have a question if we can (b) (5) As you can see that the summary statement "suggested" that the study can be completed in fewer than 5 years.

(b) (5)

We are working on the funding plan for PA-07-246 for which this application came under. It will work for us if we can (b) (5). Let us know if this can be done. Thank you.

Best,
Eunchung

Eun-Chung Park, PhD, MPA
Virology Branch, DMID, NIAID, NIH
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****

From: Aleksei Chmura[(b) (6)]

Sent: Mon 4/27/2020 10:57:48 PM (UTC-05:00)

To: Lauer, Michael (NIH/OD) [E][(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)] Linde, Emily (NIH/NIAID) [E][(b) (6)] Bulls, Michelle G. (NIH/OD) [E][(b) (6)] Alison Andre[(b) (6)]

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

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

Sincerely,

-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.

> On Apr 24, 2020, at 16:47, Lauer, Michael (NIH/OD) [E] <(b) (6)> wrote:
>
> Dear Dr. Chmura and Dr. Daszak
>
> Please see attached.
>
> 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)
Date: Thursday, April 23, 2020 at 1:50 PM
To: "Lauer, Michael (NIH/OD) [E]" <(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)
Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

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

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

> On Apr 21, 2020, at 19:28, Lauer, Michael (NIH/OD) [E] <(b) (6) wrote:
>
> 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)

From: Peter Daszak < (b) (6)
Date: Tuesday, April 21, 2020 at 7:07 PM
To: "Lauer, Michael (NIH/OD) [E]" < (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]" < (b) (6)
Subject: RE: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

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
2. 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 2R01AI110964-06 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

---

From: Lauer, Michael (NIH/OD) [E] < (b) (6)
Sent: Monday, April 20, 2020 4:31 PM
To: Kevin Olival < (b) (6) Peter Daszak < (b) (6)
Cc: Naomi Schrag < (b) (6) Black, Jodi (NIH/OD) [E] < (b) (6) Lauer, Michael (NIH/OD) [E] < (b) (6)
Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
Importance: High

Thank you Kevin

- 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 2). 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.

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)

From: Kevin Olival <(b) (6)
Date: Monday, April 20, 2020 at 4:14 PM
To: "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Cc: Naomi Schrag <(b) (6) "Black, Jodi (NIH/OD) [E]" <(b) (6)
Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

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 (b) (6) who is the PI and leading this project for EcoHealth Alliance.
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
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New York, NY 10001

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www.ecohealthalliance.org
EcoHealth Alliance develops science-based solutions to prevent pandemics *and* promote conservation

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Best, Mike

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Date: Sunday, April 19, 2020 at 11:59 AM
To: "Lauer, Michael (NIH/OD) [E]"
< (b) (6)
" (b) (6)
< (b) (6) Naomi Schrag
< (b) (6)
Cc: "Black, Jodi (NIH/OD) [E]" < (b) (6)
Subject: RE: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

Dear Dr. Lauer,
I am acknowledging receipt of this letter and will get back to you as soon as I can.
Sincerely,
Naomi Schrag

From: Lauer, Michael (NIH/OD) [E] <(b) (6)
Sent: Sunday, April 19, 2020 11:00 AM
To: (b) (6) Naomi Schrag <(b) (6)
Cc: Black, Jodi (NIH/OD) [E] <(b) (6)
Subject: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
Importance: High

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

<EcoHealth Alliance re AI grant 4 19 20.pdf>

<EcoHealth Alliance re AI grant 4 19 20[2].pdf><NoA R01AI110964-06.pdf><NoA R01AI110964-01.pdf>

<Daszak letter 4 24 20.pdf><EcoHealth Alliance re AI grant 4 19 20.pdf>

From: Lauer, Michael (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: Thur 4/23/2020 12:59:23 PM (UTC-05:00)

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) (6)

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

Many thanks Aleksei.

Best, Mike

From: Aleksei Chmura < (b) (6)
Date: Thursday, April 23, 2020 at 1:50 PM
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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)
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-Aleksei

Aleksei Chmura
Chief of Staff &
Authorized Organizational Representative

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

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(mobile)
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On Apr 21, 2020, at 19:28, Lauer, Michael (NIH/OD) [E] < (b) (6) wrote:

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- 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.

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1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)

From: Peter Daszak < (b) (6)
Date: Tuesday, April 21, 2020 at 7:07 PM
To: "Lauer, Michael (NIH/OD) [E]" < (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]" < (b) (6)
Subject: RE: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

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1. Our AOR – Dr. Aleksei Chmura, who has access to all our records
2. 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 2R01AI110964-06 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,

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President

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

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

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From: Lauer, Michael (NIH/OD) [E] <(b) (6)
Sent: Monday, April 20, 2020 4:31 PM
To: Kevin Olival <(b) (6) Peter Daszak <(b) (6)

Cc: Naomi Schrag <(b) (6) Black, Jodi (NIH/OD) [E] <(b) (6) Lauer, Michael (NIH/OD) [E] <(b) (6)
Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
Importance: High

Thank you Kevin

- 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.
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We greatly appreciate your prompt attention to this matter.

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1. I am not the PI on this award. You should contact Dr. Peter Daszak (b) (6) who is the PI and leading this project for EcoHealth Alliance.

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

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Sent: Fri 4/24/2020 3:47:48 PM (UTC-05:00)

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)

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

Attachment: Daszak letter 4 24 20.pdf

Attachment: EcoHealth Alliance re AI grant 4 19 20.pdf

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Many thanks, Mike

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NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
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<EcoHealth Alliance re AI grant 4 19 20[2].pdf><NoA R01AI110964-06.pdf><NoA R01AI110964-01.pdf>

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 AI110964, 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] Digitally signed by Lauer, Michael (NIH/OD) [E]
Date: 2020.04.24 16:41:16 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

Date: April 19, 2020

From: Michael S Lauer, MD
NIH Deputy Director for Extramural Research

Lauer, Michael (NIH/OD) [E] Digitally signed by Lauer, Michael (NIH/OD) [E] Date: 2020.04.19 10:47:40 -04'00'

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: Peter Daszak[(b) (6)

Sent: Tue 4/21/2020 12:32:20 AM (UTC-05:00)

To: Lauer, Michael (NIH/OD) [E][(b) (6) Naomi Schrag[(b) (6) Kevin Olival[(b) (6)

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

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

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

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460 West 34th Street
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Sent: Monday, April 20, 2020 6:35 PM
To: Naomi Schrag < (b) (6) Kevin Olival < (b) (6) Peter Daszak < (b) (6)

Cc: Black, Jodi (NIH/OD) [E] < (b) (6) Lauer, Michael (NIH/OD) [E] < (b) (6)
Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

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 < (b) (6)
Date: Monday, April 20, 2020 at 5:19 PM
To: "Lauer, Michael (NIH/OD) [E]" < (b) (6) Kevin Olival < (b) (6) " (b) (6) < (b) (6)
Cc: Naomi Schrag < (b) (6) "Black, Jodi (NIH/OD) [E]" < (b) (6)
Subject: RE: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

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

From: Lauer, Michael (NIH/OD) [E] < (b) (6)
Sent: Monday, April 20, 2020 4:31 PM

To: Kevin Olival <(b) (6) (b) (6)
Cc: Naomi Schrag <(b) (6) Black, Jodi (NIH/OD) [E] <(b) (6) Lauer, Michael (NIH/OD) [E] <(b) (6)
Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
Importance: High

Thank you Kevin

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We greatly appreciate your prompt attention to this matter.

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

(b) (6) (direct)
(mobile)
1.212.380.4465 (fax)
www.ecohealthalliance.org
EcoHealth Alliance develops science-based solutions to prevent pandemics *and* promote conservation

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Importance: High

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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)

<EcoHealth Alliance re AI grant 4 19 20.pdf>

From: Lauer, Michael (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: Mon 4/20/2020 5:34:32 PM (UTC-05:00)

To: Naomi Schrag[(b) (6) Kevin Olival[(b) (6) (b) (6) (b) (6)

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

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

Attachment: Screen Shot 2020-04-20 at 4.23.38 PM.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 < (b) (6)
Date: Monday, April 20, 2020 at 5:19 PM
To: "Lauer, Michael (NIH/OD) [E]" < (b) (6) Kevin Olival < (b) (6) " (b) (6) < (b) (6)
Cc: Naomi Schrag < (b) (6) "Black, Jodi (NIH/OD) [E]" < (b) (6)
Subject: RE: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

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

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Please see attached.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
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Phone: (b) (6)
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<EcoHealth Alliance re AI grant 4 19 20.pdf>

FACULTY

OLIVAL, KEVIN J.

AFFILIATION/DEPARTMENT
EcoHealth Alliance

TELEPHONE
(b) (6)

EMAIL
(b) (6)

WEBSITE
https://www.ecohealthalliance.org/personnel/dr-kevin-j-olival

BACK TO FACULTY »

©2020 COLUMBIA UNIVERSITY
A SHELTON INTERACTIVE SITE

From: Lauer, Michael (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: Tue 4/21/2020 6:28:20 PM (UTC-05:00)

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

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

Attachment: EcoHealth Alliance re AI grant 4 19 20[2].pdf

Attachment: NoA R01AI110964-06.pdf

Attachment: NoA R01AI110964-01.pdf

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)

From: Peter Daszak < (b) (6)
Date: Tuesday, April 21, 2020 at 7:07 PM
To: "Lauer, Michael (NIH/OD) [E]" < (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]" < (b) (6)
Subject: RE: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

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
2. 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 2R01AI110964-06 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

From: Lauer, Michael (NIH/OD) [E] <(b) (6)
Sent: Monday, April 20, 2020 4:31 PM
To: Kevin Olival <(b) (6) Peter Daszak <(b) (6)
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1 Center Drive, Building 1, Room 144
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<EcoHealth Alliance re AI grant 4 19 20.pdf>

Date: April 19, 2020

From: Michael S Lauer, MD
NIH Deputy Director for Extramural Research

Lauer, Michael (NIH/OD) [E] Digitally signed by Lauer, Michael (NIH/OD) [E] Date: 2020.04.19 10:47:40 -04'00'

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.

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 08/05/2019

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 2R01AI110964-06 REVISED
FAIN: R01AI110964

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
AI	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.
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) R01AI110964. 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 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 + **$27,750**F&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, 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 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.

****

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:

- 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;
- 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: Tsedav 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

RESEARCH **Issue Date:** 05/27/2014

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 1R01AI110964-01
FAIN: R01AI110964

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 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,

NIH NGA R | Version: 1 - 05/08/2014 13:52:00| Generated on: 5/27/2014 7:02:42 PM

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
AI	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 http://grants.nih.gov/grants/policy/awardconditions.htm

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.

b. 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 http://grants.nih.gov/grants/policy/awardconditions.htm 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) R01AI110964. 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 – 1R01AI110964-01

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.

~~~~~~~~~
This award includes funds for subcontract/consortium activity with Wuhan Institute of Virology, CHINA and is budgeted as follows:

	-Yr 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.
~~~~~~~~~
This award includes funds for subcontract/consortium activity with East China Normal University, CHINA 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/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 Costs	Year 1	Year 2	Year 3	Year 4	Year 5
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: Sun 4/19/2020 9:51:52 AM (UTC-05:00)

To: (b) (6) (b) (6) Naomi Schrag| (b) (6)

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

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

Attachment: EcoHealth Alliance re AI grant 4 19 20.pdf

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

Date: April 19, 2020

From: Michael S Lauer, MD
NIH Deputy Director for Extramural Research

Lauer, Michael (NIH/OD) [E] Digitally signed by Lauer, Michael (NIH/OD) [E] Date: 2020.04.19 10:47:40 -04'00'

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: Matthew R.Torsiello| (b) (6)

Sent: Fri 5/22/2020 4:11:29 PM (UTC-05:00)

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

Cc: Linde, Emily (NIH/NIAID) [E]| (b) (6) Stemmy, Erik (NIH/NIAID) [E]| (b) (6) Andrew N. Krinsky| (b) (6) Nels T. Lippert| (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| (b) (6)

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

Attachment: EcoHealth Alliance First-Level Appeal of NIH Grant Termination, dated May 22, 2020 (R01 AI 110964) (02103179xA1AB5).PDF

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 AI 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 Broadway | New York | NY | 10018
www.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 uninterrupted. 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 Katrinia Soares at reception@tarterkrinsky.com or by phone at 212-216-8000 with any questions. Thank you in advance for your courtesies during these unprecedented times.

NOTE: If regular mailing or other specific transmission type is required by terms of a contract, order or statute, please comply with those obligations and transmit the materials by the means set forth in the agreement, order or statute as well as by email.

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This email is an informal communication that is not meant to be legally binding upon the sender unless expressly noted to the contrary.

Tarter Krinsky & Drogin LLP, Attorneys-at-Law.

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*
(b) (6) *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

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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."

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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

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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.

Very truly yours,

(b) (6)

Andrew N. Krinsky

cc: (*by email*)

Dr. Erik Stemmy ((b) (6)
Ms. Emily Linde ((b) (6)

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Exhibit A

Notice of Award

RESEARCH
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: 2R01AI110964-06
FAIN: R01AI110964

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

[redacted]

[redacted]

Approved Budget	$733,750
Total Amount of Federal Funds Obligated (Federal Share)	$733,750
TOTAL FEDERAL AWARD AMOUNT	$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
AI	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) R01AI110964. 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.

[redacted]

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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:

[redacted]

****

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 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.

****

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:

- 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;
- 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

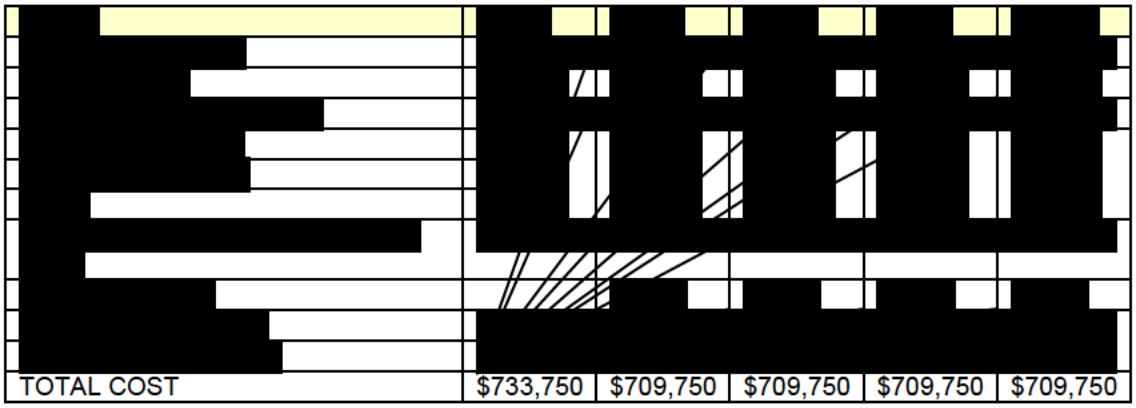
The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals 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

INSTITUTION: ECOHEALTH ALLIANCE, INC.



TOTAL COST	$733,750	$709,750	$709,750	$709,750	$709,750

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 (NIH/OD) [E] Digitally signed by Lauer, Michael (NIH/OD) [E] Date: 2020.04.19 10:47:40 -04'00'

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.

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
To: (b) (6) Naomi Schrag < (b) (6)
Cc: Black, Jodi (NIH/OD) [E] < (b) (6)
Subject: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
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: (b) (6)

2 Kevin Olival email on 20 April 2020

From: Kevin Olival <(b) (6)>
Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
Date: April 20, 2020 at 4:12:28 PM 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 (b) (6) who is the PI and leading this project for EcoHealth Alliance.
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

(b) (6) (direct)
(mobile)
1.212.380.4465 (fax)
www.ecohealthalliance.org

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

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

Mon 4/20/2020 4:31 PM

To: Kevin Olival < (b) (6) Peter Daszak < (b) (6)

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

Importance: High

2 attachments

Screen Shot 2020-04-20 at 4.23.38 PM.png; EcoHealth Alliance re AI grant 4 19 20.pdf;

Thank you Kevin

- 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 2). 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.

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)

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

4 Michael Lauer email on 20 April 2020

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

Mon 4/20/2020 6:34 PM

To:Naomi Schrag <(b) (6)>; Kevin Olival <(b) (6)>; Peter Daszak <(b) (6)>

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

1 attachment

Screen Shot 2020-04-20 at 4.23.38 PM.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 <(b) (6)>
Date: Monday, April 20, 2020 at 5:19 PM
To: "Lauer, Michael (NIH/OD) [E]" <(b) (6)>, Kevin Olival <(b) (6)>, '(b) (6)' <(b) (6)>
Cc: Naomi Schrag <(b) (6)>, "Black, Jodi (NIH/OD) [E]" <(b) (6)>
Subject: RE: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

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 regardi 2R01AI110964-06

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) Naomi Schrag < (b) (6) Kevin Olival < (b) (6)

Cc: Black, 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)

Cc:Black, Jodi (NIH/OD) [E] <(b) (6) Aleksei Chmura (b) (6) <(b) (6)>;
Stemmy, Erik (NIH/NIAID) [E] <(b) (6) (b) (6) <(b) (6)

Importance: High

1 attachment

EcoHealth Alliance re AI 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
2. 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 2R01AI110964-06 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 acknowledge receipt -- Actions needed regarding 2R01AI110964-06
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] (b) (6), Lauer, Michael (NIH/OD) [E] (b) (6)

ML

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 2R01AI110964-06
Date: April 23, 2020 at 13:50
To: Lauer, Michael (NIH/OD) [E] (b) (6)
Cc: Peter Daszak (b) (6) 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] (b) (6)
Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
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] emily.erb (b) (6), Lauer, Michael (NIH/OD) [E] (b) (6), Compliance Review (b) (6)

ML

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 2R01AI110964-06
Date: April 24, 2020 at 16:47
To: Aleksei Chmura (b) (6) Peter Daszak (b) (6)
Cc: Black, Jodi (NIH/OD) [E] jodi.black@nih.gov, 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)

ML

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)
Email: (b) (6)

From: **Aleksei Chmura** (b) (6)
Subject: Re: PLEASE READ -- Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
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)

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

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 AI110964, 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] Digitally signed by Lauer, Michael (NIH/OD) [E] Date: 2020.04.24 16:41:16 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

REL0000047878.0001

Exhibit E

SPECIFIC AIMS

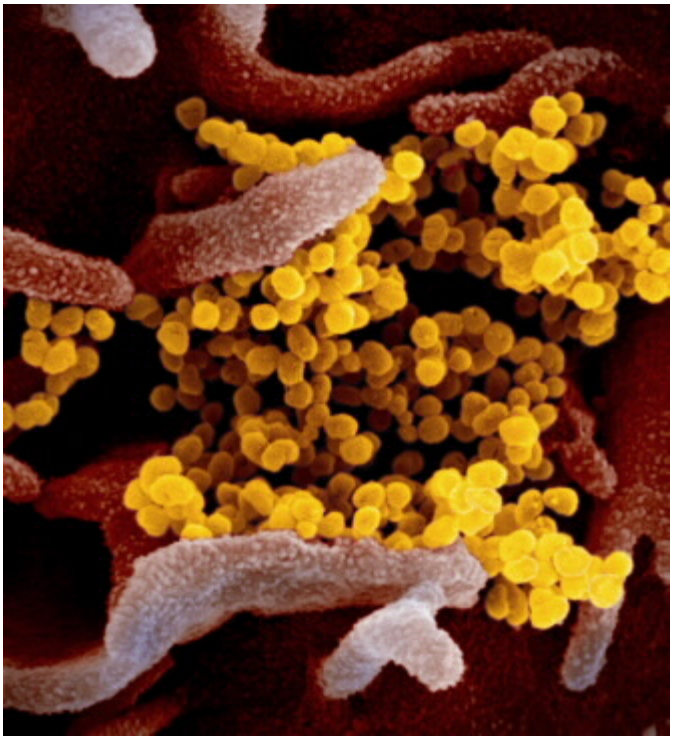
Zoonotic coronaviruses are a significant threat to global health, as demonstrated with the emergence of Severe Acute Respiratory Syndrome coronavirus (SARS-CoV) in 2002, and the continuing spread of Middle East Respiratory Syndrome (MERS-CoV). The wildlife reservoirs of SARS-CoV were identified by our 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 SARS-like 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:

Aim 1: 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 influenza-like 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.

Aim 3: *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

NIH National Institute of Allergy and Infectious Diseases

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

REL0000047878.0001

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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 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.

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.

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:

1. **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.

2. **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.

3. **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

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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 interventionagainst 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

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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.[1] 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

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

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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-to-human 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.

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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 directlybut 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

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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.

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

- **Identify viral targets for therapeutic development**. Advances in structural biology technology enable researchers to map key viral structures at an 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.

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- **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.[5] 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.
    - 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.

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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.

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[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

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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*

- **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 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-CoV-2-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

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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.

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From: Lauer, Michael (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: Wed 7/8/2020 8:50:31 PM (UTC-05:00)

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

Subject: PLEASE READ -- Re: Please read and acknowledge receipt -- update regarding 2R01AI110964-06

Attachment: Daszak 7 8 20.pdf

Dear Dr. Chmura and Dr. Daszak

Please see attached.

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)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

8 July 2020

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

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

In follow-up to my previous letter of April 24, 2020, 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 withdrawn its termination of grant R01AI110964, which supports the project *Understanding the Risk of Bat Coronavirus Emergence*. Accordingly, the grant is reinstated.

However, as you are aware, the NIH has received reports that the Wuhan Institute of Virology (WIV), a subrecipient of EcoHealth Alliance under R01AI110964, has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, create health and welfare threats to the public in China and other countries, including the United States. Grant award R01AI110964 is subject to biosafety requirements set forth in the NIH Grants Policy Statement (e.g., NIH GPS, Section 4.1.24 "Public Health Security") and the Notice of Award (e.g., requiring that "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]."). Moreover, NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients. 45 C.F.R. § 75.101.

As the grantee, EcoHealth Alliance was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). We have concerns that WIV has not satisfied safety requirements under the award, and that EcoHealth Alliance has not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance.

Moreover, as we have informed you through prior Notices of Award, this award is subject to the Transparency Act subaward and executive compensation reporting requirement of 2 C.F.R. Part

170. To date you have not reported any subawards in the Federal Subaward Reporting System.

Therefore, effective the date of this letter, July 8, 2020, NIH is suspending all activities related to R01AI110964, until such time as these concerns have been addressed to NIH's satisfaction. This suspension is taken in accordance with 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. This action is not appealable in accordance with 42 C.F.R. § 50.404 and the NIH GPS Section 8.7, Grant Appeals Procedures. However, EcoHealth Alliance has the opportunity to provide information and documentation demonstrating that WIV and EcoHealth Alliance have satisfied the above-mentioned requirements.

Specifically, to address the NIH's concerns, EcoHealth must provide the NIH with the following information and materials, which must be complete and accurate:

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.
2. Explain the apparent disappearance of Huang Yanling, a scientist / technician who worked in the WIV lab but whose lab web presence has been deleted.
3. Provide the NIH with WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns.
4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.
5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.
6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.
7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System

During this period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further asses compliance by EcoHealth Alliance and WIV, including compliance with other terms and conditions of award that may be implicated. Additionally, during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the

recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. Once the original award is reinstated, NIH will take additional steps to restrict all funding in the HHS Payment Management System in the amount of $369,819. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 CFR Part 75, including, but not limited to, terminating the grant award. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

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Sincerely,

Michael S. Lauer -S

Digitally signed by Michael S. Lauer -S
Date: 2020.07.08 21:43:41 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

From: Lauer, Michael (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: Fri 8/14/2020 4:16:52 AM (UTC-05:00)

To: Matthew R.Torsiello[(b) (6)]

Cc: Linde, Emily (NIH/NIAID) [E][(b) (6)] Stemmy, Erik (NIH/NIAID) [E][(b) (6)] Andrew N. Krinsky[(b) (6)] Nels T. Lippert[(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[(b) (6)] Lauer, Michael (NIH/OD) [E][(b) (6)]

Subject: Re: EcoHealth Alliance re Suspension of NIH Grant No. 2R01 AI 110964-6

Attachment: EcoHealth Alliance - Letter to NIH re Grant Suspension 8-13-2020 (with Exhibits)[2].pdf

Dear Mr. Torsiello – letter received.

Thank you, 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)

From: "Matthew R.Torsiello" <(b) (6)>
Date: Thursday, August 13, 2020 at 5:54 PM
To: "Lauer, Michael (NIH/OD) [E]" <(b) (6)>
Cc: "Linde, Emily (NIH/NIAID) [E]" <(b) (6)> "Stemmy, Erik (NIH/NIAID) [E]" <(b) (6)> "Andrew N. Krinsky" <(b) (6)> "Nels T. Lippert" <(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 <(b) (6)> "Linde, Emily (NIH/NIAID) [E]" <(b) (6)>
Subject: EcoHealth Alliance re Suspension of NIH Grant No. 2R01 AI 110964-6

Dr. Lauer:

Please see the attached letter from Andrew Krinsky on behalf of EcoHealth Alliance, Inc., regarding the decision by NIH to suspend NIH Research Grant 2R01 AI 110964-6 on or about July 8, 2020.

Please confirm receipt. Thank you.

Best,

Matthew

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

Tarter Krinsky & Drogin LLP
1350 Broadway | New York | NY | 10018
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COVID-19 RESOURCE CENTER

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 uninterrupted. 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 Katrinia Soares at 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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Andrew N. Krinsky, *Partner*
(b) (6), *Direct Dial*
(b) (6)

August 13, 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: Suspension of NIH Grant 2R01 AI 110964-6

Dear Dr. Lauer:

This firm represents EcoHealth Alliance, Inc. ("EcoHealth Alliance"), in connection with 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"), on July 8, 2020, to suspend grant 2R01 AI 110964-6 (the "Suspension:"), which funds the project *Understanding the Risk of Bat Coronavirus Emergence* (the "Project").

This letter constitutes EcoHealth Alliance's initial response to the Suspension, which was due to purported concerns regarding the safety of unspecified research being conducted at the Wuhan Institute of Virology ("WIV") and for EcoHealth Alliance's alleged failure to report certain subawards in connection with grant 2R01 AI 110964-6 (the "Grant").[1] As set forth in more detail below, the Suspension is unjustified as WIV has no connection to the Project or EcoHealth Alliance's current research and EcoHealth Alliance had not issued any subawards in connection with the Grant at the time of the Suspension. Moreover, NIAID is not authorized under 45 CFR §§ 75.371, 75.205, and 75.207, entitled *Specific Award Conditions*, to impose, *inter alia*, conditions that consist of demands for information regarding entities that are neither subrecipients of grant funds nor project affiliates.[2] Accordingly, EcoHealth Alliance hereby demands that the Suspension be withdrawn and all funding in the HHS Payment Management System be released immediately.

BACKGROUND

A. EcoHealth Alliance

EcoHealth Alliance is a prolific 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

[1] A copy of my prior letter, dated May 22, 2020, regarding NIH's termination of the Grant, is attached hereto as Exhibit 1.
[2] Notwithstanding NIH's lack of authority to impose extraneous conditions on the Grant and Project, EcoHealth Alliance has made a good faith effort to respond to NIH's questions regarding WIV.

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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 more than five multidisciplinary R01s. As demonstrated by Dr. Daszak's research, which produced the first ever global emerging disease "hotspots" map that identified locations in the world where viruses with pandemic potential are most likely to emerge, EcoHealth Alliance is uniquely qualified to assist in both identifying the origins of severe acute respiratory syndrome coronavirus 2 ("SARS-CoV-2") and developing and implementing strategies to combat coronavirus disease 2019 ("COVID-19").

Significantly, at this time, EcoHealth Alliance is working with several countries including, *inter alia*, Bangladesh, Côte d'Ivoire, Indonesia, Liberia, Malaysia, Republic of Congo, and Thailand to distribute PPE and provide critical reagents to test for and contain COVID-19. Notably, this effort is being supported by both the United States Department of State and the United States Agency for International Development. EcoHealth Alliance is also assisting the U.S. Geological Survey, the U.S. Fish & Wildlife Service, the International Union for Conservation of Nature, the World Health Organization, the World Organization for Animal Health, and the World Bank Group to place the COVID-19 pandemic in historical context, assess the risk of COVID-19 resurgence and spillover impacts, and determine best practices and cost-effective solutions to combat the virus. In sum, EcoHealth Alliance's research agenda is more consequential than ever.

B. NIH Issues EcoHealth Alliance A Five-Year Research Grant To Continue The Project

NIH issued EcoHealth Alliance an initial five-year research award for the Project in 2014. In 2019, EcoHealth Alliance submitted a renewal application to NIH through NIAID that contained a revised scope of work, research goals, and proposed collaborators and sought to extend the Project 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, the absence of any allegation that EcoHealth Alliance had violated the terms and conditions of its prior awards, and the importance of EcoHealth Alliance's continued research, on July 24, 2019, NIH reauthorized grant R01 AI 110964 and issued EcoHealth Alliance a notice of award in the amount of $733,750.00 funded under grant 2R01 AI 110964-6.[3]

[3] A copy of the notice of award, dated July 24, 2019, is attached hereto as Exhibit 1-A.

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C. EcoHealth Alliance Informs HHS That WIV Is Not A Subrecipient Of Grant Funds And Agrees Not To Collaborate With WIV In Connection With The Project

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 WIV. 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, Dr. 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." [4]

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.[5]

D. NIH Unlawfully Terminates The Grant "For Convenience"

Notwithstanding NIH's representation that suspension of WIV would not affect EcoHealth Alliance's ongoing research, the Grant, or the Project, on April 24, 2020, NIH notified EcoHealth Alliance by letter that, effective immediately, the Grant and Project had been terminated (the "Termination"). The purported 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.[6] As a result of the Termination, EcoHealth Alliance was notified by HHS that it was required to submit a Final Research Performance Progress Report for the Project.

E. EcoHealth Alliance Files A First-Level Appeal Of The Termination

On May 22, 2020, by letter, EcoHealth Alliance filed a first-level appeal of the Termination on NIH, pursuant to NIH Grants Policy Statement Section 8.7 and 42 CFR 50, Subpart D (the "Appeal"). (Ex. 1). In its Appeal, EcoHealth Alliance argued, *inter alia*, that: (1) NIH research grants are not subject to termination for convenience; (2) NIH's discretion to award a grant at a particular funding level did not authorize NIH to issue a post-award decision to terminate a duly awarded grant during the budget period; (3) the research goals of the Project and the NIAID are substantially identical; and (4) there was no rational basis to terminate the Grant for cause.

[4] A copy of the NIAID's letter regarding WIV, dated April 19, 2020, is attached hereto as Exhibit 1-B.
[5] A copy of the email correspondence between NIH and EcoHealth Alliance is attached hereto as Exhibit 1-C.
[6] A copy of the NIAID's letter regarding the Termination, dated April 24, 2020, is attached hereto as Exhibit 1-D.

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F. NIAID Withdraws The Termination But Suspends The Grant Due To Alleged Safety Concerns At WIV And For EcoHealth's Purported Failure To Report Subawards

Lacking a rational basis for its decision to terminate the Grant, on July 8, 2020, Dr. Lauer notified EcoHealth Alliance by letter that NIAID had withdrawn its termination of the Grant supporting the Project.[7] However, citing "bio-safety concerns" at WIV and EcoHealth Alliance's purported failure to report unspecified subawards, NIAID proceeded to immediately suspend the Grant and the Project, pursuant to 45 CFR § 75.371 and NIH Grants Policy Statement Section 8.5.2, leaving the status of the Project effectively unchanged. In addition, the Suspension seeks to impose on EcoHealth Alliance the outrageous obligation to provide NIH with information and materials in the custody and control of WIV and to somehow facilitate access by an USFG "inspection team" to WIV, as a condition for lifting the Suspension.[8]

ARGUMENT

In the Suspension, NIAID identifies two and only two grounds for its decision to suspend the Grant and the Project: (1) purported safety concerns regarding WIV; and (2) EcoHealth Alliance's purported failure to report unspecified subawards. As set forth in detail herein, EcoHealth Alliance is not conducting any research or otherwise collaborating with WIV in connection with the Project. Moreover, EcoHealth Alliance had not issued any subawards in connection with the Grant at the time of the Suspension. Accordingly, the Suspension should be withdrawn immediately.[9]

A. NIH's Purported Concern That WIV Poses A Threat To Public Health And Welfare Is Not A Basis To Suspend The Grant Or The Project As WIV Is Not A Current Subrecipient Of Grant Funds And Has No Connection To The Project

Under 45 CFR §§ 75.207, 75.205, and 75.371 and NIH Grants Policy Statement Section 8.5.2, NIAID may take one or more enforcement actions where a grant recipient has failed to materially comply with the terms and conditions of the award. Under 45 CFR 75.374, the HHS awarding agency must provide the non-Federal entity an opportunity to object and provide information challenging any suspension or termination action. Given the exclusion of WIV from the Project, and NIH's failure to identify any other safety concerns, there is no basis for NIAID to suspend the Grant or to impose additional conditions.

At all relevant times, EcoHealth Alliance has duly monitored the activities of its subrecipients as necessary to ensure that any subawards were used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward. Moreover, EcoHealth Alliance is not aware of any allegation that any subrecipient of grant 1R01 AI 110964 funds has ever used such funds for unauthorized purposes, or in violation of any Federal

[7] Please confirm that, due to the withdrawal of the Termination, EcoHealth Alliance is not required to submit a final Project report at this time.
[8] A copy of the NIAID's letter regarding the Suspension, dated July 8, 2020, is attached hereto as Exhibit 2.
[9] EcoHealth Alliance notes that the Suspension did not state any specific deadline for EcoHealth Alliance to respond to the Suspension or proposed additional conditions. Accordingly, this response is timely.

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statutes, regulations, or the terms and conditions of the subject subaward. Furthermore, NIH has never accused EcoHealth Alliance of any act that posed a risk to public welfare and safety.

Significantly, WIV is the only organization identified in the Suspension as posing a risk to public welfare and safety. As stated in my prior letter on May 22, 2020, regarding the now admittedly unlawful termination of the Grant, at NIH's express request, no Grant funds have been distributed to WIV and no contract has been signed between EcoHealth Alliance and WIV in connection with the Project. Thus, the allegation that WIV's independent research at its facility poses unspecified bio-safety concerns should have no bearing on the Project, which was in strict compliance with NIH Grants Policy Statement §§ 4 and 4.1.24, and the terms and conditions of the Notice of Award (Ex. 1-A), at the time of the Suspension.

To reiterate, WIV is not a subrecipient of any Grant funds and will not be involved in the Project in any capacity. (*see* Ex. 1-C-7). Significantly, NIAID explicitly told EcoHealth Alliance that it could exclude WIV and continue the Project without jeopardizing the Grant so long as "no grant funds [were] provided to WIV." (Ex. 1-B).

B. EcoHealth Alliance Has Duly Reported All Issued Subawards And Was In Compliance With The Transparency Act At The Time Of The Suspension

Contrary to NIAID's assertion that EcoHealth Alliance failed to report unspecified subawards, EcoHealth Alliance did not issue or sign any subawards in connection with the 2019 Grant or before July 8, 2020. Accordingly, the reporting requirements of the Federal Funding Accountability and Transparency Act (the "FFATA") did not apply at the time of the Suspension.

Regarding the Project period between 2014 and 2019, EcoHealth Alliance duly complied with all NIAID-system-only financial reporting requirements. While EcoHealth Alliance had not entered the FFATA reporting information in the Federal Subaward Reporting System ("the FSRS"), all subawards issued in connection with the 2014 Project and the 2019 Project are now fully reported in the FSRS. Notably, no one at NIAID or NIH ever contacted or otherwise notified EcoHealth Alliance that it was not in compliance. As EcoHealth Alliance has taken appropriate corrective action that fully resolves its alleged non-compliance with the FFATA, pursuant to NIH Grants Policy Statement Section 8.5.2, the Suspension should be withdrawn.

C. HHS Has No Authority To Impose New Conditions That Are Wholly Unrelated To The Project And EcoHealth Alliance's Ongoing Research

Under 45 CFR § 75.207, NIAID may impose additional specific award conditions under the following circumstances: when the applicant or recipient has a history of failure to comply with the general or specific terms and conditions of a Federal award; when an applicant or recipients fails to meet expected performance goals; and when an applicant or recipient is not otherwise responsible. Allowed conditions include: (1) requiring payments as reimbursements rather than advance payments; (2) withholding authority to proceed to the next phase until receipt of evidence of acceptable performance within a given period of performance; (3) requiring additional, more detailed financial reports; (4) requiring additional project monitoring (5) requiring the non-Federal entity to obtain technical or management assistance; or (6) establishing additional

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prior approvals. (45 CFR § 75.207[b]). The purpose of these additional conditions are to encourage the award recipients to comply with the original terms and conditions of the award, applicable statutes, and regulations.

There is no statute or NIH Grants Policy Statement provision that authorizes NIAID to impose additional conditions that consist of demands for information and materials regarding entities that are neither current subrecipients of grant funds nor connected to the research project funded by the subject grant. This makes sense, given that the purpose of imposing additional conditions is to ensure that research funded under a particular grant is conducted safely and in compliance with applicable laws.

Here, NIH's First, Second, Third, Fourth, Fifth, and Sixth proposed conditions, which require that EcoHealth Alliance, *inter alia*, provide information and materials regarding WIV, are wholly unrelated to the safety and efficacy of Project and EcoHealth Alliance's ongoing research as WIV is not a subrecipient of Grant funds (*see* Ex. 1-C-6, 7 and 8). Moreover, certain conditions, including the Sixth condition that "EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019" seek to impose impossible obligations. EcoHealth Alliance has no authority to grant NIAID access to the WIV lab facilities and is not conducting any research with WIV in connection with the Project. Whether or not EcoHealth Alliance is able to provide responses to the proposed conditions regarding WIV will not affect the safety of EcoHealth Alliance's current research, which will not involve WIV.

Without waiving any objections, in the interest of cooperation, EcoHealth Alliance has made a good faith effort to provide responses to the additional conditions (the "Requests") based on information now known to Peter Daszak, EcoHealth Alliance's President and Chief Scientist.[10]

CONCLUSION

Every single outbreak of a novel virus has been accompanied by the allegation that the subject virus was created in a lab, including, *inter alia*, HIV, Ebola, and now SARS-CoV-2. There is no credible evidence to support these theories. By comparison, we know that seventy-five percent of new emerging diseases originate in wildlife. Every species of wildlife carry these viruses, an estimated 1.7 million of which are still unknown. While many of these viruses are benign, occasionally a lethal virus will emerge that can directly infect humans. EcoHealth Alliance is a valuable resource. The instant request to resume the Project funded by the Grant presents HHS with the opportunity to support proven research regarding the threat of zoonotic disease emergence and to support scientists who are working to determine whether certain vaccines and drugs can kill the SARS-CoV-2 virus to save our lives.

At this time, EcoHealth Alliance is in compliance with all of the terms and conditions of the award including the FFATA, there is no public health concern posed by EcoHealth Alliance's

[10] A copy of EcoHealth Alliance's Objections and Responses to the Requests is attached hereto as Exhibit 3.

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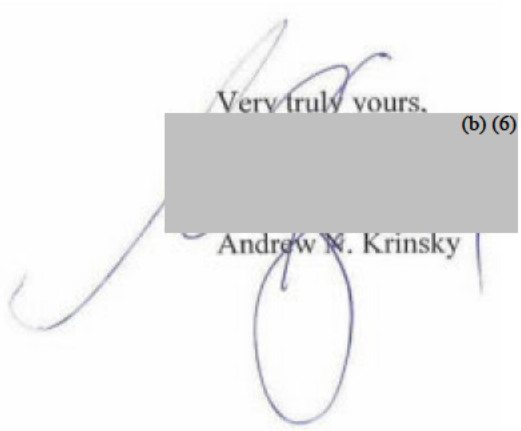
resumption of the Project, which will not involve WIV in any capacity (*see* NIH Grants Policy Sections 4 and 4.1.24), and EcoHealth Alliance has hereby provided, to the best of its ability, the information and materials requested by NIH in the Suspension. Accordingly, the Suspension should be withdrawn and all funding in the HHS Payment Management System should be released immediately.

Please note that this letter is not intended to provide an exhaustive list of all possible grounds for vacating the Suspension and may not reflect all arguments and claims that EcoHealth Alliance will assert in the event that it is required to file a first-level appeal or other action or proceeding concerning any future adverse determination by NIAID affecting the Grant or the Project. All of EcoHealth Alliance's rights and remedies to seek review of any adverse determination are expressly reserved.

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.



cc: (*by email*)

Dr. Erik Stemmy ((b) (6)
Ms. Emily Linde ((b) (6)

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Exhibit 1

Tarter Krinsky & Drogin LLP
1350 Broadway
New York, NY 10018
P 212.216.8000
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Andrew N. Krinsky, *Partner*
(b) (6), *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

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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

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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."

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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

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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, p. 1). 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.

Very truly yours,

(b) (6)

Andrew M. Krinsky

cc: (*by email*)

Dr. Erik Stemmy (b) (6)
Ms. Emily Linde (b) (6)

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Exhibit A

Notice of Award

RESEARCH
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: 2R01AI110964-06
FAIN: R01AI110964

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

[redacted]

[redacted]

Approved Budget	$733,750
Total Amount of Federal Funds Obligated (Federal Share)	$733,750
TOTAL FEDERAL AWARD AMOUNT	$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
AI	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) R01AI110964. 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.

[redacted]

****

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:

[redacted]

****

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 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.

****

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:

- 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;
- 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

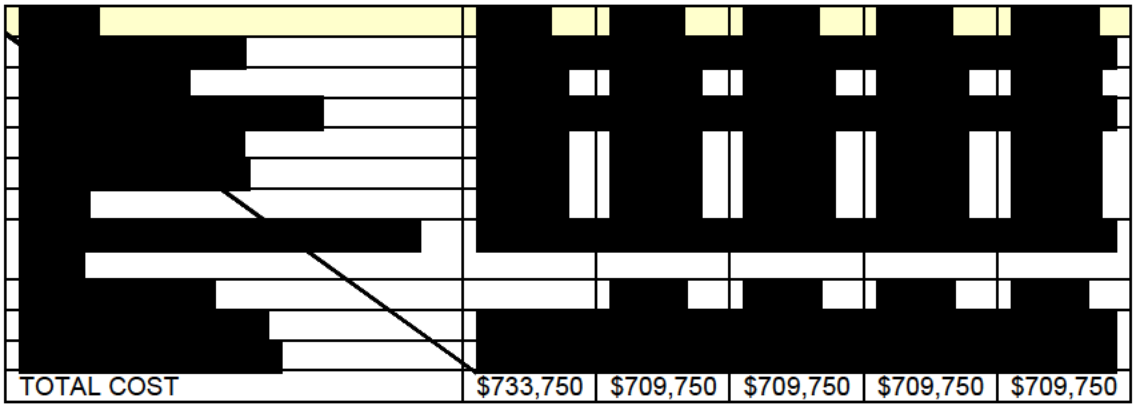
The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals 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

INSTITUTION: ECOHEALTH ALLIANCE, INC.



TOTAL COST	$733,750	$709,750	$709,750	$709,750	$709,750

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 (NIH/OD) [E] Digitally signed by Lauer, Michael (NIH/OD) [E] Date: 2020.04.19 10:47:40 -04'00'

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.

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
To: (b) (6) Naomi Schrag <(b) (6)>
Cc: Black, Jodi (NIH/OD) [E] <(b) (6)>
Subject: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
Importance: High

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

2 Kevin Olival email on 20 April 2020

From: Kevin Olival <(b) (6)>
Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
Date: April 20, 2020 at 4:12:28 PM 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 (b) (6) who is the PI and leading this project for EcoHealth Alliance.
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

(b) (6) (direct)
(mobile)
1.212.380.4465 (fax)
www.ecohealthalliance.org

3 Michael Lauer email on 20 April 2020

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

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

Mon 4/20/2020 4:31 PM

To:Kevin Olival <(b) (6) Peter Daszak <(b) (6)

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

Importance: High

2 attachments

Screen Shot 2020-04-20 at 4.23.38 PM.png; EcoHealth Alliance re AI grant 4 19 20.pdf;

Thank you Kevin

- 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 2). 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.

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)

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

4 Michael Lauer email on 20 April 2020

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

Mon 4/20/2020 6:34 PM

To:Naomi Schrag <(b) (6)>; Kevin Olival <(b) (6)>; Peter Daszak <(b) (6)>

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

1 attachment

Screen Shot 2020-04-20 at 4.23.38 PM.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 <(b) (6)>
Date: Monday, April 20, 2020 at 5:19 PM
To: "Lauer, Michael (NIH/OD) [E]" <(b) (6)>, Kevin Olival <(b) (6)>, '(b) (6)' <(b) (6)>
Cc: Naomi Schrag <(b) (6)>, "Black, Jodi (NIH/OD) [E]" <(b) (6)>
Subject: RE: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06

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 regardi 2R01AI110964-06

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) Naomi Schrag < (b) (6) Kevin Oliv al < (b) (6)

Cc Black, 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)

Cc:Black, Jodi (NIH/OD) [E] <(b) (6) Aleksei Chmura (b) (6) <(b) (6)>;
Stemmy, Erik (NIH/NIAID) [E] <(b) (6) (b) (6) <(b) (6)

Importance: High

1 attachment

EcoHealth Alliance re AI 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
2. 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 2R01AI110964-06 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 acknowledge receipt -- Actions needed regarding 2R01AI110964-06
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] (b) (6), Lauer, Michael (NIH/OD) [E] (b) (6)

ML

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 2R01AI110964-06
Date: April 23, 2020 at 13:50
To: Lauer, Michael (NIH/OD) [E] (b) (6)
Cc: Peter Daszak (b) (6) 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] (b) (6)
Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01AI110964-06
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] emily.erb (b) (6), Lauer, Michael (NIH/OD) [E] (b) (6), Compliance Review (b) (6)

ML

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 2R01AI110964-06
Date: April 24, 2020 at 16:47
To: Aleksei Chmura (b) (6) Peter Daszak (b) (6)
Cc: Black, Jodi (NIH/OD) [E] jodi.black@nih.gov, 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)

ML

Dear Dr. Chmura and Dr. Daszak

Please see attached.

10 Michael Lauer email on 24 April 2020

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 2R01AI110964-06
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)

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

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 AI110964, 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] Digitally signed by Lauer, Michael (NIH/OD) [E]
Date: 2020.04.24 16:41:16 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

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Exhibit E

SPECIFIC AIMS

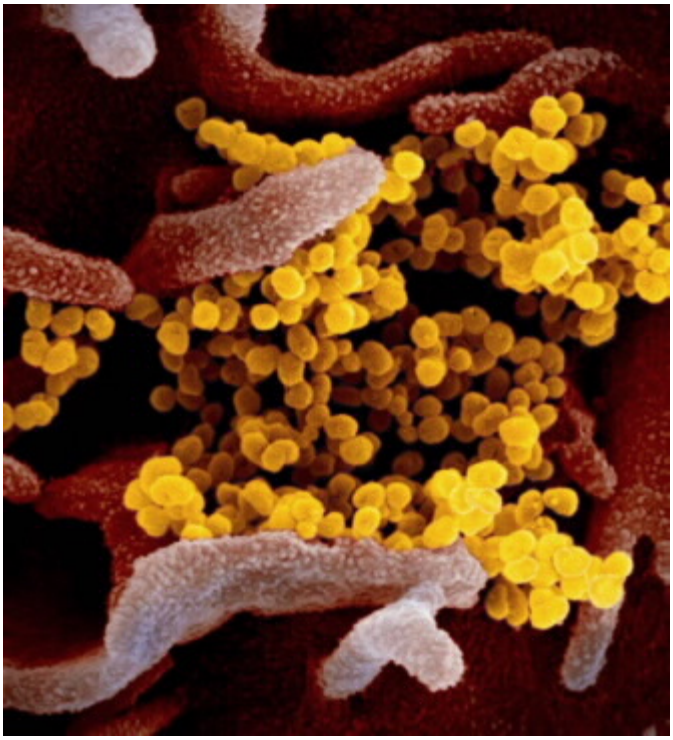
Zoonotic coronaviruses are a significant threat to global health, as demonstrated with the emergence of Severe Acute Respiratory Syndrome coronavirus (SARS-CoV) in 2002, and the continuing spread of Middle East Respiratory Syndrome (MERS-CoV). The wildlife reservoirs of SARS-CoV were identified by our 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 SARS-like 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:

Aim 1: 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 influenza-like 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.

Aim 3: *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

NIH National Institute of Allergy and Infectious Diseases

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

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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 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.

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.

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:

1. **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.

2. **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.

3. **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

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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 interventionagainst 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

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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.[1] 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

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

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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-to-human 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.

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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 directlybut 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

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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.

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

- **Identify viral targets for therapeutic development**. Advances in structural biology technology enable researchers to map key viral structures at an 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.

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- **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.[5] 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.
    - 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.

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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.

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[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

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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*

- **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 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-CoV-2-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

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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.

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Exhibit 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

8 July 2020

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

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

In follow-up to my previous letter of April 24, 2020, 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 withdrawn its termination of grant R01AI110964, which supports the project *Understanding the Risk of Bat Coronavirus Emergence*. Accordingly, the grant is reinstated.

However, as you are aware, the NIH has received reports that the Wuhan Institute of Virology (WIV), a subrecipient of EcoHealth Alliance under R01AI110964, has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, create health and welfare threats to the public in China and other countries, including the United States. Grant award R01AI110964 is subject to biosafety requirements set forth in the NIH Grants Policy Statement (e.g., NIH GPS, Section 4.1.24 "Public Health Security") and the Notice of Award (e.g., requiring that "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]."). Moreover, NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients. 45 C.F.R. § 75.101.

As the grantee, EcoHealth Alliance was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). We have concerns that WIV has not satisfied safety requirements under the award, and that EcoHealth Alliance has not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance.

Moreover, as we have informed you through prior Notices of Award, this award is subject to the Transparency Act subaward and executive compensation reporting requirement of 2 C.F.R. Part

170. To date you have not reported any subawards in the Federal Subaward Reporting System.

Therefore, effective the date of this letter, July 8, 2020, NIH is suspending all activities related to R01AI110964, until such time as these concerns have been addressed to NIH's satisfaction. This suspension is taken in accordance with 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. This action is not appealable in accordance with 42 C.F.R. § 50.404 and the NIH GPS Section 8.7, Grant Appeals Procedures. However, EcoHealth Alliance has the opportunity to provide information and documentation demonstrating that WIV and EcoHealth Alliance have satisfied the above-mentioned requirements.

Specifically, to address the NIH's concerns, EcoHealth must provide the NIH with the following information and materials, which must be complete and accurate:

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.
2. Explain the apparent disappearance of Huang Yanling, a scientist / technician who worked in the WIV lab but whose lab web presence has been deleted.
3. Provide the NIH with WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns.
4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.
5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.
6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.
7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System

During this period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further asses compliance by EcoHealth Alliance and WIV, including compliance with other terms and conditions of award that may be implicated. Additionally, during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the

recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. Once the original award is reinstated, NIH will take additional steps to restrict all funding in the HHS Payment Management System in the amount of $369,819. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 CFR Part 75, including, but not limited to, terminating the grant award. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

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Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2020.07.08 21:43:41 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

Exhibit 3

ECOHEALTH ALLIANCE'S OBJECTIONS AND RESPONSES TO NIH'S ADDITIONAL CONDITIONS ON GRANT 2R01 AI 110964-6

EcoHealth Alliance, Inc. ("EcoHealth Alliance"), by and through its attorneys, Tarter Krinsky & Drogin LLP, hereby responds and objects to the additional conditions (the Requests") imposed on grant 2R01 AI 110964-6 on July 8, 2020, by 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"), as follows:

GENERAL OBJECTIONS[1]

1. EcoHealth Alliance objects to the Requests to the extent they purport to impose obligations beyond those authorized by the NIH Grants Policy Statement and the applicable statutes and regulations.

2. EcoHealth Alliance objects to the Requests to the extent they seek information and documents that are neither relevant to the Project nor reasonably likely to affect the safety or efficacy of EcoHealth Alliance's continued research funded by grant 2R01 AI 110964-6.

3. EcoHealth Alliance objects to the Requests to the extent they seek the production of documents that are not in EcoHealth Alliance's possession, custody, or control.

4. EcoHealth Alliance objects to the Requests to the extent they are vague, ambiguous, or otherwise unclear as to the precise categories of documents and information sought.

5. EcoHealth Alliance objects to the Requests to the extent that they are overbroad, unduly burdensome, or unreasonably cumulative and duplicative.

6. EcoHealth Alliance objects to the Requests to the extent they seek documents and information concerning personal information relating to individuals not affiliated with the Project or Grant on the ground that such requests may invade the rights of privacy of such individuals.

[1] Any capitalized terms not otherwise defined herein shall have the same meaning ascribed to them in EcoHealth Alliance's letter to NIAID, dated August 12, 2020.

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7. EcoHealth Alliance objects to the Requests to the extent they seek documents and information regarding transactions or occurrences that took place on or before July 1, 2019, on the ground that such requests are overbroad, and that such documents and information are not relevant to EcoHealth Alliance's continued research funded by grant 2R01 AI 110964-6.

8. EcoHealth Alliance's Responses and Objections to the Requests (including each Request therein) shall not be interpreted as implying that: (i) responsive documents or information exist, (ii) EcoHealth Alliance acknowledges the proprietary of any Request; or (iii) that any Request propounded by NIH is either factually correct or legally binding upon EcoHealth Alliance.

9. EcoHealth Alliance specifically reserves its right to amend, modify, or supplement the objections and responses provided herein.

10. These general objections ("General Objections") are hereby incorporated by reference into each and every of EcoHealth Alliance's responses to the Requests, below.

RESPONSES AND OBJECTIONS TO THE REQUESTS

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.

Response to Request No. 1:

EcoHealth Alliance objects to the Request to the extent it seeks documents and information that are not in EcoHealth Alliance's possession, custody, or control. EcoHealth Alliance further objects to the Request to the extent it seeks information that is not relevant to the Project, which was granted prior to the discovery of SARS-CoV-2. Subject to and notwithstanding the foregoing and without prejudice thereto, EcoHealth Alliance responds that it has no knowledge or information regarding the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.

2. Explain the apparent disappearance of Huang Yanling, a scientist / technician who worked in the WIV lab but whose lab web presence has been deleted.

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Response to Request No. 2:

See General Objections. EcoHealth Alliance objects to the Request to the extent it purports to seek information or documents that are not in EcoHealth Alliance's possession, custody, or control. EcoHealth Alliance further objects to the Request to the extent it seeks information that is not relevant to the Project. EcoHealth Alliance further objects to the extent the Request seeks documents and information concerning personal information relating to individuals who are not affiliated with the Project. Subject to and notwithstanding the foregoing and without prejudice thereto, EcoHealth Alliance responds that it lacks knowledge or information regarding the alleged "disappearance of Huang Yanling" or the contention that her "lab web presence has been deleted."

3. Provide the NIH with WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns.

Response to Request No. 3:

See General Objections. EcoHealth Alliance objects to the Request to the extent it purports to seek information or documents that are not in EcoHealth Alliance's possession, custody, or control. EcoHealth Alliance further objects to the Request to the extent it seeks information that is not relevant to the Project. Subject to and notwithstanding the foregoing and without prejudice thereto, EcoHealth Alliance responds that, upon information and belief, it is not in possession, custody, or control of "WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns."

4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.

Response to Request No. 4:

See General Objections. EcoHealth Alliance objects to the Request in that it is vague, ambiguous, or otherwise unclear as to the precise categories of documents and information that are being sought and because the term "out-of-ordinary" is undefined. EcoHealth Alliance further objects to the Request to the extent it purports to seek documents or information that are not in EcoHealth Alliance's possession, custody, or control. Subject to and notwithstanding the foregoing and without prejudice thereto, EcoHealth Alliance responds that it lacks knowledge or information regarding "diminished cell-phone traffic in October 2019" and/or "roadblocks surrounding [WIV] from October 14-19, 2019."

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5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.

Response to Request No. 5:

See General Objections. EcoHealth Alliance objects to the Request to the extent it purports to seek information or documents that are not in EcoHealth Alliance's possession, custody, or control. EcoHealth Alliance further objects to the Request to the extent it seeks information that is not relevant to the Project. Subject to and notwithstanding the foregoing and without prejudice thereto, EcoHealth Alliance responds that it lacks knowledge or information regarding the contention that "WIV failed to note that the RatG13 virus…was [] isolated from an abandoned mine where three men died in 2012" and why this was not followed up.

6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.

Response to Request No. 6:

See General Objections. EcoHealth Alliance objects to the Request to the extent it seeks to impose obligations on EcoHealth Alliance that are not authorized by the NIH Grants Policy Statement or any applicable statute or regulation. EcoHealth Alliance further objects to the Request to the extent it seeks to impose obligations that are wholly unrelated to the Project or EcoHealth Alliance's ongoing research funding by the Grant. Subject to and notwithstanding the foregoing and without prejudice thereto, EcoHealth Alliance responds that, on April 19, 2020, Michael S. Lauer, MD, NIH Deputy Director for Extramural Research, sent a letter to EcoHealth Alliance on behalf of NIH that stated that EcoHealth Alliance was not allowed to collaborate with WIV regarding the Project and that it should not remit any Grant funds to WIV. On April 21, 2020, Peter Daszak of EcoHealth Alliance sent an email to Dr. Lauer that confirmed (i) no funds from the Grant had been sent to WIV, (ii) no contract had been signed between EcoHealth Alliance regarding research funded under the Grant, and (iii) EcoHealth Alliance would not provide any funds to WIV. As a result, at this time, EcoHealth Alliance is not collaborating with WIV, is not

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in possession, custody, or control of WIV, and has no authority to grant NIAID and the U.S. National Academy of Sciences access the facility to conduct an inspection.

7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System.

