From: Aleksei Chmura

To: Girma, Tseday (NIH/NIAID) [E]

Cc: Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]

Subject: Re: Grant Number: 2R01AI110964 - 06 PI Name: DASZAK, PETER

Date: Wednesday, July 17, 2019 3:53:48 PM
Attachments: EHAL FY20 Prov Indirect Agmt Signed.pdf

Tseday,

Attached is our provisional rate of (b) (4) - signed today.

Many thanks!

-Aleksei

On Jul 17, 2019, at 15:38, Girma, Tseday (NIH/NIAID) [E]

Thank you.

Tseday Girma, MPA
Grants Management Specialist
National Institutes of Allergy and Infectious Diseases
5601 Fishers Lane, Room 4E49
Rockville, MD 20852
Phone: 606

Email: (b) (6

NIAID, National Institutes of Health, DHHS

Effective January 1, 2017, NIH closeout documentation policy has changed (see NOT-OD-17-022). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the NIH RPPR Page.

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From: Aleksei Chmura (b) (6)

Sent: Wednesday, July 17, 2019 3:11 PM

To: Girma, Tseday (NIH/NIAID) [E] (b) (6)

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

(b) (6)

Subject: Re: Grant Number: 2R01Al110964 - 06 PI Name: DASZAK, PETER

Dear Tseday,

We are still waiting on our cognisant agency (DoD) to issue a provisional rate or other notice. We will do all possible to get this to you today or before 5pm tomorrow.

Cheers,

-Aleksei

Aleksei Chmura, PhD

Chief of Staff

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

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

EcoHealth Alliance leads cutting-edge scientific 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.

On Jul 17, 2019, at 12:07, Girma, Tseday (NIH/NIAID) [E] (b) (6) wrote:

Good afternoon,

The F&A rate agreement submitted in the JIT for ECHOHealth Alliance, Inc. dated 11/14/2018 has expired on 06/30/2017. Do you have any documentation that you can send us that shows you could use the expired rate. Pending the establishment of a negotiated facilities and administrative (F&A) rate, we will restrict the amount of F&A funds in excess of 10% salaries and wages exclusive of fringe benefits and may not be expended until the new F&A rate agreement is issued and you receive a revised Notice of award from NIH.

Please send us the requested information ASAP but no later than

Obtained via FOIA by White Coat Waste Project

07/18/2019

Thanks, Tseday

Tseday Girma, MPA
Grants Management Specialist
National Institutes of Allergy and Infectious Diseases
5601 Fishers Lane, Room 4E49
Rockville, MD 20852

Phone: (b) (6)

Email: (6) (6) NIAID, National Institutes of Health, DHHS

Effective January 1, 2017, NIH closeout documentation policy has changed (see NOT-OD-17-022). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the NIH RPPR Page.

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ST OF

DEPARTMENT OF THE NAVY

OFFICE OF NAVAL RESEARCH 875 NORTH RANDOLPH STREET SUITE 1425 ARLINGTON, VA 22203-1995

IN REPLY REFER TO:

Agreement Date: July 17, 2019

NEGOTIATION AGREEMENT

INSTITUTION:

ECOHEALTH ALLIANCE, INC. 460 WEST 34TH ST. 17TH FLR NEW YORK, NY 10001-2320

The Indirect Cost rate contained herein is for use on grants, contracts and/or other agreements issued or awarded to the EcoHealth Alliance, Inc. by all Federal Agencies of the United States of America, in accordance with the provisions and cost principles mandated by 2 CFR Part 200. The rate shall be used for forward pricing and billing purposes for the EcoHealth Alliance, Inc. Fiscal Year 2020. This rate agreement supersedes all previous rate agreements/determinations for Fiscal Year 2020.

Section I: RATES - TYPE: PROVISIONAL (PROV)

Indirect Rates:

<u>TYPE</u> <u>FROM</u> <u>TO</u> <u>RATE</u> <u>BASE</u> <u>APPLICABLE TO</u> <u>LOCATION</u> Prov. 07/01/19 06/30/20 (b) (4) (a) All All

DISTRIBUTION BASES

(a) Total direct costs excluding capital expenditures (buildings, individual items of equipment; alterations and renovations), the portion of each subaward in excess of \$25,000, participant support costs, and flow-through funds.

SECTION II - GENERAL TERMS AND CONDITIONS

A. LIMITATIONS: Use of the rate set forth under Section I is subject to availability of funds and to any other statutory or administrative limitations. The rate is applicable to a given grant or contract or other agreement only to the extent that funds are available. Acceptance of the rate agreed to herein is predicated upon the following conditions: (1) that no costs other than those incurred by the organization were included in this indirect cost pool as finally accepted and that such costs are legal obligations of the organization and allowable under governing cost principles; (2) that the same costs that have been treated as indirect costs are not claimed as direct costs; (3) that similar types of costs have been accorded consistent accounting treatment; and (4) that the information provided by the organization which was used as a basis for acceptance of the rate agreed to herein, and expressly relied upon by the Government in negotiating and accepting the said rate is not subsequently found to be materially incomplete or inaccurate.

- B. ACCOUNTING CHANGES: The rate contained in Section I of this agreement is based on the accounting system in effect at the time the agreement was negotiated. Changes to the method(s) of accounting for costs, which affect the amount of reimbursement resulting from the use of the rate require the prior written approval of the authorized representative of the cognizant agency for indirect costs. Such changes include but are not limited to changes in the charging of a particular type of cost from indirect to direct. Failure to obtain such approval may result in subsequent cost disallowances.
- C. PROVISIONAL RATES: The provisional rate contained in this agreement is subject to unilateral amendment by the Government or bilateral amendment by the contracting parties at any time.
 - D. USE BY OTHER FEDERAL AGENCIES: The rate set forth in Section I is negotiated in accordance with and under the authority set forth in 2 CFR Part 200. Accordingly, such rate shall be applied to the extent provided in such regulations to grants, contracts, and other agreements to which 2 CFR Part 200 applies, subject to any limitations in part A of this section. Copies of this document may be provided by either party to other federal agencies to provide such agencies with documentary notice of this agreement and its terms and conditions.
 - E. SPECIAL REMARKS: The Government's agreement with the rate set forth in Section I is not an acceptance of the EcoHealth Alliance, Inc.'s accounting practices or methodologies. Any reliance by the Government on cost data or methodologies submitted by EcoHealth Alliance, Inc. is on a non-precedence-setting basis and does not imply Government acceptance.

Accepted:

THE THE THEFT			
FOR ECOHEALTH ALLIANCE, INC.	FOR T	HE U.S. G	OVERNMENT:
(b) (6)	WOO	D.LINDA	Digitally signed by WOOD,LINDA,MORGAN,151468894
(6)(6)	.MOR	GAN.151	DAY HE HEE
	46889	20 00 04 012	cn=WOOD LINDA MORGAN 151468 6 Date: 2019.07.1715;42:35 -04'00'
ARMINE ARUSTAMYAN	(- C.) - C. (- C.)	MORGA	agasta a paragraphical and
Chief Financial Officer	Contracting Officer		er
07-17-19	7/17/	/19	
Date	Date		
For information concerning this agreeme	ent contact:		
Sharon Gales	Phone:	(b) (6)	
Office of Naval Research	E-mail:		(b) (6)
875 North Randolph Street			
Arlington, VA 22203-1995			

From: Soto, Tiffani (NIH/OD) [C]

To: Aleksei Chmura; Girma, Tseday (NIH/NIAID) [E]

Cc: (b) (6) QLAW Division of Assurances (NIH/OD)

 Subject:
 2R01AI110964-06 EcoHealth Alliance, Inc.

 Date:
 Friday, July 12, 2019 11:31:07 AM

Attachments: A7941-04.pdf

Good Morning Dr. Chmura,

Please find enclosed the approved Inter-institutional Assurance for the above mentioned grant.

Tseday, the above, mentioned grant has been added to the daily list that OLAW sends to eRA for assurance number updates. It usually takes 72 hours before the changes will reflect in the IMPAC II record.

Please contact me if you do not see the assurance update at that time.

Kind Regards,

Tiffani T. Solo

Program Assistant (Contractor)
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700 B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, Maryland 20892

Phone: (b)(6) (Main)
Phone: (b)(6) (Direct)
Email: (b)(6)

Division of Assurances

E-Fax (301) 451-5672

Email: OLAWdoa@mail.nih.gov

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.

Quote:

Tell me and I forget, Teach me and I remember, Involve me and I learn. Benjamin Franklin

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare Division of Assurances 6700B Rockledge Drive Suite 2500, MSC 6910 Bethesda, Maryland 20892

July 10, 2019

Dr. Aleksei Chmura Authorized Organizational Reprehensive EcoHealth Alliance, Inc. 460 West 34th Street, Suite 1701 New York, New York 10001

Dear Dr. Chmura:

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare Division of Assurances 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 Telephone: (301) 496-7163 Fax: (301) 451-5672

Grant#: 2-R01-AI110964-06

Project Title: Understanding the Risk of Bat

Coronavirus Emergence

Principal Investigator: Dr. Peter Daszak

Animal Facility: The University of North Carolina at

Chapel Hill

The Division of Assurances, Office of Laboratory Animal Welfare (OLAW) has reviewed and approved the new Inter-institutional 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 2015.

This Assurance with identification A7941-04 became effective on 7/10/2019. The Assurance is good for the current period of project support. Under your approved Assurance with The University of North Carolina at Chapel Hill, 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 mail.

Venita Thornton, D.V.M., M.P.H.
Senior Assurance Officer, Division of Assurances

Office of Laboratory Animal Welfare (OLAW)

Enclosure Cc: Terry Magnuson, PhD Roland Tisch, Ph.D. Tseday Girma, NIAID

ScInterinstitutional 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, Suite 1701, New York, NY 10001, USA

Project Title: (from grant application/contract proposal)

Understanding the Risk of Bat Coronavirus Emergence

Grant/Contract Number: 2-R01-AI11094& 06

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

- 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: University of North Carolina at Chapel Hill
Office of Sponsored Research
104 Airport Dr. CB# 1350
Chapel Hill, NC 27599

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.

Nottie of Awar	dee Institution: EcoH	lealth Alliand	ce
	icial: Dr. Aleksel Chr	200	**************************************
Signature:	-	(b) (6)	Date: 21 June 2019
	ed Organizational Re	nrecentative	
	et address, city, stat		
	Street, Suite 1701, I	The state of the state of	
Phone: +	(b) (6)		Fax: +1.212.380.4465
E-mall:	(b) (6)	
B. Endorsen	nent of Assured In	stitution	The second secon
			th Carolina at Chapel Hill
the second second	fficial: Terry Magnus		
Signature		(b) (6)	Date: 7/5/2019
	ncellor for Research		- Date
312 South Bld Chapel Hill NC	CONTRACTOR OF THE PARTY OF THE	e, zip code) CB #4000	-T
Phone:	(b) (6)		Fax: 919-962-1476
E-mail:	(ъ) (б)		
ACUC Chairpe	rson: Roland Sch.	PhD	V/0
Signature:		(6	Date: 7/05/19
Title: IACUC C	hair		
	et address, city, stat nent of Microbiology 27599-7290		
Phone:	(b) (6)		Fax: 919-966-8429
	(b) (6)		*
E-mail:			
	Approval: (within 3	years, pend	ling not acceptable) 2000/00 9/29/24
Date of IACUC	Approval: (within 3 (to be completed	1	ling not acceptable) was 9/29/20
Date of IACUC	taranta at a sa	1	(b) (6)
Oate of IACUC IS Approval Signature of (Venita Senior	(to be completed DLAW Official: B. Thornton, D.V.M., M Assurance Officer, Divi of Laboratory Animal V	M.P.H.	(b) (6) Date: 7/10/2019
Signature of Overita Senior Office NIH/O	(to be completed DLAW Official: B. Thornton, D.V.M., M Assurance Officer, Divi of Laboratory Animal V	M.P.H. ision of Assura Velfare (OLAV	(b) (6) Date: 7/10/2019 ances N)
Signature of Office NIH/O	(to be completed OLAW Official: B. Thornton, D.V.M., N Assurance Officer, Divi of Laboratory Animal V D/OER	M.P.H. ision of Assura Velfare (OLAV	(b) (6) Date: 7/10/2019 ances N)
Signature of Overita Senior Office NIH/O Bethe	(to be completed DLAW Official: B. Thornton, D.V.M., N Assurance Officer, Divi of Laboratory Animal V D/OER B Rockledge Drive,	M.P.H. ision of Assur. Velfare (OLAV Suite 2500-	(b) (6) Date: 7/10/2019 ances N)

III.

From: Soto, Tiffani (NIH/OD) [C]

To: Aleksei Chmura; Girma, Tseday (NIH/NIAID) [E]

Cc: (b) (6); OLAW Division of Assurances (NIH/OD)

 Subject:
 2R01AI110946-06 EcoHealth Alliance, Inc.

 Date:
 Tuesday, June 25, 2019 7:35:36 AM

Attachments: 3209 001.pdf

Good Morning Dr. Chmura,

Please find enclosed the approved Inter-institutional Assurance between EcoHealth Alliance, Inc. & Wuhan Institute of Virology.

Kind Regards.

Tiffani T. Solv

Program Analyst (Contractor)
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700 B Rockledge Drive
Suite 2500 MSC 6910

Suite 2500, MSC 6910 Bethesda, Maryland 20892

Phone: (b) (6) (Main)
Phone: (b) (6) (Direct)

Email: (b) (6)

Division of Assurances E-Fax (301) 451-5672

Email: OLAWdoa@mail.nih.gov

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Quote:

Tell me and I forget, Teach me and I remember, Involve me and I learn. Benjamin Franklin

From: OLAW-PTR5@nih.gov < OLAW-PTR5@nih.gov>

Sent: Tuesday, June 25, 2019 7:31 AM

To: Soto, Tiffani (NIH/OD) [C] (b) (6)

Subject: Attached Image



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 6700B Rockledge Drive Suite 2500, MSC 6910 Bethesda, Maryland 20892

June 24, 2019

Dr. Aleksei Chmura Authorized Organization Representative EcoHealth Alliance, Inc. 460 West 34th Street, 17 Floor New York, New York 10001

Dear Dr. Chmura:

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare Division of Assurances 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 Telephone: (301) 496-7163 Fax: (301) 451-5672

Grant #. 2-R01-Al110946-06
Project Title: Understanding the Risk of Bat
Coronavirus Emergence
Principal Investigator: Dr. Peter Daszak
Animal Facility: Wuhan Institute of Virology

The Division of Assurances, Office of Laboratory Animal Welfare (OLAW) has reviewed and approved the new Inter-institutional 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 2015.

This Assurance with identification A7941-03 became effective on 6/24/2019. The Assurance is good for the current period of project support. Under your approved Assurance with 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 mail.

Sincerely,

(b) (6)

Venita Thornton, D.V.M., M.P.H. Senior Assurance Officer, Division of Assurances Office of Laboratory Animal Welfare (OLAW)

Enclosure Cc; Dr. Yanyi Wang Dr. Xi Zhou Tseday Girma, NIAID

ScInterinstitutional 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 Floor New York, NY 10001, USA

Project Title: (from grant application/contract proposal)

Understanding the Risk of Bat Coronavirus Emergence

Grant/Contract Number: 2-R01-AI110946-06

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

- 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>U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training</u> 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, Hubei Province, 430071 P.R. 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.

Name of Awar	dee Institution: EcoHe	alth Alliance
Authorized Off	ficial: Dr. Aleksei Chmu	ıra
Signature:	(b) (6)	Date: June 21, 2019
Title: Authoriz	ed Organizational Repr	resentative
Address: (stre 460 West 34 th New York, NY	et address, city, state, Street, 17 th Floor 10001, USA	zip code)
Phone:	(b) (6)	Fax: +1.212.380.4465
E-mail:	(b) ((6)
B. Endorser	nent of Assured Inst	titution
Name of Assur	red Institution: Wuhan	Institute of Virology, Chinese Academy of Sciences
	fficial: Dr. Yanyi Wang	
	(b) (6)	
Signature:		Date: June 28th 2019
Title: Director		
Title: Director Address: (stre Xiao Hong Sha		zip code)
Title: Director Address: <i>(stre</i> Xiao Hong Sha Wuhan, Hubei	et address, city, state, en No. 44 Province, 430071 P.R. (b) (6)	zip code)
Xiao Hong Sha	n No. 44 Province, 430071 P.R.	zip code) China
Title: Director Address: (stre Xiao Hong Sha Wuhan, Hubei Phone: E-mail:	(b) (6) erson: Dr. Xi Zhou	zip code) China
Title: Director Address: (stre Xiao Hong Sha Wuhan, Hubei Phone: E-mail:	n No. 44 Province, 430071 P.R. (b) (6) (b) (6)	zip code) China
Title: Director Address: (stre Xiao Hong Sha Wuhan, Hubei Phone: E-mail: IACUC Chairpe Signature: Title: Chairma Chinese Acade	n No. 44 Province, 430071 P.R. (b) (6) (c) (c) Prson: Dr. Xi Zhou (b) (6) (d) (e) (f)	zip code) China Fax: +86.27.87198209 Date: June 28 th 2019 al Care and Use Committee, Wuhan Institute of Virology
Title: Director Address: (stre Xiao Hong Sha Wuhan, Hubei Phone: E-mail: IACUC Chairpe Signature: Title: Chairma Chinese Acade Address: (stre Xiao Hong Sha	n No. 44 Province, 430071 P.R. (b) (6) (c) (c) erson: Dr. Xi Zhou (b) (6) n of Institutional Animalmy of Science et address, city, state,	zip code) China Fax: +86.27.87198209 Date: June 28 th 2019 al Care and Use Committee, Wuhan Institute of Virology zip code)
Title: Director Address: (stre Xiao Hong Sha Wuhan, Hubei Phone: E-mail: IACUC Chairpe Signature: Title: Chairma Chinese Acade Address: (stre Xiao Hong Sha	n No. 44 Province, 430071 P.R. (b) (6) (c) (c) erson: Dr. Xi Zhou (b) (6) n of Institutional Animalmy of Science et address, city, state, in No. 44	zip code) China Fax: +86.27.87198209 Date: June 28 th 2019 al Care and Use Committee, Wuhan Institute of Virology zip code)

III. PHS Approval (to be completed by OI AW)

Venita B. Thornton, D.V.M, M.P.H.
Senior Assurance Officer, Division of Assurances
Office of Laboratory Animal Welfare (OLAW)
NIH/OD/OER
6700B Rockledge Drive
Suite 2500-MSC 6910
Bethesda, Maryland 20892

Grant/Contract #: 2R01AI110964-06 | Animal Welfare Assurance #: A7941-03

Effective Date:
6/24/2019 | Expiration Date: (duration of project, up to 5 years)

From: Aleksei Chmura

To: Girma, Tseday (NIH/NIAID) [E]

Cc: Peter Daszak; 李泓莹; Evelyn Luciano; Alison Andre

Subject: Re: Grant Number: 2R01AI110964 - 06 PI Name: DASZAK, PETER

 Date:
 Tuesday, June 11, 2019 4:55:20 PM

 Attachments:
 C&P SIMS 2019 updated.docx

C&P ZHOU 2019 updated.docx C&P HU 2019 updated.docx

Importance: High

Dear Tseday,

Apologies for the errors. The excess-in- (b) (4), (b) (6) allocation in C&Ps for Sims, Zhou, and Hu were due to copy-paste-errors and some expired or since-changed grant/time allocations. When corrected, they all are within the (b) (4), (b) (6) limit.

Please find these three C&Ps attached. Should I upload them via the Just in Time portal?

Let me know anytime, if there are any additional questions or details required.

Sincerely,

-Aleksei

Aleksei Chmura, PhD Chief of Staff

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

(b) (6) (office) (b) (6) (mobile)

www.ecohealthalliance.org

EcoHealth Alliance leads cutting-edge scientific 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: Girma, Tseday (NIH/NIAID) [E] (b) (6)

Sent: Tuesday, June 11, 2019 2:24 PM

To: Peter Daszak; Peter Daszak Cc: Stemmy, Erik (NIH/NIAID) [E]

Subject: Grant Number: 2R01AI110964 - 06 PI Name: DASZAK, PETER

Good afternoon.

Thank you for submitting the JIT for the above mentioned grant. Regarding the other support submitted for Amy Sims, Peng Zhou and Ben Hu, When I add the efforts of all the grants in the

other support (including some of the grants listed under pending that have a to be paid status), the total active support will be higher than (b) (4). (b) (6) including the effort for the above mentioned grant. While an individual may be affiliated with a number of organizations, the combination of appointments can be no higher than (b) (4). (b) (6).

Please indicate how much effort will be taken from which grants. We need specifics that shows the individuals will not go over (b) (4). (b) (6) at the time award. Please send revised other support.

Please send me the information ASAP but no later than Wednesday, 06/12/2019

Thanks, Tseday

Tseday Girma, MPA
Grants Management Specialist
National Institutes of Allergy and Infectious Diseases
5601 Fishers Lane, Room 4E49
Rockville, MD 20852

Phone: (b) (6)

Email: (b) (6)

NIAID, National Institutes of Health, DHHS

Effective January 1, 2017, NIH closeout documentation policy has changed (see NOT-OD-17-022). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the NIH RPPR Page.

*** The information in this email and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the originally intended recipient. If you have received this email in error, please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of NIAID by one of its representatives.***

Current and Pending Support
(See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for e information may delay consideration of this proposed		d other senior personnel.	Failure to provide this
mormation may dotal control of the propos		ing NSF) to which this proposal I	nas been/will be submitted.
Investigator: Amy Sims			
Support:	bmission Planned in N	Near Future	☐ *Transfer of Support
Project/Proposal Title:			
Understanding the Risk of Bat Coronavirus Emergence Source of Support: NIAID			
Total Award Amount: \$3,586,760 Total Award	Period Covered: 06/0	1/2019 - 5/31/2024	
Location of Project: EcoHealth Aliance and International	I Field and Lab Locati	ions	
Person-Months Per Year Committed to the	Cal: (b) (4).	Acad:	Sumr:
Support:	bmission Planned in N	Near Future	☐ *Transfer of
			Support
Project/Proposal Title:			
Mechanisms of MERS-CoV Entry, Cross-Species Trans	mission and Pathoger	nesis	
Source of Support: NIH/NIAID	Deviced Covered 04/00	VIE 00/04/0000	
	Period Covered: 04/20	0/15 - 03/31/2020	
Location of Project: UNC Chapel Hill	(ъ) (4),	A STATE OF THE PARTY OF THE PAR	(O.)
Person-Months Per Year Committed to the	Cal: (b) (6)	Acad:	Sumr:
Support:	bmission Planned in N	Near Future	*Transfer of Support
Project/Proposal Title:			опрон
C. C. S. C.			
Antiviral Drug Discovery and Development Center			
Source of Support: NIH/NIAID			
Total Award Amount \$2,250,000 Total Award	Period Covered: 03/0	01/19-02/28/24	
Location of Project: EcoHealth Alliance and Internation	al Field and Lab Locat	tions	
Person-Months Per Year Committed to the	Cal: (b) (4), (b)	Acad:	Sumr:
Support:	bmission Planned in N		☐ *Transfer of
			Support
Project/Proposal Title:			
5	N		
Diagnostic and Prognostic Biomarkers for Viral Severe Source of Support: NIH/NIAID	Lung Disease		
	Period Covered: 03/0	1/1.4 02/28/20	
Location of Project: UNC Chapel Hill	enod Covered. 03/0	1/14-02/20/20	
[[[[[[[[[[[[[[[[[[[Cal: (b) (4),	Anada	C
Person-Months Per Year Committed to the Support:	(b) (6)	Acad: Submission Planned in	Sumr: Transfer of
Support.	пен 🗆 Ренапу	☐ Submission Flamed in	Li Transfer of
Project/Proposal Title:			
Broad-spectrum antiviral GS-5734 to treat			
Source of Support: NIH	Award Ported Covers	d- ng/ng/17 - n7/21/22	
Total Award Amount: \$919,427 Total Location of Project: UNC Chapel Hill	Award Feriod Govered	d: 08/09/17 - 07/31/22	
Person-Months Per Year Committed to the	Cal (b) (4),	Acad:	Sumr:
*If this project has previously been funded by anot			
preceding funding period.	is agency, picaso	not also remote intermetion	The minimum and the state of

Current and Pending Support
(See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for ear information may delay consideration of this proposa	l,	and the contract of the contra
Investigator: Amy Sims	Other agencies (including NSF) to which this	proposal has been/will be submitted
Support: ☐ Current ☐ Pending ☐ Project/Proposal Title:	Submission Planned in Near Future	☐ Transfer of Support
How MERS-CoV Regulates Innate Immunity in Primary H Source of Support: NIH	luman Lung Cells	
Total Award Amount: \$250,000 Total A	ward Period Covered 07/01/19-06/30/21	
Location of Project: UNC Chapel Hill		
Person-Months Per Year Committed to the Project.	Cal: (b) (4). Acad:	Sumr:
Support: ☐ Current ☐ Pending ☐ Project/Proposal Title:	Submission Planned in Near Future	
MERS-CoV Regulates Cell Death in Primary Human Lung	g Cells	
Source of Support: NIH		
	ward Period Covered: 09/01/19-08/31/21	
Location of Project: UNC Chapel Hill		
Person-Months Per Year Committed to the Project.	Cal: (b) (4), Acad:	Sumr:
*If this project has previously been funded by anoth- preceding funding period.	er agency, please list and furnish inform	nation for immediately

Current and Pending Support
See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other	r senior personnel. Fallure to provide this	information may delay consideration of this proposal.
	Other agencies (including NSF) to	which this proposal has been/will be submitted.
Investigator: Ben Hu		
Support:	Submission Planned in Near	Future
Understanding the Risk of Bat Coronavirus Emergen	ce	
Source of Support: NIAID		
Total Award Amount: \$3,586,760 Total Aw	ard Period Covered: 06/01/201	9 - 5/31/2024
Location of Project: EcoHealth Aliance and Internation	CONTRACTOR OF THE PROPERTY OF	
Person-Months Per Year Committed to the Project.	Cal: (6) (4). (6) Aca	d: Sumr:
Support:	Submission Planned in Near	Future
Pathogenicity studies of two novel bat SARSr-CoVs of	on transgenic mice	
expressing human ACE2		
Source of Support: National Natural Science Foundation	on of China	
Total Award Amount: \$ 44,776 Total Aw	ard Period Covered: 01/01/201	9-12/31/2021
Location of Project: Wuhan Institute of Virology, Co. Person-Months Per Year Committed to the Project.	AS (b) (4). (cal: (b) (6) Aca	d: Sumr:
Support:	Submission Planned in Near	Future *Transfer of Support
Project/Proposal Title:		Array Santa Caraca Cara
PREDICT-2		
Source of Support: USAID		
Total Award Amount: \$38,000,000 Total Aw	ard Period Covered: 10/01/201	4-09/2019
Location of Project: EcoHealth Alliance, subcontract from	om UC Davis (prime)	
Person-Months Per Year Committed to the Project.	Cal: (b) (4) (b) Aca	d: Sumr:
Support:	Submission Planned in Near	Future
Bat Virology		
Source of Support: National Natural Science Foundation	on of China	
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Location of Project: Wuhan Institute of Virology, CAS	(b) (4), (b)	
Person-Months Per Year Committed to the Project.	Cal: (6) Aca	d: Sumr:
Support:	Submission Planned in Near	Future
Source of Support:		
Total Award Amount: \$ Total Aw	ard Period Covered:	
Location of Project:		
Person-Months Per Year Committed to the Project.	Cal; Aca	d: Sumr:
"If this project has previously been funded by another agency, please list an	d furnish information for immediately pred	
NSF Form 1239 (7/95)		USE ADDITIONAL SHEETS AS NECESSARY

Current and Pending Support
See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each investigator and other	er senior personnel. Failure to provide this information in	nay delay consideration of this proposal.
	Other agencies (including NSF) to which this p	roposal has been/will be submitted.
Investigator: Peng Zhou		
Support: ☐ Current ☐ Pending ☐ Project/Proposal Title:	Submission Planned in Near Future	
Understanding the Risk of Bat Coronavirus Emergen	се	
Source of Support: NIAID		
The state of the s	vard Period Covered: 06/01/2019 - 5/31/2	024
Location of Project: EcoHealth Aliance and Internation	al Field and Lab Locations	
Person-Months Per Year Committed to the Project.	Cal: (b) (4). (b) Acad:	Sumr:
Support:	Submission Planned in Near Future	
Combating the next SARS- or MERS-like emerging i	nfectious	
disease outbreak by improving active surveillance Source of Support: National Natural Science Foundati	on of China	
[[2][[[1][[[2][[4][[3][[3][[3][[3][[3][[3][[3][[3][[3	vard Period Covered: 01/01/2017-12/31/2	019
Location of Project: Wuhan Institute of Virology, CAS	and Duke-NUS	
Person-Months Per Year Committed to the Project.	Cal (b) (4), (b) Acad:	Sumr:
Support:	Submission Planned in Near Future	☐ *Transfer of Support
Interferon responses in SARS-Like Coronavirus infection Bat cells Source of Support: National Basic Research program Total Award Amount: \$100,298 Total Aw Location of Project: Wuhan Institute of Virology, CAS	of China vard Period Covered: 01/01/2018-12/31/2	022
Person-Months Per Year Committed to the Project.	(b) (4). (b) Cal: (6) Acad:	Sumr:
Support:	Submission Planned in Near Future	*Transfer of Support
Source of Support: National Natural Science Foundati	on of China	
Total Award Amount: \$232,836 Total Aw	vard Period Covered: 01/01/2019-12/31/2	021
Location of Project: Wuhan Institute of Virology		
Person-Months Per Year Committed to the Project.	Cal: (6) (4). (6) Acad:	Sumr:
Support:	Submission Planned in Near Future	
Source of Support:		
	vard Period Covered:	
Location of Project:	4.0	Auren I
Person-Months Per Year Committed to the Project.	Colt	Citizen (1)
*If this project has previously been funded by another agency, please list ar	Cal: Acad:	Sumr:

NSF Form 1239 (7/95)

Just In Time Report

	Report submitted on :	05/06/2019 11:01 PM
IRB Confirmation:		
Human Subjects Assurance Number:		
Human Subjects Education:	No Human Subjects Education was provided	
IACUC Confirmation:		

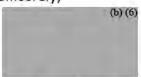
t2R01Al110964 - Understanding the Risk of Bat Coronavirus Emergence (Pl, Daszak)

6 May 2019

Dear NIAID Just-in-Time,

Please find Active and Pending Support information for ALL individuals designated in our application as Senior/Key Personnel. These individuals are as follows (below) and their respective active and pending support details are on the following pages. The order is kept identical to that in our proposal. If additional details are required, please contact me anytime.

Sincerely,



Peter Daszak President, EcoHealth Alliance 460 West 34th Street – Ste. 1701 New York, NY 10001

Count	Role	Key Personnel	Institution	Page
1	Principal Investigator	Daszak, Peter	EcoHealth Alliance	1-2
2	Co-Investigator	Shi, Zhengli	Wuhan Institute of Virology	3
3	Co-Investigator	Olival, Kevin	EcoHealth Alliance	4-5
4	Co-Investigator	Baric, Ralph	University of North Carolina at Chapel Hill	6-9
5	Co-Investigator	Ross, Noam	EcoHealth Alliance	10
6	Research Scientist	Latinne, Alice	EcoHealth Alliance	11
7	Research Scientist	Li, Hongying	EcoHealth Alliance	12
8	Co-Investigator	Francisco, Leilani	EcoHealth Alliance	13
9	Co-Investigator	Sims, Amy	University of North Carolina at Chapel Hill	14- 15
10	Research Scientist	Hagan, Emily	EcoHealth Alliance	16
11	Co-Investigator	Zhu, Guangjian	East China Normal University	17
12	Co-Investigator	Wang, Linfa	Duke-NUS Medical School	18
13	Co-Investigator	Ren, Lili	Institute of Pathogen Biology	
14			Institute of Pathogen Biology	
15	Co-Investigator	Zhou, Peng	Wuhan Institute of Virology	21
16	Co-Investigator	Hu, Ben	Wuhan Institute of Virology	22
17	Research Scientist	Chmura, Aleksei	EcoHealth Alliance	23

(See GPG Section II.D.8 for guidance on information to include on this form.)

	n may delay consi	deration of this prop		or and other senior p	ersonnel. Failt	ure to provide
Laura Marata a B	han Berent		Othe	er agencies (includin	g NSF) to whic	h this proposal
Investigator: P						
Support:	☐ Current	☐ Pending	⊠ Subm	ission Planned in Ne	ear Future	☐ *Transfer of Support
Project/Propos	al Title: AccelNet:	EpiDyn: Predicitng	Disease and	Popualtion Dynami	cs for Improved	
Source of Sup	port: NSF - EEID					
Total Award A	mount: \$358,109	To	tal Award P	eriod Covered: 09/01	1/2019-08/2020)
Location of Pro	piect: EcoHealth A	lliance, subcontract	from UC Da	vis (prime)		
		itted to the Project.	0.0	Cal: (b) (4),	Acad: 0.0	Sumr: 0.0
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Project/Proper	al Title: PREDICT	.0				or Support
		ging Pandemic Thre	oto			
		The state of the s			10011 001001	
	mount: \$38,000,00			eriod Covered: 10/01	1/2014- 09/201	9
		lliance, subcontract	from UC Da	vis (prime)	7.57	
April 1 and 1 and 1 and 1 and 1	A THE RESERVE OF THE PARTY OF T	itted to the Project.		Cal: (b) (4), (b) (6)	Acad:	Sumr:
Support:	□ Current	☐ Pending	☐ Subm	ission Planned in Ne	ear Future	☐ *Transfer of Support
Project/Propos	al Title: Understar	nding the Risk of Ba	t Coronaviru	s Emergence		or cupport
R01Al110964	ar mor ondorda	ong mo mon or ba		o Line gance		
Source of Sup	port: NIAID					
	port. THE					
Intal Award A	mount: \$3 086 73	5 To	tal Award P	eriod Covered: 06/01	1/2014-05/31/2	019
	mount: \$3,086,73			eriod Covered: 06/01	1/2014-05/31/2	019
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Location of Pro	oject: EcoHealth A s Per Year Comm	Iliance and Internation	onal Field a	nd Lab Locations (b) (4), (b) Cal: (6)	Acad:	Sumr:
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Location of Properson-Months Support: Project/Propos Source of Support: Total Award Ai Location of Properson-Months Support: Project/Propos Source of Support: Project/Propos Source of Support: Location of Properson-Months	pject: EcoHealth As Per Year Comm Current Current Cal Title: Optimal Seport: NSF – Division Current Current Current Current Current Current Current Cal Title: Understan port: NIAID mount: \$3,586,760 pject: EcoHealth As Seport: Properties of the Current Cal Title: Understan Current Cal Title: Understan Comments Seport: NIAID Complete: EcoHealth As Seport: Properties of the Comments Seport Sep	Illiance and International Internation	Submonal Field and Submonal Submonal Submonal Submonal Field and Submo	nd Lab Locations Cal: (b) (4), (b) (6) dission Planned in Ne ast Asia's Tropical F nces eriod Covered: TBD Cal: (b) (4), (b) dission Planned in Ne s Emergence eriod Covered: 06/01 and Lab Locations (b) (4),	Acad: ear Future orests Acad: ear Future 1/2019 - 5/31/20 Acad:	Sumr:

AS NECESSARY

(See GPG Section II.D.8 for guidance on information to include on this form.)