Response to Request No. 7:

See General Objections. Subject to and notwithstanding the General Objections and without prejudice thereto, EcoHealth Alliance responds that, upon information and belief, as of the date of these responses, all of EcoHealth Alliance's subawards are fully reported in the Federal Subaward Reporting System.

Dated: New York, New York
August 13, 2020

TARTER KRINSKY & DROGIN LLP
Attorneys for EcoHealth Alliance

By: _____ (b) (6)
Andrew N. Krinsky
1350 Broadway, 11th Floor
New York, New York 10018
Tel: (b) (6)

TO: Dr. Michael S. Lauer ((b) (6)
Dr. Erik Stemmy ((b) (6)
Ms. Emily Linde ((b) (6)

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From: vinu arumugham| (b) (6)

Sent: Sat 8/22/2020 8:25:46 PM (UTC-05:00)

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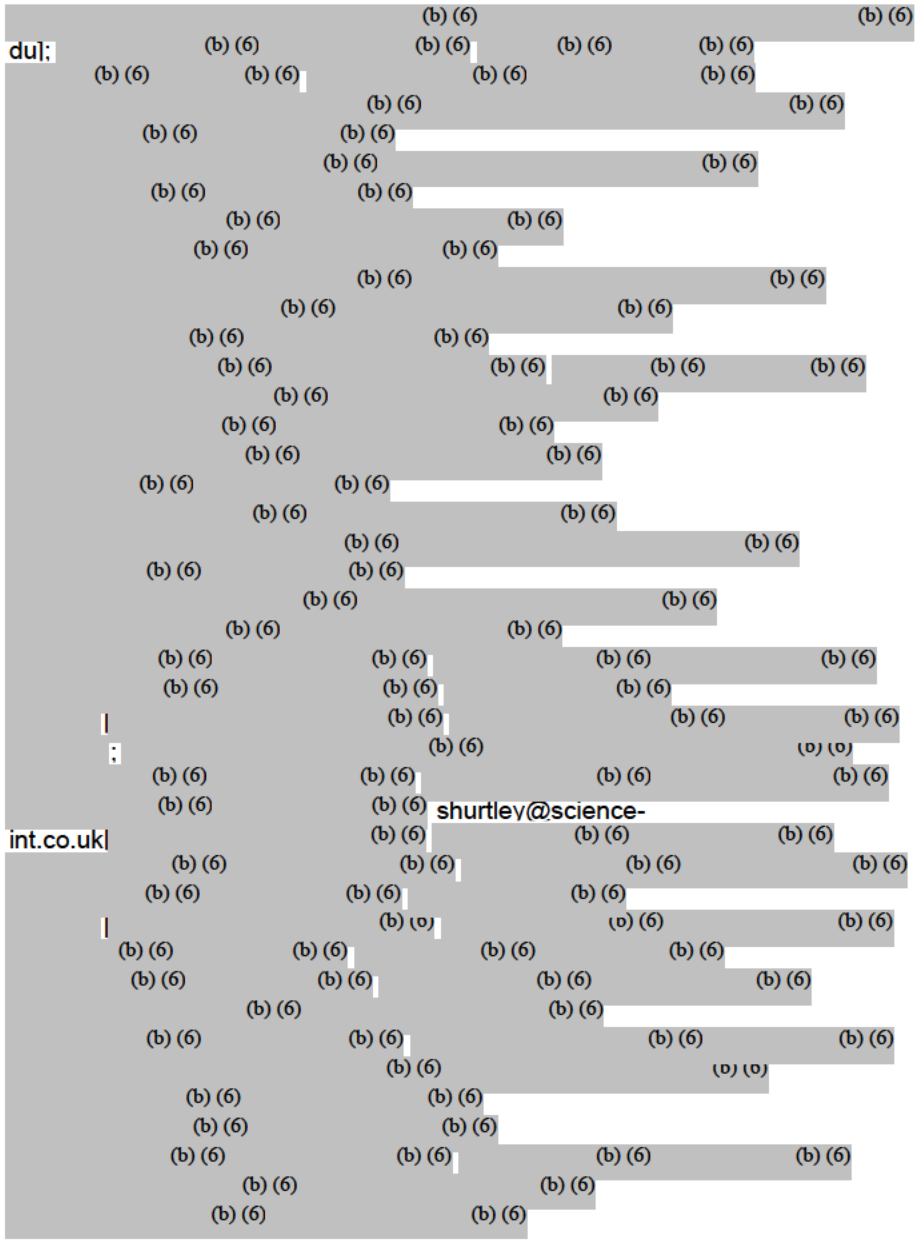

Subject: 77 mad, "Nobel scientists" are hell bent on ending humanity by creating the next pandemic virus

Peter Daszak is the scumbag who used NIH funding, insanely collecting wild infected bats and storing them at a Wuhan lab that leaks like a sieve, in the middle of a city of 11 million. As if that were not stupid enough, he performed gain-of-function research on these viruses with Wuhan labs. This guy almost successfully ended humanity by enabling Wuhan labs to create SARS-COV-2. **Not by engineering a virus but by their STUPID, SLOPPY experiments.** The Wuhan lab was transfecting HIV-1 derived plasmids into human embryonic kidney (HEK) cells. The SARS-CoV-2 virus which accidentally evolved in these HEK cells, predictably carries segments derived from HIV-1. **The smoking gun**. All done in BSL-2, where leaks are even

easier. Further, multiple researchers have found that SARS-CoV-2 was perfectly adapted to humans from the very beginning. Exactly as expected because it grew on HEK cells in a Wuhan lab. It did not jump from animals. It was created in a Wuhan lab.

Root cause of COVID-19? Biotechnology's dirty secret: Contamination. Bioinformatics evidence demonstrates that SARS-CoV-2 was created in a laboratory, unlikely to be a bioweapon but most likely a result of sloppy experiments

https://doi.org/10.5281/zenodo.3766462

Coronavirus may have been a 'cell-culture experiment' gone wrong
https://www.skynews.com.au/details/_6158843835001

SARS-CoV-2 is well adapted for humans. What does this mean for re-emergence?

https://www.biorxiv.org/content/10.1101/2020.05.01.073262v1

Now, 77 "Nobel scientists" performed the unimaginably stupid act of supporting this scumbag's "research", in a letter to the NIH. They have forever tarnished the Nobel Prize with this monumental stupidity.

https://www.sciencemag.org/sites/default/files/NL%20letter%20final.pdf

Even US labs are bio hazard labs that must be immediately shut down before they end humanity.

Near Misses at UNC Chapel Hill's High-Security Lab Illustrate Risk of Accidents With Coronaviruses

https://www.propublica.org/article/near-misses-at-unc-chapel-hills-high-security-lab-illustrate-risk-of-accidents-with-coronaviruses

Einstein has been proven right once again. Human stupidity is infinite. That is the only way to explain what these 77 "scientists" did.

Vinu

From: Lauer, Michael (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: Fri 10/23/2020 12:37:39 PM (UTC-05:00)

To: Aleksei Chmura[(b) (6)] Peter Daszak[(b) (6)]

Cc: Stemmy, Erik (NIH/NIAID) [E][(b) (6)] Erbelding, Emily (NIH/NIAID) [E][(b) (6)] Linde, Emily (NIH/NIAID) [E][(b) (6)] Bulls, Michelle G. (NIH/OD) [E][(b) (6)] Compliance Review[(b) (6)] Ta, Kristin (NIH/OD) [E][(b) (6)]

Subject: Re: PLEASE READ -- Re: Please read and acknowledge receipt -- update regarding 2R01AI110964-06

Attachment: NIH Response to EcoHealth Response to Suspension_10_23_20.pdf

Dear Dr. Chmura and Dr. Daszak

Please see attached.

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)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

23 October 2020

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

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

I am following up on Mr. Krinsky's August 13, 2020, letter on behalf of EcoHealth Alliance, Inc. ("EcoHealth") responding to NIH's suspension of grant R01AI110964, which funds the project *Understanding the Risk of Bat Coronavirus Emergence* (the "Project"). Per my letter of July 8, 2020, NIH reinstated the grant but suspended all award activities because we have concerns that the Wuhan Institute of Virology (WIV), which previously served as a subrecipient of the Project, had not satisfied safety requirements that applied to its subawards with EcoHealth, and that EcoHealth had not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance. EcoHealth objected to the suspension on the grounds that WIV has no *current* connection to the Project or EcoHealth's research, and EcoHealth had not issued any subawards in connection with the Grant *at the time of the suspension*.

The fact that EcoHealth does not currently have a subrecipient relationship with WIV and had not issued subawards to WIV at the time of suspension does not absolve EcoHealth of any past non-compliance with the terms and conditions of award for grant R01AI110964. While EcoHealth did not issue a subaward to WIV for year 6 of the grant, WIV served as a subrecipient for years 1 through 5. NIH awarded EcoHealth grant R01AI110964 in 2014, with a project period of June 1, 2014, through June 30, 2024, as renewed. In EcoHealth's grant application, EcoHealth listed Drs. Zheng Li Shi and Xing Yi Ge of WIV as co-investigators and senior/key personnel. It stated that "Drs. Shi, Zhang, and Daszak have collaborated together since 2002 and have been involved in running joint conferences, and shipping samples into and out of China." EcoHealth listed WIV as a Project/Performance Site Location. In describing WIV's facilities, EcoHealth described WIV as China's premier institute for virological research" and touted WIV's "fully equipped biosafety level 3 laboratory" and "a newly opened BLS-4 laboratory." In support of the application, Dr. Zheng Li Shi's personal statement indicated that "My lab will be responsible for diagnosis, genomics and isolation of coronavirus from wild and domestic animals in Southern China and for analyzing their receptor binding domains." The application stated that "Wuhan Institute of Virology and the Wuhan University Center for Animal Experiment BSL-3

lab have an Internal Biosafety Committee and are accredited BSL-2 and BSL 3 laboratories. All experimental work using infectious material will be conducted under appropriate biosafety standards. Disposal of hazardous materials will be conducted according to the institutional biosafety regulations."

EcoHealth requested funding specifically for activities to be carried out by WIV. NIH awarded EcoHealth a total of $749,976 for WIV's work in the following annual amounts for years 1 through 5:

	-Yr 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%	$9,896	$10,297	$11,787	$11,787	$11,787
TOTAL COSTS	$133,595	$139,015	$159,122	$159,122	$159,122

As stated in the Notices of Award for each budget period of the grant, the awards were subject to terms and conditions, which include the NIH Grants Policy Statement (GPS) and applicable HHS grant regulations. As I indicated in my letter of July 8, 2020, as a term and condition of award EcoHealth was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). See also, 45 C.F.R. § 75.342(a) ("The non-Federal entity is responsible for oversight of the operations of the Federal award supported activities."). Moreover, EcoHealth was required to "Establish and maintain effective internal control over the Federal award that provides reasonable assurance that the non-Federal entity is managing the Federal award in compliance with Federal statutes, regulations, and the terms and conditions of the Federal award[.]" 45 C.F.R. § 75.303(a). The Notice of Award stated that as a term and condition of award, "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]." Moreover, the NIH GPS provides that NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients, so these terms applied to WIV. 45 C.F.R. § 75.101.

As I stated, NIH has concerns of non-compliance with terms and conditions of award—namely, that WIV had not satisfied safety requirements under the award and that EcoHealth Alliance had not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance. Accordingly, NIH suspended all activities related to R01AI110964, pursuant to 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare.

In my letter of July 8, 2020, I provided EcoHealth with the opportunity to object and to provide information and documentation challenging the suspension. Specifically, I sought information and materials that speak to WIV's lab safety and EcoHealth's oversight of its subrecipient, and an inspection of WIV's laboratory records and facilities. I indicated that as a specific condition of award, during the period of suspension, EcoHealth Alliance may not allow research under this

project to be conducted and that no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients.

EcoHealth objected to the requests on the grounds that "NIAID is not authorized under 45 CFR§§ 75.371, 75.205, and 75.207, entitled *Specific Award Conditions*, to impose, *inter alia*, conditions that consist of demands for information regarding entities that are neither subrecipients of grant funds nor project affiliates."

These provisions are irrelevant to NIH's requests. NIH is required to permit the opportunity for recipients to object and provide information and documentation challenging a suspension, 45 C.F.R. § 75.374, so we specifically gave EcoHealth the opportunity to provide information that speaks to NIH's concerns. Moreover, as a granting agency, NIH is required to "manage and administer the Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented in full accordance with U.S. statutory and public policy requirements: Including, but not limited to, those protecting public welfare [and] the environment[.]" 45 C.F.R. § 75.300(a). In addition to seeking information that speaks to compliance with terms and conditions of award, NIH is entitled to "make site visits as warranted by program needs." 45 C.F.R. § 75.342. As a term and condition of award, NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. § 75.364); and must have "timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents" (id.). These requirements flow down to subawards to subrecipients. 45 C.F.R. § 75.101. "Non-Federal entities must comply with requirements in [45 C.F.R. Part 75] regardless of whether the non-Federal entity is a recipient or subrecipient of a Federal award." 45 C.F.R. 75.101. As the grantee, EcoHealth was required to have in place, "A requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part." 45 C.F.R. § 75.352(a)(5). For each of these reasons, NIH is justified in seeking the materials, information, and a site visit specified in my letter of July 8, 2020.

In addition to objecting to NIH's authority to seek the materials, information, and a site visit, EcoHealth has responded that it lacks knowledge or information regarding the requests; that it is not in possession, custody, or control of the specified items; and that it has no authority to grant NIAID and the U.S. National Academy of Sciences access to WIV's facility to conduct an inspection. EcoHealth's responses have not satisfied NIH's concerns that EcoHealth had failed to adequately monitor the compliance of its subrecipient, and that the subrecipient, WIV, had failed to comply with safety requirements.

Notwithstanding this, NIH is providing an additional opportunity for EcoHealth to provide information and documentation challenging these concerns of non-compliance. Accordingly, in addition to reiterating our prior requests (1) through (6) per our letter of July 8, 2020, NIH requests the following information and materials, which must be complete and accurate:

1. Provide copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award, including with respect to biosafety.
2. Describe EcoHealth's efforts to evaluate WIV's risk of noncompliance with Federal statutes, regulations, and the terms and conditions of the subaward.
3. Provide copies of all WIV biosafety reports from June 1, 2014 through May 31, 2019.

During the ongoing period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further assess whether EcoHealth Alliance and WIV complied with the terms and conditions of award, including compliance with other terms and conditions of award that may be implicated. We remind you that during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the continued suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 C.F.R. Part 75, including, but not limited to, terminating the grant award or disallowing costs. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2020.10.23 13:34:25 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy (NIAID)
Ms. Emily Linde (NIAID)

From: Peter Daszak[(b) (6)
Sent: Fri 7/23/2021 5:09:29 PM (UTC-05:00)
To: Lauer, Michael (NIH/OD) [E][(b) (6)
Cc: Aleksei Chmura[(b) (6)
Subject: Re: Regarding 2R01AI110964

Thanks very much for your email - we'll review and respond with full details within the timeframe indicated.

Cheers,

Peter

Peter Daszak
(Sent from my iPhone)

President
EcoHealth Alliance

460 West 34th Street, New York, NY10001, USA

www.EcoHealthAlliance.org

> On Jul 23, 2021, at 5:27 PM, Lauer, Michael (NIH/OD) [E]
> < (b) (6) wrote:
>
> Dear Dr. Chmura and Dr. Daszak
>
> Please see attached.
>
> 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:** Peter Daszak < (b) (6)

Date: Sunday, April 25, 2021 at 5:22 PM
To: "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Cc: Aleksei Chmura <(b) (6)
Subject: RE: Regarding 2R01AI110964

Thank you Dr. Lauer.

I hope you will consider our responses to all 10 of these conditions in the spirit that they are intended. Our research demonstrates that COVID-19 is unlikely to be the last coronavirus to spill over in China. The research that this grant funds is likely to be a critical part of the fight to prevent future spillover events. It is also a critical opportunity for the USA to have eyes and ears on the ground in a country that has seen two coronaviruses emerge and spread globally in the past 2 decades.

I urge you also to consider the toll that the termination of this grant has had on EcoHealth Alliance's reputation and our staff's welfare. During the last 12 months we have been the subject of a growing series of horrific attacks in the press, and via online conspiracy theorists, and physically (including a white powder letter delivered to my home address). This has had a damaging toll on myself, my family, and the staff at EcoHealth Alliance. These unwarranted attacks have been amplified by the public discourse around the termination and current suspension of this award.

We await your decision on this suspension with great interest and remain at-the-ready to continue this work, as do our collaborators in China.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

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

From: Lauer, Michael (NIH/OD) [E] <(b) (6)
Sent: Sunday, April 25, 2021 4:23 PM
To: Peter Daszak <(b) (6)
Cc: Aleksei Chmura <(b) (6) Lauer, Michael (NIH/OD) [E] <(b) (6)
Subject: Re: Regarding 2R01AI110964

Thank you, we were able to access to download all the files. We will review and let you know what additional information we need.

Many thanks, Mike

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

From: Peter Daszak <(b) (6)
Date: Friday, April 23, 2021 at 7:10 AM
To: "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Cc: Aleksei Chmura <(b) (6)
Subject: RE: Regarding 2R01AI110964

Thanks – I've uploaded all the files into the Box account now.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200

New York, NY 10018-6507
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

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

---

From: Lauer, Michael (NIH/OD) [E] < (b) (6)
Sent: Friday, April 23, 2021 6:11 AM
To: Peter Daszak < (b) (6)
Cc: Aleksei Chmura < (b) (6) Lauer, Michael (NIH/OD) [E] < (b) (6)
Subject: Re: Regarding 2R01AI110964

Thank you Dr. Daszak. We cannot use Dropbox due to security concerns. I've just created a Box folder. I put this letter into it and gave you Editor permission. You should be receiving an email from Box shortly. Please upload your files there.

Many thanks, Mike

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

From: Peter Daszak < (b) (6)
Date: Thursday, April 22, 2021 at 11:44 PM
To: "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Cc: Aleksei Chmura < (b) (6)
Subject: Regarding 2R01AI110964

Dear Dr. Lauer,

Please see attached our response to your request dated 4.13.21. The files we refer to in the letter can be accessed on the following Dropbox link. Please let me know if you need them sent in another format.

https://www.dropbox.com/sh/qbfw1dywds6host/AACUofeiIkA4QMALEJLH4FXza?dl=0

We look forward to hearing of your decision on our efforts to address the 10 conditions on the suspended grant.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

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

---

From: Lauer, Michael (NIH/OD) [E] < (b) (6)
Sent: Tuesday, April 13, 2021 1:17 PM
To: Peter Daszak < (b) (6)
Cc: Aleksei Chmura < (b) (6) Lauer, Michael (NIH/OD) [E] < (b) (6)
Subject: Re: Regarding R01AI110964

Many thanks again Dr. Daszak. We are continuing our review, but in the meantime please see attached. The third (last) attachment is what's new.

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)

From: "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Date: Sunday, April 11, 2021 at 5:19 PM
To: Peter Daszak < (b) (6)
Cc: Aleksei Chmura < (b) (6) "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Subject: Re: Regarding 2R01AI110964-06

Many thanks, Dr. Daszak, I received your letter. We will review it and get back to you.

Best, Mike

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

From: Peter Daszak < (b) (6)
Date: Sunday, April 11, 2021 at 4:39 PM
To: "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Cc: Aleksei Chmura < (b) (6)
Subject: Regarding 2R01AI110964-06

Dear Dr. Lauer,

Please find attached a detailed response to your two previous letters.

I hope you will take our response in the way it was intended– a good faith effort to address as far as is reasonably possible the general concerns that NIH has expressed to us, with a goal of rapid and full removal of the suspension on funding for this critically important work.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

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

---

From: Lauer, Michael (NIH/OD) [E] < (b) (6)
Sent: Wednesday, March 10, 2021 5:37 AM
To: Peter Daszak < (b) (6)
Cc: Aleksei Chmura < (b) (6) Lauer, Michael (NIH/OD) [E] < (b) (6)
Subject: Re: Regarding 2R01AI110964-06

Dear Dr. Daszak

Attached please find two letters that I sent you previously.

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: Peter Daszak < (b) (6)
Date: Thursday, March 4, 2021 at 10:02 PM
To: "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Cc: Aleksei Chmura

< (b) (6) ***Peter Daszak:]***
REDACTED>
Subject: Regarding 2R01AI110964-06

Dear Dr. Lauer,

I spoke yesterday with my program officer and other NIAID staff regarding our grant on the risk of coronavirus emergence (2R01AI110964-06) that includes collaboration with scientists at the Wuhan Institute of Virology, China. ***[Peter Daszak:]*** **REDACTED** joined the meeting and told me about his conversation with you about the conditions currently in place on our grant and my efforts to address some of them via my recent work in Wuhan with the WHO. He also commented that you would be willing to talk with me, as PI of this award, about a pathway to reinstate this grant. I would very much value this and am emailing to see if we can arrange a time that's suitable for you, perhaps next week if possible?

I'm cc'ing my assistant **REDACTED**, who can help arrange a suitable time, and also our Chief of Staff Aleksei Chmura, who I would hope could join us, as someone who can access any relevant information on this award, and gained his own Ph.D as part of our original R01 work in China. I want to reassure you that I would not request to talk with legal counsel or bring them into a conversation, and that this would be a discussion with scientists focused on the goals of the grant, focused on research to protect us all against further coronavirus spillover.

Sincerely,

Peter

Peter Daszak
President

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

USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org

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<mime-attachment>
<To EcoHealth 7 23 21 R01AI110964.pdf>
<5U01AI151797-02[2].pdf>

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From: Lauer, Michael (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: Fri 7/23/2021 4:27:41 PM (UTC-05:00)

To: Peter Daszak[(b) (6) Aleksei Chmura[(b) (6)

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

Subject: Re: Regarding 2R01AI110964

Attachment: Regarding 2R01AI110964

Attachment: To EcoHealth 7 23 21 R01AI110964.pdf

Attachment: 5U01AI151797-02[2].pdf

Dear Dr. Chmura and Dr. Daszak

Please see attached.

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: Peter Daszak < (b) (6)
Date: Sunday, April 25, 2021 at 5:22 PM
To: "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Cc: Aleksei Chmura < (b) (6)
Subject: RE: Regarding 2R01AI110964

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I urge you also to consider the toll that the termination of this grant has had on EcoHealth Alliance's reputation and our staff's welfare. During the last 12 months we have been the subject of a growing series of horrific attacks in the press, and via online conspiracy theorists, and physically (including a white powder letter delivered to my home address). This has had a damaging toll on myself, my family, and the staff at EcoHealth Alliance. These unwarranted attacks have been amplified by the

public discourse around the termination and current suspension of this award.

We await your decision on this suspension with great interest and remain at-the-ready to continue this work, as do our collaborators in China.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
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New York, NY 10018-6507
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Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

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

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From: Lauer, Michael (NIH/OD) [E] < (b) (6)
Sent: Sunday, April 25, 2021 4:23 PM
To: Peter Daszak < (b) (6)
Cc: Aleksei Chmura < (b) (6) Lauer, Michael (NIH/OD) [E] < (b) (6)
Subject: Re: Regarding 2R01AI110964

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Many thanks, Mike

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

From: Peter Daszak <(b) (6)
Date: Friday, April 23, 2021 at 7:10 AM
To: "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Cc: Aleksei Chmura <(b) (6)
Subject: RE: Regarding 2R01AI110964

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Twitter: @PeterDaszak

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

From: Lauer, Michael (NIH/OD) [E] <(b) (6)
Sent: Friday, April 23, 2021 6:11 AM
To: Peter Daszak <(b) (6)
Cc: Aleksei Chmura <(b) (6) Lauer, Michael (NIH/OD) [E] <(b) (6)
Subject: Re: Regarding 2R01AI110964

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Many thanks, Mike

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

From: Peter Daszak <(b) (6)
Date: Thursday, April 22, 2021 at 11:44 PM
To: "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Cc: Aleksei Chmura <(b) (6)
Subject: Regarding 2R01AI110964

Dear Dr. Lauer,

Please see attached our response to your request dated 4.13.21. The files we refer to in the letter can be accessed on the following Dropbox link. Please let me know if you need them sent in another format.

(b) (6)

We look forward to hearing of your decision on our efforts to address the 10 conditions on the suspended grant.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance

520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

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

---

From: Lauer, Michael (NIH/OD) [E] < (b) (6)
Sent: Tuesday, April 13, 2021 1:17 PM
To: Peter Daszak < (b) (6)
Cc: Aleksei Chmura < (b) (6) Lauer, Michael (NIH/OD) [E] < (b) (6)
Subject: Re: Regarding R01AI110964

Many thanks again Dr. Daszak. We are continuing our review, but in the meantime please see attached. The third (last) attachment is what's new.

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)

From: "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Date: Sunday, April 11, 2021 at 5:19 PM
To: Peter Daszak < (b) (6)
Cc: Aleksei Chmura < (b) (6) "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Subject: Re: Regarding 2R01AI110964-06

Many thanks, Dr. Daszak, I received your letter. We will review it and get back to you.

Best, Mike

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

From: Peter Daszak <(b) (6)
Date: Sunday, April 11, 2021 at 4:39 PM
To: "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Cc: Aleksei Chmura <(b) (6)
Subject: Regarding 2R01AI110964-06

Dear Dr. Lauer,

Please find attached a detailed response to your two previous letters.

I hope you will take our response in the way it was intended – a good faith effort to address as far as is reasonably possible the general concerns that NIH has expressed to us, with a goal of rapid and full removal of the suspension on funding for this critically important work.

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From: Lauer, Michael (NIH/OD) [E] <(b) (6)
Sent: Wednesday, March 10, 2021 5:37 AM
To: Peter Daszak <(b) (6)
Cc: Aleksei Chmura <(b) (6) Lauer, Michael

(NIH/OD) [E] < (b) (6)
Subject: Re: Regarding 2R01AI110964-06

Dear Dr. Daszak

Attached please find two letters that I sent you previously.

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: Peter Daszak < (b) (6)
Date: Thursday, March 4, 2021 at 10:02 PM
To: "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Cc: Aleksei Chmura < (b) (6) ***Peter Daszak:]***
REDACTED>
Subject: Regarding 2R01AI110964-06

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I'm cc'ing my assistant **REDACTED**, who can help arrange a suitable time, and also our Chief of Staff Aleksei Chmura, who I would hope could join us, as someone who can access any relevant information on this award, and gained his own Ph.D as part of our original R01 work in China. I want to reassure you that I would not request to talk with legal counsel or bring them into a conversation, and that this would be a discussion with scientists focused on the goals of the grant, focused on

research to protect us all against further coronavirus spillover.

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New York, NY 10001
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From: Peter Daszak[(b) (6)
Sent: Thur 4/22/2021 10:43:18 PM (UTC-05:00)
To: Lauer, Michael (NIH/OD) [E][(b) (6)
Cc: Aleksei Chmura[(b) (6)
Subject: Regarding 2R01AI110964
Attachment: Response to letter of 4.13.21.pdf

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(b) (6)

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To: Peter Daszak <(b) (6)
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NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
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Sent: Wednesday, March 10, 2021 5:37 AM
To: Peter Daszak < (b) (6)
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1 Center Drive, Building 1, Room 144
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Phone: (b) (6)

Email: (b) (6)

From: Peter Daszak <(b) (6)
Date: Thursday, March 4, 2021 at 10:02 PM
To: "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Cc: Aleksei Chmura <(b) (6) ***Peter Daszak:]*** REDACTED>
Subject: Regarding 2R01AI110964-06

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EcoHealth Alliance

Dr. Michael Lauer
Deputy Director for Extramural Research,
NIH, Bethesda, MD.

Re: R01AI110964 and 2R01AI110964
"Understanding the Risk of Bat Coronavirus Emergence"

April 23rd 2021

Dear Dr. Lauer,

I am responding your letter of 4/13/21 regarding our response to conditions placed on the suspended NIH grant 2R01AI110964 "*Understanding the Risk of Bat Coronavirus Emergence*". In particular, this letter addresses your request for documentation on our assessment of WIV's compliance with terms of our subcontracts from the initial (now expired) 5-year award:

"*…copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any and all other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award …. NIH must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. § 75.364); and must have "timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents" (id.). These requirements flow down to subawards to subrecipients. 45 C.F.R. § 75.101. "Non-Federal entities must comply with requirements in [45 C.F.R. Part 75] regardless of whether the non-Federal entity is a recipient or subrecipient of a Federal award." 45 C.F.R. 75.101. As the grantee, EcoHealth was required to have in place, "A requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part." 45 C.F.R. § 75.352(a)(5)…"*

As requested, we have supplied all EcoHealth Alliance-WIV subrecipient agreements, as well as documents pertaining to EHA's monitoring of WIV's compliance with the terms and conditions of award. The attached documents demonstrate that we have fulfilled all requirements in the CFR codes listed in your letter excerpted above. These documents include:

1. EcoHealth Alliance 2016-2019 Subrecipient Monitoring Forms for WIV. EcoHealth Alliance began this formal subrecipient monitoring policy in 2016 as per OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR 200) ("Uniform Guidance"), specifically §200.331.
2. 2006-2018 WIV Annual Reports. In addition, NIH has full reports on the programmatic results that we filed annually.
3. Wuhan Institute of Virology contracts and invoices for all 5 Years of Grant R01AI110964: 2014-2019
4. Federal Funding Accountability & Transparency Act Reports for WIV. From 2015 – 2019
5. Annual Independent Audit Reports from 2014-2019
6. Inter-Institutional Agreements from DHHS for WIV 2014 & 2019

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018
212.380.4460
EcoHealthAlliance.org

We hope these documents satisfy your request by demonstrating that EcoHealth Alliance maintained detailed records of our appropriate monitoring of WIV's performance against the conditions of our initial (now expired) R01 grant and our contracts with them.

We also would like draw your attention to our letter dated 4.11.2021 regarding plans for biosafety monitoring for the renewal R01, under which we had not yet set up a subcontract with WIV, specifically:

"8. Provide copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award, including with respect to biosafety.
As we related in response to your letter of 4/19/2020 that asked us to suspend work with WIV, we had not yet set up a subcontract with WIV for the period of this award, therefore no such subrecipient agreements exist. Our plan was to monitor WIV's compliance as we had in the 5 years prior, by means of semi-annual meetings with the lead investigator and assessments of compliance against all conditions of the award. Additionally, following the NIH's termination, then reinstatement and suspension of our funding, we have contracted with a leading lab biosafety contractor based in Southeast Asia (Dr. Paul Selleck) who has extensive experience commissioning, accrediting and auditing BSL-2, -3, and -4 labs, and has worked for over a decade at the BSL-4 Australian Animal Health Lab. We will be using their services where appropriate for foreign lab subcontractees to assess lab biosafety procedures and conduct audits, including following the full reinstatement of 2R01AI110964. Finally, we have appointed a Senior Field Veterinarian who will oversee all EcoHealth Alliance fieldwork in the region and ensure continued compliance with biosafety when conducting animal capture, sampling and sample handling. We have done this at EcoHealth Alliance's own expense, despite our unblemished record on biosafety, to pre-empt calls for further sanctions against our work given the continued attacks against EcoHealth Alliance in the press after the termination of our NIH grant."

We believe the attached documents lay out details of how we had previously monitored compliance according to the federal codes you cite, and the above response lays out an appropriate plan for biosafety monitoring. Together, we believe they appropriately and fully addresses your condition #8 for full reinstatement with access to funding for the renewal phase of the R01.

Yours sincerely,

Dr. Peter Daszak, President
(t) (b) (6); (e) (b) (6)

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018
212.380.4460
EcoHealthAlliance.org

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

23 July 2021

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

Re: R01AI110964, U01AI151797, U01AI153420

Dear Drs. Chmura and Daszak:

Thank you for your correspondence of April 11, 2021 and April 23, 2021 regarding R01AI110964. We are in the process of conducting detailed analyses of your answers to our questions and well as of the documents you sent, and we have the following additional requests:

1. Records

For us to continue our analyses, we will need to receive and review WIV's records validating expenditures specific to R01AI110964 as well as any and all monitoring, safety, and financial reports specific to R01AI110964 that WIV submitted to you. As a reminder, subawardees are required to have a financial management system that includes records that identify adequately the source and application of funds for federally-funded activities. These records must contain information pertaining to Federal awards, authorizations, obligations, unobligated balances, assets, expenditures, income and interest and be supported by source documentation. 45 C.F.R. §§ 75.101 and 75.302.

As a term and condition of award, NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. 75.364). This right of access applies not only to awardee records, but also to subawardee records. Awardees indicate their acceptance of an NIH award and its associated terms and conditions as they draw down the NIH grant funds to support the scientific project (see NIHGPS Section 5).

REL0000047832.0002

We will also need to see subaward agreements, subawardee audit reports, subawardee safety monitoring documents, subawardee progress reports submitted to you, and subawardee financial and accounting records for two other NIH EcoHealth Alliance grants. Specifically, please send us all responsive documents for:

- U01AI151797 (Daszak): subawardees Chulalongkorn Hospital, Chulalongkorn University, Duke-National Singapore University, and University of North Carolina at Chapel Hill
- U01AI153420 (Epstein): subawardees International Center for Diarrhoeal Disease Research of Bangladesh, Institute of Epidemiology Disease Control and Research of Bangladesh.

We remind you that the Notice of Award for U01AI151797 already contains the following specific award conditions that must still be satisfied by 30 days from establishment.

> Subaward Agreement Requirements: The ECOHEALTH ALLIANCE, INC. must provide NIAID with copies of all (existing and newly established) subaward agreements established under this award, including descriptions of the biosafety monitoring plans, within 30 days of establishment.
>
> Federal Funding Accountability and Transparency Subaward Reporting System (FSRS) Requirements: This award is subject to the Transparency Act subaward reporting requirement of 2 CFR Part 170, which must be reported through the Federal Funding Accountability and Transparency Subaward Reporting System (FSRS). The ECOHEALTH ALLIANCE, INC. must provide NIAID with proof of documentation of timely entries of subaward information into the FSRS within 30 days of submitting to FSRS.

2. Reports

We are also writing to notify you that a review of our records for R01AI110964 indicates that EcoHealth Alliance, Inc. is out of compliance with requirements to submit the following reports that are outlined in the NIHGPS: the Federal Financial Report (FFR, see 8.4.1.2.3 Modified Financial Reporting Requirements) and the Interim Research Performance Progress Report (I-RPPR, see NIHGPS 8.4.1.4 Final Research Performance Progress Report).

R01AI110964 was issued under the Streamlined Noncompeting Award Process (SNAP). For awards under SNAP, an FFR must be submitted within 120 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment.

Additionally, NIH requires that organizations submit an Interim-RPPR while their Type 2 application is under consideration. In the event that the Type 2 is funded, NIH treats the Interim-RPPR as the annual performance report for the final year of the previous competitive segment.

The FFR and I-RPPR for R01AI110964 were due within 120 days after the end of the project period. In this case, the competitive segment ended on May 31, 2019, and reports were due September 30, 2019. To date, NIH has still not received these reports. Compliance with Section 8, Administrative Requirements within the NIH Grants Policy Statement (NIHGPS) is a standard term and condition of award that applies to all NIH recipients.

A recipient's failure to comply with the terms and conditions of award, may cause NIH to take one or more actions on the award, depending on the severity and duration of the non-compliance. Additionally, a history of non-compliance related to R01AI110964, including reporting non-compliance, may impact other projects where EcoHealth serves as the primary grant recipient. When a recipient has a history of failure to comply with the general or specific terms and conditions of a previous Federal award, NIH may impose specific award conditions on other awards of the recipient, including withholding authority to proceed to the next phase of a project until receipt of evidence of acceptable performance (see NIHGPS Section 8.5, Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support).

In closing, please be advised that EcoHealth Alliance, Inc. must satisfy the existing specific award condition for U01AI151797 by 30 days from establishment and must provide the remaining documents and reports requested herein for all three grants (R01AI110964, U01AI151797, U01AI153420) no later than August 27, 2021.

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

Sincerely,

Lauer, Michael (NIH/OD) [E]

Digitally signed by Lauer, Michael (NIH/OD) [E]
Date: 2021.07.23 17:24:01 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
(b) (6)

cc: Ms. Emily Linde
Dr. Erik Stemmy

Recipient Information

1. Recipient Name
ECOHEALTH ALLIANCE INC.
520 8TH AVE RM 1200

NEW YORK, NY 10018

2. Congressional District of Recipient
12

3. Payment System Identifier (ID)
1311726494A1

4. Employer Identification Number (EIN)
311726494

5. Data Universal Numbering System (DUNS)
077090066

6. Recipient's Unique Entity Identifier

7. Project Director or Principal Investigator
Peter Daszak, PHD
Executive Director
(b) (6)
212 380 4474

8. Authorized Official
Dr. Peter Daszak
(b) (6)
(b) (6)
(212) 380-4460

Federal Agency Information

9. Awarding Agency Contact Information
Shaun W Gratton
Grants Management Specialist
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
(b) (6)
(b) (6)

10. Program Official Contact Information
Jean Lois Patterson

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
(b) (6)
(b) (6)

Federal Award Information

11. Award Number
5U01AI151797-02

12. Unique Federal Award Identification Number (FAIN)
U01AI151797

13. Statutory Authority
42 USC 241 31 USC 6305 42 CFR 52

14. Federal Award Project Title
Understanding Risk of Zoonotic Virus Emergence in EID Hotspots of Southeast Asia

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 06/01/2021 **– End Date** 05/31/2022	
20. Total Amount of Federal Funds Obligated by this Action	$1,505,568
20 a. Direct Cost Amount	$1,348,346
20 b. Indirect Cost Amount	$157,222
21. Authorized Carryover	$0
22. Offset	$0
23. Total Amount of Federal Funds Obligated this budget period	$1,505,568
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$1,505,568
26. Project Period Start Date 06/17/2020 **– End Date** 05/31/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$3,052,312

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Gregory P. Smith

30. Remarks

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

RESEARCH PROJECT COOPERATIVE AGREEMENT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 5U01AI151797-02

Principal Investigator(s):
Peter Daszak, PHD

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

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $1,505,568 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to EcoHealth Alliance in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 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 recipient when funds are drawn down or otherwise requested 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 U01AI151797. 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 direct questions to the Federal Agency contacts.

Sincerely yours,

Gregory P. Smith
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Version: 203 - 1/27/2021 10:14 PM | Generated on: 6/11/2021 12:07 AM

Salaries and Wages	$272,729
Fringe Benefits	$96,545
Personnel Costs (Subtotal)	$369,274
Consultant Services	$29,976
Materials & Supplies	$917
Travel	$72,168
Other	$11,991
Subawards/Consortium/Contractual Costs	$857,026
Publication Costs	$6,994

Federal Direct Costs	$1,348,346
Federal F&A Costs	$157,222
Approved Budget	$1,505,568
Total Amount of Federal Funds Authorized (Federal Share)	$1,505,568
TOTAL FEDERAL AWARD AMOUNT	$1,505,568

AMOUNT OF THIS ACTION (FEDERAL SHARE)	$1,505,568

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$1,505,568	$1,505,568
3	$1,504,400	$1,504,400
4	$1,503,220	$1,503,220
5	$1,502,037	$1,502,037

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

Fiscal Information:

Payment System Identifier:	1311726494A1
Document Number:	UAI151797A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2021

IC	CAN	2021	2022	2023	2024
AI	8472315	$1,505,568	$1,504,400	$1,503,220	$1,502,037

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

NIH Administrative Data:
PCC: M32F B / **OC**: 41029 / **Released**: Smith, Gregory 06/10/2021
Award Processed: 06/11/2021 12:07:49 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5U01AI151797-02

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 – STANDARD TERMS AND CONDITIONS – 5U01AI151797-02

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:

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).

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

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) U01AI151797. 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 SPECIFIC AWARD CONDITIONS – 5U01AI151797-02

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REL0000047832.0003

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.

Total costs requested in the non-competing grant progress report exceed the amount previously committed. Funds are awarded at the committed level from the last Notice of Award.

****

Subaward Agreement Requirements: The ECOHEALTH ALLIANCE, INC. must provide NIAID with copies of all (existing and newly established) subaward agreements established under this award, including descriptions of the biosafety monitoring plans, within 30 days of establishment.

Federal Funding Accountability and Transparency Subaward Reporting System (FSRS) Requirements: This award is subject to the Transparency Act subaward reporting requirement of 2 CFR Part 170, which must be reported through the Federal Funding Accountability and Transparency Subaward Reporting System (FSRS). The ECOHEALTH ALLIANCE, INC. must provide NIAID with proof of documentation of timely entries of subaward information into the FSRS within 30 days of submitting to FSRS.

+++++++

This award does not include funds to support research subject to the *Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (DHHS P3CO Framework) Therefore:

- For Aim 1: Identify, characterize and rank spillover risk of high zoonotic potential viruses from wildlife, the building of chimeric SARS-like bat coronaviruses will be based on the SHC014 or the pangolin coronavirus molecular clones and the building of chimeric MERS-CoV will be based on the HKU5 strain. Prior to further altering the mutant viruses you must provide NIAID with a detailed description of the proposed alterations and supporting evidence for the anticipated phenotypic characteristics of each virus.
- Alternative approaches to those referenced above, including building chimeras based on SARS-CoV-1, SARS-CoV-2, and MERS-CoV, may be subject to the DHHS P3CO Framework and must be submitted to NIAID for review and approval prior to the work commencing.

If any of the experiments proposed for Aim 1 result in a virus with a phenotype of enhanced pathogenicity and/or transmissibility, enhanced growth by more than 10 fold when compared to wild type strains, or if the mice display significant increases in weight loss, viral titer, or mortality when compared to wild-type strains, the recipient must immediately stop the work and notify the NIAID Program Officer, Grants Management Specialist, and appropriate institutional biosafety committee. Policy changes regarding the classification of these experiments or components used in these experiments may be subject to immediate halting of experimentation. No NIH funding can be used to perform such experiments until these experiments have been approved by NIAID with a revised NOA.

****

Dissemination of study data will be in accord with the Recipient's accepted genomic data sharing plan as stated on page(s) **373** 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 includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

****

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:

Jeppesen Field Consulting Australia - AUSTRALIA
Conservation Medicine Ltd. - MALAYSIA
Duke-NUS Medical School - SINGAPORE
Chulalongkorn University - THAILAND

****
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 Notice of Award (NoA) includes funds for activity with **Conservation Medicine Ltd. - MALAYSIA** in the amount of **$224,821** (**$208,167** direct costs + **$16,654** F&A costs).

****
This Notice of Award (NoA) includes funds for activity with **Duke-NUS Medical School - SINGAPORE** in the amount of **$107,915** (**$99,921** direct costs + **$7,994** F&A costs).

****
This Notice of Award (NoA) includes funds for activity with **Chulalongkorn University - THAILAND** in the amount of **$215,774** (**$199,791** direct costs + **$15,983** F&A costs).

****
This Notice of Award (NoA) includes funds for activity with **The University of North Carolina at Chapel Hill** in the amount of **$194,221** (**$124,901** direct costs + **$69,320** F&A costs).

****
This Notice of Award (NoA) includes funds for activity **The Henry M. Jackson Fdn. for the Adv'mt. of Mil. Med., Inc**. in the amount of **$114,294** (**$74,941** direct costs + **$39,353** F&A costs).

****

This award is issued as a Cooperative Agreement, a financial assistance mechanism in which substantial NIH scientific and/or programmatic involvement is anticipated in the performance of the activity. This award is subject to the Terms and Conditions of Award as set forth in Section VI: Award Administrative Information of **RFA AI-19-028**, "**Emerging Infectious Diseases Research Centers**," posted date **3/5/2019**, which are hereby incorporated by reference as special terms and conditions of this award.

This RFA may be accessed at: http://grants.nih.gov/grants/guide/index.html

****
This award is subject to the Clinical Terms of Award referenced in the 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/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.

SPREADSHEET SUMMARY
AWARD NUMBER: 5U01AI151797-02

INSTITUTION: EcoHealth Alliance

Budget	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$272,729	$272,938	$272,938	$272,938
Fringe Benefits	$96,545	$96,628	$96,628	$96,628
Personnel Costs (Subtotal)	$369,274	$369,566	$369,566	$369,566
Consultant Services	$29,976	$15,000	$15,000	$15,000
Materials & Supplies	$917	$7,918	$7,918	$7,918
Travel	$72,168	$72,225	$72,225	$72,225
Other	$11,991	$27,000	$27,000	$27,000
Subawards/Consortium/Contractual Costs	$857,026	$855,344	$854,164	$852,981
Publication Costs	$6,994			
TOTAL FEDERAL DC	$1,348,346	$1,347,053	$1,345,873	$1,344,690
TOTAL FEDERAL F&A	$157,222	$157,347	$157,347	$157,347
TOTAL COST	$1,505,568	$1,504,400	$1,503,220	$1,502,037

Facilities and	Year 2	Year 3	Year 4	Year 5

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Administrative Costs				
F&A Cost Rate 1	32%	32%	32%	32%
F&A Cost Base 1	$491,320	$491,709	$491,709	$491,709
F&A Costs 1	$157,222	$157,347	$157,347	$157,347

From: Peter Daszak[(b) (6)
Sent: Fri 4/23/2021 6:08:10 AM (UTC-05:00)
To: Lauer, Michael (NIH/OD) [E][(b) (6)
Cc: Aleksei Chmura[(b) (6)
Subject: RE: Regarding 2R01AI110964

Thanks – I've uploaded all the files into the Box account now.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

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

---

From: Lauer, Michael (NIH/OD) [E] < (b) (6)
Sent: Friday, April 23, 2021 6:11 AM
To: Peter Daszak < (b) (6)
Cc: Aleksei Chmura < (b) (6) Lauer, Michael (NIH/OD) [E] < (b) (6)
Subject: Re: Regarding 2R01AI110964

Thank you Dr. Daszak. We cannot use Dropbox due to security concerns. I've just created a Box folder. I put this letter into it and gave you Editor permission. You should be receiving an email from Box shortly. Please upload your files there.

Many thanks, Mike

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

From: Peter Daszak <(b) (6)
Date: Thursday, April 22, 2021 at 11:44 PM
To: "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Cc: Aleksei Chmura <(b) (6)
Subject: Regarding 2R01AI110964

Dear Dr. Lauer,

Please see attached our response to your request dated 4.13.21. The files we refer to in the letter can be accessed on the following Dropbox link. Please let me know if you need them sent in another format.

(b) (6)

We look forward to hearing of your decision on our efforts to address the 10 conditions on the suspended grant.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507

USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

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

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From: Lauer, Michael (NIH/OD) [E] < (b) (6)
Sent: Tuesday, April 13, 2021 1:17 PM
To: Peter Daszak < (b) (6)
Cc: Aleksei Chmura < (b) (6) Lauer, Michael (NIH/OD) [E] < (b) (6)
Subject: Re: Regarding R01AI110964

Many thanks again Dr. Daszak. We are continuing our review, but in the meantime please see attached. The third (last) attachment is what's new.

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)

From: "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Date: Sunday, April 11, 2021 at 5:19 PM
To: Peter Daszak < (b) (6)
Cc: Aleksei Chmura < (b) (6) "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Subject: Re: Regarding 2R01AI110964-06

Many thanks, Dr. Daszak, I received your letter. We will review it and get back to you.

Best, Mike

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

From: Peter Daszak <(b) (6)
Date: Sunday, April 11, 2021 at 4:39 PM
To: "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Cc: Aleksei Chmura <(b) (6)
Subject: Regarding 2R01AI110964-06

Dear Dr. Lauer,

Please find attached a detailed response to your two previous letters.

I hope you will take our response in the way it was intended– a good faith effort to address as far as is reasonably possible the general concerns that NIH has expressed to us, with a goal of rapid and full removal of the suspension on funding for this critically important work.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

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

From: Lauer, Michael (NIH/OD) [E] <(b) (6)
Sent: Wednesday, March 10, 2021 5:37 AM
To: Peter Daszak <(b) (6)
Cc: Aleksei Chmura <(b) (6) Lauer, Michael (NIH/OD) [E] <(b) (6)
Subject: Re: Regarding 2R01AI110964-06

Dear Dr. Daszak

Attached please find two letters that I sent you previously.

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: Peter Daszak < (b) (6)
Date: Thursday, March 4, 2021 at 10:02 PM
To: "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Cc: Aleksei Chmura < (b) (6) ***Peter Daszak:]*** REDACTED>
Subject: Regarding 2R01AI110964-06

Dear Dr. Lauer,

I spoke yesterday with my program officer and other NIAID staff regarding our grant on the risk of coronavirus emergence (2R01AI110964-06) that includes collaboration with scientists at the Wuhan Institute of Virology, China. ***[Peter Daszak:]*** **REDACTED** joined the meeting and told me about his conversation with you about the conditions currently in place on our grant and my efforts to address some of them via my recent work in Wuhan with the WHO. He also commented that you would be willing to talk with me, as PI of this award, about a pathway to reinstate this grant. I would very much value this and am emailing to see if we can arrange a time that's suitable for you, perhaps next week if possible?

I'm cc'ing my assistant **REDACTED**, who can help arrange a suitable time, and also our Chief of Staff Aleksei Chmura, who I would hope could join us, as someone who can access any relevant information on this award, and gained his own Ph.D as part of our original R01 work in China. I want to reassure you that I would not request to talk with legal counsel or bring them into a conversation, and that this would be a discussion with scientists focused on the goals of the grant, focused on research to protect us all against further coronavirus spillover.

Sincerely,

Peter

Peter Daszak
President

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

Tel.: (b) (6)
Website: www.ecohealthalliance.org

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

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From: Peter Daszak[(b) (6)
Sent: Wed 4/14/2021 1:24:38 PM (UTC-05:00)
To: Lauer, Michael (NIH/OD) [E][(b) (6)
Cc: Aleksei Chmura[(b) (6)
Subject: RE: Regarding R01AI110964

Thank you Dr. Lauer – we will work on this and get back to you with a response and supplementary documents as appropriate.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

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

---

From: Lauer, Michael (NIH/OD) [E] < (b) (6)
Sent: Tuesday, April 13, 2021 1:17 PM
To: Peter Daszak < (b) (6)
Cc: Aleksei Chmura < (b) (6) Lauer, Michael (NIH/OD) [E] < (b) (6)
Subject: Re: Regarding R01AI110964

Many thanks again Dr. Daszak. We are continuing our review, but in the meantime please see attached. The third (last) attachment is what's new.

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)

From: "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Date: Sunday, April 11, 2021 at 5:19 PM
To: Peter Daszak < (b) (6)
Cc: Aleksei Chmura < (b) (6) "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Subject: Re: Regarding 2R01AI110964-06

Many thanks, Dr. Daszak, I received your letter. We will review it and get back to you.

Best, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
Bethesda, MD 20892
301-496-1096
(b) (6)

From: Peter Daszak < (b) (6)
Date: Sunday, April 11, 2021 at 4:39 PM
To: "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Cc: Aleksei Chmura < (b) (6)
Subject: Regarding 2R01AI110964-06

Dear Dr. Lauer,

Please find attached a detailed response to your two previous letters.

I hope you will take our response in the way it was intended– a good faith effort to address as far as is reasonably possible the general concerns that NIH has expressed to us, with a goal of rapid and full removal of the suspension on funding for this critically important work.

Cheers,

Peter

Peter Daszak
President

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Twitter: @PeterDaszak

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

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From: Lauer, Michael (NIH/OD) [E] < (b) (6)
Sent: Wednesday, March 10, 2021 5:37 AM
To: Peter Daszak < (b) (6)
Cc: Aleksei Chmura < (b) (6) Lauer, Michael (NIH/OD) [E] < (b) (6)
Subject: Re: Regarding 2R01AI110964-06

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Sincerely,
Michael S Lauer, MD

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

From: Peter Daszak < (b) (6)
Date: Thursday, March 4, 2021 at 10:02 PM
To: "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Cc: Aleksei Chmura < (b) (6) ***Peter Daszak:]*** REDACTED>
Subject: Regarding 2R01AI110964-06

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I spoke yesterday with my program officer and other NIAID staff regarding our grant on the risk of coronavirus emergence (2R01AI110964-06) that includes collaboration with scientists at the Wuhan Institute of Virology, China. ***[Peter Daszak:]*** **REDACTED** joined the meeting and told me about his conversation with you about the conditions currently in place on our grant and my efforts to address some of them via my recent work in Wuhan with the WHO. He also commented that you would be willing to talk with me, as PI of this award, about a pathway to reinstate this grant. I would very much value this and am emailing to see if we can arrange a time that's suitable for you, perhaps next week if possible?

I'm cc'ing my assistant **REDACTED**, who can help arrange a suitable time, and also our Chief of Staff Aleksei Chmura, who I would hope could join us, as someone who can access any relevant information on this award, and gained his own Ph.D as part of our original R01 work in China. I want to reassure you that I would not request to talk with legal counsel or bring them into a conversation, and that this would be a discussion with scientists focused on the goals of the grant, focused on research to protect us all against further coronavirus spillover.

Sincerely,

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From: Lauer, Michael (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: Tue 4/13/2021 12:17:06 PM (UTC-05:00)

To: Peter Daszak[(b) (6)

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

Subject: Re: Regarding R01AI110964

Attachment: Daszak Response to NIH April 2021 re. reactivation and suspension of 2R01AI110964.pdf

Attachment: Re: Regarding 2R01AI110964-06

Attachment: To Daszak 4 13 21.pdf

Many thanks again Dr. Daszak. We are continuing our review, but in the meantime please see attached. The third (last) attachment is what's new.

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)

From: "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Date: Sunday, April 11, 2021 at 5:19 PM
To: Peter Daszak < (b) (6)
Cc: Aleksei Chmura < (b) (6) "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Subject: Re: Regarding 2R01AI110964-06

Many thanks, Dr. Daszak, I received your letter. We will review it and get back to you.

Best, Mike

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NIH Deputy Director for Extramural Research
One Center Drive, Building 1, Room 144
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EcoHealth Alliance

Dr. Michael Lauer
Deputy Director for Extramural Research,
NIH, Bethesda, MD.

Response to the Reinstatement and immediate suspension of 2R01AI110964
"Understanding the Risk of Bat Coronavirus Emergence"

April 11th 2021

Dear Dr. Lauer,

I am responding your letters of 7/8/2020 and 10/3/2020 regarding the reinstatement and immediate suspension of NIH grant 2R01AI110964 "*Understanding the Risk of Bat Coronavirus Emergence*", that was terminated "for convenience" on 4/24/2020. In particular, this letter addresses the conditions you state would need to be fulfilled in order for us to have access to the funds to continue this work.

As you know, we had not set up any subcontracts to the Wuhan Institute of Virology under this renewal R01. Immediately following NIH's letter on 4/19/2020 that the WIV was being 'investigated', we suspended all plans for contractual work with WIV. This termination of a funded relationship with the institute makes it extraordinarily difficult and more likely impossible to provide the information requested about an autonomous foreign organization – as would also be the case for a domestic one - that our organization neither works with currently, nor has control over.

Additionally, our collaborative work with the Wuhan Institute of Virology prior to your grant termination letter of 4/24/2020 and that planned in the suspended grant, is wholly unrelated to many of the conditions listed below. These conditions also pertain to certain events and situations that in no way involve EcoHealth Alliance or are not under our control. Thus, most of the conditions below are either unrelated to EcoHealth Alliance's planned research in our highly rated, approved and funded grant application, and/or to the biosafety of our continued research funded by the suspended grant when it is reinstated in full.

Furthermore, in our recent correspondence with NIH regarding the latest in a series of FoIA requests, we were informed (1/26/2021 – see email correspondence at the end of this letter) by an NIH staff member Garcia-Malene Gorka that "any indication from my program that there is an ongoing investigation into WIV can now be disregarded, as we recently confirmed there are no pending investigations into that organization." Because this was the explanation in your initial letter of 4/19/2020 for the decisions from your office regarding restrictions on, termination of, then reinstatement and suspension of our grant, we believe that these decisions should now be reassessed.

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Despite our concerns about the relevance, fairness, or ability to fulfil the conditions as set forth in detail below, I have made extensive efforts to satisfy NIH's broad concerns, and have provided details of how these are relevant to each condition below. This includes serving as an expert on the WHO-China joint Mission on the Animal Origins of COVID-19, which involved 1 month on the ground in China (including 2 weeks locked in quarantine), at great personal burden and risk to me, to our organization, and to my family. I undertook this mission at a time when I have had increasing levels of personal attack and harassment, including a white-powder letter to my home address a few weeks after the details of our grant termination went public, and death threats that begun at the same time and continue to this day. It is clear in the wording of these attacks that many are a direct result of dangerous conspiracy theories inadvertently amplified by NIH's grant termination, and repeated in the conditions listed below. This type of harassment has accelerated to the point that personal security guards are now stationed at my home address, where I have also had to install invasive equipment and set up procedures to protect my family against expected violent attacks. Additionally, I now meet regularly with FBI agents and others at my home to monitor these threats. As I am sure you appreciate, this has a significant toll on my work, my personal life and my family.

Below, I detail our response to each of the conditions placed on our suspended grant, in an effort to provide as much information as possible and to explain the limitations on what we can do to respond. I look forward to your reply and hope that these will allow NIH to lift the suspension on funding so that we can continue our work to help protect our nation, indeed the global population, against future coronavirus pandemics. Should you wish, I feel certain we may discuss these points without legal counsel in a scientist-to-scientist conversation, as you have suggested verbally to others at NIH, and they have conveyed to me.

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence. We believe this condition is effectively impossible for us to fulfil, for the following reasons. Firstly, there is no scientific nor administrative rationale for us to attempt to obtain a SARS-CoV-2 aliquot given that it is not part of our funded collaboration with WIV. Secondly, EcoHealth Alliance scientists do not have any capacity to work on such an aliquot (EHA does not conduct virological laboratory work on SARS-CoV-2) in the USA. This further reduces the validity of a scientific basis for this request to WIV. Thirdly, EcoHealth Alliance scientists were not part of the work that WIV conducted to determine the viral sequence of SARS-CoV-2, and this was not part of our (then active) R01 funded collaboration. This is publicly stated by the lack of EHA authors listed on the paper and the lack of acknowledgement of our grant as a funding source for this work. This publicly discounts any claim of sample ownership or control. Fourthly, the collaborative research laid out in our now-suspended grant does not include the shipping of human viral isolates out of China. Finally, during the last 16 months, there has been a series of vitriolic attacks from the US Government accusing China of bioengineering and releasing SARS-CoV-2 or of otherwise allowing COVID to become pandemic. Given these attacks, and WIV's status as a government entity, it seems to us incredulous that any request, particularly without scientific rationale, from a US non-profit to a Chinese Government laboratory for an active sample of a pathogenic human virus would likely be successful. We note that 1) to our knowledge China has not supplied such an aliquot to any formal request from a government; and 2) that if circumstances were reversed and a Chinese non-

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governmental institution requested a similar pathogenic viral aliquot from a US government BSL-4 laboratory, this would also be unlikely to be fulfilled.

While we understand that it may be of scientific interest to some US-based researchers to analyze this viral sequence, this scientific interest could easily be satisfied without the need for an aliquot. The full genome of this viral sequence was uploaded to a freely accessible database on January 10 2020, and has been used widely by scientists in the USA (included those funded by NIH) and around the world in their work. Furthermore, isolates of the virus from patients in Thailand and Australia during early 2020 are essentially the same, and have been shared extensively.

2. Explain the apparent disappearance of Huang Yanling, a scientist / technician who worked in the WIV lab but whose lab web presence has been deleted.

International experts on the WHO COVID-19 origins mission, including myself, asked direct questions on this issue to staff at WIV, including the Director of the institute, the P4 Lab Director, Dr. Shi and others. The response from all was consistent, as stated in the WHO mission report published 3/30/2020: "This person according the WIV staff was an alumnus who graduated in 2015 and was now working in a different province and did not accept to talk with media. The person had been contacted and tested and ascertained to be healthy."

Given that the WHO team was not given access to this individual, and that China's personal privacy laws are preclude our ability to insist on a meeting, it is difficult to see how a request from a US non-profit would have been approved. It seems at the least to be significantly outside the remit of a US-based non-profit organization to inquire further about the whereabouts of a citizen of a foreign country who has never to our knowledge been involved in our work, and over whom we have no control, influence, nor legal responsibility.

Finally, while many conspiracy theorists have suggested that the lack of a web presence of this person suggests some nefarious activity, there are dozens of unremarkable and routine reasons why a person may be removed from a web listing of employees or students. Not least of these is when a staff member leaves an institution, or a student graduates.

3. Provide the NIH with WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns.

We believe that WIV senior staff comments reported in the WHO COVID origins mission report directly address this request in that they publicly state that no significant safety issues were found in their laboratory prior to, or following, the emergence of COVID. Any questions regarding the safety of the WIV also need to be put into the context of the widely published history of this lab as being built to international safety engineering standards, adhering to international safety practice standards indicated in the BMBL, and with lead WIV staff trained in safety in the United States by a known authority running the BSL-4 lab at the University of Texas Medical Branch in Galveston (as reported in the U.S. Dept of State cables). Furthermore, no verifiable evidence of safety issues have been reported prior to, or following the U.S. Dept of State cables.

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Regarding the U.S. Dept. of State cables, these do not in fact provide evidence of safety concerns at the laboratory. Neither do they convincingly imply safety issues. In fact, they may be simply interpreted as a request for funding from a diplomatic mission set up to further joint US-China research. It is important to note that initially only very limited phrases from these cables were selectively leaked by a Washington Post reporter in an opinion piece that did not verify nor quote direct sources. This opinion piece is demonstrably incomplete in its reporting, however it has been widely cited as providing evidence of safety issues at WIV (https://www.washingtonpost.com/opinions/2020/04/14/state-department-cables-warned-safety-issues-wuhan-lab-studying-bat-coronaviruses/). I have some detailed knowledge of the background to these cables because the diplomatic visit to WIV that they report was a direct result of our NIH-funded work. As part of EcoHealth Alliance's work in China over the past 15 years, including that funded by NIAID, I visited the US Embassy in Beijing regularly and was involved in discussions with US Embassy staff to set up a field visit to the WIV in order to generate goodwill between the US and China at a time when President Trump was planning a state visit. I did this out of a sense of duty to our government, and to the NIH so that our project could help foster goodwill between our countries, as well as provide an indication of the importance of NIH's work. Following the US Embassy staff mission, I was told by people privy to the cable's contents that the articles were positive and supportive of the work we were doing under NIAID funding, and that the trip was a success.

Now that the full text of these cables (embedded at the end of this letter) has been released with minor redactions (https://news.slashdot.org/story/20/07/20/0611205/full-text-of-us-state-department-cables-finally-released-showing-safety-in-chinese-lab), it seems that this more positive interpretation is justified. As you can see in the excerpts below, the request for more laboratory technician support could be reasonably interpreted as simply a request for the funding for more laboratory technician support, rather than a statement that the lab was unsafe, particularly given that the visit was set up as part of an effort to further develop US-China collaborative research opportunities. Furthermore, the cables are extremely positive about the importance of the collaborative work we were conducting with WIV under NIAID funding:

"**REDACTED** noted that the new lab has a serious shortage of appropriately trained technicians and investigators needed to safely operate this high-containment laboratory. University of Texas Medical Branch in Galveston (UTMB), which has one of several well-established BSL-4 labs in the United States (supported by the National Institute of Allergy and Infectious Diseases (NIAID of NIH)), has scientific collaborations with WIV, which may help alleviate this talent gap over time. Reportedly, researchers from GTMB are helping train technicians who work in the WIV BSL-4 lab. Despite this they would welcome more help from U.S. and international organizations as they establish "gold standard" operating procedures and training courses for the first time in China."

"The ability of WIV scientists to undertake productive research despite limitations on the use of the new BSL-4 facility is demonstrated by a recent publication on the origins of SARS. Over a five-year study **REDACTED** (and their research team) widely sampled bats in Yunnan province with funding support from NIAID/NIH, USAID, and several Chinese funding agencies. The study results were published in PLoS

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Pathogens online on Nov. 30, 2017 (1), and it demonstrated that a SARS-like coronaviruses isolated from horseshoe bats in a single cave contain all the building blocks of the pandemic SARS-coronavirus genome that caused the human outbreak. These results strongly suggest that the highly pathogenic SARS-coronavirus originated in this bat population. Most importantly, the researchers also showed that various SARS-like coronaviruses can interact with ACE2, the human receptor identified for SARS coronavirus. This finding strongly suggests that SARS-like coronaviruses from bats can be transmitted to humans to cause SARS-like disease. From a public health perspective, this makes the continued surveillance of SARS-like corona viruses in bats and study of the animal-human interface critical to future emerging coronavirus outbreak prediction and prevention."

4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.

The WIV staff categorically stated to the WHO mission that their lab is audited annually and no unusual events have been identified. The reports of diminished cell-phone traffic and roadblocks have not been verified or published by reliable sources. Furthermore, should hard evidence of diminished cell-phone traffic and roadblocks exist, it is not necessarily indicative of any issues related to concerns about the laboratory studies underway or safety or security incidents within the laboratory. These issues could be explained by any one of a series of issues that occur regularly in the US without nefarious connotations. For example, they could be due to roadwork or other infrastructure repair or maintenance, technical problems with cell-phone transmission, or rerouting of traffic as regularly occurs in Washington DC and other cities due to transport of visiting dignitaries or other events. Finally, there is no credible reason to think that any request a US non-profit might make to the Chinese government for an explanation of traffic or cell-phone issues would result in any response.

5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.

Since your letter of 7/8/2020, it has been widely reported that WIV scientists have published an addendum to their original paper in *Nature* that described SARS-CoV-2 and compared it phylogenetically to RaTG13. In this follow-up publication, they explain the rationale for conducting work in this mine, and any potential connection to the miner's illnesses and deaths. Importantly, they state that serological results in their lab at the time of the incident did not show that these miners were positive for SARSr-CoVs as some media articles have suggested. They then re-tested the miner samples in 2020 using a range of assays, and found no evidence of SARS-related CoV, nor of SARS-CoV-2 specific antibodies or nucleic acid. During the meeting of the WHO mission team with WIV staff, they were asked a series of questions about the miner's illnesses. The responses were that, while symptoms identified were similar to COVID in that they had pneumonia (a common occupational hazard for miners), their symptoms were also similar to other bacterial or fungal pneumonias. This, and the lack of evidence for SARSr-CoV infection, led them to conclude that SARS or COVID infection was not the cause of these miner's illnesses.

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6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV fieldwork (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.

The WHO mission was negotiated at the very highest levels as the legitimate way to proceed in an investigation of COVID-19 origins, particularly with such critical geopolitical ramifications from this pandemic. Given the intensity of political attacks and conspiracy theories around this lab, it is unreasonable to expect that the Chinese government or WIV would respond to a request from a US non-profit for an outside inspection team. The 11 international expert members of the WHO team included authorities on epidemiology, animal-origin viral infections and One Health. Members of this team have extensive experience conducting lab audits (e.g. Dr. Peter Ben Embarek), running laboratories dealing with human clinical samples (e.g. Drs. Dominic Dwyer, Thea Fischer), and commissioning, managing and accrediting laboratories in foreign countries (myself, Dr. Fabian Leendertz). The WHO-China Joint Study report details the field site visits to multiple labs in Wuhan, including the WIV and summarizes our findings. This includes information on the management of the WIV, safety at the labs, audits and training and testing of staff. I acted in good faith to try to conform to the WHO terms of reference while ensuring that as much information on the laboratory was provided in the report. This information specifically addresses one of your questions above, with categorical statements from WIV senior staff that they did not have SARS-CoV-2 in their possession prior to December 2019.

After returning to the USA, and in the weeks prior to the publication of the report, I worked hard to make sure this critical information was shared as rapidly as possible with the US Government and agencies, including by:

- Briefing Drs. Anthony Fauci and Clifford Lane of NIAID on the findings of the mission;
- Presenting a full talk about the work to the NIAID COVID PI group that meets weekly
- Briefing FBI and other US Government intelligence agency staff
- Briefing members of the US NASEM Forum on Microbial Threats
- Briefing staff on the White House National Security Council
- Briefing staff on the House Committee for Science, Space, and Technology

7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System

This has been done and all subawards fully reported as soon as we could once you notified us of this requirement in your letter of 7/8/2020.

8. Provide copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award, including with respect to biosafety.

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As we related in response to your letter of 4/19/2020 that asked us to suspend work with WIV, we had not yet set up a subcontract with WIV for the period of this award, therefore no such subrecipient agreements exist. Our plan was to monitor WIV's compliance as we had in the 5 years prior, by means of semi-annual meetings with the lead investigator and assessments of compliance against all conditions of the award. Additionally, following the NIH's termination, then reinstatement and suspension of our funding, we have contracted with a leading lab biosafety contractor based in Southeast Asia (Dr. Paul Selleck) who has extensive experience commissioning, accrediting and auditing BSL-2, -3, and -4 labs, and has worked for over a decade at the BSL-4 Australian Animal Health Lab. We will be using their services where appropriate for foreign lab subcontractees to assess lab biosafety procedures and conduct audits, including following the full reinstatement of 2R01AI110964. Finally, we have appointed a Senior Field Veterinarian who will oversee all EcoHealth Alliance fieldwork in the region and ensure continued compliance with biosafety when conducting animal capture, sampling and sample handling. We have done this at EcoHealth Alliance's own expense, despite our unblemished record on biosafety, to pre-empt calls for further sanctions against our work given the continued attacks against EcoHealth Alliance in the press after the termination of our NIH grant.

9. Describe EcoHealth's efforts to evaluate WIV's risk of noncompliance with Federal statutes, regulations, and the terms and conditions of the subaward.
Over a 15-year period of collaboration with WIV, we have found no evidence to suggest that there was any element of noncompliance with any of the conditions of the grants or contracts covering our collaboration. Our interactions with all staff at the institute have been professional, respectful, open, and with a focus on the science at a very high level. This has contributed to a relationship built on trust and one that is entirely comparable to our scientific collaborations with laboratories in the US, Europe, Australia, Thailand and over 20 other countries. We continue to believe that this laboratory is highly competent and is an extremely low risk for undisclosed accidental release of virus, and there is no verifiable indication as to why we should not continue to believe so. We would of course consider a change in this assessment if significant and verifiable evidence of lab biosafety issues or breach of other Federal statutes are brought forth, but to date we are aware of none.

10. Provide copies of all WIV biosafety reports from June 1, 2014 through May 31, 2019.
Given the intense geopolitical pressure around the accusations that WIV intentionally or accidentally released SARS-CoV-2 (something which the WHO mission deemed 'extremely unlikely'), obtaining such information is not a plausible option at present.

11. Additional information, re. Lack of ongoing investigation into Wuhan Institute of Virology by NIH:

From: Garcia-Malene, Gorka (NIH/OD) [E] < (b) (6)
Sent: Tuesday, January 26, 2021 12:20:51 PM
To: [REDACTED]
Cc: [REDACTED] Bartok, Lauren (NIH/NIAID) [E]; NIH FOIA
Subject: [EXT] FW: FOIA Case No. 55702 re: EcoHealth Alliance & Grant No. R01AI110964-6

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018
212.380.4460
EcoHealthAlliance.org

Good afternoon, **[REDACTED]** –

I'd like to insert myself into the unfolding FOIA conversation in hopes of providing some helpful context. Our records show that this competing renewal has in fact been funded. In addition, any indication from my program that there is an ongoing investigation into WIV can now be disregarded, as we recently confirmed there are no pending investigations into that organization. If we can agree on the above, all that would remain is to receive your proposed redactions to the records sought under the FOIA request.

Please let me know if there are any questions. I look forward to facilitating the Pre-Disclosure Notification process as efficiently as possible.

Best regards.

Gorka Garcia-Malene |FOIA Officer for the National Institutes of Health

From: [REDACTED]
Sent: Monday, January 25, 2021 5:21 PM
To: Bartok, Lauren (NIH/NIAID) [E] <(b) (6)
Cc: [REDACTED]
Subject: FOIA Case No. 55702 re: EcoHealth Alliance & Grant No. R01AI110964-6

Dear Ms. Bartok:

As you may recall, this firm represents EcoHealth Alliance, Inc. ("EcoHealth Alliance"), with respect to certain FOIA requests, including the instant request, FOIA Case No. 55702. The instant request seeks the same documents sought last year in FOIA Case No. 53996, regarding the research project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant 2R01AI110964. A copy of our prior letter regarding FOIA 53996 is available via the link provided below using the password **[REDACTED]**. On the grounds set forth in the letter, FOIA 53996 was denied in its entirety.

Likewise, FOIA 55702 should be denied and the grant documents should be withheld. First, grant 2R01AI110964-06 remains an unfunded competing renewal grant that is the subject of a pending first-level appeal and, thus, the materials are not subject to disclosure under NIH Grants Policy Statement §2.3.11.2.2. Moreover, in the context of the appeal, NIH has made multiple requests for further information regarding The Wuhan Institute of Virology ("WIV"), which requests indicate that a law enforcement investigation concerning WIV remains ongoing. Second, as demonstrated by the recent attack on the US Capital fueled by disinformation and conspiracy theories, the need to protect the privacy of EcoHealth Alliance's employees and affiliates is more important than ever. Last, while EcoHealth Alliance did not initially identify that the grant proposal contained confidential-commercial and propriety information, this is not dispositive. Moreover, since the

EcoHealth Alliance
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filing of the renewal application, there has been a global COVID-19 pandemic, which has sparked international and highly competitive research in the area of bat coronaviruses.

At the very least, the responsive documents will require significant redactions. While the grant documents were previously reviewed and redacted in connection with FOIA 53996, we require a further opportunity to review the documents to confirm, *inter alia*, that all personnel information has been removed given the heightened risk of harm in this unprecedented political environment. Accordingly, EcoHealth Alliance respectfully requests a forty-five (45) day extension of time to respond to FOIA 55702, to allow sufficient time for EcoHealth Alliance to conduct a further review of the responsive documents and provide an updated letter response that incorporates recent developments and specific justifications for additional redactions.

Please confirm that NIH will deny FOIA 55702 in its entirety or that NIH is agreeable to EcoHealth Alliance's request for an extension of time to provide a particularized response to FOIA 55702. Please also confirm NIH's receipt of this email.

Thank you.

Best,
[REDACTED]

FOIA Case No. 53996 - EcoHealth Alliance's Letter Response to FOIA Request, dated June 5, 2020 (With Exhibits)
[REDACTED]

[REDACTED]

Tarter Krinsky & Drogin LLP
1350 Broadway | New York | NY | 10018
www.tarterkrinsky.com | LinkedIn
COVID-19 RESOURCE CENTER

12. Publicly released details of U.S. Department of State Cables regarding visit to Wuhan Institute of Virology, as cited in condition #3 above. These are available from a number of sources, including the Washington Post and (https://news.slashdot.org/story/20/07/20/0611205/full-text-of-us-state-department-cables-finally-released-showing-safety-in-chinese-lab).

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SBU

MRN:	18 BEIJING 138
Date/DTG:	Jan 19, 2018 / 190739Z JAN 18
From:	AMEMBASSY BEIJING
Action:	WASHDC, SECSTATE *ROUTINE*
E.O.:	13526
TAGS:	SHLH, ETRD, ECON, PGOV, CN
Captions:	SENSITIVE
Reference:	17 WUHAN 48
Subject:	China Opens First Bio Safety Level 4 Laboratory

1. (SBU) **Summary and Comment:** The Chinese Academy of Sciences (CAS) has recently established what is reportedly China's first Biosafety Level 4 (BSL-4) laboratory in Wuhan. This state-of-the-art facility is designed for prevention and control research on diseases that require the highest level of biosafety and biosecurity containment. Ultimately, scientists hope the lab will contribute to the development of new antiviral drugs and vaccines, but its current productivity is limited by a shortage of the highly trained technicians and investigators required to safely operate a BSL-4 laboratory and a lack of clarity in related Chinese government policies and guidelines. (b)(5)

(b)(5)

(b)(5) **End Summary and Comment.**

China Investing in Infectious Disease Control

2. (U) Between November 2002 and July 2003, China faced an outbreak of Severe Acute Respiratory Syndrome (SARS), which, according to the World Health Organization, resulting in 8,098 cases and leading to 774 deaths reported in 37 countries. A majority of cases occurred in China, where the fatality rate was 9.6%. This incident convinced China to prioritize international cooperation for infectious disease control. An aspect of this prioritization was China's work with the Jean Merieux BSL-4 Laboratory in Lyon, France, to build China's first high containment laboratory at Wuhan's Institute of Virology (WIV), an institute under the auspices of the Chinese Academy of Sciences (CAS). Construction took 11 years and $44 million USD, and construction on the facility was completed on January 31, 2015. Following

REL0000047819.0001

two years of effort, which is not unusual for such facilities, the WIV lab was accredited in February 2017 by the China National Accreditation Service for Conformity Assessment. It occupies four floors and consists of over 32,000 square feet. WIV leadership now considers the lab operational and ready for research on class-four pathogens (P4), among which are the most virulent viruses that pose a high risk of aerosolized person-to-person transmission.

Unclear Guidelines on Virus Access and a Lack of Trained Talent Impede Research

3. (SBU) In addition to accreditation, the lab must also receive permission from the National Health and Family Planning Commission (NHFPC) to initiate research on specific highly contagious pathogens. According to some WIV scientists, it is unclear how NHFPC determines what viruses can or cannot be studied in the new laboratory. To date, WIV has obtained permission for research on three viruses: Ebola virus, Nipah virus, and Xinjiang hemorrhagic fever virus (a strain of Crimean Congo hemorrhagic fever found in China's Xinjiang Province). Despite this permission, however, the Chinese government has not allowed the WIV to import Ebola viruses for study in the BSL-4 lab. Therefore, WIV scientists are frustrated and have pointed out that they won't be able to conduct research project with Ebola viruses at the new BSL-4 lab despite of the permission.

(b)(6)

(b)(6) Thus, while the BSL-4 lab is ostensibly fully accredited, its utilization is limited by lack of access to specific organisms and by opaque government review and approval processes. As long as this situation continues, Beijing's commitment to prioritizing infectious disease control - on the regional and international level, especially in relation to highly pathogenic viruses, remains in doubt.

(b)(6) noted that the new lab has a serious shortage of appropriately trained technicians and investigators needed to safely operate this high-containment laboratory. University of Texas Medical Branch in Galveston (UTMB), which has one of several well-established BSL-4 labs in the United States (supported by the National Institute of Allergy and Infectious Diseases (NIAID of NIH)), has scientific collaborations with WIV, which may help alleviate this talent gap over time. Reportedly, researchers from GTMB are helping train technicians who work in the WIV BSL-4 lab. Despite this, (b)(6) they would welcome more help from U.S. and international organizations as they establish "gold standard" operating procedures and training courses for the first time in China. As China is building more BSL-4 labs, including one in Harbin Veterinary Research Institute subordinated to the Chinese Academy of Agricultural Sciences (CAAS) for veterinary research use (b)(6) the training for technicians and investigators working on dangerous pathogens will certainly be in demand.

Despite Limitations, WIV Researchers Produce SARS Discoveries

6. (SBU) The ability of WIV scientists to undertake productive research despite limitations on the use of the new BSL-4 facility is demonstrated by a recent publication on the origins of SARS. Over a five-year study, (b)(6) (and their research team) widely sampled bats in Yunnan province with funding support from NIAID/NIH, USAID, and several Chinese funding agencies. The study results were published in PLoS Pathogens online on Nov. 30, 2017 (1), and it demonstrated that a SARS-like coronaviruses isolated from horseshoe bats in a single cave contain all the building blocks of the pandemic SARS-coronavirus genome that caused the human outbreak. These results strongly suggest that the highly pathogenic SARS-coronavirus originated in this bat population. Most importantly, the researchers also showed that various SARS-like coronaviruses can interact with ACE2, the human receptor identified for SARS-coronavirus. This finding strongly suggests that SARS-like coronaviruses from bats can be transmitted to humans to cause SARS-like disease. From a public health perspective, this makes the continued surveillance of SARS-like coronaviruses in bats and study of the animal-human interface critical to future emerging coronavirus outbreak prediction and prevention. (b)(5) (b)(5) WIV scientists are allowed to study the SARS-like coronaviruses isolated from bats while they are precluded from studying human-disease causing SARS coronavirus in their new BSL-4 lab until permission for such work is granted by the NHFCP.

1. Hu B, Zeng L-P, Yang X-L, Ge X-Y, Zhang W, Li B, et al. (2017) Discovery of a rich gene pool of bat SARS-related coronaviruses provides new insights into the origin of SARS coronavirus. PLoS Pathog 13(11): e1006698. https://doi.org/10.1371/journal.ppat.1006698

Signature:	BRANSTAD
Drafted By:	(b)(6)
Cleared By:	
Approved By:	
Released By:	
Info:	CHINA POSTS COLLECTIVE *ROUTINE*
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SBU

We await your response at the earliest opportunity.

Yours sincerely,

Dr. Peter Daszak
President

(t) (b) (6); (e) (b) (6)
cc. Dr. Aleksei A. Chmura (Chief-of-Staff)

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018
212.380.4460
EcoHealthAlliance.org

From: Lauer, Michael (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: Wed 3/10/2021 4:37:01 AM (UTC-06:00)

To: Peter Daszak[(b) (6)

Cc: Aleksei Chmural (b) (6) Alison Andrel (b) (6) Lauer, Michael (NIH/OD) [E]| (b) (6)

Subject: Re: Regarding 2R01AI110964-06

Attachment: Daszak 7 8 20.pdf

Attachment: NIH Response to EcoHealth Response to Suspension_10_23_20.pdf

Dear Dr. Daszak

Attached please find two letters that I sent you previously.

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: Peter Daszak < (b) (6)
Date: Thursday, March 4, 2021 at 10:02 PM
To: "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Cc: Aleksei Chmura < (b) (6) Alison Andre < (b) (6)
Subject: Regarding 2R01AI110964-06

Dear Dr. Lauer,

I spoke yesterday with my program officer and other NIAID staff regarding our grant on the risk of coronavirus emergence (2R01AI110964-06) that includes collaboration with scientists at the Wuhan Institute of Virology, China. Dr. Matthew Fenton joined the meeting and told me about his conversation with you about the conditions currently in place on our grant and my efforts to address some of them via my recent work in Wuhan with the WHO. He also commented that you would be willing to talk with me, as PI of this award, about a pathway to reinstate this grant. I would very much value this and am emailing to see if we can arrange a time that's suitable for you, perhaps next week if possible?

I'm cc'ing my assistant Alison Andre, who can help arrange a suitable time, and also our Chief of Staff Aleksei Chmura, who I would hope could join us, as someone who can access any relevant information on this award, and gained his own Ph.D as part of our original R01 work in China. I want to reassure you that I would not request to talk with legal counsel or bring them into a conversation, and that this would be a discussion with scientists focused on the goals of the grant, focused on research to protect us all against further coronavirus spillover.

Sincerely,

Peter

Peter Daszak
President

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

Tel.: (b) (6)
Website: www.ecohealthalliance.org

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

8 July 2020

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

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

In follow-up to my previous letter of April 24, 2020, 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 withdrawn its termination of grant R01AI110964, which supports the project *Understanding the Risk of Bat Coronavirus Emergence*. Accordingly, the grant is reinstated.

However, as you are aware, the NIH has received reports that the Wuhan Institute of Virology (WIV), a subrecipient of EcoHealth Alliance under R01AI110964, has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, create health and welfare threats to the public in China and other countries, including the United States. Grant award R01AI110964 is subject to biosafety requirements set forth in the NIH Grants Policy Statement (e.g., NIH GPS, Section 4.1.24 "Public Health Security") and the Notice of Award (e.g., requiring that "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]."). Moreover, NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients. 45 C.F.R. § 75.101.

As the grantee, EcoHealth Alliance was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). We have concerns that WIV has not satisfied safety requirements under the award, and that EcoHealth Alliance has not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance.

Moreover, as we have informed you through prior Notices of Award, this award is subject to the Transparency Act subaward and executive compensation reporting requirement of 2 C.F.R. Part

170. To date you have not reported any subawards in the Federal Subaward Reporting System.

Therefore, effective the date of this letter, July 8, 2020, NIH is suspending all activities related to R01AI110964, until such time as these concerns have been addressed to NIH's satisfaction. This suspension is taken in accordance with 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. This action is not appealable in accordance with 42 C.F.R. § 50.404 and the NIH GPS Section 8.7, Grant Appeals Procedures. However, EcoHealth Alliance has the opportunity to provide information and documentation demonstrating that WIV and EcoHealth Alliance have satisfied the above-mentioned requirements.

Specifically, to address the NIH's concerns, EcoHealth must provide the NIH with the following information and materials, which must be complete and accurate:

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.
2. Explain the apparent disappearance of Huang Yanling, a scientist / technician who worked in the WIV lab but whose lab web presence has been deleted.
3. Provide the NIH with WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns.
4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.
5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.
6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.
7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System

During this period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further asses compliance by EcoHealth Alliance and WIV, including compliance with other terms and conditions of award that may be implicated. Additionally, during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the

recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. Once the original award is reinstated, NIH will take additional steps to restrict all funding in the HHS Payment Management System in the amount of $369,819. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 CFR Part 75, including, but not limited to, terminating the grant award. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

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Sincerely,

Michael S. Lauer -S

Digitally signed by Michael S. Lauer -S
Date: 2020.07.08 21:43:41 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

23 October 2020

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

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

I am following up on Mr. Krinsky's August 13, 2020, letter on behalf of EcoHealth Alliance, Inc. ("EcoHealth") responding to NIH's suspension of grant R01AI110964, which funds the project *Understanding the Risk of Bat Coronavirus Emergence* (the "Project"). Per my letter of July 8, 2020, NIH reinstated the grant but suspended all award activities because we have concerns that the Wuhan Institute of Virology (WIV), which previously served as a subrecipient of the Project, had not satisfied safety requirements that applied to its subawards with EcoHealth, and that EcoHealth had not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance. EcoHealth objected to the suspension on the grounds that WIV has no *current* connection to the Project or EcoHealth's research, and EcoHealth had not issued any subawards in connection with the Grant *at the time of the suspension*.

The fact that EcoHealth does not currently have a subrecipient relationship with WIV and had not issued subawards to WIV at the time of suspension does not absolve EcoHealth of any past non-compliance with the terms and conditions of award for grant R01AI110964. While EcoHealth did not issue a subaward to WIV for year 6 of the grant, WIV served as a subrecipient for years 1 through 5. NIH awarded EcoHealth grant R01AI110964 in 2014, with a project period of June 1, 2014, through June 30, 2024, as renewed. In EcoHealth's grant application, EcoHealth listed Drs. Zheng Li Shi and Xing Yi Ge of WIV as co-investigators and senior/key personnel. It stated that "Drs. Shi, Zhang, and Daszak have collaborated together since 2002 and have been involved in running joint conferences, and shipping samples into and out of China." EcoHealth listed WIV as a Project/Performance Site Location. In describing WIV's facilities, EcoHealth described WIV as China's premier institute for virological research" and touted WIV's "fully equipped biosafety level 3 laboratory" and "a newly opened BLS-4 laboratory." In support of the application, Dr. Zheng Li Shi's personal statement indicated that "My lab will be responsible for diagnosis, genomics and isolation of coronavirus from wild and domestic animals in Southern China and for analyzing their receptor binding domains." The application stated that "Wuhan Institute of Virology and the Wuhan University Center for Animal Experiment BSL-3

lab have an Internal Biosafety Committee and are accredited BSL-2 and BSL 3 laboratories. All experimental work using infectious material will be conducted under appropriate biosafety standards. Disposal of hazardous materials will be conducted according to the institutional biosafety regulations."

EcoHealth requested funding specifically for activities to be carried out by WIV. NIH awarded EcoHealth a total of $749,976 for WIV's work in the following annual amounts for years 1 through 5:

	-Yr 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%	$9,896	$10,297	$11,787	$11,787	$11,787
TOTAL COSTS	$133,595	$139,015	$159,122	$159,122	$159,122

As stated in the Notices of Award for each budget period of the grant, the awards were subject to terms and conditions, which include the NIH Grants Policy Statement (GPS) and applicable HHS grant regulations. As I indicated in my letter of July 8, 2020, as a term and condition of award EcoHealth was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). See also, 45 C.F.R. § 75.342(a) ("The non-Federal entity is responsible for oversight of the operations of the Federal award supported activities."). Moreover, EcoHealth was required to "Establish and maintain effective internal control over the Federal award that provides reasonable assurance that the non-Federal entity is managing the Federal award in compliance with Federal statutes, regulations, and the terms and conditions of the Federal award[.]" 45 C.F.R. § 75.303(a). The Notice of Award stated that as a term and condition of award, "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]." Moreover, the NIH GPS provides that NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients, so these terms applied to WIV. 45 C.F.R. § 75.101.

As I stated, NIH has concerns of non-compliance with terms and conditions of award—namely, that WIV had not satisfied safety requirements under the award and that EcoHealth Alliance had not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance. Accordingly, NIH suspended all activities related to R01AI110964, pursuant to 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare.

In my letter of July 8, 2020, I provided EcoHealth with the opportunity to object and to provide information and documentation challenging the suspension. Specifically, I sought information and materials that speak to WIV's lab safety and EcoHealth's oversight of its subrecipient, and an inspection of WIV's laboratory records and facilities. I indicated that as a specific condition of award, during the period of suspension, EcoHealth Alliance may not allow research under this

project to be conducted and that no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients.

EcoHealth objected to the requests on the grounds that "NIAID is not authorized under 45 CFR§§ 75.371, 75.205, and 75.207, entitled *Specific Award Conditions*, to impose, *inter alia*, conditions that consist of demands for information regarding entities that are neither subrecipients of grant funds nor project affiliates."

These provisions are irrelevant to NIH's requests. NIH is required to permit the opportunity for recipients to object and provide information and documentation challenging a suspension, 45 C.F.R. § 75.374, so we specifically gave EcoHealth the opportunity to provide information that speaks to NIH's concerns. Moreover, as a granting agency, NIH is required to "manage and administer the Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented in full accordance with U.S. statutory and public policy requirements: Including, but not limited to, those protecting public welfare [and] the environment[.]" 45 C.F.R. § 75.300(a). In addition to seeking information that speaks to compliance with terms and conditions of award, NIH is entitled to "make site visits as warranted by program needs." 45 C.F.R. § 75.342. As a term and condition of award, NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. § 75.364); and must have "timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents" (id.). These requirements flow down to subawards to subrecipients. 45 C.F.R. § 75.101. "Non-Federal entities must comply with requirements in [45 C.F.R. Part 75] regardless of whether the non-Federal entity is a recipient or subrecipient of a Federal award." 45 C.F.R. 75.101. As the grantee, EcoHealth was required to have in place, "A requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part." 45 C.F.R. § 75.352(a)(5). For each of these reasons, NIH is justified in seeking the materials, information, and a site visit specified in my letter of July 8, 2020.

In addition to objecting to NIH's authority to seek the materials, information, and a site visit, EcoHealth has responded that it lacks knowledge or information regarding the requests; that it is not in possession, custody, or control of the specified items; and that it has no authority to grant NIAID and the U.S. National Academy of Sciences access to WIV's facility to conduct an inspection. EcoHealth's responses have not satisfied NIH's concerns that EcoHealth had failed to adequately monitor the compliance of its subrecipient, and that the subrecipient, WIV, had failed to comply with safety requirements.

Notwithstanding this, NIH is providing an additional opportunity for EcoHealth to provide information and documentation challenging these concerns of non-compliance. Accordingly, in addition to reiterating our prior requests (1) through (6) per our letter of July 8, 2020, NIH requests the following information and materials, which must be complete and accurate:

1. Provide copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award, including with respect to biosafety.
2. Describe EcoHealth's efforts to evaluate WIV's risk of noncompliance with Federal statutes, regulations, and the terms and conditions of the subaward.
3. Provide copies of all WIV biosafety reports from June 1, 2014 through May 31, 2019.

During the ongoing period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further assess whether EcoHealth Alliance and WIV complied with the terms and conditions of award, including compliance with other terms and conditions of award that may be implicated. We remind you that during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the continued suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 C.F.R. Part 75, including, but not limited to, terminating the grant award or disallowing costs. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2020.10.23 13:34:25 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy (NIAID)
Ms. Emily Linde (NIAID)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

13 April 2021

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

Re: NIH Grant R01AI110964 and your letter of April 11, 2021

Dear Drs. Chmura and Daszak:

Thank you for your letter of April 11, 2021. We are reviewing your responses in detail.

In the meantime, though, and in interest of expediting our review, we would note that our previous letters were concerned with NIH Grant R01AI110964 (which started on started on June 1, 2014 as documented in RePORTER) and not solely with 2R01AI110964-06. Therefore, as we asked on October 23, 2020, please send us copies of *all* EcoHealth Alliance – WIV subrecipient agreements as well as any and all other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award, including with respect to biosafety. While we understand that you may not have activated a subaward for year 6, we would expect there to be substantial documentation of your oversight of WIV subaward activities during years 1 through 5.

Also, as we asked, please send us copies of *all* biosafety reports; we would expect that as part of your oversight you would have copies of all such reports through at least year 5.

As a reminder, as a term and condition of award, NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. § 75.364); and must have "timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents" (id.). These requirements flow down to subawards to subrecipients. 45 C.F.R. § 75.101. "Non-Federal entities must comply with requirements in [45 C.F.R. Part 75] regardless of whether the non-Federal entity is a recipient or subrecipient of a Federal award." 45 C.F.R. 75.101. As the grantee, EcoHealth was required to have in place, "A requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part." 45 C.F.R. § 75.352(a)(5). For each of these reasons, NIH is justified in seeking the materials, information, and a site visit as requested.

Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2021.04.13 13:12:57 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

From: Peter Daszak[(b) (6)

Sent: Thur 3/4/2021 8:59:11 PM (UTC-06:00)

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

Cc: Aleksei Chmural (b) (6) Alison Andre[(b) (6)

Subject: Regarding 2R01AI110964-06

Dear Dr. Lauer,

I spoke yesterday with my program officer and other NIAID staff regarding our grant on the risk of coronavirus emergence (2R01AI110964-06) that includes collaboration with scientists at the Wuhan Institute of Virology, China. Dr. Matthew Fenton joined the meeting and told me about his conversation with you about the conditions currently in place on our grant and my efforts to address some of them via my recent work in Wuhan with the WHO. He also commented that you would be willing to talk with me, as PI of this award, about a pathway to reinstate this grant. I would very much value this and am emailing to see if we can arrange a time that's suitable for you, perhaps next week if possible?

I'm cc'ing my assistant Alison Andre, who can help arrange a suitable time, and also our Chief of Staff Aleksei Chmura, who I would hope could join us, as someone who can access any relevant information on this award, and gained his own Ph.D as part of our original R01 work in China. I want to reassure you that I would not request to talk with legal counsel or bring them into a conversation, and that this would be a discussion with scientists focused on the goals of the grant, focused on research to protect us all against further coronavirus spillover.

Sincerely,

Peter

Peter Daszak
President

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

Tel.: (b) (6)
Website: www.ecohealthalliance.org

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

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From: Lauer, Michael (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: Sun 8/29/2021 1:02:31 PM (UTC-05:00)

To: Aleksei Chmura[(b) (6)

Cc: Peter Daszak[(b) (6) Stemmy, Erik (NIH/NIAID) [E][(b) (6) Gratton, Shaun (NIH/NIAID) [E][(b) (6) Erbelding, Emily (NIH/NIAID) [E][(b) (6) Cassetti, Cristina (NIH/NIAID) [E][(b) (6) Linde, Emily (NIH/NIAID) [E][(b) (6) Armine Arustamyan[(b) (6) Joe Riccardi[(b) (6) Lauer, Michael (NIH/OD) [E][(b) (6)

Subject: Re: Regarding 2R01AI110964

Attachment: Re: Regarding 2R01AI110964

Thank you Dr. Chmura for your response and for the documents. And thank you for uploading the documents into the Box folder.

We will review and get back to you.

Best, Mike

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

From: Aleksei Chmura < (b) (6)
Date: Friday, August 27, 2021 at 12:00 PM
To: "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Cc: Peter Daszak < (b) (6) "Stemmy, Erik (NIH/NIAID) [E]" < (b) (6) "Gratton, Shaun (NIH/NIAID) [E]" < (b) (6) "Erbelding, Emily (NIH/NIAID) [E]" < (b) (6) "Cassetti, Cristina (NIH/NIAID) [E]" < (b) (6) "Linde, Emily (NIH/NIAID) [E]" < (b) (6) Armine Arustamyan < (b) (6) Joe Riccardi < (b) (6)
Subject: Re: Regarding 2R01AI110964

Dear Dr. Lauer,

Please find our response to your letter from 23 July 2021, attached.

Sincerely,

-Aleksei

Aleksei Chmura, PhD
Chief of Staff &
Authorized Organizational Representative

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018, USA

(b) (6) (direct)
(mobile)
Aleksei MacDurian (Skype)

www.ecohealthalliance.org

Visit our blog: www.ecohealthalliance.org/blog

EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that promote conservation and prevent pandemics.

On Fri, Jul 23, 2021 at 5:27 PM Lauer, Michael (NIH/OD) [E] < (b) (6) wrote:

Dear Dr. Chmura and Dr. Daszak

Please see attached.

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)

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From: Aleksei Chmura[(b) (6)]
Sent: Fri 8/27/2021 10:57:22 AM (UTC-05:00)
To: Lauer, Michael (NIH/OD) [E][(b) (6)]
Cc: Peter Daszak[(b) (6)] Stemmy, Erik (NIH/NIAID) [E][(b) (6)] Gratton, Shaun (NIH/NIAID) [E][(b) (6)] Erbelding, Emily (NIH/NIAID) [E][(b) (6)] Cassetti, Cristina (NIH/NIAID) [E][(b) (6)] Linde, Emily (NIH/NIAID) [E][(b) (6)] Armine Arustamyan[(b) (6)] Joe Riccardi[(b) (6)]
Subject: Re: Regarding 2R01AI110964
Attachment: To EcoHealth 7 23 21 R01AI110964.pdf
Attachment: EHA response to NIH request for further documentation 8.27.21.pdf
Attachment: ATT00001.txt

Dear Dr. Lauer,

Please find our response to your letter from 23 July 2021, attached.

Sincerely,

-Aleksei

Aleksei Chmura, PhD
Chief of Staff &
Authorized Organizational Representative

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018, USA

(b) (6)(direct)
(mobile)
Aleksei MacDurian (Skype)

www.ecohealthalliance.org

Visit our blog: www.ecohealthalliance.org/blog

EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that promote conservation and prevent pandemics.

On Fri, Jul 23, 2021 at 5:27 PM Lauer, Michael (NIH/OD) [E] <(b) (6)> wrote:

Dear Dr. Chmura and Dr. Daszak

Please see attached.

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)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

23 July 2021

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

Re: R01AI110964, U01AI151797, U01AI153420

Dear Drs. Chmura and Daszak:

Thank you for your correspondence of April 11, 2021 and April 23, 2021 regarding R01AI110964. We are in the process of conducting detailed analyses of your answers to our questions and well as of the documents you sent, and we have the following additional requests:

1. Records

For us to continue our analyses, we will need to receive and review WIV's records validating expenditures specific to R01AI110964 as well as any and all monitoring, safety, and financial reports specific to R01AI110964 that WIV submitted to you. As a reminder, subawardees are required to have a financial management system that includes records that identify adequately the source and application of funds for federally-funded activities. These records must contain information pertaining to Federal awards, authorizations, obligations, unobligated balances, assets, expenditures, income and interest and be supported by source documentation. 45 C.F.R. §§ 75.101 and 75.302.

As a term and condition of award, NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. 75.364). This right of access applies not only to awardee records, but also to subawardee records. Awardees indicate their acceptance of an NIH award and its associated terms and conditions as they draw down the NIH grant funds to support the scientific project (see NIHGPS Section 5).

REL0000047836.0001.0001

We will also need to see subaward agreements, subawardee audit reports, subawardee safety monitoring documents, subawardee progress reports submitted to you, and subawardee financial and accounting records for two other NIH EcoHealth Alliance grants. Specifically, please send us all responsive documents for:

- U01AI151797 (Daszak): subawardees Chulalongkorn Hospital, Chulalongkorn University, Duke-National Singapore University, and University of North Carolina at Chapel Hill
- U01AI153420 (Epstein): subawardees International Center for Diarrhoeal Disease Research of Bangladesh, Institute of Epidemiology Disease Control and Research of Bangladesh.

We remind you that the Notice of Award for U01AI151797 already contains the following specific award conditions that must still be satisfied by 30 days from establishment.

> Subaward Agreement Requirements: The ECOHEALTH ALLIANCE, INC. must provide NIAID with copies of all (existing and newly established) subaward agreements established under this award, including descriptions of the biosafety monitoring plans, within 30 days of establishment.
>
> Federal Funding Accountability and Transparency Subaward Reporting System (FSRS) Requirements: This award is subject to the Transparency Act subaward reporting requirement of 2 CFR Part 170, which must be reported through the Federal Funding Accountability and Transparency Subaward Reporting System (FSRS). The ECOHEALTH ALLIANCE, INC. must provide NIAID with proof of documentation of timely entries of subaward information into the FSRS within 30 days of submitting to FSRS.

2. Reports

We are also writing to notify you that a review of our records for R01AI110964 indicates that EcoHealth Alliance, Inc. is out of compliance with requirements to submit the following reports that are outlined in the NIHGPS: the Federal Financial Report (FFR, see 8.4.1.2.3 Modified Financial Reporting Requirements) and the Interim Research Performance Progress Report (I-RPPR, see NIHGPS 8.4.1.4 Final Research Performance Progress Report).

R01AI110964 was issued under the Streamlined Noncompeting Award Process (SNAP). For awards under SNAP, an FFR must be submitted within 120 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment.

Additionally, NIH requires that organizations submit an Interim-RPPR while their Type 2 application is under consideration. In the event that the Type 2 is funded, NIH treats the Interim-RPPR as the annual performance report for the final year of the previous competitive segment.

The FFR and I-RPPR for R01AI110964 were due within 120 days after the end of the project period. In this case, the competitive segment ended on May 31, 2019, and reports were due September 30, 2019. To date, NIH has still not received these reports. Compliance with Section 8, Administrative Requirements within the NIH Grants Policy Statement (NIHGPS) is a standard term and condition of award that applies to all NIH recipients.

A recipient's failure to comply with the terms and conditions of award, may cause NIH to take one or more actions on the award, depending on the severity and duration of the non-compliance. Additionally, a history of non-compliance related to R01AI110964, including reporting non-compliance, may impact other projects where EcoHealth serves as the primary grant recipient. When a recipient has a history of failure to comply with the general or specific terms and conditions of a previous Federal award, NIH may impose specific award conditions on other awards of the recipient, including withholding authority to proceed to the next phase of a project until receipt of evidence of acceptable performance (see NIHGPS Section 8.5, Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support).

In closing, please be advised that EcoHealth Alliance, Inc. must satisfy the existing specific award condition for U01AI151797 by 30 days from establishment and must provide the remaining documents and reports requested herein for all three grants (R01AI110964, U01AI151797, U01AI153420) no later than August 27, 2021.

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

Sincerely,

Lauer, Michael (NIH/OD) [E]

Digitally signed by Lauer, Michael (NIH/OD) [E]
Date: 2021.07.23 17:24:01 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
(b) (6)

cc: Ms. Emily Linde
Dr. Erik Stemmy

EcoHealth Alliance

27 August 2021

Dr. Michael S. Lauer
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Lauer,

In response to your requests for (1) records and (2) reports in your letter dated 23 July 2021, we provide the following responses and documentation. The requested files are too large to transmit via email, so they may be downloaded via the following Drop Box link. Let us know, if another method of file transfer would be preferred.

Drop Box Link:

https://www.dropbox.com/sh/a9giijpbrkotedc/AABQeJVmPK3OJyLAe_TurHJRa?dl=0

Responses:

1. **Records**

R01AI110964
01 WIV Documents.pdf

1. WIV Subaward Contracts & Invoices Y1-Y5
2. WIV Risk Assessment Matrixes 2016*-2019
3. WIV FFATA Reports from 2015-2019
4. WIV Annual Reports 2014-2016
5. WIV DHHS PHS NIH OLAW Approvals for 2014-2019 and 2019-2024
6. WIV Subrecipient Monitoring 2016*-2019

**EcoHealth Alliance began a formal Uniform Guidance subrecipient monitoring policy in 2016 as per OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR §200.331).*

02 EHA FFRs from 2014-2019.pdf

U01AI151797
01 Chulalongkorn Documents.pdf

1. Chulalongkorn Subaward Contract and Invoices
2. Chulalongkorn Subaward email and confirmation to NIAID

3. Chulalongkorn Risk Assessment Matrix
4. Chulalongkorn Audit
5. Chulalongkorn COI Policy
6. Chulalongkorn Subrecipient Monitoring

02 Duke-NUS Documents.pdf

1. Duke-NUS Subaward Contract*
2. Duke-NUS Subaward email and confirmation to NIAID
3. Duke-NUS Risk Assessment Matrix
4. Duke-NUS Audit
5. Duke-NUS COI Policy

**Contract signed in Aug 2021, so Duke-NUS Subrecipient Monitoring form will be available early 2022*

03 UNC Documents.pdf

1. UNC Subaward Contract and Invoices
2. UNC Subaward email and confirmation to NIAID
3. UNC Risk Assessment Matrix
4. UNC Audit
5. UNC COI Policy
6. UNC Subrecipient Monitoring

04 FSRA-FFATA EID-SEARCH.pdf

In addition to the records listed above, we are fully in compliance with the award conditions for U01AI151797. Specifically, from the NoA language: (a) all subaward contract agreements including descriptions of biosafety monitoring plans and (b) proof of documentation of timely entries of subaward information into the FSRS reporting have been provided to our NIAID Program Officer and Grants Management Specialist within 30-days of establishment of the subaward contract or submitting subaward information to the FSRS, respectively. In the files above and following each Subaward Contract and Invoices, we have documentation of emails and responses of these reports and communications.

U01AI153420

01 icddrb Documents.pdf

1. icddr,b Subaward Contract and Invoices
2. icddr,b Risk Assessment Matrix
3. icddr,b Audit
4. icddr,b COI Policy
5. icddr,b Subrecipient Monitoring

02 IEDCR Documents.pdf

1. IEDCR Subaward Contract and Invoices
2. IEDCR Risk Assessment Matrix
3. IEDCR Desk-Audit Questionnaire **in lieu of Audit document*
4. IEDCR COI Policy
5. IEDCR Subrecipient Monitoring

03 FSRS-FFATA Nipah Bangladesh.pdf

2. Reports

a. The interim report (I-RPPR) for R01AI110964 has been submitted via the Interim-RPPR option in the eRA Commons system. Program Officer Erik Stemmy and Grants Management Specialist Shaun Gratton have been notified.
b. Documentation of our submission of all quarterly FFR reports for years 1-6 (2014-2019) for R01AI110964 are included in the Drop Box link, above. Note that following the notice of award for 2R01AI110964 (24-July-19), its termination (27-Apr-20), subsequent of suspension (15-Jul-20), there was a change (01 Jan 21) to the process by which FFRs are required to be submitted such that the US DHHS Payment Management System (PMS) is now used instead of eRA Commons. The PMS does not recognize our previously-terminated, now-suspended grant number and we have requested that the PMS update their system to approve this grant number (update request number UPDA0229501). We have followed up as recently as this morning 8/27/21 (ticket number 264975). As soon as PMS updates their system, we will submit the report and notify our program officer and grants management specialist and send documentation.
c. Reporting for U01AI151797, and U01AI153420 is up to date.

If any additional details or information are required, please let us know. We look forward to hearing from you.

Sincerely,

Peter Daszak, PhD
President, EcoHealth Alliance

Aleksei Chmura, PhD
Chief of Staff & AOR

From: Lauer, Michael (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: Sun 8/29/2021 1:02:30 PM (UTC-05:00)

To: Aleksei Chmura[(b) (6)

Cc: Peter Daszak[(b) (6) Stemmy, Erik (NIH/NIAID) [E][(b) (6) Gratton, Shaun (NIH/NIAID) [E][(b) (6) Erbelding, Emily (NIH/NIAID) [E][(b) (6) Cassetti, Cristina (NIH/NIAID) [E][(b) (6) Linde, Emily (NIH/NIAID) [E][(b) (6) Armine Arustamyan[(b) (6) Joe Riccardi[(b) (6) Lauer, Michael (NIH/OD) [E][(b) (6)

Subject: Re: Regarding 2R01AI110964

Attachment: Re: Regarding 2R01AI110964

Thank you Dr. Chmura for your response and for the documents. And thank you for uploading the documents into the Box folder.

We will review and get back to you.

Best, Mike

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

From: Aleksei Chmura < (b) (6)
Date: Friday, August 27, 2021 at 12:00 PM
To: "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Cc: Peter Daszak < (b) (6) "Stemmy, Erik (NIH/NIAID) [E]" < (b) (6) "Gratton, Shaun (NIH/NIAID) [E]" < (b) (6) "Erbelding, Emily (NIH/NIAID) [E]" < (b) (6) "Cassetti, Cristina (NIH/NIAID) [E]" < (b) (6) "Linde, Emily (NIH/NIAID) [E]" < (b) (6) Armine Arustamyan < (b) (6) Joe Riccardi < (b) (6)
Subject: Re: Regarding 2R01AI110964

Dear Dr. Lauer,

Please find our response to your letter from 23 July 2021, attached.

Sincerely,

-Aleksei

Aleksei Chmura, PhD
Chief of Staff &
Authorized Organizational Representative

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018, USA

(b) (6) (direct)
(mobile)
Aleksei MacDurian (Skype)

www.ecohealthalliance.org

Visit our blog: www.ecohealthalliance.org/blog

EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that promote conservation and prevent pandemics.

On Fri, Jul 23, 2021 at 5:27 PM Lauer, Michael (NIH/OD) [E] < (b) (6) wrote:

Dear Dr. Chmura and Dr. Daszak

Please see attached.

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)

Disclaimer

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From: Aleksei Chmura[(b) (6)]
Sent: Fri 8/27/2021 10:57:22 AM (UTC-05:00)
To: Lauer, Michael (NIH/OD) [E][(b) (6)]
Cc: Peter Daszak[(b) (6)] Stemmy, Erik (NIH/NIAID) [E][(b) (6)] Gratton, Shaun (NIH/NIAID) [E][(b) (6)] Erbelding, Emily (NIH/NIAID) [E][(b) (6)] Cassetti, Cristina (NIH/NIAID) [E][(b) (6)] Linde, Emily (NIH/NIAID) [E][(b) (6)] Armine Arustamyan[(b) (6)] Joe Riccardi[(b) (6)]
Subject: Re: Regarding 2R01AI110964
Attachment: To EcoHealth 7 23 21 R01AI110964.pdf
Attachment: EHA response to NIH request for further documentation 8.27.21.pdf
Attachment: ATT00001.txt

Dear Dr. Lauer,

Please find our response to your letter from 23 July 2021, attached.

Sincerely,

-Aleksei

Aleksei Chmura, PhD
Chief of Staff &
Authorized Organizational Representative

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018, USA

(b) (6)(direct)
(mobile)
Aleksei MacDurian (Skype)

www.ecohealthalliance.org

Visit our blog: www.ecohealthalliance.org/blog

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

23 July 2021

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

Re: R01AI110964, U01AI151797, U01AI153420

Dear Drs. Chmura and Daszak:

Thank you for your correspondence of April 11, 2021 and April 23, 2021 regarding R01AI110964. We are in the process of conducting detailed analyses of your answers to our questions and well as of the documents you sent, and we have the following additional requests:

1. Records

For us to continue our analyses, we will need to receive and review WIV's records validating expenditures specific to R01AI110964 as well as any and all monitoring, safety, and financial reports specific to R01AI110964 that WIV submitted to you. As a reminder, subawardees are required to have a financial management system that includes records that identify adequately the source and application of funds for federally-funded activities. These records must contain information pertaining to Federal awards, authorizations, obligations, unobligated balances, assets, expenditures, income and interest and be supported by source documentation. 45 C.F.R. §§ 75.101 and 75.302.

As a term and condition of award, NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. 75.364). This right of access applies not only to awardee records, but also to subawardee records. Awardees indicate their acceptance of an NIH award and its associated terms and conditions as they draw down the NIH grant funds to support the scientific project (see NIHGPS Section 5).

REL0000047875.0001.0001

We will also need to see subaward agreements, subawardee audit reports, subawardee safety monitoring documents, subawardee progress reports submitted to you, and subawardee financial and accounting records for two other NIH EcoHealth Alliance grants. Specifically, please send us all responsive documents for:

- U01AI151797 (Daszak): subawardees Chulalongkorn Hospital, Chulalongkorn University, Duke-National Singapore University, and University of North Carolina at Chapel Hill
- U01AI153420 (Epstein): subawardees International Center for Diarrhoeal Disease Research of Bangladesh, Institute of Epidemiology Disease Control and Research of Bangladesh.

We remind you that the Notice of Award for U01AI151797 already contains the following specific award conditions that must still be satisfied by 30 days from establishment.

> Subaward Agreement Requirements: The ECOHEALTH ALLIANCE, INC. must provide NIAID with copies of all (existing and newly established) subaward agreements established under this award, including descriptions of the biosafety monitoring plans, within 30 days of establishment.
>
> Federal Funding Accountability and Transparency Subaward Reporting System (FSRS) Requirements: This award is subject to the Transparency Act subaward reporting requirement of 2 CFR Part 170, which must be reported through the Federal Funding Accountability and Transparency Subaward Reporting System (FSRS). The ECOHEALTH ALLIANCE, INC. must provide NIAID with proof of documentation of timely entries of subaward information into the FSRS within 30 days of submitting to FSRS.

2. Reports

We are also writing to notify you that a review of our records for R01AI110964 indicates that EcoHealth Alliance, Inc. is out of compliance with requirements to submit the following reports that are outlined in the NIHGPS: the Federal Financial Report (FFR, see 8.4.1.2.3 Modified Financial Reporting Requirements) and the Interim Research Performance Progress Report (I-RPPR, see NIHGPS 8.4.1.4 Final Research Performance Progress Report).

R01AI110964 was issued under the Streamlined Noncompeting Award Process (SNAP). For awards under SNAP, an FFR must be submitted within 120 days after the end of the competitive segment and must report on the cumulative support awarded for the entire segment.

Additionally, NIH requires that organizations submit an Interim-RPPR while their Type 2 application is under consideration. In the event that the Type 2 is funded, NIH treats the Interim-RPPR as the annual performance report for the final year of the previous competitive segment.

The FFR and I-RPPR for R01AI110964 were due within 120 days after the end of the project period. In this case, the competitive segment ended on May 31, 2019, and reports were due September 30, 2019. To date, NIH has still not received these reports. Compliance with Section 8, Administrative Requirements within the NIH Grants Policy Statement (NIHGPS) is a standard term and condition of award that applies to all NIH recipients.

A recipient's failure to comply with the terms and conditions of award, may cause NIH to take one or more actions on the award, depending on the severity and duration of the non-compliance. Additionally, a history of non-compliance related to R01AI110964, including reporting non-compliance, may impact other projects where EcoHealth serves as the primary grant recipient. When a recipient has a history of failure to comply with the general or specific terms and conditions of a previous Federal award, NIH may impose specific award conditions on other awards of the recipient, including withholding authority to proceed to the next phase of a project until receipt of evidence of acceptable performance (see NIHGPS Section 8.5, Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support).

In closing, please be advised that EcoHealth Alliance, Inc. must satisfy the existing specific award condition for U01AI151797 by 30 days from establishment and must provide the remaining documents and reports requested herein for all three grants (R01AI110964, U01AI151797, U01AI153420) no later than August 27, 2021.