	Peter Daszak	deration of this propo		her agencies	(includin	g NSF) to whic	h this proposal
Support:	☐ Current	□ Pending	Sub	mission Plan	ned in Ne	ear Future	☐ *Transfer of Support
Source of Su		A network of network	ks liliking	ecology, com	servation	i, and disease t	amergence
	Amount: \$748,847	Tot	al Award	Period Cover	ed: 10/0	1/019 – 09/30/2	12
	roject: US and Inter		ai / iiiai b	1 01100 00101			
	hs Per Year Comm		0.0	Cal:	(b) (4), (b) (6)	Acad: 0.0	Sumr: 0.0
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(See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided this information may delay consideration of this		stigator and other senio	r personnel. Fail	ure to provide
Investigator: Zhengli Shi		Other agencies (include	ling NSF) to whic	h this proposal
Support:		Submission Planned in	A second	☐ *Transfer of Support
Project/Proposal Title: Geographical distribution	on and genet	ic variation of pathogen	s in Africa	
Source of Support: SAJC201605 Sino-Africa J	Joint Researc	h Center, Chinese Acad	demy of Sciences	
Total Award Amount: \$ 447,760		ard Period Covered: 01		
Location of Project: Wuhan Insitute of Virology	& Sino-Afric	a Joint Research Cente	er, Chinese Acade	emy of Sciences
Person-Months Per Year Committed to the Pro	oject. 0.0	Cal: (b) (4),	Acad: 0.0	Sumr: 0.0
Support:	ng 🗆	Submission Planned in	Near Future	☐ *Transfer of Support
Project/Proposal Title: Evolution mechanism of	of the adaptio	n of bat SARS-related o	coronaviruses to h	nost receptor
Source of Support: 31770175 National Natura	Science Fo	undation of China		
Total Award Amount: \$ 98,507	Total Aw	ard Period Covered: 01	/01/2018-12/31/2	021
Location of Project: Wuhan Insitute of Virology				
Person-Months Per Year Committed to the Pre		Cal: (b) (4),	Acad:	Sumr:
Support:	ng 🗆	Submission Planned in	Near Future	☐ *Transfer of Support
R01Al110964 Source of Support: NIAID Total Award Amount: \$3,086,735 Location of Project: Wuhan Insitute of Virology	y, Chinese Ad			
Person-Months Per Year Committed to the Pro		Cal: (b) (4).	Acad:	Sumr:
Support:	ng 📙	Submission Planned in	Near Future	☐ *Transfer of Support
Project/Proposal Title: Genetic evolution and t				es
Source of Support: XDB29010000 The strateg		내 가는 가능성이 작대가 하나서 보다 이 없었다.		
Total Award Amount: \$1,305,970		ard Period Covered: 07	/01/2018-06/30/2	023
Location of Project: Wuhan Institute of Virolog		(b) (4)		
Person-Months Per Year Committed to the Pre	the second second second	Cal: (b) (6)	Acad:	Sumr:
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Source of Support: Total Award Amount:	Total Ave	ard Period Covered:		
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*If this project has previously been funded by a preceding funding period.	0.40		23000	2 40 th t
NSF Form 1239 (10/99)				TIONAL SHEETS AS NECESSARY

(See GPG Section II.D.8 for guidance on information to include on this form.)

Support: Current Pending Submission Planned in Near Transfer of Support Future Project/Proposal Title: AccelNet: Integrating Mammalian Ecology, Conservation Biology, and Zoonotic Disease Research Project Support: NSF Total Award Amount: \$749,138 Total Award Period Covered: 10/01/19 – 9/30/22 Description of Project: Global Person-Months Per Per Year Committed to the Cal: (6) (6) Acad: Sumr: Support: Current Pending Submission Planned in Near Transfer of Support Folial Award Amount: \$2,349,106 Total Award Period Covered: 11/01/19 – 10/31/22 Description of Project: USA, Georgia, Jordan Person Months Per Year Committed to the Cal: (6) (6) Acad: Sumr: Support: Current Pending Submission Planned in Near Transfer of Support Future Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence Source of Support: NIH Fotal Award Amount: \$3,586,760 Total Award Period Covered: 06/01/19 – 05/31/24 Description of Project: US and China Person-Months Per Year Committed to the Cal: (6) (6) Acad: Sumr: Support: Current Pending Submission Planned in Near Transfer of Support Person-Months Per Year Committed to the Cal: (6) (6) Acad: Sumr: Support: Current Pending Submission Planned in Near Transfer of Support Project/Proposal Title: Drivers of Nipah virus spillover across Bangladesh Source of Support: NIH NIAID Total Award Period Covered: 09/01/2019 – 08/31/2024 Description Project: USA, Global Person-Months Per Year Committed to the Cal: (6) (6) Acad: Sumr: Person-Months Per Year Committed to the Cal: (6) (6) Acad: Sumr: Person-Months Per Year Committed to the Cal: (6) (6) Acad: Sumr: Person-Months Per Year Committed to the Cal: (6) (6) Acad: Sumr: Person-Months Per Year Committed to the Cal: (6) (6) Acad: Sumr: Person-Months Per Year Committed to the Cal: (6) (6) Acad: Cal: (6) (6) Acad: Cal: (6) (6) Acad: Cal: (6) (Officer (1992), to Balting	Ot	her agencies (inclu	ding NSF)	to which this proposal has
Future Project/Proposal Title: AccelNet: Integrating Mammalian Ecology, Conservation Biology, and Zoonotic Disease lessarch Source of Support: NSF fotal Award Amount: \$749,138	nvestigator: Kevin Olival				
Research Source of Support: NSF Total Award Amount: \$749,138	Support:			n Near	☐ *Transfer of Suppo
Total Award Period Covered: 10/01/19 – 9/30/22 Location of Project: Global Person-Months Per Year Committed to the Cal: (6) (6) Acad: Sumr: Support: Current Pending Support: Future Project/Proposal Title: Strengthening biosurveillance and early detection capabilities for MERS-CoV and Other coronaviruses in USCENTCOM and USEUCOM Source of Support: GHERI Total Award Amount: \$2,849,106 Total Award Period Covered: 11/01/19 – 10/31/22 Location of Project: USA, Georgia, Jordan Person-Months Per Year Committed to the Cal: (6) (6) Acad: Sumr: Support: Gurrent Pending Submission Planned in Near Transfer of Support Future Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence Source of Support: US and China Person-Months Per Year Committed to the Cal: (6) (6) Acad: Sumr: Support: US and China Person-Months Per Year Committed to the Cal: (6) (6) Acad: Sumr: Support: During Submission Planned in Near Transfer of Support Proture Source of Support: NIH Total Award Amount: \$3,586,760 Total Award Period Covered: 06/01/19 – 05/31/24 Location of Project: US and China Person-Months Per Year Committed to the Cal: (6) (6) Acad: Sumr: Support: During Submission Planned in Near Transfer of Support Proture Project/Proposal Title: Drivers of Nipah virus spillover across Bangladesh Source of Support: NIH NIAID Total Award Period Covered: 09/01/2019 – 08/31/2024 Location of Project: USA, Global Person-Months Per Year Committed to the Cal: (6) (6) Acad: Sumr: Support: DTRA Foral Award Amount: \$4,391,444 Total Award Period Covered: 10/02/2017 – 10/01/2022 Location of Project: USA, Western Asia Person-Months Per Year Committed to the Cal: (6) (6) Acad: Sumr: Support: DTRA Foral Award Amount: \$4,391,444 Total Award Period Covered: 10/02/2017 – 10/01/2022	Project/Proposal Title: AccelNet: Inte Research	egrating Mammalia	an Ecology, Conse	rvation Biol	ogy, and Zoonotic Disease
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NSF Form 1239 (10/99)

Support:	□ Current	☐ Pending	☐ Submission Pla Future	anned in	n Near	☐ *Transfer of Support
Project/Pro	oosal Title: Under	standing the Ris	k of Coronavirus Em	ergenc	е	
	upport: NIH NIA Amount: \$3,086		ital Award Period Co	vered: I	09/01/2016	- 08/31/2021
The second secon	Project: USA, G			b) (4).	33,01,2010	00/01/2021
	ths Per Year Co		2 - Y	b) (6)	Acad:	Sumr:
Support:	□ Current	Pending	Submission Pla	anned i	n Near	☐ *Transfer of Support
Project/Proj	oosal Title: Emer	ging Pandemic T	hreats: PREDICT2			
Source of S	upport: USAID					
	Amount: \$21,00	0,000 To	tal Award Period Co	vered:	10/01/2014	- 09/30/2019
	Project: Global oths Per Year Co	mmitted to the	Cal:	(b) (4). (b) (6)-	Acad:	Sumr:

(See GPG Section II.D.8 for guidance on information to include on this form.)

	salete Davida			Other agencies (including I	NSF) to which thi	is proposal has been/will be submitte
nvestigator: R			_			
Support: Project/Proposa	⊠ Current al Title:	☐ Pending	ш	Submission Planned in N	ear Future	☐ *Transfer of Support
Natural history Source of Supp		nsmission patterns	of sapo	ovirus in a Nicaraguan birt	h cohort	
Total Award Am	ount: \$500,513	т.	otal Aw	ard Period Covered: 09/2	27/16-08/31/21	
ocation of Proj	ect: UNC Chape	Hill		-		
Person-Months	Per Year Commit	tted to the Project.		Cal: (b) (4),	Acad:	Sumr:
Support: Project/Proposa	⊠ Current al Title:	☐ Pending		Submission Planned in N	ear Future	☐ *Transfer of Support
Nicaraguan Em Source of Supp		mic Diseases (NEE	D)			
otal Award Am	ount: \$230,000	T	otal Aw	ard Period Covered: 05/1	0/18-02/28/23	
ocation of Proj	ect: UNC Chape	Hill		as a		
Person-Months	Per Year Commit	tted to the Project.		Cal: (b) (4), (b) (6)	Acad:	Sumr:
Support:	□ Current	☐ Pending		Submission Planned in N	ear Future	☐ Transfer of Support
	acterization of Fur	nctional RNA Struct	ures in	the ZikV genome		
Molecular Chare Source of Supp Total Award Am Location of Proj	acterization of Fur ort: NIH nount: \$150,000 ject: UNC Chape	T Hill		ard Period Covered 02/05		
Molecular Chare Source of Supp Fotal Award Am Location of Proj Person-Months	acterization of Fur ort: NIH nount: \$150,000 ject: UNC Chape Per Year Commit	T Hill tted to the Project.		ard Period Covered 02/05 Cal: (b) (4),	Acad:	Sumr:
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Molecular Chara Source of Supp Fotal Award Am Location of Proj Person-Months Support: Project/Proposa Understanding I Source of Supp Fotal Award Am Location of Proj	acterization of Fur ort: NIH nount: \$150,000 ject: UNC Chape Per Year Commit Current al Title: the Risk of Bat Co ort: NIAID nount \$3,586,760 ject: EcoHealth A	T Hill Itted to the Project. Pending pronavirus Emerger T Illiance and Internat	otal Aw	Cal: (6) (4), (b) (6) Submission Planned in N ard Period Covered: 06/	Acad: ear Future 01/2019 - 5/31	☐ *Transfer of Support
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Molecular Chara Source of Supp Fotal Award Am Location of Proj Person-Months Support: Project/Proposa Understanding I Source of Supp Fotal Award Am Location of Proj	acterization of Furort: NIH nount: \$150,000 ject: UNC Chape Per Year Commit Current al Title: the Risk of Bat Coort: NIAID nount \$3,586,760 ject: EcoHealth A Per Year Commit	T Hill Itted to the Project. Pending pronavirus Emerger T Illiance and Internat	otal Aw	Cal: (b) (4), Submission Planned in N ard Period Covered: 06/ eld and Lab Locations	Acad: ear Future 01/2019 - 5/31 Acad:	☐ *Transfer of Support
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Current and Pending Support (See GPG Section II.D.8 for guidance on information to include on this form.)

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nvestigator: Ral	ph Baric			Other agencies (including i	NSF) to which this	proposal has been/will be submitted
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		efense Pathogens	s in the C	Collaborative Cross		
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Support: Project/Proposal	☑ Current Title:	☐ Pending		Submission Planned in N	ear Future	☐ *Transfer of Support
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Current and Pending Support (See GPG Section II.D.8 for guidance on information to include on this form.)

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nvestigator: F				Other agencies (including N	NSF) to which this	proposal has been/will be submitte
Support: Project/Proposa	☐ Current al Title:	☐ Pending		Submission Planned in N	ear Future	☐ *Transfer of Support
Determinants o Source of Supp		elity in Replication a	and Path	nogenesis		
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ocation of Pro	ject: UNC Chape	Hill		DAY AND		
Person-Months	Per Year Commit	tted to the Project.		Cal: (b) (4).	Acad:	Sumr:
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Broad-spectrun Source of Supp		4 to treat MERS-C	oV and	related emerging CoV		
otal Award Am	nount: \$919,427	া	otal Aw	ard Period Covered: 08/0	9/17-07/31/22	
ocation of Pro	ject: UNC Chape	Hill		(b) (d)		
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Support:	□ Current	☐ Pending		Submission Planned in N	ear Future	☐ Transfer of Support
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(See GPG Section II.D.8 for guidance on information to include on this form.)

Investigator: Ralph Baric		Other agencies (in	cluding N	SF) to which th	is proposal has been/will be submitted
Support:	ending [Submission Plani	ned in Ne	ear Future	☐ *Transfer of Support
Total Award Amount: \$3,220,355	Total A	ward Period Cover	ed: 03/01	/19-02/29/24	
Location of Project: UNC Chapel Hill Person-Months Per Year Committed to the	ne Project	Cal:	(b) (4). (b) (6)	Acad:	Sumr:

See GPG Section II.D.8 for guidance on information to include on this form.) The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal. Other agencies (including NSF) to which this proposal has been/will be submitted. Investigator: Noam Ross □ Pending Support: ☐ Current Submission Planned in Near Future ☐ *Transfer of Support Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence Source of Support: NIAID Total Award Period Covered: 06/01/2019 - 5/31/2024 Total Award Amount: \$3,586,760 Location of Project: EcoHealth Aliance and International Field and Lab Locations Person-Months Per Year Committed to the Project. Sumr: (b) (6) Pending □ Current ☐ Submission Planned in Near Future ☐ *Transfer of Support Support: Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence R01Al110964 Source of Support: NIAID Total Award Amount: \$3,086,735 Total Award Period Covered: 06/01/14 - 05/31/19 Location of Project: EcoHealth Aliance and International Field and Lab Locations (b) (4). Person-Months Per Year Committed to the Project. Sumr: (b) (6) Support: Current Pending Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Source of Support: Total Award Amount: \$ Total Award Period Covered: Location of Project: Person-Months Per Year Committed to the Project. Cal: Acad: Sumr: Pendina Support: Current Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Source of Support: Total Award Period Covered: Total Award Amount: \$ Location of Project: Person-Months Per Year Committed to the Project. Cal: 1.0 Sumr: Pending Submission Planned in Near Future Support: Current *Transfer of Support Project/Proposal Title: Source of Support. Total Award Amount: \$ Total Award Period Covered: Location of Project:

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Person-Months Per Year Committed to the Project.

If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period. USE ADDITIONAL SHEETS AS NECESSARY

See GPG Section II.D.8 for guidance on information to include on this form.) The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal. Other agencies (including NSF) to which this proposal has been/will be submitted. Investigator: Alice Latinne □ Pending Support: ☐ Current Submission Planned in Near Future ☐ *Transfer of Support Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence Source of Support: NIAID Total Award Period Covered: 06/01/2019 - 5/31/2024 Total Award Amount: \$3,586,7 Location of Project: EcoHealth Alliance and International Field and Lab Locations Person-Months Per Year Committed to the Project. Sumr: (b) (6) □ Current Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support Support: Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence R01Al110964 Source of Support: NIAID Total Award Period Covered: 06/01/14 - 05/31/19 Total Award Amount: \$3,086,735 Location of Project: EcoHealth Aliance and International Field and Lab Locations Person-Months Per Year Committed to the Project. Sumr: Acad: Support: Current Pending Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Source of Support: Total Award Amount: \$ Total Award Period Covered: Location of Project: Person-Months Per Year Committed to the Project. Cal: Acad: Sumr: Pendina Support: Current Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Source of Support: Total Award Period Covered: Total Award Amount: \$ Location of Project: Person-Months Per Year Committed to the Project. Acad: Sumr: Pending Support: Current Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Source of Support: Total Award Amount: \$ Total Award Period Covered: Location of Project:

'If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

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USE ADDITIONAL

Person-Months Per Year Committed to the Project.

See GPG Section II.D.8 for guidance on information to include on this form.) The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal. Other agencies (including NSF) to which this proposal has been/will be submitted. Investigator: Hongying Li □ Pending Support: ☐ Current Submission Planned in Near Future ☐ *Transfer of Support Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence Source of Support: NIAID Total Award Period Covered: 06/01/2019 - 5/31/2024 Total Award Amount: \$3,586,760 Location of Project: EcoHealth Aliance and International Field and Lab Locations Person-Months Per Year Committed to the Project. Sumr: □ Current Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support Support: Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence R01Al110964 Source of Support: NIAID Total Award Period Covered: 06/01/14 - 05/31/19 Total Award Amount: \$3,086,735 Location of Project: EcoHealth Aliance and International Field and Lab Locations Person-Months Per Year Committed to the Project. Acad: Sumr: Support: ☐ Current Pending ☐ Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Source of Support: Total Award Amount: \$ Total Award Period Covered: Location of Project: Person-Months Per Year Committed to the Project. Cal: Acad: Sumr: Pendina Support: Current Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Source of Support: Total Award Period Covered: Total Award Amount: \$ Location of Project: Person-Months Per Year Committed to the Project. Acad: Sumr: Pending Support: Current Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Source of Support: Total Award Amount: \$ Total Award Period Covered: Location of Project:

If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period. NSF Form 1239 (7/95)

Person-Months Per Year Committed to the Project.

(See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for information may delay consideration of this proportion		ormor personnie	. Tallate to provide this
mormation may delay consideration of this prope		SF) to which this p	roposal has been/will be submitted.
Investigator: Leilani Francisco			
Support:	☐ Submission Planned in	Near Future	☐ *Transfer of Support
CNH-L: Land-use change and microbial spillover	as a coupled natural-human	system	
ON 7 E. Earla add onlings and moropial spillovor	as a soupled natural norman	system.	
Source of Support: NSF CNH			
Total Award Amount: \$1,599,991 To	tal Award Period Covered: 07/1/	2018-07/1/202	1
Location of Project: EcoHealth Alliance, Uganda and			
Person-Months Per Year Committed to the Project.	Cal: (b) (4). (b) (6)	Acad:	Sumr:
Support: Current Pending Project/Proposal Title: PREDICT-2	☐ Submission Planned in	Near Future	☐ *Transfer of Support
Source of Support: USAID Emerging Pandemic Th	oreats		
[10] 10 [10] [10] [10] [10] [10] [10] [1	tal Award Period Covered: 10/1/	2017 - 9/30/20	18
Location of Project: EcoHealth Alliance, subcontra	ct from UC Davis (prime)		77
Person-Months Per Year Committed to the Project.	Cal: (b) (4),	Acad:	Sumr:
Support: Current Pending	☐ Submission Planned in		☐ *Transfer of Support
Project/Proposal Title:			
Understanding the Risk of Bat Coronavirus Emer	rgence		
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Source of Support: NIAID			
Total Award Amount: \$3,586,760 To	tal Award Period Covered: 06/0		024
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Current and Pending Support (See GPG Section II.D.8 for guidance on information to include on this form.)

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information may delay consideration of this proposa		hich this proposal has been/will be submitted.
Investigator: Amy Sims	le mar agentice (moleanighter y le	
Support:	Submission Planned in Near Futi	re
Understanding the Risk of Bat Coronavirus Emergence Source of Support: NIAID		
Total Award Amount: \$3,586,760 Total A	ward Period Covered: 06/01/2019	- 5/31/2024
Location of Project: EcoHealth Aliance and International		
Person-Months Per Year Committed to the Project.	Cal: (b) (4). Acad	Sumr:
Support:	Submission Planned in Near Futu	re
Mechanisms of MERS-CoV Entry, Cross-Species Transm Source of Support: NIH/NIAID	ission and Pathogenesis	
Total Award Amount: \$605,933 Total A	ward Period Covered: 04/20/15 - 0	3/31/2020
Location of Project: UNC Chapel Hill	AND AND	
Person-Months Per Year Committed to the Project.	Cal. (b) (4), Acad	Sumr:
Support:	Submission Planned in Near Futi	re Transfer of Support
Project/Proposal Title:		
MERS-CoV Supplement for OMICs Proposal Source of Support: NIH		
	ward Period Covered 06/01/13 05/	21/10
Location of Project: University of Wisconsin	ward i criod devered dere if id der	31/13
Person-Months Per Year Committed to the Project.	Cal: (b) (4), Acad	Sumr:
Support:	Submission Planned in Near Futi	200,000
Project/Proposal Title:	J Oddinission Filamied in Wear Fall	Transfer of Support
,		
Antiviral Drug Discovery and Development Center		
Source of Support: NIH/NIAID		
	ward Period Covered: 03/01/19-0	2/28/24
Location of Project: EcoHealth Alliance and International	Field and Lab Locations	
Person-Months Per Year Committed to the Project.	Cal: (b) (4). Acad	Sumr:
Support:	Submission Planned in Near Futi	
Project/Proposal Title:		
Diagnostic and Prognostic Biomarkers for Viral Severe Lu Source of Support: NIH/NIAID	ng Disease	
Total Award Amount: \$889,074 Total A	ward Period Covered: 03/01/14-02	/28/20
Location of Project: UNC Chapel Hill	(b) (4),	
Person-Months Per Year Committed to the Project.	Cal (b) (6) Acad	Sumr:
*If this project has previously been funded by another	er agency, please list and furnis	h information for immediately
preceding funding period.	The state of the s	

Current and Pending Support (See GPG Section II.D.8 for guidance on information to include on this form.)

The following information shou information may delay conside			r senior personr	nel. Failure to provide this
Investigator: Amy Sims	anov, or time propos		NSF) to which this p	proposal has been/will be submitted.
Support:	☐ Pending	Submission Planned in N	ear Future	☐ *Transfer of Support
Mechanisms of MERS-CoV Entry, Source of Support: NIH/NIAID	Cross-species Transi	mission and Pathogenesis		
Total Award Amount: \$605,933	Total	Award Period Covered: 04/2	20/15-03/31/20	
Location of Project: EcoHealth Ali	ance and Internationa	of the second se		
Person-Months Per Year Committee	ed to the Project.	Cal: (b) (4),	Acad:	Sumr:
Support: Current Project/Proposal Title:	☐ Pending	Submission Planned in N	ear Future	□ *Transfer of Support
Broad-spectrum antiviral GS-5734 Source of Support: NIH	to treat MERS-CoV a	nd related emerging CoV		
Total Award Amount: \$919,427	Total	Award Period Covered: 08/0	9/17 - 07/31/22	
Location of Project: UNC Chapel	Hill	(N) (A)		
Person-Months Per Year Committ	ed to the Project.	Cal: (b) (4),	Acad:	Sumr:
Support:	⊠ Pending	Submission Planned in N	lear Future	☐ Transfer of Support
How MERS-CoV Regulates Innate Source of Support: NIH	Immunity in Primary	Human Lung Cells		
Total Award Amount: \$250,000	Total	Award Period Covered 07/01	1/19-06/30/21	
Location of Project: UNC Chapel	Hill	110 8 8 6 8 5 E		
Person-Months Per Year Committee	ed to the Project.	Cal (b) (4),	Acad:	Sumr:
Support:	⊠ Pending	Submission Planned in N	ear Future	□ *Transfer of Support
How MERS-CoV Regulates Innate	lmmunity in Primary	Human Lung Cells		
Source of Support: NIH Total Award Amount \$275,000	Total	Award Period Covered: 03/	01/19-02/28/24	
Location of Project: UNC Chapel		made i eniod covered. 03/	01/10-02/20/24	
Person-Months Per Year Committ		Cal: (b) (4),	Acad:	Sumr:
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preceding funding period.	con funded by affor	nor agency, picase not an	id (dimari intoffii	ation for infinediately

Current and Pending Support

See GPG Section II.D.8 for guidance on information to include on this form.) The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal. Other agencies (including NSF) to which this proposal has been/will be submitted. Investigator: Emily Hagan □ Pending Support: ☐ Current ☐ Submission Planned in Near Future ☐ *Transfer of Support Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence Source of Support: NIAID Total Award Period Covered: 06/01/2019 - 5/31/2024 Total Award Amount: \$3,586,760 Location of Project: EcoHealth Aliance and International Field and Lab Locations Person-Months Per Year Committed to the Project. Acad: Sumr: ☐ Current Pendina ☐ Submission Planned in Near Future ☐ *Transfer of Support Support: Project/Proposal Title: Source of Support: Total Award Amount: \$ Total Award Period Covered: Location of Project: Person-Months Per Year Committed to the Project. Acad: Sumr: Cal: Support: Current Pending Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Source of Support: Total Award Period Covered: Total Award Amount: \$ Location of Project: Person-Months Per Year Committed to the Project. Cal: Acad: Sumr: Pendina Submission Planned in Near Future Support: Current *Transfer of Support Project/Proposal Title: Source of Support: Total Award Period Covered: Total Award Amount: \$ Location of Project: Person-Months Per Year Committed to the Project. Acad: Sumr: Pending Submission Planned in Near Future Support: Current *Transfer of Support Project/Proposal Title: Source of Support: Total Award Amount: \$ Total Award Period Covered: Location of Project: Person-Months Per Year Committed to the Project.

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If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period. USE ADDITIONAL SHEETS AS NECESSARY

Current and Pending Support See GPG Section II.D.8 for guidance on information to include on this form.) The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal. Other agencies (including NSF) to which this proposal has been/will be submitted. Investigator: Guangjian Zhu □ Pending Support: ☐ Current Submission Planned in Near Future ☐ *Transfer of Support Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence Source of Support: NIAID Total Award Period Covered: 06/01/2019 - 5/31/2024 Total Award Amount: \$3,586,760 Location of Project: EcoHealth Aliance and International Field and Lab Locations Person-Months Per Year Committed to the Project. Sumr: (b) (6) □ Current Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support Support: Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence 1R01Al110964 Source of Support: NIAID Total Award Period Covered: 06/01/2014- 5/31/2019 Total Award Amount: \$2,500,000 Location of Project: EcoHealth Alliance Person-Months Per Year Committed to the Project. Sumr: Acad: Support: ☐ Current Pending Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Source of Support: Total Award Period Covered: Total Award Amount: \$ Location of Project: Person-Months Per Year Committed to the Project. Cal: 0.0 Acad: Sumr: Pendina Support: Current Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Source of Support: Total Award Period Covered: Total Award Amount: \$ Location of Project: Person-Months Per Year Committed to the Project. Acad: Sumr: Pending Support: Current Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Source of Support:

'If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period.

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USE ADDITIONAL

Location of Project:

Total Award Amount: \$

Person-Months Per Year Committed to the Project.

USE ADDITIONAL SHEETS AS NECESSARY

Total Award Period Covered:

Current and Pending Support (See GPG Section II.D.8 for guidance on information to include on this form.)

The following information should be provided for each		enior personne	. Failure to provide this
information may delay consideration of this proposal Investigator: Linfa Wang		NSF) to which th	is proposal has been/will be
Support:	Submission Planned in Ne	ear Future	☐ *Transfer of Support
Source of Support: NIAID			
Total Award Amount: \$3,586,760 Total A	ward Period Covered: 06/01	1/2019 - 5/31/202	24
Location of Project: EcoHealth Allance and International F	ield and Lab Locations		
Person-Months Per Year Committed to the Project.	Cal:	Acad:	Sumr:
Support: ☐ Current ☐ Pending ☐ Project/Proposal Title:	Submission Planned in Ne	ear Future	☐ Transfer of Support
Combating the next SARS-or MERS-like emerging infection	ous disease outbreak by acti	ive surveillance	
Source of Support: National Research Foundation, Singa			
Total Award Amount: SGD\$416,421 Total A	ward Period Covered: 01/01	1/2017 - 31/12/20	019
Location of Project: Duke-NUS Medical School, Singapor	re		
Person-Months Per Year Committed to the Project.	Cal: (b) (4),	Acad:	Sumr:
Support:	Submission Planned in Ne	ear Future	☐ *Transfer of Support
Investigating Febrile Deaths in Tanzania (INDITE)			
Source of Support: NIH			
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Location of Project: Duke-NUS Medical School, Singapo			
Person-Months Per Year Committed to the Project.	Cal: (b) (4).	Acad:	Sumr:
*If this project has previously been funded by anothe preceding funding period.	r agency, please list and f	furnish informat	ion for immediately

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USE ADDITIONAL SHEETS AS NECESSARY

Current and Pending Support See GPG Section II.D.8 for guidance on information to include on this form.) The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal. Other agencies (including NSF) to which this proposal has been/will be submitted. Investigator: Lili Ren □ Pending Support: ☐ Current Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence Source of Support: NIAID Total Award Amount: \$3,586,760 Total Award Period Covered: 06/01/2019 - 5/31/2024 Location of Project: EcoHealth Aliance and International Field and Lab Locations Person-Months Per Year Committed to the Project. Cal: (b) (6) Sumr: Acad: ☐ *Transfer of Support □ Current Pending Submission Planned in Near Future Support: Project/Proposal Title: Key Project of Infectious Diseases Etiology of respiratory tract infections and viral variations Source of Support: Ministry of Science and Technology of China Total Award Amount: \$812,000 Total Award Period Covered: 01/01/2017 - 12/31/2020 Location of Project: China Person-Months Per Year Committed to the Project. Acad: Sumr: Cal: (b) (6) Support: □ Current Pending Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Key Project of Infectious Diseases Techniques for pathogens indentification of respiratory tract infections Source of Support: Ministry of Science and Technology of China Total Award Period Covered: 1/01/2018 - 12/31/2020 Total Award Amount: \$222,300 Location of Project: China Person-Months Per Year Committed to the Project. Acad: Sumr: Pendina Support: Current Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Source of Support: Total Award Period Covered: Total Award Amount: \$ Location of Project: Person-Months Per Year Committed to the Project. Acad: Sumr: Pending *Transfer of Support Support: Current Submission Planned in Near Future Project/Proposal Title: Source of Support: Total Award Amount: \$ Total Award Period Covered:

If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period. NSF Form 1239 (7/95)

Person-Months Per Year Committed to the Project.

Location of Project:

USE ADDITIONAL SHEETS AS NECESSARY

Current and Pending Support

See GPG Section II.D.8 for guidance on information to include on this form.) The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal. Other agencies (including NSF) to which this proposal has been/will be submitted. Investigator: Guo Li □ Pending Support: ☐ Current Submission Planned in Near Future ☐ *Transfer of Support Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence Source of Support: NIAID Total Award Period Covered: 06/01/2019 - 5/31/2024 Total Award Amount: \$3,586,760 Location of Project: EcoHealth Aliance and International Field and Lab Locations Person-Months Per Year Committed to the Project. Sumr: (b) (6) *Transfer of Support □ Current Pending Submission Planned in Near Future Support: Project/Proposal Title: Key technologies for the identification and identification of important respiratory viruses and establishment of reference libraries Source of Support: Ministry of Science and Technology of China Total Award Period Covered: 01/01/2018 - 12/31/2020 Total Award Amount: \$255,401 Location of Project: China Person-Months Per Year Committed to the Project. Acad: Sumr: Support: Current Pending ☐ Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Source of Support: Total Award Amount: \$ Total Award Period Covered: Location of Project: Person-Months Per Year Committed to the Project. Cal: Acad: Sumr: Pendina Support: Current Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Source of Support: Total Award Period Covered: Total Award Amount: \$ Location of Project: Person-Months Per Year Committed to the Project. Acad: Sumr: Pending *Transfer of Support Support: Current Submission Planned in Near Future Project/Proposal Title: Source of Support: Total Award Amount: \$ Total Award Period Covered:

If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period. NSF Form 1239 (7/95)

Person-Months Per Year Committed to the Project.

Location of Project:

USE ADDITIONAL SHEETS AS NECESSARY

Current and Pending Support See GPG Section II.D.8 for guidance on information to include on this form.) The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal. Other agencies (including NSF) to which this proposal has been/will be submitted. Investigator: Peng Zhou □ Pending Support: ☐ Current Submission Planned in Near Future ☐ *Transfer of Support Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence Source of Support: NIAID Total Award Period Covered: 06/01/2019 - 5/31/2024 Total Award Amount: \$3,586,760 Location of Project: EcoHealth Aliance and International Field and Lab Locations Person-Months Per Year Committed to the Project. Cal: Sumr: Acad: (b) (6) □ Current Pendina ☐ Submission Planned in Near Future ☐ *Transfer of Support Support: Project/Proposal Title: Combating the next SARS- or MERS-like emerging infectious disease outbreak by improving active surveillance Source of Support: National Natural Science Foundation of China Total Award Period Covered: 01/01/2017-12/31/2019 Total Award Amount: \$ 358,210 Location of Project: Wuhan Institute of Virology, CAS and Duke-NUS Person-Months Per Year Committed to the Project. Sumr: Acad: Support: □ Current Pending Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Interferon responses in SARS-Like Coronavirus infected Bat cells Source of Support: National Basic Research program of China Total Award Amount: \$100,298 Total Award Period Covered: 01/01/2018-12/31/2022 Location of Project: Wuhan Institute of Virology, CAS Person-Months Per Year Committed to the Project. Cal: Acad: Sumr: □ Current Pending Submission Planned in Near Future *Transfer of Support Support: Project/Proposal Title: Bat Virology Source of Support: National Natural Science Foundation of China Total Award Amount: \$232,836 Total Award Period Covered: 01/01/2019-12/31/2021 Location of Project: Wuhan Institute of Virology Person-Months Per Year Committed to the Project. Cal: Acad: Sumr: (b) (6) □ Current Support: Pending Submission Planned in Near Future ☐ *Transfer of Support Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence R01Al110964 Source of Support: NIAID Total Award Amount: \$3,086,735 Total Award Period Covered: 06/01/14 - 05/31/19

If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period. NSF Form 1239 (7/95)

USE ADDITIONAL

Person-Months Per Year Committed to the Project.