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

Sincerely,

Lauer, Michael (NIH/OD) [E]

Digitally signed by Lauer, Michael (NIH/OD) [E]
Date: 2021.07.23 17:24:01 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
(b) (6)

cc: Ms. Emily Linde
Dr. Erik Stemmy

EcoHealth Alliance

27 August 2021

Dr. Michael S. Lauer
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Lauer,

In response to your requests for (1) records and (2) reports in your letter dated 23 July 2021, we provide the following responses and documentation. The requested files are too large to transmit via email, so they may be downloaded via the following Drop Box link. Let us know, if another method of file transfer would be preferred.

Drop Box Link:

https://www.dropbox.com/sh/a9giijpbrkotedc/AABQeJVmPK3OJyLAe_TurHJRa?dl=0

Responses:

1. **Records**

R01AI110964
01 WIV Documents.pdf

1. WIV Subaward Contracts & Invoices Y1-Y5
2. WIV Risk Assessment Matrixes 2016*-2019
3. WIV FFATA Reports from 2015-2019
4. WIV Annual Reports 2014-2016
5. WIV DHHS PHS NIH OLAW Approvals for 2014-2019 and 2019-2024
6. WIV Subrecipient Monitoring 2016*-2019

**EcoHealth Alliance began a formal Uniform Guidance subrecipient monitoring policy in 2016 as per OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR §200.331).*

02 EHA FFRs from 2014-2019.pdf

U01AI151797
01 Chulalongkorn Documents.pdf

1. Chulalongkorn Subaward Contract and Invoices
2. Chulalongkorn Subaward email and confirmation to NIAID

3. Chulalongkorn Risk Assessment Matrix
4. Chulalongkorn Audit
5. Chulalongkorn COI Policy
6. Chulalongkorn Subrecipient Monitoring

02 Duke-NUS Documents.pdf

1. Duke-NUS Subaward Contract*
2. Duke-NUS Subaward email and confirmation to NIAID
3. Duke-NUS Risk Assessment Matrix
4. Duke-NUS Audit
5. Duke-NUS COI Policy

**Contract signed in Aug 2021, so Duke-NUS Subrecipient Monitoring form will be available early 2022*

03 UNC Documents.pdf

1. UNC Subaward Contract and Invoices
2. UNC Subaward email and confirmation to NIAID
3. UNC Risk Assessment Matrix
4. UNC Audit
5. UNC COI Policy
6. UNC Subrecipient Monitoring

04 FSRA-FFATA EID-SEARCH.pdf

In addition to the records listed above, we are fully in compliance with the award conditions for U01AI151797. Specifically, from the NoA language: (a) all subaward contract agreements including descriptions of biosafety monitoring plans and (b) proof of documentation of timely entries of subaward information into the FSRS reporting have been provided to our NIAID Program Officer and Grants Management Specialist within 30-days of establishment of the subaward contract or submitting subaward information to the FSRS, respectively. In the files above and following each Subaward Contract and Invoices, we have documentation of emails and responses of these reports and communications.

U01AI153420

01 icddrb Documents.pdf

1. icddr,b Subaward Contract and Invoices
2. icddr,b Risk Assessment Matrix
3. icddr,b Audit
4. icddr,b COI Policy
5. icddr,b Subrecipient Monitoring

02 IEDCR Documents.pdf

1. IEDCR Subaward Contract and Invoices
2. IEDCR Risk Assessment Matrix
3. IEDCR Desk-Audit Questionnaire **in lieu of Audit document*
4. IEDCR COI Policy
5. IEDCR Subrecipient Monitoring

03 FSRS-FFATA Nipah Bangladesh.pdf

2. Reports

a. The interim report (I-RPPR) for R01AI110964 has been submitted via the Interim-RPPR option in the eRA Commons system. Program Officer Erik Stemmy and Grants Management Specialist Shaun Gratton have been notified.
b. Documentation of our submission of all quarterly FFR reports for years 1-6 (2014-2019) for R01AI110964 are included in the Drop Box link, above. Note that following the notice of award for 2R01AI110964 (24-July-19), its termination (27-Apr-20), subsequent of suspension (15-Jul-20), there was a change (01 Jan 21) to the process by which FFRs are required to be submitted such that the US DHHS Payment Management System (PMS) is now used instead of eRA Commons. The PMS does not recognize our previously-terminated, now-suspended grant number and we have requested that the PMS update their system to approve this grant number (update request number UPDA0229501). We have followed up as recently as this morning 8/27/21 (ticket number 264975). As soon as PMS updates their system, we will submit the report and notify our program officer and grants management specialist and send documentation.
c. Reporting for U01AI151797, and U01AI153420 is up to date.

If any additional details or information are required, please let us know. We look forward to hearing from you.

Sincerely,

Peter Daszak, PhD
President, EcoHealth Alliance

Aleksei Chmura, PhD
Chief of Staff & AOR

From: Aleksei Chmura[(b) (6)

Sent: Fri 8/27/2021 10:57:22 AM (UTC-05:00)

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

Cc: Peter Daszak[(b) (6) Stemmy, Erik (NIH/NIAID) [E][(b) (6) Gratton, Shaun (NIH/NIAID) [E][(b) (6) Erbelding, Emily (NIH/NIAID) [E][(b) (6) Cassetti, Cristina (NIH/NIAID) [E][(b) (6) Linde, Emily (NIH/NIAID) [E][(b) (6) Armine Arustamyan[(b) (6) Joe Riccardi[(b) (6)

Subject: Re: Regarding 2R01AI110964

Attachment: To EcoHealth 7 23 21 R01AI110964.pdf

Attachment: EHA response to NIH request for further documentation 8.27.21.pdf

Attachment: ATT00001.txt

Dear Dr. Lauer,

Please find our response to your letter from 23 July 2021, attached.

Sincerely,

-Aleksei

Aleksei Chmura, PhD
Chief of Staff &
Authorized Organizational Representative

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018, USA

(b) (6) (direct)
(mobile)
Aleksei MacDurian (Skype)

www.ecohealthalliance.org

Visit our blog: www.ecohealthalliance.org/blog

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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)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

23 July 2021

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

Re: R01AI110964, U01AI151797, U01AI153420

Dear Drs. Chmura and Daszak:

Thank you for your correspondence of April 11, 2021 and April 23, 2021 regarding R01AI110964. We are in the process of conducting detailed analyses of your answers to our questions and well as of the documents you sent, and we have the following additional requests:

1. Records

For us to continue our analyses, we will need to receive and review WIV's records validating expenditures specific to R01AI110964 as well as any and all monitoring, safety, and financial reports specific to R01AI110964 that WIV submitted to you. As a reminder, subawardees are required to have a financial management system that includes records that identify adequately the source and application of funds for federally-funded activities. These records must contain information pertaining to Federal awards, authorizations, obligations, unobligated balances, assets, expenditures, income and interest and be supported by source documentation. 45 C.F.R. §§ 75.101 and 75.302.

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REL0000047874.0001

We will also need to see subaward agreements, subawardee audit reports, subawardee safety monitoring documents, subawardee progress reports submitted to you, and subawardee financial and accounting records for two other NIH EcoHealth Alliance grants. Specifically, please send us all responsive documents for:

- U01AI151797 (Daszak): subawardees Chulalongkorn Hospital, Chulalongkorn University, Duke-National Singapore University, and University of North Carolina at Chapel Hill
- U01AI153420 (Epstein): subawardees International Center for Diarrhoeal Disease Research of Bangladesh, Institute of Epidemiology Disease Control and Research of Bangladesh.

We remind you that the Notice of Award for U01AI151797 already contains the following specific award conditions that must still be satisfied by 30 days from establishment.

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In closing, please be advised that EcoHealth Alliance, Inc. must satisfy the existing specific award condition for U01AI151797 by 30 days from establishment and must provide the remaining documents and reports requested herein for all three grants (R01AI110964, U01AI151797, U01AI153420) no later than August 27, 2021.

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

Sincerely,

Lauer, Michael (NIH/OD) [E]

Digitally signed by Lauer, Michael (NIH/OD) [E]
Date: 2021.07.23 17:24:01 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
(b) (6)

cc: Ms. Emily Linde
Dr. Erik Stemmy

EcoHealth Alliance

27 August 2021

Dr. Michael S. Lauer
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Lauer,

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02 EHA FFRs from 2014-2019.pdf

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5. Chulalongkorn COI Policy
6. Chulalongkorn Subrecipient Monitoring

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2. Duke-NUS Subaward email and confirmation to NIAID
3. Duke-NUS Risk Assessment Matrix
4. Duke-NUS Audit
5. Duke-NUS COI Policy

**Contract signed in Aug 2021, so Duke-NUS Subrecipient Monitoring form will be available early 2022*

03 UNC Documents.pdf

1. UNC Subaward Contract and Invoices
2. UNC Subaward email and confirmation to NIAID
3. UNC Risk Assessment Matrix
4. UNC Audit
5. UNC COI Policy
6. UNC Subrecipient Monitoring

04 FSRA-FFATA EID-SEARCH.pdf

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U01AI153420

01 icddrb Documents.pdf

1. icddr,b Subaward Contract and Invoices
2. icddr,b Risk Assessment Matrix
3. icddr,b Audit
4. icddr,b COI Policy
5. icddr,b Subrecipient Monitoring

02 IEDCR Documents.pdf

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2. IEDCR Risk Assessment Matrix
3. IEDCR Desk-Audit Questionnaire **in lieu of Audit document*
4. IEDCR COI Policy
5. IEDCR Subrecipient Monitoring

03 FSRS-FFATA Nipah Bangladesh.pdf

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b. Documentation of our submission of all quarterly FFR reports for years 1-6 (2014-2019) for R01AI110964 are included in the Drop Box link, above. Note that following the notice of award for 2R01AI110964 (24-July-19), its termination (27-Apr-20), subsequent of suspension (15-Jul-20), there was a change (01 Jan 21) to the process by which FFRs are required to be submitted such that the US DHHS Payment Management System (PMS) is now used instead of eRA Commons. The PMS does not recognize our previously-terminated, now-suspended grant number and we have requested that the PMS update their system to approve this grant number (update request number UPDA0229501). We have followed up as recently as this morning 8/27/21 (ticket number 264975). As soon as PMS updates their system, we will submit the report and notify our program officer and grants management specialist and send documentation.
c. Reporting for U01AI151797, and U01AI153420 is up to date.

If any additional details or information are required, please let us know. We look forward to hearing from you.

Sincerely,

Peter Daszak, PhD
President, EcoHealth Alliance

Aleksei Chmura, PhD
Chief of Staff & AOR

From: Peter Daszak[(b) (6)
Sent: Fri 10/22/2021 7:59:02 AM (UTC-05:00)
To: Lauer, Michael (NIH/OD) [E][(b) (6) Aleksei Chmura[(b) (6)
Subject: RE: Please read and acknowledge receipt -- Regarding R01AI110964

Dear Michael,

We're confirming receipt of your Oct 20th letter.

We're working to provide the information you requested in that letter and will respond by the date you listed.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

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

---

From: Lauer, Michael (NIH/OD) [E] < (b) (6)
Sent: Friday, October 22, 2021 6:12 AM
To: Peter Daszak < (b) (6) Aleksei Chmura < (b) (6)
Cc: Lauer, Michael (NIH/OD) [E] < (b) (6)
Subject: Please read and acknowledge receipt -- Regarding R01AI110964

Dear Dr. Chmura and Dr. Daszak

Please:

- Confirm receipt of this letter, sent to you on Wednesday, October 20, 2021.
- Provide the dates of work for the experiments described in Figure 13 of the August 3, 2021, RPPR.
- Ensure that all sequences from all the work conducted under this grant are posted immediately to NCBI.

We continue to look forward to receiving all materials by close-of-business Wednesday, October 27, 2021.

Sincerely,
Michael S Lauer, MD

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

From: "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Date: Wednesday, October 20, 2021 at 1:05 PM
To: Peter Daszak <(b) (6) Aleksei Chmura <(b) (6)
Cc: "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Subject: Regarding R01AI110964

Dear Dr. Chmura and Dr. Daszak

Please see attached.

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)

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From: Lauer, Michael (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: Fri 10/22/2021 5:12:18 AM (UTC-05:00)
To: Peter Daszak[(b) (6)] Aleksei Chmura[(b) (6)]
Cc: Lauer, Michael (NIH/OD) [E][(b) (6)]
Subject: Please read and acknowledge receipt -- Regarding R01AI110964
Attachment: To EcoHealth 10 13 21 R01AI110964 10 20 21.pdf
Attachment: EH interim progress report.pdf

Dear Dr. Chmura and Dr. Daszak

Please:

- Confirm receipt of this letter, sent to you on Wednesday, October 20, 2021.
- Provide the dates of work for the experiments described in Figure 13 of the August 3, 2021, RPPR.
- Ensure that all sequences from all the work conducted under this grant are posted immediately to NCBI.

We continue to look forward to receiving all materials by close-of-business Wednesday, October 27, 2021.

Sincerely,
Michael S Lauer, MD

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

From: "Lauer, Michael (NIH/OD) [E]" <(b) (6)>
Date: Wednesday, October 20, 2021 at 1:05 PM
To: Peter Daszak <(b) (6)> Aleksei Chmura <(b) (6)>
Cc: "Lauer, Michael (NIH/OD) [E]" <(b) (6)>
Subject: Regarding R01AI110964

Dear Dr. Chmura and Dr. Daszak

Please see attached.

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)

20 October 2021

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

Re: R01AI110964, U01AI151797, U01AI153420

Dear Drs. Chmura and Daszak:

Thank you for your correspondence (including supporting materials) of August 27, 2021, regarding R01AI110964, U01AI151797, U01AI153420. We also note that you submitted on August 3, 2021, an interim RPPR for the R01AI110964 budget period of June 1, 2018 to May 31, 2019.

For us to continue our analyses, as required by the NIH Grants Policy Statement, 4.1.1.2, NIH requires verification of IACUC approval; therefore, please provide us documentation from the WIV IACUC regarding approval for field work (e.g. work in caves to collect materials from live bats) supported by R01AI110964. We also need to see all remaining unpublished data supported by this same grant that you have not already reported in your RPPRs. If all such data supported by this grant has been reported (either through peer-reviewed publication or through RPPRs), please indicate.

We look forward to receiving these materials by no later than close-of-business on Wednesday, October 27, 2021.

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

Sincerely,

Lauer, Michael (NIH/OD) [E]
Digitally signed by Lauer, Michael (NIH/OD) [E]
Date: 2021.10.20 12:55:59 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
(b) (6)

cc: Ms. Emily Linde
Dr. Erik Stemmy

NIH National Institute of Mental Health

A. COVER PAGE

Project Title: Understanding the Risk of Bat Coronavirus Emergence	
Grant Number: 5R01AI110964-05	Project/Grant Period: 06/01/2014 - 05/31/2019
Reporting Period: 06/01/2018 - 05/31/2019	Requested Budget Period: 06/01/2018 - 05/31/2019
Report Term Frequency: Annual	Date Submitted: 08/03/2021
Program Director/Principal Investigator Information: PETER DASZAK , PHD BS Phone Number: (b) (6) Email: (b) (6)	Recipient Organization: ECOHEALTH ALLIANCE, INC. ECOHEALTH ALLIANCE, INC. 520 EIGHTH AVENUE NEW YORK, NY 100181620 DUNS: 077090066 EIN: 1311726494A1 RECIPIENT ID:
Change of Contact PD/PI: NA	
Administrative Official: ALEKSEI CHMURA 460 W 34th St., 17th Floor New York, NY 10001 Phone number: (b) (6) Email: (b) (6)	Signing Official: ALEKSEI CHMURA 460 W 34th St., 17th Floor New York, NY 10001 Phone number: (b) (6) Email: (b) (6)
Human Subjects: Yes HS Exempt: NA Exemption Number: Phase III Clinical Trial: NA	Vertebrate Animals: NA
hESC: No	Inventions/Patents: No

B. ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

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 recent emergence Middle East Respiratory Syndrome (MERS-CoV). The wildlife reservoirs of SARS-CoV were identified by our group as bat species, and since then hundreds of novel bat-CoVs have been discovered (including >260 by our group). These, and other wildlife species, are hunted, traded, butchered and consumed across Asia, creating a largescale human-wildlife interface, and high risk of future emergence of novel CoVs. To understand the risk of zoonotic CoV emergence, we propose to examine 1) the transmission dynamics of bat-CoVs across the human-wildlife interface, and 2) how this process is affected by CoV evolutionary potential, and how it might force CoV evolution. We will assess the nature and frequency of contact among animals and people in two critical human-animal interfaces: live animal markets in China and people who are highly exposed to bats in rural China. In the markets we hypothesize that viral emergence may be accelerated by heightened mixing of host species leading to viral evolution, and high potential for contact with humans. In this study, we propose three specific aims and will screen free ranging and captive bats in China for known and novel coronaviruses; screen people who have high occupational exposure to bats and other wildlife; and examine the genetics and receptor binding properties of novel bat-CoVs we have already identified and those we will discover. We will then use ecological and evolutionary analyses and predictive mathematical models to examine the risk of future bat-CoV spillover to humans. This work will follow 3 specific aims:

Specific Aim 1: Assessment of CoV spillover potential at high risk human-wildlife interfaces. We will examine if: 1) wildlife markets in China provide enhanced capacity for bat-CoVs to infect other hosts, either via evolutionary adaptation or recombination; 2) the import of animals from throughout Southeast Asia introduces a higher genetic diversity of mammalian CoVs in market systems compared to within intact ecosystems of China and Southeast Asia; We will interview people about the nature and frequency of contact with bats and other wildlife; collect blood samples from people highly exposed to wildlife; and collect a full range of clinical samples from bats and other mammals in the wild and in wetmarkets; and screen these for CoVs using serological and molecular assays.

Specific Aim 2: Receptor evolution, host range and predictive modeling of bat-CoV emergence risk. We propose two competing hypotheses: 1) CoV host-range in bats and other mammals is limited by the phylogenetic relatedness of bats and evolutionary conservation of CoV receptors; 2) CoV host-range is limited by geographic and ecological opportunity for contact between species so that the wildlife trade disrupts the 'natural' co-phylogeny, facilitates spillover and promotes viral evolution. We will develop CoV phylogenies from sequence data collected previously by our group, and in the proposed study, as well as from Genbank. We will examine co-evolutionary congruence of bat-CoVs and their hosts using both functional (receptor) and neutral genes. We will predict host-range in unsampled species using a generalizable model of host and viral ecological and phylogenetic traits to explain patterns of viral sharing between species. We will test for positive selection in market vs. wild-sampled viruses, and use data to parameterize mathematical models that predict CoV evolutionary and transmission dynamics. We will then examine scenarios of how CoVs with different transmissibility would likely emerge in wildlife markets.

Specific Aim 3: Testing predictions of CoV inter-species transmission. We will test our models of host range (i.e. emergence potential) experimentally using reverse genetics, pseudovirus and receptor binding assays, and virus infection experiments in cell culture and humanized mice. With bat-CoVs that we've isolated or sequenced, and using live virus or pseudovirus infection in cells of different origin or expressing different receptor molecules, we will assess potential for each isolated virus and those with receptor binding site sequence, to spill over. We will do this by sequencing the spike (or other receptor binding/fusion) protein genes from all our bat-CoVs, creating mutants to identify how significantly each would need to evolve to use ACE2, CD26/DPP4 (MERS-CoV receptor) or other potential CoV receptors. We will then use receptor-mutant pseudovirus binding assays, in vitro studies in bat, primate, human and other species' cell lines, and with humanized mice where particularly interesting viruses are identified phylogenetically, or isolated. These tests will provide public health-relevant data, and also iteratively improve our predictive model to better target bat species and CoVs during our field studies to obtain bat-CoV strains of the greatest interest for understanding the mechanisms of cross-species transmission.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

File Uploaded : Year 5 NIAID CoV Report Accomplishments Final.pdf

B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

For this reporting period, is there one or more Revision/Supplement associated with this award for which reporting is required?

No

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

File Uploaded : B4 Training.pdf

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

1. Conference and University Lectures: PI Daszak and Co-investigators Shi, Epstein, Olival, and Zhang gave invited conference and university lectures at The US-China Dialogue on the Challenges of Emerging Infections, Laboratory Safety and Global Health Security in Galveston, US; the US-China Workshop on Frontiers in Ecology and Evolution of Infectious Diseases in Berkeley, US and Shenzhen, China; the Sino-Germany symposium "Globalization-Challenge and Response for Infectious Diseases" in Hamburg, Germany; the 8th International Symposium on Emerging Viral Diseases in Wuhan, China; the Global Virome Project meeting, Bangkok, Thailand; the Western Asia Bat Research Network (WAB-Net) workshop, Tbilisi, Georgia; the International Conference on Emerging Infectious Diseases (ICEID), Atlanta, US; the North American Society for Bat Research (NASBR) Conference, Puerta Vallerta, Mexico; and the 3rd Symposium of Biodiversity and Health in Southeast Asia, Chiayi, Taiwan

2. Agency and other briefing: PI Daszak and Co-investigators Shi, Olival presented this project at the Cary Institute for Ecosystem Studies, New York, US; the National Institute for Viral Disease Control and Prevention, China CDC; the Chinese Academy of Sciences; and the Chinese Academy of Medical Sciences

3. Public outreach: PI Daszak and Co-investigator Shi, Epstein, Olival, have presented this work to the general public in a series of meetings over Year 5 including at a Cosmos Club briefing that EcoHealth Alliances hosts in Washington DC, multiple meetings of the China National Virome Project and the Global Virome Project in China, Europe, Australia, Southeast Asia and Latin America. As in Year 4, Co-Investigator Zhu introduced this work to the conservation and ecological research community in China through field training workshops.

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

Not Applicable

The results of the 5th year of our R01 work are detailed below. They include:

Specific Aim 1: Assessment of CoV spillover potential at high-risk human-wildlife interfaces

During Year 5, we finalized the analysis of both quantitative and qualitative data from human surveillance in three provinces in Southern China: Yunnan, Guangxi, and Guangdong provinces.

1.1 High-risk human-animal interaction increase bat coronavirus spillover potential among rural residents in southern China

We conducted a cross-sectional biological behavioral surveillance in Yunnan, Guangxi, and Guangdong provinces from 2015 to 2017. From 8 study sites, a total of 1,596 residents were enrolled, of these, 1,585 participants completed the questionnaires and 11 participants withdrew from the questionnaire interview due to personal schedule reasons. After the interviews, 1,497 participants provided biological samples for lab analysis **(Fig. 1)**.

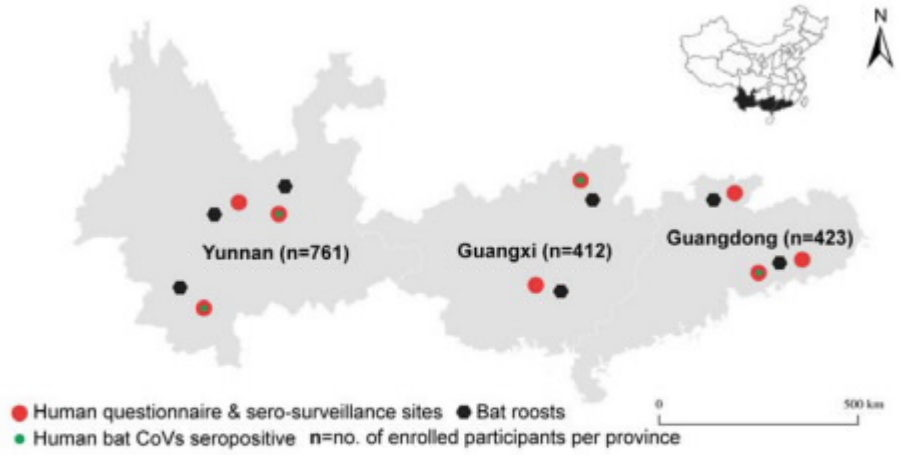

Fig. 1: Eight field surveillance sites for human questionnaire & sero-surveillance with concurrent bat sampling in Yunnan, Guangxi, Guangdong provinces in Southern China. Bat coronavirus sero-positivity were detected in human population in four sites in this study

1.1.1 Demographics

There were more female (62%) than male (38%) from the communities participated in this study. Most participants were adults over 45 years old (69%) and had been living in the community for more than 5 years (97%) with their family members (95%). A majority relied on a comparatively low family annual per capita income less than 10,000 RMB (86%), which is below the national level of per capita disposable income of rural households from 2015 to 2017. Most participants (98%) had not received a higher education from college and were making a living on crop production (76%). 9% of the participants frequently traveled outside the county as migrant laborers.Some participants were working in sectors where frequent human-animal contacts occur, such as the animal production business (1.7%), wild animal trade (0.5%), slaughterhouses or abattoirs (0.5%), protected nature reserve rangers (0.4%) or in wildlife restaurants (0.3%). It was common for participants to have multiple part-time jobs as income sources **(Table 1)**.

Variable	Total	
	N	Valid %
Gender (n= 1,574)		
Female	968	61.5
Male	605	38.4
Other	1	0.1
Age (n=1,582)		
Under 18 years	71	4.5
18 to 44 years	420	26.5
45 to 64 years	780	49.3
Age 65 or older	311	19.7
Province (n=1,585)		
Guang Dong	420	26.5
Guang Xi	412	26.0
Yun Nan	753	47.5
Time of residence (n=1,568)		
< 1 month	4	0.3
1 month – 1 year	12	0.8
1 year – 5 years	26	1.7
> 5 years	1,526	97.3
Family annual per capita income (RMB) (n=1,565)		
<1000	271	17.3
1001-10000	1067	68.2
>10000	227	14.5
Activities to earn livelihood since last year		
Extraction of minerals, gas, oil, timber (n=1,566)	5	0.3
Crop production (n=1,569)	1,196	76.2
Wildlife restaurant business (n=1,564)	5	0.3
Wild/exotic animal trade/market business (n=1,566)	8	0.5
Rancher/farmer animal production business (n=1,566)	27	1.7
Meat processing, slaughterhouse, abattoir (n=1,567)	8	0.5
Zoo/sanctuary animal health care (n=1,565)	1	0.1
Protected area worker (n=1,567)	7	0.4
Hunter/trapper/fisher (n=1,565)	3	0.2
Forager/gatherer/non-timber forest product collector (n=1,566)	4	0.3
Migrant laborer (n=1,567)	144	9.2
Nurse, doctor, healer, community health worker (n=1567)	7	0.4
Construction (n=1,564)	41	2.6
Other (n=1,568)	293	18.7
Highest level of education you completed (n=1,570)		
None	428	27.3
Primary School	632	40.3
Secondary school/Polytechnic school	479	30.5
College/university/professional	31	2.0
Live with family (n=1,564)		
No	73	4.7
Yes	1491	95.3

Table 1: Demographics of study participants. Total counts differ due to missing responses.

1.1.2 Animal contact and exposure to bat coronaviruses

Serological testing of serum samples from 1,497 local residents revealed 9 individuals (0.6%) were positive for bat coronavirus, indicating exposure at any point in their life to bat-born SARS-related Coronavirus (n=7, Yunnan) and HKU10 Coronavirus (n=2, Guangxi), or other coronaviruses that are phylogenetically closely related to these two coronaviruses (Table 2). All individuals who tested positive (male=6, female=3) were over 45 years old, and most (n=8)

were making a living from crop production.None of those participants reported any symptoms in the preceding 12 months in the interview.

Site	# tested	Bat CoV + (%)	SARSr-CoV Rp3 + (%)	HKU10 + (%)	HKU9 + (%)	MERS-CoV+ (%)
Jinning, Yunnan	209	6 (2.87)	6 (2.87)	-	-	-
Mengla, Yunnan	168	1 (0.6)	1 (0.6)	-	-	-
Jinghong, Yunnan	212	-	-	-	-	-
Lufeng, Yunnan	144	-	-	-	-	-
Guangdong	420	-	-	-	-	-
Guangxi	412	2 (0.48)	-	2 (0.48)	-	-

Table 2: ELISA testing of human sera for 4 bat CoVs

Due to the low rate of sero-positivity, we did not conduct statistical comparisons of animal-contact behavior by coronavirus outcome. Figure 2 shows animal contact rates among the survey population (n= 1,585) and among sero-positive individuals (n=9).Participants reported common contact with poultry and rodents/shrews, and most animal contact occurred in domestic settings through raising animal or food preparation activities.

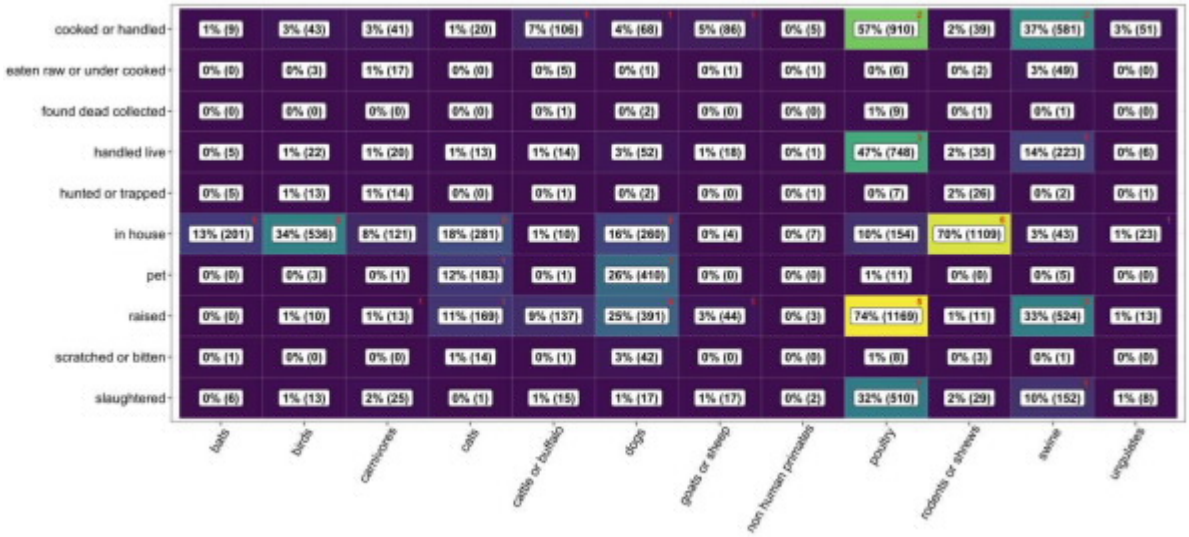

Fig. 2: Animal contact by taxa and activities. Values and shading represent survey population; red numbers in upper-right corners of cells indicate the number of sero-positive individuals with the given contact.

1.1.3 Self-report SARI/ILI symptoms and animal contact

Among the 1,565 participants who responded, 17% (n=265) had experienced fever with cough and shortness of breath or difficulty breathing (38, 14%), indicative of severe acute respiratory infection (SARI), or fever with muscle aches; cough, or sore throat (192, 72%), indicative of influenza like illness (ILI), or both symptoms (35, 13%) in the past 12 months.

LASSO analyses of the associations between animal contact and self-report SARI or ILI symptoms showed that eating raw or undercooked carnivores (OR = 1.6; bootstrap support = 0.67) was the most salient predictor of experiencing SARI or ILI symptoms, followed by slaughtering poultry as a resident of Guangxi province (OR = 1.4; support = 0.68); having an income below 10,000 as a resident of Guangxi province (OR = 1.3; support = 0.84); domestic

contact with bats (OR = 1.3 ; support = 0.63) and domestic contact with rodents or shrews as a resident of Guangdong province (OR = 1.2; support = 0.63) **(Fig. 3)**.

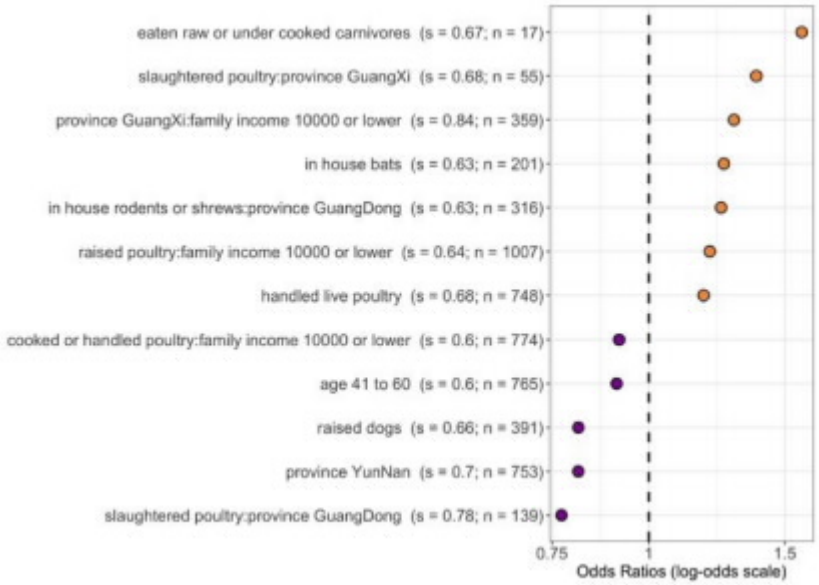

Fig. 3: Most salient predictors of self-reported ILI and/or SARI symptoms in the last year (s = bootstrap support; n = count positive out of 1585 respondents). Bootstrap support values = 0.6 are demonstrated here meaning they were identified as associated with the outcome for 60% or more of the bootstrap iterations. Odds ratios > 1 (orange) are positively associated with the outcome, and odds ratios <1 (purple) are negatively associated with the outcome.

This study provides serological evidence of subclinical or asymptomatic bat-born SARS-related Coronavirus and HKU10 Coronavirus spillover event(s) in rural communities in Southern China, highlights the associations between human-animal interaction and zoonotic spillover risk. The rate of seropositivity observed in this study is clearly lower than would be seen for established human infections. However it has important implications for predicting and preventing pandemics:

1. It indicates that spillover of novel bat-CoVs is detectable if populations that live within areas inhabited by likely bats hosts are targeted. **This provides a pathway to identify spillover events rapidly, perhaps even before a SARS-like disease can become established in people**;
2. It allows us to calculate the likely number of people infected by novel bat SARSr-CoVs annually in this region. Our preliminary analyses suggest that if similar seroprevalence occurs in human populations across the region bat SARSr-CoV hosts inhabit, **there may be as many as the low hundreds of thousands to over a million people infected each year in South China and Southeast Asia.** We aim to conduct a detailed analysis of this in the future.
3. It highlights ways to refine surveillance that could help prevent pandemics, by targeting populations where seroprevalence suggests that they are **at higher risk due to behavioral preferences (e.g. wildlife hunting, farming, or trading)** or where **early-stage SARS-like illnesses could be identified using syndromic surveillance of clinics**.

Contact with poultry and rodents/shrews were commonly reported among participants and associated with self-reported ILI and/or SARI symptoms, which suggests that domestic animals, in addition to wildlife, are an important link in understanding the coronavirus transmission from bat to human populations, indirect exposure might occur through contact with live domestic animals in house or market when the animals had prior exposure to bat coronavirus.

When clinical evidence is limited, undiagnosed or subclinical symptoms similar to SARI and ILI in a population should be brought to our attention as indicators in monitoring zoonotic pathogen spillover events, and considered for prevention strategies. This is particularly important in rural community settings, where people have a higher level of exposure to both domestic and wild animals, but may not seek diagnosis or treatment in a timely fashion, thus slowing the processes of early detection and response.

1.2 Qualitative Approach to Developing Zoonotic Risk Mitigation Strategies in Southern China

To explore the potential drivers of zoonotic exposure and the opportunities for intervention, we conducted field observation and semi-structured ethnographic interviews among 88 community members who have frequent exposure to wildlife and domestic animals and/or have extensive local knowledge in 9 sites in Yunnan, Guangdong, and Guangxi provinces.

The majority of participants in this study were adults between 31 to 50 years of age, residing in rural or suburban areas. Most earned their livelihoods from multiple sources, primarily in crop production, subsistence animal farming, small business, and other temporary jobs as migrant workers. Risk and protective factors were identified at the individual, community, and policy levels regarding potential zoonosis exposures, recommending risk-mitigation strategies with the strengthened policy enforcement and multi-sectoral collaboration among human, animal, and environment health programs **(Fig. 4).**

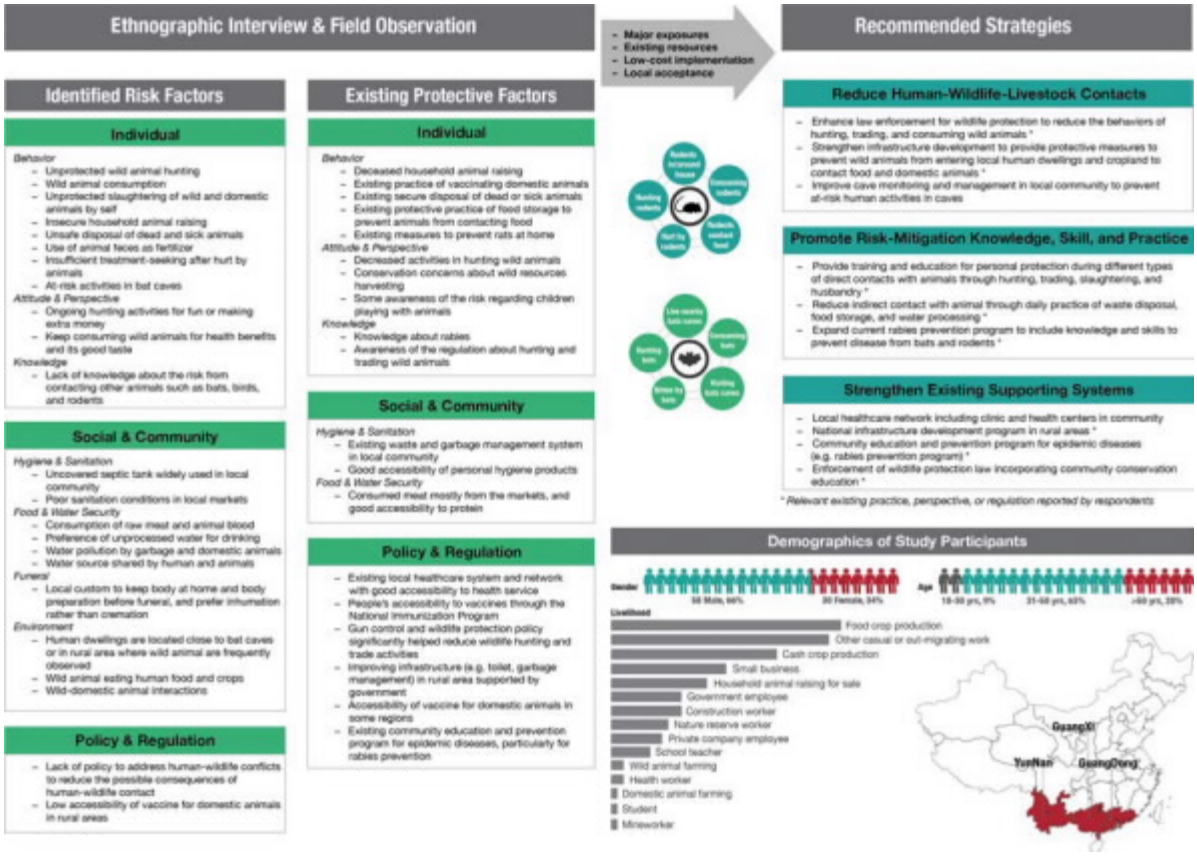

Fig. 1: Community Zoonosis Exposure Risk Mitigation Strategy Development Process. Leveraging ethnographic interview and observational research data to identify risk andprotective factors and develop risk-mitigation recommendations

This demonstrated a qualitative approach to understand the zoonotic risks in community, and provided guidance for future research and interventions with focused potential zoonotic risks for disease control and prevention in southern China and a broader area with similar ecological, culture, and demographic contexts.

Specific Aim 2: Receptor evolution, host range and predictive modeling of bat-CoV emergence risk

2.1 Bat CoV PCR detection and sequencing from live-sampled bat populations

From May to October 2018, we collected 1,697 rectal swabs, oral swabs, and feces specimens from 26 bat species in Hubei, Shandong, Yunnan and Guangdong Provinces across southern, central and northern China in Year 5, all specimen were tested for CoV RNA and 109 (6.4%) were positive. SARS-related coronaviruses were discovered in *Rhinolophus sinicus* samples from Yunnan and Hubei provinces while HKU2-related coronaviruses were detected in *R.sinicus* from Hubei. HKU5-related and HKU10-related coronaviruses were identified in *Pipistrellus abramus* from Shandong and *Hipposideros larvatus* from Guangdong, respetively. *Scotophilus* coronavirus 512 was detected in Guangdong. Addtionally, two novel *Pipistrellus* alphacoronaviruses were found in Shandong province in northern China **(Fig. 5)**.

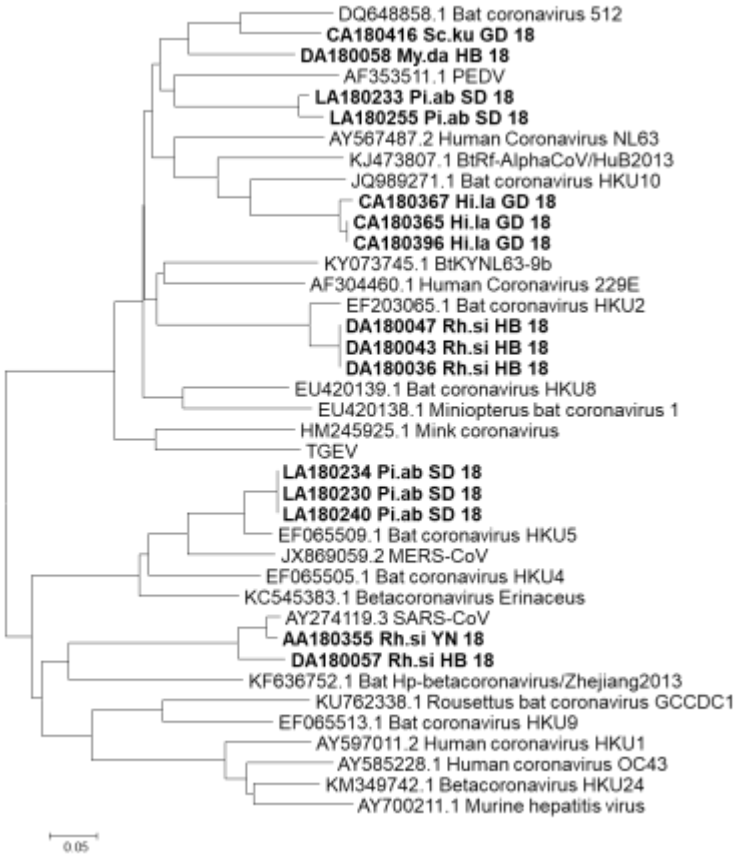

Fig. 2: Phylogenetic analysis of partial RdRp gene of CoV (440-nt partial sequence)

2.2 Bat coronavirus host-virus phylogeography in China

Our dataset includes all CoV RdRp sequences isolated from bat specimens collected by our team from 2008-2015 (Alpha-CoVs: n = 491 – Beta-CoVs: n = 326), including those collected under prior NIAID funding (1 R01 AI079231), and funding from Chinese Federal Agencies. All Chinese bat CoV RdRp sequences available in GenBank were also added to

our dataset (Alpha-CoVs: n = 226 – Beta-CoVs: n = 206). Phylogenetic trees were reconstructed for Alpha- and Beta-CoVs separately using Bayesian inference (BEAST 1.8).

2.2.1 Ancestral hosts and cross-species transmission

We used ancestral character state reconstruction and a Bayesian stochastic search variable selection (BSSVS) to identify host switches between bat families **(Fig. 6)** and genera **(Fig. 7)** that occurred along the branches of the phylogenetic tree and calculated BF to estimate the significance of these non-zero transition rates. We identified nine and three highly supported (BF > 10) **inter-family** host transition rates for alpha- and beta-CoVs, respectively **(Figs. 6A and 6B)**. To quantify the intensity of these host switches, we estimated the number of state changes (Markov jumps) along the significant inter-family transition rates **(Figs. 6C and 6D)**. The total estimated number of inter-family host jump events was more than eight times higher in the evolutionary history of alpha- (n = 90) than beta-CoVs (n = 11) in China. Host transition events from Rhinolophidae and Miniopteridae were greater than from other families for alpha-CoVs while Rhinolophidae were the highest donor family for beta-CoVs. Rhinolophidae and Hipposideridae were the families receiving the highest numbers of transition events for alpha- and beta-CoVs, respectively **(Figs. 6C and 6D)**.

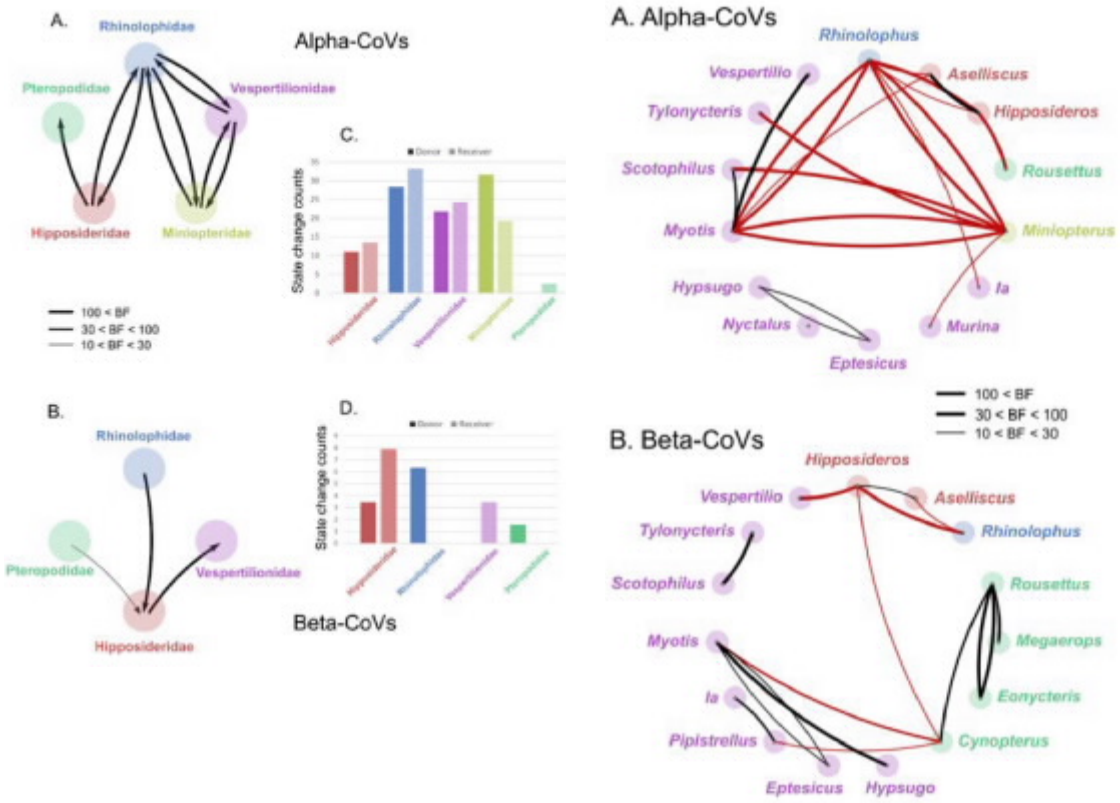

Figure 3: Non-zero transition rates between bat families for alpha- **(A)** and beta-CoVs **(B)** and their significance level (Bayes factor, BF), BF < 10 are considered as non-significant. Arrows indicate the direction of the transition; arrow thickness is proportional to the transition significance level. Histograms show total number of state changes (Markov jumps) from/to each bat family along the significant inter-family transition rates for alpha- **(C)** and beta-CoVs **(D)**.

Figure 4: Non-zero transition rates between bat genera for alpha- **(A)** and beta-CoVs **(B)** and their significance level (Bayes factor, BF), BF < 10 are considered as non-significant. Lines with a rightward curvature depict transitions from that bat genus, while lines with leftward curvature depict transition to that bat genus. Inter-family transitions are highlighted in red.

At the genus level, we identified 20 highly supported inter-genus host transition rates for alpha-CoVs **(Fig. 7A)**. *Rhinolophus* and *Myotis* were the donor genera in four of these transitions while *Miniopterus* and *Rhinolophus* were each the recipients of four of these transitions **(Fig. 7A)**. Sixteen highly supported inter-genus transition rates were identified for beta-CoVs **(Fig.7B)**. Four of these 16 host switches originated in *Cynopterus* while three of them ended in *Myotis* **(Fig. 7B)**. Fifteen out of the 20 significant pairwise host transitions (75%) for alpha-CoVs involved two genera belonging to different bat families, while this proportion is only 6/16 (37.5%) for beta-CoVs. This confirmed the highest number of inter-family host transitions for alpha-CoVs. The estimated total number of inter-genus host switches was almost two times higher for alpha- (n = 123) than beta-CoVs (n = 70).

These findings indicate that alpha-CoVs were able to switch hosts more frequently and between more distantly related taxa during their evolution and suggest that phylogenetic distance among hosts represents higher constraint on host switches for beta- than alpha-CoVs.

2.2.2 CoV spatiotemporal dispersal in China

We also used our Bayesian discrete phylogeographic model using zoogeographic regions as character states to reconstruct the spatiotemporal dynamics of CoV dispersal in China. Eleven and seven highly significant (BF > 10) dispersal routes within China were identified for alpha- and beta-CoVs, respectively **(Fig. 8A and 8B)**. The Rhinacovirus lineage that includes HKU2 and SADS-CoV likely originated in SO region while all other alpha-CoV lineages likely arose in SW China and spread to other regions before several dispersal events occurred from SO and NO in all directions **(Fig. 8A)**.

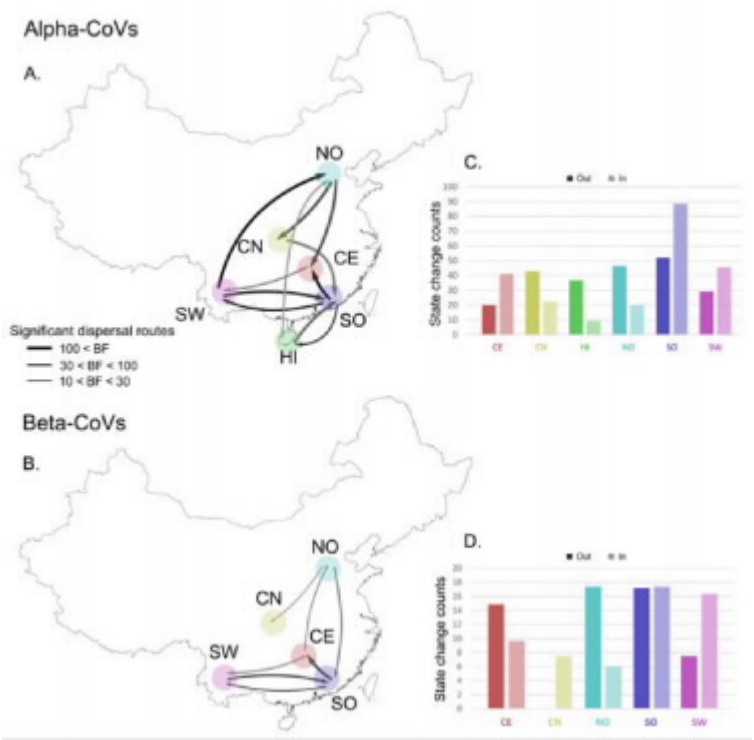

Fig. 8: Significant dispersal routes among China zoogeographic regions for alpha- **(A)** and beta-CoVs **(B)**. Arrows indicate the direction of the transition; arrow thickness is proportional to the transition significance level. Darker arrow colors indicate older dispersal events. **Fig. 8 (C & D)** Histograms of total number of state changes (Markov jumps) from/to each region along the significant dispersal routes for alpha- **(C)** and beta-CoVs **(D)**. NO, Northern region; CN, Central northern region; SW, South western region; CE, Central region; SO, Southern region; HI, Hainan island.

The oldest inferred dispersal movements among beta-CoVs occurred among SO and SW regions **(Fig. 8B)**. SO region is the likely origin of Merbecovirus (Lineage C, including HKU4 and

HKU5) and Sarbecovirus subgenera (Lineage B, including HKU 3 and SARS-related CoVs) while Nobecovirus (lineage D) and Hibecovirus (lineage E) subgenera originated in SW China. Then several dispersal movements likely originated from SO and CE **(Fig. 8B)**. More recent southward dispersal from NO was observed.

The estimated total number of migration events along these significant dispersal routes is four times higher for alpha- (n = 227) than beta-CoVs (n = 57). SO has the highest number of outbound and inbound migration events for alpha-CoVs **(Fig. 8C)**. For beta-CoVs, the highest numbers of outbound migration events have been estimated from NO and SO while SO and SW have the highest numbers of inbound migration events **(Fig. 8D)**.

Our Bayesian ancestral reconstructions revealed the high importance of South western and Southern China as centers of diversification for both alpha- and beta-CoVs. These two regions are clearly hotspots of CoV phylo-diversity, harboring evolutionary old and phylogenetically diverse lineages of alpha- and beta- CoVs.

2.2.3 Phylogenetic diversity

In order to quantitatively evaluate the diversity and the clustering process in our phylogenies, the Mean Phylogenetic Distance (MPD) and the Mean Nearest Taxon Distance (MNTD) statistics and their standardized effect size (SES) were calculated for each zoogeographic region, bat family and genus. The SES corresponds to the difference between the phylogenetic distances in the observed communities versus null communities built by randomly reshuffling tip labels 1000 times along the entire phylogeny. Low and negative SES values denote phylogenetic clustering, high and positive values indicate phylogenetic over-dispersion while values close to 0 show random dispersion.

Significant negative SES MPD values ($p < 0.05$), indicating basal phylogenetic clustering, were observed within all bat families and genera for both alpha- and beta-CoVs, except within *Aselliscus* and *Tylonycteris* for alpha-CoVs **(Figs. 9A & B)**. Negative and mostly significant SES MNTD values, reflecting phylogenetic structure closer to the tips, were also observed within most bat families and genera for alpha- and beta-CoVs but we found non-significant positive SES MNTD value for Vespertilionidae and *Pipistrellus* for beta-CoVs (Fig. 4A and 4B). In general, we observed lower phylogenetic diversity for beta- than alpha-CoVs within all bat families and most genera when looking at SES MPD, while similar level of diversity are observed when looking at SES MNTD **(Figs. 9A & B)**. These results suggest stronger basal clustering (at the deeper nodes) for beta-CoVs than alpha-CoVs.

Chinese zoogeographic regions don't harbor a random set of CoVs as alpha- and beta-CoV strains within most regions are more closely related than expected by chance as denoted by negative and mostly significant values of MPD and MNTD **(Fig. 9C)**. However, positive SES MPD value for alpha-CoVs in SW indicate wider evolutionary diversity in that region **(Fig. 9C)**.

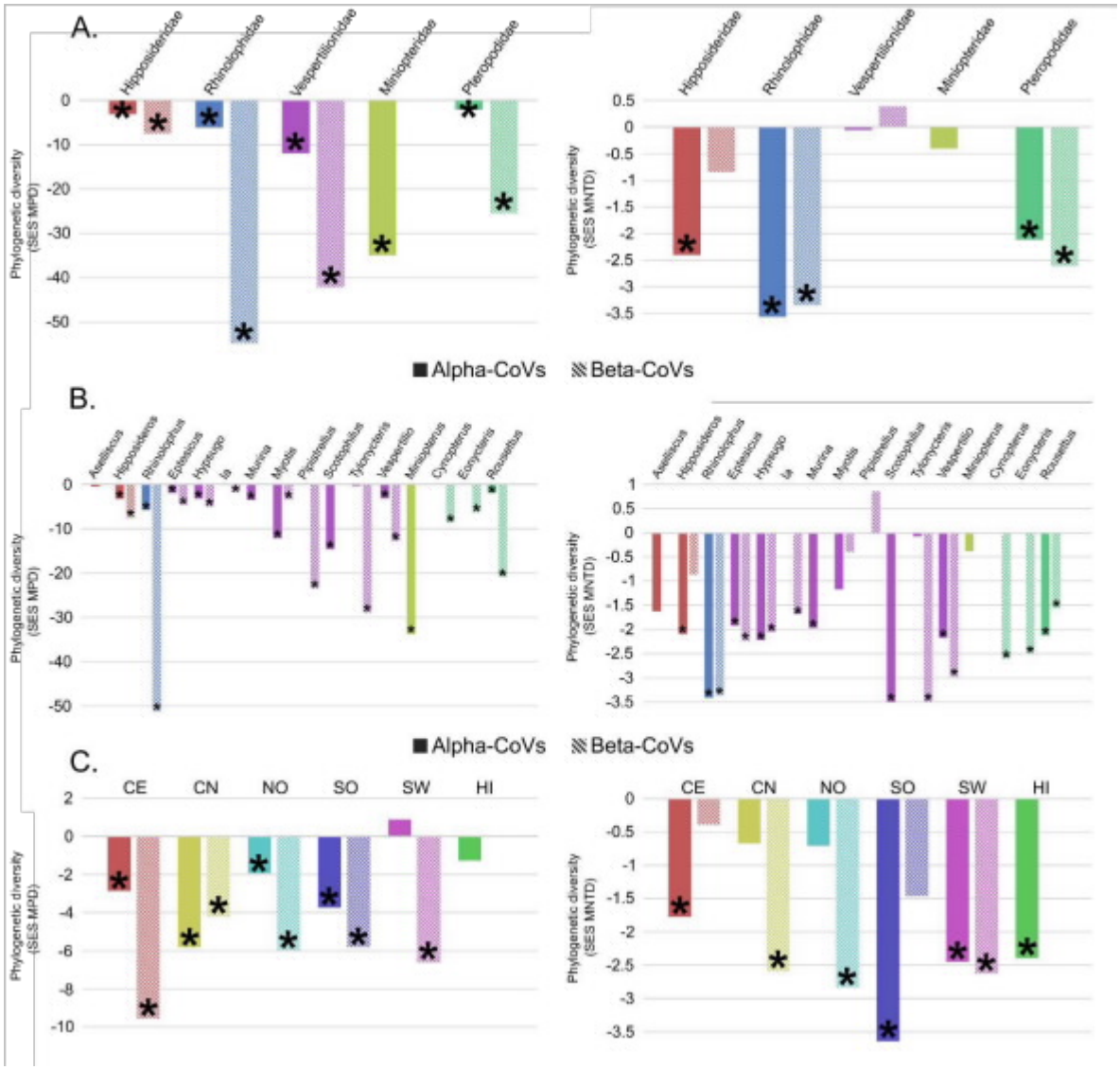

Fig. 9: CoV phylogenetic diversity bat families **(A),** genera **(B),** and zoogeographic regions **(C)**: SES MPD, standardized effect size of Mean Phylogenetic D istance **(Left)**; and SES MNTD, standardized effect size of Mean Nearest Taxon Distance **(Right)**. Values departing significantly from null model (p-value < 0.05) indicated with an asterisk. NO, Northern region; CN, Central northern region; SW, South western region; CE, Central region; SO, Southern region; HI, Hainan island.