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Sumr:

(6) (6)

Location of Project: EcoHealth Aliance and International Field and Lab Locations

Current and Pending Support

See GPG Section II.D.8 for guidance on information to include on this form.) The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal. Other agencies (including NSF) to which this proposal has been/will be submitted. Investigator: Ben Hu □ Pending Support: ☐ Current ☐ Submission Planned in Near Future ☐ *Transfer of Support Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence Source of Support: NIAID Total Award Period Covered: 06/01/2019 - 5/31/2024 Total Award Amount: \$3,586,760 Location of Project: EcoHealth Aliance and International Field and Lab Locations Person-Months Per Year Committed to the Project. Sumr: Acad: (b) (6) □ Current Pendina ☐ Submission Planned in Near Future ☐ *Transfer of Support Support: Project/Proposal Title: Pathogenicity studies of two novel bat SARSr-CoVs on transgenic mice expressing human ACE2 Source of Support: National Natural Science Foundation of China Total Award Period Covered: 01/01/2019-12/31/2021 Total Award Amount: \$ 44,776 Location of Project: Wuhan Institute of Virology, CAS Person-Months Per Year Committed to the Project. Acad: Sumr: (b) (6) Support: □ Current Pending ☐ Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence R01Al110964 Source of Support: NIAID Total Award Period Covered: 06/01/14 - 05/31/19 Total Award Amount: \$3,086,735 Location of Project: EcoHealth Aliance and International Field and Lab Locations Person-Months Per Year Committed to the Project. Acad: Sumr: Submission Planned in Near Future Support: □ Current Pendina ☐ *Transfer of Support Project/Proposal Title: Bat Virology Source of Support: National Natural Science Foundation of China Total Award Period Covered: 01/01/2019-12/31/2021 Total Award Amount: \$232,836 Location of Project: Wuhan Institute of Virology, CAS Person-Months Per Year Committed to the Project. Acad: Sumr: □ Current Pending ☐ Submission Planned in Near Future Support: *Transfer of Support Project/Proposal Title: PREDICT-2 Source of Support: USAID Total Award Amount: \$38,000,000 Total Award Period Covered: 10/01/2014- 09/2019 Location of Project: EcoHealth Alliance, subcontract from UC Davis (prime) Person-Months Per Year Committed to the Project. (b) (6)

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If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period. USE ADDITIONAL SHEETS AS NECESSARY

Current and Pending Support

See GPG Section II.D.8 for guidance on information to include on this form.) The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal. Other agencies (including NSF) to which this proposal has been/will be submitted. Investigator: Aleksei Chmura □ Pending Support: ☐ Current Submission Planned in Near Future ☐ *Transfer of Support Project/Proposal Title: U.S.-China Collab: Spillover, co-infection and control of bat-origin livestock coranavirusese Source of Support: NSF Total Award Period Covered: 07/01/2019 - 6/30/2024 Total Award Amount: \$2,497,738 Location of Project: US International Field and Laboratory Locations Person-Months Per Year Committed to the Project. Sumr: Acad: (b) (6) *Transfer of Support □ Current Pending Submission Planned in Near Future Support: Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence R01Al110964 Source of Support: NIAID Total Award Amount: \$3,086,735 Total Award Period Covered: 06/01/14 - 05/31/19 Location of Project: EcoHealth Aliance and International Field and Lab Locations Person-Months Per Year Committed to the Project. Sumr: Support: ☐ Current □ Pending ☐ Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Understanding the Risk of Bat Coronavirus Emergence Source of Support: NIAID Total Award Amount: \$3,586,760 Total Award Period Covered: 06/01/2019 - 5/31/2024 Location of Project: EcoHealth Alliance and International Field and Lab Locat Cal: (b) (4), (b) Person-Months Per Year Committed to the Project. Acad: Sumr: Submission Planned in Near Future Support: Current Pendina ☐ *Transfer of Support Project/Proposal Title: Source of Support: Total Award Period Covered: Total Award Amount: \$ Location of Project: Person-Months Per Year Committed to the Project. Acad: Sumr: Pending Support: Current Submission Planned in Near Future *Transfer of Support Project/Proposal Title: Source of Support: Total Award Amount: \$ Total Award Period Covered: Location of Project:

NSF Form 1239 (7/95)

Person-Months Per Year Committed to the Project.

If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding period. USE ADDITIONAL SHEETS AS NECESSARY



06 May 2019

Tseday Girma
Grants Management Specialist
National Institutes of Allergy and Infectious Diseases
5601 Fishers Lane, Room 4E24
Rockville, MD 20852

Dear Tseday,

Please find below our responses to the requested Just-in-Time information requested in your email dated 30 April 2019 for our proposal (2R01Al110964) titled *Understanding the Risk of Bat Coronavirus Emergence* (PI, Daszak).

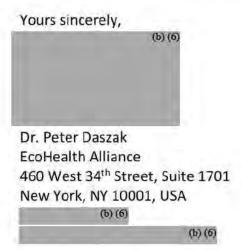
- Current Other Support: Our AOR/SRO has uploaded the other current support information for all senior/key personnel on our proposal via the eRA Commons JIT page.
- 2) IRB Approval Date: Our current (1R01Al110964) NIAID human subject research IRB approvals from Hummingbird IRB and the Medical Ethics Review Board at the School of Health Sciences of Wuhan University are still valid until October 1, 2019. The human subject research study under our proposal (2R01Al110964) will be reviewed for approval by both US and Chinese IRBs through Hummingbird IRB (IORG0007741, IRB00009289, US) and the Medical Ethics Review Board of the Institute of Pathogen Biology of the Chinese Academy of Medical Sciences (FWA00016236, China). Our new human subject research protocol will be submitted to both IRBs by the deadline of 01 June 2019 with review and approvals expected no later than the Meeting and Approval Date of 31 July 2019. We will inform NIAID immediately upon confirmation and provide the date in eRA Commons.

- Dissemination Plan required for NIH-funded clinical trial: No clinical trials are planned under our proposed work. We have human subjects and have provided both the Study Population Criteria and Protection & Monitoring Plan in our proposal.
- 4) <u>Documentation of the Required Education in the Protection of Human Subject Research Participants:</u> All key personnel involved with human subject research have passed the Collaborative Institutional Training Initiative (CITI) Program Human Subjects Research Course. All details have been uploaded via the eRA Commons JIT page.
- 5) IACUC: Our current (1R01Al110964) NIAID protocol IACUC approval is from Tufts University (#G2017-32) through our inter-institutional agreement with them and this expires on 29 February 2020. The OLAW Assurance number listed in eRA Commons (A4059-01) is correct. We will submit our amended protocol for IACUC review by the pre-review deadline of 15th May 2019. The Tufts IACUC Meeting and Approval Date will be on 5th June 2019, we will inform NIAID immediately upon confirmation and provide the date in eRA Commons.

6) Other:

- a. EcoHealth Alliance's EIN number is 31-1726494
- b. The latest F&A rate agreement for the University of North Carolina Chapel Hill dated 23 November 2016 with a rate of 55% is attached
- c. EcoHealth Alliance's latest F&A rate agreement dated 14 November 2018 with a rate of (6) (4) is attached

If you have any other questions, please contact me anytime. We are very appreciative of your consideration and look forward to further details.



COLLEGES AND UNIVERSITIES RATE AGREEMENT

EIN: 566001393A1

ORGANIZATION:

University of North Carolina at Chapel

Hill

2114 Administrative Office Building

CB # 1350

Chapel Hill, NC 27599-1350

DATE:11/23/2016

FILING REF.: The preceding

agreement was dated

05/16/2012

The rates approved in this agreement are for use on grants, contracts and other agreements with the Federal Government, subject to the conditions in Section III.

SECTION I: Facilities And Administrative Cost Rates				
RATE TYPES:	FIXED	FINAL PROV	. (PROVISIONAL) PRED.	(PREDETERMINED)
	EFFECTIVE P	ERIOD		
TYPE	FROM	TO	RATE(%) LOCATION	APPLICABLE TO
PRED.	07/01/2016	06/30/2017	52.00 On-Campus	Organized Research
PRED.	07/01/2017	06/30/2020	55.50 On-Campus	Organized Research
PRED.	07/01/2016	06/30/2020	28.00 Off-Campus (A)	Organized Research
PRED.	07/01/2016	06/30/2020	26.00 Off-Campus (B)	Organized Research
PRED.	07/01/2016	06/30/2020	50.00 On-Campus	Instruction
PRED.	07/01/2016	06/30/2020	28.00 Off-Campus (A)	Instruction
PRED.	07/01/2016	06/30/2020	26.00 Off-Campus (B)	Instruction
PRED.	07/01/2016	06/30/2020	36.00 On-Campus	Other Sponsored Activities
PRED.	07/01/2016	06/30/2020	28.00 Off-Campus (A)	Other Sponsored Activities
PRED.	07/01/2016	06/30/2020	26.00 Off-Campus (B)	Other Sponsored Activities

ORGANIZATION: University of North Carolina at Chapel Hill

AGREEMENT DATE: 11/23/2016

TYPE	FROM	TO	RATE(%) LOCATION	APPLICABLE TO
PROV.	07/01/2020	Until Amended		Use same rates and conditions as those cited for fiscal year ending June

*BASE

Modified total direct costs, consisting of all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel and up to the first \$25,000 of each subaward (regardless of the period of performance of the subawards under the award). Modified total direct costs shall exclude equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of \$25,000. Other items may only be excluded when necessary to avoid a serious inequity in the distribution of indirect costs, and with the approval of the cognizant agency for indirect costs.

⁽A) Off-Campus, Adjacent -- Activites performed within the commuting area of Chapel Hill, N.C.

⁽B) Off-Campus, Remote -- Activities performed outside the commuting area of Chapel Hill, N.C.

ORGANIZATION: University of North Carolina at Chapel Hill

AGREEMENT DATE: 11/23/2016

SECTION II: SPECIAL REMARKS

TREATMENT OF FRINGE BENEFITS:

The fringe benefits are specifically identified to each employee and are charged individually as direct costs. The directly claimed fringe benefits are listed below.

TREATMENT OF PAID ABSENCES

Vacation, holiday, sick leave pay and other paid absences are included in salaries and wages and are claimed on grants, contracts and other agreements as part of the normal cost for salaries and wages. Separate claims are not made for the cost of these paid absences.

OFF-CAMPUS DEFINITION: For all activities performed in facilities not owned by the institution or to which rent is directly allocated to the project(s) the off-campus rate will apply. Grants or contracts will not be subject to more than one F&A cost rate. If more than 50% of a project is performed off-campus, the off-campus rate will apply to the entire project.

Treatment of Transit Service and Network Infrastructure: These costs are based on an annual fixed fee assessed on salaries and wages identified to each employee. Costs are subject to the same principles and definitions described in Sections II and III of this agreement.

Fringe Benefits include: Pension/Retirement, FICA/Medicare, Workers' Compensation, Unemployment Insurance, Health Insurance, Short-Term Disability, and State Severance Pay Plan.

Supplemental Fringe Benefits for members of the Physicians and Associates Practice Plan include: Supplemental Health Insurance, Dental Insurance, Supplemental Retirement, Group Life Insurance, Long-Term Disability, Accidental Death & Dismemberment, and Vision.

Equipment means an article of nonexpendable tangible personal property having a useful life of more than one year, and an acquisition cost of \$5,000 or more per unit.

ORGANIZATION: University of North Carolina at Chapel Hill

AGREEMENT DATE: 11/23/2016

SECTION III: GENERAL

A. LIMITATIONS:

The rates in this Agreement are subject to any statutory or administrative limitations and apply to a given grant, contract or other agreement only to the extent that funds are available. Acceptance of the rates is subject to the following conditions: (1) Only costs incurred by the organization were included in its facilities and administrative cost pools as finally accepted: such costs are legal obligations of the organization and are allowable under the governing cost principles; (2) The same costs that have been treated as facilities and administrative costs are not claimed as direct costs; (3) Similar types of costs have been accorded consistent accounting treatment; and (4) The information provided by the organization which was used to establish the rates is not later found to be materially incomplete or inaccurate by the Federal Government. In such situations the rate(s) would be subject to renegotiation at the discretion of the Federal Government.

B. ACCOUNTING CHANGES:

This Agreement is based on the accounting system purported by the organization to be in effect during the Agreement period. Changes to the method of accounting for costs which affect the amount of reimbursement resulting from the use of this Agreement require prior approval of the authorized representative of the cognizant agency. Such changes include, but are not limited to, changes in the charging of a particular type of cost from facilities and administrative to direct. Failure to obtain approval may result in cost disallowances.

C. FIXED RATES:

If a fixed rate is in this Agreement, it is based on an estimate of the costs for the period covered by the rate. When the actual costs for this period are determined, an adjustment will be made to a rate of a future year(s) to compensate for the difference between the costs used to establish the fixed rate and actual costs.

D. USE BY OTHER FEDERAL AGENCIES:

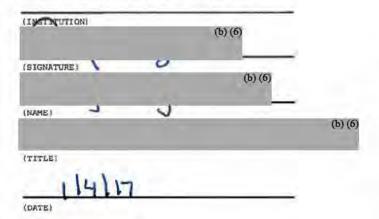
The rates in this Agreement were approved in accordance with the authority in Title 2 of the Tode of Federal Regulations, Part 200 (2 CFR 200), and should be applied to grants, contracts and other agreements covered by 2 CFR 200, subject to any limitations in A above. The organization may provide copies of the Agreement to other Federal Agencies to give them early notification of the Agreement.

E. OTHER:

If any Federal contract, grant or other agreement is reimbursing facilities and administrative costs by a means other than the approved rate(s) in this Agreement, the organization should (1) credit such costs to the affected programs, and (2) apply the approved rate(s) to the appropriate base to identify the proper amount of facilities and administrative costs allocable to these programs.

BY THE INSTITUTION:

University of North Carolina at Chapel Hill



ON BEHALF OF THE FEDERAL GOVERNMENT:

A W. Mayes	Depaully segrent by Charyl W Mayers At Oil and J. Schwerterment, sweeted, new-PMC swi-Produc, 0 9:2542, 1920(300, 100; 1 1 - 2000) 12 (404 am-Charyl W Mayers At Date: 2010; 12:20:31 12:34 475 Cd*
(SIGNATURE)	
Darryl W. Mayes	
(NAME)	
Deputy Director, Cost	: Allocation Services
	: Allocation Services
(TITLE)	Allocation Services
(TITLE)	: Allocation Services
(TITLE) 11/23/2016	Steven Zuraf

Page 4 of 4

Water with

DEPARTMENT OF THE NAVY

OFFICE OF NAVAL RESEARCH 875 NORTH RANDOLPH STREET SUITE 1425 ARLINGTON, VA 22203-1995

IN REPLY REFER TO

Agreement Date: November 14, 2018 [Supersedes Agreement Dated: June 30, 2016]

NEGOTIATION AGREEMENT

INSTITUTION:

ECOHEALTH ALLIANCE, INC. 460 WEST 34TH ST. 17TH FLR NEW YORK, NY 10001-2320

The Indirect Cost and Fringe Benefits rates contained herein are for use on grants, contracts and other agreements with all Federal Agencies of the United States of America, in accordance with the provisions and cost principles mandated by 2 CFR Part 200. These rates shall be used for final billing purposes for EcoHealth Alliance, Inc. for Fiscal Year 2017. This rate agreement supersedes all previous rate agreements/determinations for Fiscal Year 2017.

Section I: RATES - TYPE: FINAL (FINAL)

Indirect Rates:

TYPE FROM TO RATE BASE APPLICABLE TO LOCATION (a) All All

Fringe Benefits Rates:

TYPE FROM TO RATE BASE APPLICABLE TO LOCATION (b) All All

DISTRIBUTION BASES

- (a) Modified Total Direct Costs (MTDC) means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and up to the first \$25,000 of each subaward (regardless of the period of performance of the subawards under the award). MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of \$25,000.
- (b) Total Salaries and Wages less Donated Services.

SECTION II - GENERAL TERMS AND CONDITIONS

A. LIMITATIONS: Use of the rates set forth under Section I is subject to any statutory or administrative limitations and is applicable to a given grant, contract, or other agreement only to the extent that funds are available. Acceptance of the rates agreed to herein is predicated upon the following conditions: (1) that no costs other than those incurred by the recipient/contractor were included in this indirect cost pool as finally accepted and that such costs are legal obligations of the recipient/contractor and allowable under governing cost principles; (2) that the same costs that have

been treated as indirect costs are not claimed as direct costs; (3) that similar types of costs have been accorded consistent accounting treatment; and (4) that the information provided by the recipient/contractor which was used as a basis for acceptance of the rates agreed to herein, and expressly relied upon by the Government in negotiating and accepting the said rates is not subsequently found to be materially incomplete or inaccurate.

- B. ACCOUNTING CHANGES: The rates contained in Section I of this agreement are based on the accounting system in effect at the time the agreement was negotiated. Changes to the method(s) of accounting for costs, which affect the amount of reimbursement resulting from the use of these rates require the prior approval of the authorized representative of the cognizant negotiation agency. Such changes include but are not limited to changes in the charging of a particular type of cost from indirect to direct. Failure to obtain such approval may result in subsequent cost disallowances.
- C. USE BY OTHER FEDERAL AGENCIES: The rates set forth in Section I are negotiated in accordance with and under the authority set forth in 2 CFR Part 200. Accordingly, such rates shall be applied to the extent provided in such regulations to grants, contracts, and other agreements to which 2 CFR Part 200 applies, subject to any limitations in part A of this section. Copies of this document may be provided by either party to other federal agencies to provide such agencies with documentary notice of this agreement and its terms and conditions.
- D. SPECIAL REMARKS: The Government's agreement with the rates set forth in Section I is not an acceptance of the EcoHealth Alliance, Inc.'s accounting practices or methodologies. Any reliance by the Government on cost data or methodologies submitted by EcoHealth Alliance, Inc. is on a non-precedence-setting basis and does not imply Government acceptance.

Accepted:

FOR THE U.S. GOVERNMENT:
KERSEY.SHEA.DE Digitally signed by KERSEY SHEADEL ORES, 1049331149
LORES.10493311 Disc = U.S., o=U.S., Government out=Doll out=PKI, out=USN,
49 cr=KERSEY.SHEA.DELORES,1049.13114/ Date 2018.11.21 [227:47-6500]
SHEA D. KERSEY
Contracting Officer
November 21, 2018
Date
Phone: (b) (6)
E-mail: (b) (6)

2R01Al110964 - Understanding the Risk of Bat Coronavirus Emergence (Pl, Daszak)

6 May 2019

Dear NIAID Just-in-Time,

Please find details on the Collaborative Institutional Training Initiative (CITI) Program Human Subjects Research Training for *all* individuals designated in our application who will be involved in human subject research. These individuals are as follows (below). The order is kept identical to that in our proposal. *All* individuals have taken and passed the following courses on the dates (below):

- Social and Behavioral Research Best Practices for Clinical Research
- Social and Behavioral Responsible Conduct of Research
- Biomedical Researchers and staff
- Public Health Researchers
- Social-Behavioral-Education Researchers

CITI Program URL: https://www.citiprogram.org

If additional details and certificates are required, please contact me anytime.

Sincerely, (b) (6)

Peter Daszak President, EcoHealth Alliance 460 West 34th Street – Ste. 1701

New York, NY 10001

Last	First	Role	Training	Date of Training
Daszak	Peter	PD/PI	Collaborative Institutional Training initiative (CITI)	30-Jan-19
Shi	Zhengli	Co-Investigator	Collaborative Institutional Training initiative (CITI)	3-May-19
Olival	Kevin	Co-Investigator	Collaborative Institutional Training initiative (CITI)	18-Jan-16
Ross	Noam	Co-Investigator	Collaborative Institutional Training initiative (CITI)	29-Jan-19
Latinne	Alice	Co-Investigator	Collaborative Institutional Training initiative (CITI)	22-Jan-19
Li	Hongying	Co-Investigator	Collaborative Institutional Training initiative (CITI)	20-Dec-18
Francisco	Leilani	Co-Investigator	Collaborative Institutional Training initiative (CITI)	28-Feb-17
Hagan	Emily	Co-Investigator	Collaborative Institutional Training Initiative (CITI)	9-May-17
Zhu	Guangjian	Co-Investigator	Collaborative Institutional Training initiative (CITI)	3-May-19
Ren	Lill	Co-Investigator	Collaborative Institutional Training initiative (CITI)	2-May-19
Li	Guo	Co-Investigator	Collaborative Institutional Training initiative (CITI)	2-May-19
Chmura	Aleksei	Co-Investigator	Collaborative Institutional Training initiative (CITI)	25-Jan-19

From: Girma, Tseday (NIH/NIAID) [E]

To: Aleksei Chmura

Cc: Peter Daszak; 李泓童; Alison Andre

Subject: RE: Grant Number: 2R01AI110964 - 06 PI Name: DASZAK, PETER

Date: Thursday, May 2, 2019 2:02:00 PM

Good afternoon,

Thank you for your email. Please see my responses to your questions below:

- . IRB review of the research protocol is required prior to award, please submit the approval date with the JIT.
- Regarding the IACUC approval, the Grants Policy statement says "It is an institutional responsibility to ensure that the
 research described in the application is congruent with any corresponding protocols approved by the IACUC."
 http://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1_public_policy_requirements_and_objectives.htm#Animal
 Please provide the IACUC approval date with the JIT which confirms that the research described in the application is
 congruent with any corresponding protocols approved by the IACUC.
- If you are not conducting clinical trials, just respond in the JIT stating the same. You don't need to extract the section from the application.

If you are unable to provide the IRB and IACUC approval dates as described above by the JIT submission deadline, please let me know when you will be to submit it.

Hope this answers your questions.

Thanks, Tseday

From: Aleksei Chmura (b) (6)
Sent: Thursday, May 2, 2019 9:11 AM

To: Girma, Tseday (NIH/NIAID) [E] (b) (6)

Cc: Peter Daszak (b) (6); 李泓萤 (b) (6); Alison Andre (b) (6)

Subject: Re: Grant Number: 2R01Al110964 - 06 Pl Name: DASZAK, PETER

Dear Tseday,

I confirm receipt of your email on behalf of the PI Dr. Peter Daszak. We will get these items or information submitted via eRA Commons by the 6th.

A two quick questions in advance:

- We have not yet IACUC nor IRB review and approval of our proposed protocols. If we receive notification of award, then we would be ready to rapidly submit these for review for the next cycle of each committee. Is this (dates and institution names) all that we would be required to provide presently for the JIT?
- We will not conduct clinical trials, but we have human subjects. We have provided both the Study Population Criteria and Protection & Monitoring Plan in our proposal. Should we extract these to include for JIT and state that we are not conducting clinical trials?

Many thanks!

-Aleksei

Aleksei Chmura, PhD Chief of Staff

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

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

EcoHealth Alliance leads cutting-edge scientific 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: Girma, Tseday (NIH/NIAID) [E] (b) (6)

Sent: Tuesday, April 30, 2019 11:00 AM

To: Peter Daszak; Peter Daszak Cc: Stemmy, Erik (NIH/NIAID) [E]

Subject: Grant Number: 2R01Al110964 - 06 Pl Name: DASZAK, PETER

<image002.jpg>

April 30, 2019

GRANT NUMBER - 2R01Al110964 - 06 PI Name: DASZAK, PETER

The above referenced application is being considered for funding by the National Institute of Allergy and Infectious Diseases. Please note that this request is not a guarantee of funding. Official notification of funding is only made by issuance of a Notice of Award (NoA).

The following Just-In-Time information (JIT) identified is requested:

x	1) Current Other Support - Provide active and pending support information for ALL individuals
designated in an ap	plication as key personnel.
	There is no form page for providing other support, although a sample format page is available at https://grants.nih.gov/grants/forms/othersupport.htm
x	2) IRB approval date (NIH does not require a copy of the IRB certification/approval). See NOT-OD-19-
	055. Pending or out-of-date approvals are not acceptable. If IRB has not met, provide anticipated
	meeting date. Information regarding the Federal Wide Assurance
	website: http://grants.nih.gov/grants/policy/hs/fags_aps_assurances.htm
x	3) Dissemination Plan required for NIH-funded clinical trial that addresses how the expectations of NO
	OD-16-149will be met. Additional
	guidance at https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-
	human-subjects-and-clinical-trials-information.htm#4.7
x	4) Documentation of the required education in the Protection of Human Subject Research Participants
	for all key personnel involved in HS research.
x	5) IACUC approval date (NIH does not require a copy of the IACUC certification/approval). Pending or

out-of-date approvals are not acceptable.

If IACUC has not met, provide anticipated meeting date.

Information regarding IACUCs can be found at http://grants.nih.gov/grants/olaw/faos.htm



6) Other

- i. Confirm institution's Entity Identification Number (EIN) is 1311726494A1.
- ii. Confirm the latest F&A agreement for University of North Carolina Chapel Hill is dated 11/23/2016 and the F&A rate is 55.5%. If this is not correct, send a copy of your latest F&A rate agreement with your JIT response.
- iii. Submit your latest F&A Agreement for ECOHEALTH ALLIANCE, INC

The requested Just In Time (JIT) information must be submitted via eRA Commons <u>INIH Guide Notice NOT-DD-12-101</u>) by <u>Monday. May 6th 2019.</u> If unable to submit the requested information through eRA Commons, please contact your Grants Management Specialist. Timely submission of the above information will enable us to expedite the issuance of an award should the application be identified for funding.

Sincerely,

Tseday Girma, MPA Grants Management Specialist National Institutes of Allergy and Infectious Diseases 5601 Fishers Lane, Room 4E24 Rockville, MD 20852

Phone: (b) (6)

Email: (b) (6)

NIAID, National Institutes of Health, DHHS

Effective January 1, 2017, NIH closeout documentation policy has changed (see NOT-OD-17-022). NIH is no longer accepting Final Progress Reports (FPR), Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the NIH RPPR Page.

*** The information in this email and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the originally intended recipient. If you have received this email in error, please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of NIAID by one of its representatives.***

From: Graham, Adam (NIH/NIAID) [E]

To: (b) (6) <u>Stemmy, Erik (NIH/NIAID) [E]</u>; (b) (6

Cc: Linde, Emily (NIH/NIAID) [E]; Glowinski, Irene (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Ford, Andrew

(NIH/NIAID) [E]; Khurana, Dhana (NIH/NIAID) [E]

Subject: Grant Number: 5R01AI110964 - 05 PI Name: DASZAK, PETER

Date: Thursday, July 5, 2018 3:25:00 PM Attachments: R01Al110964 - Daszak 6-25-18.pdf

image001.png

Good afternoon,

Attached is a letter notifying you that the GoF Research Funding Pause has been lifted via the HHS P3CO Framework and that the GoF term-of-award was removed when the next last Type 5 notice-of-award was issued.

Please let us know if you have any questions.

Adam Graham

Grants Management Specialist DHHS, NIH, NIAID, GMP Room 4E40, MSC 9833 5601 Fishers Lane Bethesda, MD 20892

(b) (6)

(b) (6)

Effective January 1, 2017, NIH closeout policy has changed (see <u>NOT-OD-17-022</u>). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the <u>NIH RPPR Page</u>.



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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

July 05, 2018

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

RE: 5R01AI110964-05

Dear Mr. Chmura:

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

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

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

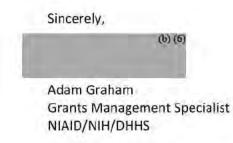
In accordance with the HHS P3CO Framework, research involving an enhanced PPP is subject to additional HHS department-level review. NIAID re-reviewed the grant application and other information provided by you, and made the following assessment:

The experiments to generate MERS-like or SARS-like chimeric coronaviruses, are not subject to the HHS P3CO Framework. The terms and conditions of the award have been revised to indicate that should experiments proposed in this award result in a virus with enhanced growth by more than 1 log compared to wild type strains, you must notify your NIAID Program Officer and

Grants Management Specialist immediately and that further research involving the resulting virus(es) may require review by the DHHS in accordance with the HHS P3CO Framework.

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

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





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

CC: Dr. Peter Daszak

Ms. Emily Linde

Dr. Emily Erbelding

Dr. Irene Glowinski

Dr. Andrew Ford

From: Aleksei Chmura

To: Graham, Adam (NIH/NIAID) [E]

Subject: Fwd: Grant Number: 5R01Al110964 - 05 PI Name: DASZAK, PETER

Date: Thursday, June 14, 2018 11:15:57 PM

Importance: High

Dear Adam,

I am resending the email, below. Apologies if it did not go through earlier for any reason. Please confirm receipt. If I do not hear back from you, I will try calling you tomorrow (Friday) morning.

Cheers!

-Aleksei

Begin forwarded message:

From: Aleksei Chmura (b) (6)

Subject: Re: Grant Number: 5R01Al110964 - 05 Pl Name: DASZAK,

PETER

Date: June 13, 2018 at 22:45:47 GMT+8

To: "Graham, Adam (NIH/NIAID) [E]" (b) (6)

Cc: "Dr. Peter Daszak" (b) (6), "Stemmy, Erik

(NIH/NIAID) [E]" (b) (6)

Adam,

Thanks again for your help with this! Please find the details with updates as per section G9, below.

As per last year, we will not be subcontracting any funds to the intuitions in these countries. All efforts expended in these countries will be from collaborating partners and not funded by our award. PI, Co-Investigators or other team members may conduct short field trips to assess markets, identify wildlife in them, and arrange for shipment of samples of bats and other high-risk host species in countries that neighbor China (Burma, Vietnam, Cambodia, Laos) and that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia).

If you need any additional information, email, text, or call me anytime (+ (b) (6) and I will provide it as rapidly as possible.

Cheers,

-Aleksei

Organisation Name: San Pya Clinic

Country: BURMA

Description of Foreign Component: PI or Co-Investigators to conduct short field trip to assess markets, identify wildlife in them, and arrange for shipment of bats and other high-risk host species to Wuhan Institute of Virology Laboratory in China.

Organization Name: Institut Pasteur du Cambodge

Country: CAMBODIA

Description of Foreign Component: PI or Co-Investigators to conduct short field trip to assess markets, identify wildlife in them, and arrange for shipment of bats and other high-risk host species to Wuhan Institute of Virology Laboratory in China.

Organization Name: Primate Research Center at Bogor Agricultural University Country: INDONESIA

Description of Foreign Component: PI or Co-Investigators to conduct short field trip to assess markets, identify wildlife in them, and arrange for shipment of bats and other high-risk host species to Wuhan Institute of Virology Laboratory in China.

Organization Name: Conservation Medicine, Ltd.

Country: MALAYSIA

Description of Foreign Component: PI or Co-Investigators to conduct short field trip to assess markets, identify wildlife in them, and arrange for shipment of bats and other high-risk host species to Wuhan Institute of Virology Laboratory in China.

Organization Name: King Chulalongkorn Memorial Hospital

Country: THAILAND

Description of Foreign Component: PI or Co-Investigators to conduct short field trip to assess markets, identify wildlife in them, and arrange for shipment of bats and other high-risk host species to Wuhan Institute of Virology Laboratory in China.

Organization Name: Hanoi Agricultural University

Country: VIETNAM

Description of Foreign Component: PI or Co-Investigators to conduct short field trip to assess markets, identify wildlife in them, and arrange for shipment of bats and other high-risk host species to Wuhan Institute of Virology Laboratory in China.

Organization Name: National Animal Health Laboratory

Country: LAOS

Description of Foreign Component: PI or Co-Investigators to conduct short field trip to assess markets, identify wildlife in them, and arrange for shipment of bats and other high-risk host species to Wuhan Institute of Virology Laboratory in China.

From: Aleksei Chmura

To: Normil, Carine (NIH/NIAID) [C]

Cc: Stemmy, Erik (NIH/NIAID) [E]; Dr. Peter Daszak; Smith, Philip (NIH/NIAID) [E]; Alison Andre Subject: Re: Publication compliance for Grant Number: 5R01AI110964 - 04 PI Name: DASZAK, PETER

Date: Wednesday, May 31, 2017 10:59:35 AM

Attachments: bib.pdf
Importance: High

Dear Carine,

Please find the attached documentation of this publication being in compliance with NIH Public Access Policy.

Many thanks most,

Sincerely,

-Aleksei

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

www.ecohealthalliance.org

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On 23 May 2017, at 13:12, Normil, Carine (NIH/NIAID) [C] (b) (6) wrote:

Good afternoon:

Your progress report for the above referenced award has a non-compliant publication.

Please take the necessary steps to bring

(b) (4)

(b) (4) into compliance with the NIH Public

Access Policy.

To comply with the policy, please <u>reply</u> to this email and provide a PDF generated report from My NCBI that includes evidence of compliance (PMCID number) for this

publication. If you believe the above referenced publication does not fall under the Public Access Policy, please provide a brief explanation. A response is appreciated by **June 15, 2017**.

If you have questions about the Policy, feel free to contact me via email at (b) (6) or send a note to Public Access@nih.gov.

Best regards, Carine

Carine Normil

Grants Management Specialist (Contractor)

Grants Management Program, DEA, NIAID, NIH, HHS 5601 fishers Lane, Rm 4G46, Bethesda, Maryland 20892

Phone: (b) (6)

Fax: (301)-493-0597

Email: (b) (6)

<image001.jpg>

Publications Reported for this Reporting Period

NIH Public Access Compliance	Citation
Complete	(b) (4

From: Normil, Carine (NIH/NIAID) [C] To: Cc: Stemmy, Erik (NIH/NIAID) [E]; Subject: Publication compliance for Grant Number: 5R01AI110964 - 04 PI Name: DASZAK, PETER Date:

Tuesday, May 23, 2017 1:12:00 PM

Importance:

Good afternoon:

Your progress report for the above referenced award has a non-compliant publication. Please take the necessary steps to bring (b) (4) (b) (4) into compliance with the NIH Public Access Policy.

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Grants Management Program, DEA, NIAID, NIH, HHS 5601 fishers Lane, Rm 4G46, Bethesda, Maryland 20892

Phone:

Fax: (301)-493-0597

(b) (6) Email:



From: Aleksei MacDurian

To: Smith, Philip (NIH/NIAID) [E]

Subject: Re: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Date: Wednesday, May 03, 2017 4:10:18 PM

Dear Philip,

Sincere apologies for my tardy reply. I was out-of-office the past two days unexpectedly and am just catching up with emails.

There are no planned in-country costs associated with these foreign sites. All testing costs will be at the Wuhan Institute of Virology in China - our current, approved partner under our award.

Many thanks!

-Aleksei

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

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On Fri, Apr 28, 2017 at 5:29 PM, Smith, Philip (NIH/NIAID) [E] (b) (6) wrote:

Hi Aleksei,

Can you provide the direct and indirect costs for the foreign sites we are adding (Cambodia, Indonesia, Lao People's Democratic Republic, Malaysia, Myanmar, Thailand, Vietnam)? Once this is received we can issue a revised NOA approving these sites.

Thanks,

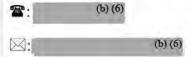
Philip Smith

Grants Management Specialist

Grants Management Program, DEA, NIAID, NIH

5601 Fishers Lane, Rm 4E48, MSC 9833 GMP

Rockville, Maryland 20892-9824



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From: Aleksei Chmura

To: Stemmy, Erik (NIH/NIAID) [E]

Cc: Greer, Jenny (NIH/NIAID) [E]; Smith, Philip (NIH/NIAID) [E]
Subject: Re: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Date: Friday, February 17, 2017 10:19:33 PM

Attachments: NIH-NIAID 5R01AI110964 Additional Site Q and A.pdf

Dear Erik,

Please find our responses in the attached PDF. If you need any additional details, please let me know.

Many thanks!

-Aleksei

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

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On Feb 15, 2017, at 08:52, Stemmy, Erik (NIH/NIAID) [E] (b) (6) wrote:

Hi Aleksei,

I know you said nothing will be changing from your currently approved animal studies, but it would be helpful for me in preparing the foreign clearance request if you could write a few concise sentences about the new animal work addressing the following points:

- · Kind or species of animal and number to be used
- · Location of the source of the animals, if known
- A brief description of the sampling (blood draw, swab, etc)
- · Location from where the animals will be obtained (source)
- If possible, what will be done with the animals after the project ends (e.g., euthanized)

Obtained via FOIA by White Coat Waste Project

Let me know if you have any questions.

Thanks!

Erik

From: Aleksei Chmura (b) (6)

Sent: Monday, February 13, 2017 4:23 PM

To: Greer, Jenny (NIH/NIAID) [E] (b) (6)

Cc: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Smith, Philip (NIH/NIAID) [E]

(b) (6)

Subject: Re: Year 2 Report for 5R01Al110964 - 02 PI Name: DASZAK, PETER

Super! Thanks, Jenny.

Erik and Philip - please let me know, if you have any questions or require additional details. We look forward to your responses.

Sincerely,

-Aleksei

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

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On Feb 13, 2017, at 16:18, Greer, Jenny (NIH/NIAID) [E]

Aleksei,

Thank you for your email. I am copying Erik on this response so he can make sure he has everything needed to initiate a request for each of these foreign sites. I am also copying Philip Smith, the grants management specialist assigned to this grant for this fiscal year. Please don't hesitate to contact either of them with any questions you may have.

Please note that this response does not constitute approval and it will take at least 3 weeks for a final determination to be made.

Thanks again! And have a great afternoon!

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone:
(b) (6)
Email:
(b) (6)

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From: Aleksei Chmura (b) (6)

Sent: Friday, February 10, 2017 2:54 PM

To: Greer, Jenny (NIH/NIAID) [E] (b) (6)

Subject: Re: Year 2 Report for 5R01Al110964 - 02 Pl Name: DASZAK,

PETER

Dear Jenny,

I am just following up with item 1 and 1a from your email below. As per Peter's email (also below), we would like to request prior approval for collecting non-human animal samples in 7 countries: Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Thailand, and Vietnam.

No new animals will be introduced nor any new field procedures, we have submitted IACUC protocol modification - for geographic locations only - and will provide approval dates as soon as they are available.

No work will be conducted until we have your approval and IACUC approval.

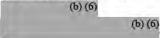
Testing would be conducted locally and if any samples were to be transferred to China these would be only extracted viral DNA - and not the original sample material.

Samples will be collected by either our current China field team personnel working directly with our collaborators in these countries or by respective in-country personnel and require no more than 10% budget modification total (from already budgeted China fieldwork) for any non-China in-country work.

Here is the list of our local in-country contacts and institutions:

Cambodia

Veasna Duong Institut Pasteur du Cambodge No. 5 Monivong Boulevard P.O Box. 983, Phnom Penh, Cambodia



Indonesia

Joko Pamungkas
Primate Research Center at Bogor Agricultural University
JalanLodayaII/5,Bogor16151, Indonesia

(b) (6)
(b) (6)

Lao People's Democratic Republic

Watthana Theppangna
National Animal Health Laboratory
Department of Livestock and Fisheries
Ministry of Agriculture and Forestry, Vientiane, Lao PDR

(b) (6)

Malaysia

Tom J. Hughes
Conservation Medicine, Ltd.
Suite 4A, Level 4, Main Office Tower
Financial Park Complex, Jalan Merdeka, 87000
Federal Territory of Labuan, Malaysia
(b) (6)
(b) (6)

Myanmar

Aung Than Toe San Pya Clinic 20/256, Insein Road Yangon 11051, Myanmar (b) (6) (b) (6)

Thailand

Supaporn Wacharapluesadee
Neuroscience Center for Research and Development
King Chulalongkorn Memorial Hospital
Rama 4 Road
Patumwan, Bangkok, Thailand 10330

(b) (6)

(b) (6) (b) (6)

Vietnam

Nguyen Huu Nam
Faculty of Animal and Veterinary Science
Hanoi Agricultural University
Trauquy, Gialâm, Hanoi, Vietnam

(b) (6)

(b) (6)

If it will be easier to have a quick chat about this, I am happy to call anytime. Also, if this request should be sent more formally as a letter attachment, we can do that rapidly as well.

I hope you and yours had a lovely Holiday and are surviving the blizzard!

Cheers,

-Aleksei

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

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On Aug 1, 2016, at 12:39, Greer, Jenny (NIH/NIAID) [E] (b) (6) wrote:

Thank you for your email. To answer your questions:

- To do any work in countries other than China, you
 will need to request prior approval from NIH. To do
 so, submit a formal request, including the names,
 institutions, and full contact information of any
 institutions with which you will collaborate for such
 activities. Be sure to indicate whether animal or
 human research will be conducted and what funds, if
 any, will be going into these countries. The approval
 process for new foreign sites takes at least 3 weeks,
- 1a . If you are introducing new animals into the project, then there may be additional requirements from the Office of Laboratory Animal Welfare (OLAW). Again, you would need to submit a formal request, providing a scientific justification for the inclusion of new species on the project, and, if appropriate, a new Vertebrate Animal Section. If additional IACUC approvals are required, you will need to provide us with the IACUC approval dates (but **not** a copy of the actual approval).
 - 2. These individuals are not listed in the Notice of Award as key personnel, so, from a grants management perspective, you do not need to get prior approval for this change. That said, if this change or other such personnel changes would have a significant impact on the scope of the project or the science itself, you would need to at least run it by your Program Officer. And if it is determined that personnel changes would cause a scope change, then you would need grants management approval as well.
 - 3. I do not know what you are asking here. It looks like we have approved both the Wuhan University and ECNU for work on this project. Therefore, no additional prior approval is required for changes unless otherwise specified in the NIH Grants Policy Statement (eg, a change of scope).

Please don't hesitate to contact me with any additional questions. I will be available until 2:30 eastern and then again on Wednesday.

All the best,

Jenny

Jenny Greer

Grants Management Specialist DHHS/NIH/NIAID/DEA/GMP

5601 Fishers Lane, Room 4E49, MSC 9833

Bethesda, MD 20892-9824

Phone: (b) (6)

Email: (b) (6

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From: Aleksei MacDurian

(b) (6)

Sent: Sunday, July 31, 2016 6:06 AM

To: Greer, Jenny (NIH/NIAID) [E] (b) (6)

Subject: Re: Year 2 Report for 5R01Al110964 - 02 Pl Name:

DASZAK, PETER

Dear Jenny,

Since you were not cc'ed on the original email, I wanted to follow up with you on three things from Dr. Daszak's email to Erik (included below):

- 1) Do we need to formally request permission to sample species of bats and other high-risk [rodents and carnivore] hosts in countries that neighbor China (Myanmar, Vietnam, Cambodia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia). Under this award our current US and China IACUC approved protocol via Tufts University and Wuhan Institute of Virology permits us to sample these species in these regions.
- 2) We provided Dr. Noam Ross' CV with our Year 2 Report. Dr. Ross has replaced Dr. Hosseini who is no longer working on this project. Do we need to do anything else for this? I have attached his Biosketch here for reference.

3) Our Human surveillance work and local IRB approval have all been through the Wuhan University School of Public Health (WUSPH) in China (DUNS No. 529049295). We would like now - in Years 3 - 5 of our award to subcontract directly with them rather than with the institution on our current budget: East China Normal University (ECNU) School of Life Sciences. The Wuhan University School of Public Health budget amount would be the same annual amount as currently budgeted for East China Normal University in these same years.

It may be easier to briefly chat about these questions via telephone. If so, you may reach me at + (b) (6) anytime.

Many thanks!

-Aleksei

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

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On Fri, May 13, 2016 at 5:55 PM, Peter Daszak (b) (6) wrote:

Dear Erik,

I just wanted to let you know that we submitted our Year 2 Report yesterday (attached as a pdf).

It's been a pretty productive year, and some of the highlights include: collecting samples from 15 bat genera in southern China with 280 (12%) testing positive for coronaviruses; SARS-like coronaviruses being detected in Rhinolophus spp. bats in both Yunnan and Guangdong provinces; 7 published papers from work under our award

(including one in *J. Virol.* and one in press at *J. Virol*); 218 quantitative interviews with samples and 47 qualitative coded interviews conducted transcribed and translated.

In the report, I highlight the reduced amount of wildlife in the local markets within Southern China compared to that we've seen before, as well as the continued expansion of the Chinese wildlife trade within SE Asia so that it is now a largescale international activity. It means that SL-CoVs we find in the wildlife trade would likely have an origin in adjacent countries. Given that our collaborators and field team in China have great contacts in these countries, and EHA also has field teams in many of them, we would like to conduct short field trips to assess markets, identify wildlife in them, and sample species of bats and other high-risk hosts in countries that neighbor China (Myanmar, Vietnam, Cambodia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia). All samples collected would still be tested at the Wuhan Institute of Virology in China. Is there a formal process to ask for permission for this, or is the report and this email appropriate?

I also wanted to let you know about a recent personnel change. Since Dr. Parviez Hosseini has moved to earlier this year, we hired another senior researcher Noam Ross to conduct data analysis and spatial mapping. Our Year 2 report includes his CV. Noam has great enthusiasm and I am eager to see his work on our data collected to date. He has already been out to China is hitting the ground running!

We have had great successes this past year and I'd be happy to discuss any of them with you, if you'd like.

Cheers,

Peter

Peter Daszak

President

EcoHealth Alliance

460 West 34th Street – 17th Floor New York, NY 10001

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

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1. Kind or species of animal and number to be used:

Species taxa	Family, Genus or Species Name	Target numbers
Fruit bats	e.g.: Cynopterus, Rousettus, Eonycterus spp.	900 individuals (30
Insectivorous	e.g.: Rhinilophidae, Hipposideridae,	individuals from 30
bats	Emballonuridae, Vespertillionidae,	different species)
	Mollsidae, Miniopteridae spp.	### #################################
Rodents	e.g: Chinese bamboo rat (<i>Rhizomys</i> sinensis), Malayan porcupine (<i>Hystrix</i> brachyura), bandicoot (<i>Bandicota indica</i>)	900 individuals
Small Carnivores	e.g.: Raccoon dog (<i>Nyctereutes</i> procyonoides), Asian Palm civet (<i>Paradoxurus hemaphroditus</i>), ferret	500 individuals
	badger (Melogale moschata)	

2. Location of the source of the animals, if known:

Free-ranging bat surveys and bats in wet markets: China, Malaysia, Thailand, Cambodia, Lao PDR, Myanmar, Vietnam, and Indonesia.

Other mammals: We will opportunistically sample the other aforementioned taxa that are also sold in live animal markets, trading locations or bred on farms to supply markets throughout southeast Asia. Species and numbers of animals sampled from markets will be based on animal availability.

3. A brief description of the sampling (blood draw, swab, etc)

Bat capture. Free-ranging bats will be captured using either a mist net or harp trap and bats are removed from the net as soon as they become entangled to minimize stress and prevent injury. Bats will be manually restrained during sampling. Bats that are fractious may be anesthetized for restraint purposes in order to maximize safety for the bat and handler. Depending on the species and size of bat, swabs will be taken from the oropharynx, urogenital tract, and rectum. Fresh feces will be collected if available, in which case a rectal swab will not be collected. Blood will be collected from either from the cephalic vein or from the radial artery or vein using a 25-gauge needle. Bats are held for a maximum of six hours and then released following sample collection. We will euthanize 2 individuals per bat species for organ tissue banking.

Wild and captive bred rodent capture. Free-ranging rodents will be captured using box traps. Captive bred rodents (e.g. at rodent farms) will be manually captured and restrained. Traps for free-ranging rodents will be checked a minimum of every 12 hours, including once in the morning. Captive bred and wild rodent sampling procedures (including anesthesia, if necessary), will involve manual restraint, venipuncture, mucosal swabs, fecal, and urine sample collection.

Other small mammals: Anesthesia will be used to restrain small mammals such as civets and ferret badgers. Animals will be monitored continuously while recovering from anesthesia and will only be released once fully recovered from anesthesia. Animals that are sourced from markets and that may potentially be consumed, will be manually restrained without anesthesia, if possible, so that they may be returned to the vendor. Otherwise, the animal will be sampled and then euthanized via exsanguination

(cardiac puncture) while under anesthesia, then disposed of using biohazard protocols in order to prevent subsequent human or animal consumption.

4. Location from where the animals will be obtained (source):

Markets and surrounding caves/forest: sites will be identified along value chain routes linking southern China to southeast Asian countries that serve as sources for the Chinese market system. Specific field sites have not yet been determined.

5. If possible, what will be done with the animals after the project ends (e.g., euthanized)

All wild animals will be released unharmed after sampling at the capture location. 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 in accordance with the AVMA guidelines for euthanasia (2013). 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.

From: Aleksei MacDurian

To: Smith, Philip (NIH/NIAID) [E]

Subject: Re: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Date: Wednesday, May 03, 2017 4:10:18 PM

Dear Philip,

Sincere apologies for my tardy reply. I was out-of-office the past two days unexpectedly and am just catching up with emails.

There are no planned in-country costs associated with these foreign sites. All testing costs will be at the Wuhan Institute of Virology in China - our current, approved partner under our award.

Many thanks!

-Aleksei

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

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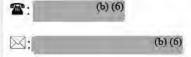
Philip Smith

Grants Management Specialist

Grants Management Program, DEA, NIAID, NIH

5601 Fishers Lane, Rm 4E48, MSC 9833 GMP

Rockville, Maryland 20892-9824



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From: Bernabe, Gayle (NIH/NIAID) [E]

To: Yuan, Liz (NIH/FIC) [E]; Officer, Jackie (NIH/FIC) [E]

Cc: Stemmy, Erik (NIH/NIAID) [E]; Smith, Philip (NIH/NIAID) [E]; Handley, Gray (NIH/NIAID) [E]; Meegan, James

(NIH/NIAID) [E]; Arcuri, Guy (NIH/NIAID) [E]; Dominique, Joyelle (NIH/NIAID) [E]; Rosa, William (NIH/NIAID)

E

Subject: FACTS: Project for BURMA on queue for SDC: R01AI110964-03; DASZAK, PETER

Date: Saturday, March 25, 2017 12:34:57 PM

Attachments: Burma InfoShare Post Concurrence EcoHealth Alliance March 2017.docx

Dear Liz and Jackie:

Please find attached the "Burma Assistance Activity InfoShare & Post/Mission Concurrence Request" form for grant Al110964-03 (Burma).

Please let us know if additional information is needed.

Thank you and kind regards, Gayle

Gayle Bernabe, MPH

Regional Program Officer-East/SE Asia and the Pacific

Office of Global Research (OGR)

National Institute of Allergy and Infectious Diseases

National Institutes of Health

Department of Health and Human Services

5601 Fishers Ln Rm 1E M5C 9802

Bethesda, MD 20892-9802 (For courier deliveries: 20852)

Phone: **(b) (6)** Fax: (301) 480-2954

Email (b) (6)

Disclamer

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Submitted by

Name: (b) (6)

Title: Understanding the Risk of Bat

Coronavirus Emergence – 5R01Al110964-03

Agency/Office: DHHS/NIH

Date Submitted: 3/24/2017

Post/Mission Concurrence: Choose an item.
Post/Mission Comments: Click here to enter text.

Activity:	The National Institute of Allergy and Infectious Diseases (NIAID), at the National Institutes of Health (NIH), has a pending award to the EcoHealth Alliance, Inc., New York, grant number 5R01Al110964-03. If approved, this award would involve a foreign collaboration in Myanmar. The aims of this research project are to examine the mechanism through which coronaviruses jump from animal hosts/reservoirs to humans (spillover events). To accomplish this work the U.S. Principal Investigator (PI) and his team will conduct detailed surveillance for coronaviruses at eight sites throughout in Asia (China, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Thailand, and Vietnam). Sampling sites will include urban centers, rural areas, and live animal markets. Samples will be collected from animals from each of these sites, and will be analyzed to determine what coronaviruses are present, and whether the viruses are able to infect humans.	
	The investigators plan to collect samples from bats (900 samples total across all sites), rodents (900 samples total across all sites), and small carnivores such as palm civets and ferret badgers (500 samples total across all sites). Animals will be captured and lightly anesthetized if necessary. They will be swabbed (mouth/nose, urogenital tract, and rectum), and a small amount of blood will be collected. If available, feces and urine will also be collected. All wild animals will be released unharmed after sampling. Of animals that are collected from live markets, a maximum of two per species may be humanely euthanized for organ tissue sampling. All animal work will be performed by trained individuals in accordance with the American Veterinary Medical Association guidelines, and the project is overseen by veterinarians. This work has also been reviewed and approved by the investigator's Institutional Animal Care and Use Committee.	
USG Strategic Goal:	Resilient Communities	
Responsible USG Agency/Technical Office:	DHHS/NIH/National Institute of Allergy and Infectious Diseases (NIAID)	
Mechanism:	Grant	
Prime Partner:	EcoHealth Alliance, New York; Dr. Peter Daszak (Work will be conducted by in-country collaborators. In year 4 the PI will conduct a single site visit.)	
Sub-Recipients:	San Pya Clinic, Yangon; Dr. Aung Than Toe	

Duration and Start/End Dates:	2 year project; new sampling work will begin in new budget period 6/1/2017 and continue through the end of the award 5/31/2019	
Funding:	HHS Appropriations – FY2017 FY Choose an item. Account Choose an item. Budget Notwithstanding Authority (NWA) Please indicate which NWA is being used.	
Immediate Cost:	No funds will be sent directly to Myanmar.	
Total Estimated Cost:	No funds will be sent directly to Myanmar.	
Funding Approval:	This research grant was reviewed by experts in the scientific field and recommended for funding consideration. The NIAID Advisory Council approved the funding of this grant. Research protocols will be cleared through Myanmar and US Institutional Review Boards.	
Assistance to the GOB:	No - Assistance to GOB No assistance is being provided to the Government of Burma. NIH provides funding for research activities only.	
Congressional Notification:	Has your program been notified to Congress? When? Not required	
Beneficiary(ies):	Burmese people and San Pya Clinic staff	
*Check this box ☑ to confirm that your agency/office has consisted the relevant legal advisors regarding this activity and that those have confirmed the necessary legal authority to provide this assisted the confirmed the necessary legal authority to provide this assisted the confirmed the necessary legal authority to provide this assisted to confirm activity participants/vendors have screened for inclusion on the SDN list. https://sdnsearch.ofac.tm While the Burma Sanctions Program ended in October 2016, of sanctions programs might include people or entities in Burma. Comment: CDC office has offered to confirm for Principal Investigators.) *Check this box ☐ to confirm due diligence for gross violators or rights (GVHR) has been conducted. If not, please indicate		
	why: *Check this box 🗵 to confirm that Leahy Vetting has been/will be performed for all assistance to security forces, consistent with Embassy in Rangoon Leahy Vetting Policy. (NIAID Comment: Vetting will be performed if post can provide information regarding this policy and how to complete Leahy Vetting.) *If this activity requires travel to the United States, please note that certain Burmese nationals are subject to visa restrictions in the 2008 JADE Act, as detailed in 17 State 1214. (NIAID Comment: NIAID notes this requirement and has made program officer aware of restrictions.)	
Other considerations:		

Additional	There are no restrictions on this work proposed in Myanmar. The funding
Comments:	will only be used to support coronavirus research which will be conducted by collaborators in San Pya Clinic, which is a non-government organization. No funds are presently planned to be sent to Myanmar. This is a new project conducted in Myanmar and does not duplicate any known projects in this area.
	NIH has legislative authority that allows NIH to award funds directly and indirectly to foreign institutions based on scientific merit. NIH is subject to all USG sanctions and other superseding actions and NIH acknowledges that and appreciates careful review by the Embassy committee and others on the ground in Myanmar.

From: Stemmy, Erik (NIH/NIAID) [E]

To: Bernabe, Gayle (NIH/NIAID) [E]; Smith, Philip (NIH/NIAID) [E]

Subject: RE: (Foreign Clearance - BURMA) Grant Number: 5R01AI110964 - 03 PI Name: DASZAK , PETER (Embassy

Request Form)

Date: Friday, March 24, 2017 2:50:06 PM

Attachments: Re Out of Office RE Year 2 Report for 5R01Al1110964 - 02 PI Name DASZAK PETER.msq

Burma InfoShare Post Concurrence EcoHealth Alliance_March 2017.docx

Hello Gayle and Philip,

My apologies for the slow response. The PI responded on Monday, but I was out of the office on a site visit until last night. Please see attached and let me know if that is sufficient information. Of particular note, the PI said in the attached message that they don't plan on sending any funds directly in country to Burma; they're just coordinating the transfer of samples from the collection site to the collaborator lab in China. Let me know if you need more info from me.

Many thanks,

Erik

From: Bernabe, Gayle (NIH/NIAID) [E]

Sent: Wednesday, March 22, 2017 1:54 PM

To: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Smith, Philip (NIH/NIAID) [E]

(b) (6)

Cc: Bernabe, Gayle (NIH/NIAID) [E] (b) (6)

Subject: RE: (Foreign Clearance - BURMA) Grant Number: 5R01Al110964 - 03 PI Name: DASZAK,

PETER (Embassy Request Form)

Dear Erik and Philip:

I just wanted to follow-up with this project and the Embassy request form needed for clearance.

Your time and input are appreciated.

Thanks and kind regards,

Gayle

From: Bernabe, Gayle (NIH/NIAID) [E]

Sent: Thursday, March 16, 2017 1:04 PM

To: Stemmy, Erik (NIH/NIAID) [E] (6) (6); Smith, Philip (NIH/NIAID) [E]

(b) (6)

Cc: Bernabe, Gayle (NIH/NIAID) [E] (b) (6)

Subject: FW: (Foreign Clearance - BURMA) Grant Number: 5R01Al110964 - 03 PI Name: DASZAK,

PETER (Embassy Request Form)

Dear Erik and Philip:

For any projects involving Burma, the U.S. Embassy/Post has requested NIH to submit the attached form. I tried to fill it out with information from the FACTS record, as well as standard language that

Obtained via FOIA by White Coat Waste Project

(b) (5)

has been used for other projects with Burma. Please review it and update any information specific to the activities to be done in Burma, including the text highlighted in yellow.

Once this form is complete, it will be submitted to FIC.

Thank you for your time.

Kind regards, Gayle

Gayle Bernabe, MPH

Regional Program Officer-East/SE Asia and the Pacific

Office of Global Research (OGR)

National Institute of Allergy and Injectious Diseases

National Institutes of Health

Department of Health and Human Services

5601 Fishers Ln Rm 1E MSC 9802

Bethesda, MD 20892-9802 [For courier deliveries: 20852]

Phone: (b) (6)

Fax: (301) 480-2954

Email: (b) (6)

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From: "Arcuri, Guy (NIH/NIAID) [E]" (b) (6)

Date: Friday, March 10, 2017 at 9:41 AM

To: "Smith, Philip (NIH/NIAID) [E]" (b) (6), NIAID State Dept Clearance

(b) (6)

Cc: "Bernabe, Gayle (NIH/NIAID) [E]" (6) (6)

Subject: RE: (Foreign Clearance - BURMA) Grant Number: 5R01Al110964 - 03 Pl Name: DASZAK,

PETER; OGR Contact: Gayle Bernabe

Your request has been received and will be reviewed for DGR by Gayle Bernabe.

Thank you,

V/R,

From: Smith, Philip (NIH/NIAID) [E]

Sent: Thursday, March 09, 2017 3:14 PM

To: NIAID State Dept Clearance (b) (6)

Subject: (Foreign Clearance - BURMA) Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Good Afternoon,

The following request for foreign clearance is ready for review. This request is to add protocols to already approved sites in Brazil:

Grant Number: 5R01Al110964 - 03

P.I.: DASZAK, PETER

Applicant Organization: ECOHEALTH ALLIANCE, INC.

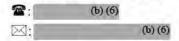
Foreign Country: BURMA

GMS: Philip Smith PO: Stemmy, Erik

Thank you,

Philip Smith

Grants Management Specialist Grants Management Program, DEA, NIAID, NIH 5601 Fishers Lane, Rm 4E48, MSC 9833 GMP Rockville, Maryland 20892-9824



Effective October 1, 2014, NIH closeout policy has changed (see <u>NOT-OD-14-084</u>). In order to avoid unilateral closeout, final reports must be submitted in a timely manner. Failure to submit accurate final reports could result in enforcement actions such as revisions to NOA funding levels, or delay in future funding.

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From: Peter Daszak

Sent: Mon, 20 Mar 2017 18:32:16 +0000

To: Stemmy, Erik (NIH/NIAID) [E]; Alison Andre

Cc: Aleksei Chmura;Smith, Philip (NIH/NIAID) [E];Evelyn Luciano

Subject: Re: Out of Office RE: Year 2 Report for 5R01Al110964 - 02 PI Name: DASZAK,

PETER

Importance: High

Hi Erik,

Here are the answers to your questions:

1. Will Dr Daszak (or other EcoHealth staff) plan to spend time directly in country in Myanmar? If so, please provide an approximate % of time.

We are in initial planning of approach with these countries including Myanmar and time spent this year in Myanmar would primarily be by our collaborators and *not* EHA staff. In Yr 4, we will probably need to budget one site visit conducted by Dr. Peter Daszak and Senior Personnel Dr. Olival and/or by our field veterinarian. Please let us know what restrictions there might be for this...

2. How long do you anticipate the sampling will continue? That is, through the remainder of the R01, or a shorter amount of time?

Sampling will be conducted a minimum of four times over then remainder of the R01.

3. Can you confirm the total amount of US\$ to be sent to Myanmar for the work?

No funds are presently planned to be sent to Myanmar. We plan to coordinate collaborative transfer of samples from Myanmar to our partner Lab in China.

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

Sent: Thursday, March 16, 2017 2:11 PM

To: Peter Daszak; Alison Andre

Cc: Aleksei Chmura; Smith, Philip (NIH/NIAID) [E]; Evelyn Luciano

Subject: RE: Out of Office RE: Year 2 Report for 5R01Al110964 - 02 PI Name: DASZAK, PETER

Thank you Peter!

Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825

Phone: (b) (6) Email: (b) (6) Getting ready to publish? Share the good news with your program officer asap! NIAID may be able to help publicize your article. And, remember to list your NIAID grant or contract number in the publication. ******* NOTE: This material is intended for the individual or entity to which it is addressed. It may contain privileged, confidential information that is protected from disclosure under applicable laws. If you are not the addressee, or a person authorized to deliver the document to the addressee, please note that you are strictly prohibited from reviewing, copying, disclosing, disseminating or distributing this material or any other action based on the contents of this material. If you have received this communication in error, please permanently delete this from your system immediately. Thank you. From: Peter Daszak (b) (6) Sent: Thursday, March 16, 2017 2:10 PM To: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Alison Andre Cc: Aleksei Chmura (b) (6); Smith, Philip (NIH/NIAID) [E] (b) (6); Evelyn Luciano Subject: RE: Out of Office RE: Year 2 Report for 5R01Al110964 - 02 PI Name: DASZAK, PETER Hi Erik, I've just returned from travel and we'll get answers to you on this by Monday COB. Cheers, Peter Peter Daszak President EcoHealth Alliance

460 West 34th Street - 17th Floor

(b) (6) (direct)

New York, NY 10001

+1.212.380.4465 (fax)

www.ecohealthalliance.org

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.

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

Sent: Thursday, March 16, 2017 1:33 PM

To: Alison Andre

Cc: Peter Daszak; Aleksei Chmura; Smith, Philip (NIH/NIAID) [E]

Subject: FW: Out of Office RE: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Hello Alison,

I received an out of office message from Aleksei. I am working on new foreign clearances for the grant referenced above, and need some additional information for the site in Myanmar. Would you be able to help address the questions below?

Thank you,

Erik

- -Will Dr Daszak (or other EcoHealth staff) plan to spend time directly in country in Myanmar? If so, please provide an approximate % of time.
- -How long do you anticipate the sampling will continue? That is, through the remainder of the R01, or a shorter amount of time?
- -Can you confirm the total amount of US\$ to be sent to Myanmar for the work?

From: Aleksei Chmura	(b) (6)
TOTAL AICKSCI CHINGIN	(-) (-)

Sent: Thursday, March 16, 2017 1:23 PM

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

Subject: Out of Office RE: Year 2 Report for 5R01Al110964 - 02 PI Name: DASZAK, PETER

Thank you for your email.

I will be out of the office and traveling until 20 March 2017. During this time, I may not have regular access to emails and voice messages. If you should need immediate assistance, please contact Alison Andre at (b) (6). Otherwise, I will respond to your message as soon as possible.

Sincerely,

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

(b) (6) (direct) (b) (6) (mobile)

Aleksei MacDurian (Skype)

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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.

Submitted by

Name: (b) (6)
Title: Understanding the Risk of Bat

Coronavirus Emergence – 5R01Al110964-03 Agency/Office: DHHS/NIH Date Submitted: 3/16/2017

Post/Mission Concurrence: Choose an item.
Post/Mission Comments: Click here to enter text.

Activity:	The National Institute of Allergy and Infectious Diseases (NIAID), at the National Institutes of Health (NIH), has a pending award to the EcoHealth Alliance, Inc., New York, grant number 5R01Al110964-03. If approved, this award would involve a foreign collaboration in Myanmar. The aims of this research project are to examine the mechanism through which coronaviruses jump from animal hosts/reservoirs to humans (spillover events). To accomplish this work the U.S. Principal Investigator (PI) and his team will conduct detailed surveillance for coronaviruses at eight sites throughout in Asia (China, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Thailand, and Vietnam). Sampling sites will include urban centers, rural areas, and live animal markets. Samples will be collected from animals from each of these sites, and will be analyzed to determine what coronaviruses are present, and whether the viruses are able to infect humans.	
	The investigators plan to collect samples from bats (900 samples total across all sites), rodents (900 samples total across all sites), and small carnivores such as palm civets and ferret badgers (500 samples total across all sites). Animals will be captured and lightly anesthetized if necessary. They will be swabbed (mouth/nose, urogenital tract, and rectum), and a small amount of blood will be collected. If available, feces and urine will also be collected. All wild animals will be released unharmed after sampling. Of animals that are collected from live markets, a maximum of two per species may be humanely euthanized for organ tissue sampling. All animal work will be performed by trained individuals in accordance with the American Veterinary Medical Association guidelines, and the project is overseen by veterinarians. This work has also been reviewed and approved by the investigator's Institutional Animal Care and Use Committee.	
USG Strategic Goal:	Resilient Communities	
Responsible USG Agency/Technical Office:	DHHS/NIH/National Institute of Allergy and Infectious Diseases (NIAID)	
Mechanism:	Grant	
Prime Partner:	EcoHealth Alliance, New York; Dr. Peter Daszak (Work will be conducted by in-country collaborators. In year 4 the PI will conduct a single site visit)	
Sub-Recipients:	San Pya Clinic, Yangon; Dr. Aung Than Toe	

Duration and Start/End Dates:	2 year project; new sampling work will begin in new budget period 6/1/2017 and continue through the end of the award 5/31/2019	
Funding:	HHS Appropriations = FY2017 FY Choose an item. Account Choose an item Budget Notwithstanding Authority (NWA) Please indicate which NWA is being used.	
Immediate Cost	\$3,000 for San Pya Clinic	
Total Estimated Cost:	Total cost for San Pya Clinic (\$3,000 over X years)	
Funding Approval:	This research grant was reviewed by experts in the scientific field and recommended for funding consideration. The NIAID Advisory Council approved the funding of this grant. Research protocols will be cleared through Myanmar and US Institutional Review Boards.	
Assistance to the GOB:	No - Assistance to GOB No assistance is being provided to the Government of Burma. NIH provides funding for research activities only.	
Congressional Notification:	Has your program been notified to Congress? When? Not required	
Beneficiary(ies):	Burmese people and San Pya Clinic staff	
*Check this box ⊠ to confirm that your agency/office has consulted the relevant legal advisors regarding this activity and that those off have confirmed the necessary legal authority to provide this assist. *Check this box ☐ to confirm activity participants/vendors have be screened for inclusion on the SDN list. https://sdnsearch.ofac.treas While the Burma Sanctions Program ended in October 2016, other sanctions programs might include people or entities in Burma. (NI Comment: CDC office has offered to confirm for Principal Investigators.) *Check this box ☐ to confirm due diligence for gross violators of he rights (GVHR) has been conducted. If not, please indicate why: *Check this box ☒ to confirm that Leahy Vetting has been/will be performed for all assistance to security forces, consistent with Emt		
Other	Rangoon Leahy Vetting Policy. (NIAID Comment: Vetting will be performed if post can provide information regarding this policy and how to complete Leahy Vetting.) "If this activity requires travel to the United States, please note that certain Burmese nationals are subject to visa restrictions in the 2008 JADE Act, a detailed in 17 State 1214. (NIAID Comment: NIAID notes this requirement and has made program officer aware of restrictions.)	
otner considerations:		

(b) (5)

Additional Comments:	There are no restrictions on this work proposed in Myanmar. The funding will only be used to support coronavirus research which will be conducted by collaborators in San Pya Clinic, which is a non-government organization. This is a new project conducted in Myanmar and does not duplicate any known projects in this area.
	NIH has legislative authority that allows NIH to award funds directly and indirectly to foreign institutions based on scientific merit. NIH is subject to all USG sanctions and other superseding actions and NIH acknowledges that and appreciates careful review by the Embassy committee and others on the ground in Myanmar.

From: Greer, Jenny (NIH/NIAID) [E] To: Smith, Philip (NIH/NIAID) [E]

Subject: FW: FACTS: State Department Clearance Request Approved

Date: Friday, March 17, 2017 9:16:24 AM

Jenny Green Grants Management Specialist DHHS/NIH/NIAID/DEA/GMP 5601 Fishers Lane, Room 4E49, MSC 9833

Bethesda, MD 20892-9824

Phone: (b) (6)

(b) (6) Email:

Effective January 1, 2017, NIH closeout policy has changed (see NOT-0D-17-022). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the NIH RPPR Page.

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From: era-notify@mail.nih.gov [mailto:era-notify@mail.nih.gov]

Sent: Friday, March 17, 2017 5:14 AM

To: NIAID FCTS <NIAIDFCTS@niaid.nih.gov>; Stemmy, Erik (NIH/NIAID) [E] (b) (6); (b) (6); Greer, Jenny (NIH/NIAID) [E]

Bernabe, Gayle (NIH/NIAID) [E]

Subject: FACTS: State Department Clearance Request Approved

*** This is an automated notification - Please do not reply to this message. ***

Project Number: R01AI110964-03 PI Name: PETER DASZAK

Project Title: Understanding the Risk of Bat Coronavirus Emergence

Country: THAILAND

SDCR Initiated By: Gayle Bernabe

SDCR Status: Approved

Action Comment: We note that the PIs include USAID Regional Development Mission for Asia partners currently undertaking similar work in the same countries through the Emerging Pandemic Threats PREDICT 2 project. The distinction between that project and this one is not immediately clear.

If you have any questions, please contact the eRA Help Desk at

http://grants.nih.gov/support/index.html OR call 1-866-504-9552 (tty: 301-451-5939) OR helpdesk@od.nih.gov.

From: Aleksei Chmura

To: Stemmy, Erik (NIH/NIAID) [E]

Cc: Greer, Jenny (NIH/NIAID) [E]; Smith, Philip (NIH/NIAID) [E]
Subject: Re: Year 2 Report for 5R01Al110964 - 02 PI Name: DASZAK, PETER

Date: Friday, February 17, 2017 10:19:33 PM

Attachments: NIH-NIAID 5R01AI110964 Additional Site Q and A.pdf

Dear Erik,

Please find our responses in the attached PDF. If you need any additional details, please let me know.

Many thanks!

-Aleksei

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

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On Feb 15, 2017, at 08:52, Stemmy, Erik (NIH/NIAID) [E] (b) (6) wrote:

Hi Aleksei,

I know you said nothing will be changing from your currently approved animal studies, but it would be helpful for me in preparing the foreign clearance request if you could write a few concise sentences about the new animal work addressing the following points:

- · Kind or species of animal and number to be used
- · Location of the source of the animals, if known
- A brief description of the sampling (blood draw, swab, etc)
- · Location from where the animals will be obtained (source)
- If possible, what will be done with the animals after the project ends (e.g., euthanized)

Obtained via FOIA by White Coat Waste Project

(b) (5)

Let me know if you have any questions.

Thanks!

Erik

From: Aleksei Chmura (b) (6)

Sent: Monday, February 13, 2017 4:23 PM

To: Greer, Jenny (NIH/NIAID) [E] (b) (6)

Cc: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Smith, Philip (NIH/NIAID) [E]

(b) (6)

Subject: Re: Year 2 Report for 5R01Al110964 - 02 PI Name: DASZAK, PETER

Super! Thanks, Jenny.