2.3 Characterization of SADSr-CoV coronaviruses diversity and distributions

In previous project years, our team identified and characterized Swine Acute Diarrheal Syndrome coronavirus (SADS-CoV), a novel swine virus causing outbreaks in farms in multiple Chinese provinces.In this year, we were able to identify SADS-related CoVs in bats from our wild bat sampling.In >17,000 bat and other mammals at 47 sites across southern China, we found 78 new SADSr-CoVs[11], all in 9 bat species, with mean prevalence of 0.1 to 37.5%.

Our phylogenetic analysis suggests that pig SADS-CoV recently spilled over from *R. sinicus* or *R. affinis* bats **(Fig. 10 Left)** However, analysis of full pig viral genomes from 4 initially infected

farms suggests that either the virus evolved as it circulated or that multiple spillover events occurred **(Fig. 10 Right)**.

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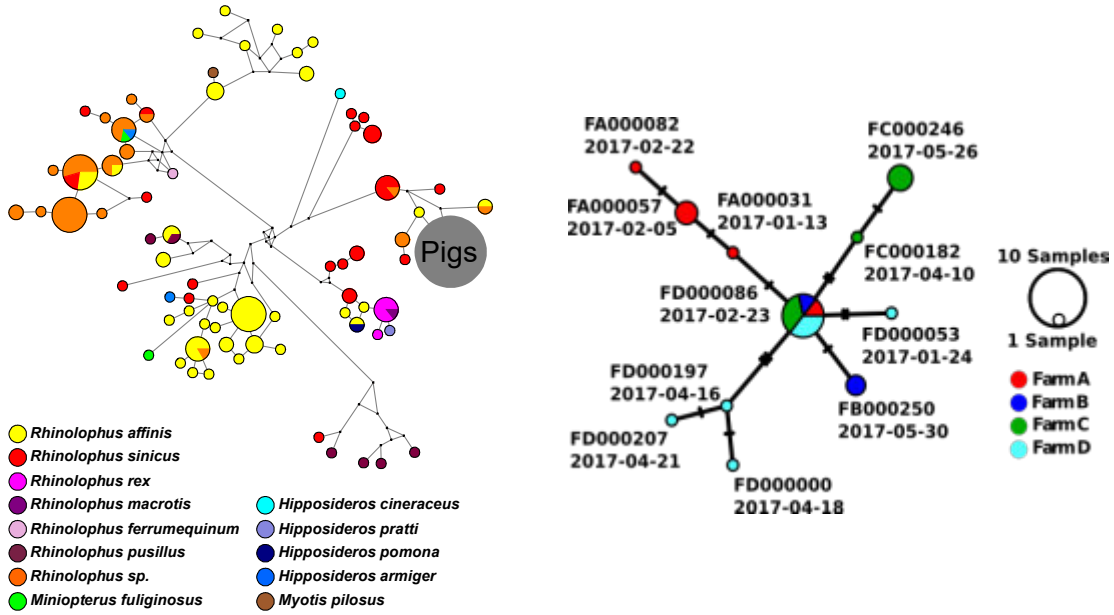

!

Fig. 10: Left: Median joining network of conserved RdRp gene fragment of 198 unique SADSr -CoV sequences discovered in China under our previous funding. Size of circle proportional to the number specimens with identical viral sequences. **Right:** Median joining network of S ADS-CoV full genome sequence data from 4 infected pigs farms in S. China.

We built species distribution models of the major bat species hosts of SADSr-CoVs across southeast Asia to determine the areas where their ranges intersect with large swine operations similar to those of the original outbreak.We found that these are Southern China (including Taiwan), throughout Vietnam, the Philippines, and Thailand. Compared to other countries, China had the largest area of bat-pig overlap with 329,847 km2 (3.4% of total country area) and 2,127,006 pigs located within predicted bat distributions. By Chinese province, the largest area of overlap was found in Jiangsu (35,226 km2 amounting to 34.3% of the province's area and 242,299 pigs within this area). Sichuan had the largest pig population at risk (the pig population within an area that intersects with predicted bat occurrence), at 274,353 heads over 26,015 km2 (5.4% of the total area of the province) **(Figs. 11 & 12)**.

Fig. 5: Areas of bat-pig overlap where probability of SADS-CoV Rhinolophus spp. reservoir occurrence is high (>75%) and pig densities are indicative of intensive pig farming (>100 heads per km2).

Fig. 6: Top: Country-level, and **Bottom:** province-level estimate of swine populations at-risk based on overlap between modeled populations of bat species known to be SADSr-CoV hosts and large swine operations.

Specific Aim 3: Testing Predictions of CoV Inter-Species Transmission

3.1 *In vivo* infection of Human ACE2 (hACE2) expressing mice with SARSr-CoV S protein variants

In Year 5, we continued with *in vivo* infection experiments of diverse bat SARSr-CoVs on transgenic mice expressing human ACE2. Mice were infected with 4 strains of SARSr-CoVs with different S protein, including the full-length recombinant virus of SARSr-CoV WIV1 and three chimeric viruses with the backbone of WIV1 and S proteins of SHC014, WIV16 and Rs4231, respectively. Pathogenicity of the 4 SARSr-CoVs was evaluated by recording the survival rate of challenged mice in a 2-week course. All of the 4 SARSr-CoVs caused lethal infection in hACE2 transgenic mice, but the mortality rate vary among 4 groups of infected mice **(Fig. 13a)**. 14 days post infection, 5 out of 7 mice infected with WIV1 remained alive (71.4%), while only 2 of 8 mice infected with rWIV1-SHC014 S survived (25%). The survival rate of mice infected with rWIV1-WIV16S and rWIV1-4231S were 50%. Viral replication was confirmed by quantitative PCR in spleen, lung, intestine and brain of infected mice. In brain, rWIV1, rWIV1-WIV16S and rWIV1-4231S cannot be detected 2 days or 4 days post infection. However, rWIV1-SHC014 was detected at all time points and showed an increasing viral titer after infection. The viral load reached more than 10^9 genome copies/g at the dead point **(Fig. 13b)**. We also conducted histopathological section examination in infected mice. Tissue lesion and lymphocytes infiltration can be observed in lung, which is more significant in mice infected with rWIV1-SHC014 S **(Fig. 13d)** than those infected with rWIV1 **(Fig. 13c)**. These results suggest that the pathogenicity of SHC014 is higher than other tested bat SARSr-CoVs in transgenic mice that express hACE2.

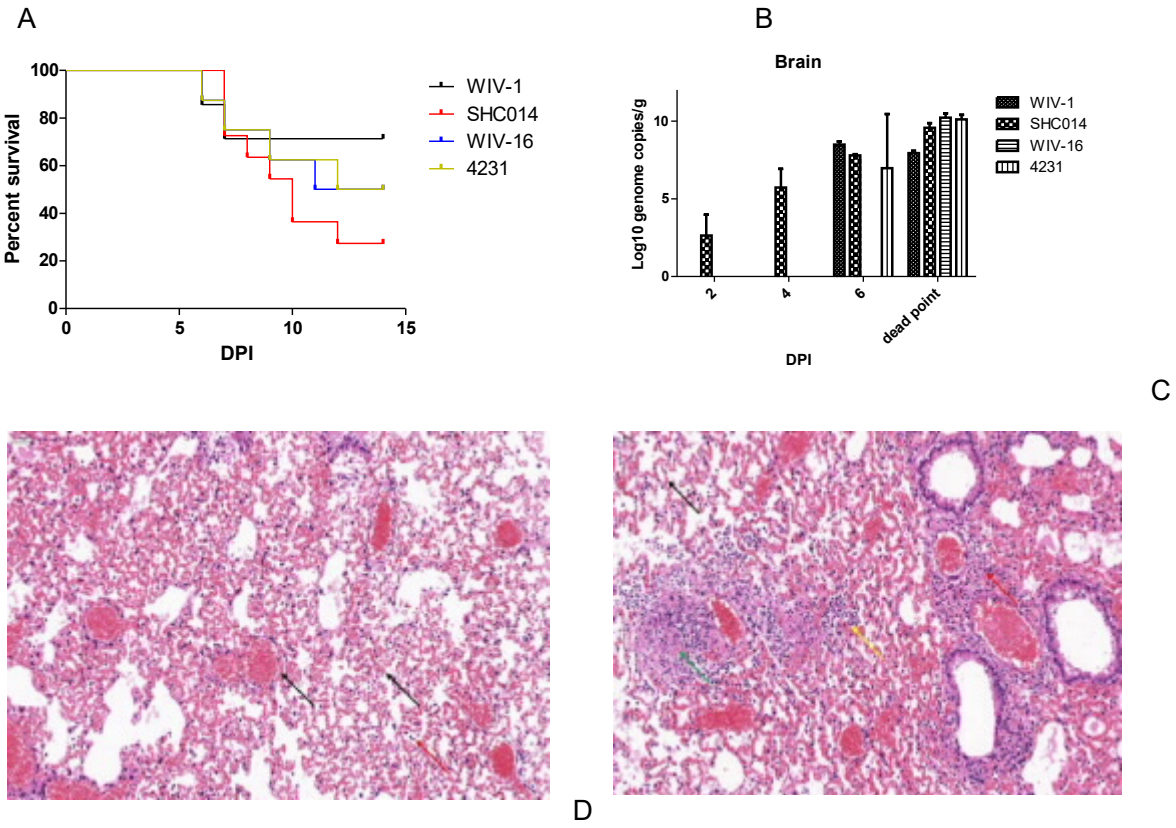

Fig. 13: *In vivo* infection of SARSr-CoV in hACE2-expressing mice. **(A)** Survival rate of hACE2_mice after infection **(B)** Viral load in brains of infected hACE2 -expressing mice. **(C)** Histopathological section of lung tissue of mice infected with rWIV1. **(D)** Histopathological section of lung tissue of mice infected with rWIV1-SHC014 S.

3.2 Assessment of interspecies transmission risk of bat HKU4-related coronaviruses

Taking a similar reverse genetics strategy that we used in SARSr-CoV studies, we constructed the full-length infectious clone of MERS-CoV, and replaced the RBD of MERS-CoV with the RBDs of various strains of HKU4-related coronaviruses previously identified in bats from different provinces in southern China. The full-length MERS-CoV and chimeric viruses with RBDs of HKU4r-CoVs were then rescued. Immunofluorescence assay showed that these chimeric MERS-HKU4rRBD coronaviruses were able to infect human cells from different tissues including lung, liver, intestine and kidney **(Fig. 14 Left)**. Moreover, efficient replication of the chimeric HKU4r-CoVs were detected by real-time PCR in HeLa cells that expressed human DPP4 receptor **(Fig. 14 Right)**. The results suggest potential risk of the bat HKU4r-CoVs for cross-species infection in humans.

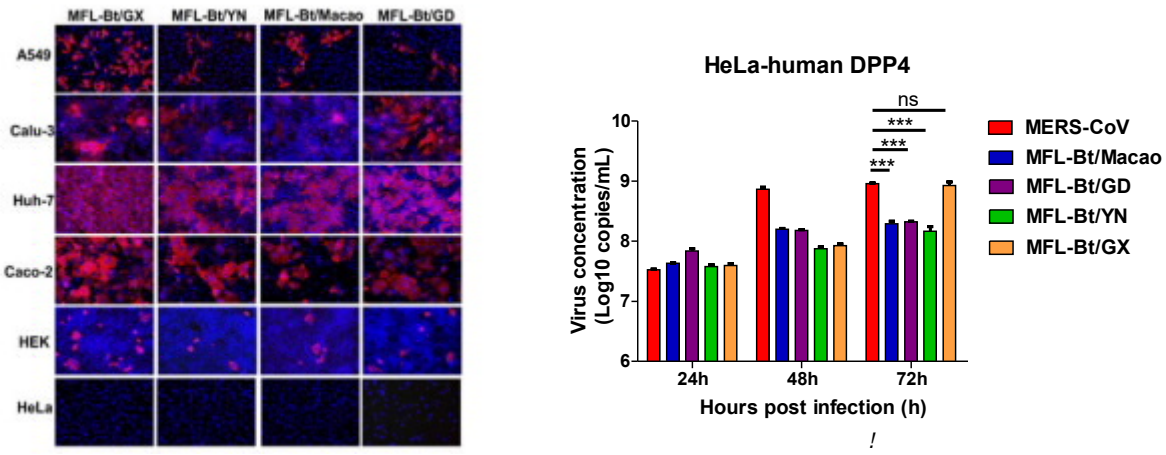

Fig. 7: Left: Immunofluorescence assay confirms Infection of 4 chimeric viruses with the backbone of MERS-CoV and RBD of bat HKU4r-CoVs in different cell lines derived from human tissues. **Right:** Replication of MERS-HKU4rRBD CoVs in HeLa cells expressing human DPP4 was d etermined by real-time PCR.

1. Conference and University lectures: We continued to provide human subject research trainings to chief physicians and nurses at local clinics, staff from Yunnan Institute of Endemic Diseases Control and Prevention, students from Dali College and Wuhan University for both qualitative and quantitative research.
2. Agency and other briefing: Dr. Guangjian Zhu provided training to 18 field team members from the Dali College and 4 Wuhan Insitute of Virology laboratory team members regarding biosafety and PPE use, bats and rodents sampling.
3. Public outreach: PI Daszak, and Co-investigators Shi, Epstein, and Olival presented the Year 5 results of this project to the public via interviews with national central and local television, social media, newspaper and journals in China and the US.

C. PRODUCTS

C.1 PUBLICATIONS

Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph) during the reporting period resulting directly from this award?

No

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

NOTHING TO REPORT

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Have inventions, patent applications and/or licenses resulted from the award during the reporting period? No

If yes, has this information been previously provided to the PHS or to the official responsible for patent matters at the grantee organization? No

C.5 OTHER PRODUCTS AND RESOURCE SHARING

NOTHING TO REPORT

D. PARTICIPANTS

D.1 WHAT INDIVIDUALS HAVE WORKED ON THE PROJECT?

Commons ID	S/K	Name	Degree(s)	Role	Cal	Aca	Sum	Foreign Org	Country	SS
DASZAK	Y	DASZAK, PETER	BS,PHD	PD/PI	(b) (4), (b) (6)					NA
	N	KE, CHANGWEN	PHD	Co-Investigator				Center for Disease Control and Prevention of Guangdon g Province	CHINA	NA
	N	ZHANG, YUNZHI	PHD	Co-Investigator				Yunnan Provincial Institute of Endemic Diseases Control & Prevention	CHINA	NA
	N	ZHU, GUANGJIAN	PHD	Co-Investigator				East China Normal University	CHINA	NA
MACDURIAN	N	Chmura, Aleksei	BS,PHD	Non-Student Research Assistant						NA
NOAMROSS	N	Ross, Noam Martin	PhD	Co-Investigator						NA
OLIVAL	N	Olival, Kevin J.	PHD	Co-Investigator						NA
SHUYIZHANG	N	Zhang, Shu-yi	PHD	Co-Investigator				East China Normal University	CHINA	NA
ZHENGLISHI	N	SHI, ZHENGLI	PhD	Co-Investigator				Wuhan Institute of Virology	CHINA	NA
	N	GE, XINGYI	PHD	Co-Investigator				Wuhan Institute of Virology	CHINA	NA
JEPSTEIN14	N	EPSTEIN, JONATHAN H	MPH,DVM,BA,PHD	Co-Investigator						NA

Glossary of acronyms:
S/K - Senior/Key
DOB - Date of Birth
Cal - Person Months (Calendar)
Aca - Person Months (Academic)
Sum - Person Months (Summer)
Foreign Org - Foreign Organization Affiliation
SS - Supplement Support
RE - Reentry Supplement
DI - Diversity Supplement
OT - Other
NA - Not Applicable

D.2 PERSONNEL UPDATES

D.2.a Level of Effort

Not Applicable
D.2.b New Senior/Key Personnel Not Applicable
D.2.c Changes in Other Support Not Applicable
D.2.d New Other Significant Contributors Not Applicable
D.2.e Multi-PI (MPI) Leadership Plan Not Applicable

E. IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES?

Not Applicable

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

NOTHING TO REPORT

E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER?

Not Applicable

E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

Dollar Amount	Country
$66,500	CHINA

G. SPECIAL REPORTING REQUIREMENTS SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

NOTHING TO REPORT

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

Sub-Project ID	Study ID	Study Title	Delayed Onset	Clinical Trial	NCT	NIH-Defined Phase 3	ACT
	58010	Understanding the Risk of Bat Coronavirus Emergence-PROTOCOL-001	NO	NO		NO	

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

NOT APPLICABLE

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Not Applicable

G.8 PROJECT/PERFORMANCE SITES

Not Applicable

G.9 FOREIGN COMPONENT

Organization Name: Wuhan Institute of Virology
Country: CHINA

Description of Foreign Component: Principal Laboratory for all Research in China and detailed in our Specific Aims
G.10 ESTIMATED UNOBLIGATED BALANCE Not Applicable
G.11 PROGRAM INCOME Not Applicable
G.12 F&A COSTS Not Applicable

Section 1 - Basic Information (Study 58010)

OMB Number: 0925-0001

Expiration Date: 02/28/2023

1.1. Study Title *

Understanding the Risk of Bat Coronavirus Emergence-PROTOCOL-001

1.2. Is this study exempt from Federal Regulations * ☐ Yes ● No

1.3. Exemption Number ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8

1.4. Clinical Trial Questionnaire *

1.4.a. Does the study involve human participants?	● Yes	☐ No
1.4.b. Are the participants prospectively assigned to an intervention?	☐ Yes	● No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	☐ Yes	● No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	☐ Yes	● No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics (Study 58010)

2.1. Conditions or Focus of Study		
2.2. Eligibility Criteria		
2.3. Age Limits	Min Age:	Max Age:
2.3.a. Inclusion of Individuals Across the Lifespan		
2.4. Inclusion of Women and Minorities		
2.5. Recruitment and Retention Plan		
2.6. Recruitment Status	Not yet recruiting	
2.7. Study Timeline		
2.8. Enrollment of First Participant (SEE SECTION 6.3)		

2.9. Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
IER 58010	Foreign	

Inclusion Enrollment Report 58010

1. Inclusion Enrollment Report Title* : China Study Report

2. Using an Existing Dataset or Resource* : ☐ Yes • No

3. Enrollment Location Type* : ☐ Domestic • Foreign

4. Enrollment Country(ies): CHN: CHINA

5. Enrollment Location(s):

6. Comments:

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	1230	1230	0	0	2460
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	0	0	0	0	0
White	0	0	0	0	0
More than One Race	0	0	0	0	0
Total	1230	1230	0	0	2460

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	980	616	0	0	0	0	0	0	0	1596
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	980	616	0	0	0	0	0	0	0	1596

Section 3 - Protection and Monitoring Plans (Study 58010)

3.1. Protection of Human Subjects

3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site? ☐ Yes ☐ No ☐ N/A

If yes, describe the single IRB plan

3.3. Data and Safety Monitoring Plan

3.4. Will a Data and Safety Monitoring Board be appointed for this study? ☐ Yes ☐ No

3.5. Overall structure of the study team

Section 4 - Protocol Synopsis (Study 58010)

4.1. Study Design

4.1.a. Detailed Description

4.1.b. Primary Purpose

4.1.c. Interventions

Type	Name	Description

4.1.d. Study Phase

Is this an NIH-defined Phase III Clinical Trial? ☐ Yes • No

4.1.e. Intervention Model

4.1.f. Masking ☐ Yes ☐ No

☐ Participant ☐ Care Provider ☐ Investigator ☐ Outcomes Assessor

4.1.g. Allocation

4.2. Outcome Measures

Type	Name	Time Frame	Brief Description

4.3. Statistical Design and Power

4.4. Subject Participation Duration

4.5. Will the study use an FDA-regulated intervention? ☐ Yes ☐ No

4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational Device Exemption (IDE) status

4.6. Is this an applicable clinical trial under FDAAA? (SEE SECTION 6.6)

4.7. Dissemination Plan

I. OUTCOMES

I.1 What were the outcomes of the award?

The aims of our grant (R01AI110964) were to: 1) Analyze the risk that there could be a repeat of the SARS outbreak, due to bat coronaviruses still circulating in China; 2) Work out how we can predict which bat viruses would be most likely to emerge, so that we can prevent new outbreaks; 3) Using lab tests, find out if any of the coronaviruses still present in bat populations in China have the potential to infect people. The overall goal of this work is to help design vaccines and therapeutics against future potentially emerging viruses, work out which communities are on the frontline of a new potential outbreak, and reduce the risk of them being infected by analyzing their risk behavior. During this 5-year period of work, we made significant discoveries leading to 18 peer-reviewed scientific papers, including in some of the world's foremost scientific journals.

Overall, our work shows that bats in China harbor a high number and diversity of coronaviruses, some closely related to SARS-CoV (the virus that caused the SARS pandemic in 2003). We sampled over 16,000 individual bats and found evidence of hundreds of different SARS-related coronavirus genetic sequences. We found out that bats across China harbor these viruses, and that they are common, with 6.7% of bats sampled being positive. Many of these bats are found across China, Southeast Asia, South Asia and beyond, suggesting viruses with zoonotic potential may exist in those regions also. Many of these bats are abundant, and roost and feed close to people and livestock, suggesting high potential for future viral spillover. We also dentified one cave system in Yunnan Province with horseshoe bats that had diverse SARSr-CoVs, including some with S proteins able to use human ACE2 as entry receptors. Bats in this cave carried SARSr-CoVs with all unique genetic elements of the SARS-CoV outbreak virus, suggesting that this site may be a potential public health risk.

To analyze which viruses were a potential public health risk, we managed to culture three strains of SARSr-CoVs from bat feces: WIV1, WIV16 and Rs4874. We used the genetic codes of some of the other viruses we found in bats and inserted the spike protein genes of those viruses (the proteins that attach to cells) into the cultured viruses. By doing this experiment we showed that other viruses may also be able to infect human cells, and were able to do this safely without the need to culture large amounts of virus. We also showed that some of these viruses cause SARS-like illness in mice that are adapted to have similar cell surface receptors to people. This work proves that there is a clear and present danger for future emergence of novel SARS-like viruses in people. We also demonstrated that outbreaks can happen in livestock. In 2016-17, we analyzed fecal samples from pigs at 5 farms in South China affected by a fatal diarrheal disease. We discovered a new coronavirus, Swine Acute Diarrheal Syndrome coronavirus (SADS-CoV), and showed that it originates in bats, caused the death of more than 20,000 pigs, but also is able to infect human cells in the lab.

Our work has produced predictive algorithms to map hotspots of viral risk so that public health measures can be taken to protect communities at the frontline of potentially the next SARS pandemic. We have produced new reagents and viral cultures that can be used by labs across the world to design novel vaccines and therapeutics against SARS-CoV and other related viruses that might emerge in the future. Finally, our work has been used directly by the WHO to list SARS-related coronaviruses as one of the highest priority group of pathogens with pandemic potential, so that efforts can be taken to stop a future pandemic before it happens.

From: Lauer, Michael (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: Sat 11/20/2021 7:07:57 PM (UTC-06:00)

To: Peter Daszak[(b) (6) Aleksei Chmura[(b) (6)

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

Subject: Re: Response to your letter of November 5th

Attachment: Response to Dr. Lauer November 2021.pdf

Thank you, Dr. Daszak, we received your response.

Best, Mike

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

From: Peter Daszak < (b) (6)
Date: Friday, November 19, 2021 at 12:38 PM
To: "Lauer, Michael (NIH/OD) [E]" < (b) (6) Aleksei Chmura < (b) (6)
Subject: Response to your letter of November 5th

Dear Dr. Lauer,

Please see the attached response to your letter of November 5th 2021

Yours sincerely,

Peter

Peter Daszak

President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

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

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From: Lauer, Michael (NIH/OD) [E] < (b) (6)
Sent: Tuesday, November 9, 2021 7:46 AM
To: Peter Daszak < (b) (6) Aleksei Chmura
< (b) (6)
Cc: Lauer, Michael (NIH/OD) [E] < (b) (6)
Subject: Re: Please read and acknowledge receipt -- Re: Response to your request from last Friday
Importance: High

Dear Drs. Chmura and Daszak

Please acknowledge receipt.

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)
(b) (6)

From: "Lauer, Michael (NIH/OD) [E]" < (b) (6)
Date: Friday, November 5, 2021 at 8:03 AM
To: Peter Daszak < (b) (6) Aleksei Chmura
< (b) (6)
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Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

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

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November 18th 2021

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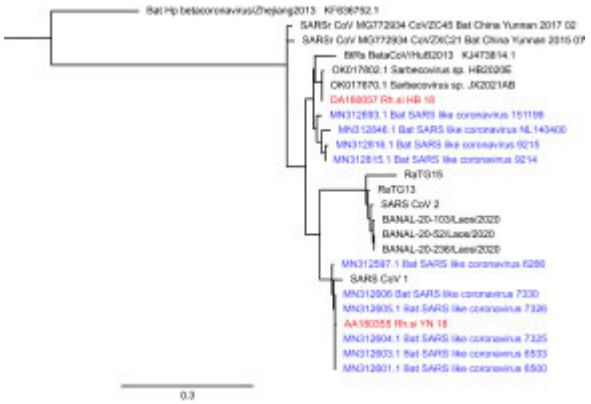

This will allow scientists from around the world to conduct their own analyses to compare the genetic information from these viruses with others we have reported previously, and with SARS-CoV and SARS-

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1) Regulation for the collection of genetic resources. This took effect on 1/1/12 and is still in force: https://www.mee.gov.cn/ywgz/fgbz/bz/bzwb/stzl/201109/t20110919_217418.shtml
2) List of State Protected Species. Any animal that is listed as protected requires specific permits to collect or sample. Neither bats nor the other species we worked with under our NIH funding were covered by this rule. The list was revised on 2/5/21: http://www.gov.cn/xinwen/2021-02/09/content_5586227.htm

Even though IACUCs are not required by China, the fieldwork in China that we conducted under our R01 is covered by the Inter-institutional agreement we cited in our letter of October 26th, and by our relevant US institutional IACUC approval.

In response to your request for "complete and dated copies of the original laboratory notebook entries and of the original electronic files that led to the generation of the Year 4 RPPR Figure 35 and the Year 5 I-RPPR Figure 13, along with all their accompanying texts". We do not have copies of these, which were created by and retained by the WIV. Nonetheless, I have forwarded your letter to the WIV, and will let you know their response as soon as WIV replies to our request.

Finally, I would like to comment that we strongly believe it is in the interests of the American public, and people of all nations, to continue doing our best to keep communication open with collaborators in China, so that we can analyze and publish data from our work, advance the science of pandemic prevention, and protect the public from pandemic threats. In this spirit, we look forward to filing our next annual report for R01AI110964, despite this grant being suspended and funding not available to us, as we did in June of 2021. In our next report, we will include any further analyses of the work conducted previously, and advance copies of publications we aim to submit. We will do this in the normal way, through the NIH RPRR reporting system, with copies sent to our NIAID Program Officer, Dr. Erik Stemmy.

Yours sincerely,

Dr. Peter Daszak, President

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520 Eighth Avenue, Suite 1200
New York, NY 10018
212.380.4460
EcoHealthAlliance.org

From: Peter Daszak[(b) (6)
Sent: Tue 11/9/2021 9:29:46 AM (UTC-06:00)
To: Lauer, Michael (NIH/OD) [E][(b) (6) Aleksei Chmura[(b) (6)
Subject: RE: Please read and acknowledge receipt -- Re: Response to your request from last Friday

Yes – receipt acknowledged and we're working on getting further information for you as requested.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
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From: Lauer, Michael (NIH/OD) [E] < (b) (6)
Sent: Tuesday, November 9, 2021 7:46 AM
To: Peter Daszak < (b) (6) Aleksei Chmura < (b) (6)
Cc: Lauer, Michael (NIH/OD) [E] < (b) (6)
Subject: Re: Please read and acknowledge receipt -- Re: Response to your request from last Friday
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Date: Friday, November 5, 2021 at 8:03 AM
To: Peter Daszak < (b) (6) Aleksei Chmura < (b) (6)
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To: "Lauer, Michael (NIH/OD) [E]" < (b) (6) "Tabak, Lawrence (NIH/OD) [E]" < (b) (6) "Tabak, Lawrence (NIH/OD) [E]" < (b) (6) "Tabak, Lawrence (NIH/OD) [E]" < (b) (6)
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From: Peter Daszak[(b) (6)
Sent: Fri 11/19/2021 11:37:32 AM (UTC-06:00)
To: Lauer, Michael (NIH/OD) [E][(b) (6) Aleksei Chmura[(b) (6)
Subject: Response to your letter of November 5th
Attachment: Response to Dr. Lauer November 2021.pdf

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Yours sincerely,

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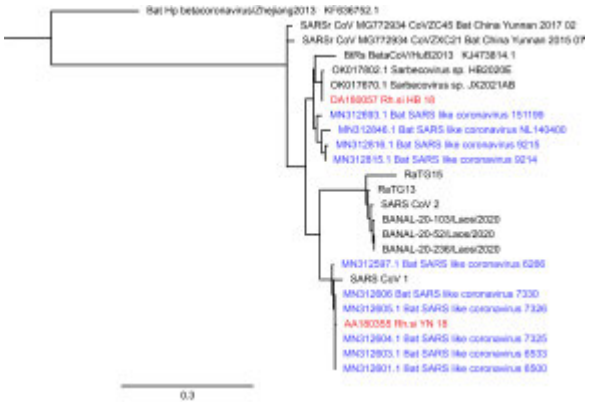

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From: Lauer, Michael (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: Tue 10/26/2021 1:12:32 PM (UTC-05:00)

To: Peter Daszak[(b) (6)] Tabak, Lawrence (NIH/OD) [E][(b) (6)]

Cc: Aleksei Chmura[(b) (6)] Aklin, Courtney (NIH/OD) [E][(b) (6)] Hayes, Darla (NIH/OD) [E][(b) (6)] Burrus-Shaw, Cyndi (NIH/OD) [E][(b) (6)] Mazerik, Jessica (NIH/OD) [E][(b) (6)] Lauer, Michael (NIH/OD) [E][(b) (6)]

Subject: Re: Response to your request from last Friday

Attachment: Response to your request from last Friday

Thank you Dr. Daszak for your response.

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)

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Date: Tuesday, October 26, 2021 at 1:34 PM
To: "Lauer, Michael (NIH/OD) [E]" < (b) (6) "Tabak, Lawrence (NIH/OD) [E]" < (b) (6) "Tabak, Lawrence (NIH/OD) [E]" < (b) (6) "Tabak, Lawrence (NIH/OD) [E]" < (b) (6)
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From: Peter Daszak[(b) (6)

Sent: Tue 10/26/2021 12:32:16 PM (UTC-05:00)

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

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Attachment: 01 Tabak to Comer Letter.pdf

Attachment: 02 eRA Commons Year 4 Report Submission Date.pdf

Attachment: 03 Daszak to Stemmy Email.pdf

Attachment: 04 Rationale for recombinant virus experiments.pdf

Attachment: 05 eRA Commons Year 5 Report Submission Date.pdf

Attachment: 06 Email with NIH Grants Management Specialist re. YR 5 report.pdf

Attachment: 07 SADS and HKU2 data and analyses.pdf

Attachment: 08 Southeast Asia SARSr-CoV Spillover hotspots analysis.pdf

Attachment: 09 IIA WIV.pdf

Attachment: Response to Dr. Lauer October 2021.pdf

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

October 20, 2021

The Honorable James Comer
Ranking Member, Committee on Oversight and Reform
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Comer:

Thank you for your continued interest in the work of the National Institutes of Health (NIH). I am writing today to provide additional information and documents regarding NIH's grant to EcoHealth Alliance, Inc.

It is important to state at the outset that published genomic data demonstrate that the bat coronaviruses studied under the NIH grant to EcoHealth Alliance, Inc. and subaward to the Wuhan Institute of Virology (WIV) are not and could not have become SARS-CoV-2. Both the progress report and the analysis attached here again confirm that conclusion, as the sequences of the viruses are genetically very distant.

The fifth and final progress report for Grant R01AI110964, awarded to EcoHealth Alliance, Inc. is attached with redactions only for personally identifiable information. This progress report was submitted to NIH in August 2021 in response to NIH's compliance enforcement efforts. It includes data from a research project conducted during the 2018-19 grant period using bat coronavirus genome sequences already existing in nature.

The limited experiment described in the final progress report provided by EcoHealth Alliance was testing if spike proteins from naturally occurring bat coronaviruses circulating in China were capable of binding to the human ACE2 receptor in a mouse model. All other aspects of the mice, including the immune system, remained unchanged. In this limited experiment, laboratory mice infected with the SHC014 WIV1 bat coronavirus became sicker than those infected with the WIV1 bat coronavirus. As sometimes occurs in science, this was an unexpected result of the research, as opposed to something that the researchers set out to do. Regardless, the viruses being studied under this grant were genetically very distant from SARS-CoV-2.

The research plan was reviewed by NIH in advance of funding, and NIH determined that it did not to fit the definition of research involving enhanced pathogens of pandemic potential (ePPP) because these bat coronaviruses had not been shown to infect humans. As such, the research was not subject to departmental review under the HHS P3CO Framework. However, out of an abundance of caution and as an additional layer of oversight, language was included in the terms and conditions of the grant award to EcoHealth that outlined criteria for a secondary review, such as a requirement that the grantee report immediately a one log increase in growth. These

measures would prompt a secondary review to determine whether the research aims should be re-evaluated or new biosafety measures should be enacted.

EcoHealth failed to report this finding right away, as was required by the terms of the grant. EcoHealth is being notified that they have five days from today to submit to NIH any and all unpublished data from the experiments and work conducted under this award. Additional compliance efforts continue.

The second document is a genetic analysis demonstrating that the naturally occurring bat coronaviruses used in experiments under the NIH grant from 2014-2018 are decades removed from SARS-CoV-2 evolutionarily. The analysis compares the sequence relationships between:

- SARS-CoV-1, the cause of the SARS outbreak in 2003;
- SARS-CoV-2, the cause of COVID-19 pandemic;
- WIV-1, a naturally occurring bat coronavirus used in experiments funded by the NIH;
- RaTG13, one of the closest bat coronavirus relatives to SARS-CoV-2 collected by the Wuhan Institute of Virology; and
- BANAL-52, one of several bat coronaviruses recently identified from bats living in caves in Laos.

While it might appear that the similarity of RaTG13 and BANAL-52 bat coronaviruses to SARS-CoV-2 is close because it overlaps by 96-97%, experts agree that even these viruses are far too divergent to have been the progenitor of SARS-CoV-2. For comparison, today's human genome is 96% similar to our closest ancestor, the chimpanzee. Humans and chimpanzees are thought to have diverged approximately 6 million years ago.

The analysis attached confirms that the bat coronaviruses studied under the EcoHealth Alliance grant could not have been the source of SARS-CoV-2 and the COVID-19 pandemic.

If you or your staff have questions, NIH would be pleased to brief you on these documents.

Lawrence A. Tabak, D.D.S., Ph.D.
Principal Deputy Director

RPPR Menu ?

Application Information	
Award Number:	5R01AI110964-05
Institution:	ECOHEALTH ALLIANCE, INC.
PD/PI Name:	DASZAK, PETER
Project Title:	Understanding the Risk of Bat Coronavirus Emergence
Due Date:	04/15/2018
Current Reviewer:	Agency
Status:	Submitted to Agency

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Routing History

Reviewer Name	Action	Notification Sent	Date of Action	Next Reviewer Name	Comments
Daszak, Peter	Initiate	04-13-2018 10:58:29	04-13-2018 10:58:29	Daszak, Peter	
Daszak, Peter	Route	04-13-2018 05:51:01	04-13-2018 05:51:01	Chmura, Aleksei	
Chmura, Aleksei	Submit	04-13-2018 05:54:58	04-13-2018 05:54:58	Agency	

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RE: 5R01AI110964 Coronavirus Year 4 Report

1 message

Peter Daszak <[redacted] Wed, Apr 25, 2018 at 9:25 PM
To: "Stemmy, Erik (NIH/NIAID) [E]" <[redacted]
Cc: "[redacted] < [redacted] Aleksei Chmura < [redacted] Hongying Li
< [redacted] Alison Andre < [redacted]

….and here's the report attachment….

Cheers,

Peter

Peter Daszak

President

EcoHealth Alliance

460 West 34th Street – 17th Floor

New York, NY 10001

Tel. [redacted]

www.ecohealthalliance.org

@PeterDaszak

@EcoHealthNYC

EcoHealth Alliance leads cutting-edge research into the critical connections between human and wildlife health and delicate ecosystems. With this science we develop solutions that prevent pandemics and promote conservation.

From: Peter Daszak
Sent: Wednesday, April 25, 2018 9:16 PM
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: (b) (6) Aleksei Chmura; Hongying Li; Alison Andre
Subject: 5R01AI110964 Coronavirus Year 4 Report

Dear Erik,

I just wanted to send you a pdf of our Year 4 Report which I submitted last week. We've had some fantastic results this past year and I've put these in the report summary, but also included the discovery of SADS-CoV as another key findings. As you'll see, we're on track to hit all the major goals of the project by the end of Yr5, including human questionnaires and sampling, risk modeling, more in-depth viral characterization and discovery.

I know you've likely not had chance to read the report yet, but I also wanted to check-in with you soon about submitting a new proposal/renewal to build on the work we've done. You suggested that this would be good timing when we met last summer, and right now I'm looking at the November 5th 2018 deadline (renewal). I have a couple of questions on this: First, I've not submitted a renewal before the end of a current R01, and just want to check that this is the standard procedure. Our R01 officially ends in May 31st 2019. Secondly, I wanted to check in which study section would be best for this. The original proposal went to CFRS-Clinical Research and Field Studies of Infectious Diseases. I've asked Alison to set up a time for us to have a quick chat sometime in the next few weeks if possible.

Cheers,

Peter

Peter Daszak

President

EcoHealth Alliance

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Year 4 NIAID CoV Report.pdf
2664K

EcoHealth Alliance

Dear Drs. Greer and Stemmy,

June 8, 2016

We appreciate your rapid review of our proposed work for year 3 of our R01 (5R01AI110964-03). We have provided the details you requested, below, including alternative strategies if we remove work that could be deemed gain of function. We look forward to your response and will modify our workplan accordingly. In the meantime, please rest assured that none of the proposed work for Specific Aim #3 that you have requested information about will begin.

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

Firstly, we would like to reiterate that this work is *proposed* for year 3, and none has been conducted to date. Furthermore, we will not proceed with any of this unless we are given the go-ahead by NIAID. The goal of our proposed work to construct MERS and MERS-like chimeric CoVs is to understand the potential origins of MERS-CoV in bats by studying bat MERS-like CoVs in detail. The chimeric viruses will be used to ascertain receptor usage and infectivity of bat MERS-related CoVs *in vitro* and in a mouse model. To achieve this purpose, our aim is to firstly construct a MERS-CoV infectious clone based on the genomic sequence of EMC2012 (GenBank no. NC_019843) and then chimeric CoVs with the replacement of the spike envelope genes from bat derived MERS-like CoVs. We have very recently discovered a small number (9 different strains) of bat MERS-like CoVs in 99 samples from bats in Guangxi, Guangdong, and Szechuan provinces. Phylogenetically, these bat viruses are not very close to MERS-CoV (only 63-66% homology to the S-protein of MERS-CoV).

We aim to test the chimeric viruses for receptor usage of DPP4 (the MERS-CoV receptor) in cells and then in DPP4 transgenic mice, to see if these bat viruses have any capacity to use the same receptor. That said, given the phylogenetic distance from MERS-CoV, we believe it is *highly unlikely* that these bat spike proteins attach to DPP4, and if so, that they would have any pathogenic potential. Finally, should any of these recombinants show evidence of enhanced virus growth >1 log in cells expressing the human, bat, mouse or other DPP4 receptor over wildtype parental backbone MERS-CoV strain or grow more efficiently in human airway epithelial cells, we will immediately: i) stop all experiments with the mutant, ii) inform our NIAID Program Officer and the Wuhan Institute of Virology IBC of these results and iii) participate in decision making trees to decide appropriate paths forward.

In addition, your progress report makes reference to two chimeric bat SARS-like CoVs constructed on a WIV-1 backbone.
NIAID requests additional information on these strains of SARS-like CoVs, including: the dates the strains were created; whether the chimeric viruses exhibit enhanced pathogenicity and/or transmissibility in

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mammals via the respiratory route compared to wild type SARS-CoV; and what research plans you have for these chimeric viruses.

These two chimeric bat-like CoVs were constructed on September 24, 2015. They use the backbone of a group 2b SARS-like bat CoV WIV1 and the spike proteins of two newly discovered bat SL-CoVs (Rs7327 and RsSHC014). The construction of these chimeric viruses aims to understand the receptor usage and infectivity of bat SL-CoVs that may be progenitors of SARS-CoV. We have not yet tested the pathogenicity of these viruses in animals.

We believe that this work would not be considered GoF because the pause specifically targeted experiments that altered the pathogenicity or transmissibility of SARS-CoV, MERS-CoV and any influenza virus. Our molecular clone is WIV1, which is a group 2b SARS-like bat coronavirus that has never been demonstrated to infect humans or cause human disease. It is about 10% different from SARS-CoV. Thus, we feel that introducing other group 2b SARS-like bat coronavirus spike glycoproteins into WIV1 is not subject to the pause. Moreover, we are introducing progressively more distant S glycoproteins into WIV1 (The RBD of Rs7327 differs from WIV1 in several amino acid residues while RsSHC014 is even more distantly related phylogenetically), so it seems progressively less likely that any of these viruses would be more pathogenic or transmissible than the SARS-CoV. This is further supported by the fact that Prof. Ralph Baric's group (Menacherya *et al*., 2015, Nature Medicine, 21 (12):1508-1512; Menacherya *et al*., 2016, PNAS, 113 (11): 3048-3053) took WIV1 spike and inserted it onto a SARS-CoV backbone and showed reduced pathogenicity in mice with human ACE-2 relative to SARS-CoV (mortality rates were much lower, therefore this is *loss-of-function*). This strongly suggests that the chimeric bat spike/bat backbone viruses should not have enhanced pathogenicity in animals.

Finally, as proposed above for the MERS-like viruses, should any of these recombinants show evidence of enhanced virus growth >1 log in cells expressing the human, bat, mouse or civet receptor over wildtype parental backbone SARS-CoV strain or grow more efficiently in human airway epithelial cells, we will immediately: i) stop all experiments with the mutant, ii) inform our NIAID Program Officer and the Wuhan Institute of Virology IBC of these results and iii) participate in decision making trees to decide appropriate paths forward.

If it is determined that the above research DOES include GoF work subject to the funding pause, provide detailed information on what research will remain viable with the removal of the GoF work and appropriate budget adjustments. Options include:

o For the specific aims that propose GoF work, provide a detailed description of changes that can be made to remove the GoF work but maintain the specific aim(s); or

o Remove the specific aims and experiments that are subject to the pause from the Research Plan and request to have the award budget renegotiated.

If these proposed activities within Specific Aim #3 are considered gain of function, we would propose changing them as follows:

1) Instead of the proposed work on MERS-like chimeric CoVs, we would
    a. model the 3-D structure of bat MERS-like CoV spike to assess its potential to bond to DPP4; and
    b. build pseudoviruses with MERS-like CoV spike to conduct experiments for DPP4 binding.

2) Instead of the proposed work on SARS-like chimeric bat CoVs, we would build pseudoviruses with the spike proteins from these viruses and assess receptor binding *in vitro*.

We look forward to your response to our letter and will not conduct any of this proposed work until we hear back from you.

Yours sincerely,

Dr. Peter Daszak

PI
President and Chief Scientist
EcoHealth Alliance

Tel: (b) (6)
e-mail: (b) (6)

Interim RPPR Menu ?

Application Information	
Award Number:	5R01AI110964-05
Institution:	ECOHEALTH ALLIANCE, INC.
PD/PI Name:	DASZAK, PETER
Project Title:	Understanding the Risk of Bat Coronavirus Emergence
Due Date:	N/A
Current Reviewer:	Agency
Status:	Submitted to Agency

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Routing History

Reviewer Name	Action	Notification Sent	Date of Action	Next Reviewer Name	Comments
Daszak, Peter	Initiate	07-24-2019 08:47:42	07-24-2019 08:47:42	Daszak, Peter	
Daszak, Peter	Route	07-27-2021 03:03:32	07-27-2021 03:03:32	Chmura, Aleksei	
Chmura, Aleksei	Submit	08-03-2021 12:44:14	08-03-2021 12:44:14	Agency	

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EcoHealth Alliance

Aleksei Chmura <(b) (6)>

Re: Questions about 2R01AI110964-06 (PI: Daszak)

1 message

Aleksei Chmura <(b) (6)> Tue, Jul 30, 2019 at 2:55 PM
To: "Girma, Tseday (NIH/NIAID) [E]" <(b) (6)>

Tseday,

Thanks for the update. I know you are likely inundated with questions from other awardees as well.

Call or email me anytime.

Cheers!

-Aleksei

On Jul 30, 2019, at 14:49, Girma, Tseday (NIH/NIAID) [E] <(b) (6)> wrote:

Hi Aleksei,

I received your inquiry – I will respond tomorrow. I may also have questions about the revised budget on the type 2 application.

Thanks,
Tseday

From: Aleksei Chmura <(b) (6)>
Sent: Tuesday, July 30, 2019 1:38 PM
To: Girma, Tseday (NIH/NIAID) [E] <(b) (6)>
Subject: Questions about 2R01AI110964-06 (PI: Daszak)

Dear Tseday,

Many thanks for all your help and support during our application and JIT processes for this continued award. We are excited about our continued work and progress over the next 5 years!

Two quick queries for you:

1) I see that now that we may commence our Year 5 annual report in eRA Commons' RPPR. Peter just initiated our Year 5 report. We were already prepared to submit this and expect to have everything uploaded and submitted by the end of July. Will this be ok and is there a due-date?

2) Since this is Year 6 of our award, may we roll-over any un-expended funds from Year 5 as we would usually do within a 5-year award? Our start-date for Year 6 is 01 July 2019, so does that mean we may not request reimbursement for any expenses from the end of our Year 5 (31 May 2019) to beginning of Year 6 (01 July 2019) or are these allowable 'continuation' or 'start-up' or 'close-out' costs?

Cheers,

-Aleksei

Aleksei Chmura, PhD
Chief of Staff

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Diversity and spillover risk of Swine Acute Diarrhea Syndrome-related coronaviruses in China and Southeast Asia

Bats have been identified as the likely reservoir hosts of several coronaviruses (CoVs) affecting human and livestock health. In this study, we assessed the diversity and evolution of the virus associated with fatal swine acute diarrhea syndrome (SADS-CoV) that was identified in pigs in China in 2017 and its close relative, HKU2-CoV, an alphacoronavirus previously identified in horseshoe bats.

We identified a large, natural diversity of HKU2-related coronaviruses circulating in bats in China. Phylogenetic analyses suggest these viruses should be re-classified into at least two distinct CoV species, corresponding to two well-supported monophyletic clades. We also found evidence for stronger phylogenetic clustering by sampling location than host species among this group of viruses, which is suggestive of infrequent long-distance transmission of HKU2-related CoVs between locations in southern China. Our ancestral state reconstruction analysis further indicated that *R. affinis* has played a significant role in the evolution of HKU2-CoV in southern China and was identified as the most likely reservoir host of the virus that spilled over into pigs as SADS-CoV.

We further combined bat species distribution models with pig density data to identify areas most likely to be at risk of bat-to-pig and pig-to-pig transmission of HKU2-related coronaviruses in Southeast Asia. Specific high-risk areas were identified in China, northern and southern Vietnam, the Philippines, and central Thailand. Increased surveillance of pigs in these regions would therefore be warranted to support the timely detection of bat CoV spillover events and mitigate the risk of future outbreaks.

PCR screening

RNA was extracted from 200 µl of rectal swab samples or fecal pellets with the High Pure Viral RNA Kit (Roche) following the manufacturer's instructions. RNA was eluted in 50 µl elution buffer before storage at -80°C. A hemi-nested RT-PCR (Invitrogen) was used to detect CoV RNA using a set of primers targeting a 440-nt fragment of the RdRp gene and optimized for bat CoV detection (Watanabe, et al. 2010). Host species identification of positive samples was confirmed using a cytochrome b (cytb) DNA barcoding protocol (Irwin, et al. 1991).

Results

Table 1: Number of HKU2r-CoV and SADSr-CoV sequences available for each host species, Mean Phylogenetic Distance (mpd.obs) and its standardized effect size (mpd.obs.z) observed within each host. One-tailed p-values (quantiles) were calculated after randomly reshuffling tip labels 1000 times along the entire phylogeny. Significant p-value (mpd.obs.p) are highlighted in bold.

Host species	n	mpd.obs	mpd.rand.mean	mpd.rand.sd	mpd.obs.rank	mpd.obs.z	mpd.obs.p
Rhinolophus affinis	170	0.055	0.075	0.002	1.000	**-10.022**	**0.001**
Rhinolophus sinicus	73	0.065	0.075	0.004	4.000	**-2.553**	**0.004**
Rhinolophus shameli	51	0.046	0.075	0.004	1.000	**-6.412**	**0.001**
Rhinolophus pusillus	43	0.040	0.075	0.005	1.000	**-7.488**	**0.001**
Rhinolophus macrotis	15	0.007	0.074	0.009	1.000	**-7.550**	**0.001**
Rhinolophus thomasi	9	0.046	0.075	0.012	5.000	**-2.381**	**0.005**
Rhinolophus subbadius	5	0.012	0.075	0.018	1.000	**-3.620**	**0.001**
Rhinolophus ferrumequinum	2	0.116	0.073	0.037	836.000	1.175	0.835

Rhinolophus stheno	1	NA	NA	NA	NA	NA	NA
Hipposideros armiger	2	0.091	0.074	0.036	738.000	0.462	0.737
Hipposideros gentilis	2	0.113	0.074	0.036	824.000	1.072	0.823
Hipposideros pratti	2	0.002	0.072	0.039	2.000	**-1.805**	**0.002**
Hipposideros cineraceus	1	NA	NA	NA	NA	NA	NA
Myotis ricketti	2	0.010	0.074	0.036	31.000	**-1.826**	**0.031**
Myotis sp.	1	NA	NA	NA	NA	NA	NA
Myotis pilosus	1	NA	NA	NA	NA	NA	NA
Miniopterus fuliginosus	2	0.095	0.075	0.037	732.500	0.537	0.732
Pipistrellus abramus	2	0.009	0.074	0.037	34.000	**-1.784**	**0.034**
Rousettus leschenaultii	2	0.127	0.074	0.038	877.000	1.385	0.876
Unknown bat host	41	NA	NA	NA	NA	NA	NA
Pigs	19	0.005	0.075	0.008	1.000	**-8.884**	**0.001**

Table 2: Number of HKU2r-CoV and SADSr-CoV sequences available for each province, Mean Phylogenetic Distance (mpd.obs) and its standardized effect size (mpd.obs.z) observed within each province. One-tailed p-values (quantiles) were calculated after randomly reshuffling tip labels 1000 times along the entire phylogeny. Significant p-value (mpd.obs.p) are highlighted in bold.

Province of origin	n	mpd.obs	mpd.rand.mean	mpd.rand.sd	mpd.obs.rank	mpd.obs.z	mpd.obs.p
Yunnan	230	0.044	0.069	0.002	1.000	**-15.958**	**0.001**
Guangdong	129	0.050	0.069	0.003	1.000	**-7.584**	**0.001**
Guangxi Zhuang AR	45	0.059	0.069	0.005	19.000	**-2.176**	**0.019**
Hainan	14	0.027	0.069	0.009	1.000	**-4.503**	**0.001**
Zhejiang	9	0.009	0.069	0.012	1.000	**-5.106**	**0.001**
Hong Kong SAR	6	0.004	0.070	0.015	1.000	**-4.397**	**0.001**
Fujian	5	0.059	0.069	0.017	320.000	-0.600	0.320
Hubei	4	0.006	0.069	0.019	2.000	**-3.205**	**0.002**
Hunan	2	0.007	0.068	0.034	29.000	**-1.772**	**0.029**
Thailand	1	NA	NA	NA	NA	NA	NA
Xizang	1	NA	NA	NA	NA	NA	NA

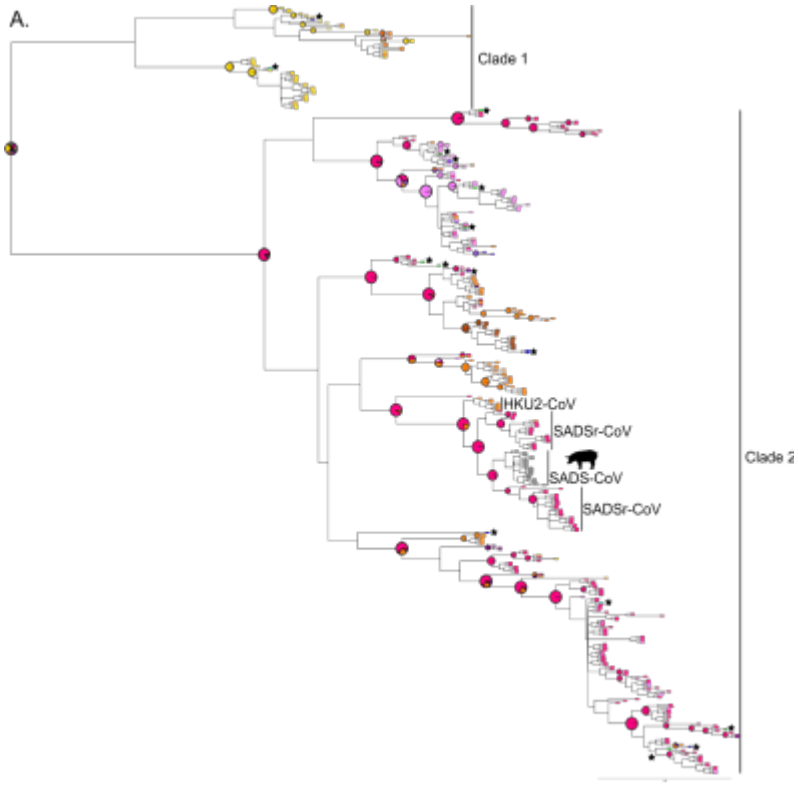

Figure 1: (A) Bayesian MCC phylogeny of HKU2r-CoVs and SADSr-CoVs in southern China for sequences with known hosts only.

Species distribution modelling

Figure 2: Areas of bat-pig overlap where probability of SADS-CoV *Rhinolophus* spp. reservoir (*R. affinis*, *R. sinicus* and *R. pusillus*) occurrence is high (>75%) and pig densities are indicative of intensive pig farming (>100 heads per km^2).

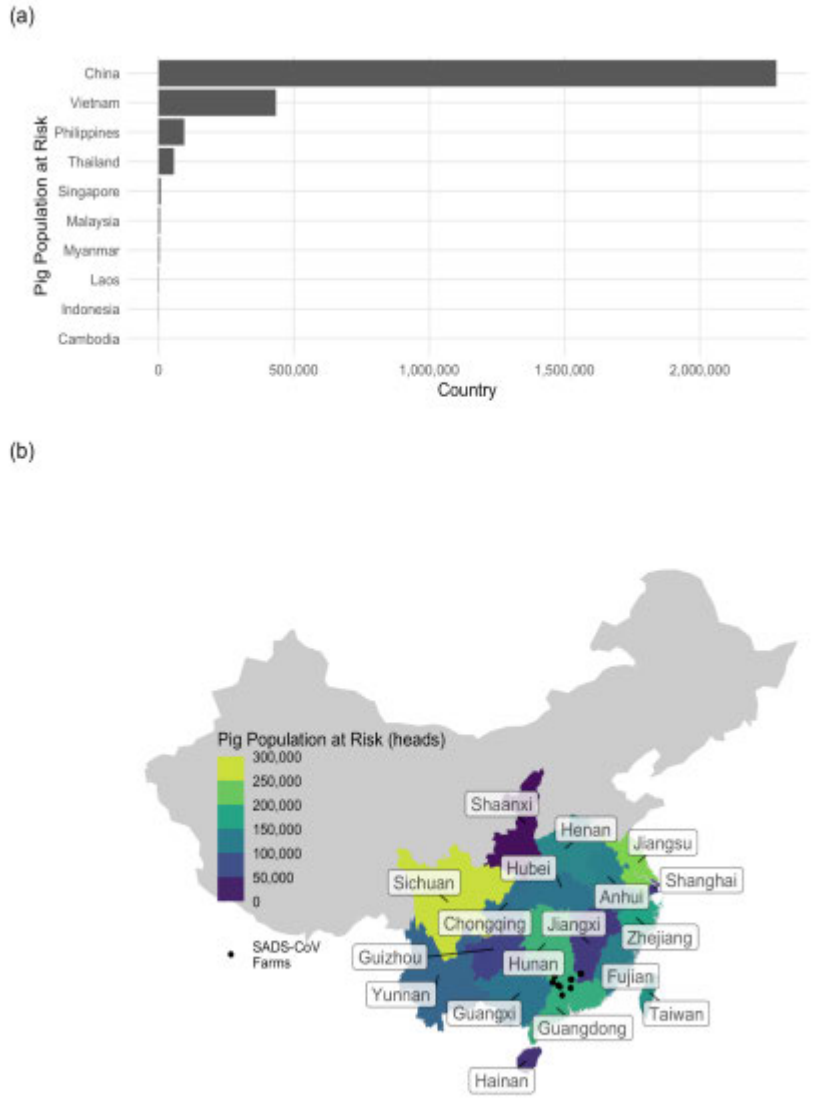

Figure 3: Total pig population at risk by country, and Chinese province. Pig population at risk is defined by the number of pigs (heads) within an area that intersects with predicted bat occurrence (>75%).