Erik and Philip - please let me know, if you have any questions or require additional details. We look forward to your responses.

Sincerely,

-Aleksei

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

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On Feb 13, 2017, at 16:18, Greer, Jenny (NIH/NIAID) [E]

Aleksei,

Thank you for your email. I am copying Erik on this response so he can make sure he has everything needed to initiate a request for each of these foreign sites. I am also copying Philip Smith, the grants management specialist assigned to this grant for this fiscal year. Please don't hesitate to contact either of them with any questions you may have.

Please note that this response does not constitute approval and it will take at least 3 weeks for a final determination to be made.

Thanks again! And have a great afternoon!

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone:
(b) (6)
Email:
(b) (6)

Effective January 1, 2017, NIH closeout policy has changed (see <u>NOT-OD-17-022</u>). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the <u>NIH RPPR Page</u>.

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From: Aleksei Chmura (b) (6)

Sent: Friday, February 10, 2017 2:54 PM

To: Greer, Jenny (NIH/NIAID) [E] (b) (6)

Subject: Re: Year 2 Report for 5R01Al110964 - 02 Pl Name: DASZAK,

PETER

Dear Jenny,

I am just following up with item 1 and 1a from your email below. As per Peter's email (also below), we would like to request prior approval for collecting non-human animal samples in 7 countries: Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Thailand, and Vietnam.

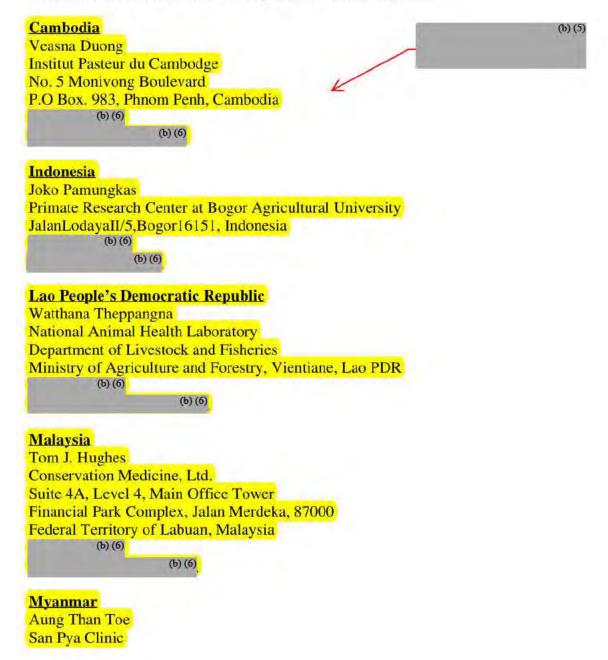
No new animals will be introduced nor any new field procedures, we have submitted IACUC protocol modification - for geographic locations only - and will provide approval dates as soon as they are available.

No work will be conducted until we have your approval and IACUC approval.

Testing would be conducted locally and if any samples were to be transferred to China these would be only extracted viral DNA - and not the original sample material.

Samples will be collected by either our current China field team personnel working directly with our collaborators in these countries or by respective in-country personnel and require no more than 10% budget modification total (from already budgeted China fieldwork) for any non-China in-country work.

Here is the list of our local in-country contacts and institutions:



```
20/256, Insein Road
Yangon 11051, Myanmar
       (b) (6)
                (b) (6)
Thailand
Supaporn Wacharapluesadee
Neuroscience Center for Research and Development
King Chulalongkorn Memorial Hospital
Rama 4 Road
Patumwan, Bangkok, Thailand 10330
                  (b) (6)
              (b) (6)
Vietnam
Nguyen Huu Nam
Faculty of Animal and Veterinary Science
Hanoi Agricultural University
Trauguy, Gialâm, Hanoi, Vietnam
               (b) (6)
```

If it will be easier to have a quick chat about this, I am happy to call anytime. Also, if this request should be sent more formally as a letter attachment, we can do that rapidly as well.

I hope you and yours had a lovely Holiday and are surviving the blizzard!

Cheers,

-Aleksei

Aleksei Chmura

Senior Coordinator of Operations

(b) (6)

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

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On Aug 1, 2016, at 12:39, Greer, Jenny (NIH/NIAID) [E] (b) (6) wrote:

Thank you for your email. To answer your questions:

- To do any work in countries other than China, you
 will need to request prior approval from NIH. To do
 so, submit a formal request, including the names,
 institutions, and full contact information of any
 institutions with which you will collaborate for such
 activities. Be sure to indicate whether animal or
 human research will be conducted and what funds, if
 any, will be going into these countries. The approval
 process for new foreign sites takes at least 3 weeks,
- 1a . If you are introducing new animals into the project, then there may be additional requirements from the Office of Laboratory Animal Welfare (OLAW). Again, you would need to submit a formal request, providing a scientific justification for the inclusion of new species on the project, and, if appropriate, a new Vertebrate Animal Section. If additional IACUC approvals are required, you will need to provide us with the IACUC approval dates (but **not** a copy of the actual approval).
 - 2. These individuals are not listed in the Notice of Award as key personnel, so, from a grants management perspective, you do not need to get prior approval for this change. That said, if this change or other such personnel changes would have a significant impact on the scope of the project or the science itself, you would need to at least run it by your Program Officer. And if it is determined that personnel changes would cause a scope change, then you would need grants management approval as well.
 - 3. I do not know what you are asking here. It looks like we have approved both the Wuhan University and ECNU for work on this project. Therefore, no additional prior approval is required for changes unless otherwise specified in the NIH Grants Policy Statement (eg, a change of scope).

Please don't hesitate to contact me with any additional questions. I will be available until 2:30 eastern and then again on Wednesday.

All the best,

Jenny

Jenny Greer

Grants Management Specialist DHHS/NIH/NIAID/DEA/GMP

5601 Fishers Lane, Room 4E49, MSC 9833

Bethesda, MD 20892-9824

Phone: (b) (6)

Email: (b) (6

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From: Aleksei MacDurian

(b) (6)

Sent: Sunday, July 31, 2016 6:06 AM

To: Greer, Jenny (NIH/NIAID) [E] (b) (6)

Subject: Re: Year 2 Report for 5R01Al110964 - 02 Pl Name:

DASZAK, PETER

Dear Jenny,

Since you were not cc'ed on the original email, I wanted to follow up with you on three things from Dr. Daszak's email to Erik (included below):

- 1) Do we need to formally request permission to sample species of bats and other high-risk [rodents and carnivore] hosts in countries that neighbor China (Myanmar, Vietnam, Cambodia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia). Under this award our current US and China IACUC approved protocol via Tufts University and Wuhan Institute of Virology permits us to sample these species in these regions.
- 2) We provided Dr. Noam Ross' CV with our Year 2 Report. Dr. Ross has replaced Dr. Hosseini who is no longer working on this project. Do we need to do anything else for this? I have attached his Biosketch here for reference.

3) Our Human surveillance work and local IRB approval have all been through the Wuhan University School of Public Health (WUSPH) in China (DUNS No. 529049295). We would like now - in Years 3 - 5 of our award to subcontract directly with them rather than with the institution on our current budget: East China Normal University (ECNU) School of Life Sciences. The Wuhan University School of Public Health budget amount would be the same annual amount as currently budgeted for East China Normal University in these same years.

It may be easier to briefly chat about these questions via telephone. If so, you may reach me at + anytime.

Many thanks!

-Aleksei

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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On Fri, May 13, 2016 at 5:55 PM, Peter Daszak (b) (6) wrote:

Dear Erik,

I just wanted to let you know that we submitted our Year 2 Report yesterday (attached as a pdf).

It's been a pretty productive year, and some of the highlights include: collecting samples from 15 bat genera in southern China with 280 (12%) testing positive for coronaviruses; SARS-like coronaviruses being detected in Rhinolophus spp. bats in both Yunnan and Guangdong provinces; 7 published papers from work under our award

(including one in *J. Virol.* and one in press at *J. Virol*); 218 quantitative interviews with samples and 47 qualitative coded interviews conducted transcribed and translated.

In the report, I highlight the reduced amount of wildlife in the local markets within Southern China compared to that we've seen before, as well as the continued expansion of the Chinese wildlife trade within SE Asia so that it is now a largescale international activity. It means that SL-CoVs we find in the wildlife trade would likely have an origin in adjacent countries. Given that our collaborators and field team in China have great contacts in these countries, and EHA also has field teams in many of them, we would like to conduct short field trips to assess markets, identify wildlife in them, and sample species of bats and other high-risk hosts in countries that neighbor China (Myanmar, Vietnam, Cambodia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia). All samples collected would still be tested at the Wuhan Institute of Virology in China. Is there a formal process to ask for permission for this, or is the report and this email appropriate?

I also wanted to let you know about a recent personnel change. Since Dr. Parviez Hosseini has moved to earlier this year, we hired another senior researcher Noam Ross to conduct data analysis and spatial mapping. Our Year 2 report includes his CV. Noam has great enthusiasm and I am eager to see his work on our data collected to date. He has already been out to China is hitting the ground running!

We have had great successes this past year and I'd be happy to discuss any of them with you, if you'd like.

Cheers,

Peter

Peter Daszak

President

EcoHealth Alliance

460 West 34th Street – 17th Floor New York, NY 10001

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www.ecohealthalliance.org

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1. Kind or species of animal and number to be used:

Species taxa	Family, Genus or Species Name	Target numbers
Fruit bats	e.g.: Cynopterus, Rousettus, Eonycterus spp.	900 individuals (30
Insectivorous	e.g.: Rhinilophidae, Hipposideridae,	individuals from 30
bats	Emballonuridae, Vespertillionidae,	different species)
	Mollsidae, Miniopteridae spp.	### #################################
Rodents	e.g: Chinese bamboo rat (<i>Rhizomys</i> sinensis), Malayan porcupine (<i>Hystrix</i> brachyura), bandicoot (<i>Bandicota indica</i>)	900 individuals
Small Carnivores	e.g.: Raccoon dog (<i>Nyctereutes</i> procyonoides), Asian Palm civet (<i>Paradoxurus hemaphroditus</i>), ferret	500 individuals
	badger (Melogale moschata)	

2. Location of the source of the animals, if known:

Free-ranging bat surveys and bats in wet markets: China, Malaysia, Thailand, Cambodia, Lao PDR, Myanmar, Vietnam, and Indonesia.

Other mammals: We will opportunistically sample the other aforementioned taxa that are also sold in live animal markets, trading locations or bred on farms to supply markets throughout southeast Asia. Species and numbers of animals sampled from markets will be based on animal availability.

3. A brief description of the sampling (blood draw, swab, etc)

Bat capture. Free-ranging bats will be captured using either a mist net or harp trap and bats are removed from the net as soon as they become entangled to minimize stress and prevent injury. Bats will be manually restrained during sampling. Bats that are fractious may be anesthetized for restraint purposes in order to maximize safety for the bat and handler. Depending on the species and size of bat, swabs will be taken from the oropharynx, urogenital tract, and rectum. Fresh feces will be collected if available, in which case a rectal swab will not be collected. Blood will be collected from either from the cephalic vein or from the radial artery or vein using a 25-gauge needle. Bats are held for a maximum of six hours and then released following sample collection. We will euthanize 2 individuals per bat species for organ tissue banking.

Wild and captive bred rodent capture. Free-ranging rodents will be captured using box traps. Captive bred rodents (e.g. at rodent farms) will be manually captured and restrained. Traps for free-ranging rodents will be checked a minimum of every 12 hours, including once in the morning. Captive bred and wild rodent sampling procedures (including anesthesia, if necessary), will involve manual restraint, venipuncture, mucosal swabs, fecal, and urine sample collection.

Other small mammals: Anesthesia will be used to restrain small mammals such as civets and ferret badgers. Animals will be monitored continuously while recovering from anesthesia and will only be released once fully recovered from anesthesia. Animals that are sourced from markets and that may potentially be consumed, will be manually restrained without anesthesia, if possible, so that they may be returned to the vendor. Otherwise, the animal will be sampled and then euthanized via exsanguination

(cardiac puncture) while under anesthesia, then disposed of using biohazard protocols in order to prevent subsequent human or animal consumption.

4. Location from where the animals will be obtained (source):

Markets and surrounding caves/forest: sites will be identified along value chain routes linking southern China to southeast Asian countries that serve as sources for the Chinese market system. Specific field sites have not yet been determined.

5. If possible, what will be done with the animals after the project ends (e.g., euthanized)

All wild animals will be released unharmed after sampling at the capture location. 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 in accordance with the AVMA guidelines for euthanasia (2013). 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.

From: Aleksei MacDurian

To: Smith, Philip (NIH/NIAID) [E]

Subject: Re: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Date: Wednesday, May 03, 2017 4:10:18 PM

Dear Philip,

Sincere apologies for my tardy reply. I was out-of-office the past two days unexpectedly and am just catching up with emails.

(b) (5)

There are no planned in-country costs associated with these foreign sites. All testing costs will be at the Wuhan Institute of Virology in China - our current, approved partner under our award.

Many thanks!

-Aleksei

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

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On Fri, Apr 28, 2017 at 5:29 PM, Smith, Philip (NIH/NIAID) [E] (b) (6) wrote:

Hi Aleksei,

Can you provide the direct and indirect costs for the foreign sites we are adding (Cambodia, Indonesia, Lao People's Democratic Republic, Malaysia, Myanmar, Thailand, Vietnam)? Once this is received we can issue a revised NOA approving these sites.

Thanks,

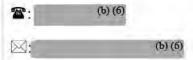
Philip Smith

Grants Management Specialist

Grants Management Program, DEA, NIAID, NIH

5601 Fishers Lane, Rm 4E48, MSC 9833 GMP

Rockville, Maryland 20892-9824



Effective January 1, 2017, NIH closeout documentation policy has changed (see <u>NOT-OD-17-022</u>). NIH is no longer accepting Final Progress Reports (FPR), Grantees must now report final project outcomes using the new F-RPPR, For instructions on how to submit the new F-RPPR please see instructions on the <u>NIH RPPR Page</u>.

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From: Bernabe, Gayle (NIH/NIAID) [E]

Yuan, Liz (NIH/FIC) [E]; Officer, Jackie (NIH/FIC) [E]

Cc: Stemmy, Erik (NIH/NIAID) [E]; Smith, Philip (NIH/NIAID) [E]; Handley, Gray (NIH/NIAID) [E]; Meegan, James (NIH/NIAID) [E]; Arcuri, Guy (NIH/NIAID) [E]; Dominique, Joyelle (NIH/NIAID) [E]; Rosa, William (NIH/NIAID)

(b) (5)

(b) (5)

IF1

Subject: FACTS: Project for BURMA on queue for SDC: R01AI110964-03; DASZAK, PETER

Date: Saturday, March 25, 2017 12:34:57 PM

Attachments: Burma InfoShare Post Concurrence EcoHealth Alliance March 2017.docx

Dear Liz and Jackie:

To:

Please find attached the "Burma Assistance Activity InfoShare & Post/Mission Concurrence Request" form for grant Al110964-03 (Burma).

Please let us know if additional information is needed.

Thank you and kind regards, Gayle

Gayle Bernabe, MPH
Regional Program Officer-East/SE Asia and the Pacific
Office of Global Research (OGR)
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Department of Health and Human Services
5601 Fishers Ln Rm 1E MSC 9802

Bethesda, MD 20892-9802 [For courier deliveries: 20852]

Phone: **(b) (6)** Fax: (301) 480-2954

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Disclamer

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Submitted by

Name: (b) (6)

Title: Understanding the Risk of Bat

Coronavirus Emergence – 5R01Al110964-03

Agency/Office: DHHS/NIH

Date Submitted: 3/24/2017

Post/Mission Concurrence: Choose an item.
Post/Mission Comments: Click here to enter text.

Activity:	The National Institute of Allergy and Infectious Diseases (NIAID), at the National Institutes of Health (NIH), has a pending award to the EcoHealth Alliance, Inc., New York, grant number 5R01Al110964-03. If approved, this award would involve a foreign collaboration in Myanmar. The aims of this research project are to examine the mechanism through which coronaviruses jump from animal hosts/reservoirs to humans (spillover events). To accomplish this work the U.S. Principal Investigator (PI) and his team will conduct detailed surveillance for coronaviruses at eight sites throughout in Asia (China, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Thailand, and Vietnam). Sampling sites will include urban centers, rural areas, and live animal markets. Samples will be collected from animals from each of these sites, and will be analyzed to determine what coronaviruses are present, and whether the viruses are able to infect humans.
	The investigators plan to collect samples from bats (900 samples total across all sites), rodents (900 samples total across all sites), and small carnivores such as palm civets and ferret badgers (500 samples total across all sites). Animals will be captured and lightly anesthetized if necessary. They will be swabbed (mouth/nose, urogenital tract, and rectum), and a small amount of blood will be collected. If available, feces and urine will also be collected. All wild animals will be released unharmed after sampling. Of animals that are collected from live markets, a maximum of two per species may be humanely euthanized for organ tissue sampling. All animal work will be performed by trained individuals in accordance with the American Veterinary Medical Association guidelines, and the project is overseen by veterinarians. This work has also been reviewed and approved by the investigator's Institutional Animal Care and Use Committee.
USG Strategic Goal:	Resilient Communities
Responsible USG Agency/Technical Office:	DHHS/NIH/National Institute of Allergy and Infectious Diseases (NIAID)
Mechanism:	Grant
Prime Partner:	EcoHealth Alliance, New York; Dr. Peter Daszak (Work will be conducted by in-country collaborators. In year 4 the PI will conduct a single site visit.)
Sub-Recipients:	San Pya Clinic, Yangon; Dr. Aung Than Toe

Duration and Start/End Dates:	2 year project; new sampling work will begin in new budget period 6/1/2017 and continue through the end of the award 5/31/2019
Funding:	HHS Appropriations – FY2017 FY Choose an item. Account Choose an item. Budget Notwithstanding Authority (NWA) Please indicate which NWA is being used.
Immediate Cost:	No funds will be sent directly to Myanmar.
Total Estimated Cost:	No funds will be sent directly to Myanmar.
Funding Approval:	This research grant was reviewed by experts in the scientific field and recommended for funding consideration. The NIAID Advisory Council approved the funding of this grant. Research protocols will be cleared through Myanmar and US Institutional Review Boards.
Assistance to the GOB:	No - Assistance to GOB No assistance is being provided to the Government of Burma. NIH provides funding for research activities only.
Congressional Notification:	Has your program been notified to Congress? When? Not required
Beneficiary(ies):	Burmese people and San Pya Clinic staff
Legal Determination:	*Check this box \(\subseteq \) to confirm that your agency/office has consulted with the relevant legal advisors regarding this activity and that those officers have confirmed the necessary legal authority to provide this assistance. *Check this box \(\subseteq \) to confirm activity participants/vendors have been screened for inclusion on the SDN list. https://sdnsearch.ofac.treas.gov/ . While the Burma Sanctions Program ended in October 2016, other sanctions programs might include people or entities in Burma. (NIAID Comment: CDC office has offered to confirm for Principal Investigators.) *Check this box \(\subseteq \) to confirm due diligence for gross violators of human rights (GVHR) has been conducted. If not, please indicate why:
	*Check this box to confirm that Leahy Vetting has been/will be performed for all assistance to security forces, consistent with Embassy in Rangoon Leahy Vetting Policy. (NIAID Comment: Vetting will be performed if post can provide information regarding this policy and how to complete Leahy Vetting.) *If this activity requires travel to the United States, please note that certain Burmese nationals are subject to visa restrictions in the 2008 JADE Act, as detailed in 17 State 1214. (NIAID Comment: NIAID notes this requirement and has made program officer aware of restrictions.)
Other considerations:	

Additional	There are no restrictions on this work proposed in Myanmar. The funding
Comments:	will only be used to support coronavirus research which will be conducted by collaborators in San Pya Clinic, which is a non-government organization. No funds are presently planned to be sent to Myanmar. This is a new project conducted in Myanmar and does not duplicate any known projects in this area.
	NIH has legislative authority that allows NIH to award funds directly and indirectly to foreign institutions based on scientific merit. NIH is subject to all USG sanctions and other superseding actions and NIH acknowledges that and appreciates careful review by the Embassy committee and others on the ground in Myanmar.

From: Stemmy, Erik (NIH/NIAID) [E]

To: Bernabe, Gayle (NIH/NIAID) [E]; Smith, Philip (NIH/NIAID) [E]

Subject: RE: (Foreign Clearance - BURMA) Grant Number: 5R01AI110964 - 03 PI Name: DASZAK , PETER (Embassy

Request Form)

Date: Friday, March 24, 2017 2:50:06 PM

Attachments: Re Out of Office RE Year 2 Report for 5R01Al1110964 - 02 PI Name DASZAK PETER.msq

Burma InfoShare Post Concurrence EcoHealth Alliance_March 2017.docx

Hello Gayle and Philip,

My apologies for the slow response. The PI responded on Monday, but I was out of the office on a site visit until last night. Please see attached and let me know if that is sufficient information. Of particular note, the PI said in the attached message that they don't plan on sending any funds directly in country to Burma; they're just coordinating the transfer of samples from the collection site to the collaborator lab in China. Let me know if you need more info from me.

Many thanks,

Erik

From: Bernabe, Gayle (NIH/NIAID) [E]

Sent: Wednesday, March 22, 2017 1:54 PM

To: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Smith, Philip (NIH/NIAID) [E]

(b) (6)

Cc: Bernabe, Gayle (NIH/NIAID) [E] (b) (6)

Subject: RE: (Foreign Clearance - BURMA) Grant Number: 5R01Al110964 - 03 PI Name: DASZAK,

PETER (Embassy Request Form)

Dear Erik and Philip:

I just wanted to follow-up with this project and the Embassy request form needed for clearance.

Your time and input are appreciated.

Thanks and kind regards,

Gayle

From: Bernabe, Gayle (NIH/NIAID) [E]

Sent: Thursday, March 16, 2017 1:04 PM

To: Stemmy, Erik (NIH/NIAID) [E] (6) (6); Smith, Philip (NIH/NIAID) [E]

(b) (6)

Cc: Bernabe, Gayle (NIH/NIAID) [E] (6) (6)

Subject: FW: (Foreign Clearance - BURMA) Grant Number: 5R01Al110964 - 03 PI Name: DASZAK,

PETER (Embassy Request Form)

Dear Erik and Philip:

For any projects involving Burma, the U.S. Embassy/Post has requested NIH to submit the attached form. I tried to fill it out with information from the FACTS record, as well as standard language that

Obtained via FOIA by White Coat Waste Project

(b) (5)

has been used for other projects with Burma. Please review it and update any information specific to the activities to be done in Burma, including the text highlighted in yellow.

Once this form is complete, it will be submitted to FIC.

Thank you for your time.

Kind regards, Gayle

Gayle Bernabe, MPH
Regional Program Off

Regional Program Officer-East/SE Asia and the Pacific

Office of Global Research (OGR)

National Institute of Allergy and Injectious Diseases

National Institutes of Health

Department of Health and Human Services

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From: "Arcuri, Guy (NIH/NIAID) [E]" (b) (6)

Date: Friday, March 10, 2017 at 9:41 AM

To: "Smith, Philip (NIH/NIAID) [E]" (b) (6), NIAID State Dept Clearance

(b) (6)

Cc: "Bernabe, Gayle (NIH/NIAID) [E]" (b) (6)

Subject: RE: (Foreign Clearance - BURMA) Grant Number: 5R01Al110964 - 03 Pl Name: DASZAK,

PETER; OGR Contact: Gayle Bernabe

Your request has been received and will be reviewed for DGR by Gayle Bernabe.

Thank you,

V/R,

From: Smith, Philip (NIH/NIAID) [E]

Sent: Thursday, March 09, 2017 3:14 PM

To: NIAID State Dept Clearance (b) (6)

Subject: (Foreign Clearance - BURMA) Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Good Afternoon,

The following request for foreign clearance is ready for review. This request is to add protocols to already approved sites in Brazil:

Grant Number: 5R01Al110964 - 03

P.I.: DASZAK, PETER

Applicant Organization: ECOHEALTH ALLIANCE, INC.

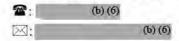
Foreign Country: BURMA

GMS: Philip Smith PO: Stemmy, Erik

Thank you,

Philip Smith

Grants Management Specialist Grants Management Program, DEA, NIAID, NIH 5601 Fishers Lane, Rm 4E48, MSC 9833 GMP Rockville, Maryland 20892-9824



Effective October 1, 2014, NIH closeout policy has changed (see <u>NOT-OD-14-084</u>). In order to avoid unilateral closeout, final reports must be submitted in a timely manner. Failure to submit accurate final reports could result in enforcement actions such as revisions to NOA funding levels, or delay in future funding.

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From: Peter Daszak

Sent: Mon, 20 Mar 2017 18:32:16 +0000

To: Stemmy, Erik (NIH/NIAID) [E]; Alison Andre

Cc: Aleksei Chmura;Smith, Philip (NIH/NIAID) [E];Evelyn Luciano

Subject: Re: Out of Office RE: Year 2 Report for 5R01Al110964 - 02 PI Name: DASZAK,

PETER

Importance: High

Hi Erik,

Here are the answers to your questions:

1. Will Dr Daszak (or other EcoHealth staff) plan to spend time directly in country in Myanmar? If so, please provide an approximate % of time.

We are in initial planning of approach with these countries including Myanmar and time spent this year in Myanmar would primarily be by our collaborators and *not* EHA staff. In Yr 4, we will probably need to budget one site visit conducted by Dr. Peter Daszak and Senior Personnel Dr. Olival and/or by our field veterinarian. Please let us know what restrictions there might be for this...

2. How long do you anticipate the sampling will continue? That is, through the remainder of the R01, or a shorter amount of time?

Sampling will be conducted a minimum of four times over then remainder of the R01.

3. Can you confirm the total amount of US\$ to be sent to Myanmar for the work?

No funds are presently planned to be sent to Myanmar. We plan to coordinate collaborative transfer of samples from Myanmar to our partner Lab in China.

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

Sent: Thursday, March 16, 2017 2:11 PM

To: Peter Daszak; Alison Andre

Cc: Aleksei Chmura; Smith, Philip (NIH/NIAID) [E]; Evelyn Luciano

Subject: RE: Out of Office RE: Year 2 Report for 5R01Al110964 - 02 PI Name: DASZAK, PETER

Thank you Peter!

Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825

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

Getting ready to publish? Share the good news with your program officer asap! NIAID may be able to help publicize your article. And, remember to list your NIAID grant or contract number in the publication.

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From: Peter Daszak	(6) (6)	
Sent: Thursday, March 16, 2017 2:10 PM		
To: Stemmy, Erik (NIH/NIAID) [E]	(b) (6); Alison Andre	(6) (6)
Cc: Aleksei Chmura	6) (6); Smith, Philip (NIH/NIAID) [E]	
(b) (6); Evelyn Luciano	(b) (6)	
Subject: RF: Out of Office RF: Year 2 Report f	or 5R01AI110964 - 02 PL Name: DASZAK, PETER	

Hi Erik,

I've just returned from travel and we'll get answers to you on this by Monday COB.

Cheers,

Peter

Peter Daszak

President

EcoHealth Alliance 460 West 34th Street – 17th Floor New York, NY 10001

(b) (6) (direct) +1.212.380.4465 (fax)

www.ecohealthalliance.org

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.

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

Sent: Thursday, March 16, 2017 1:33 PM

To: Alison Andre

Cc: Peter Daszak; Aleksei Chmura; Smith, Philip (NIH/NIAID) [E]

Subject: FW: Out of Office RE: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Hello Alison,

I received an out of office message from Aleksei. I am working on new foreign clearances for the grant referenced above, and need some additional information for the site in Myanmar. Would you be able to help address the questions below?

Thank you,

Erik

- -Will Dr Daszak (or other EcoHealth staff) plan to spend time directly in country in Myanmar? If so, please provide an approximate % of time.
- -How long do you anticipate the sampling will continue? That is, through the remainder of the R01, or a shorter amount of time?
- -Can you confirm the total amount of US\$ to be sent to Myanmar for the work?

From: Aleksei Chmura	(b) (6)
TOTAL AICKSCI CIIIIIIII	(-) (-)

Sent: Thursday, March 16, 2017 1:23 PM

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

Subject: Out of Office RE: Year 2 Report for 5R01Al110964 - 02 PI Name: DASZAK, PETER

Thank you for your email.

I will be out of the office and traveling until 20 March 2017. During this time, I may not have regular access to emails and voice messages. If you should need immediate assistance, please contact Alison Andre at (b) (6). Otherwise, I will respond to your message as soon as possible.

Sincerely,

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

(b) (6) (direct) (b) (6) (mobile)

Aleksei MacDurian (Skype)

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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.

Submitted by

Name: (b) (6)
Title: Understanding the Risk of Bat

Coronavirus Emergence – 5R01Al110964-03 Agency/Office: DHHS/NIH Date Submitted: 3/16/2017

Post/Mission Concurrence: Choose an item.
Post/Mission Comments: Click here to enter text.

Activity:	The National Institute of Allergy and Infectious Diseases (NIAID), at the National Institutes of Health (NIH), has a pending award to the EcoHealth Alliance, Inc., New York, grant number 5R01Al110964-03. If approved, this award would involve a foreign collaboration in Myanmar. The aims of this research project are to examine the mechanism through which coronaviruses jump from animal hosts/reservoirs to humans (spillover events). To accomplish this work the U.S. Principal Investigator (PI) and his team will conduct detailed surveillance for coronaviruses at eight sites throughout in Asia (China, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Thailand, and Vietnam). Sampling sites will include urban centers, rural areas, and live animal markets. Samples will be collected from animals from each of these sites, and will be analyzed to determine what coronaviruses are present, and whether the viruses are able to infect humans.
	The investigators plan to collect samples from bats (900 samples total across all sites), rodents (900 samples total across all sites), and small carnivores such as palm civets and ferret badgers (500 samples total across all sites). Animals will be captured and lightly anesthetized if necessary. They will be swabbed (mouth/nose, urogenital tract, and rectum), and a small amount of blood will be collected. If available, feces and urine will also be collected. All wild animals will be released unharmed after sampling. Of animals that are collected from live markets, a maximum of two per species may be humanely euthanized for organ tissue sampling. All animal work will be performed by trained individuals in accordance with the American Veterinary Medical Association guidelines, and the project is overseen by veterinarians. This work has also been reviewed and approved by the investigator's Institutional Animal Care and Use Committee.
USG Strategic Goal:	Resilient Communities
Responsible USG Agency/Technical Office:	DHHS/NIH/National Institute of Allergy and Infectious Diseases (NIAID)
Mechanism:	Grant
Prime Partner:	EcoHealth Alliance, New York; Dr. Peter Daszak (Work will be conducted by in-country collaborators. In year 4 the PI will conduct a single site visit)
Sub-Recipients:	San Pya Clinic, Yangon; Dr. Aung Than Toe

Duration and Start/End Dates:	2 year project; new sampling work will begin in new budget period 6/1/2017 and continue through the end of the award 5/31/2019
Funding:	HHS Appropriations – FY2017 FY Chaose an item. Account Chaose an item. Budget Notwithstanding Authority (NWA) Please indicate which NWA is being used.
Immediate Cost:	\$3,000 for San Pya Clinic
Total Estimated Cost:	Total cost for San Pya Clinic (\$3,000 over X years)
Funding Approval:	This research grant was reviewed by experts in the scientific field and recommended for funding consideration. The NIAID Advisory Council approved the funding of this grant. Research protocols will be cleared through Myanmar and US Institutional Review Boards.
Assistance to the GOB:	No - Assistance to GOB No assistance is being provided to the Government of Burma. NIH provides funding for research activities only.
Congressional Notification:	Has your program been notified to Congress? When? Not required
Beneficiary(ies):	Burmese people and San Pya Clinic staff
Legal Determination:	*Check this box to confirm that your agency/office has consulted with the relevant legal advisors regarding this activity and that those officers have confirmed the necessary legal authority to provide this assistance. *Check this box to confirm activity participants/vendors have been screened for inclusion on the SDN list. https://sdnsearch.ofac.treas.gov/ . While the Burma Sanctions Program ended in October 2016, other sanctions programs might include people or entities in Burma. (NIAID Comment: CDC office has offered to confirm for Principal Investigators.) *Check this box to confirm due diligence for gross violators of human rights (GVHR) has been conducted. If not, please indicate why.
	*Check this box to confirm that Leahy Vetting has been/will be performed for all assistance to security forces, consistent with Embassy in Rangoon Leahy Vetting Policy. (NIAID Comment: Vetting will be performed if post can provide information regarding this policy and how to complete Leahy Vetting.) *If this activity requires travel to the United States, please note that certain Burmese nationals are subject to visa restrictions in the 2008 JADE Act, as detailed in 17 State 1214. (NIAID Comment: NIAID notes this requirement and has made program officer aware of restrictions.)
Other considerations:	

(b) (3

Additional Comments:	There are no restrictions on this work proposed in Myanmar. The funding will only be used to support coronavirus research which will be conducted by collaborators in San Pya Clinic, which is a non-government organization. This is a new project conducted in Myanmar and does not duplicate any known projects in this area.
	NIH has legislative authority that allows NIH to award funds directly and indirectly to foreign institutions based on scientific merit. NIH is subject to all USG sanctions and other superseding actions and NIH acknowledges that and appreciates careful review by the Embassy committee and others on the ground in Myanmar.

 From:
 Green, Jenny (NIH/NIAID) [E]

 To:
 Smith, Philip (NIH/NIAID) [E]

Subject: FW: FACTS: State Department Clearance Request Approved

Date: Friday, March 17, 2017 9:16:24 AM

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833

Bethesda, MD 20892-9824

Phone: (b) (6)

Email: (b) (6)

Effective January 1, 2017, NIH closeout policy has changed (see <u>NOT-OD-17-022</u>). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the <u>NIH RPPR Page</u>.

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From: era-notify@mail.nih.gov [mailto:era-notify@mail.nih.gov]

Sent: Friday, March 17, 2017 5:14 AM

To: NIAID FCTS <NIAIDFCTS@niaid.nih.gov>; Stemmy, Erik (NIH/NIAID) [E] (b) (6);

Bernabe, Gayle (NIH/NIAID) [E] (6) (6) ; Greer, Jenny (NIH/NIAID) [E]

(b) (6)

Subject: FACTS: State Department Clearance Request Approved

*** This is an automated notification - Please do not reply to this message. ***

Project Number: R01AI110964-03 PI Name: PETER DASZAK

Project Title: Understanding the Risk of Bat Coronavirus Emergence

Country: THAILAND

SDCR Initiated By: Gayle Bernabe

SDCR Status: Approved

Action Comment: We note that the PIs include USAID Regional Development Mission for Asia partners currently undertaking similar work in the same countries through the Emerging Pandemic Threats PREDICT 2 project. The distinction between that project and this one is not immediately clear.

If you have any questions, please contact the eRA Help Desk at

http://grants.nih.gov/support/index.html OR call 1-866-504-9552 (tty: 301-451-5939) OR helpdesk@od.nih.gov.

Greer, Jenny (NIH/NIAID) [E]

(b) (6) Aleksei Chmura From: Thursday, October 06, 2016 12:26 PM Sent: To: Greer, Jenny (NIH/NIAID) [E] Cc: Hongying Li Fwd: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER Subject: Follow Up Flag: Follow up Completed Flag Status: Categories: Foreign Dear Jenny, Apologies for the delay, here are the details for the new institution that will be an even switch-out for East China Normal University (so no modification to budget or project aims): CONTACT/PI: Dr. Shiyue Li TITLE: Professor Committee Director and Professor of Epidemiology and Health Statistics INSTITUTION: Wuhan University School of Public Health (b) (6) EMAIL: TELEPHONE: (b) (6) INSTITUTION NAME: Wuhan University School of Public Health DUNS NUMBER: 529049295 No Animal Research Conducted. Human Research Conducted as per IRB approval. Please let me know, if you require further information. Many thanks! -Aleksei On Aug 1, 2016, at 18:18, Greer, Jenny (NIH/NIAID) [E] (b) (б) wrote: Aleksei, Sounds good.

Erik will have to confirm, but from my perspective, we're fine.

how much money, if any will go to the institution. You can include this information with the request referenced in 1.
Jenny
Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone: (b) (6)
Email: (b) (6)
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From: Aleksei MacDurian (b) (6) Sent: Monday, August 01, 2016 12:51 PM To: Greer, Jenny (NIH/NIAID) [E] (b) (6) Subject: Re: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER
Thanks, Jenny!
Quick replies:

3. If this is a new institution, please provide a contact person with all their contact information, the name of the institution, an indication of whether animal or human research will be conducted here and

- 1) We will put together a formal request for the additional countries. These will be only for non-human animal sampling.
- 1a) No new animal species will be introduced to the project.
- 2) You are correct and as there is no significant change in scope of the project just (sorry to sound so cavalier!) a change in individual not work performed. Peter already notified Erik about this change in personnel, so are we ok here?
- 3) We do work with Wuhan Institute of Virology on this award, but not with Wuhan University School of Public Health. These two Institutions are distinct though both located fairly close to each other in Wuhan! one is Chinese Academy of Science and the other is University. There will not be a change in scope of work. It is just that we could subcontract directly to Wuhan University for the human surveillance work in China.

Cheers,

-Aleksei

Aleksei Chmura Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

(b) (6) (direct) (b) (6) (mobile)

Aleksei MacDurian (Skype)

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Thank you for your email. To answer your questions:

- 1. To do any work in countries other than China, you will need to request prior approval from NIH. To do so, submit a formal request, including the names, institutions, and full contact information of any institutions with which you will collaborate for such activities. Be sure to indicate whether animal or human research will be conducted and what funds, if any, will be going into these countries. The approval process for new foreign sites takes at least 3 weeks.
- 1a. If you are introducing new animals into the project, then there may be additional requirements from the Office of Laboratory Animal Welfare (OLAW). Again, you would need to submit a formal request, providing a scientific justification for the inclusion of new species on the project, and, if appropriate, a new Vertebrate Animal Section. If additional IACUC approvals are required, you will need to provide us with the IACUC approval dates (but **not** a copy of the actual approval).
- 2. These individuals are not listed in the Notice of Award as key personnel, so, from a grants management perspective, you do not need to get prior approval for this change. That said, if this change or other such personnel changes would have a significant impact on the scope of the project or the science itself, you would need to at least run it by your Program Officer. And if it is determined that personnel changes would cause a scope change, then you would need grants management approval as well.
- 3. I do not know what you are asking here. It looks like we have approved both the Wuhan University and ECNU for work on this project. Therefore, no additional prior approval is required for changes unless otherwise specified in the NIH Grants Policy Statement (eg, a change of scope).

Please don't hesitate to contact me with any additional questions. I will be available until 2:30 eastern and then again on Wednesday.

All the best,

Jenny

Jenny Greer

Grants Management Specialist

DHHS/NIH/NIAID/DEA/GMP

5601 Fishers Lane, Room 4E49, MSC 9833

Bethesda, MD 20892-9824

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

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From: Aleksei MacDurian (b) (6) Sent: Sunday, July 31, 2016 6:06 AM

To: Greer, Jenny (NIH/NIAID) [E] (b) (6)

Subject: Re: Year 2 Report for 5R01Al110964 - 02 PI Name: DASZAK, PETER

Dear Jenny,

Since you were not cc'ed on the original email, I wanted to follow up with you on three things from Dr. Daszak's email to Erik (included below):

- 1) Do we need to formally request permission to sample species of bats and other high-risk [rodents and carnivore] hosts in countries that neighbor China (Myanmar, Vietnam, Cambodia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia). Under this award our current US and China IACUC approved protocol via Tufts University and Wuhan Institute of Virology permits us to sample these species in these regions.
- 2) We provided Dr. Noam Ross' CV with our Year 2 Report. Dr. Ross has replaced Dr. Hosseini who is no longer working on this project. Do we need to do anything else for this? I have attached his Biosketch here for reference.
- 3) Our Human surveillance work and local IRB approval have all been through the Wuhan University School of Public Health (WUSPH) in China (DUNS No. 529049295). We would like now in Years 3 5 of our award to subcontract directly with them rather than with the institution on our current budget: East China Normal University (ECNU) School of Life Sciences. The Wuhan University School of Public Health budget amount would be the same annual amount as currently budgeted for East China Normal University in these same years.

It may be easier to briefly chat about these questions via telephone. If so, you may reach me at (b) (6) anytime.
Many thanks!
-Aleksei
Aleksei Chmura
Senior Coordinator of Operations
EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001
(b) (6) (direct) (b) (6) (mobile)
Aleksei MacDurian (Skype)
www.ecohealthalliance.org
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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, May 13, 2016 at 5:55 PM, Peter Daszak 60 60 wrote:
Dear Erik,
I just wanted to let you know that we submitted our Year 2 Report yesterday (attached as a pdf).
It's been a pretty productive year, and some of the highlights include: collecting samples from 15 bat genera in southern China with 280 (12%) testing positive for coronaviruses; SARS-like coronaviruses being detected in <i>Rhinolophus</i> spp. bats in both Yunnan and Guangdong provinces; 7 published papers from work under our award (including one in <i>J. Virol.</i> and one in press at <i>J. Virol</i>); 218 quantitative

In the report, I highlight the reduced amount of wildlife in the local markets within Southern China compared to that we've seen before, as well as the continued expansion of the Chinese wildlife trade within SE Asia so that it is now a largescale international activity. It means that SL-CoVs we find in the wildlife trade would likely have an origin in adjacent countries. Given that our collaborators and field team in China have great contacts in these countries, and EHA also has field teams in many of them, we would like to conduct short field trips to assess markets, identify wildlife in them, and sample species of bats and other high-risk hosts in countries that neighbor China (Myanmar, Vietnam, Camb odia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia). All samples collected would still be tested at the Wuhan Institute of Virology in China. Is there a formal process to ask for permission for this, or is the report and this email appropriate?

I also wanted to let you know about a recent personnel change. Since Dr. Parviez Hosseini has moved to the US Department of State as an Information Advisor earlier this year, we hired another senior researcher Noam Ross to conduct data analysis and spatial mapping. Our Year 2 report includes his CV. Noam has great enthusiasm and I am eager to see his work on our data collected to date. He has already been out to China is hitting the ground running!

We have had great successes this past year and I'd be happy to discuss any of them with you, if you'd like.

Cheers,

Peter

Peter Daszak

President

EcoHealth Alliance

460 West 34th Street - 17th Floor

New York, NY 10001

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Greer, Jenny (NIH/NIAID) [E]

From: Stemmy, Erik (NIH/NIAID) [E]

Sent: Thursday, September 01, 2016 8:48 AM

To: Aleksei Chmura

Cc: Greer, Jenny (NIH/NIAID) [E]

Subject: RE: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Hi Aleksei and Jenny,

Very sorry to have missed this bit from the original email last month. I don't have any problem with the change, and don't need anything else for Dr Ross from my side. Please just be sure to include a brief summary of the change in your next progress report. I believe we are just missing the details of new foreign site (apologies if I've missed it), so we can update the foreign clearance.

Erik

From: Aleksei Chmura (b) (6)

Sent: Monday, August 29, 2016 12:51 PM

To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: Greer, Jenny (NIH/NIAID) [E] (b) (6)

Subject: Re: Year 2 Report for 5R01Al110964 - 02 PI Name: DASZAK, PETER

Dear Erik,

I am just following up from Peter's email and to confirm that you approve item 2, below. In particular, do you require any additional documentation or details about Dr. Noam Ross, who is replacing Dr. Parviez Hossini under our award? I have attached his recent NIH formatted CV for reference. This personnel change-out does not alter our project aims nor our budget.

Many thanks!

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

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On Mon, Aug 1, 2016 at 6:18 PM, Greer, Jenny (NIH/NIAID) [E] (b) (6) wrote:

Aleksei,

- 1. Sounds good.
- 2. Erik will have to confirm, but from my perspective, we're fine.
- 3. If this is a new institution, please provide a contact person with all their contact information, the name of the institution, an indication of whether animal or human research will be conducted here and how much money, if any will go to the institution. You can include this information with the request referenced in 1.

Jenny	
Jenny Greer	
Grants Manage	ement Specialist
DHHS/NIH/NIA	ND/DEA/GMP
5601 Fishers La	ane, Room 4E49, MSC 9833
Bethesda, MD	20892-9824
Phone	(6) (6)
Email:	(b) (6)

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From: Aleksei MacDurian (b) (6)
Sent: Monday, August 01, 2016 12:51 PM

To: Greer, Jenny (NIH/NIAID) [E] (b) (6)

Subject: Re: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

Thanks, Jenny!

Quick replies:
1) We will put together a formal request for the additional countries. These will be only for non-human animal sampling.
1a) No new animal species will be introduced to the project.
2) You are correct and as there is no significant change in scope of the project - just (sorry to sound so cavalier!) a change in individual not work performed. Peter already notified Erik about this change in personnel, so are we ok here?
3) We do work with Wuhan Institute of Virology on this award, but not with Wuhan University School of Public Health. These two Institutions are distinct - though both located fairly close to each other in Wuhan! - one is Chinese Academy of Science and the other is University. There will not be a change in scope of work. It is just that we could subcontract directly to Wuhan University for the human surveillance work in China.
Cheers,
-Aleksei
Aleksei Chmura Senior Coordinator of Operations
EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001
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On Mon, Aug 1, 2016 at 5:39 PM, Greer, Jenny (NIH/NIAID) [E]	(b) (6) wrote:
Thank you for your email. To answer your questions:	
1. To do any work in countries other than China, you will need to request price a formal request, including the names, institutions, and full contact information collaborate for such activities. Be sure to indicate whether animal or human restunds, if any, will be going into these countries. The approval process for new formal contact in the second countries.	n of any institutions with which you wil search will be conducted and what
1a. If you are introducing new animals into the project, then there may be Office of Laboratory Animal Welfare (OLAW). Again, you would need to submit justification for the inclusion of new species on the project, and, if appropriate, additional IACUC approvals are required, you will need to provide us with the IA the actual approval).	a formal request, providing a scientific a new Vertebrate Animal Section. If
2. These individuals are not listed in the Notice of Award as key personnel, so perspective, you do not need to get prior approval for this change. That said, if changes would have a significant impact on the scope of the project or the scierun it by your Program Officer. And if it is determined that personnel changes would need grants management approval as well.	this change or other such personnel nce itself, you would need to at least
3. I do not know what you are asking here. It looks like we have approved bot work on this project. Therefore, no additional prior approval is required for chan NIH Grants Policy Statement (eg, a change of scope).	
Please don't hesitate to contact me with any additional questions. I will be avai on Wednesday.	lable until 2:30 eastern and then again
All the best,	
Jenny	
Jenny Greer	
Grants Management Specialist	
DHHS/NIH/NIAID/DEA/GMP	

5601 Fishers Lane, Room 4E49, MSC 9833

Bethesda, MD 20892-9824

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

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From: Aleksei MacDurian (b) (6)

Sent: Sunday, July 31, 2016 6:06 AM

To: Greer, Jenny (NIH/NIAID) [E] (b) (6)

Subject: Re: Year 2 Report for 5R01Al110964 - 02 PI Name: DASZAK, PETER

Dear Jenny,

Since you were not cc'ed on the original email, I wanted to follow up with you on three things from Dr. Daszak's email to Erik (included below):

- 1) Do we need to formally request permission to sample species of bats and other high-risk [rodents and carnivore] hosts in countries that neighbor China (Myanmar, Vietnam, Cambodia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia). Under this award our current US and China IACUC approved protocol via Tufts University and Wuhan Institute of Virology permits us to sample these species in these regions.
- 2) We provided Dr. Noam Ross' CV with our Year 2 Report. Dr. Ross has replaced Dr. Hosseini who is no longer working on this project. Do we need to do anything else for this? I have attached his Biosketch here for reference.
- 3) Our Human surveillance work and local IRB approval have all been through the Wuhan University School of Public Health (WUSPH) in China (DUNS No. 529049295). We would like now in Years 3 5 of our award to subcontract directly with them rather than with the institution on our current budget: East China Normal University (ECNU) School of Life Sciences. The Wuhan University School of Public Health budget amount would be the same annual amount as currently budgeted for East China Normal University in these same years.

(b) (6) anytime.	ne. If so, you may reach me at
Many thanks!	
-Aleksei	
Aleksei Chmura	
Senior Coordinator of Operations	
EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001	
(b) (6) (direct) (b) (6) (mobile)	
Aleksel MacDurian (Skype)	
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EcoHealth Alliance leads cutting-edge research into the critical connections between human we develop solutions that promote conservation and prevent pandemics.	n and wildlife health and delicate ecosystems. With this scien
On Fri, May 13, 2016 at 5:55 PM, Peter Daszak	(b) (6) wrote:
Dear Erik,	
I just wanted to let you know that we submitted our Year 2 Report ye	esterday (attached as a pdf).
It's been a pretty productive year, and some of the highlights include southern China with 280 (12%) testing positive for coronaviruses; SAI Rhinolophus spp. bats in both Yunnan and Guangdong provinces; 7 pt (including one in <i>J. Virol.</i> and one in press at <i>J. Virol</i>); 218 quantitative coded interviews conducted transcribed and translated.	RS-like coronaviruses being detected in ublished papers from work under our award

Obtained via FOIA by White Coat Waste Project

In the report, I highlight the reduced amount of wildlife in the local markets within Southern China compared to that

we've seen before, as well as the continued expansion of the Chinese wildlife trade within SE Asia so that it is now a largescale international activity. It means that SL-CoVs we find in the wildlife trade would likely have an origin in adjacent countries. Given that our collaborators and field team in China have great contacts in these countries, and EHA also has field teams in many of them, we would like to conduct short field trips to assess markets, identify wildlife in them, and sample species of bats and other high-risk hosts in countries that neighbor China (Myanmar, Vietnam, Cambodia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia). All samples collected would still be tested at the Wuhan Institute of Virology in China. Is there a formal process to ask for permission for this, or is the report and this email appropriate?

I also wanted to let you know about a recent personnel change. Since Dr. Parviez Hosseini has moved to the US Department of State as an Information Advisor earlier this year, we hired another senior researcher Noam Ross to conduct data analysis and spatial mapping. Our Year 2 report includes his CV. Noam has great enthusiasm and I am eager to see his work on our data collected to date. He has already been out to China is hitting the ground running!

conduct data analysis and spatial mapping. Our Year 2 report includes his CV. Noam has great enthusiasm ar eager to see his work on our data collected to date. He has already been out to China is hitting the ground re
We have had great successes this past year and I'd be happy to discuss any of them with you, if you'd like.
Cheers,
Peter

Peter Daszak

President

EcoHealth Alliance

460 West 34th Street - 17th Floor

New York, NY 10001

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Greer, Jenny (NIH/NIAID) [E]

From: Stemmy, Erik (NIH/NIAID) [E]

Sent: Thursday, September 01, 2016 8:48 AM

To: Aleksei Chmura

Cc: Greer, Jenny (NIH/NIAID) [E]

Subject: RE: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER

(b) (5)

Hi Aleksei and Jenny,

Very sorry to have missed this bit from the original email last month. I don't have any problem with the change, and don't need anything else for Dr Ross from my side. Please just be sure to include a brief summary of the change in your next progress report. I believe we are just missing the details of new foreign site (apologies if I've missed it), so we can update the foreign clearance.

Erik

From: Aleksei Chmura [mailto:chmura@ecohealthalliance.org]

Sent: Monday, August 29, 2016 12:51 PM

To: Stemmy, Erik (NIH/NIAID) [E] <erik.stemmy@nih.gov>
Cc: Greer, Jenny (NIH/NIAID) [E] <jenny.greer@nih.gov>

Subject: Re: Year 2 Report for 5R01Al110964 - 02 PI Name: DASZAK, PETER

Dear Erik,

I am just following up from Peter's email and to confirm that you approve item 2, below. In particular, do you require any additional documentation or details about Dr. Noam Ross, who is replacing Dr. Parviez Hossini under our award? I have attached his recent NIH formatted CV for reference. This personnel change-out does not alter our project aims nor our budget.

Many thanks!

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

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On Mon, Aug 1, 2016 at 6:18 PM, Greer, Jenny (NIH/NIAID) [E] (b) (6) wrote:

Aleksei,

Greer, Jenny (NIH/NIAID) [E] (b) (6) Aleksei Chmura From: Thursday, October 06, 2016 12:26 PM Sent: To: Greer, Jenny (NIH/NIAID) [E] Cc: Hongying Li Fwd: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER Subject: (b) (5) Follow Up Flag: Follow up Flag Status: Completed Categories: Foreign Dear Jenny, Apologies for the delay, here are the details for the new institution that will be an even switch-out for East China Normal University (so no modification to budget or project aims): CONTACT/PI: Dr. Shiyue Li TITLE: Professor Committee Director and Professor of Epidemiology and Health Statistics INSTITUTION: Wuhan University School of Public Health (b) (6) EMAIL: TELEPHONE: (b) (6) INSTITUTION NAME: Wuhan University School of Public Health DUNS NUMBER: 529049295 No Animal Research Conducted. Human Research Conducted as per IRB approval. Please let me know, if you require further information. Many thanks! -Aleksei

1. Sounds good.

Aleksei,

2. Erik will have to confirm, but from my perspective, we're fine.

On Aug 1, 2016, at 18:18, Greer, Jenny (NIH/NIAID) [E]

(b) (6) wrote:

how much money, if any will go to the institution. You can include this information with the request referenced in 1.
Jenny
Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone: (b) (6)
Email: (b) (6)
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From: Aleksei MacDurian Sent: Monday, August 01, 2016 12:51 PM To: Greer, Jenny (NIH/NIAID) [E] Subject: Re: Year 2 Report for 5R01AI110964 - 02 PI Name: DASZAK, PETER
Thanks, Jenny!
Quick replies:

3. If this is a new institution, please provide a contact person with all their contact information, the name of the institution, an indication of whether animal or human research will be conducted here and

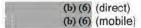
- We will put together a formal request for the additional countries. These will be only for non-human animal sampling.
 No new animal species will be introduced to the project.
 You are correct and as there is no significant change in scope of the project just (sorry to
- 2) You are correct and as there is no significant change in scope of the project just (sorry to sound so cavalier!) a change in individual not work performed. Peter already notified Erik about this change in personnel, so are we ok here?
- 3) We do work with Wuhan Institute of Virology on this award, but not with Wuhan University School of Public Health. These two Institutions are distinct though both located fairly close to each other in Wuhan! one is Chinese Academy of Science and the other is University. There will not be a change in scope of work. It is just that we could subcontract directly to Wuhan University for the human surveillance work in China.

Cheers,

-Aleksei

Aleksei Chmura Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001



Aleksei MacDurian (Skype)

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Thank you for your email. To answer your questions:

- 1. To do any work in countries other than China, you will need to request prior approval from NIH. To do so, submit a formal request, including the names, institutions, and full contact information of any institutions with which you will collaborate for such activities. Be sure to indicate whether animal or human research will be conducted and what funds, if any, will be going into these countries. The approval process for new foreign sites takes at least 3 weeks.
- 1a. If you are introducing new animals into the project, then there may be additional requirements from the Office of Laboratory Animal Welfare (OLAW). Again, you would need to submit a formal request, providing a scientific justification for the inclusion of new species on the project, and, if appropriate, a new Vertebrate Animal Section. If additional IACUC approvals are required, you will need to provide us with the IACUC approval dates (but **not** a copy of the actual approval).
- 2. These individuals are not listed in the Notice of Award as key personnel, so, from a grants management perspective, you do not need to get prior approval for this change. That said, if this change or other such personnel changes would have a significant impact on the scope of the project or the science itself, you would need to at least run it by your Program Officer. And if it is determined that personnel changes would cause a scope change, then you would need grants management approval as well.
- 3. I do not know what you are asking here. It looks like we have approved both the Wuhan University and ECNU for work on this project. Therefore, no additional prior approval is required for changes unless otherwise specified in the NIH Grants Policy Statement (eg, a change of scope).

Please don't hesitate to contact me with any additional questions. I will be available until 2:30 eastern and then again on Wednesday.

All the best,

Jenny

Jenny Greer

Grants Management Specialist

DHHS/NIH/NIAID/DEA/GMP

5601 Fishers Lane, Room 4E49, MSC 9833

Bethesda, MD 20892-9824



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

July 7, 2016

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

RE: 5 R01AI110964-03

Dear Mr. Chmura:

Thank you for your correspondence of June 28th, 2016, regarding the October 17, 2014 White House announcement of a U.S. Government-wide pause on certain gain-of-function (GoF) experiments and its potential impact on your research (http://www.whitehouse.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research). The research funding pause pertains to GoF research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the resulting virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.

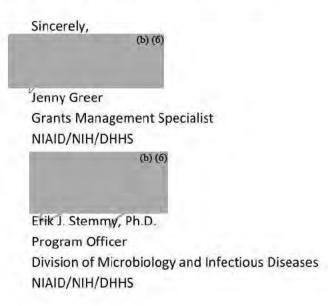
NIAID reviewed the original grant application, and the additional information provided by you, and made the following assessments regarding Aim 3 of the above-referenced grant:

- NIAID is in agreement that the work proposed under Aim 3 to generate MERS-like or SARS-like chimeric coronaviruses (CoVs) is <u>not</u> subject to the GoF research funding pause. This determination is based on the following: (1) the chimeras will contain only S glycoprotein genes from phylogenetically distant bat CoVs; and (2) recently published work demonstrating that similar chimeric viruses exhibited reduced pathogenicity. Therefore it is <u>not</u> reasonably anticipated that these chimeric viruses will have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.
- NIAID acknowledges that if any of the MERS-like or SARS-like chimeras generated under this
 grant show evidence of enhanced virus growth greater than 1 log over the parental backbone
 strain, Dr. Daszak will immediately stop all experiments with these viruses and provide the NIAID
 Program Officer and Grants Management Specialist, and Wuhan Institute of Virology
 Institutional Biosafety Committee, with the relevant data and information related to these
 unanticipated outcomes.

Please remember that the institution must comply in full with all terms and conditions placed on this grant. As indicated above, NIAID determinations are based on information from multiple sources, but primarily on our communication with you about the details of your proposed experiments and your research results. Should NIAID's determination change based on information obtained through the U.S. Government GoF deliberative process, described here

http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf, you will be notified; however, until such time, or until the GoF research funding pause is lifted, NIAID's determination, indicated above, is final.

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



CC: Dr. Peter Daszak Ms. Mary Kirker

Dr. Irene Glowinski

Dr. Andrew Ford

From: Aleksei Chmura

To: Stemmy, Erik (NIH/NIAID) [E]

Cc: Dr. Peter Daszak; Greer, Jenny (NIH/NIAID) [E]

Subject: Re: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Date: Tuesday, June 28, 2016 11:58:13 PM

Attachments: Response to GoF letter, 5R01Al110964 - 03 DASZAK, PETER.pd

Dear Erik.

Prof. Zhengli Shi has confirmed that the Wuhan Institute of Virology Institutional Biosafety Committee would be immediately notified as per Peter's comments below. Please find the updated letter attached.

If you require further details, let us know anytime.

Sincerely,

-Aleksei

Aleksei Chmura

Authorized Organizational Representative & Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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On Jun 28, 2016, at 11:22, Stemmy, Erik (NIH/NIAID) [E] (b) (6) wrote:

Thanks Peter! Please have Aleksei send us an updated letter once you have one.

Erik

Sent with Good (www.good.com)

----Original Message-----

From: Peter Daszak (b) (6)

Sent: Tuesday, June 28, 2016 08:02 AM Eastern Standard Time



Dear Drs. Greer and Stemmy,

June 8, 2016

We appreciate your rapid review of our proposed work for year 3 of our R01 (5R01Al110964-03). 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



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.





We look forward to your response to our letter and will not conduct any of this proposed work until we hear back from you.

PI President and Chief Scientist

EcoHealth Alliance

Tel: e-mail: (b) (6)

To: Stemmy, Erik (NIH/NIAID) [E]

Cc: Greer, Jenny (NIH/NIAID) [E]; Aleksei Chmura

Subject: RE: Grant Number: 5R01Al110964 - 03 PI Name: DASZAK, PETER

Sorry for not responding more quickly Erik — I've been at meetings for the last couple of weeks. You are correct to identify a mistake in our letter. UNC has no oversight of the chimera work, all of which will be conducted at the Wuhan Institute of Virology. This was a clerical error because we used some language that I asked Ralph Baric to give me because I wanted to make sure we followed an approach that has some precedence.

We will clarify tonight with Prof. Zhengli Shi exactly who will be notified if we see enhanced replication, and then amend and re-send the letter to you so it is clear. I will also confirm with Zhengli the make-up of the Wuhan Institute of Virology's Institutional Biosafety Committee. However, my understanding is that I will be notified straight away, as PI, and that I can then notify you at NIAID.

Apologies for the error!

Cheers.

Peter

Peter Daszak

President

EcoHealth Alliance 460 West 34th Street – 17th Floor New York, NY 10001

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

Sent: Monday, June 27, 2016 3:49 PM

To: Peter Daszak

Cc: Greer, Jenny (NIH/NIAID) [E]; Aleksei Chmura

Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Hi Peter,

Just wanted to follow up with you to see if you had a chance to look in to the IBC question I sent earlier this month. Please let us know.

Thanks, Erik

Sent with Good (www.good.com)

----Original Message----

From: Stemmy, Erik (NIH/NIAID) [E]

Sent: Friday, June 17, 2016 03:38 PM Eastern Standard Time

To: Dr. Peter Daszak

Cc: Greer, Jenny (NIH/NIAID) [E]; Aleksei Chmura

Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Hi Peter,

Thanks very much for providing the additional information. I did have a couple of follow up questions for you. Can you clarify where the work with the chimeric viruses will actually be performed? Your original application described the BSL3 facilities at the Wuhan Institute of Virology, but your response letter indicated that you would notify the UNC IBC if you observed enhanced replication with any of the proposed chimeras. Therefore it's not clear where the studies are being performed. Please also clarify whether EcoHealth Alliance has its own IBC, and how the UNC IBC would be involved in the oversight of this work.

Many thanks,

Erik

Erik J. Stemmy, Ph.D.

Program Officer

Respiratory Diseases Branch

Division of Microbiology and Infectious Diseases NIAID/NIH/HHS

5601 Fishers Lane, Room 8E18

Bethesda, MD 20892-9825

Phone: (6) (6)

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

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	09, 2016 5:56 PM	
To: Aleksel Chmura		(b) (6)
Cc: Dr. Peter Daszak		(b) (6) Stemmy, Erik (NIH/NIAID) [E]
(b)	(6)	
Subject : RE: Grant Nu	mber: 5R01Al110	0964 - 03 PI Name: DASZAK, PETER
Thank you for your qu	ick response!	
Jenny		
Jenny Greer		
Grants Management S	Specialist	
DHHS/NIH/NIAID/DEA	/GMP	
5601 Fishers Lane, Ro	om 4E49, MSC 98	333
Bethesda, MD 20892-	9824	
Phone: (b) (6)		
Email:	(b) (6)	

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From: Aleksei Chmura	(b) (6)		
Sent: Thursday, June 09, 2016 5:43 PM			
To: Greer, Jenny (NIH/NIAID) [E]	(6) (6)		
Cc: Dr. Peter Daszak	(b) (6) Stemmy, Erik (NIH/NIAID) [E]		
(b) (6); Kirker, Mary (N	H/NIAID) [E] (b) (6)		
Glowinski, Irene (NIH/NIAID) [E]	(b) (6) Ford, Andrew (NIH/NIAII		
[E] (b) (6)			
Subject: Pay Grant Number: EP01 Al1 100	A D2 DI Namo: DACZAK DETER		

Dear Jenny,

I concur with the detailed response that Dr. Daszak just sent to you in response to the Gain of Function questions in your email from 28th May. Please let me know

anytime, if you require any further information.

Many thanks!

Aleksei Chmura

Authorized Organizational Representative & Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

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On Jun 9, 2016, at 17:37, Greer, Jenny (NIH/NIAID) [E] (b) (6) wrote:

Peter,

Thank you for providing this response. We will review it shortly. In the meantime, I look forward to receiving concurrence from your authorized business official.

Thanks again!

Jenny

Jenny Greer Grants Management Specialist DHHS/NIH/NIAID/DEA/GMP 5601 Fishers Lane, Room 4E49, MSC 9833 Bethesda, MD 20892-9824

Phone: (b) (6) (b) (c) (b) (d)

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From: Peter Daszak

Sent: Thursday, June 09, 2016 5:23 PM

To: Greer, Jenny (NIH/NIAID) [E]

(b) (6)

Cc: Stemmy, Erik (NIH/NIAID) [E]

(b) (6)

Glowinski, Irene (NIH/NIAID)

[E]

(b) (6)

(b) (6)

Ford, Andrew (NIH/NIAID) [E]

Subject: RE: Grant Number: 5R01Al110964 - 03 PI Name: DASZAK, PETER

Importance: High

Dear Jenny and Erik,

Please find our response letter to your email below, attached. I really appreciate you giving us the chance to clarify these details and look forward to your decision on our proposed work. As stated clearly in the letter, we will not (of course) move forward with any of the proposed work in Specific Aim #3 until we hear back from you with directions.

Cheers,

Peter

Peter Daszak

President

EcoHealth Alliance 460 West 34th Street – 17th Floor New York, NY 10001

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From: Greer, Jenny (NIH/NIAID) [E] (b) (6)

Sent: Saturday, May 28, 2016 5:15 PM

To: Aleksei Chmura

Cc: Stemmy, Erik (NIH/NIAID) [E]; Peter Daszak; Kirker, Mary (NIH/NIAID) [E]; Glowinski, Irene (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E] Subject: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Dear Mr. Chmura,

Please find attached an important message about this grant. Your immediate response will be much appreciated.

All the best,

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824

Phone. (b) (6)

Email: (b) (6)

"Effective October 1, 2014, NIH closeout policy has changed (see NOT-OD-14-084). In order to avoid unilateral closeout, final reports must be submitted in a timely manner. Failure to submit accurate final reports could result in enforcement actions such as revisions to NOA funding levels, or delay in future funding."

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Greer, Jenny (NIH/NIAID) [E]

From: Aleksei Chmura (b) (6)

Sent: Thursday, June 09, 2016 5:43 PM
To: Greer, Jenny (NIH/NIAID) [E]

Cc: Dr. Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]; Kirker, Mary (NIH/NIAID) [E]; Glowinski,

Irene (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]

Subject: Re: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Dear Jenny,

I concur with the detailed response that Dr. Daszak just sent to you in response to the Gain of Function questions in your email from 28th May. Please let me know anytime, if you require any further information.

Many thanks!

Aleksei Chmura

Authorized Organizational Representative & Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

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On Jun 9, 2016, at 17:37, Greer, Jenny (NIH/NIAID) [E] (b) (6) wrote:

Peter,

Thank you for providing this response. We will review it shortly. In the meantime, I look forward to receiving concurrence from your authorized business official.

Thanks again!

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824

Phone: (b) (6) Email: (b) (6) Disclaimer: The information in this email and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the originally intended recipient. If you have received this email in error, please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of NIAID by one of its representatives.

From: Peter Daszak

Sent: Thursday, June 09, 2016 5:23 PM

To: Greer, Jenny (NIH/NIAID) [E]

(b) (6)

Cc: Stemmy, Erik (NIH/NIAID) [E]

(b) (6); Kirker, Mary (NIH/NIAID) [E]

(b) (6); Glowinski, Irene (NIH/NIAID) [E]

(b) (6); Ford, Andrew (NIH/NIAID) [E]

Subject: RE: Grant Number: 5R01Al110964 - 03 PI Name: DASZAK, PETER

Importance: High

Dear Jenny and Erik,

Please find our response letter to your email below, attached. I really appreciate you giving us the chance to clarify these details and look forward to your decision on our proposed work. As stated clearly in the letter, we will not (of course) move forward with any of the proposed work in Specific Aim #3 until we hear back from you with directions.

Cheers,

Peter

Peter Daszak

President

EcoHealth Alliance 460 West 34th Street – 17th Floor New York, NY 10001

(b) (6) (direct) (b) (6) (fax)

www.ecohealthalliance.org

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From: Greer, Jenny (NIH/NIAID) [E] (b) (6)

Sent: Saturday, May 28, 2016 5:15 PM

To: Aleksei Chmura

Cc: Stemmy, Erik (NIH/NIAID) [E]; Peter Daszak; Kirker, Mary (NIH/NIAID) [E]; Glowinski, Irene

(NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]

Subject: Grant Number: 5R01Al110964 - 03 PI Name: DASZAK, PETER

Dear Mr. Chmura,

Please find attached an important message about this grant. Your immediate response will be much appreciated.

All the best,

Jenny

Jenny Greer Grants Management Specialist DHHS/NIH/NIAID/DEA/GMP 5601 Fishers Lane, Room 4E49, MSC 9833 Bethesda, MD 20892-9824

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

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From: Peter Daszak

To: Greer, Jenny (NIH/NIAID) [E]; Aleksei Chmura

Cc: Stemmy, Erik (NIH/NIAID) [E]; Kirker, Mary (NIH/NIAID) [E]; Glowinski, Irene (NIH/NIAID) [E]; Ford, Andrew

(NIH/NIAID) [E]

Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Date: Thursday, June 09, 2016 5:23:51 PM

Attachments: Response to GoF letter, 5R01AI110964 - 03 DASZAK, PETER.pdf

Importance: High

Dear Jenny and Erik,

Please find our response letter to your email below, attached. I really appreciate you giving us the chance to clarify these details and look forward to your decision on our proposed work. As stated clearly in the letter, we will not (of course) move forward with any of the proposed work in Specific Aim #3 until we hear back from you with directions.

Cheers,

Peter

Peter Daszak

President

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From: Greer, Jenny (NIH/NIAID) [E] (b) (6)

Sent: Saturday, May 28, 2016 5:15 PM

To: Aleksei Chmura

Cc: Stemmy, Erik (NIH/NIAID) [E]; Peter Daszak; Kirker, Mary (NIH/NIAID) [E]; Glowinski, Irene

(NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]

Subject: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Dear Mr. Chmura,



Dear Drs. Greer and Stemmy,

June 8, 2016

We appreciate your rapid review of our proposed work for year 3 of our R01 (5R01Al110964-03). 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 UNC 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



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 UNC IBC of these results and iii) participate in decision making trees to decide appropriate paths forward.

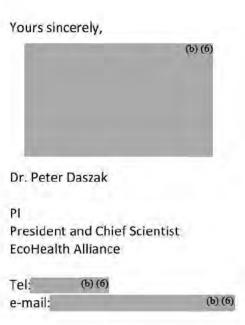
If it is determined that the above research DOES include GoF work subject to the funding pause, provide detailed information on what research will remain viable with the removal of the GoF work and appropriate budget adjustments. Options include:

- 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
- Remove the specific aims and experiments that are subject to the pause from the Research Plan and request to have the award budget renegotiated.





We look forward to your response to our letter and will not conduct any of this proposed work until we hear back from you.