A strategy to assess spillover risk of bat SARS-related coronaviruses in Southeast Asia

Abstract

Emerging diseases caused by coronaviruses of likely bat origin (e.g. SARS, MERS, SADS and COVID-19) have disrupted global health and economies for two decades.

Evidence suggests that some bat SARS-related coronaviruses (SARSr-CoVs) could infect people directly, and that their spillover is more frequent than previously recognized. Each zoonotic spillover of a novel virus represents an opportunity for evolutionary adaptation and further spread; therefore, quantifying the extent of this "hidden" spillover may help target prevention programs. We derive biologically realistic range distributions for known bat SARSr-CoV hosts and quantify their overlap with human populations. We then use probabilistic risk assessment and data on human-bat contact, human SARSr-CoV seroprevalence, and antibody duration to estimate that ~400,000 people (median: ~50,000) are infected with SARSr-CoVs annually in South and Southeast Asia. These data on the geography and scale of spillover can be used to target surveillance and prevention programs for potential future bat-CoV emergence.

Introduction

Emerging coronaviruses (CoVs) of wildlife origin have significantly disrupted global health security and economies during the last two decades[1,2]. Severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS) CoVs caused significant human morbidity and mortality in 2002 and 2012 respectively[3,4]. Swine Acute Diarrheal Syndrome CoV caused substantial mortality in pigs in southern China during 2016 and 2019[5,6]. The emergence of SARS-CoV-2 in 2019 led to the current COVID-19 pandemic that has caused millions of cases and deaths, with economic loss likely to be in the tens of trillions of US dollars[2,7]. Efforts to increase preparedness and improve surveillance for emerging coronaviruses therefore represent a priority for global health programs[8].

Phylogenetic analysis suggests that SARS-CoV, MERS-CoV, SADS-CoV, and SARS-CoV-2 originate within CoV lineages from bat reservoir hosts[6,9-11]. The initial spillovers of SARS and MERS into human populations are thought to have occurred via intermediate hosts (palm civets and dromedary camels, respectively[12,13]). However, the role of civets in the emergence of SARS is uncertain, and other bat SARSr-CoVs can directly infect human cells, including airway epithelial cells, and thus have potential to spill over directly from bats to humans[14-16]. It is uncertain what proportion of bat SARSr-CoVs can infect people either directly or indirectly (via an intermediate or amplifier host). However, serological evidence of prior infection with SARSr-CoVs in communities living near bat populations in China prior to the emergence of COVID-19, including in people who reported no contact with SARSr-CoV intermediate hosts, suggests direct bat-to-human transmission might occur in some regions[17,18]. Direct bat-to-human spillover events may occur more frequently than has been reported, but go unrecognized because they

cause mild symptoms, cause symptoms that are similar to other infections, result in small numbers of cases, or lack sustained chains of human-to-human transmission. However, every wildlife-to-human spillover event represents an opportunity for viral adaptation permitting human-to-human spread[19-22]. Quantifying the extent of these undetected spillovers could therefore be important to identifying risk of future epidemics or pandemics.

Surveys of bats in China have revealed high diversity of SARSr-CoVs, and often high prevalence (5-10%) in rhinolophid and hipposiderid species that are widely distributed, abundant, resilient to habitat perturbation and are synanthropic (have contact and often interactions with human populations)[23-25]. Many of the bat species and genera known to harbor these β-CoVs occur in Southeast Asia, a hotspot of bat diversity with 441 species reported, 115 (around a quarter) of which are rhinolophids or hipposiderids[26]. While some related β-CoVs have been reported outside China (including within Africa), phylogenetic analyses of SARSr-CoVs indicate that regions of south China and parts of neighboring countries (Myanmar, Lao PDR, and Vietnam) act as areas of evolutionary diversification with high diversity of these viruses. However, sampling in China has been far more intense than in nearby Southeast Asian or South Asian countries, and diversity of these viruses is also likely high in these regions[23]. Furthermore, many of these less well-sampled countries are undergoing dynamic social and environmental changes correlated with zoonotic emergence (e.g. rapid human population growth, movement of rural residents to urban centers, extensive wildlife farming and trade, and rapid land conversion from pristine forested habitats to agricultural monocultures), and thus might represent hitherto unreported hotspots for coronavirus spillover risk[23,27-32].

In this study, we use host distribution modeling, ecological, and epidemiological data to estimate the geographic distribution of SARSr-CoV exposure risk, and likely rate of unreported zoonotic spillover in China, South and Southeast Asia. Our results provide the most detailed estimates to date of the distribution and species richness of bat hosts of SARSr-CoVs, and suggest that human exposure to and spillover of SARSr-CoVs may be substantially underestimated. Our approach provides proof of concept for systematic risk assessment of zoonotic spillover, and a strategy to identify key geographic areas that can be prioritized for targeted surveillance of wildlife, livestock, and humans. Given the challenges of identifying the origins of COVID-19 and pathways by which SARS-CoV-2 spilled over to people[33,34], this approach may also aid efforts to identify the geographic sites where spillover first occurred.

Results

We assembled a list of 23 known SARSr-CoV bat host species, mainly members of the *Rhinolophidae* and *Hipposideridae*, occurring in the geographic region of interest (Table S1). We derived an area of habitat (AOH) for each species (Fig. 1, also see rationale for using this approach in Methods), by refining the IUCN geographic range of each species using habitat suitability, elevation limits, and the boundaries of a broadly defined region including parts of South Asia, China and Southeast Asian countries. Removing unsuitable areas of bat occurrence within the IUCN geographic ranges highly improved assessment of species distribution. For example, the reduction in area from the original IUCN geographic range to the more refined AOH for each species ranged from 42% (*Rhinolophus malayanus*) to almost 100% (*R. hipposideros*), with a median of 68% reduction (Fig. S1). Notably, the reduction in area was 55% for *R. rex*, the only species in our list assessed as endangered by the IUCN Red List.

We validated species AOHs using cleaned occurrence records downloaded from the Global Biodiversity Information Facility (GBIF; see Methods for details of data cleaning and validation). After data cleaning, no occurrence records remained for three species (*Hipposideros pratti*, *R. ferrumequinum*, and *R. hipposideros*), while 1-179 (median = 13) occurrence points remained for all other species (Table S2). In validating each species' AOH with GBIF occurrence points, we found among species with ≥1 occurrence point, the median percent of points (buffered by 5 km) that overlapped a species' AOH was 64% (Table S2). Among species with at least 30 occurrence points (n = 7), the median overlap was 84%. Overlap was >80% for five species: *R. creaghi* (31/31, 100%), *R. malayanus* (8/8, 100%), *Chaerephon plicatus* (45/53, 85%), *H. galeritus* (37/44, 84%), and *H. larvatus* (41/49, 84%).

The size of individual species AOHs varied widely, but generally, the largest AOHs encompassed the most people (Fig. 2a). For example, the AOH of *R. affinis* was the largest of all species, covering ~1.9 million km^2, and it encompassed ~132 million people (2nd highest of any species). Two species had AOHs with more limited area but relatively high human population density: *Nyctalus leisleri* (~262 people/km^2) and *R. stheno* (~226 people/km^2; Fig. 2a, Fig. S2). Within species AOHs, forest habitats and 'carbonate' (limestone) rock outcrops (used as a proxy for cave distribution) typically comprised the largest proportion of suitable habitat (Fig. 2b). Two species (*R. stheno* and *R. malayanus*) had high proportions (>50%) of artificial habitats, including plantations and arable land.

The consensus area of all SARSr-CoV bat host species, created by mosaicking the 23 species AOHs, comprised ~4.5 million km^2. We calculated that ~478 million people live within this consensus area, which covered most of Lao PDR, Cambodia, Thailand, Vietnam, Nepal, Bhutan, peninsular Malaysia, Myanmar, southeast China, and the western islands of Indonesia (Fig. 3a). Bat species distribution was patchier in India, Sri Lanka, East Malaysia, and the Philippines. Species richness ranged from 1-14 species, with the highest richness of SARSr-CoV bat host species in southern China, eastern Myanmar, and northern Lao PDR (Fig. 3a). When we visualized areas with both high host richness and large human populations ('relative spillover risk'), southern China remained a hotspot, while other areas emerged as important because of their high human population sizes (e.g. Java, parts of northern India; Fig. 3b).

After calculating the number of people living in the consensus area of SARSr-CoV bat host species, we further incorporated data from the literature on bat-human contacts, human SARSr-CoV seroprevalence, and SARS antibody duration to estimate the extent of hidden bat-human spillover of SARSr-CoVs in Southeast Asia (see Supplemental Material for details of probabilistic risk assessment methods). We estimated that within the consensus area of SARSr-CoV bat host species, an average of 407,422 people (median: 53,225; range: 1 - 35,632,228) are infected with SARSr-CoVs each year in Southeast Asia (Fig. S3). Sensitivity analyses indicated that the probability of antibody detection given contact with a bat, and the probability of contact with a bat, contributed most to variance in the outcome (Fig. S4). In the process of identifying datasets of value for each step of the probability analysis, we also assessed datasets that are not available or for which quality could be improved, and would likely provide more accurate assessments of risk (Fig. 4).

Discussion

Our paper reports an analytical framework to assess SARSr-CoV spillover risk in a region that includes the site of the first spillover of SARS-CoV, and likely of SARS-CoV-2. By incorporating data on biologically plausible host distributions for all bat species known to harbor SARSr-CoVs in South and Southeast Asia, on human population counts, on behavior of people in the region that drives bat-human contact, and on seroprevalence in people and duration of antibody persistence, we are able to provide detailed maps of potential bat-to-human SARSr-CoV spillover hotspots, as well as estimates of the number of people infected by this viral group annually. Our approach may assist in better identifying regions for targeted surveillance of local communities at risk of spillover, for conducting viral discovery programs to identify novel bat-CoVs, for COVID-19 origins tracing, and for estimating human surveillance targets to identify spillover events earlier and more accurately. All of these are key goals for pandemic preparedness and prevention[35-38], and if used to target future surveillance and disease control, may help to reduce the risk of future COVID-like outbreaks.

Our analysis identifies regions in southern China, northeastern Myanmar, Lao PDR, and northern Vietnam as having the highest diversity of SARSr-CoV bat host species. These hotspots of SARSr-CoV bat reservoir host diversity may be particularly fruitful sites for viral discovery of novel SARSr-CoVs, assuming that viral diversity scales with host species diversity[39]. This finding supports conclusions from prior phylogenetic analyses that particularly diverse SARSr-CoV lineages are found in southern China, and that it may be a center of evolutionary origin for this group of β-CoVs[23]. It also helps explain the recent identification of multiple strains of

SARSr-CoVs in southern China[32,40,41] and southeast Asian countries[31], despite small sample sizes. It suggests that the less intense sampling in countries bordering southern China has led to an underestimate of the diversity of these viruses there. Given that the bat species known to host the closest relatives of SARS-CoV-2 are found in this region, these maps may also guide efforts to identify the viral clade from which a progenitor virus emerged[23,32,34]. The map of bat SARSr-CoV host diversity combined with human population density points to hotspots of bat-to-human exposure risk (and potential for human-to-human spread) in southern China and bordering countries, but also in the populous regions of Indonesia. This map may be useful in targeting surveillance to identify SARSr-CoV spillover events in people, including syndromic surveillance for SARS- or COVID-like respiratory disease in communities within these hotspots, as proposed previously[18,24,35,39]. It may also provide guidance for studies of where initial spillover of the progenitor of SARS-CoV-2 may have occurred, although epidemiological and other data suggest this would most likely have been in China or neighboring countries[33,34].

Our estimate that an average of ~400,000 (median ~50,000) people are infected with SARSr-CoVs each year in Southeast Asia suggests that bat-to-human SARSr-CoV spillover is common in the region, and is undetected by surveillance programs and clinical studies in the majority of cases. While the data suggest significant levels of exposure, many of the diverse viral strains that infect people in the region each year may not be able to replicate well in people, cause illness, or be transmitted sufficiently among people to cause an outbreak. This has been shown in theoretical models of disease emergence[21,42], and supports earlier evidence from studies of non-human primate virus spillover[43], that cross-species transmission of novel animal-origin viruses is not the rate-limiting step in pandemic viral emergence. However, given the relatively large

number of people likely to be infected each year with bat-CoVs, it is plausible that illnesses or clusters of cases due to novel bat-CoV infection occur regularly within the region, and are either not reported, or otherwise missed by clinical surveillance. Evidence of underreporting has been demonstrated for other bat-origin viral infections. For example, targeted syndromic surveillance of encephalitis patients in a small number of clinics in Bangladesh showed that Nipah virus causes outbreaks annually with an overall mortality rate of ~70%, despite it only recently being reported from the country[44]. Efforts to increase surveillance for novel SARSr-CoVs (and other bat-origin viruses) in clinical cohorts, particularly using syndromic surveillance, may identify the rate of missed cases, and pre-empt larger scale outbreaks. Estimating the true rate of spillover of previously unknown, potentially zoonotic animal-origin viruses is difficult without serological or genomic surveillance data. For most viruses, the duration of infection in humans is relatively short, e.g. the infectious period for COVID-19 is 2-3 weeks[45], and if spillover is rare, PCR surveillance is unlikely to give valuable data on spillover rates due to lack of positives. One exception is for viruses with long infectious periods such as lentiviruses and some retroviruses, and a previous genomic surveillance study of wildlife hunters in Africa was able to find 10/1099 (0.9%) prevalence of non-human primate origin simian foamy viruses[46]. Because detectable antibodies or T cell responses are more long-lived, serological surveys or activated T cell testing represent more valid strategies to estimate spillover rates.

Our calculation of undetected spillover represents the first published attempt to identify the rate of spillover of novel coronaviruses from bats to people. It relies on a number of input variables and we attempted to account for uncertainty by assigning a probability distribution to each variable, but recognize that further data would likely help refine estimates of SARSr-CoV

198 spillover rates. Perhaps most critical is a lack of information on the role of intermediate hosts in
199 the emergence of SARSr-CoVs. It has been postulated that civets and other commonly farmed
200 and traded mammalian species played a role in the emergence of SARS-CoV by acting as
201 efficient amplifier hosts within wildlife farms and markets[12,47-50]. SARS-CoV-2 can infect civets,
202 raccoon dogs, and other mammals commonly farmed and traded for food in the region[51,52].
203 SARS-CoV-2 has also caused significant outbreaks in animals bred for fur (e.g. mink, raccoon
204 dogs) that have in some cases led to transmission to people[53,54]. These and other data led an
205 international team to conclude that the most likely pathway for COVID emergence was from bats
206 to people through a farmed mammalian intermediate host[33]. Accurate data are not available on
207 the number of wildlife farms and potential intermediate hosts bred each year, or on the market
208 systems that supply live animals into cities within China and Southeast Asia. It was estimated
209 that 14 million people were employed in the wildlife farming system within China alone during
210 2016, in an industry worth $77 billion annually[55,56]. Additionally, some of these potential
211 intermediate hosts occur naturally in the region (e.g. pangolins, civets), and other livestock
212 species that are extremely common (e.g. pigs, cattle, rabbits) are susceptible to SARSr-CoVs
213 either naturally or experimentally[52]. Spillover of SARSr-CoVs may therefore be substantially
214 skewed to people who have high exposure to these species, and this would likely have been
215 missed in the relatively small serological surveys upon which our analyses are currently based.
216 Thus, better estimates of the role of farmed and traded intermediate hosts are likely to
217 substantially increase the estimated spillover rates of SARSr-CoVs across the region.
218
219 Other data could improve our estimates. These include expanded survey data on the background
220 seroprevalence of bat SARSr-CoVs in people across different populations and geographies,

221 analysis of how specific risk behaviors correlate with seroprevalence, and studies of how
222 serological titers and duration of antibody persistence relate to severity of infection. We
223 estimated bat-human contact using data from previous human-animal contact surveys and
224 ethnographic investigations, but contacts likely vary widely across the region due to different
225 cultural practices and traditions[57,58]. The type of contact may be critical to assessing the risk of
226 transmission (e.g. hunting and butchering vs. living near a bat colony), and some types of contact
227 may be unrecognized and therefore unreported (e.g. exposure to feces or urine on surfaces).
228 Some of the contact data we identified in our systematic literature search (see Supplemental
229 Material for details) were from populations targeted because of known high risk of bat contact
230 due to occupational or environmental exposure and are likely upwardly biased due to non-
231 random study design. Expanded bat viral survey data would also likely improve our estimates,
232 first by obtaining more contemporary, accurate species presence records, and also by identifying
233 previously unknown SARSr-CoV hosts, improving species-specific estimates of SARSr-CoV
234 prevalence, and clarifying how environmental (e.g. location, season, year) and host trait (e.g. sex,
235 age, body condition) factors affect viral shedding[59-62]. Finally, it is also possible that taxonomic
236 errors have occurred in the data we analyzed. Taxonomic standards in viral discovery and
237 surveillance studies vary widely, and point to a need for better taxonomic training of field teams,
238 standardized DNA 'barcoding' of hosts, collection of voucher specimens, and closer
239 collaboration among disease ecologists, virologists, field biologists and taxonomists[63,64].
240
241 Our refinement of species ranges has likely produced the most accurate contemporary picture of
242 SARSr-CoV bat host species occurrence to date, and demonstrates substantial range modification
243 for many species, reflecting rapid land use change throughout the region. The AOHs we

produced may be useful for targeting surveillance to key species. For example, only a few species AOHs contained a sizable proportion (≥ 25%) of one or more artificial habitats (Fig. 2b): *R. malayanus* (arable land, plantations), *R. stheno* (plantations, arable land), and *N. leisleri* (pastureland). These species may be more likely to come into contact with humans and could represent a particularly important spillover risk considering that global analyses demonstrate zoonotic host diversity increases in areas with anthropogenically modified habitats[65]. Cave habitats were classified by the IUCN as suitable for nearly all species in our analyses, and carbonate rock outcrops (used here as a proxy for caves) made up a large proportion of species AOHs. Visiting caves, collecting guano, and using bat guano in crop production are likely particularly high-risk activities given these findings[66-69]. Our validation process indicated good agreement between species AOHs and GBIF occurrence data, suggesting that the maps we generated accurately reflect species presence for occurrence records collected after 1990. Limitations of AOH maps[70] include the potential inaccuracy of the IUCN species ranges[71], habitat suitability assignments, and elevation limits. Additionally, the map of terrestrial habitat types we used in our analyses[72,73] did not include caves, an important habitat type for many bat species. We used carbonate rock outcrop data as a proxy for cave distribution and this could be ground-truthed.

Our analytical framework provides a strategy that has potential for improving preparedness for emerging diseases and pandemic risk. It has produced maps that can be used to conduct more cost-effective field surveys for viral discovery programs, and estimates of spillover rates that can guide targeted human surveillance to identify clusters of cases of a new CoV infection earlier and help prevent spread. It may also give vital guidance for efforts to identify the reservoir hosts

of the SARS-CoV-2 progenitor, and the sites of COVID origins or first emergence[34]. Our analysis pipeline and framework are based on open-source code and can therefore serve as a resource to update and modify spillover risk maps and estimates as new data become available. These could include serological surveys in people using new diagnostic assays that can detect virus-specific neutralizing antibodies to differentiate COVID-19 variants, vaccine strains, and different clades of bat SARSr-CoVs[74], or data from ethnographic surveys that identify changes in bat-to-human contact as habitats are increasingly modified or laws to reduce hunting or wildlife trade reduce consumption are enforced. Finally, our framework can be rapidly adapted for spillover risk assessment of other viral groups, such as the HKU-2/SADS-CoV α-CoVs that have recently been found able to infect primary human airway epithelial cells *in vitro*, and therefore pose a heightened spillover risk, or any of the other ~25 viral families that include known zoonoses[39].

Methods

1. Compilation of SARSr-CoV bat host data

We identified all bat species from which molecular evidence of SARSr-CoV infection had been reported, and for which associated sequence confirmation data were available. We supplemented a recently compiled list[75] with hosts listed in other more recent publications[23,30,31,41,76-78]. We removed duplicate records and hosts only identified to genus level. We considered *Rhinolophus paradoxolophus* to be a subspecies of *R. rex*[79]. We excluded *R. monoceros* because, although recent work has retained it as a distinct species[80], no recent assessment of the species has been published by the IUCN Red List of Threatened Species. *Hipposideros pomona* and *H. gentilis*

were split in 2018, with *H. pomona* restricted to a small area in southern India while *H. gentilis* is broadly distributed across Southeast Asia[81]. Although *H. pomona* was listed as a host species in [23] from field sampling in China, we therefore substituted *H. gentilis* in our analyses. We chose to not include several bat species that were predicted to be SARSr-CoV reservoirs using host-trait or species network models[82,83], as these predictions remain unvalidated, and vary in reliability across models.

We restricted the compiled list of SARSr-CoV bat hosts to those with geographic distributions either partially or entirely within Southeast Asia, and included the following countries and administrative regions: Bangladesh, Bhutan, Brunei, Cambodia, China, Hong Kong SAR, Macao SAR, India, Indonesia, Lao People's Democratic Republic, Malaysia, Myanmar, Nepal, the Philippines, Singapore, Sri Lanka, Thailand, Timor-Leste, and Vietnam. See Table S1 for the finalized list of SARSr-CoV bat hosts. Note that while we use the term 'Southeast Asia', the region we considered has broader range than is used for political definitions of the region and includes China and parts of South Asia, due to the extensive range of some of the bat host species.

2. Calculation and validation of host area of habitat

All analyses were performed in the R statistical environment v. 4.0.3 (R Core Team 2020). To derive a biologically realistic area of habitat (AOH) within our Southeast Asia region for each SARSr-CoV bat host reservoir species, we refined species ranges by incorporating data on habitat suitability and elevation limits[70]. We used an AOH approach rather than ecological niche modeling (ENM) because ENMs rely on presence data, and this was difficult to find within

GBIF, particularly when we excluded older records that may not reflect current distributions. Secondly, ENMs have the potential to overestimate range sizes and are thus not useful for identifying more precisely areas for surveillance, for example. To derive the AOH for each species, we downloaded its geographic range from the IUCN Red List of Threatened Species[84] (last update: March 25, 2021), overlaid it onto a raster map of terrestrial habitat types[72,73], and selected areas of the map that occurred within its range (Fig. 1a). We then selected areas of suitable habitat (as determined by IUCN) for each species (Fig. 1b, Table S1; see Supplemental Material for further details). Finally, we overlaid elevation data (Shuttle Radar Topography Mission data obtained with the getData function of the "raster" package[85]) onto each species' range and habitat map and selected areas that fell within a species' elevation limits (Fig. 1c; Table S1); these remaining areas represented the species' AOH. Using the "raster" package, we calculated the size (in km^2) of each species' AOH and compared it to the size of its original IUCN range. Note that all analyses were restricted by the regional boundaries of Southeast Asia as defined above.

We validated the AOH of each species using occurrence data downloaded from the Global Biodiversity Information Facility (GBIF) using the "rgbif" package[86,87]. We cleaned GBIF data by removing records with inaccurate or imprecise coordinate data (i.e. no coordinates, identical longitude and latitude, coordinates of 0, coordinate uncertainty > 35 km, coordinates in the ocean, country–coordinate mismatch), records from areas outside our geographically defined region, records of absence rather than presence, and records with unreliable data sources (e.g. fossil specimen, literature, unknown). We removed records within 5km of country capitals, within 1km of country/province centroids, and within 100m of biodiversity institutions. We

removed records before 1991, as older records tend to have less precise location data[88] and could reflect species ranges that have since shifted. Within each species, we removed records with duplicate coordinates. Cleaning was facilitated with the "CoordinateCleaner" package[89]. For each species, we buffered each of its occurrence points by five kilometers and calculated the percent of buffered points that overlapped the species' AOH.

3. Estimation of bat-human overlap, bat species richness, and habitat proportions

To identify regions where human populations might be exposed directly or indirectly to SARSr-CoV bat hosts, we overlaid human population count data on each host species' AOH. We used a 1-km resolution raster of 2020 population count data from WorldPop[90] and resampled it with bilinear interpolation using the "gdalUtils" package[91] so that its extent and resolution matched that of the habitat raster. We calculated the number of people living within the AOH of each species separately, and divided this by the size of each AOH to obtain average human population density values. As living in areas with high diversity of SARSr-CoV bat hosts and large human populations may increase the likelihood of human-bat contact, viral spillover, and subsequent pathogen spread, we also visualized bat species richness and bat species richness multiplied by human population size (which we term "relative spillover risk") across the consensus map. To examine the relative importance of different habitat types to SARSr-CoV bat hosts, we calculated the proportion (by area) of each habitat type within the AOH of each species.

4. Estimating human exposure to and infection with SARSr-CoVs

We used a probabilistic risk assessment to estimate the extent of SARSr-CoV spillover from bats to humans. We assumed that the number of people infected with SARSr-CoVs by bats each year

359 is equal to 1) the number of people who live in the consensus area of SARSr-CoV bat hosts,
360 multiplied by 2) the probability that a human comes into contact with a bat, multiplied by 3) the
361 probability that a bat-human contact leads to a serologically detectable human infection,
362 multiplied by 4) the probability that serological detection is due to an infection within the
363 previous year. To inform our choice of distribution for each input variable, we gathered data
364 from the literature on human-bat contacts, human SARSr-CoV seroprevalence, and human
365 SARS antibody duration (see the Supplemental Material for details). We accounted for
366 uncertainty and/or variation associated with the input variables by assigning a probability
367 distribution (rather than a single fixed value) to each. We performed Latin hypercube sampling
368 with the "lhs" package[92] to generate 400,000 sets of input combinations and calculated the total
369 number of people infected for each set of inputs, creating an output distribution. We then
370 calculated summary statistics (mean, median, range) for this distribution. Finally, we performed
371 a global sensitivity analysis by calculating Sobol sensitivity analyses to understand the relative
372 contribution of each input variable to the outcome.
373
374

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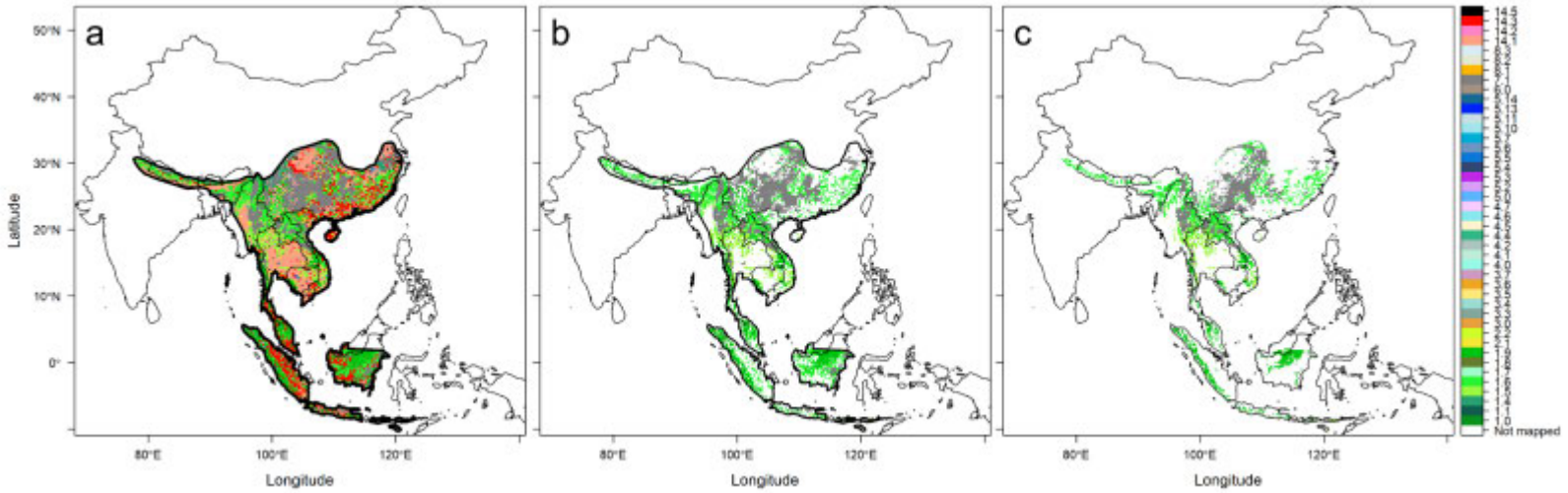
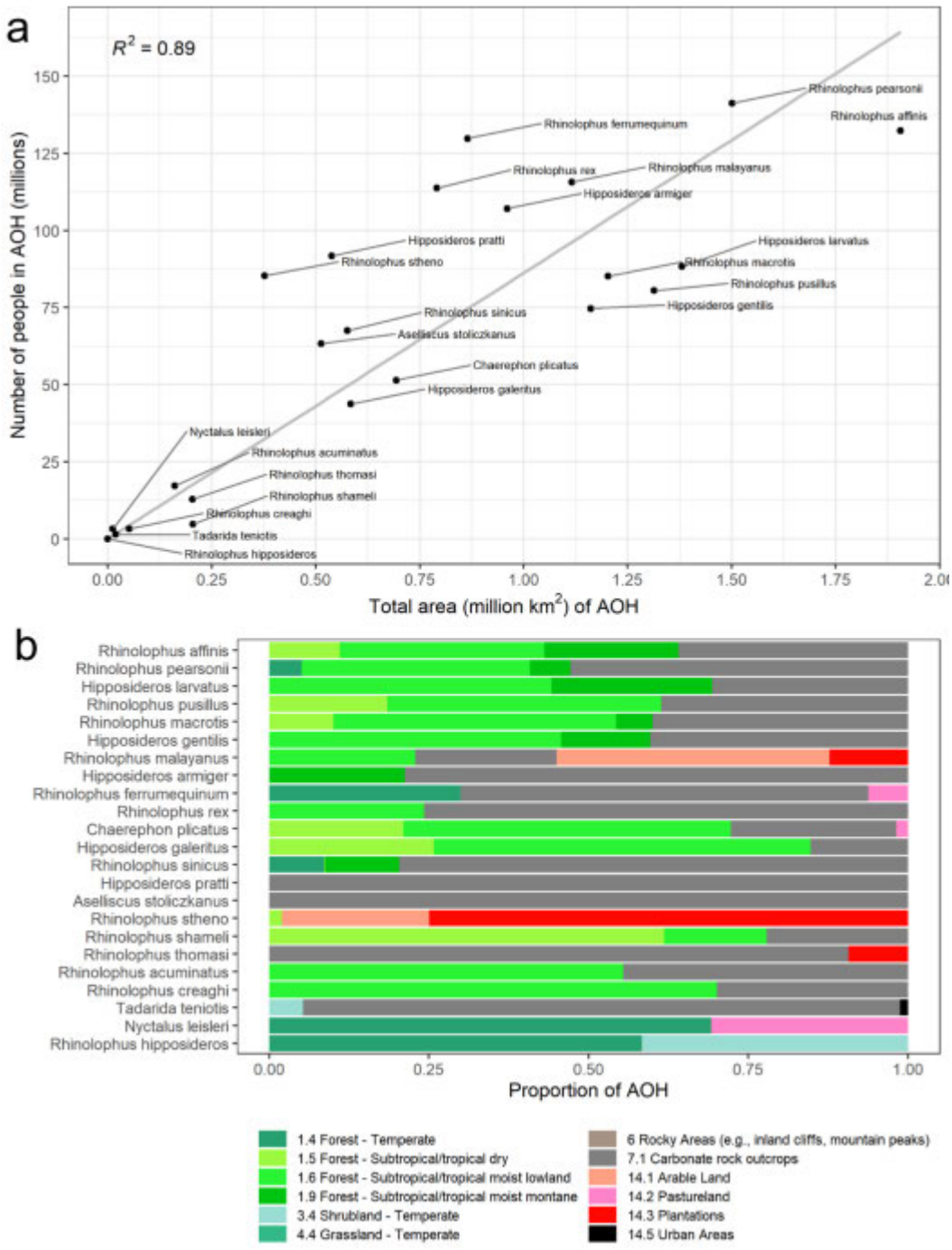
Figure 1. Representative illustration of IUCN range refinement by habitat type and elevation limits to create area of habitat (AOH). a The IUCN range of *Rhinolophus affinis*, outlined in black, is overlaid on a map of terrestrial habitat types, and the habitat map is restricted to only the species range. **b** Only suitable habitat types within the species range are retained. **c** After further restricting habitat by the elevation limits of the species, the remaining habitat represents the AOH of *R. affinis*. The color scheme follows that of [72,73], with the addition of gray used for habitat type 7.1 (caves; carbonate rock outcrops used as proxy). Names of habitat types are found in Fig. 2b and Table S1.

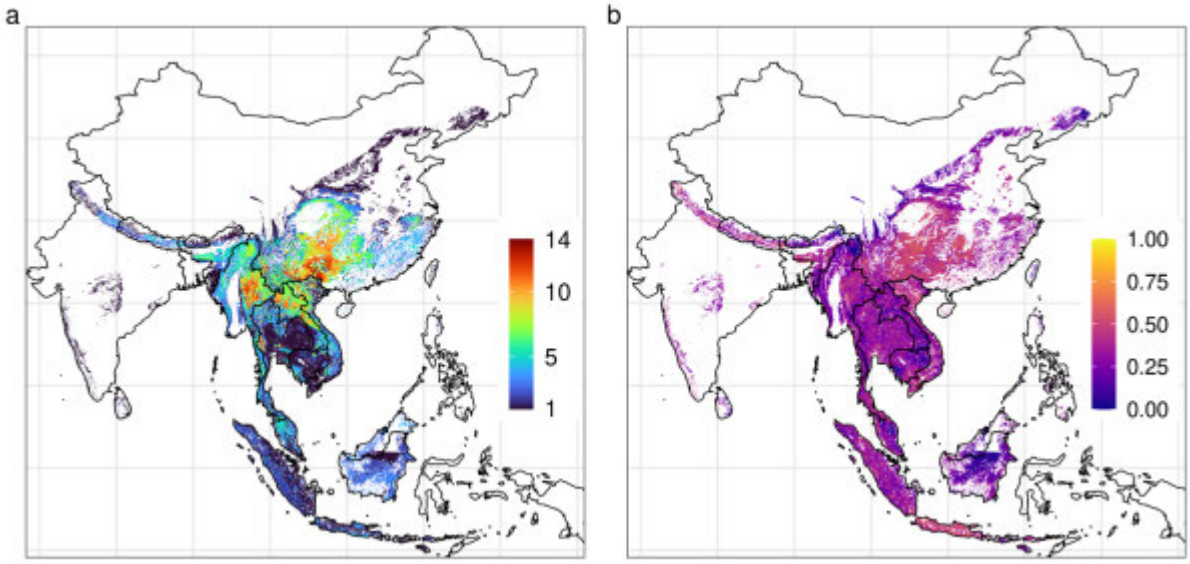


609 **Figure 2. Relationships among AOH size, number of people, and habitat proportions. a**
610 Scatterplot showing the total number of people living in each AOH versus the total area, for each
611 SARSr-CoV bat host species. A best-fit line was fit through the origin, for which the R^2 is
612 displayed. **b** Proportion of each habitat type within species AOHs. Species are listed in order of
613 decreasing AOH size. Color scheme follows that of Jung and colleagues[72,73], with the addition of
614 gray for caves (carbonate rock outcrops used as proxy).
615

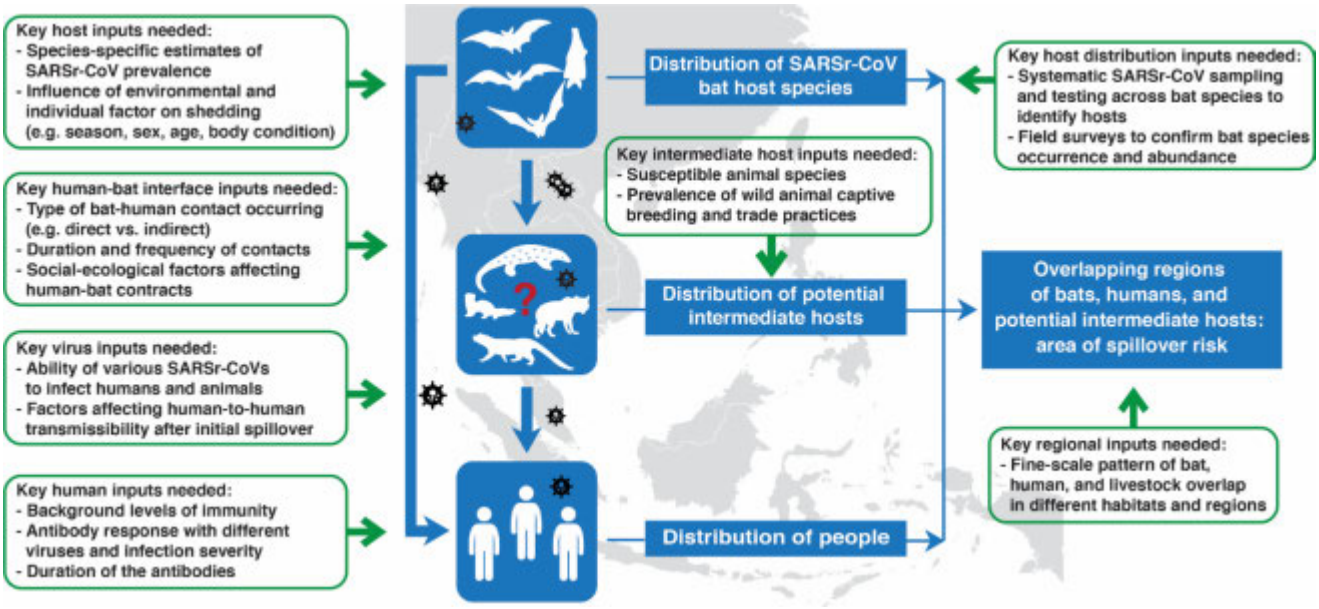

a
R^2 = 0.89
Number of people in AOH (millions)
Total area (million km^2) of AOH
Rhinolophus pearsonii
Rhinolophus affinis
Rhinolophus ferrumequinum
Rhinolophus rex
Rhinolophus malayanus
Hipposideros armiger
Hipposideros pratti
Rhinolophus stheno
Hipposideros larvatus
Rhinolophus macrotis
Rhinolophus pusillus
Hipposideros gentilis
Rhinolophus sinicus
Aselliscus stoliczkanus
Chaerephon plicatus
Hipposideros galeritus
Nyctalus leisleri
Rhinolophus acuminatus
Rhinolophus thomasi
Rhinolophus shameli
Rhinolophus creaghi
Tadarida teniotis
Rhinolophus hipposideros
b
Proportion of AOH
1.4 Forest - Temperate
1.5 Forest - Subtropical/tropical dry
1.6 Forest - Subtropical/tropical moist lowland
1.9 Forest - Subtropical/tropical moist montane
3.4 Shrubland - Temperate
4.4 Grassland - Temperate
6 Rocky Areas (e.g., inland cliffs, mountain peaks)
7.1 Carbonate rock outcrops
14.1 Arable Land
14.2 Pastureland
14.3 Plantations
14.5 Urban Areas

616

Figure 3. Hotspot maps of Southeast Asia. a Species richness of SARSr-CoV bat host species in Southeast Asia. This map was created by overlaying AOH maps for all 23 SARSr-CoV bat host species. **b** Bat host species richness * human population count, or "relative spillover risk". Values were log(x + 1) transformed and then normalized to a 0-1 scale.



623 **Figure 4. Conceptual figure depicting key data inputs to better estimate spillover of**
624 **SARSr-CoVs from bats to humans, and gaps in the available data.**
625



626

EcoHealth Alliance

Aleksei Chmura <(b) (6)>

Re: Animal Welfare Interinstitutional Assurance #A7941-01 - EcoHealth Alliance & Wuahn Institute of Virology - 1R01AI110964-01

1 message

Aleksei Chmura <(b) (6)> Thu, May 8, 2014 at 10:38 AM
To: "Williams, Barbara (NIH/OD) [C]" <(b) (6)>
Cc: Shi Zhengli <(b) (6)> "Dr. Daszak Peter" <(b) (6)> "Pone, Laura (NIH/NIAID) [E]" <(b) (6)> "OLAW Division of Assurances (NIH/OD)" <(b) (6)> "Dr. Epstein Jon" <(b) (6)>

Dear Dr. Williams,

Many thanks for the notification and copy!

Sincerely,

Aleksei Chmura
Program Coordinator & Authorized Organizational Representative
EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(b) (6) (direct)
(b) (6) (mobile)
(b) (6) (China)
Aleksei MacDurian (Skype)

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EcoHealth Alliance integrates innovative science-based solutions and partnerships that increase capacity to achieve two interrelated goals: protecting global health by preventing the outbreak of emerging diseases and safeguarding ecosystems by promoting conservation.

On 08 May 2014, at 09:44:38, Williams, Barbara (NIH/OD) [C] <(b) (6)> wrote:

Dear Dr. Chmura,

Attached is a copy of the signed, approved Animal Welfare Interinstitutional Assurance needed between EcoHealth Alliance and the Wuhan Institute of Virology, for animal research to be conducted under grant 1R01AI110964-01. The Assurance number is A7941-01 and became effective on 5/7/2014. I am also mailing this information to you.

Barbara Williams
Program Analyst
Office of Laboratory Animal Welfare, NIH
Phone: (b) (6)
Email: (b) (6)

Division of Assurances
E-fax : 301-480-3117

Email: (b) (6)

General Disclaimer
Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

Animal Welfare Interinstitutional Assurance #A7941-01.pdf
240K

DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive
RKL 1, Suite 360, MSC 7982
Bethesda, Maryland 20892-7982
Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive, Suite 360
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 451-5672

May 7, 2014

Project: 1 R01 AI 110964-01
Project Title: Understanding the Risk of Bat Coronavirus Emergence
Principal Investigator: Dr. Peter Daszak
Animal Facility: Wuhan Institute of Virology

Dr. Aleksei Chmura
Authorized Organizational Representative
EcoHealth Alliance
460 West 34th Street, 17th Floor
New York, New York 10001

Dear Dr. Chmura:

The Division of Assurances, Office of Laboratory Animal Welfare (OLAW), has reviewed and approved the new Interinstitutional Assurance which was submitted by your institution in compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) revised August 2002.

The Assurance, with identification **#A7941-01,** became effective on 05/07/2014. The Assurance is good for the current period of support. Under your approved Assurance with the Wuhan Institute of Virology, their Institutional Animal Care and Use Committee (IACUC) is authorized to conduct subsequent reviews of this project.

The Assurance is a key document in defining the relationship of your Institution to the PHS and the cooperating institution's IACUC, since they set forth the responsibilities and procedures of your Institution regarding the care and use of laboratory animals.

A copy of the approved Assurance is enclosed. If I can be of any further assistance, please feel free to contact me by phone or email.

Sincerely,

(b) (6)

Eileen Morgan
Director, Division of Assurances
Office of Laboratory Animal Welfare

Enclosure

cc:
Dr. Xinwen Chen
Dr. Wuxiang Guan
Ms. Laura Pone, NIAID

REL0000047839.0001.0009

Interinstitutional Assurance

The Interinstitutional Assurance is used by U.S. institutions that receive Public Health Service (PHS) funds through a grant or contract award when the institution has neither its own animal care and use program, facilities to house animals, nor an Institutional Animal Care and Use Committee (IACUC) and will conduct the animal activity at an Assured institution (named as a performance site).

I. Awardee Institution

Name of Awardee Institution: EcoHealth Alliance
Address: *(street address, city, state, zip code)* 460 West 34TH STREET, 17TH FL. NEW YORK, NY 10001, USA
Project Title: *(from grant application/contract proposal)* UNDERSTANDING THE RISK OF BAT CORONAVIRUS EMERGENCE
Grant/Contract Number: R01 AI 110964
Principal Investigator: DR. PETER DASZAK

A. Applicability

This Interinstitutional Assurance between the awardee institution and the Assured institution is applicable to research, research training, and biological testing involving live vertebrate animals supported by the PHS and conducted at the Assured institution.

B. Awardee and Assured Institutional Responsibilities

i. The institutions agree to comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

ii. The institutions agree to be guided by the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training and comply with the PHS Policy on Humane Care and Use of Laboratory Animals (Policy).

iii. The institutions acknowledge and accept responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, the institutions will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use.

iv. The awardee institution acknowledges and accepts the authority of the IACUC of the Assured institution where the animal activity will be performed and agrees to abide by all conditions and determinations as set forth by that IACUC.

Name of Assured Institution: WUHAN INSTITUTE OF VIROLOGY, CHINESE ACADEMY OF SCIENCES
Address: *(street address, city, state, zip code)* XIAO HONG SHAN NO. 44 WUHAN, 430071, CHINA

II. Institutional Endorsement

By signing this document, the authorized official at the awardee institution and the Institutional Official and IACUC Chairperson at the Assured institution (performance site) provide their assurances that the project identified in Part I will be conducted in compliance with the PHS Policy and the Assurance of the Assured institution.

A. Endorsement of Awardee Institution

REL0000047839.0001.0009

Name of Awardee Institution: EcoHealth Alliance	
Authorized Official: Aleksei Chmura	
Signature: (b) (6)	Date:20 March 2014
Title: Authorized Organizational Representative	
Address: *(street address, city, state, zip code)* 460 WEST 34TH ST., 17TH FL. NEW YORK, NY 10001, USA	
Phone: (b) (6)	Fax:+1.212.380.4465
E-mail: (b) (6)	

B. Endorsement of Assured Institution

Name of Assured Institution: WUHAN INSTITUTE OF VIROLOGY, CHINESE ACADEMY OF SCIENCES	
Institutional Official: Xinwen Chen	
Signature (b) (6)	Date: 30 April 2014
Title: Director of Wuhan Institute of Virology, Chinese Academy of Sciences	
Address: *(street address, city, state, zip code)* Xiao Hong Shan No.44 Wuhan, 430071, China	
Phone: (b) (6)	Fax: 86-27-87199106
E-mail: (b) (6)	
IACUC Chairperson: Wuxiang Guan	
Signature: (b) (6)	Date: 30 April 2014
Title: Chairman of Institutional Animal Care and Use Committee, Wuhan Institute of Virology, Chinese Academy of Science	
Address: *(street address, city, state, zip code)* Xiao Hong Shan No.44 Wuhan, 430071, China	
Phone: (b) (6)	Fax: 86-27-87197258
E-mail: (b) (6)	
Date of IACUC Approval: *(within 3 years, pending not acceptable)* 3/25/2014	

III. PHS Approval *(to be completed by OLAW)*

Signature of OLAW Official: (b) (6)	Date: 5/7/2014
Eileen M. Morgan **Director, Division of Assurances** **Office of Laboratory Animal Welfare (OLAW)** **National Institutes of Health** **RKL1, Suite 360 – MSC 7982** **6705 Rockledge Drive** **Bethesda, MD 20892-7982**	
Grant/Contract #:1R01AI110964-01	Animal Welfare Assurance #: A7941-01
Effective Date: 5/7/2014	Expiration Date: *(duration of project, up to 5 years)*

REL0000047839.0001.0009

EcoHealth Alliance

October 26th 2021

Dear Dr Lauer (cc'ing Dr. Tabak),

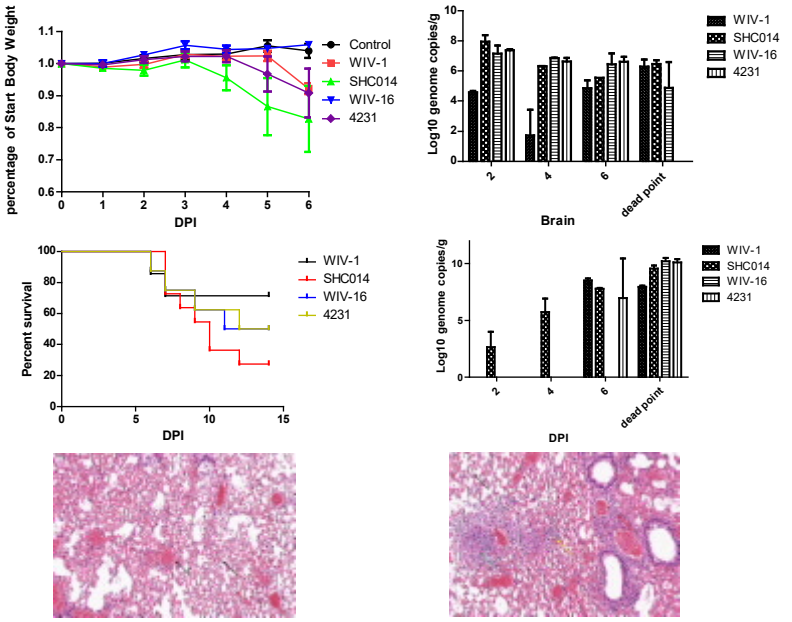
I am responding to your letter requesting IACUC information and unpublished data from our original R01. As I read your letter, I realized that this request is likely related to a letter from Dr. Tabak to Congressional member Comer released publicly on the 20th October *(PDF attachment #1)*. In his letter Dr. Tabak referred to a mouse infection experiment in our FoIA'd year 5 report, and stated that *"EcoHealth failed to report this finding right away, as was required by the terms of the grant"*. The experiment referred to is, in fact, the same one we reported in our Year 4 Report on April 13, 2018. There was just the one experiment conducted, with results from follow-up analyses included in the Year 5 Report. **Thus, EcoHealth did in fact comply with all reporting requirements**. We respectfully would like to clarify this below:

Firstly, Dr. Tabak's letter appears to refer to our year 5 report, and we note that in your email accompanying you also refer to a *Figure 13* from that year 5 report. However, as is visible in the pattern of viral genome measurements, this figure closely resembles *Figure 35* from our year 4 report, but with follow-up histopathological and survival data added (both are inserted, below). The reason for this is that **both figures *are from the same experiment* – conducted in 2018 and, as noted above, reported rapidly to NIH on 13th April 2018 in our Year 4 report.** Proof of submission on that date is attached *(PDF attachment #2)*. It is very important that these facts be acknowledged, as they clearly show that EcoHealth Alliance is *not* out of compliance with our oversight and reporting obligations, and in fact reported this experiment over 3 years and 6 months ago.

In our modified NoA, we were instructed to *"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"*. The Year 4 report was filed in the NIH system on April 13th 2018 and a copy emailed to our Program Officer at NIAID on April 25th 2018 *(PDF attachment #3)*. At no time did program staff indicate to us that this work required further clarification or secondary review. In fact, our report was deemed sufficient for the Year 5 to be awarded without delay. Our relationship with NIH has always been that if we are asked for information, we respond and follow up in a timely manner. If NIH had indicated to us at any point that any issues needed further clarification, we would of course have complied immediately with any request, as we have always done. On June 8th 2016, we wrote to NIH to explain the rationale for these planned experiments and suggested alternative approaches involving non-infectious virus-like particles *(PDF attachment #4)*. Had NIH reviewed our 2018 report and found a need to change the nature of this work, we could have simply shifted to that alternative strategy. No such review or request was reported or made to us.

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018
212.380.4460
EcoHealthAlliance.org

REL0000047839.0001.0010



Year 4 report Figure 35 (Top 2 graphs). *In vivo infection of SARSr-CoVs in hACE2-expressing mice. Left: Body weight change; Right: Viral genome copies per gram in lung tissue*

Year 5 report Figure 13 (Below)**:** *In vivo infection of SARSr-CoV in hACE2-expressing mice. Survival rate, viral genome copies/gram, histopathology WIV-1, histopathology rWIV1-SHC014 S.*

Secondly, the direction in our revised Year 3 NoA, was that we should report experiments in which *"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"*. In virological terms, "virus growth" normally refers to viral titer measuring the concentration of infectious viruses by plaque assay. The experiment we reported to NIH actually shows genome copies per gram *not* viral titer. We have been advised by senior virologists that data on genome copies per gram usually do not accurately equate to viral titer, since genomic material from inactivated, incompletely formed, or dead virus are also measured. Viral titers were not conducted in this experiment. We also note that the genome copy data for SHC014 are only enhanced relative to the WIV1 backbone at the earliest part of the experiment and by day 6-8, there was no discernably significant difference among the different viral types. This suggests that differences, if real, were transient. Given the small number of mice, it is also uncertain whether the survival and weight loss data were statistically relevant, and as no further replications of this experiment were performed, we are unable to corroborate these initial results. We assume that these were the rationale NIH used at the time for *not* highlighting this work as requiring further clarification or secondary review.

Thirdly, regarding the timing of our year 5 (final) report. As we informed you previously, and as is documented by the NIH receipt system itself *(PDF attachment #5)*, we first uploaded this report on time, in July 2019 (the final allowable date for submission would have been September 30th 2019). However, by the time we tried to officially submit, our R01 grant had been renewed (July 24th 2019) and the system locked us out from submitting a normal annual final Year 5 report at that point. On July 30th 2019, we requested further information about the submission of the Year 5 report from the NIH Grants Management Specialist who had been dealing with our renewal, but we did not receive a response to

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our questions (*PDF attachment #6)*. NIH also did not send any subsequent request to us for the Year 5 report, despite the reality that we were in frequent communication with staff during that period. Because the new award had been made and the work was permitted to commence we had no indication there was anything missing, and assumed that the Year 1 report for the renewal grant would provide all of the relevant information. It is standard NIH policy to contact a grant recipient if additional information of reporting is required. We heard nothing further from NIH in the period subsequent to this until your letter in April 2020 requesting that we not fund work at WIV, which we complied with, and then the termination notice you sent a few days later. We presumed at that point that no further reporting was required of us, however when we received a request from your office on July 23rd 2021 for the year 5 report, we immediately took steps to file the report. We were finally able to get the system to accept our report within 11 days, but only after considerable efforts from NIH staff to circumvent the system's lockout. Note also that, even though the grant was terminated and then suspended, and funding is not available to us to work on this, we have continued to comply with NIH reporting requests, and submitted reporting for Years 6 and 7 of this grant.

We take our compliance oversight role very seriously at EcoHealth Alliance, and hope you understand our need to correct these misinterpretations. We have cc'd Dr. Tabak so that he is aware, and we hope he understands that we are making these comments respectfully, and that we acknowledge these are complex technical issues that can be easily misinterpreted. We would like to point out that these types of mistakes about the timing or nature of our reporting can be better addressed by contacting us to request clarification prior to responding to any congressional inquiry. This will help ensure factually correct responses and will save our organization and staff from undue disparagement and unjustified accusation of inappropriate behavior that have now ensued in the press. We believe it is very important that the impressions the Congressional inquiry may take away from the incorrect information provided them be addressed quickly and clearly. We remain, of course, ready to respond to any future questions you or Dr. Tabak may have. We are also available to work with program staff at NIAID on any future technical questions – as would be normal procedure for a grantee.

Request for IACUC information and unpublished data.

As requested in your letter, we have provided unpublished data below and in pdf attachments. We would like to respectfully point out that our NIH grant funding for this work was terminated in a letter from you in April 24th 2020. The grant was then suspended and the funds remain unavailable to us due to the logistically near-impossible conditions that NIH has placed on us, and that we have addressed in previous correspondence. In your letter of April 24th 2020, you instructed us to discontinue all of our contractual work with WIV. Both the lack of funding, and the instruction to cease contractual work with WIV have led to significant disruption of the normal interactions and dialog among collaborating scientists. Despite these challenges, we have continued to comply with all requests from your office. We have also made significant efforts to analyze data we have access to, and to draft papers and publish our work in international peer-reviewed journals, and to upload sequence data to Genbank. We strongly believe doing whatever we can to collate, analyze, and publish data we have from our prior efforts is critical to advancing science and protecting US citizens and people of all nations from future pandemic threats. However, because of the limitations placed on us by NIH our progress has been substantially

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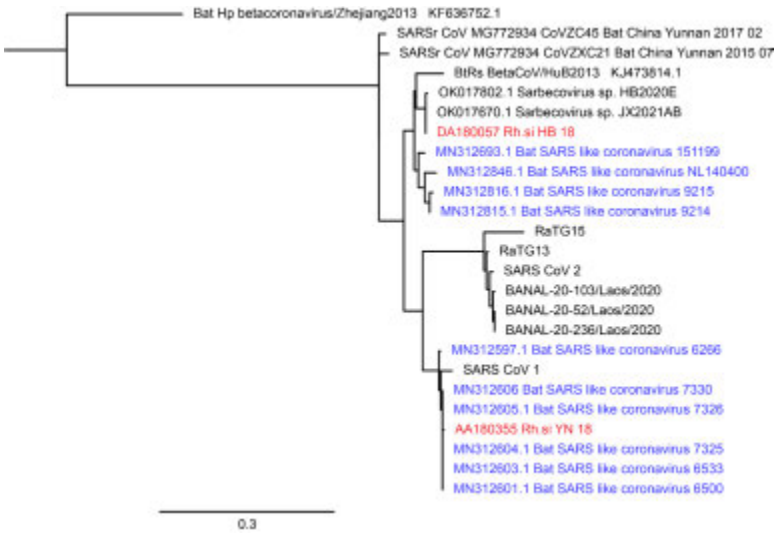
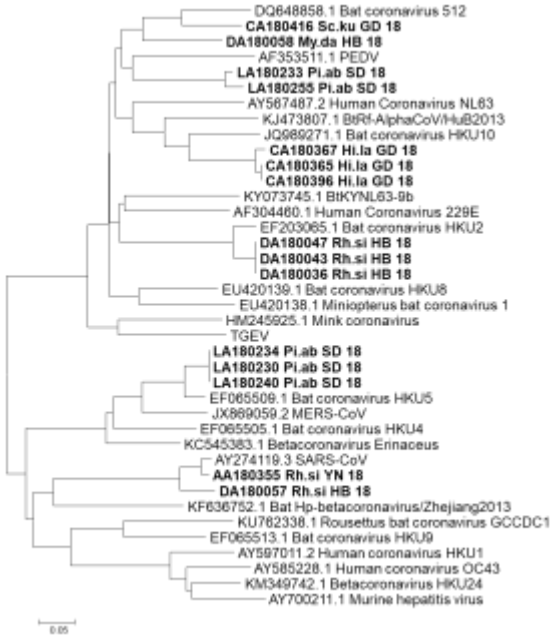
slowed. What we have provided below <u>within the 5-day time limit given to us by Dr. Tabak and yourself</u>, is a good-faith attempt to supply available data as quickly as we are able. These include:

1. A phylogenetic tree of two new SARSr-CoV RdRp sequences reported in ***Figure 5*** *from our 5 year report.* These are from *Rhinolophus sinicus* bats sampled in Hubei and Yunnan provinces, respectively, in 2018. The tree below clearly demonstrates they these viruses (shown in red) are not related closely to SARS-CoV-2, and that the recently-described BANAL coronaviruses are the closest relatives of the pandemic strain. The RdRp sequences for these two viruses are now going through approval process by Chinese authorities so that they can be uploaded to Genbank at the earliest possible opportunity.