Please find attached an important message about this grant. Your immediate response will be much appreciated.

All the best,

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824

Phone: (b) (6)

Email: (b) (6)

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

May 28, 2016

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

RE: 5R01Al110964-03

Dear Mr. Chmura:

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

Aim 3: Testing predictions of CoV inter-species transmission

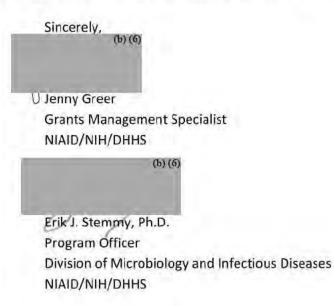
As per the funding pause announcement, new USG funding will <u>not</u> be released for GoF research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route. Therefore, the next non-competing segment of the award that starts June 1, 2016 cannot be released until a determination is reached based on the receipt and review of the information requested below. The research funding pause would not apply to characterization or testing of naturally occurring influenza, MERS, or SARS viruses, unless the tests are reasonably anticipated to increase transmissibility and/or pathogenicity.

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

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

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

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



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

 From:
 Normil, Carine (NIH/NIAID) [C]

 To:
 Greer, Jenny (NIH/NIAID) [E]

Subject: FW: Year 2 Report for 5R01Al110964 - 02 PI Name: DASZAK, PETER

Date: Friday, May 13, 2016 12:57:57 PM

Attachments: Year 2 NIAID CoV Report as submitted via eRA Commons.pdf

Importance: High

From: Peter Daszak (b) (6)

Sent: Friday, May 13, 2016 12:55 PM

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

Cc: Normil, Carine (NIH/NIAID) [C] (b) (6); Pone, Laura (NIH/NIAID) [E]

(b) (6); Aleksei Chmura (b) (6)

Subject: Year 2 Report for 5R01Al110964 - 02 Pl Name: DASZAK, PETER

Importance: High

Dear Erik,

I just wanted to let you know that we submitted our Year 2 Report yesterday (attached as a pdf).

It's been a pretty productive year, and some of the highlights include: collecting samples from 15 bat genera in southern China with 280 (12%) testing positive for coronaviruses; SARS-like coronaviruses being detected in *Rhinolophus* spp. bats in both Yunnan and Guangdong provinces; 7 published papers from work under our award (including one in *J. Virol.* and one in press at *J. Virol*); 218 quantitative interviews with sa mples and 47 qualitative coded interviews conducted transcribed and translated.

In the report, I highlight the reduced amount of wildlife in the local markets within Southern China compared to that we've seen before, as well as the continued expansion of the Chinese wildlife trade within SE Asia so that it is now a largescale international activity. It means that SL-CoVs we find in the wildlife trade would likely have an origin in adjacent countries. Given that our collaborators and field team in China have great contacts in these countries, and EHA also has field teams in many of them, we would like to conduct short field trips to assess markets, identify wildlife in them, and sample species of bats and other high-risk hosts in countries that neighbor China (Myanmar, Vietnam, Cambodia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia). All samples collected would still be tested at the Wuhan Institute of Virology in China. Is there a formal process to ask for permission for this, or is the report and this email appropriate?

I also wanted to let you know about a recent personnel change. Since Dr. Parviez Hosseini has moved to the US Department of State as an Information Advisor earlier this year, we hired another senior researcher Noam Ross to conduct data analysis and spatial mapping. Our Year 2 report includes his CV. Noam has great enthusiasm and I am eager to see his work on our data collected to date. He has already been out to China is hitting the ground running!

We have had great successes this past year and I'd be happy to discuss any of them with you, if you'd like.

Cheers,

Peter

Peter Daszak

President

EcoHealth Alliance 460 West 34th Street – 17th Floor New York, NY 10001

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

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A. COVER PAGE

Grant Number: 5R01Al110964-03	Project/Grant Period: 06/01/2014 - 05/31/2019	
Reporting Period: 06/01/2015 - 05/31/2016	Requested Budget Period: 06/01/2016 - 05/31/2017	
Report Term Frequency: Annual	Date Submitted: 05/13/2016	
Program Director/Principal Investigator Information: PETER DASZAK , BS PHD Phone number: (b) (6) Email: (b) (6)	Recipient Organization: ECOHEALTH ALLIANCE, INC. ECOHEALTH ALLIANCE, INC. 460 W 34TH ST 17TH FLOOR NEW YORK, NY 100012320 DUNS: 077090066 EIN: 1311726494A1 RECIPIENT ID:	
Change of Contact PD/PI: N/A		
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: No Exemption Number: Phase III Clinical Trial:	Vertebrate Animals: Yes	
nESC: 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 2 NIAID CoV Report 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: Year 2 NIAID CoV Report Professional Development.pdf

RPPR FINAL

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, Ge, and Zhang gave >100 invited University and Conference lectures including Forum on Microbial Threats (National Academies of Science), Symposium at École du Val-de-Grâce in Paris, Leadership Roundtable at Concordia University Montreal, 1st annual Global Pandemic Policy Summit at Texas A&M Univ., Intl. Conf. of the Wildlife Disease Association in Australia, Intl. Conf. of Conservation Biol in Montpellier France, Michigan State University, Duke University, WDA, ISID conference, Zoological Society of London Symposium, Future Earth meeting, North American Bat Research Symposium, and others that included specific discussion of the current project and results.

- 2) Agency and other briefings: PI Daszak and Research Technician Dr. Guangjian Zhu introduced this project to potential collaborators within the following agencies: Forestry Dept of Peoples' Republic of China, FAO, TNC, TRAFFIC, China CDC, and TA Foundation in Beijing China in meetings (2015) and also at presentations at the first Wildlife and Public Health Workshop in China (2016) co-hosted by EcoHealth Alliance, the State Forestry Administration of China, and China CDC.
- 3) Public outreach: PI Daszak presented this work to members of the NIH, NSF, DoD, IUCN, EPA, and the general public, at an EcoHealth Alliance meeting hosted by the Cosmos Club, Washington D.C. (2015); PI Daszak and Co-investigator Zhu reported on this project at a Wildlife Trade and Public Health Seminar, Beijing (2016); PI Daszak introduced this project in a lecture on Pandemics at a New York Academy of Science Panel (2016); Co-PI Y-Z Zhang presented project and results-to-date to department heads and senior researchers at Infectious Disease Departments of four Yunnan Hospitals (2015)

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

Specific Aim 1: Assessment of CoV spillover potential at high risk human-wildlife interfaces.

- Given the reduced amount of wildlife in the local markets within Southern China, and the continued expansion of the Chinese wildlife trade within SE Asia, we would like to conduct short field trips to assess markets, identify wildlife in them, and sample species of bats and other high-risk hosts in countries that neighbor China (Myanmar, Vietnam, Cambodia, Lao PDR) and others that supply wildlife to the international trade to China (Thailand, Malaysia, Indonesia. EcoHealth Alliance has other activities in these countries which would provide leverage to reduce costs of fieldwork, and samples would be tested in Wuhan, China.
- Following the successful collection of ethnographic interviews and focus groups in Year 2, we will be analyzing the qualitative data collection from Years 1 and 2.
- Finalize and conduct survey collection tool for a network study of wildlife farmers using a questionnaire to characterize and map the wildlife value chain.
- After the success of our pilot studies in Year 2, we will continue targeted (at individuals with high risk of exposure to bats), integrated behavioral and biological survey work in Yunnan and expand to Guangxi and Guangdong provinces.
- We will commence our anonymized, surveillance data collection from acutely ill hospital in-patients who satisfy syndromic eligibility criteria; have complete medical records; non-normative laboratory confirmed diagnostic results; and suspected acute viral infection. Eligibility criteria are: (a) suspected acute viral infection; (b) fever > 38°C, and (c) presenting symptoms of at least one of the following: •Encephalitis of unknown origin
- •Hemorrhagic fever of unknown origin
- Respiratory disease
- olnfluenza-like illness (ILI)
- oSevere Acute Respiratory like Illness (SARI)
- ·Rash
- Diarrhea

Some patients with particular infections such as with HIV, HCV, and HBV, may be excluded from the study on that basis. Hospital surveillance has the advantage of monitoring an acutely ill population. Anonymized, passive hospital surveillance allows for data collection and viral testing from all eligible hospital patients thereby limiting population sample bias and increasing the likelihood of identifying positive cases. The strengths of this approach are enormous: an unbiased patient population; prospectively collected, anonymized patient data; a low resource effort with a high efficiency design; and impactful research potential for both case series and case control studies. We have already secured approval from the Institutional Review Boards of the Wuhan School of Public Health and Hummingbird IRB.

Specific Aim 2: Receptor evolution, host range and predictive modeling of bat-CoV emergence risk. Future steps to optimize the model of role of species diversity in CoV emergence risk will include:

- Test and implement our respondent-driven survey to collect specific data on the diversity, abundance, and turnover of species along the wildlife trade network in south China.
- Model viral mixing across the full range parameters found along the wildlife trade network to identify the trade nodes with highest mixing potential. This will include a network analysis of market facility/site connectivity including wild harvest sites, wildlife farming operations, transit holding facilities, and small and large wildlife markets.
- Phylogeographic study of bat-CoV to better understand the geographic distribution and evolution of bat-CoV genetic diversity in south

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China.

- Phylogeographic study of bat host (Rhinolophus) species to assess the connectivity of bat populations and infer their historical movements and demographic history to improve our understanding of CoV transmission among bat populations in southern China. Preliminary sequences data has been generated and will be completed and analyzed.

- Cophylogenetic analyses of bat host and CoV phylogenies to assess frequency of cross-species transmission. Comparison of Alphaand Beta-CoV cophylogenetic patterns building on Year 2 analyses using published sequences and also including Spike gene and additional sequences obtained in Year 2.
- Test and implement our respondent-driven survey to assess diversity, abundance, and turnover of species along the wildlife trade network.
- Examine co-evolutionary congruence of bat-CoVs and their hosts using both functional (receptor) and neutral genes;
- Parameterize mathematical models that predict CoV evolutionary and transmission dynamics
- Continued surveillances of SARS-like CoVs and lineage C betacoronaviruses (MERS-related CoVs) in Southern China;
- Full-length genome sequencing and evolution analysis of SARS-like coronaviruses identified from different bat species and different geographical locations across China;
- Full-length genome sequencing and evolution analysis of Lineage C betacoronaviruses identified from different bat species and different geographical locations across China;
- Full-length genome sequencing and evolution analysis of HKU9-related and HKU10-related bat coronaviruses in China;

Specific Aim 3: Testing predictions of CoV inter-species transmission. The following experiments will be undertaken in Year 2:

- Humanized mice with human ACE2 receptors will be infected with WIV1 and the two rescued chimeric SARS-like coronaviruses to determine the tissue tropism and pathogenicity of bat SL-CoV
- Isolation of novel bat coronaviruses. Live virus or pseudovirus will be used to infect cells of different origin or expressing different receptor molecules. Spillover potential for each isolated virus will be assessed.
- An infectious clone of full-length MERS-CoV will be constructed using reverse genetic method. Using the S sequence of different MERS-related viruses identified from Chinese bats, the chimeric viruses with S gene of bat MERS-related coronaviruses and backbone of the infectious clone of MERS-CoV will be constructed to study the receptor usage and infectivity of bat MERS-related coronavirus.
- Surveillance of infection in human populations by SARS-like CoVs. This work will be performed at locations in Yunnan, Guangxi, and Guangdong provinces, in previously identified areas with human populations of high risk of exposure to bats. PCR and ELISA will be used, respectively, for detection of viral replicase gene and antibodies against the viral nucleocapsid protein.

B.2 (Year 2 NIAID CoV Report Final.pdf) B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

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Year 1 Report: Understanding the Risk of Bat Coronavirus Emergence

Award Number: 1R01Al110964-02

Section 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

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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.1a Have the major goals changed since the initial competing award or previous report? No.

B.2 What was accomplished under these goals?

Specific Aim 1: Assessment of CoV spillover potential at high risk human-wildlife interfaces

In year 2, we continued and expanded the qualitative research begun at the end of Year 1. In addition, a community based integrated biological behavioral surveillance system was developed and pilot tested to identify specific animal exposure risk factors associated with biological evidence of exposure to SARS-like CoV (i.e., seropositive status).

QUALITATIVE RESEARCH

Targeted, in-depth ethnographic interviews were conducted with 47 individuals (18 women; 29 men) in rural Southern China where wildlife trade routes have been documented. Yunnan, Guangxi and Guangdong provinces were specifically selected for study because they have large wildlife populations, a diversity of wildlife species and numerous live animal markets. Individuals who were 18 years of age or older and who were able to provide informed consent were eligible to participate. Twenty-three (49%) in-depth interviews were conducted in Yunnan province at nine different sites, 24 (51%) in Guangxi province at six different sites. In addition, one focus group was conducted in Guangxi. The study was approved by the Institutional Review Boards of the Wuhan School of Public Health and Hummingbird IRB.

Recruitment sites in each province included forested areas or preserves, wildlife farms, hunting areas, wildlife restaurants, live animal markets, caves where people dwell or collect guano and residential areas/farms near known bat caves or roosts. Participants were recruited primarily through local contacts developed as part of wildlife conservation and health research conducted by team members over the past decade. Contacts including wildlife conservationists and researchers, local government health outreach workers and wildlife farmers facilitated introductions and provided referrals. To achieve a sample with sufficient representation of categories of interest, participants were recruited using

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purposive sampling, which provides minimum quotas in terms of sex, age and wildlife exposure setting (e.g., live animal market, forest preserve).

The five core themes that guided the in-depth discussions are: 1) human-animal contact, 2) unusual illness experience and response, 3) socioeconomics and daily living, 4) biosafety and 5) human environments and movement/travel. An ethnographic interview guide was developed with examples of questions that could be asked for each theme. In addition, field based participant-observation was ongoing throughout the study and involved observing and talking informally with people in their own natural setting. Field notes were maintained of these ongoing observations and discussions.

Table 1: Species Observed in Wetmarkets in Guangdong Province from 2015 - 2016

Genus species	Common Name		
Prionailurus bengalensis	Leopard Cat		
Nyctereutes procyonoides	Raccoon Dog		
Sus scrofa	Wild Boar		
Lepus sinensis	Chinese Hare		
Arctonyx collaris	Hog Badger		
Hystrix brachyura	Porcupine		
Marmota sp.	Marmot		
Rhizomes sinensis	Bamboo Rat		
Erinaceus sp.	Hedgehog		
Mustela putorius	Ferrets		
Muridae	Rat (species unknown)		
Myocastor coypus	Nutria		
Vulpes sp.	Fox		
Mustela sibirica	Siberian weasel		
Paguma larvata	Masked Palm Civet		
Felis catus	Domestic Cat		
Canis lupus familiaris	Domestic Dog		
Cervinae	Sambar Deer		
Ovis aries	Sheep		
Capra sp.	Domestic Goat		
Ratus norvegicus	Common Rat		

Interviews were conducted between March and June 2105 by 10 trained interviewers, none of whom had social science training. Interviewers conducted between one and 22 interviews; three interviewers conducted two thirds of all interviewers. Interviews lasted between 20 and 60 minutes, and were taperecorded and transcribed verbatim before they were translated into English. All participants received cooking oil valued at US\$10 in appreciation of their time.

The data are currently being coded and an analytic database is being constructed. Initial insights include observations by a number of participants, especially those who are older, that there has been a decrease in wildlife in the surrounding environment. This decrease is attributed to many factors including infrastructure development. The government has invested resources to build new roads and renovate local infrastructure with the intention of increasing tourism. This has reduced forested area.

Observations by research staff in live animal markets in Guangzhou found wildlife to be plentiful (see Table 1), although no bats were seen for sale during the observation period.

In contrast, wildlife was not found in live animal markets at the sites we visited in either Yunnan or Guangxi. This is a change from previous research visits to the same or similar communities, when bats, rodents and wild boar could be found. Locals in Yunnan and Guangxi attribute the change to conservation law enforcement. The success of conservation enforcement may have moved hunting and trapping underground and made the capture of local wildlife less economically feasible than other income generating activities.

Preliminary analyses are underway. Three specific studies in support of Specific Aim 1 are being developed: the changing wildlife trade in Southern China, the economics of wildlife farming, and zoonotic disease risks resulting from a rapidly changing wildlife trade.

INTEGRATED BIOLOGICAL BEHAVIORAL SURVEILLANCE PILOT STUDY

Currently, mechanisms of zoonotic viral spillover are unknown. In order to evaluate potential risk factors, it is necessary to measure both exposure and outcome data. Therefore, a behavioral risk survey was developed that assessed both animal exposure and experiences of unusual illness both during lifetime and in the past 12 months. In addition, participants were requested to provide serum to test for previous exposure to SARS-like CoV. The integrated surveillance was pilot tested in October 2015 among residents living near bat caves or roosts where SARS-like-CoV has been previously detected in the bat population in Jinning County, Yunnan. Please view the full survey here:

https://www.dropbox.com/s/sv62neywuvl027r/Questionnaire%20Complete.docx?dl=0



Of 218 participants, 139 (64%) were women and 79 (36%) were men, with a mean age of 48 (range: 12-80). Most reported being farmers (87%, and see chart to left); a majority were long term residents (97%). Animal exposures in the past year were extensive, including general (e.g., buying live animals at markets [61%]) and intimate (e.g., being scratched or bitten [9%], slaughter

[38%]). In fact, two-thirds of participants reported handling recently killed animal parts and 2 out of 5 reported slaughtering animals. Only 20 (9%) participants reported known exposure to bats.

Standardized syndromic case definitions informed questions concerning unusual illness experience (e.g. severe acute respiratory infections [SARI], influenza-like illness [ILI]). Lifetime, 12 month and unusual illness experience in family for the past 12 months were assessed for all participants. In the past year, SARI was reported by 4 (2%) respondents and for 4 additional family members. Table 2 provides data for all unusual illness experience assessed. None of the participants were found to be seropositive for SARS-like CoV.

Table 2. Unusual Illness Experience

Symptoms	Ever	Past 12 months	Family (12m)
Severe Acute Respiratory Infections (SARI)	15 (6.9%)	4 (1.8%)	4 (1.8%)
Influenza Like Illness (ILI)	54 (24.8%)	16 (7.3%)	26 (11.9%)
Encephalitis	19 (8.7%	4 (1.8%)	3 (1.4%)
Hemorrhagic Fever	0 (0.0%)	0 (0.0%)	0 (0.0%)
Fever with Diarrhea /Vomiting	12 (5.5.%)	2 (0.9%)	3 (1.4%)
Fever with Rash	2 (0.9%)	2 (0.9%)	3 (1.4%)

Although the sample size was small, animal exposures among those who reported unusual illness experiences in the past 12 months were evaluated. Of the four respondents who reported SARI symptoms, 75% reported: raising animals, animals in the home, preparing recently killed animals and buying live animals; 50% reported slaughter. Among the 16 respondents who reported ILI symptoms, 12 (75%) reported handling/preparing recently killed animals, 11 (69%) Handling live animals or having animals in the home, 10 (63%) reported slaughtering/killing animals or buying live animals at wet market, 9 (56%) raised live animals, 7 (44%) reported a pet, and 1 (6%) reported animal feces near food or eating animal touched or damaged food, hunting, or eating raw/undercooked animal products. Finally, among the four respondents who reported encephalitis symptoms, 3 (75%) reported hunting, handling or raising animals, 2 (50%) reported animals in the home, 1 (25%) reported having animals as pets, slaughtering/killing animals, or having bought live animals at wet market.

Respondents were asked about the source of their unusual illnesses. None reported any kind of animal exposure as a potential source of infection and most stated they had no idea how they had become infected. However, when asked about potential behavior changes made at live animal markets in the last 12 months, participants reported a great deal of change. In particular, respondents reported buying live animals less often (38%), only buying farmed wildlife (54%) or buying meat at the supermarket (23%). (See Table 3).

Table 3: Behavior Change at Wet Market in the last 12 months

N	(%)
4	(3.0)
5	(3.8)
80	(60.6)
30	(22.7)
50	(37.9)
71	(53.8)
39	(29.5)
	4 5 80 30 50 71

The results of this pilot study conducted with a largely female farmer population found high levels of unusual illness, as well as high levels of exposure to animals. There was a notable lack of knowledge of animals' ability to transmit infection. Despite this lack of knowledge, there may be a sense of unease about animal exposures, given the fairly dramatic behavior changes reported at live animal markets. The finding of a reduction in wildlife purchase may be due to sensitivity to the legality of wildlife trade, biasing respondents towards not admitting purchasing wildlife. Although, there were no participants seropositive for SARS-like CoV, serological data may add support to the findings from self-reported syndromic surveillance, once serological assays are optimized.

In preparation for full implementation of the integrated biological behavioral surveillance, the survey has been programmed as an application for use on either a mobile device or computer. Electronic data collection will facilitate survey implementation in the field and quality control of the data being collected. Four field team leads were trained on behavioral survey data collection, data collection technologies (the tablet application) and analysis.

Nucleic acid test results of human biological samples

Testing High-Risk Human Populations for Coronavirus Infection

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Surveillance of CoV infections in human populations by SARS-like CoVs was significantly expanded in Year 2, including both custom-built ELISA serology (an assay developed by the Wuhan Institute of Virology to test antibodies against the N protein of SL-CoV) and PCR detection of viral RNA.

Serological test for SL-CoV antibodies in human samples from Jinning, Yunnan Province In order to assess past exposure to bat CoVs, 223 human sera samples were collected in villages in proximity to the bat habitat from which two SL-CoVs with potential for interspecies infection, WIV1 and WIV16, were discovered in our previous research. An ELISA developed by the Wuhan Institute of Virology was used to test antibodies against the N protein of SL-CoV. A number of human specimens generated high OD values and neutralization test to WIV1 and WIV16 was then performed. These findings are encouraging; however, no neutralization antibodies were detected. In Year 3, we will continue to validate and optimize these ELISA assays and other serological tests to obtain data on past CoV exposure.

PCR test for CoV Nucleic Acid in human samples from several Provinces

We tested 405 individual human samples for CoV RNA to identify evidence of active infection in human populations and to obtain sequence data on strain variation. Individual samples (4 each) were pooled prior to nucleic acid extraction then tested using PCR. When a group tested positive, we then conducted the confirmation test in the individual samples. One single sample (14XN611) from someone who had identified as having had a fever and suffered both a cough and headache in the past 7-days was then identified to be positive for HCoV-HKU1. The low number of PCR detections in human specimens is not unexpected, and will be improved in Year 3-5 by better targeting syndromic individuals for specimen collection and continuing to optimize PCR assays. Refined serological assays (above) will provide sufficient data to assess past exposure to specific CoV lineages, and optimizing of PCR detections will allow for more CoV positive human sequences moving forward.

Specific Aim 2: Receptor evolution, host range and predictive modeling of bat-CoV emergence risk

Bat CoV PCR detection and sequencing from live-sampled bat populations

We collected 1,714 anal swab samples, 677 fecal samples, 53 blood samples, and 38 serum samples from 15 bat genera in Guangdong, Yunnan, Sichuan, Hubei, Hunan, Guizhou, Guangxi provinces (Table 4).

Table 4 Bat Samples collected for CoV surveillance in 2015

Sample date	Sample location An		Fecal	Blood	Serum	
Mar. 2015	Huidong, Guangdong	69		1804		
Jun. 2015	Guangdong	495		12		
Apr. 2015	Menglun, Yunnan	51	an an	H229	222	
May 2015	Jinning, Yunnan		193			
May. 2015	Mojiang, Yunnan	93				
Oct. 2015	Oct. 2015 Jinning, Yunnan			(mm)		

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Dec 2015	Jingna, Yunnan	15	15	13	13
Dec, 2015	Miaoxin, Yunnan		42	28	25
Jul, 2015	Zigong, Sichuan	128		Letter)	
Aug, 2015	Hubei		332		
Sep, 2015	Xianning, Hubei		95		
Aug, 2015	Jishou, Hunnan	204			
Aug-Sep, 2015	Tongren, Guizhou	438			
Dec, 2015 Longzhou, Guangxi		191			
	Total	1714	677	53	38

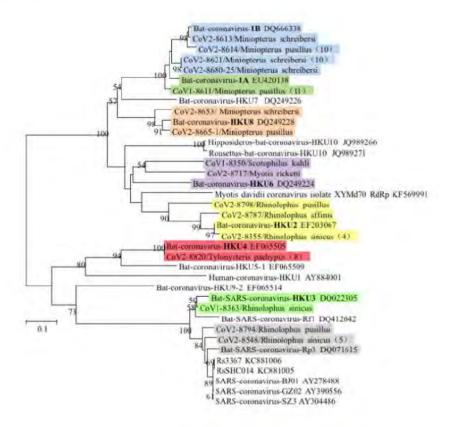
We tested 2,256 samples for CoV RNA and 280 tested positive. The total positive rate is 12.4% (Table 5). Diverse alphacoronaviruses related to Bat CoV 1A, 1B, HKU2, HKU6, HKU7, HKU8 and HKU10 were identified; SARS-like coronaviruses were detected in *Rhinolophus* bats in both Yunnan and Guangdong (Fig 1). Novel lineage B betacoronaviruses more distantly related to SARS-CoV than other SL-CoVs were detected in *Vespertilo superans* in Sichuan. HKU4-related coronaviruses were found in *Tynolycteris pachypus* in Guangdong and Guangxi while HKU5-related coronaviruses were found to be highly prevalent in *Vespertilio superans* in Zigong, Sichuan (41 bats out of 128 tested positive).

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Table 5 Test result of bat CoV surveillance in 2015 – 12% positive (280/2,256)

	Yunnan	Guangdong	Hubei	Sichuan	Guangxi	Guizhou	Hunan	Total		
Bat species	No.positive/No.tested									
Rhinolophus spp.	47/98	12/103				16/225	8/63	83/489		
Hipposideros spp.	0/35	0/51	26/152			0/131	0/91	26/460		
la io						0/3		0/3		
Pipistrellus spp.	1/1	0/19				0/2	0/4	1/26		
Miniopterus spp.	6/7	34/83				2/6		42/96		
Eonycteris spp.	0/3							0/3		
Vespertilio superans				41/128				41/128		
Myotis spp.		1/38				0/70	0/35	1/143		
Taphozous spp.	0/25					0/1		0/26		
Tynolycteris pachypus		8/25			27/191			35/216		
Scotophilus kuhlii		1/1						1/1		
Eptesicus fuscus		0/1						0/1		
Tadrida spp.		0/5						0/5		
Barbastella							0/1	0/1		
Nyclatus velutiaus							0/10	0/10		
Fecal samples	28/468		22/180					50/648		
Sub-total	82/637	56/326	48/332	41/128	27/191	18/438	8/204	280/225		

A



В

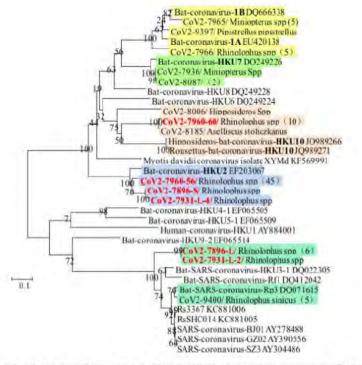


Fig 1 Phylogenetic analysis of partial RdRp gene of CoV (440-nt partial sequence). CoVs identified in 2015 are named by the sample numbers. Sequence amplified from samples co-infected with two CoV strains are indicated in red. (A) CoVs detected in Guangdong. (B) CoVs detected in Yunnan.

Cophylogenetic analysis of CoV host switching

We completed preliminary cophylogenetic analysis of bat host — CoV sequences using data published in the literature and available on Genbank. Two figures from these analyses are highlighted below (Figs 2 and 3) and these methods are currently being extended using partial RdRp CoV and bat mitochondrial DNA sequences from a large number of bat specimens found CoV positive in Year 2 (Table 5, above).

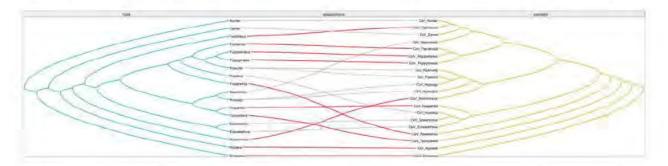
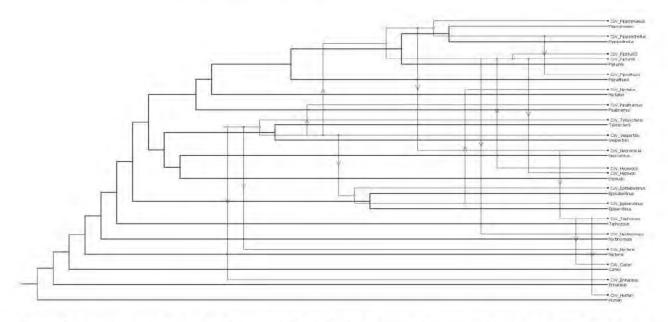


Figure 2: Tanglegram depicting the pattern of infection of bats (and outlier mammalian hosts) by CoVs. The CoV tree was reconstructed from DNA sequences available in GenBank (partial RdRp gene) using Bayesian inference (MrBayes). The topology of host tree was reconstructed using the mammal and bat phylogenies available in Asher & Helgen (2010) and Agnarsson et al. (2011), using methods our group has previously applied to bat parasite cophylogenetic analyses (Lei and Olival 2014). Both ParaFit (ParaFitGlobal = 64957.61, p-value = 0.001) and PACo (m2 = 366.44, p-value = 0.013) provided evidence for significant global congruence between the two topologies, and evidence for coevolution. Lines connecting taxa indicate host-CoV associations. Red lines indicate significant host-CoV associations as indicated by ParaFit (p \leq 0.05, 999 permutations).



<u>Figure 3</u>: Reconstruction of one of 3 potentially optimal solutions of reconciled host-CoV trees recovered from a Jane analysis. Black and blue lines represent the host and CoV trees, respectively. For each solution, the number of co-speciation events inferred by Jane was always significantly greater than expected by chance. Jane inferred 4 co-speciation events (hollow colored circles), 1 duplication (solid

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colored circle), 14 host switches (solid colored circle with arrow), 0 loss and 0 failure to diverge.

Our findings demonstrate co-speciation alone is not sufficient to explain the observed co-phylogenetic pattern and several host switches can be specifically identified. This is the case even if a significant global signal of co-speciation has been detected. This work highlights, the need for these types of detailed cophylgoenetic analyses to best explain the evolutionary history and host-switching of bat-CoVs.

References cited for the above analysis: Agnarsson, I., Zambrana-Torrelio, C.M., Flores-Saldana, N.P. & May-Collado, L.J. (2011) A time-calibrated species-level phylogeny of bats (Chiroptera, Mammalia). PLOS Currents, 3:RRN1212. Asher, R.J. & Helgen, K.M. (2010) Nomenclature and placental mammal phylogeny. BMC Evolutionary Biology, 10, 1-9. Lei BR, Olival KJ (2014) Contrasting Patterns in Mammal—Bacteria Coevolution: Bartonella and Leptospira in Bats and Rodents. PLoS Negl Trop Dis 8(3): e2738.

Market Characterization Model Parameterization

Our ongoing observational research and mapping of farms and markets suggests that rapid changes in the market and regulatory environment are changing the nature and location of the wildlife market trade. The nexus of the wildlife trade and the potential hotspots of interspecies viral mixing is now in many cases in animal storage facilities and transport between high-volume customers. To define realistic parameters for intermixing wildlife species in areas of high potential mixing, we have developed a preliminary survey and sampling protocol to assess these values as animals move along the value chain — through these storage facilities - using respondent-driven questionnaires to follow and sample along the wildlife trade network and reveal hidden nodes and sites of intermixing of species.

We have expanded our intermixing modeling framework to incorporate the variations along this value chain, where the diversity, abundance, residence time, and contact rates between species change as animals move through the trade network.

Specific Aim 3: Testing predictions of CoV inter-species transmission.

In Year 2, we continued surveillance for novel SARS-like CoVs from bats in Yunnan and Guangdong provinces and obtained full genome sequence for 11 CoV isolates. Full genome analysis of these CoV isolates was completed, including phylogenetic and recombination analyses. Importantly, recombination analysis of the full-length SL-CoV genome sequences from a single bat population revealed that frequent recombination events among different SL-CoV strains occur. Several SL-CoVs that are more genetically similar to SARS-CoV (2003) than any previously discovered were also identified from bat populations in Yunnan province. Full genome analysis suggests that an epicenter of SL-CoV occurs in rhinolophid bats and provides more insight into the evolutionary origin of SARS-CoV.

Full-length genome sequencing of SL-CoVs identified from a single bat colony

To date, including preliminary data submitted for this R01 that we are now analyzing under the current funding, we have conducted 5-years of surveillance of SL-CoV in a single bat colony in Yunnan Province (from 2011 to 2015), leading to the discovery of diverse novel SL-CoVs. Based on genotyping of these SL-CoVs by the region corresponding to the receptor-binding domain (RBD) of SARS-CoVs, 11 isolates were selected and full-length genome sequencing was performed in Year 2.

These SL-CoVs, including four others isolated previously from this colony, Rs3367, RsSHC014, WIV1 and WIV16, are highly diversified in the S gene, but share similar sequence identity to SARS-CoV in ORF1ab (Fig 4). Genomic phylogenetic analysis showed that the SL-CoVs detected in this colony are more closely

related to SARS-CoVs from other geographic regions, especially three isolates, WIV16, Rs4874 and Rs4231 (Fig 5). Notably, among the 15 SL-CoVs, two isolates, Rs4084 from *Rhinolophus sinicus* and Rf4092 from *Rhinolophus ferrumequinum*, are highly similar to SARS-CoV in the ORF8 region (Fig 5). Rf4092 possessed a single ORF8 of the same length (369bp) as that in civet SARS-CoV SZ3, and the sequence showed only 10 nucleotide substitution (Fig 6). The ORF8 sequence of Rs4084 is highly similar to that of Rf4092, however in the region corresponding to the 29-bp deletion acquired in human SARS CoVs (e.g Tor2), a shorter deletion of only 5-bp is present, resulting in two overlapping ORF8s, ORF8a and ORF8b. The position of start codon and stop codon of the two ORFs were consistent with those in human strains (Fig 6).

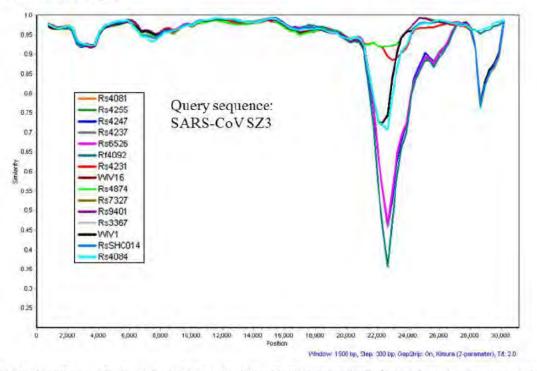


Fig 4. Simplot analysis of the 15 SL-CoVs identified from a single bat colony in Yunnan. SARS-CoV SZ3 is used as query sequence.