2. We have requested that the 13 other novel RdRp sequences (in bold) included in Figure 5 of our year 5 report to be uploaded to Genbank. These are now going through the approval process by the Chinese authorities so that that they can be uploaded to Genbank at the earliest possible opportunity.



Year 5 report Fig. 1 (left): Phylogenetic analysis of partial RdRp gene of CoV (440-nt partial sequence)

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3. We supply new analyses of our work on SADSr-CoVs and HKU2-CoVs *(PDF attachment #7)* that was referred to in our Year 5 report. These viruses are alpha-coronaviruses, not the beta-coronavirus group that contains the viruses responsible for SARS or COVID-19. We are currently drafting a paper on this work for submission to an international peer-reviewed scientific journal. All SADSr-CoV and HKU2 sequences have been uploaded to Genbank, and following widely-accepted scientific standards and norms, will be released publicly once the paper is accepted for publication. Considering that none of these viruses are related to either SARS-CoV or SARS-CoV-2, we believe this is an appropriate balance between public health interests and the need to maintain integrity of the scientific process of discovery, analysis, peer-review, and publication.

4. We supply a manuscript submitted for review that cites our R01 grant *(PDF attachment #8)*. This paper analyzes hotspots for SARSr-CoV spillover in China, Southeast Asia and South Asia. It identifies a large geographic area that acts as an interface for bat-to-human spillover of CoVs, with spillover hostspots in southern China, Myanmar, Laos, Vietnam, and further potential for viral emergence across the whole region. It also estimates the number of people infected annually with novel bat-SARSr-CoVs as a median of 50,000 and a mean of 400,000. This highlights a substantial public health risk, further consolidates our underlying assumption that viruses like SARS-CoV-2 are far more likely to have emerged via a so-called 'natural' pathway than a so-called 'lab-leak', and provides a much-needed road-map for targeting sample collection and surveillance for future spillover events. The analyses are new, but based on already-published data.

5. We provide our DHHS/NIH Office of Laboratory Animal Welfare Interinstitutional Agreement for the WIV animal work on this grant *(PDF attachment #9)*. As required by DHHS/NIH and NIH Grants Policy, the Interinstitutional Agreement document for R01AI110964 was approved and signed by the NIH/OLAW Assured Institution (WIV) IACUC chairperson, the WIV Director, and the NIH Office of Laboratory Animal Welfare Division of Assurances Director. The effective date of our Interinstitutional Agreement is 07 May 2014 for our award (R01AI110964) that started on the 1st of June 2014. Both the Interinstitutional Agreement and the confirmatory email from NIH copying our NIH/NIAID program grants management specialist are included here.

Please let me know if you have additional questions or if it would be helpful to schedule a meeting to review the information submitted with this letter.

Yours sincerely,

Dr. Peter Daszak, President

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From: Lauer, Michael (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: Fri 11/5/2021 7:03:15 AM (UTC-05:00)

To: Peter Daszak[(b) (6) Aleksei Chmura[(b) (6)

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

Subject: Please read and acknowledge receipt -- Re: Response to your request from last Friday

Attachment: To EcoHealth R01AI110964 11 5 21 clean.pdf

Dear Drs. Chmura and Daszak

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)

From: Peter Daszak < (b) (6)
Date: Tuesday, October 26, 2021 at 1:34 PM
To: "Lauer, Michael (NIH/OD) [E]" < (b) (6) "Tabak, Lawrence (NIH/OD) [E]" < (b) (6) "Tabak, Lawrence (NIH/OD) [E]" < (b) (6) "Tabak, Lawrence (NIH/OD) [E]" < (b) (6)
Cc: Aleksei Chmura < (b) (6) "Aklin, Courtney (NIH/OD) [E]" < (b) (6) "Hayes, Darla (NIH/OD) [E]" < (b) (6) "Burrus-Shaw, Cyndi (NIH/OD) [E]" < (b) (6) "Mazerik, Jessica (NIH/OD) [E]" < (b) (6)
Subject: Response to your request from last Friday

Dear Michael,

Please see attached a response to your request, as well as 9 PDF attachments detailing the rationale for our response, and supplying data you requested.

Cheers,

Peter

Peter Daszak
President

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New York, NY 10018-6507
USA

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Website: www.ecohealthalliance.org
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

5 November 2021

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

Re: R01AI110964

Dear Drs. Chmura and Daszak:

Thank you for your correspondence (including supporting materials) of October 26, 2021. We are requesting additional materials regarding Institutional Animal Care and Use Committee (IACUC) approval for the field work, and the experiments reported in the Year 4 Research Performance Progress Report (RPPR) and Year 5 interim-RPPR (I-RPPR).

IACUC Approval

As we noted before and as required by the NIH Grants Policy Statement (GPS), 4.1.1.2, NIH requires verification of IACUC approval of those sections of the grant application that involve use of vertebrate animals. As noted by the NIH Office of Laboratory Animal Welfare (OLAW) cover letter accompanying your Interinstitutional Agreement for the WIV animal work, "under your approved Assurance with the Wuhan Institute of Virology, their Institutional Animal Care and Use Committee (IACUC) is authorized to carry out subsequent reviews of this project." In the final Vertebrate Animal Section of your Just-in-Time materials submitted on May 16, 2014 for 1 R01 AI110964-01, you stated that "all animal work to be done at Wuhan has been approved by the Wuhan IRB (IACUC) #WIVA05201402. Animals will be housed in a BSL-3 facility and will be under the care of a full-time veterinarian." Thus, it appears that the WIV IACUC approved "all animal work to be done at Wuhan."

In my October 20, 2021 letter, I requested documentation from the *WIV IACUC* regarding approval for *field work* (e.g., work in caves to collect materials from live bats) supported by R01AI110964. You responded by sending us OLAW documentation, not WIV IACUC documentation. This is not documentation demonstrating that the WIV IACUC explicitly approved the field work, the work done outside the BSL-3 facility that involved free-ranging bats and rodents. Therefore, we again ask for you to provide us with *WIV IACUC* documentation of approval for *field work* involving free-ranging bats and wild rodents, or to confirm that no such approval was obtained.

Experiments Described in Year 4 RPPR and Year 5 I-RPPR

In the text description of your Year 5 RPPR Figure 13, you stated, "In Year 5, we continued with in vivo infection experiments of diverse bat SARSr-CoVs on transgenic mice expressing human ACE2. Mice were infected with 4 strains of SARSr-CoVs with different S protein…" In your October 26, 2021 correspondence, you stated that Figure 13 of your Year 5 I-RPPR and Figure 35 of your Year 4 RPPR are taken from the same experiment. You ask that "these facts be acknowledged."

For us to further understand the details of these experiments, please send us complete and dated copies of the original laboratory notebook entries and of the original electronic files that led to the generation of the Year 4 RPPR Figure 35 and the Year 5 I-RPPR Figure 13, along with all their accompanying texts (e.g., the Year 5 I-RPPR text in which you stated that "rWIV1-SHC014 was detected at all time points and showed an increasing viral titer after infection…")

Our document requests – for documentation of WIV IACUC approval for field work, the original laboratory notebook entries, and the original electronic files underlying the Year 4 RPPR Figure 35 and the Year 5 I-RPPR Figure 13 – are consistent with the term and condition of award that NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. 75.364). This right of access applies not only to awardee records, but also to subawardee records. Awardees indicate their acceptance of an NIH award and its associated terms and conditions as they draw down the NIH grant funds to support the scientific project (see NIHGPS Section 5).

We look forward to receiving these materials by no later than close-of-business on Friday, November 19, 2021.

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

Sincerely,

Lauer, Michael (NIH/OD) [E]
Digitally signed by Lauer, Michael (NIH/OD) [E]
Date: 2021.11.05 07:56:18 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
(b) (6)

cc: Ms. Emily Linde
Dr. Erik Stemmy

From:	Peter Daszak[(b) (6)
Sent:	Fri 1/21/2022 3:09:03 PM (UTC-06:00)
To:	Lauer, Michael (NIH/OD) [E][(b) (6) Aleksei Chmura[(b) (6)
Cc:	Stemmy, Erik (NIH/NIAID) [E][(b) (6)
Subject:	RE: [EXTERNAL] Re: Please read and acknowledge receipt -- Two letters to EcoHealth Alliance -- January 6, 2022
Attachment:	Attachment 1. Just in Time response to NIH Feb 2014 re. Inter institutional assurance details.pdf
Attachment:	EHA response to Dr. Lauer January 21st 2022 1 page.pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear Dr. Lauer,

Please find our response to your letter of the 6th January re. our suspended R01, and an attachment documenting that we had informed NIH about our inter-institutional assurance details in February of 2014, as required by normal protocols.

We will respond to your other letter of the 6th January within 30 days as suggested by NIH.

Cheers,

Peter

Peter Daszak
President

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USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

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From: Lauer, Michael (NIH/OD) [E] <(b) (6)
Sent: Friday, January 7, 2022 4:09 PM
To: Aleksei Chmura <(b) (6)
Cc: Peter Daszak <(b) (6) Lauer, Michael (NIH/OD) [E] <(b) (6)
Subject: Re: [EXTERNAL] Re: Please read and acknowledge receipt -- Two letters to EcoHealth Alliance -- January 6, 2022

Thank you Dr. Chmura for the update.

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)

From: Aleksei Chmura <(b) (6)
Date: Friday, January 7, 2022 at 1:58 PM
To: "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Cc: Peter Daszak <(b) (6)
Subject: [EXTERNAL] Re: Please read and acknowledge receipt -- Two letters to EcoHealth Alliance -- January 6, 2022

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Dear Dr. Lauer,

Our staff are out-of-office all next week. We will respond as soon as possible by the end of the week of the 24th of January.

I have had look through the compliance issues mentioned and I believe we are compliant on all of these already. We will send evidence of this within the next 30 days as you requested.

Sincerely,

-Aleksei

Aleksei Chmura, PhD
Chief of Staff &
Authorized Organizational Representative

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On Jan 6, 2022, at 16:35, Lauer, Michael (NIH/OD) [E] < (b) (6) wrote:

Dear Drs. Chmura and Daszak

Please see attached.

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)

<January 2022 To EcoHealth R01AI110964 final.pdf><January 2022 EHA SAC CAP letter final.pdf><G2014-48 IACUC approval letter 05.09.21[1].pdf><Mail Attachment.eml><G2017-32 IACUC approval letter 03.21.17[1].pdf>

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EcoHealth Alliance

February 11, 2014

JUST IN TIME REQUESTED INFORMATION

1R01AI110964 *Understanding the Risk of Bat Coronavirus Emergence* (PI, Daszak)

Dear Laura Pone,

In response to your email from the 10th of February we have provided responses below to the information requested as below:

1) Human Subjects Assurance documentation. Include grant specific IRB approval date. Grant specific IRB approvals must include either the project title or grant number.
2) Documentation of the Required Education in the Protection of Human Subject Research Participants for all personnel involved.
3) IACUC verification statement/letter with approval date.
4) Response to Summary Statement Concern Regarding:
    a. Protection of Human Subjects
    b. Overlap
5) Copy of EcoHealth Alliance's most recent F&A rate agreement.

RESPONSES:

1) **IRB:** Our IRB with Tufts University Health Science through our inter-institutional agreement with them is in process and the FWA for this is **FWA00004517**.

2) **EDUCATION IN THE PROTECTION OF HUMAN SUBJECT RESEARCH PARTICIPANTS** for all personnel involved is underway and we will provide certificates for Daszak, Epstein, Ge, Shi, Zhu, Ke, Olival, Zhang, Olival, and Zhang **before the end of February**.

3) **IACUC:** Our IACUC approval is also pending with Tufts University through our inter-institutional agreement with them. The OLAW Assurance number listed (**A4059-01)** is correct. Once we have an IACUC date, we will inform NIH immediately.

4) **A: PROTECTION OF HUMAN SUBJECTS**: We have revised this and specifically included language to address the following: **(a)** the survey is totally voluntary and the subjects may withdraw at any time**, (b)** the survey is anonymous and there is no connection between the surveyed individual ID and the clinical samples, and **(c)** we have a signed confidentiality agreement with NIH that protects the PIs from having to disclose information about the study**.** The following addresses the SRG concerns about protection of human subjects and applies to both human studies described in the proposal:

a. Survey of people highly exposed to wildlife in Guangxi, Yunnan, and Fujian provinces

REL0000047856.0001

[redacted]

5) **F&A RATE AGREEMENT:** We have already uploaded the latest EcoHealth Alliance F&A rate agreement via the Just In Time interface in eRA Commons.

If you have any other questions, please contact me anytime. We are very appreciative of your consideration and look forward to further details.

Yours sincerely,

(b) (6)

Aleksei Chmura
Program Coordinator & AOR
EcoHealth Alliance
460 West 34th Street, 17th Fl.
New York, NY 10001, USA
(b) (6)
(b) (6)

REL0000047856.0001

EcoHealth Alliance

January 21st 2022

Dear Dr Lauer,

I am responding to your letter of 1.6.2022 commenting on the IACUC information related to fieldwork in China under R01AI110964, and requesting an update from WIV, should one be available.

1) Regarding the IACUC information. Thank you for informing us that you are satisfied with the IACUC information pertaining to our award. In our previous letter we informed you that EcoHealth Alliance's own IACUC approval was granted via our inter-institutional assurance with a US university. This is standard procedure for organizations that do not have an in-house IACUC committee and is an arrangement that we had informed NIH about in 2014 (see attached excerpt from a letter sent by EHA to Dr. Laura Pone of NIH on 2/11/2014). In fact, details of our inter-institutional assurance have been known to NIH since at least 2007 when IACUC approval was granted via this mechanism for 2R01TW005869 (Daszak PI) funded through the NIH Fogarty International Center. Had details of the inter-institutional assurance and IACUC proposal been requested clearly in previous communication from your office, we would have provided them. As previously stated, at all relevant times, on all proposals and reports, and in response to all letters from NIH, EcoHealth Alliance has responded to requests for information in a timely manner, and with full compliance.

2) Regarding your request for WIV lab notes etc. As requested by NIH, we passed on your request to WIV, but have not received any further information from them. We will inform you if and when we receive a response.

Yours sincerely,

(b) (6)

Dr. Peter Daszak, President

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REL0000047856.0002

From: Aleksei Chmura[(b) (6)
Sent: Fri 1/7/2022 12:58:10 PM (UTC-06:00)
To: Lauer, Michael (NIH/OD) [E][(b) (6)
Cc: Peter Daszak[(b) (6)
Subject: [EXTERNAL] Re: Please read and acknowledge receipt -- Two letters to EcoHealth Alliance -- January 6, 2022

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear Dr. Lauer,
Our staff are out-of-office all next week. We will respond as soon as possible by the end of the week of the 24th of January.

I have had look through the compliance issues mentioned and I believe we are compliant on all of these already. We will send evidence of this within the next 30 days as you requested.

Sincerely,

-Aleksei

Aleksei Chmura, PhD
Chief of Staff &
Authorized Organizational Representative

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> On Jan 6, 2022, at 16:35, Lauer, Michael (NIH/OD) [E]
> < (b) (6) wrote:
>
> Dear Drs. Chmura and Daszak
>
> Please see attached.

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)

<January 2022 To EcoHealth R01AI110964 final.pdf><January 2022 EHA SAC CAP letter final.pdf><G2014-48 IACUC approval letter 05.09.21[1].pdf><Mail Attachment.eml><G2017-32 IACUC approval letter 03.21.17[1].pdf>

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From:	Lauer, Michael (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent:	Thur 1/6/2022 3:35:08 PM (UTC-06:00)
To:	Peter Daszak[(b) (6) Aleksei Chmura[(b) (6)
Cc:	Lauer, Michael (NIH/OD) [E][(b) (6)
Subject:	Please read and acknowledge receipt -- Two letters to EcoHealth Alliance -- January 6, 2022
Attachment:	January 2022 To EcoHealth R01AI110964 final.pdf
Attachment:	January 2022 EHA SAC CAP letter final.pdf
Attachment:	G2014-48 IACUC approval letter 05.09.21[1].pdf
Attachment:	Epstein G2020-04 is Approved!
Attachment:	G2017-32 IACUC approval letter 03.21.17[1].pdf

Dear Drs. Chmura and Daszak

Please see attached.

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)

6 January 2022

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

Re: R01AI110964

Dear Drs. Chmura and Daszak:

Thank you for your correspondence of November 18, 2021. We are following up on your response to our request for Institutional Animal Care and Use Committee (IACUC) approval for the field work, and your response to our request for laboratory notebook entries and electronic files related to the experiments described in the Year 4 RPPR and Year 5 I-RPPR.

IACUC Approval

As we noted before and as required by the NIH Grants Policy Statement (GPS), 4.1.1.2, NIH requires verification of IACUC approval of those sections of the grant application that involve use of vertebrate animals. As noted by the NIH Office of Laboratory Animal Welfare (OLAW) cover letter accompanying your Interinstitutional Agreement for the WIV animal work, "under your approved Assurance with the Wuhan Institute of Virology, their Institutional Animal Care and Use Committee (IACUC) is authorized to carry out subsequent reviews of this project." In the final Vertebrate Animal Section of EcoHealth's Just-in-Time materials submitted on May 16, 2014 for 1 R01 AI110964-01, you stated that "all animal work to be done at Wuhan has been approved by the Wuhan IRB (IACUC) #WIVA05201402. Animals will be housed in a BSL-3 facility and will be under the care of a full-time veterinarian."

In my November 5, 2021, letter I requested documentation from the *WIV IACUC* regarding approval for *field work* (e.g., work in caves to collect materials from live bats) supported by R01AI110964. In your November 18, 2021, letter you indicated that no such *WIV IACUC* documentation exists. You stated, "the fieldwork in China that we conducted under our R01 is covered by the Inter-institutional agreement we cited in our letter of October 26th, and by our relevant US institutional IACUC approval."

Through our own search, we have confirmed that the field work was in deed approved by an IACUC. We understand that one of your co-investigators, Dr. Jonathan Epstein, submitted the field work proposal to the Tufts University IACUC; the Tufts University IACUC provided approval; and NIAID accepted the use of the Tufts University IACUC. However, in response to our requests for documentation of IACUC approval, you did not identify who the US institutional IACUC was, nor did you provide us with the Tufts University IACUC approval documentation. We had to obtain the documentation directly from Tufts University. While we are satisfied that the field work was approved by an IACUC, EcoHealth's inability or unwillingness to

provide the Tufts University IACUC documentation to us upon request raises questions about the quality and rigor of EcoHealth's record-keeping.

Laboratory Notebooks and Electronic Files

In my letter of November 5, 2021, I asked you to send us by no later than Friday, November 19, 2021, complete and dated copies of the original laboratory notebook entries and of the original electronic files that led to the generation of the Year 4 RPPR Figure 35 and the Year 5 I-RPPR Figure 13, along with all their accompanying texts (e.g., the Year 5 I-RPPR text in which you stated that "rWIV1-SHC014 was detected at all time points and showed an increasing viral titer after infection…") . On November 18, 2021, you responded: "We do not have copies of these, which were created by and retained by the WIV. Nonetheless, I have forwarded your letter to the WIV, and will let you know their response as soon as WIV replies to our request." We are following up to confirm whether you received a response from WIV and whether the materials are forthcoming.

As a reminder, it is critical to note that our request for the original laboratory notebook entries and the original electronic files underlying the Year 4 RPPR Figure 35 and the Year 5 I-RPPR Figure 13 is consistent with the term and condition of award which provides that NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. 75.364). It is also consistent with the term and condition of award that "The Federal Government has the right to obtain…the data produced under a Federal award." (45 C.F.R. 75.322(d)). Moreover, as a term and condition of award, unless extended by the Federal awarding agency, all "records pertinent to a Federal award must be retained for a period of three years from the date of submission of the final expenditure report or, for Federal awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, respectively, as reported to the HHS awarding agency or pass-through entity in the case of a subrecipient." (45 C.F.R. 75.361). NIH's rights of access "are not limited to the required retention period but last as long as the records are retained." (45 C.F.R. 75.364(c)). These rights and requirements apply not only to EcoHealth's records and data, but also to WIV's records and data, regardless of whether WIV is an active subawardee of EcoHealth at this time. Awardees indicate their acceptance of an NIH award and its associated terms and conditions as they draw down the NIH grant funds to support the scientific project (see NIHGPS Section 5). If an awardee fails to comply with the terms and conditions of award, and NIH determines that noncompliance cannot be remedied with specific award conditions, the NIH may take one or more enforcement actions, including terminating the award in whole or in part, disallowing all or part of the cost of the activity or action not in compliance, and withholding further federal awards for the project. (45 C.F.R. 75.371).

Upon receipt of this letter, please confirm whether you have received a response from WIV and whether the materials are forthcoming. If the materials are forthcoming, we request that they be provided to us no later than close-of-business on January 14, 2022.

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

Sincerely,

Lauer, Michael (NIH/OD) [E]
Digitally signed by Lauer, Michael (NIH/OD) [E]
Date: 2022.01.06 16:21:33 -05'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
(b) (6)

cc: Ms. Emily Linde
Dr. Erik Stemmy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

January 6, 2022

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

Re: U01AI151797 and U01AI153420

Dear Drs. Chmura and Daszak:

I am writing to inform you of the actions that the National Institutes of Health (NIH) is taking with respect to grants administration at EcoHealth Alliance (EcoHealth). Pursuant to 45 C.F.R. § 75.207 and the NIH Grants Policy Statement Chapter 8.5, NIH is imposing specific award conditions on EcoHealth's active awards, U01AI151797 and U01AI153420. EcoHealth has demonstrated a history of failure to comply with several elements of the terms and conditions of grant awards not only for these active awards, but also for the suspended award, R0AI110964. Specifically, we have identified deficiencies in the timely submission of financial and Research Performance Progress Reports (RPPR), compliance with the Federal Funding Accountability and Transparency Act (FFATA) via FFATA Subaward Reporting System (FSRS), and other monitoring requirements.

NIH has reviewed the materials you provided in prior correspondence and determined that EcoHealth's subaward agreements do not contain required components, as outlined in 45 C.F.R. § 75.352 and the NIH GPS 15.2.1, and are out of compliance. Specifically:

Written Agreement Requirements	**Compliance - Status**
All requirements imposed by the pass-through entity on the subrecipient so that the Federal award is used in accordance with Federal statutes, regulations and the terms and conditions of the Federal award. ("The terms and conditions of Federal-awards (including [45 CFR 75]) flow down to subawards to subrecipients" 45 CFR 75.101(b))	Non-compliant: Not provided.
Any additional requirements that the pass-through entity imposes on the subrecipient in order for the pass-through entity to meet its own responsibility to the HHS awarding agency including identification of any required financial and performance reports.	Non-compliant: The agreements lacked clear requirements for when financial and performance reports are due, and what must be included in them. In addition, the recipient failed to submit the reports, when requested.
A requirement that the subrecipient permit EcoHealth and auditors to have access to the subrecipient's records and financial statements as necessary for EcoHealth to meet the requirements under 45 CFR part 75.	Non-compliant: Not provided.
Procedures for directing and monitoring the research effort.	Non-compliant: Not provided.

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If the subrecipient's Investigators must comply with the subrecipient's Financial Conflict of Interest policy, the subrecipient shall certify as part of the written agreement that its policy complies with the 2011 revised FCOI regulation (42 CFR 50 Subpart F). If the subrecipient cannot provide such certification, the agreement shall state that the subrecipient's Investigators are subject to the Financial Conflict of Interest policy of the awardee Institution for disclosing Significant Financial Interests that are directly related to the subrecipient's work for the awardee Institution.	Non-compliant: Subrecipient FCOI policy not provided, nor was there a certification as part of the written agreement demonstrating compliance with the 2011 revised FCOI regulation (42 CFR 50 Subpart F).
A provision addressing ownership and disposition of data produced under the consortium agreement. This includes whether cell lines, samples or other resources will be freely available to other investigators in the scientific community or will be provided to particular investigators only.	Non-compliant: Not provided.
A provision making the NIH data sharing and inventions and patent policy, including a requirement to report inventions to the recipient (see Administrative Requirements-Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources), applicable to each consortium participant and its employees in order to ensure that the rights of the parties to the consortium agreement are protected and that the recipient can fulfill its responsibilities to NIH.	Non-compliant: Not provided.
Incorporation of applicable public policy requirements and provisions indicating the intent of each consortium participant to comply, including submission of applicable assurances and certifications (see Public Policy Requirements, Objectives, and Other Appropriation Mandates).	Non-compliant: The agreement does not incorporate applicable public policy requirements.

NIH further identified non-compliance within EcoHealth's subaward agreement and invoices with the Wuhan Institute of Virology on grant R01AI110964, where it showed that EcoHealth did not charge the correct Facilities and Administrative (F&A) rate of 8 percent for the cost of compliance (see NIH GPS 16.6) which is required for all foreign awards. NIH identified that an inappropriate F&A was charged at a rate of 11 percent for years 2-5 of the subaward agreement.

When NIH identifies a recipient's history of non-compliance with the general or specific terms and conditions of NIH grant awards, NIH may take proactive actions to protect the Federal government's interests and may impose additional specific award conditions as needed (see 45 CFR 75.207 and NIH GPS 8.5). Given the non-compliance in the aforementioned areas, NIH is implementing specific award conditions (SAC) on all active awards to EcoHealth (U01AI151797 and U01AI153420), as follows.

- The expanded authority for automatic no-cost extensions is withdrawn. This will require that EcoHealth request and receive written prior approval from the appropriate NIH awarding Institute or Center (IC) before any extensions of the final budget period.

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- Automatic carryover authorities are withdrawn. This will require EcoHealth to request and receive written approval to carry over any unobligated balances on all awards prior carrying over unobligated balances from one budget period to any subsequent budget period.
- EcoHealth is required to submit semi-annual RPPRs and Federal Financial Reports to the awarding IC.

EcoHealth must develop and successfully implement a Corrective Action Plan (CAP) for these awards with milestones to address and correct the deficiencies noted in this letter. The Corrective Action Plan, at a minimum, must include the following:

- Show proof of written policies and procedures for the development and issuance of subaward agreements, and a plan for revising the policies to address any deficiencies. The policy must include procedures for ensuring the appropriate F & A rate is applied to all subawards.
- Provide NIH with copies of updated subaward agreements for all active awards that correct the deficiencies noted above and demonstrate compliance with the NIH GPS 15.2.1 Written Agreement. The subaward agreements must state the correct F&A rate which, for foreign subrecipients is 8% (see NIH GPS 16.6).
- Show proof of written policies and procedures for timely submission of financial and progress reporting, and a plan for revising the policies to address any deficiencies.
- Show proof of written policies and procedures for subaward reporting as required by FFATA (see NIH GPS 8.4.1.5.5), and a plan for revising the policies to address any deficiencies.
- Provide NIH with copies of FSRS reporting for all subawards.

Once NIH reviews the CAP and determines that EcoHealth has successfully implemented it and has corrected the deficiencies noted in this letter, we will remove the SACs on the active awards without additional action on the part of EcoHealth. If we determine that additional information and actions are required, we will notify EcoHealth so that we can ensure compliance and, ultimately, remove the SACs.

Please provide the CAP to me within 30 days of receipt of this letter. If you have questions or would like to request reconsideration of the specific award conditions on the active awards, please feel free to contact me via email.

Sincerely,

Lauer, Michael (NIH/OD) [E] Digitally signed by Lauer, Michael (NIH/OD) [E] Date: 2022.01.06 16:25:16 -05'00'

Michael S. Lauer, M.D.
NIH Deputy Director for Extramural Research
(b) (6)

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Institutional Animal Care and Use Committee
Tufts University & Tufts Medical Center
136 Harrison Avenue
Boston, Massachusetts 02111
Phone: (617) 636-5612 Fax: (617) 636-8354

Approval Notice

To: **Dr. Jonathan Epstein**

From: Barry Goldin, Ph.D., Chair (b) (6)
Institutional Animal Care and Use Committee
136 Harrison Avenue

Date: May 9, 2014

Protocol: #G2014-48
"Understanding the Risk of Bat Coronavirus Emergence"

The above-named protocol was reviewed and **approved** by this institution's Institutional Animal Care and Use Committee on **May 8, 2014**.

Your agreement to abide by the animal care and use policies of this institution also covers this following:

* Any **change** in the species, number, or use of animals as described in this protocol must be amended and approved before the change occurs.

* **THIS APPROVAL LETTER IS NOT TO BE USED FOR A GRANT VERIFICATION LETTER.** Release of the approval date to the grant agency requires verification of this protocol by the IACUC with the grant to be funded. This process is performed upon request. Please complete the IACUC Congruency Request Form and submit the relevant documents to the IACUC office for each proposal.

*No live vertebrate animal may be obtained without specific permission from DLAM/LAMS/CBU. No live vertebrate animal may be removed from any DLAM/LAMS/CBU facility unless it is described in your approved protocol.

* If this protocol includes work that requires **Institutional Biosafety Committee (IBC) or chemical hazard approval**, you will need to obtain those approvals **PRIOR** to the initiation of that work.

PLEASE MAKE SURE THAT EVERYONE LISTED ON THE PROTOCOL IS AWARE OF THE PROCEDURAL DETAILS APPROVED.

From: Holm, Ann[(b) (6)

Sent: Wed 3/18/2020 9:17:29 AM (UTC-05:00)

To: (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6)

Subject: Epstein G2020-04 is Approved!

Attachment: Epstein G2020-04 final.docx

Hello,
IACUC protocol #G2020-04 "Understanding the Risk of Bat Coronavirus Emergence" is approved. The final version is attached to this email for your records.
If you have any question or concerns, please feel free to contact me.
Thanks,
Ann
REMINDERS:
*If you need either Institutional Biosafety Committee or Chemical Hazard Approval throughout the lifetime of this protocol, it must be obtained PRIOR to the initiation of that specific work.
*If you need an Owner's Consent Form CSRC Acceptance for this protocol, it must be obtained PRIOR to the initiation of that specific work.
*If you need to provide the approval date of this protocol to a funding agency within its three-year lifespan, you will need to send us a copy of the proposal to compare with the protocol. After we have verified your animal protocol with the pending proposal, we will send you a Verification letter, which can be forwarded to the funding agency. The IACUC approval date cannot be released without this institutional verification.
If you have any additional questions or concerns, please feel free to contact me.

Ann Holm, CPIA
IACUC Coordinator
Cummings School of Veterinary Medicine
Tufts University
200 Westboro Road- BLD 17
North Grafton, MA
ph: (b) (6)
IACUC website: http://viceprovost.tufts.edu/iacuc/

Tufts University-Tufts Medical Center & the Human Nutrition Research Center on Aging
Institutional Animal Care and Use Committee (IACUC)
Telephone: 617-636-0496 **Email:** iacuc-office@tufts.edu
Website: http://viceprovost.tufts.edu/iacuc/

ANIMAL CARE AND USE PROTOCOL

FOR IACUC OFFICE USE ONLY

PROTOCOL #:	G2020-04 (G2017-32)
APPROVAL DATE:	
EXPIRATION DATE:	

I. GENERAL INFORMATION

PRINCIPAL INVESTIGATOR:	Jonathan H. Epstein	DEGREE(S):	DMV, MPH, PhD
ACADEMIC POSITION/TITLE:	Vice President for Science and Outreach		
DEPT/DIV or COMPANY NAME:	EcoHealth Alliance		
E-MAIL ADDRESS:	(b) (6)		
DIRECT PHONE #:	(b) (6)	EMERGENCY PHONE #:	(b) (6)
YEARS OF EXPERIENCE WITH PROCEDURES:	19		
YEARS OF EXPERIENCE WITH SPECIES:	19		
PROVIDE JUSTIFICATION for an exception to the *IACUC Policy on the Definition of PI* below:			
PROTOCOL TITLE:	Understanding the Risk of Bat Coronavirus Emergence		

II. VERIFICATION OF REGULATORY APPROVALS

Please check all that correspond to this IACUC protocol. Double-click on a box and then select "checked" to mark your selection. Note that the Principal Investigator is responsible for ensuring that the appropriate permits and approvals remain up-to-date.

☐	**Institutional Biosafety Committee (IBC)** Registration Number(s):	☐	**TU Radiation Safety or TMC Health Physics** (e.g. use of irradiator, lasers, x-rays, UV, radiation, etc.) Hazard Name(s):
☐	**Environmental Health and Safety (EHS)** **Chemical Hazard** Indicate chemicals that require an EHS registration and Safety Plan. Chemical Hazard Name(s): Applicable Tufts CMS/LAMS Safety Plan(s):	☐	**Wildlife Permit(s)** Permit(s) issued for:
☐	**Clinical Studies Review Committee (CSRC) Review**		

III. PROJECT OBJECTIVES AND JUSTIFICATION

Federal regulations mandate that the responses to the questions in this section must be understandable to a **layperson**. Therefore, please **simplify** or **define** all field-specific terms/phrases. The target audience is a non-

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scientist that must understand the objectives and importance of the project from the explanations written below. **Lay language is defined as 8th grade reading level.**

A. Specific OBJECTIVES of this project. State the hypothesis(es) to be tested and provide the explicit goals.

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 recent emergence of Middle East Respiratory Syndrome (MERS-CoV). The wildlife reservoirs of SARS-CoV were identified by our group as bat species, and since then hundreds of novel bat-CoVs have been discovered (including >260 by our group). These, and other wildlife species, are hunted, traded, butchered and consumed across Asia, creating significant opportunity for bats and people to come into contact, thereby increasing the risk of coronavirus transmission.

To understand the risk of zoonotic CoV emergence, we will examine **1)** how bat-CoVs spill over from bats to people in wildlife markets, through trade routes, and other known and potential transmission routes and **2)** how transmission from bats to humans is influenced by viral genetics, and how it might force changes to the coronavirus that could increase its ability to spread among people. We will assess the nature and frequency of contact among animals and people in two critical environments in southeast Asia: 1) live animal markets and trade routes and 2) rural areas where people hunt bats. In the markets, we believe that the high degree of contact people, bats, and other mammals have via handling and butchering activities may create circumstances that allow the virus to change such that it is more likely to be able to infect people. In this study, we will test both wild bats and examine the genetic properties of newly discovered coronaviruses. This information will be used to determine whether viruses we find have the potential to cause large-scale epidemics.

To achieve these aims, we will collect a full range of clinical samples from bats in the wild and test these for coronaviruses.

Once we identify novel coronaviruses in wildlife, we will run tests in the lab to determine what speciesof bats the viruses could infect and we will examine the structural and genetic properties of the receptors they use to bind to host cells. This will provide information about a virus's potential to infect humans.

B. Describe the potential CONTRIBUTIONS AND SIGNIFICANCE OF THIS PROJECT to human and/or animal health and to the advancement of knowledge.

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 Angiotensin-Converting Enzyme 2 (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? Our proposed work builds on our 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.

C. Justify the USE OF ANIMALS. Researchers must consider the replacement of live animal models (in vitro,

computer models, etc.) to accomplish the objectives of the proposed study. Select the applicable justification(s) that explain why live animals are required. If none apply, choose "Other" and provide your own reasoning.

- ☐ The complexity of the processes or mechanisms being studied cannot be duplicated with in vitro models (e.g. cell culture), computer simulation, or with simpler species (e.g. invertebrates).
- ☐ There is not enough information about the processes being studied to design in vitro/non-living models.
- ☐ Animal tissues are required for the development of an in vitro system.
- ☐ Methods have already been tested in vitro and must now be performed in live animals; or preclinical studies in living animals are necessary prior to human testing.
- ☐ This is a behavioral, learning, or developmental study which must be performed in live animals.
- ☐ Participants/students must interact with live animals to develop competence in animal handling and performing procedures (i.e. teaching and training protocols).
- ☒ Other: (Provide justification below)

The central aim of this research is to understand the diversity of coronaviruses, including SARS-like CoVs that exist in bats in southern China, Cambodia, Thailand, Vietnam, Laos, Myanmar, Indonesia, Singapore, and Malaysia and to examine the ability of these viruses to infect humans and create a pandemic threat. In order to achieve these aims, it is necessary to collect biological samples from species in the wild to test them for coronavirus RNA. The purpose of this study is to conduct targeted, but extensive surveillance of bat populations in Southeast Asia to detect coronaviruses that may pose a risk to the health of both humans and animals.

IV. SPECIES INFORMATION

A. Please list the species to be used. Boxes can be duplicated for additional species.

Species name	Fruit bats e.g. *Cynopterus, Rousettus,* and *Eonycterus* spp.	Species name	Insectivorous bats, e.g. *Rhinolophidae, Hipposideridae, Emballonuridae, Vespertillionidae, Molossidae,* and *Miniopteridae* spp.

B. Justify the choice of species. Explain why each animal model was selected. Describe the unique characteristics each species has that are necessary for your investigations.

This study is a surveillance study, designed to identify and characterize coronaviruses circulating in animals in the wildlife of Southeast Asia. Bats (Order *Chiroptera*) are the natural reservoir for coronaviruses, including SARS and MERS CoVs. Targeted bat species will include microchiropterans ('small bats' or 'microbats') that are usually insectivorous (e.g. *Pippistrellus* or *Rhinolophus* spp.), and megachiropterans (large bats or 'megabats') that are usually frugivorous (e.g. *Rousettus* or *Eonycterus* spp.). Sampling will focus on species in the family Rhinolophidae, genus *Rhinolophus*., but will also include individuals in the related genera *Hipposideros* and *Aselliscus*. All species of bats do not exceed ~100 grams in weight.

C. Transgenic animals. Will transgenic animals be used, created, or bred? If yes, continue by confirming the box below: ☐ Yes ☒ No

☐ **I confirm** that neither parental transgenic rodent contains the following genetic modifications: (i) incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses; or (ii) incorporation of a transgene that is under the control of a gammaretroviral long terminal repeat (LTR); and the transgenic rodent that results from this breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses.

Note: *This confirmation means the transgenic rodents are exempt from the NIH Guidelines and IBC approval is not required. If this exemption cannot be confirmed, or the transgenic animals are not rodents, IBC approval is required. Contact the Biosafety Office if you have questions about this section.*

V. REGULATORY EXCEPTIONS

Per regulations, the items listed below must be approved by the IACUC. Please mark the correct box and provide the requested justification in the text box.

1. Are **multiple major survival surgeries** performed on the same animal? According to *the Guide*, major survival surgery "penetrates and exposes a body cavity, produces substantial impairment of physical or physiologic functions, or involves extensive tissue dissection or transection." Some surgical procedures characterized as minor may induce substantial post-procedural pain or impairment and should be similarly justified if performed more than once in a single animal.
   - ☒ No
   - ☐ Yes. Provide scientific justification for multiple survival surgeries & timeframe between surgeries below:

2. Are unanesthetized animals **restrained** for **more than 30 minutes**? See *IACUC Policy for Physical Restraint of Research Animals.*
   - ☒ No
   - ☐ Yes. Provide scientific justification below:

3. Are **non-pharmaceutical grade (NPG) substances** used in live animals?
   Check these references for availability of animal pharmaceuticals and human pharmaceuticals.
   - ☒ No.
   - ☐ Yes. If NPG grade substances must be used, please identify the justification(s) below:
     - ☐ No pharmaceutical grade veterinary or human drug is available or consistently available.
     - ☐ Although a pharmaceutical grade drug is available, the NPG drug is required to replicate methods from previous studies.
     - ☐ Although a pharmaceutical grade drug is available, a greater concentration, different formulation, or route of administration is required.
     - ☐ The available pharmaceutical grade formulation contains preservatives or inactive ingredients that confound the research goals of the study.
     - ☐ Other (provide justification below).

   Note: NPG substances will be the highest-grade available and formulated aseptically using sterile and biocompatible solutions appropriate for the route of administration. In addition, NPG substances administered parenterally (IV, IP, IM, SC) will be sterilized according to the *IACUC Policy on the Use of Expired Medical Materials and Pharmaceutical-Grade Compounds,* or else justified below.

4. Will **water or food be restricted** during any portion of the project? See *IACUC Policy on Food/Fluid Restriction or Deprivation* for specific protocol requirements.
   - ☒ No
   - ☐ Yes. Provide scientific justification below and the time limits for the restriction or deprivation (see Policy for these definitions).

5. Do you require an experimental exception for **single housing** of social species? See *IACUC Policy on Single Housing of Research Animals*.
   - ☒ No
   - ☐ Yes. Provide scientific justification below:

6. Do you require an exception from standard **husbandry practices** or **environmental conditions** recommended in *the Guide* or Animal Welfare Regulations (e.g. prolonged cage or bedding change intervals, cage size, alteration of

temperature, humidity, light level/cycle, use of wire bottom caging, removal of bedding substrate, exclusion from environmental enrichment, etc.)? ☒ No ☐ Yes. Describe and justify below:
7. Describe and justify any other exceptions to *the Guide*, Animal Welfare Regulations, or IACUC Policies not addressed above.
N/A

VI. NON- STANDARD HOUSING AND CARE

Describe specialized care and housing practices that do NOT constitute Regulatory Exceptions as described above.

1. Describe any **alterations of standard caging** or **specialized husbandry practices** that are not regulatory exemptions (e.g. use of metabolic caging, pinnacle caging, nonstandard enrichment conditions, etc.).
N/A
2. **Non-standard drinking water**: For ANY additives placed in the drinking water, provide the following information: 1) Name of additive, 2) Concentration/Dose/Volume, and 3) Frequency or Duration that treated water will be given.
N/A
3. **Non-standard diet/chow**: For ANY specialized diets used in place of the standard chow, provide the following information: 1) Name of diet; 2) Dietary composition, including name and concentration of any drugs formulated into the diet, and 3) Frequency or Duration. ☐ Confirm diet(s) are nutritionally balanced. If it is not, provide scientific justification:
N/A
4. **Therapeutic restrictions**: In an emergency, animals will be treated or euthanized by the veterinary staff to relieve suffering if deemed necessary. Investigators will be contacted prior to diagnostic testing, therapy, or euthanasia whenever possible. If contact is not possible, please respond below:

☒	No therapeutic restrictions exist.
☐	Confirm that if therapeutic restrictions exist, the research staff will notify the veterinary staff in advance regarding treatment limitations.

NOTE: If emergency euthanasia is necessary, specimens will be saved only if prior arrangements have been made with the veterinary staff.

VII. EXPERIMENTAL DESIGN

Explain the experimental design addressing the bulleted items below. Some details are requested in other sections (e.g. Section VIII Procedural Details, Section IX Surgery Description) so please avoid unnecessary duplication. Organize each experiment by number or letter and use the same organization system in Section XIII "Animal Number Justification".

- Outline the experimental design sequentially. Flow charts add clarity and are highly recommended.
- Describe all procedures and time intervals between them.
- Include information on study duration and scientific endpoints.

Bat capture, restraint, and sampling. Free-ranging bats will be captured using either a mist net or harp trap. The net system is operated and monitored by two people during the entire capture period and bats are removed from the net immediately following becoming entangled to minimize stress and prevent injury. Bats will be released at the site of capture, after sampling. In our previous experience, a maximum of 30 bats may be safely held and processed by a team of three people per trapping period. Duration of trapping will depend on the capture rate. Bats are placed into a pillowcase or small cloth bag and hung from a branch or post until	

samples are collected. Bats are held for a maximum of 5 hours though typically less than 3 hours and released after sampling.

Sample Collection: Bats will be manually restrained during sampling. Bats will not require anesthetization as all target species are under 100g in weight and easily, safely handled by our experienced, trained personnel Swabs will be taken from the oropharynx, urogenital tract, and rectum of bats. Fresh feces and urine will be collected as available, in which case a rectal swab will not be collected. Specimens will be collected during field surveys using our previously validated, non-lethal capture and sampling methods to capture bats and collect blood, oral swabs, and feces and/or rectal swabs for viral discovery. All bats that we capture will be restrained using 'momentary restraint' as defined by the IACUC Policy on Physical Restraint of Research Animals while specimens are collected. Morphological measurements, sex, age, and reproductive status of each bat will be first recorded by a dedicated field technician before specimens are collected.

- Blood samples. We will use one of two previously proven techniques to collect blood.
  - i. A 75 µL glass heparinized hematocrit tube to collect blood (not to exceed 6 µL per gram of body weight). Each bat will be restrained in one hand while the wing is gently extended by the wrist. The radial vein will be punctured using the tip of a sterile 25 gauge needle. Blood will be collected in the hematocrit tube, and the blood flow immediately stopped applying pressure to site of bleeding using a cotton ball until bleeding ceases (approximately 1 minute). Hematocrit tubes will be centrifuged, scored, and snapped to collect plasma.
  - ii. The second option for blood collection uses the same restraint and puncture technique, but pipettes for blood collection instead of hematocrit tubes. For blood collection from these bats we will collect up to 10% total blood volume using a 20 µL or 200 µL pipette gun (Smith et al. 2009).

  For each technique, venipuncture site will be inspected to ensure hemostasis prior to release of each bat.
- Oral swabs**.** We will use a sterile, polyester-tipped swab, rubbing the swab tip gently but thoroughly against the back of the animal's throat, and saturating the swab with saliva.
- Rectal swabs (if separate fecal samples are not available). Sterile swabs will be dipped into sterile saline for lubrication before being inserted gently into the bat's rectum. If a bat is too small for the swab to comfortably fit into the rectum without risk of tissue trauma, we will not collect fecal swabs.

The purpose of our study is to identify potential zoonotic viruses and characterize the natural pathogen pool at each site and during each one-time per-location sampling period. Thus, we are not conducting longitudinal wildlife sampling (recapture over seasons or years), i.e. to measure changes in seroprevalence over time in wildlife. From our experience recapture rates are too low (<1%), but in order to avoid resampling the same individual bat during a sampling event and to obtain high quality host DNA for species identification/audit confirmation (e.g. DNA 'barcoding'), we will take wing biopsy punches of all captured bats. Punching small holes in wing membranes of bats is a procedure that has been used widely for over 30 years for marking of bats in the field. It is a temporary marking technique, since wing punches heal and close-up very quickly: typically, within 2-3 weeks. There are no known hazards to wing-punching. Wing tissue in bats heals very rapidly. Use of sterile instruments and aseptic procedures will minimize potential for infection or for transmission of disease when multiple bats are sampled**.** Wing punches will be taken to serve as biopsy tissue samples and have become a preferred method for obtaining biopsy tissue samples of wild bats for population genetics and taxonomic studies.

Punched holes as large as 14-17 mm diameter in wing membranes of pallid bats have been shown to heal rapidly (within weeks). We will follow wing biopsy methods detailed by Worthington, Wilmer and Barratt (1996) to sample a circular area of 3 mm in diameter. This is only about 8% of the maximum area noted by Davis and Doster (1972) in pallid bats. No irreversible changes to the biopsy site or decrease in bat survival are known to result from these procedures, which have been used in genetic studies of multiple species of bats. Sampling will be from the distal third of the plagiopatagium. Antiseptic surgical preparation of the sample area (3 wipes with Betasept swabs or similar antiseptic) will be made, followed by a 3 mm round punch biopsy of

the wing taken with a previously sterilized and sterile packaged skin biopsy punch.

Biosafety/Occupational Health and Safety Plan

- All field personnel are required to use appropriate personal protective equipment to prevent exposure to zoonotic pathogens that may be encountered during fieldwork (e.g., coronaviruses, filoviruses, lyssaviruses, and paramyxoviruses). Specifically, each personnel will wear, at minimum, a P100 or N95 respirator, protective eyewear, nitrile gloves, and dedicated long-sleeved clothing including washable shoes. For urine or fecal roost sampling all personnel involved will wear full hooded-coveralls.
- All personnel handling bats or bat samples for this project are required to receive pre-exposure rabies vaccination. In addition, personnel with frequent contact with bats will be required to have titers checked every two years to ensure appropriate protective levels following CDC and WHO guidelines. If any personnel are bitten or scratched by a bat or stuck with a needle, the wound will be washed with soap and water for 5 minutes and then thoroughly cleaned with benzalkonium chloride antiviral wipes. The team member will then be given a rabies vaccine booster in the field and will follow up for the second booster three days later.
- To reduce the probability of spreading pathogenic agents to different sampling localities, we will ensure that all reusable equipment is disinfected with Virkon or a similar disinfectant immediately after use. All disposable collection equipment will be disposed of by collecting in a sharps container and biohazard bags in the field, and then brought to a nearby laboratory or hospital to be autoclaved and incinerated. No biohazardous materials will be brought to Tufts campus. Specimens will be tested in regional laboratories in China, Thailand, and at other partner institute laboratories with the appropriate biosecurity standards for the level of the pathogen (BSL-2).
- All personnel will be informed of the symptoms associated with potential exposure to any zoonotic pathogens that they may encounter in the field, including, but not limited to, fever, excessive coughing, difficulty breathing, diarrhea, vomiting, and/or rash. Personnel will be instructed to immediately visit a medical profession in the event they experience any symptoms, as well as to inform key personnel.

Field Personnel Training

- We are asking for an exemption from the Mandatory Animal Care and Use presentation and quiz for training at Tufts University. This exemption will only be used for our field personnel since English is often not the first language and use of the Tufts animal facilities and forms is not relevant to them.
- The field personnel are also provided training in multiple other ways, including:
  - They will receive and review the approved protocol. The PI will cover the procedures in the protocol in detail prior to implementation, with any IACUC amendments to protocols managed in the same fashion.
  - The IACUC office has provided a truncated version of the Mandatory Animal Care and Use training presentation that includes the regulatory and IACUC-specific information. We will ensure that all field personnel are given this presentation and have the opportunity to ask questions.

JUSTIFICATION FOR CATEGORY E PROCEDURES. Please provide **scientific justification** if pain and/or significant distress is an unavoidable part of the research/procedures and why it cannot be alleviated.

N/A

VIII. PROCEDURAL DETAILS

A. EXPERIMENTAL ADMINISTRATIONS

Recommended Needle Sizes (Gauge)

Species	SQ	IP	IV	IM	Oral Gavage
Mouse	23-30 G	25-27 G	26-28 G	27 G	18-24 G

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Rat	20-27 G	23-27 G	21-23 G	25 G	13-20 G
Hamster	25 G	23-25 G	25-27 G	25 G	
Guinea Pig	23-25 G	23-25 G	25-27 G	25 G	
Bird	21-25 G	N/A	25-27 G	25-27 G	

Provide justification only if requesting larger needle sizes than recommended above.
N/A

Please copy the table below for each experimental substance administered. Do not include anesthetics, analgesics, water, or diet provisions addressed in separate sections.

1) Name of substance	
2) Volume	
3) Dosage, if appropriate	
4) Route	☐ SQ ☐ IP ☐ IV ☐ IM ☐ PO ☐ Other: _____

B. IMPLANTS

1) Type and material of implant	
2) Site(s) of implantation	
3) Size of implant	
4) Method of sterilization for implant	
5) Length of time of implantation	
6) Removal procedure (N/A, if post-mortem)	
7) For drugs, compounds, or other substances administered via pump or pellet, provide dosage (in mg/kg/day) and confirm how sterility of the substance will be ensured prior to loading.	
N/A	

C. SURVIVAL BLOOD COLLECTION

Acceptable Rodent Blood Sample Volumes

Body weight (g)	Circulating Blood Volume (CBV) (ml)	10% CBV (ml) every 2 wks†
20	1.10 – 1.40	.11 – .14
25	1.37 – 1.75	.14 – .18
30	1.65 – 2.10	.17 – .21
35	1.93 – 2.45	.19 – .25
40	2.20 – 2.80	.22 – .28
125	6.88 – 8.75	.69 – .88
150	8.25 – 10.50	.82 – 1.0
200	11.00 – 14.00	1.1 – 1.4
250	13.75 – 17.50	1.4 – 1.8
300	16.50 – 21.00	1.7 – 2.1
350	19.25 – 24.50	1.9 – 2.5

† max cumulative sample volume for that sampling frequency

If more than one experiment includes survival blood collections, please copy the table below as needed.

Specify Experiment(s):	Samples collection

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1) Blood draw method and anatomical area used	25 G (gauge) needle will be used to lacerate the vein and blood will be collected using a hematocrit tube or a 20 µL or 200 µL pipette gun Possible venipuncture sites include the propatagial (cephalic) vein, the uropatagial (saphenous) vein or the brachial vein.
2) Maximum volume for each blood draw	Hematocrit tube: Collect up to 0.6% body mass of blood (e.g., 6µL per gram of body weight) 20 µL or 200 µL pipette gun: up to 10% total blood volume
3) Frequency of draws	Once per bat.
4) Maximum number of draws/animal	Wild caught, free-ranging bat will have only 1 blood draw before release
If requesting larger volumes than recommended, provide scientific justification below:	
N/A	

D. BEHAVIORAL TESTS

Name of behavioral test	Time required for each testing and/or training session	Frequency of testing/training sessions and interval between sessions	Duration of testing/training sessions
For example: Morris water maze	*1 minute*	*2-4 trials/day, 6 hrs apart*	*4 days*
N/A			

METHODS USED		
1) Please describe the goals and performance expected for each test.		
N/A		
2) Will an apparatus be used?	☐ No ☐ Yes	If yes, please describe below.
3) Will aversive stimuli be used?	☐ No ☐ Yes	If yes, describe the stimulus and its intensity, duration and frequency of administration below.
4) Please describe limits to deprivation or aversive stimuli if desired response does not occur.		
N/A		
5) Will rewards be used?	☐ No ☐ Yes	If yes, please describe below.
6) Please describe other techniques to be used below, if applicable.		
N/A		

E. EXPERIMENTAL TUMOR GROWTH

1) Indicate if spontaneous neoplasia or induced tumor? (*If spontaneous, then skip to #5)*		N/A
2) Identity and source of the tumor	N/A	
3) Is the tumor of **rodent origin** or been passaged **in rodents**?		☐ Yes ☐ No
If **yes**, they must be tested for contamination with adventitious agents unless it has been produced in SPF animals in a Tufts barrier. For more info contact Tufts CMS/CBU/LAMS.		
4) Is the tumor of **human origin**?		☐ Yes ☐ No
If **yes,** IBC approval must be obtained **prior to use.** Human source materials require IBC approval.		

5) Provide primary site(s) of anticipated tumor growth and any expected sites of metastasis, if applicable.	N/A
6) Provide method of measuring tumor growth	N/A
7) Provide maximum size and dimension of tumor	N/A

F. USE OF ANTIBODY PREPARATIONS OR OTHER BIOLOGICS

1) Are antibody preparations used? If yes, continue by checking the appropriate box(es) below:	☐ Yes* ☒ No
☐ Antibodies will be obtained commercially (off the shelf) *OR* ☐ Antibodies will be custom made. If custom made, continue below: ☐ in vitro tissue culture techniques used *OR* ☐ in vivo techniques used. If live animals are used, continue below: ☐ in-house production (describe in Section VII) *OR* ☐ vendor produced (see Custom Antibody policy for list of approved vendors)	
2) Are other biologics (e.g. blood, serum, cellular components) used?	☐ Yes* ☒ No
*If **yes,** they must be tested for contamination with adventitious agents unless it has been produced in SPF animals in a Tufts barrier. For more information, please contact: Tufts CMS - Boston Campus: 617-636-6488 CBU – 617-556-3201 LAMS - Grafton Campus: 508-887-4511	

G. DETAILS OF ANESTHESIA/SEDATION NOT used for surgery or euthanasia.

→ Click link for commonly used anesthetics: Anesthesia formulary by species

You may copy and paste the appropriate regimen based on procedure type. Additional rows can be added as necessary.

Name of procedure(s):	Sample collection		
Anesthetic/Sedation Name	**Dose**	**Route**	**Re-dose/Maintenance**

Methods used to monitor anesthetic/sedation (check all that apply):	☐ Responsiveness to stimuli
	☐ Respiratory rate/effort
	☐ Other:
☐ All animals are monitored continuously while under anesthesia. ☐ Supplemental heat is provided while the animal is under anesthesia. See Tufts CMS website for list of Tufts CMS/LAMS approved Thermoregulatory Devices.	

IX. SURGERY DESCRIPTION

If more than one surgery is being added, please copy the table below and answer questions 1-6 for each individual surgery. See *IACUC Policy for Conducting Survival Surgical Procedures in Rodents*. Please note that there are additional requirements for non-rodent species. Exsanguinations that require a skin incision to expose the vessel and perfusions need to be described as terminal surgeries.

1) Name of surgery:	Confirm if ☐ survival or ☐ terminal
2) Check the relevant boxes for this surgery:	
The following are all required for survival surgery. Please provide scientific justification to omit or change. Terminal surgeries only require continuous monitoring under anesthesia (the last box). ☐ Disinfection of the surgical area/table. ☐ Surgeon is properly prepared for each surgery. This includes, at a minimum, sterile gloves, mask, and gown. Disposable or clean lab coats may only be used for non-USDA species.	

☐ Animal is appropriately prepped for surgery by the following steps:
1. Provision of eye lubricant
2. Removal of the fur/hair
3. Disinfectant/ethanol wipe of the skin (3x for each scrub).

☐ Supplemental heat is provided while the animal is under anesthesia. See Tufts CMS website for list of Tufts CMS/LAMS Approved Thermoregulatory Devices for Rodents.

☐ All animals are monitored continuously while under anesthesia.

3) Anesthetic details:

→ Click link for commonly used anesthetics: Anesthesia formulary by species

You may copy and paste the appropriate regimen based on surgery type. Additional rows can be added as necessary.

Anesthetic Name	Dose	Route	Re-dose/Maintenance

Methods used to monitor anesthetic depth (check all that apply):	☐ Tail/toe pinch
	☐ Respiratory rate/effort
	☐ Other:
Methods used for intraoperative monitoring (USDA species only)	

4) How are the surgical instruments sterilized for survival surgery?

5) Describe the surgery in detail including skin incision, all manipulations, closure, and suture information. *There is no need to repeat details confirmed in Part 2 and 3 above.*

☐ Confirm initial dose of analgesia will be given prior to making the incision OR justify if this cannot be done.

☐ Confirm sutures and/or wound clips will be removed 7-14 days postoperatively.

6) Analgesic regimen: → Click link for commonly used analgesics: Analgesic drug formulary by species

You may copy and paste the appropriate regimen based on surgery type. Additional rows can be added as necessary. Multiple analgesics may be chosen to provide flexibility. When multiple analgesics are selected, indicate and/or below.

Analgesic Name	Dose	Route	Duration of Treatment	
				☐ and ☐ or ☐ +/-
				☐ and ☐ or ☐ +/-

X. ANIMAL CARE AND MONITORING

A. What adverse effects may occur because of the experiments and/or from surgery? Describe expected experimental effects, distress, pain, significant discomfort, morbidity, etc. Indicate how adverse effects will be alleviated (e.g. with analgesia, nursing care, nutritional support or euthanasia).

For surgery, include what methods will be used to avoid tissue infection, inflammation, erosion, or accidental removal of any implants, and how they will be alleviated if present?

We do not anticipate that any of the sampling procedures will cause more than minimal stress or discomfort. Our sampling protocols are safe and effective and procedures for collecting blood, saliva, urine, and feces are minimally invasive. Occasionally, animals may exhibit signs of distress from manual restraint. In the event that there is an adverse reaction to manual restraint, where an animal shows signs of respiratory distress, the animal will be immediately released into a bag and monitored for recovery. From our prior experience, wild animals that become stressed from handling recover if released at the first signs of distress.

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While we do not anticipate any severe adverse events related to the capture or sampling of free ranging wildlife, we will observe all animals caught in traps and nets for injuries. Veterinary care of wildlife in the field is limited. Any animal with an injury that is deemed life-threatening, or significant enough to prevent survival upon release, will be humanely euthanized. Any animal that is injured in the course of restraint or sampling such that it is deemed unable to survive if released or if appears to be in severe pain due to injury, will be humanely euthanized. Animals that are caught and moribund (depressed mentation, non-responsive to stimuli, emaciated and weak or exhibiting neurological signs), will be humanely euthanized.

Subdermal hematomas may occasionally result from venipuncture. If this occurs, pressure will be applied to the venipuncture site immediately and until hemostasis occurs. No further blood collection will be attempted from this animal.

We do not perform blood collection through an artery. As the artery and vein are right next to each other it is possible that the artery may be punctured as well. In this case we will hold off the vessel for a longer time period, once hemostasis is achieved we will place the bat in a bag for a few more minutes (~10 minutes) and then recheck hemostasis prior to release. As above no further blood collection will be attempted with this animal.

B. Describe any expected clinically detectable phenotype(s), which develop spontaneously or will develop as a result of experimental manipulation. Clarify any potential detrimental effects to the animals' health.

N/A

C. Humane endpoint criteria Clearly list the criteria used to determine when euthanasia will be performed, even if prior to the experimental endpoint (e.g. tumor size and/or necrosis, % body weight gain/loss, body condition, inability to eat or drink, behavioral abnormalities, clinical symptoms, signs of toxicity, etc.)

Animals will be released at point of capture after sample collection.

D. Describe the frequency and the length of the time that ALL animals will be observed to evaluate pain/distress during the lifespan of the protocol. Include information about the general observation of animals during time periods when they are not involved in experiments. Also include post-operative care and monitoring required at least daily for 72 hours after surgery (where the day of surgery is considered Day 0).

***NOTE: Protocol personnel are responsible for monitoring animals as described below. Routine health checks by the veterinary staff do not fulfil this requirement.**

Procedure or Experiment name(s)	**Frequency of observations/monitoring** Include frequency of both observation and weighing (if applicable). Include how monitoring will change if health status changes.
Capture/sampling of free ranging bats	Nets will be monitored continuously for bats. Bats will be observed in the net, prior to and during sampling.

XI. LOCATION OF ANIMALS

1. Are live animals ever used outside of centralized facilities?	☐ Yes ☐ No ☒ N/A as this is a field study.

NOTE: *Animals can only be outside of the centralized facility for less than 12 hours (for USDA species) or less than 24 hours (for other species), unless the area is an IACUC approved satellite facility.*

If you answered **yes** above, please complete questions 1A-B. If you answered **other location**, please complete question 2.

1A. Name of procedure or indicate if satellite housing (e.g. name of surgery, sacrifice/ tissue harvest, imaging, monitoring, etc.)	**Building and Room Number**	**Is the room already approved by the IACUC?**	**Longest time frame animals will be present**
☐ sacrifice/tissue harvest		☐ yes ☐ no	

☐ survival surgery		☐ yes ☐ no	
☐ non-survival surgery		☐ yes ☐ no	
☐ satellite housing		☐ yes ☐ no	
☒ other: sample collection	Southeast Asia	☒ yes ☐ no	<5hrs

1B. Provide justification below for removing animals from central facilities.

2. Provide description(s) and justification for field studies and use of other locations.

The samples collected from bats in this study are used to study the risk of coronavirus transmission. We will collect clinical samples (as detailed above) from bats in the wild and test these for coronaviruses, so that we can study emergent disease in Southeast Asia.

XII. DISPOSITION OF ANIMALS FOLLOWING STUDY

Provide details of euthanasia for each species. **Even if the experimental plan does not include euthanasia, protocols must include an emergency plan in case it becomes necessary.** No animal may be adopted, reused, or given away without advance permission from Tufts CMS, LAMS, or CBU.

- Copy and paste the chart below for each different species, if necessary.
- If an inhalant is selected as the euthanizing agent, a secondary method of euthanasia is required. See IACUC Policy on Euthanasia.
- Methods of euthanasia must be consistent with the AVMA Guidelines or otherwise scientific justification must be provided below.

Species name	Bats (from order *Chiroptera*)
Primary euthanasia method	conscious cervical dislocation
Confirm secondary euthanasia method is used when required	☒ Cervical dislocation, decapitation, thoracotomy, exsanguination, or major organ removal performed following the primary method
Other euthanasia methods:	N/A

☒ **A physical method of sacrifice will be used without prior anesthesia or sedation** (i.e. conscious cervical dislocation or decapitation). Please provide justification below. See *IACUC Policy on Euthanasia* and *IACUC Policy for Maintenance of Blades for Use in Conscious Decapitation*.

As per the IACUC Policy on Euthanasia, cervical dislocation will meet a performance standard of luxation of the cervical vertebra without primary crushing of the vertebrae and spinal cord, thereby inducing rapid unconsciousness. Though not expected based upon prior experience sampling these species in the wild, cervical dislocation will only be performed by individuals with a demonstrated high degree of technical proficiency. We intend to release all bats at the point of capture; however, individuals may be euthanized if deemed necessary to alleviate pain and suffering in the rare event that an individual suffers a mortal injury. We will use cervical dislocation as a primary euthanasia method. This would always be performed by a trained professional who has 10+ years' experience in this technique. For any individual bats euthanized, a thoracotomy, exsanguination, or major organ removal may be performed.

☒ **Euthanasia is not expected or required. Emergency only.**

XIII. ANIMAL NUMBER JUSTIFICATION

1. EXPLANATION FOR THE NUMBER OF ANIMALS REQUESTED.

- Please reference the experiments according to the organizational system used in Section VII.
- Explain how the number of animals requested was determined. Include justification for the group sizes, the

number of groups/experiment, the number of repetitions, etc. The number of animals should be the minimum number required to obtain statistically valid results. Please include a description of the statistical analyses, including tests, power and probability levels utilized, if applicable.
- Include which pain/distress category (C, D, or E) the animals belong in.
- You are encouraged to include a table or flowchart.

Species and number used in study: The purpose of this study is to conduct targeted, but extensive surveillance of bat populations in Southeast Asia to detect coronaviruses that may pose a risk to the health of both humans and animals. The experimental work is designed to understand the ability of bat coronaviruses to bind to human receptors. In this renewal application, we propose a total bat sample size of 8,800, which is comparable to our initial R01 effort (5000 animals). These animals will be sampled from approximately 15-20 species collected across 4 provinces. Given the approximate 5-12% prevalence of SARSr-CoVs in *Rhinolophus* spp. at our previous sites during our initial R01. Assuming a conservative prevalence rate of 12%, a sample size of n=110 individuals per species will allow us to detect SARSr-CoV using PCR with a precision of 93.8% (assuming a confidence interval of 95%). We will sample a minimum of 110 individuals from approximately 20 different bat species from sites across four provinces in Southern China (Yunnan, Guangxi, Guizhou and Guangdong) (110 individuals x 20 bat species x 4 provinces = 8,800). In every situation, sampling of wildlife will be conducted in the most humane manner while minimizing the impacts on individual animals and their wild populations. In all instances, the fewest number of animals will be sampled that will provide valid information and statistical inference for the pathogen and disease of interest and every effort will be made to minimize stress and discomfort for the animal.

2. TOTAL NUMBER OF ANIMALS USED FOR BREEDING. Provide the total number of animals bred under this protocol. Please provide a clear distinction between which of the animals bred will be used in the experiments and which are used for maintenance or culled only.

Mouse		Rat		Other	

If bred in-house, provide a table/chart below that organizes the number expected from breeding.

Include all parents and offspring born. Estimate litter size, litters per female, and how many offspring that may be culled based on Mendelian genetics or other methods. If typical litter size is unknown, estimate 10 pups per pregnancy for rodents. All animals born must be accounted for, even if not used in the experiments.

3. TOTAL NUMBER OF ANIMALS. Please provide the total number of animals required during the 3-year approval period of this protocol. For each species, identify the number of animals utilized in each USDA pain/distress category. Be sure these category subtotals are equal to the total number requested. ALL animals, regardless of whether they are used in experiments, MUST be accounted for in the protocol.

USDA Category C – Procedures with minimal, momentary, or no distress.
USDA Category D – Use of appropriate anesthetics, tranquilizers, or analgesics to alleviate pain and/or distress.
USDA Category E – Animals may experience unrelieved pain and/or distress without intervention.

Species name	Bat spp.		
Category C	8,800		
Category D	0		
Category E	0		
Total number requested	**8,800**		

XIV. SEARCH FOR ALTERNATIVES

Federal regulations mandate that you describe how the lack of alternative methods was verified for each potentially painful/distressing procedure or disease **(ONLY for Category D and/or E procedures).** Category C procedures do not need an alternative search.

A. GENERAL SEARCH INFORMATION	
The database(s) searched	*Web of Science* and *Google Scholar*
The date that the search was conducted	13 January 2020
The years covered by the search	1995-2019

B. DESCRIBE YOUR SEARCH STRATEGY BELOW

Recommended Search Strategy ➔ "*procedure*" and "*species*" and "*alternative*" = # references

The Committee must be able to understand the keywords and search strategy used. The number of references for each keyword combination must also be provided.

Example: Use of anesthesia in mice = *[anesthesia + mouse + alternative] = # of references retrieved.*

C. PROVIDE A NARRATIVE FOR EACH SEARCH. The Committee must be readily able to assess whether the search topics were appropriate and whether the search was sufficiently thorough.

XV. PROTOCOL PERSONNEL

Protocol personnel must be added via a Supplement P. All personnel must complete their IACUC requirements **prior** to being approved protocol personnel. More information on completing these requirements & how to add personnel is found here. Contact the IACUC office at iacuc-office@tufts.edu or 617-636-0496 with any questions.

XVI. PRINCIPAL INVESTIGATOR ASSURANCE OF COMPLIANCE

As the individual responsible for this project, I confirm the following:

- ☒ *The information contained in this protocol is true and accurate, and to the best of my knowledge conforms to Tufts University/Tufts Medical Center IACUC, NIH, USDA, and MDPH policies on the use of animals in research and teaching.*
- ☒ *I have considered alternatives to the biological models used in this project and have found these other methods unacceptable on scientific or educational grounds.*
- ☒ *I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.*
- ☒ *I accept responsibility for ensuring that all personnel involved in this project will be trained regarding any potential biological, chemical, and radiological hazards, relevant safety practices, and emergency procedures. If applicable, I confirm that all relevant institutional regulatory requirements (e.g. Chemical Safety Plan, IBC Registration, Radioactive Materials Permit, etc.) will be followed.*
- ☒ *I will complete all IACUC personnel requirements, as described in the Policy on Requirements for Personnel Working with IACUC-Covered Animals **prior** to working with animals **OR** within 2 months of the approval of my protocol, **whichever comes first**.*
- ☒ *All personnel involved in this project will be added to the protocol using a Supplement P. All personnel involved will agree to participate in the study and will be aware of the approved procedures by reading the approved protocol and amendments. All individuals involved will be instructed in the humane care, handling, and use of animals, and I will review their qualifications. I will properly train all individuals performing euthanasia and will maintain training records as required in the IACUC Policy on Euthanasia.*
- ☒ *No change will be made to procedures, care or housing without prior written notification to and approval by the Institutional Animal Care and Use Committee (IACUC).*
- ☒ *I understand that it is non-compliant to release an IACUC approval date without documentation of a congruency comparison conducted by the IACUC Office. For more information, please see the Policy on Requiring a Congruency Comparison Prior to Release of IACUC Approval Dates.*
- ☒ *I accept responsibility for complying with Material Transfer Agreement requirements. For more information, please see Material Transfer guidance on the Tufts Tech Transfer website.*

☒ *I understand that failure to comply with IACUC policies and procedures will jeopardize Tufts University's or Tufts University-Tufts Medical Center's Animal Welfare Assurances on file with the NIH, and may lead to revocation of my privileges to conduct animal research at this institution.*

Jonathan H. Epstein	01 March 2020
Principal Investigator (*provide electronic signature*)	Date

By typing your name, you are submitting an electronic signature that confirms your understanding and adherence to the above statements and IACUC policies. This is considered legal documentation and confirmation of your agreement to execute all activities as approved.

Institutional Animal Care and Use Committee
Tufts University & Tufts Medical Center
136 Harrison Avenue
Boston, Massachusetts 02111
Phone: (617) 636-4109 Fax: (617) 636-8354

Approval Notice

To: **Dr. Jonathan Epstein**

From: Philip Hinds, Chair (b) (6)
Institutional Animal Care and Use Committee
136 Harrison Avenue

Protocol: #G2017-32
"Understanding the Risk of Bat Coronavirus Emergence"

The above-named protocol was reviewed and **approved** by this institution's Institutional Animal Care and Use Committee on **March 21, 2017.**

Your agreement to abide by the animal care and use policies of this institution also covers this following:

* Any **change** in the species, number, or use of animals as described in this protocol must be amended and approved before the change occurs.

*** THIS APPROVAL LETTER IS NOT TO BE USED FOR A GRANT VERIFICATION LETTER.** Release of the approval date to the grant agency requires verification of this protocol by the IACUC with the grant to be funded. This process is performed upon request. Please complete the IACUC Congruency Request Form and submit the relevant documents to the IACUC office for each proposal.

*No live vertebrate animal may be obtained without specific permission from DLAM/LAMS/CBU. No live vertebrate animal may be removed from any DLAM/LAMS/CBU facility unless it is described in your approved protocol.

* If this protocol includes work that requires **Institutional Biosafety Committee (IBC) or chemical hazard approval**, you will need to obtain those approvals **PRIOR** to the initiation of that work.

PLEASE MAKE SURE THAT EVERYONE LISTED ON THE PROTOCOL IS AWARE OF THE PROCEDURAL DETAILS APPROVED.

From: Lauer, Michael (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: Thur 1/6/2022 3:29:59 PM (UTC-06:00)

To: Peter Daszak[(b) (6) Aleksei Chmura[(b) (6)

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

Subject: Please read and acknowledge receipt -- Two letters to EcoHealth Alliance -- January 6, 2022

Attachment: January 2022 To EcoHealth R01AI110964 final.pdf

Attachment: January 2022 EHA SAC CAP letter final.pdf

Dear Drs. Chmura and Daszak

Please see attached.

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)

6 January 2022

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

Re: R01AI110964

Dear Drs. Chmura and Daszak:

Thank you for your correspondence of November 18, 2021. We are following up on your response to our request for Institutional Animal Care and Use Committee (IACUC) approval for the field work, and your response to our request for laboratory notebook entries and electronic files related to the experiments described in the Year 4 RPPR and Year 5 I-RPPR.

IACUC Approval

As we noted before and as required by the NIH Grants Policy Statement (GPS), 4.1.1.2, NIH requires verification of IACUC approval of those sections of the grant application that involve use of vertebrate animals. As noted by the NIH Office of Laboratory Animal Welfare (OLAW) cover letter accompanying your Interinstitutional Agreement for the WIV animal work, "under your approved Assurance with the Wuhan Institute of Virology, their Institutional Animal Care and Use Committee (IACUC) is authorized to carry out subsequent reviews of this project." In the final Vertebrate Animal Section of EcoHealth's Just-in-Time materials submitted on May 16, 2014 for 1 R01 AI110964-01, you stated that "all animal work to be done at Wuhan has been approved by the Wuhan IRB (IACUC) #WIVA05201402. Animals will be housed in a BSL-3 facility and will be under the care of a full-time veterinarian."

In my November 5, 2021, letter I requested documentation from the *WIV IACUC* regarding approval for *field work* (e.g., work in caves to collect materials from live bats) supported by R01AI110964. In your November 18, 2021, letter you indicated that no such *WIV IACUC* documentation exists. You stated, "the fieldwork in China that we conducted under our R01 is covered by the Inter-institutional agreement we cited in our letter of October 26th, and by our relevant US institutional IACUC approval."

Through our own search, we have confirmed that the field work was in deed approved by an IACUC. We understand that one of your co-investigators, Dr. Jonathan Epstein, submitted the field work proposal to the Tufts University IACUC; the Tufts University IACUC provided approval; and NIAID accepted the use of the Tufts University IACUC. However, in response to our requests for documentation of IACUC approval, you did not identify who the US institutional IACUC was, nor did you provide us with the Tufts University IACUC approval documentation. We had to obtain the documentation directly from Tufts University. While we are satisfied that the field work was approved by an IACUC, EcoHealth's inability or unwillingness to

provide the Tufts University IACUC documentation to us upon request raises questions about the quality and rigor of EcoHealth's record-keeping.

Laboratory Notebooks and Electronic Files

In my letter of November 5, 2021, I asked you to send us by no later than Friday, November 19, 2021, complete and dated copies of the original laboratory notebook entries and of the original electronic files that led to the generation of the Year 4 RPPR Figure 35 and the Year 5 I-RPPR Figure 13, along with all their accompanying texts (e.g., the Year 5 I-RPPR text in which you stated that "rWIV1-SHC014 was detected at all time points and showed an increasing viral titer after infection…") . On November 18, 2021, you responded: "We do not have copies of these, which were created by and retained by the WIV. Nonetheless, I have forwarded your letter to the WIV, and will let you know their response as soon as WIV replies to our request." We are following up to confirm whether you received a response from WIV and whether the materials are forthcoming.

As a reminder, it is critical to note that our request for the original laboratory notebook entries and the original electronic files underlying the Year 4 RPPR Figure 35 and the Year 5 I-RPPR Figure 13 is consistent with the term and condition of award which provides that NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. 75.364). It is also consistent with the term and condition of award that "The Federal Government has the right to obtain…the data produced under a Federal award." (45 C.F.R. 75.322(d)). Moreover, as a term and condition of award, unless extended by the Federal awarding agency, all "records pertinent to a Federal award must be retained for a period of three years from the date of submission of the final expenditure report or, for Federal awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, respectively, as reported to the HHS awarding agency or pass-through entity in the case of a subrecipient." (45 C.F.R. 75.361). NIH's rights of access "are not limited to the required retention period but last as long as the records are retained." (45 C.F.R. 75.364(c)). These rights and requirements apply not only to EcoHealth's records and data, but also to WIV's records and data, regardless of whether WIV is an active subawardee of EcoHealth at this time. Awardees indicate their acceptance of an NIH award and its associated terms and conditions as they draw down the NIH grant funds to support the scientific project (see NIHGPS Section 5). If an awardee fails to comply with the terms and conditions of award, and NIH determines that noncompliance cannot be remedied with specific award conditions, the NIH may take one or more enforcement actions, including terminating the award in whole or in part, disallowing all or part of the cost of the activity or action not in compliance, and withholding further federal awards for the project. (45 C.F.R. 75.371).

Upon receipt of this letter, please confirm whether you have received a response from WIV and whether the materials are forthcoming. If the materials are forthcoming, we request that they be provided to us no later than close-of-business on January 14, 2022.

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

Sincerely,

Lauer, Michael (NIH/OD) [E]
Digitally signed by Lauer, Michael (NIH/OD) [E]
Date: 2022.01.06 16:21:33 -05'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
(b) (6)

cc: Ms. Emily Linde
Dr. Erik Stemmy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

January 6, 2022

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

Re: U01AI151797 and U01AI153420

Dear Drs. Chmura and Daszak:

I am writing to inform you of the actions that the National Institutes of Health (NIH) is taking with respect to grants administration at EcoHealth Alliance (EcoHealth). Pursuant to 45 C.F.R. § 75.207 and the NIH Grants Policy Statement Chapter 8.5, NIH is imposing specific award conditions on EcoHealth's active awards, U01AI151797 and U01AI153420. EcoHealth has demonstrated a history of failure to comply with several elements of the terms and conditions of grant awards not only for these active awards, but also for the suspended award, R0AI110964. Specifically, we have identified deficiencies in the timely submission of financial and Research Performance Progress Reports (RPPR), compliance with the Federal Funding Accountability and Transparency Act (FFATA) via FFATA Subaward Reporting System (FSRS), and other monitoring requirements.

NIH has reviewed the materials you provided in prior correspondence and determined that EcoHealth's subaward agreements do not contain required components, as outlined in 45 C.F.R. § 75.352 and the NIH GPS 15.2.1, and are out of compliance. Specifically:

Written Agreement Requirements	**Compliance - Status**
All requirements imposed by the pass-through entity on the subrecipient so that the Federal award is used in accordance with Federal statutes, regulations and the terms and conditions of the Federal award. ("The terms and conditions of Federal-awards (including [45 CFR 75]) flow down to subawards to subrecipients" 45 CFR 75.101(b))	Non-compliant: Not provided.
Any additional requirements that the pass-through entity imposes on the subrecipient in order for the pass-through entity to meet its own responsibility to the HHS awarding agency including identification of any required financial and performance reports.	Non-compliant: The agreements lacked clear requirements for when financial and performance reports are due, and what must be included in them. In addition, the recipient failed to submit the reports, when requested.
A requirement that the subrecipient permit EcoHealth and auditors to have access to the subrecipient's records and financial statements as necessary for EcoHealth to meet the requirements under 45 CFR part 75.	Non-compliant: Not provided.
Procedures for directing and monitoring the research effort.	Non-compliant: Not provided.

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If the subrecipient's Investigators must comply with the subrecipient's Financial Conflict of Interest policy, the subrecipient shall certify as part of the written agreement that its policy complies with the 2011 revised FCOI regulation (42 CFR 50 Subpart F). If the subrecipient cannot provide such certification, the agreement shall state that the subrecipient's Investigators are subject to the Financial Conflict of Interest policy of the awardee Institution for disclosing Significant Financial Interests that are directly related to the subrecipient's work for the awardee Institution.	Non-compliant: Subrecipient FCOI policy not provided, nor was there a certification as part of the written agreement demonstrating compliance with the 2011 revised FCOI regulation (42 CFR 50 Subpart F).
A provision addressing ownership and disposition of data produced under the consortium agreement. This includes whether cell lines, samples or other resources will be freely available to other investigators in the scientific community or will be provided to particular investigators only.	Non-compliant: Not provided.
A provision making the NIH data sharing and inventions and patent policy, including a requirement to report inventions to the recipient (see Administrative Requirements-Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources), applicable to each consortium participant and its employees in order to ensure that the rights of the parties to the consortium agreement are protected and that the recipient can fulfill its responsibilities to NIH.	Non-compliant: Not provided.
Incorporation of applicable public policy requirements and provisions indicating the intent of each consortium participant to comply, including submission of applicable assurances and certifications (see Public Policy Requirements, Objectives, and Other Appropriation Mandates).	Non-compliant: The agreement does not incorporate applicable public policy requirements.

NIH further identified non-compliance within EcoHealth's subaward agreement and invoices with the Wuhan Institute of Virology on grant R01AI110964, where it showed that EcoHealth did not charge the correct Facilities and Administrative (F&A) rate of 8 percent for the cost of compliance (see NIH GPS 16.6) which is required for all foreign awards. NIH identified that an inappropriate F&A was charged at a rate of 11 percent for years 2-5 of the subaward agreement.

When NIH identifies a recipient's history of non-compliance with the general or specific terms and conditions of NIH grant awards, NIH may take proactive actions to protect the Federal government's interests and may impose additional specific award conditions as needed (see 45 CFR 75.207 and NIH GPS 8.5). Given the non-compliance in the aforementioned areas, NIH is implementing specific award conditions (SAC) on all active awards to EcoHealth (U01AI151797 and U01AI153420), as follows.

- The expanded authority for automatic no-cost extensions is withdrawn. This will require that EcoHealth request and receive written prior approval from the appropriate NIH awarding Institute or Center (IC) before any extensions of the final budget period.

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- Automatic carryover authorities are withdrawn. This will require EcoHealth to request and receive written approval to carry over any unobligated balances on all awards prior carrying over unobligated balances from one budget period to any subsequent budget period.
- EcoHealth is required to submit semi-annual RPPRs and Federal Financial Reports to the awarding IC.

EcoHealth must develop and successfully implement a Corrective Action Plan (CAP) for these awards with milestones to address and correct the deficiencies noted in this letter. The Corrective Action Plan, at a minimum, must include the following:

- Show proof of written policies and procedures for the development and issuance of subaward agreements, and a plan for revising the policies to address any deficiencies. The policy must include procedures for ensuring the appropriate F & A rate is applied to all subawards.
- Provide NIH with copies of updated subaward agreements for all active awards that correct the deficiencies noted above and demonstrate compliance with the NIH GPS 15.2.1 Written Agreement. The subaward agreements must state the correct F&A rate which, for foreign subrecipients is 8% (see NIH GPS 16.6).
- Show proof of written policies and procedures for timely submission of financial and progress reporting, and a plan for revising the policies to address any deficiencies.
- Show proof of written policies and procedures for subaward reporting as required by FFATA (see NIH GPS 8.4.1.5.5), and a plan for revising the policies to address any deficiencies.
- Provide NIH with copies of FSRS reporting for all subawards.

Once NIH reviews the CAP and determines that EcoHealth has successfully implemented it and has corrected the deficiencies noted in this letter, we will remove the SACs on the active awards without additional action on the part of EcoHealth. If we determine that additional information and actions are required, we will notify EcoHealth so that we can ensure compliance and, ultimately, remove the SACs.

Please provide the CAP to me within 30 days of receipt of this letter. If you have questions or would like to request reconsideration of the specific award conditions on the active awards, please feel free to contact me via email.

Sincerely,

Lauer, Michael (NIH/OD) [E] Digitally signed by Lauer, Michael (NIH/OD) [E] Date: 2022.01.06 16:25:16 -05'00'

Michael S. Lauer, M.D.
NIH Deputy Director for Extramural Research
(b) (6)

REL0000047896.0002

From: Lauer, Michael (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: Sun 2/6/2022 10:07:32 AM (UTC-06:00)

To: Peter Daszak[(b) (6)] Aleksei Chmura[(b) (6)]

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

Subject: Re: [EXTERNAL] RE: Please read and acknowledge receipt -- Two letters to EcoHealth Alliance -- January 6, 2022

Attachment: EcoHealth Alliance U01 CAP.pdf

Attachment: EHA response to NIH request for additional subrecipient contract details on U01s.pdf

Thank you Dr. Daszak for your letter and for your CAP. We will review and get back to you.

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)

From: Peter Daszak < (b) (6) >
Date: Friday, February 4, 2022 at 8:16 PM
To: "Lauer, Michael (NIH/OD) [E]" < (b) (6) > Aleksei Chmura < (b) (6) >
Subject: [EXTERNAL] RE: Please read and acknowledge receipt -- Two letters to EcoHealth Alliance -- January 6, 2022

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

As requested, a detailed response to the additional requirements you list in your second Jan 6th letter, re. our U01 awards.

Also attached is a CAP.

Peter Daszak

President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: (b) (6)
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

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

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From: Lauer, Michael (NIH/OD) [E] < (b) (6)
Sent: Thursday, January 6, 2022 4:35 PM
To: Peter Daszak < (b) (6) Aleksei Chmura < (b) (6)
Cc: Lauer, Michael (NIH/OD) [E] < (b) (6)
Subject: Please read and acknowledge receipt -- Two letters to EcoHealth Alliance -- January 6, 2022

Dear Drs. Chmura and Daszak

Please see attached.

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)

Disclaimer

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EcoHealth Alliance: Proposed Corrective Action Plan

4 February 2022

Excluding any COVID-19 related delays, and by 30 April 2022 if possible, EcoHealth Alliance will have completed the following items and provided documentation to NIH as appropriate.

1. The following language will be added to all contracts: *As applicable, the subrecipient agrees to adhere to all requirements contained in 2 CFR 200 (Uniform Administrative requirements, Cost Principles, and Audit Requirements for Federal Awards) and 45 CFR 75 (Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards). The subrecipient acknowledges responsibility for CFR requirements for funds received under this agreement.*
2. EcoHealth Alliance will expand the details of financial and performance reporting requirements, and make them uniform across each subrecipient contract.
3. Language will be added to our contracts as follows: *The subrecipient agrees to permit EcoHealth Alliance to have access to its records and financial statements as necessary for EcoHealth Alliance to meet the requirements under 45 CFR part 75.*
4. Details on EcoHealth Alliance's procedures for directing and monitoring research efforts will be added to contracts.
5. The following language will be added to our subrecipient contracts: *The subrecipient shall either 1) certify as part of the written agreement that its policy complies with the 2011 revised FCOI regulation (42 CFR 50 Subpart F); or 2) if the subrecipient cannot provide such certification, the agreement shall state that the subrecipient's Investigators are subject to the Financial Conflict of Interest policy of the awardee Institution for disclosing Significant Financial Interests that are directly related to the subrecipient's work for the awardee Institution.*
6. The data-sharing and management details already agreed upon in the award will be added to our contracts with subrecipients.
7. Contracts will include indicated language on inventions and patents.
8. Additional language will be added to all subcontracts as follows: *As applicable, the subrecipient will adhere to all NIH Grants Policy Statement Public Policy Requirements and Objectives (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1_public_policy_requirements_and_objectives.htm), including submission of applicable assurances and certifications (see Public Policy Requirements, Objectives, and Other Appropriation Mandates).*
9. Policies will be provided to NIH for the development and issuance of EcoHealth Alliance subaward agreements including a plan for revisions to address deficiencies and ensuring subawards include the appropriate F & A rate and subaward reporting as required by FFATA.
10. Updated subaward agreements for all active NIH awards will be provided to NIH and include (a) language on timely submission of financial and progress reporting.
11. Copies of FSRS reporting for all subawards will be provided to NIH.

EcoHealth Alliance

04 February 2022

Dr. Michael S. Lauer
NIH Deputy Director for Extramural Research

Dear Dr. Lauer:

I am writing in response to your letter dated 06 January 2022 regarding two awards to EcoHealth Alliance U01AI151797 and U01AI153420. These awards concern research that is critical to building US defenses against emerging diseases so as to protect US citizens, and others around the world against future pandemics. Both proposals received high scores during independent review at NIH, and both were considered a high priority for funding by NIH. The research under these contracts has led to important findings that have already been made public and are being used by the US government to bolster pandemic preparedness plans. At no point since these contracts were awarded has NIAID program staff questioned the work being undertaken, nor our compliance with the rigorous oversight that these contracts involve. We are therefore concerned that, in what appears to be in direct response to partisan political pressure, the NIH Office of the Director has generated a series of unusual, additional compliance actions on EcoHealth Alliance's scientific research.

Like other actions from your office with respect to EcoHealth Alliance, these have been taken without the involvement of program staff, which is not normal for NIH grants and contracts. We have also been informed that our program officer for R01AI110964 will no longer be able to respond to emails regarding that suspended award. For U01AI151797, we received the attached Notice of Award on 6/17/2020, which was then revised on 8/28/2020 (also attached) to include three additional requirements that are not part of the normal procedure of contract management and are not covered anywhere in NIH guidelines. We discussed this with NIAID program staff who indicated that these additions came from the Office of the Director and that they were unable to discuss them, again indicating that normal procedures have been circumvented. In 2021, we discussed the additional requirements with other awardees on the CREID network, which our U01 is part of, and heard of no other award that has been subjected to this additional burdensome oversight.

Despite our concerns, we have responded to your inquiries in good faith and will comply fully with these additional requirements. In your letter you stated that "EcoHealth Alliance has demonstrated a history of failure to comply with several elements of the terms and conditions of grant awards." To the contrary, EcoHealth Alliance has a long history of rapid compliance with all reasonable NIH requests including the many additional requests we have received over the past two years. Our program officers can attest to our maintenance of high-quality, regular communications, proactivity, and eagerness to

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212.380.4460
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REL0000047852.0002

address rapidly and transparently any and all constructive criticisms. Indeed, should any of the additional requirements in your letter have been brought up to us by NIH/NIAID program staff over the last 18 months, we would have rapidly incorporated them.

Accordingly, we have reviewed the table of requirements in your 06 January 2022 letter. We have carefully gone through our records and believe that we are already in broad compliance with the requirements of NIH subrecipient administration. We have indicated this in our response to each of the 8 items you raised, and we welcome this opportunity to clarify our stance. We also acknowledge your instructions, and have indicated additional language that we will add to our subcontract agreements for each of the points you've raised and have attached a proposed CAP, with a timeline for these new additional requirements to be implemented. We also want to assure you that EcoHealth Alliance remains committed to timely compliance with all requirements for our existing and future NIH awards. In that vein, we have read the revised NoA that we received this week (2/2/22) for both U01s and will submit semi-annual reports by the 15th as requested, despite the short turnaround time and the fact that our CAP has not yet been finalized.

ITEM 1: All requirements imposed by the pass-through entity on the subrecipient so that the Federal award is used in accordance with Federal statutes, regulations and the terms and conditions of the Federal award. ("The terms and conditions of Federal-awards (including [45 CFR 75]) flow down to subawards to subrecipients" 45 CFR 75.101(b)).

STATUS (NIH): Non-compliant: Not provided.

RESPONSE (EHA): We believe our actions were compliant with NIH regulations in that our contracts specifically state that subrecipients must *adhere to all requirements contained in 2 CFR 200 (Uniform Administrative requirements, Cost Principles, and Audit Requirements for Federal Awards)*. Our understanding is that 2 CFR 200 is the "Authority" for Title 45 CFR 75 and therefore the former is inclusive of the latter. We had already provided this information to NIH: As per our revised NoA for U01AI151797 and as requested by NIH, we provided our Program Officer and Grants Management Specialist with copies of all contracts within 30 days of them being signed. Additionally, following the request from Dr. Lauer (NIH) for subrecipient (Chulalongkorn, Duke-NUS, UNC, icddr,b, and IEDCR) "subaward agreements, subawardee audit reports, subawardee safety monitoring documents, subawardee progress reports, and subawardee financial and accounting records" on 23 July 2021, we provided all documents by the 27 August 2021 deadline as requested.

CAP: We will add the following language to all contracts: "As applicable, the subrecipient agrees to adhere to all requirements contained in 2 CFR 200 (Uniform Administrative requirements, Cost Principles, and Audit Requirements for Federal Awards) and 45 CFR 75 (Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards). The subrecipient acknowledges responsibility for CFR requirements for funds received under this agreement."

ITEM 2: Any additional requirements that the pass-through entity imposes on the subrecipient in order for the pass-through entity to meet its own responsibility to the HHS awarding agency including identification of any required financial and performance reports.

STATUS (NIH): Non-compliant: The agreements lacked clear requirements for when financial and performance reports are due, and what must be included in them. In addition, the recipient failed to submit the reports, when requested.

RESPONSE (EHA): We believe that our actions were compliant with NIH regulations, with respect to both the substance and timeliness of reports. As shown on page 12 of our contract with Chulalongkorn University and page 6 of the contract with iccdr,b (attached), our contracts clearly state that subrecipients must provide programmatic and financial reporting annually, invoice and provide financial reports quarterly, and provide all other reports as requested by NIAID and EcoHealth Alliance. In addition, we are in regular, frequent contact with subrecipients (weekly, 2-weekly, monthly conference calls and in-person meetings) during which we request program updates and verbal progress reports. Finally, during normal course of business, EHA often requests written updates. Our subrecipients invariably comply with each and all requests.

Regarding EcoHealth Alliance submitting reports to NIH when requested: As per our revised NoA for U01AI151797 and as requested by NIH, we provided our Program Officer and Grants Management Specialist with copies of all contracts within 30 days of them being signed. Additionally, following the request from Dr. Lauer (NIH) for subrecipient (Chulalongkorn, Duke-NUS, UNC, icddr,b, and IEDCR) "subaward agreements, subawardee audit reports, subawardee safety monitoring documents, subawardee progress reports, and subawardee financial and accounting records" on 23 July 2021, we provided all documents by the 27 August 2021 deadline as requested.

CAP: EcoHealth Alliance will expand the details of financial and performance reporting requirements, and make them uniform across each subrecipient contract.

ITEM 3: A requirement that the subrecipient permit EcoHealth and auditors to have access to the subrecipient's records and financial statements as necessary for EcoHealth to meet the requirements under 45 CFR part 75.

STATUS (NIH): Non-compliant: Not provided.

RESPONSE (EHA): We believe that our actions were compliant with NIH regulations. We did include language on subrecipient audit requirements in our contracts and did provide this information in a timely way to NIH. As shown on page 5 Section X of our contract with Chulalongkorn University, our contracts require that subrecipients agree that "EcoHealth Alliance may, at its own expense, examine, audit, or have audited the records of Chulalongkorn University insofar as they relate to activities supported by this agreement." Thus, by signing the contract, each subrecipient *de facto* agrees to permit access to their records and financial statements. As per our NoA for U01AI151797, we provided our Program Officer and Grants Management Specialist with copies of all contracts within 30-days of signing. Additionally, requests for subrecipient (Chulalongkorn, Duke-NUS, UNC, icddr,b, and IEDCR) "subaward agreements, subawardee audit reports, subawardee safety monitoring documents, subawardee progress reports, and subawardee financial and accounting records" were requested by Dr. Lauer (NIH) and provided on 27 August 2021.

CAP: Language will be added to our contracts as follows: "The subrecipient agrees to permit EcoHealth Alliance to have access to its records and financial statements as necessary for EcoHealth Alliance to meet the requirements under 45 CFR part 75.*"*

ITEM 4: Procedures for directing and monitoring the research effort.

STATUS (NIH): Non-compliant: Not provided.

RESPONSE (EHA): We did have adequate procedures in place for directing and monitoring the research efforts of subrecipients. In compliance with NIH Grants Policy Statement, all EcoHealth Alliance contracts with subrecipients state: "The researcher acknowledges that EcoHealth Alliance is implementing, and over the course of this agreement will continue to implement, reasonable monitoring and oversight to assure the continuing truth of these representations and certifications." As per our NoA for U01AI151797, we provided our Program Officer and Grants Management Specialist with copies of all contracts within 30-days of signing. Additionally, requests for subrecipient (Chulalongkorn, Duke-NUS, UNC, icddr,b, and IEDCR) "subaward agreements, subawardee audit reports, subawardee safety monitoring documents, subawardee progress reports, and subawardee financial and accounting records" were requested by Dr. Lauer (NIH) and provided on 27 August 2021.

CAP: Additional detail of the procedures we normally undertake for directing and monitoring the research effort will be added to our contracts.

ITEM 5: If the subrecipient's Investigators must comply with the subrecipient's Financial Conflict of Interest policy, the subrecipient shall certify as part of the written agreement that its policy complies with the 2011 revised FCOI regulation (42 CFR 50 Subpart F). If the subrecipient cannot provide such certification, the agreement shall state that the subrecipient's Investigators are subject to the Financial Conflict of Interest policy of the awardee Institution for disclosing Significant Financial Interests that are directly related to the subrecipient's work for the awardee Institution.

STATUS (NIH): Non-compliant: Subrecipient FCOI policy not provided, nor was there a certification as part of the written agreement demonstrating compliance with the 2011 revised FCOI regulation (42 CFR 50 Subpart F).

RESPONSE (EHA): We did provide the requisite information on FCOI to NIH in a timely way in compliance with this requirement. Subrecipient *subaward agreements, subawardee audit reports, subawardee safety monitoring documents, subawardee progress reports, and subawardee financial and accounting records* were provided to NIH on 27 August 2021. These contained documentation of EcoHealth Alliance's certification of subrecipients' FCOI policies. All subrecipient contracts contain the following language: "Financial Conflict of Interest: The researcher certifies and represents that no Significant Financial Conflict of Interest exists regarding their participation in this project that would influence their research. They furthermore agree that if such a conflict develops during the course of this project they will promptly notify and disclose that conflict in writing to the EHA Principal Investigator and the EHA Chief Financial Officer and may be required to develop a plan of corrective action to resolve that matter. This requirement shall extend to all individuals."

CAP: As noted, it seems from the above that we are already in compliance with this requirement. However, to remove any doubt, the CAP will indicate that we will add the following language to our contracts: "The subrecipient shall either 1) certify as part of the written agreement that its policy complies with the 2011 revised FCOI regulation (42 CFR 50 Subpart F); or 2) if the subrecipient cannot provide such certification, the agreement shall state that the subrecipient's Investigators are subject to the Financial Conflict of Interest policy of the awardee Institution for disclosing Significant Financial Interests that are directly related to the subrecipient's work for the awardee Institution."

ITEM 6: A provision addressing ownership and disposition of data produced under the consortium agreement. This includes whether cell lines, samples or other resources will be freely available to other investigators in the scientific community or will be provided to particular investigators only.

STATUS (NIH): Non-compliant: Not provided.

RESPONSE (EHA): This conclusion is premature. Our data sharing and management plans were carefully reviewed and approved by peer-reviewers and NIH program and grants management staff prior to our awards being made. Our EID-SEARCH award is part of the NIAID CREID network, for which agreements are still being finalized among the centers on data-sharing and management. Once they are in final form, we will of course provide the policies to NIH and comply with them in our research. We are in compliance with and in regular communication with our NIAID program officers and the CREID coordinating center.

CAP: The data-sharing and management details already agreed upon in the award will be added to our contracts with subrecipients.

ITEM 7: A provision making the NIH data sharing and inventions and patent policy, including a requirement to report inventions to the recipient (see Administrative Requirements-Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources), applicable to each consortium participant and its employees in order to ensure that the rights of the parties to the consortium agreement are protected and that the recipient can fulfill its responsibilities to NIH.

STATUS (NIH): Non-compliant: Not provided.

RESPONSE (EHA): We did not include these provisions in our contracts for the simple reasons that the production of inventions or patents is not a specific aim of our work with subrecipients, nor do we expect the work to produce inventions or patents.

CAP: Contracts will now include the indicated language on inventions and patents.

ITEM 8: Incorporation of applicable public policy requirements and provisions indicating the intent of each consortium participant to comply, including submission of applicable assurances and certifications (see Public Policy Requirements, Objectives, and Other Appropriation Mandates).

STATUS (NIH): Non-compliant: The agreement does not incorporate applicable public policy requirements.

RESPONSE (EHA): All of our contracts with subrecipients already include a statement that subrecipients are required to adhere to all Federal regulations pertaining to NIH subcontracts. This is indicated on page 5 of the contract with icddr,b: “As applicable, the researcher agrees to adhere to all requirements contained in 2 CFR 200 (Uniform Administrative requirements, Cost Principles, and Audit Requirements for Federal Awards) and 2 CFR 700” and on page 5 of the contract with Chulalongkorn University: “As applicable, Chulalongkorn University agrees to adhere to all requirements contained in OMB Circular A-122 during the term of the agreement.” Our assumption was that this language covered adherence to the applicable public policy requirements.

CAP: To leave no doubt on this question, we will add additional language to all subcontracts as follows: "As applicable, the subrecipient will adhere to all NIH Grants Policy Statement Public Policy Requirements and Objectives (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1_public_policy_requirements_and_objectives.htm), including submission of applicable assurances and certifications (see Public Policy Requirements, Objectives, and Other Appropriation Mandates)."

In summary, our proposed CAP will include the details above and we will also address the following requests in your letter:

- Show proof of written policies and procedures for the development and issuance of subaward agreements, and a plan for revising the policies to address any deficiencies. The policy must include procedures for ensuring the appropriate F & A rate is applied to all subawards.
- Provide NIH with copies of updated subaward agreements for all active awards that correct the deficiencies noted above and demonstrate compliance with the NIH GPS 15.2.1 Written Agreement. The subaward agreements must state the correct F&A rate which, for foreign subrecipients is 8% (see NIH GPS 16.6).
- Show proof of written policies and procedures for timely submission of financial and progress reporting, and a plan for revising the policies to address any deficiencies.
- Show proof of written policies and procedures for subaward reporting as required by FFATA (see NIH GPS 8.4.1.5.5), and a plan for revising the policies to address any deficiencies.
- Provide NIH with copies of FSRS reporting for all subawards.

I hope that our responses to your concerns have clarified areas where there may have been some misunderstanding. Please don't hesitate to contact me for further discussion of any of these points, including the provisions in our proposed CAP.

I look forward to your confirmation of our CAP, so we may proceed with the amendments rapidly, and so that we can get back to the critical research in the national interest focused on predicting and preventing pandemics that these contracts involve.

Sincerely,

(b) (6)

Peter Daszak, PhD
President, EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018, USA
(b) (6)
www.ecohealthalliance.org

Dr. Peter Daszak
President

(t) (b) (6); (e) (b) (6)

From: Lauer, Michael (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]

Sent: Fri 8/19/2022 1:51:01 PM (UTC-05:00)

To: Peter Daszak[(b) (6)] Aleksei Chmura[(b) (6)]

Cc: Bulls, Michelle G. (NIH/OD) [E][(b) (6)] Lauer, Michael (NIH/OD) [E][(b) (6)] Linde, Emily (NIH/NIAID) [E][(b) (6)] Bundesen, Liza (NIH/OD) [E][(b) (6)]

Subject: Please read and acknowledge receipt -- R01AI110964

Attachment: To EHA 8 19 22.pdf

Dear Dr. Chmura and Dr. Daszak

Please see attached.

Sincerely,
Michael S Lauer, MD

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

August 19, 2022

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

Re: R01AI110964

Dear Drs. Chmura and Daszak:

Thank you for your response dated, January 21, 2022, and all of your prior correspondence on the above-mentioned grant. In am writing to inform you that the National Institutes of Health (NIH) is taking the following actions with respect to grant R01AI110964, as more fully described in this letter:

(1) NIH is terminating the subaward from EcoHealth Alliance (EHA) to the Wuhan Institute of Virology (WIV) due to material non-compliance with terms and conditions of award that cannot be remedied by specific award conditions. This will be accomplished as a partial termination of the award to EHA under 45 CFR 75.371(c).
(2) NIAID will work with EHA to explore renegotiating the remainder of the award to proceed without involvement from WIV, if the award can be renegotiated without representing a significant scientific departure from the original, peer reviewed project. If the award is not able to be renegotiated without such a departure, then NIH will request a bilateral termination, and EHA may submit a new competitive (Type 1) application for funding of the revised project.
(3) If the remaining award can be renegotiated successfully, then NIAID will issue a revised award, subject to specific award conditions outlined below, which include that EHA must conduct or arrange for the conduct of onsite subrecipient facility inspections every 6 months to ensure that subaward activities are being properly executed.

Termination in Part

In my previous correspondence, dated November 5, 2021, and again on January 6, 2022, NIH requested from EHA complete and dated copies of the original laboratory notebook entries and of the original electronic files from the Wuhan Institute of Virology (WIV), that led to the generation of the Year 4 RPPR Figure 35 and the Year 5 I-RPPR Figure 13, along with all their accompanying texts (e.g., the Year 5 I-RPPR text in in which you stated that "rWIV1-SHC014 was detected at all time points and showed an increasing viral titer after infection…"). You responded that EHA relayed the request to WIV, but that EHA has not received a response from WIV and will inform NIH once the response is received. To date, NIH has not received the requested items.

We have also examined the subaward agreement from EHA to WIV, and we found that the agreement did not include "a requirement that the subrecipient [WIV] permit the pass-through entity [EHA] and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through

entity to meet the requirements of this part" as required under 45 C.F.R. 75.352. The agreement also did not include "all requirements imposed by the pass-through entity on the subrecipient so that the Federal award is used in accordance with Federal statutes, regulations and the terms and conditions of the Federal award[.]" 45 CFR 75.352. One such term and condition is that "The HHS awarding agency, Inspectors General, the Comptroller General of the United States, and the pass-through entity, or any of their authorized representatives, must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts." 45 CFR 75.364. The terms and conditions of Federal awards, including 45 CFR 75.364, flow down to subawards to subrecipients. 45 CFR 75.101(b). The subaward agreement to WIV did not indicate that the NIH, Inspectors General, the Comptroller General of the United States, and the pass-through entity (EHA), or any of their authorized representatives, must have the right of access to any documents, papers, or other records of the non-Federal entity (WIV) which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts.

As provided under 45 CFR 75.371, "If a non-Federal entity fails to comply with Federal statutes, regulations, or the terms and conditions of a Federal award, the HHS awarding agency or pass-through entity may impose additional conditions, as described in § 75.207. If the HHS awarding agency or pass-through entity determines that noncompliance cannot be remedied by imposing additional conditions, the HHS awarding agency or pass-through entity may take one or more [enforcement] actions, as appropriate in the circumstances[.]" 45 CFR 75.371. Such actions may include partly terminating the Federal award. Id. at 75.371(c).

NIH has determined that WIV's refusal to provide the requested records, and EHA's failure to include the required terms in WIV's subaward agreement represent material failures to comply with the terms of award. NIH has further determined that in these circumstances, WIV's refusal to provide records cannot be remedied by imposing additional conditions, and that a partial termination of award (i.e., termination of the subaward to WIV) is the only appropriate action.

Renegotiation of Award

As a result of NIH's termination of the subaward to WIV, we ask that EHA outline, within 30 days of this letter, how EHA will accomplish the purpose of the grant that was originally awarded without the subaward arrangement with WIV. This will require EHA to provide us with a change in scope outlining how the scope of the work will be modified to save the overall project while removing that portion of the research that was supported by WIV. Any change of scope, however, may not represent a significant scientific departure from the original peer reviewed project. If the change represents a significant departure from the original peer reviewed project, then NIH will request a bilateral termination of the remaining award, and EHA may submit a new competitive (Type 1) application for funding of the revised project. NIAID will work directly with EHA on such negotiations, including in reviewing EHA's proposal and discussing any needed scientific and budgetary adjustments.

Specific Award Conditions

If the remaining award is able to be renegotiated successfully, then the revised award will be subject to specific award conditions pursuant to 45 CFR 75.371 and 45 CFR 75.207. As provided under 45 CFR 75.371, "If a non-Federal entity fails to comply with Federal statutes, regulations, or the terms and conditions of a Federal award, the HHS awarding agency or pass-through entity may impose additional conditions, as described in § 75.207."

NIH will be imposing these specific award conditions, because NIH has determined that for grant R01AI110964, apart from the WIV-related non-compliance noted above, EHA failed to comply with

requirements for the timely submission of financial and Research Performance Progress Reports (RPPR), and compliance other monitoring requirements. Additionally, EHA's subaward agreements for the R01AI110964 grant did not contain required components, as outlined in 45 C.F.R. § 75.352 and the NIH GPS 15.2.1, and were out of compliance. Specifically:

Written Agreement Requirements	**Compliance - Status**
All requirements imposed by the pass-through entity on the subrecipient so that the Federal award is used in accordance with Federal statutes, regulations and the terms and conditions of the Federal award. ("The terms and conditions of Federal-awards (including [45 CFR 75]) flow down to subawards to subrecipients" 45 CFR 75.101(b))	Non-compliant: Not provided.
Any additional requirements that the pass-through entity imposes on the subrecipient in order for the pass-through entity to meet its own responsibility to the HHS awarding agency including identification of any required financial and performance reports.	Non-compliant: The agreements lacked clear requirements for when financial and performance reports are due, and what must be included in them. In addition, the recipient failed to submit the reports, when requested.
A requirement that the subrecipient permit EcoHealth and auditors to have access to the subrecipient's records and financial statements as necessary for EcoHealth to meet the requirements under 45 CFR part 75.	Non-compliant: Not provided.
Procedures for directing and monitoring the research effort.	Non-compliant: Not provided.
If the subrecipient's Investigators must comply with the subrecipient's Financial Conflict of Interest policy, the subrecipient shall certify as part of the written agreement that its policy complies with the 2011 revised FCOI regulation (42 CFR 50 Subpart F). If the subrecipient cannot provide such certification, the agreement shall state that the subrecipient's Investigators are subject to the Financial Conflict of Interest policy of the awardee Institution for disclosing Significant Financial Interests that are directly related to the subrecipient's work for the awardee Institution.	Non-compliant: Subrecipient FCOI policy not provided, nor was there a certification as part of the written agreement demonstrating compliance with the 2011 revised FCOI regulation (42 CFR 50 Subpart F).
A provision addressing ownership and disposition of data produced under the consortium agreement. This includes whether cell lines, samples or other resources will be freely available to other investigators in the scientific community or will be provided to particular investigators only.	Non-compliant: Not provided.
A provision making the NIH data sharing and inventions and patent policy, including a requirement to report inventions to the recipient (see Administrative Requirements-Availability of	Non-compliant: Not provided.

Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources), applicable to each consortium participant and its employees in order to ensure that the rights of the parties to the consortium agreement are protected and that the recipient can fulfill its responsibilities to NIH.	
Incorporation of applicable public policy requirements and provisions indicating the intent of each consortium participant to comply, including submission of applicable assurances and certifications (see Public Policy Requirements, Objectives, and Other Appropriation Mandates).	Non-compliant: The agreement does not incorporate applicable public policy requirements.

NIH further identified that EHA did not charge the correct Facilities and Administrative (F&A) rate of 8 percent (see NIH GPS 16.6) to the foreign subawards under R01AI110964.

NIH has determined that in these circumstances, these violations can be remedied by imposing additional conditions. 45 CFR 75.371. Accordingly, if the remaining award is able to be renegotiated successfully, then the revised award will include the following specific award conditions:

(1) EHA must conduct or arrange for the conduct of onsite subrecipient facility inspections every 6 months to ensure that subaward activities are being properly executed.

(2) EHA must provide NIH with copies of updated subaward agreements for R01AI110964 that correct the deficiencies noted in the table above and demonstrate compliance with the NIH GPS 15.2.1 Written Agreement. The subaward agreements must state the correct F&A rate which, for foreign subrecipients is 8% (see NIH GPS 16.6).

(3) The expanded authority for automatic no-cost extensions will be withdrawn. This will require that EHA request and receive written prior approval from NIAID before any extensions of the final budget period.

(4) Automatic carryover authorities will be withdrawn. This will require EHA to request and receive written approval to carry over any unobligated balances on all awards prior carrying over unobligated balances from one budget period to any subsequent budget period.

(5) EHA is required to submit semi-annual RPPRs and Federal Financial Reports to NIAID.

(6) Provide NIAID with copies of FSRS reporting for all subawards issued under the revised R01AI119064.

These specific award conditions will be in place for a period of at least 3 years from the date of the revised Notice of Award with an annual review to ensure proper compliance.

This letter represents the final decision of the Chief Grants Management Officer, NIAID, NIH. However, the NIH reserves the right to take additional compliance actions as needed, such as disallowing funds or imposing additional specific award conditions, if the HHS Office of Inspector General identifies other noncompliance and/or recommends such actions as a result of its audit of EcoHealth.

I note that the partial termination (i.e., termination of the subaward) is appealable. Accordingly, the partial termination shall be final and in effect unless within 30 days after receiving this decision, you deliver a written notice of appeal of the partial termination to:

Michelle G. Bulls
NIH Grant Appeals Officer
National Institutes of Health
(b) (6)
6705 Rockledge Drive, Room 3534/MSC 7963
Bethesda, MD 20892-7963

Please include a copy of this decision, your appeal justification, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be postmarked no later than 30 days after the postmarked date of this notice.

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

Sincerely,

Michael S. Lauer -S
Digitally signed by Michael S. Lauer -S
Date: 2022.08.19 13:32:40 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
(b) (6)