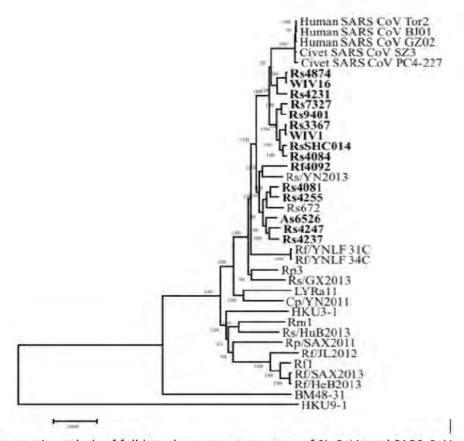
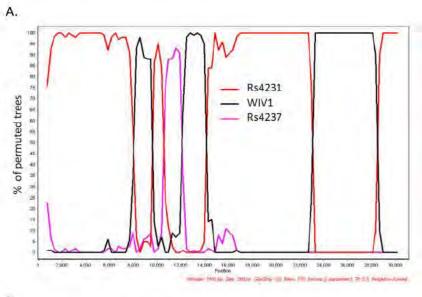


Fig 5. Phylogenetic analysis of full-length genome sequences of SL-CoVs and SARS-CoVs. Isolates identified in the single investigated bat colony in Yunnan in in bold.



Fig 6. Alignment of ORF8 nucleotide sequences of SARS-CoV and bat SL-CoVs. The red box indicates the 29-nt deletion present in SARS-CoV of middle and late phase.

Recombination analysis of the full-length genome sequences reveals frequent recombination events among different SL-CoV strains circulating in this bat population. For example, WIV16 appears to be a recombination product of WIV1 and Rs4231. An important breakpoint is identified between the N-terminal domain (NTD) and RBD region in the S gene (Fig 7A). Consequently, WIV16 is identical to Rs4231 and WIV1 in NTD and RBD of the spike protein, respectively, and is highly homologous to SARS-CoV in both NTD and RBD. This makes it the SL-CoV most closely related to the direct progenitor of SARS-CoV discovered to date. Moreover, evidence is found to support the hypothesis that the direct progenitor of SARS-CoV was generated from recombination of WIV16 with Rf4092 at the site near ORF8. This work, which identifies diverse SL-CoVs highly homologous to SARS-CoV in different regions of the genome, suggests that rhinolophid bats are an evolutionary epicenter of SL-CoV and offers more insights into the evolutionary origin of SARS-CoV.



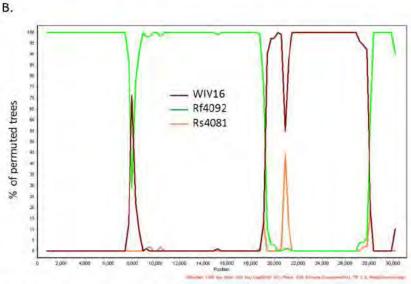


Fig 7 Bootscan analysis of full-length genome sequences of SL-CoVs. (A) WIV16 is used as query sequence. (B) SARS-CoV SZ3 is used as the query sequence. (Kimura model, window size, 1500bp, step size, 300bp)

PI: Daszak, Peter

Additional Year 2 items for Specific Aim 3:

- The infectious clone of WIV1 was successfully constructed using reverse genetic methods;
- Two chimeric bat SARS-like coronavirus strains were constructed by replacing the S gene in the backbone of WIV1;
- Permission to import mice with human ACE2 to China was obtained, so as to conduct the
 experimental infections proposed in our R01 specific aims.

Specific Goals Not Met.

- Comparative cophylogenetic analyses of bat host and CoV RdRp and Spike gene phylogenies, to assess patterns of evolutionary congruence and frequency of cross-species transmission (This will be conducted in year 3);
- Animal infection experiments of SARS-like coronaviruses were not done, because of the
 unavailability of mice with human ACE2 in Year 2. We now have secured these mice and will
 begin this work in year 3.
- Sampling of bat and other mammalian species in markets to screen for CoVs. We will begin this
 work in year 3.

Section C: Accomplishments: Publications

PUBLISHED

Xing-Yi Ge, Ning Wang, Wei Zhang, Ben Hu, Bei Li, Yun-Zhi Zhang, Ji-Hua Zhou, Chu-Ming Luo, Xing-Lou Yang, Li-Jun Wu, Bo Wang, Yun Zhang, Zong-Xiao Li, and Zheng-Li Shi. Coexistence of multiple coronaviruses in several bat colonies in an abandoned mineshaft. *Virologica Sinica* 31, 31–40 (2016).

Mei-Niang Wang, Wei Zhang, Yu-Tao Gao, Ben Hu, Xing-Yi Ge, Xing-Lou Yang, Yun-Zhi Zhang, Zheng-Li Shi. Longitudinal surveillance of SARS-like coronaviruses in bats by quantitative real-time PCR, *Virologica Sinica* 31(1): 78-80 (2016).

Cristin C. W. Young and Kevin J. Olival. Optimizing Viral Discovery in Bats. PLoS ONE 11(2) (2016).

Kevin J. Olival. To Cull, or Not To Cull, Bat is the Question. *Ecohealth* 13, 6–8 (2015).

Xing-Lou Yang, Ben Hu, Bo Wang, Mei-Niang Wang, Qian Zhang, Wei Zhang, Li-Jun Wu, Xing-Yi Ge, Yun-Zhi Zhang, Peter Daszak, Lin-Fa Wang, Zheng-Li Shi. Isolation and characterization of a novel bat coronavirus closely related to the direct progenitor of Severe Acute Respiratory Syndrome Coronavirus, *Journal of Virology* 90(6): 3253-6 (2015).

Ben Hu, Xingyi Ge, Lin-Fa Wang, Zhengli Shi. Bat origin of human coronaviruses. *Virology Journal* 12 (1): 221 (2015)

ACCEPTED, IN PRESS

Lei-Ping Zeng, Yu-Tao Gao, Xying-Yi Ge, Qian Zhang, Cheng Peng, Xinglou Yang, Bin Tan, Jing Chen, Aleksei Chmura, Peter Daszak, and Zheng-Li Shi. Bat SARS-like coronavirus WIV1 encodes an extra accessory protein ORFX involving in modulation of host immune response. *Journal of Virology* (in press, 2016)

1R01Al110964 Year 2 Report

PI: Daszak, Peter

B.4 What opportunities for training and professional development has the project provided?

We presented our project to graduate students, laboratory personnel, directors, and doctors from three Hospitals in Yunnan Province: Yunnan Provincial Institute of Endemic Diseases Control & Prevention (YNCDC); Dali Provincial Hospital; and The Third People's Hospital of Kunming. Select doctors at YNCDC (1) and Dali Provincial Hospital (3) were trained in the passive Hospital surveillance project protocols.

We trained graduate students from Dali School of Public Health (1) and the Wuhan University School of Public Health (3) in qualitative behavioral risk data collection methodologies and data collection technologies, survey data collection and analysis. These were also enrolled in and passed the Human Subjects Research Course provided by the Collaborative Institutional Training Initiative (CITI Program) at the University of Miami (http://citiprogram.org). The CITI Program is a leading provider of research education content with web based training materials serving millions of learners at academic institutions, government agencies, and commercial organizations in the U.S. and around the world.

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?

Yes

Publications Reported for this Reporting Period

Public Access Compliance	Citation					
Complete	Yang XL, Hu B, Wang B, Wang MN, Zhang Q, Zhang W, Wu LJ, Ge XY, Zhang YZ, Daszak P, Wang LF, Shi ZL. Isolation and Characterization of a Novel Bat Coronavirus Closely Related to the Direct Progenitor of Severe Acute Respiratory Syndrome Coronavirus. J Virol. 2015 Dec 30;90(6):3253-6. PubMed PMID: 26719272; PubMed Central PMCID: PMC4810638.					
Complete	Olival KJ. To Cull, or Not To Cull, Bat is the Question. Ecohealth. 2016 Mar;13(1):6-8. PubMed PMID: 26631385; PubMed Central PMCID: PMC4833651.					

Non-compliant Publications Previously Reported for this Project

Public Access Compliance	Citation	
Non-Compliant		(b) (4)

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

C.5 OTHER PRODUCTS AND RESOURCE SHARING

C.5.a Other products

NOTHING TO REPORT

C.5.b Resource sharing

NOTHING TO REPORT

D. PARTICIPANTS

FINAL

D.1 WHAT INDIVIDUALS HAVE WORKED ON THE PROJECT? Commons ID Name SSN DOB Degree(s Role Cal Aca Sum Foreign Country SS Org (b) (4), (b) (6) (b) (6) (b) (6) DASZAK, (b) (6) BS.PHD PD/PI NA Y PETER (b) (6) N HOSSEINI, (b) (6) BS.PHD Co-NA **PARVIEZ** Investigator RANA PhD (b) (6) Y Ross, (b) (6) Co-NA Noam Investigator Martin (b) (6) PHD N OLIVAL, (b) (6) Co-NA KEVIN J Investigator KE, CHANGWE PHD N Center CHINA NA Investigator Disease Control and Preventio n of Guangdo ng Province N ZHANG, (b) (6) PHD Co-East CHINA NA SHUYI Investigator China Normal Universit N ZHANG. PHD Co-CHINA NA (b) (6) Yunnan YUNZHI Investigator Provincia Institute Endemic Diseases Control Preventio PHD CHINA N ZHU, (b) (6) Co-East NA **GUANGJIA** Investigator China Normal Universit PHD Wuhan CHINA N GE, XINGYI Co-NA Institute Investigator Virology (b) (6) MPH, DV N EPSTEIN, (b) (6) Co-NA JONATHAN M,BA,PH Investigator H D (b) (6) BS N CHMURA, (b) (6) NA Non-ALEKSEI A Student Research Assistant N PhD Wuhan SHI, (b) (6) Co-CHINA NA

RPPR FINAL

ZHENGLI	Investigator	Institute of Virology
Glossary of acronyms: S/K - Senior/Key DOB - Date of Birth	Foreign Org - Foreign C SS - Supplement Suppo RE - Reentry Suppleme	ort
Cal - Person Months (Calendar)	DI - Diversity Suppleme	nt
Aca - Person Months (Academic)	OT - Other	500 500 500 500 500 500 500 500 500 500
Sum - Person Months (Summer)	NA - Not Applicable	

D.2 PERSONNEL UPDATES

D.2.a Level of Effort

Will there be, in the next budget period, either (1) a reduction of 25% or more in the level of effort from what was approved by the agency for the PD/PI(s) or other senior/key personnel designated in the Notice of Award, or (2) a reduction in the level of effort below the minimum amount of effort required by the Notice of Award?

No

D.2.b New Senior/Key Personnel

Are there, or will there be, new senior/key personnel?

Yes

File uploaded: Noam Ross CV 2016.pdf

D.2.c Changes in Other Support

Has there been a change in the active other support of senior/key personnel since the last reporting period?

No

D.2.d New Other Significant Contributors

Are there, or will there be, new other significant contributors?

No

D.2.e Multi-PI (MPI) Leadership Plan

Will there be a change in the MPI Leadership Plan for the next budget period?

NA

Noam Ross



EDUCATION

University of California

Davis, CA

Doctoral Candidate in Ecology

Expected Completion Summer 2015

- Dissertation Committee: Alan Hastings (major professor, Ecology), David Rizzo (Plant Pathology), Jim Sanchirico (Natural Resource Economics)
- · Dissertation Research: "Managing Emerging Forest Disease Under Uncertainty"

Brown University

Providence, RI

Bachelor of Science in Environmental Science, Magna Cum Laude

May 2006

- Honors Thesis: "Soil Organic Matter in Northern Mongolia: Permafrost and Land-Use interactions"
- Phi Beta Kappa, Sigma Xi, Environmental Science Honors, Rosenberger Prize for Outstanding Service

SCIENTIFIC PUBLICATIONS

- Carl Boettiger*, Noam Ross*, Alan Hastings (2013) Early Warning Signals: The Charted And Uncharted Territories. Theoretical Ecology http://dx.doi.org/10.1007/s12080-013-0192-6
- Fuller, Kate, David Kling, Kaelin Kroetz, Noam Ross, and James N. Sanchirico (2013) Economics and Ecology of Open-Access Fisheries. In: Shogren, J.F., (ed.) Encyclopedia of Energy, Natural Resource, and Environmental Economics, Vol. 2 Encyclopedia of Energy, Natural Resource, and Environmental Economics p.39-49. Amsterdam: Elsevier. http://dx.doi.org/10.1016/B978-0-12-375067-9.00114-5

In preparation

- Ross, Noam. Comparative dynamics of SI and multi-infection disease models. To be submitted to Ecology Letters.
- Ross, Noam. CMP: An R package for modeling under-dispersed data. To be submitted to Methods in Ecology and Evolution.

*Co-equal authorship

POSTERS

- Ross, Noam. "Optimal Control of Disease in Space: An Approach Using Individual-based Models,"
 June 1-4, 2014. 12th Annual Conference of Ecology and Evolution of Infectious Disease, Fort Collins,
 Colorado.
- Ross, Noam. "Designing Protective Treatments for Forest Disease Using a Spatial Point Process Model," November 20-21, 2014. California Forest Pest Council Annual Meeting, McClellan, CA.
- Ross, Noam. "Optimal Control of Forest Disease Under Changing Community and Spatial Structure," November 4-18, 2013. Sustainable Management of Natural Resources Workshop, Mathematical Biosciences Institute, Columbus, OH.

PRESENTATIONS

- Ross, Noam, "Fungal Disease Mortality: Modeling for Management of Sudden Oak Death." Dec 1, 2014 Invited talk at EcoHealth Alliance, New York, NY.
- Ross, Noam, "Modeling forest disease using a macroparasite framework," Agust 13, 2014. 99th Annual Ecological Society of America Meeting, Sacramento, CA.
- Ashander, Jamie, Kelly Gravuer, Megan Kelso, Mary E. Mendoza and Noam Ross "Managing River-Floodplains Systems: A Historical and Ecological Perspective" September 14, 2002. Presentation at NSF REACH IGERT Floodplains Workshop

AWARDS + FELLOWSHIPS (Total received \$225,429)

Don Dahlsten Memorial Grant (\$325)

California Forest Pest Council, 2012

Designing Protective Treatments for Forest Disease Using Spatial Point Process Models

NSF IGERT Bridge Fellowship (\$57,500)

UC Davis, CA, 2012

Managing Emerging Forest Disease Under Uncertainty

• NSF IGERT Traineeship in Rapid Environmental Change (\$115,00)

UC Davis, CA, 2010

Modifying River-Floodplain Systems: A Historical and Ecological Approach

UC Davis Graduate Group in Ecology Fellowship (\$40,604)

UC Davis, CA, 2010

NSF Research Experience for Undergraduates Fellowship (\$8,000)
 Acad. of Natural Sciences, PA, 2005

Undergraduate Research Fellowship (\$4,000)

Brown University, RI, 2003

SERVICE + PROJECTS

Workshop Instructor, Software Capentry and Data Carpentry Foundations

Jan 2015-Present

Student Rep, UC Davis Graduate Group in Ecology Executive Committee

Sep 2013-Present

Reviewer: Theoretical Ecology (4 reviews)

Feb 2013-Present

 Web Developer and Technology Chair, Ecology Graduate Student Association June 2013—Present Creator + Maintainer of graduate student blog, resources, and news site (egsa.ucdavis.edu)

Founder + Organizer, Davis R Users' Group

Sep 2012-Present

Created users group that provides tutoring and seminars to graduate students in 10+ departments

• Contributor, R packages knitr, knitcitations, rcrossref, rethinking

2012-Present Sep 2012

Organizer: NSF REACH IGERT Workshop on Multiple Goals in Floodplain Restoration
 Organizer, UC Davis Conference on Ecology and the Business Sector

Apr 2011

• Organizer, UC Davis Graduate Group in Ecology Symposium

May 2010-2011

• External Reviewer, World Resources Institute Corporate Ecosystem Services Review

Jan 2008

• External Reviewer, McKinsey-Clinton Global Initiative Forestry Project

Mar 2008

• Business Stewardship Volunteer, NY Coastal Marine Resources Center

Feb-Apr 2007

OTHER WORK EXPERIENCE

GreenOrder New York, NY

Analyst, Senior Analyst: Corporate Environmental Strategy + Governance

Sep 2006-Oct 2009

- Conducted environmental performance analysis for products in energy, transportation, and water sectors
- Created green product metrics system R&D stage-gating system for construction products manufacturer
- Managed engagement with equipment rental company to identify growth opportunities in green building
- Performed market and competitive analyses for a wide array of clients in retail, real estate financial and cleantech sectors; prepared and delivered client presentations; managed projects
- · Managed analysts performing environmental product certifications and market research
- Developed firm seminar series and analyst training materials; conducted trainings on topics including auditing, statistical analysis, and environmental performance benchmarking
- Audited certifications for environmental products and facility performance

Wal-Mart Providence, RI

Contract Researcher/Consultant: Energy Efficient Products Initiative

May-Sep 2006

Developed forecasting model for sales of energy-efficient lamps at Wal-Mart stores

Created guidelines for design of lamp recycling program

Brown University Facilities Management

Providence, RI

Administrative, Research, + Teaching Assistant: Energy and Design

Jan 2003-May 2006

- Developed energy-use and financial projections for university energy usage scenarios
- Performed background research and feasibility analysis for university energy efficiency projects
- Provided tutoring, logistical support and web design for two courses in sustainable design
- · Responsible for maintenance of energy efficient, low-impact building

Hovsgol Lake Global Environmental Facility and Brown University

Mongolia + Providence, RI

National Science Foundation REU Fellow, Thesis Research

Advisor: Clyde Goulden

June 2005-May 2006

 Independent research on climate-land use interactions on permafrost soil carbon storage Plant surveys, soil pit excavation, soil physical and chemical analysis, soil microbial process incubations

Marine Biological Laboratory Ecosystems Center

Woods Hole, MA Aug-Dec 2004

Semester in Environmental Science Student

Advisor: Charles Hopkinson

- Examined effects of nitrogen pollution on structure of microplankton food webs
- Microcosm experiments, fluorescence microscopy, dissolved nutrient analysis, planktonic growth incubations

Brown Center for Environmental Studies

Providence, RI

 $Under graduate\ Research\ Fellow$

Advisor: Steven Hamburg

Jun-Aug 2003

- Conducted research in biogeochemistry at Hubbard Brook Experimental Forest and surrounding region; oversaw soil pit excavation by undergraduate and graduate field crew
- Plant surveys, forest floor measurements, litter collection, soil pit excavation, soil physical and chemical analysis, GIS analysis in ESRI ArcMap

PUBLICATIONS IN POPULAR PRESS

- "Extinction Debt,"(Initial author) Wikipedia. Wikimedia Foundation, Inc., February 23, 2011 http://en.wikipedia.org/wiki/Extinction_debt
- "If Everyone Moves to the City, What Gets Left Behind?" *Good.is*, January 17, 2011. http://www.good.is/post/if-everyone-moves-to-the-city-what-is-left-behind/
- "Why the Ethanol Debate Isn't Helping Anyone," *GreenBiz.com*, Jun 3, 2009. http://www.greenbiz.com/blog/2009/06/03/why-ethanol-debate-isnt-helping-anyone
- "Four Lean, Green Strategies for an Uncertain Economy," (with Andrew Shapiro) *Harvard Business Review's Leading Green*, Oct 29, 2008. http://blogs.hbr.org/2008/10/4-lean-green-strategies-for-an/
- "What a Silent Spring Means for Business Risk," GreenBiz.com, Mar 6, 2007.
 http://www.greenbiz.com/blog/2007/03/05/what-silent-spring-means-business-risk

FINAL

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
211699	CHINA

RPPR

F. CHANGES

FINAL

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE
Not Applicable
F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM
NOTHING TO REPORT
F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS
F.3.a Human Subjects
No Change
F.3.b Vertebrate Animals
No Change
F.3.c Biohazards
No Change
F.3.d Select Agents
No Change

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G. 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** G.4.a Does the project involve human subjects? Is the research exempt from Federal regulations? Does this project involve a clinical trial? No G.4.b Inclusion Enrollment Data Report Attached: Understanding the Risk of Bat Coronavirus Emergence-PROTOCOL-001 G.4.c ClinicalTrials.gov Does this project include one or more applicable clinical trials that must be registered in ClinicalTrials.gov under FDAAA? No G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT Are there personnel on this project who are newly involved in the design or conduct of human subjects research? No 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** Does this project involve vertebrate animals? Yes **G.8 PROJECT/PERFORMANCE SITES**

Address

Congressional

Organization Name:

DUNS

RPPR FINAL

		District		
Primary: EcoHealth Alliance, Inc.	077090066	NY-010	460 West 34th Street 17th Floor New York NY 100012317	
Wuhan Institute of Virology	529027474		Xiao Hong Shan, No. 44 Wuchang District Wuhan	
East China Normal University	420945495		3663 Zhongshan Beilu Shanghai	
ECOHEALTH ALLIANCE	077090066		ECOHEALTH ALLIANCE, INC. 460 W 34TH ST NEW YORK NY 100012320	
EcoHealth Alliance, Inc.	077090066	NY-010	460 West 34th Street 17th Floor New York NY 100012317	
Wuhan Institute of Virology	529027474		Xiao Hong Shan, No. 44 Wuchang District Wuhan	
East China Normal University	420945495		3663 Zhongshan Beilu Shanghai	

G.9 FOREIGN COMPONENT

Organization Name: Wuhan Institute of Virology

Country: CHINA

Description of Foreign Component:

Principal Laboratory for all Research in China as per section G8 (above) and detailed in our Specific Aims

Organization Name: East China Normal University

Country: CHINA

Description of Foreign Component:

Principal Coordinating Team for all project field work as per section G8 (above) and detailed in our Specific Aims

G.10 ESTIMATED UNOBLIGATED BALANCE

G.10.a Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year's total approved budget?

No

G.11 PROGRAM INCOME

Is program income anticipated during the next budget period?

No

G.12 F&A COSTS

Is there a change in performance sites that will affect F&A costs?

No

Inclusion Enrollment Report

Inclusion Data Record (IDR) #: 166195 Using an Existing Dataset or Resource: No

Delayed Onset Study ?: No Clinical Trial: No

Enrollment Location: Foreign NIH Defined Phase III Clinical Trial: No

Study Title: Understanding the Risk of Bat Coronavirus Emergence-PROTOCOL-001

Planned Enrollment

Planned Enrollment Total: 2,460

NOTE: Planned enrollment data exists in the previous format; the PD/PI did not enter the planned enrollment information in the modified format and was not required to do so. Only the total can be provided.

Cumulative Enrollment

	Ethnic Categories									
Racial Categories	Not	Hispanic or L	_atino	Н	Hispanic or Latino		Unknown/Not Reported Ethnicity			Total
	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	157	108	0	0	0	0	0	0	0	265
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	157	108	0	0	0	0	0	0	0	265

Greer, Jenny (NIH/NIAID) [E] From: Normil, Carine (NIH/NIAID) [C] Sent: Friday, May 13, 2016 10:21 AM To: Greer, Jenny (NIH/NIAID) [E] Subject: FW: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER Importance: High From: Aleksei MacDurian (b) (6) Sent: Friday, May 13, 2016 9:58 AM To: Normil, Carine (NIH/NIAID) [C] Cc: Dr. Peter Daszak (b) (6); Stemmy, Erik (NIH/NIAID) [E] (b) (6); Pone, (b) (6) Laura (NIH/NIAID) [E] Subject: Re: Grant Number: 5R01Al110964 - 03 PI Name: DASZAK, PETER Importance: High Dear Carine. Dr. Daszak submitted his report yesterday. (b) (4) listed from the past year is non-compliant. We received a warning that one of the publications We have been in touch with NCBI about removing the non-compliant reference as we are not able to remove it via Dr. Daszak's account. As of this week, Dr. Daszak's My NCBI bibliography is correct, but it appears that the eRA Commons form has not yet populated or updated? (b) (6) if there are any questions or additional details necessary. Please let me know any time Many thanks! Aleksei Chmura Senior Coordinator of Operations Authorized Organizational Representative EcoHealth Alliance 460 West 34th Street - 17th floor New York, NY 10001 (b) (6) (direct)

www.ecohealthalliance.org

Aleksei MacDurian (Skype)

Visit our blog: www.ecohealthalliance.org/blog

(b) (6) (mobile)

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.

(b) (6). wrote:

Dear Dr. Daszak,

This is the second communication from NIAID requesting that you file the progress report for the above-referenced grant that was due no later than April 15, 2016. Please submit the delinquent report by May 12, 2016.

If you experience any difficulties meeting the submission deadline, please contact me immediately. Otherwise, please be advised that continued late submission of your non-competing grant progress report and any subsequently requested documentation will result in a reduction of time and/or funds for this grant.

Thank you, Carine

Carine Normil

Grants Management Specialist (Contractor)

Grants Management Program, DEA, NIAID, NIH, HHS 5601 fishers Lane, Rm 4G46, Bethesda, Maryland 20892

Phone (b) (6)

Fax: (301)-493-0597

Email: (b) (6)

<image001.jpg>

Disclaimer:

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From: Aleksei Chmura

To: Pone, Laura (NIH/NIAID) [E]

Cc: Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]

Subject: Re: Grant Number: 5R01AI110964 - 02 PI Name: DASZAK, PETER

Date: Monday, June 08, 2015 4:36:13 PM

Dear Laura.

Apologies for our delay in response. Our PIs were out-of-office last week and I wanted to confirm the details in the response. Here, below, are answers to the questions.

The PI mentioned recruiting participants at bat caves, wet markets etc., would the PI please discuss the method of recruitment on how participants would be approached to be involved in the study?

Our study will include adults living or working in the study sites selected as priority surveillance sites with high risk for viral spillover, evolution, amplification, and spread (i.e., 'hotspots'). Study sites are prioritized by identifying areas considered high-risk for contact with wildlife known to be associated with zoonotic viral diversity and with ecological and epidemiological conditions associated with disease emergence. Locations of the one-on-one interviews and focus groups will be in targeted 'hotspot' areas and determined ahead of time based upon our previous research and substantiated by observational research conducted by our research team. Sites will be selected to ensure inclusion of individuals that have contact with live, wild, and farmed animals through either direct contact (raising, hunting, selling, trading, or purchasing) or indirect contact (animals living in or entering dwellings, buildings, caves, or gardens/crops).

In order to participate in one-on-one interviews for the qualitative study, an individual must have direct or indirect contact with live animals, which includes raising, hunting, selling, trading, and/or purchasing live animals. Indirect contact includes living in or entering dwellings, buildings or gardens/crops e.g., bat roosts along roofs, rats or other animals invading stored food or crops. Our research team will use existing, local contacts for introductions to qualifying individuals who may be eligible and interested in participating. Efforts will be made to include a large variety of people with exposure to wildlife especially and initially targeting people who have more power or influence (e.g. farm owners, market leaders, restaurant owners, work-group leaders) as well as those with less (e.g. market vendors and cleaners, rat catchers, individual shoppers).

Our team will recruit adults living at the site or working or visiting the site by asking individuals if they would like to participate. Our study is completely voluntary. Our team will be thoroughly trained on communicating the research objectives and will be able to address any questions that potential subjects may have. As part of the informed consent process, both written and oral descriptions of the study will be provided in Chinese and via an interpreter if participants are not fluent in Mandarin and speak a local dialect. Contact details of our trained field-team coordinator will be provided to all subjects. All personnel on our research team will be available on site to answer questions from the study subjects.

In our previous set of questions we asked about maintaining the privacy of subjects, specifically we would like the PI to discuss how will be ensure and maintain privacy of participants during the one-on-one interviews, e.g., what is the location of the interviews?

One-on-one interviews for our qualitative survey locations will be identified prior to the interviews and will be performed in quiet and private areas where there are no other individuals present within a 10-foot distance. Specific sites for interviews will depend on the type of targeted "hotspot" area and may be in farming or rural areas, inside wildlife restaurants, behind animal storage sheds, in private rooms of dwellings, or in offices of business owners, hotel meeting rooms, etc. If necessary, a barrier will be created so that no other individuals may view the participant while interviews are conducted in order to maintain confidentiality. Research procedures will not include accessing personal health information.

To ensure compliance with informed consent procedures, all potential one-on-one interviewees will be given a consent form prior to being asked to participate. The participant will review the consent form with our research staff and will be given time to ask questions. When reviewing the consent form with participants, our research staff will explain details of the study including why each participant was selected, potential risks to participation, how participation is beneficial, that participation is completely voluntary, and that s/he may withdraw participation at any time. It will be explained that the researchers will not share responses. A small token or gift equivalent to no more than \$10 USD will be provided to each participant upon completion of the one-on-one interview.

Measures will be taken to assure the respect, dignity, and freedom of each participant. Each participant's identity will remain anonymous. All responses recorded from participants (of either one-on-one or focus group interviews) will not have names or any identifying details included with recoded responses. Results will be transcribed and/or translated into English and reports will be in aggregate form only. No individual names will ever be reported or published. For the purposes of achieving the aims of our study, data derived from interviews will be analyzed in aggregate by region within a province, without revealing any names of individuals and names/locations of specific markets. This will serve to minimize the legal and economic risks to specific markets or vendors that may provide information about potentially unlawful actions. Dr. Daszak the PI has entered into a confidentiality agreement with NIH to further protect study subjects from the release of any personally identifying information.

There is mentioned of focus group interviews, would the PI please explain which groups of participants are included and the location of the focus groups?

Focus group interview locations for the qualitative study will be identified prior to the focus group sessions and will be performed in quiet and private areas where there are no other individuals present. Specific sites for interviews depend on the type of targeted "hotspot" area and may be in farming or rural areas, inside wildlife restaurants, in private rooms of dwellings, or in offices of business owners, hotel meeting rooms, etc. If necessary, a barrier will be created so that no individuals other than those in the focus group may view or otherwise interfere with the focus group in order to maintain confidentiality. Research procedures in the current study will not include accessing personal health information.

To ensure compliance with informed consent procedures, all potential focus group participants will be given a consent form prior to being asked to participate. The participant will review the consent form with our research staff and will be given time to ask questions. When reviewing the consent form with participants, our research staff will explain details of the study including why each participant was selected, potential risks to participation, how participation is beneficial, that participation is completely voluntary, and that s/he may withdraw participation at any time. It will be explained that the researchers will not share responses. A small token or gift equivalent to no more than \$10 USD will be provided to each participant upon completion of the focus group interview.

For both focus group and one-on-one participants, our research team will use existing, local contacts for introductions to individuals who are eligible and interested in being interviewed. Efforts will be made to include a large variety of people with exposure to wildlife especially targeting people who have more power or influence (e.g. farm owners, market leaders) as well as those with less (e.g. market cleaners, rat catchers, individual vendors or shoppers).

Our team will recruit adults living at the site or working or visiting the site by asking individuals if they would like to participate. The study is completely voluntary. Our team will be thoroughly trained on communicating the research objectives and will be able to address any questions that potential subjects may have. As part of the informed consent process, both written and oral descriptions of the study will be provided in Chinese and via an interpreter if a local dialect is required. Contact details of our trained field-team coordinator will be provided to all subjects and all personnel on our research team will be available on site to answer questions from the study subjects.

Lastly, in addition to following up with participants who test positive for coronavirus in 6 months, what is the PI's plan for linking positive participants to treatment?

The test we will use is not a diagnostic test for SARS-like Coronaviruses. We will be identifying SARS-like Coronavirus from genetic fragments using consensus PCR. We will also be conducting serological assays, which represent exposure, but not active virus. There is no treatment for Coronavirus unless there is acute illness in which case treatment would be supportive care. If a participant tests antibody positive for SARS-like Coronaviruses, this would be a measure of past exposure and no treatment would be necessary. If SARS-like Coronavirus RNA is found, we will inform the participant that SARS-like Coronavirus was identified and that she or he should seek medical attention if respiratory symptoms occur and inform doctor of possible SARS-like Coronavirus infection.

Please note that our study has an initial qualitative component with the one-on-one interviews and focus groups as detailed above and a separate survey component with questionnaires and biological specimen collection. No clinical specimens will be collected in the initial qualitative component. For clarity, here are details on participant and site selection for our survey component:

A site-specific approach to 'hotspot' identification has been widely used in infectious disease research. Specific well-defined sites are referred to as 'clusters.' Cluster sampling is a standardized sampling methodology that is used when it is either impossible or impractical to compile an exhaustive list of the elements that make up the target population. Usually, as is the case in our study, the population elements are already grouped into subpopulations, e.g., wildlife market vendors, hunters, people who live in caves that have bats. To conduct a cluster sample, clusters (i.e., hotspot settings) are identified and selected for inclusion. If the cluster is small enough, the entire cluster of respondents may be approached to be included in the final sample. This is considered to be a one-stage cluster sample. However, if the cluster is large, then a two-stage cluster sample must be obtained; that is, only a subset of respondents from the cluster will be included in the final sample.

In order to obtain a subset of respondents from large clusters, systematic random sampling will be used. The procedure involved in systematic random sampling is easy, can be done manually and is a commonly used method in two-stage cluster sampling. A random starting point is selected to begin the study. From that point the study staff will move X units (e.g., market stalls, dwellings, houses near a cave) and select that unit for study participation. For example, in a large wildlife market, the first vendor would be selected for study participation. Upon completion of the study requirements, study staff would move 3 stalls down and select a stall on the right for study participation. Upon completion the staff would move another 3 stalls down and select a stall on the right for participation and so on. Only one person per unit (e.g., household, market stall) will be interviewed.

In order to improve recruitment within target communities, introductory visits will be made to each of the selected study site. These visits will be advertised through word of mouth or letter to town leaders depending on the size of the community/site. The letter will inform the community that a research team will be coming on a particular day(s) to discuss health related to animal contact. The letter would not be for advertising recruitment purposes. It would only be used to inform the community of the research visit(s).

During these visits, discussions and meetings will be held to educate, sensitize, and inform people about infections animals may carry, which may then be transferred to humans and cause disease and potential pathways for disease spread/emergence. When appropriate and following approval from local representatives, the research team will post flyers to inform the community of when the team will be coming back to speak to them about enrollment. This "town hall" meeting is completely voluntary, and those interested would likely attend. Although local representatives may be present to introduce the study team members, he/she will not be involved in the recruitment of the participants for the study. Once initial group meetings have been completed, and the type of research to be performed introduced, individual sessions with trained counselors, nurses, and phlebotomists (as appropriate) will be set up for interested persons. Every effort will be made to minimize any form of coercion in this protocol. Local representatives will not play a role in the recruitment of participants. During the consent process, local representatives will not be present when the consent is discussed with the participant. If research visits or enrollment will be held at a workplace, subjects shall be clearly informed during the recruitment process that their

participation in the study will not impact their employment. Translators will be provided, if participants are not fluent in Mandarin.

To ensure compliance with informed consent procedures, all potential participants will be given a consent form prior to being asked to participate. The participant will review the consent form with our research staff and will be given time to ask questions. When reviewing the consent form with participants, our research staff will explain details of the study including why each participant was selected, potential risks to participation, how participation is beneficial, that participation is completely voluntary, and that s/he may withdraw participation at any time. It will be explained that the researchers will not share responses. A small token or gift equivalent to no more than \$10 USD will be provided to each participant following his/her time spent in the study.

Measures will be taken to assure the respect, dignity, and freedom of each participant. Each participant's identity will remain anonymous. Each participant will be assigned a coded identification number that will link his or her responses to their clinical specimens, but any identifying information will be kept separate from these data and held in a secure, locked cabinet by the local investigator on-site. Researchers and investigators handling the data will not have access to participant names. The participants' identifiable data and contact information will be kept until the end of the study and then destroyed. Results will be translated into English and reports will be in aggregate form only; no individual names will ever be reported or published. For the purposes of achieving the aims of our study, data derived from questionnaires will be analyzed in aggregate by region within a province, without revealing the names of individuals and names/locations of specific markets. This will serve to minimize the legal and economic risks to specific markets or vendors that may provide information about potentially unlawful actions. Dr. Daszak the PI has entered into a confidentiality agreement with NIH to further protect study subjects from the release of any personally identifying information.

Please let me know, if you have further questions.

Many thanks most,

Sincerely,

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

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Econealth 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 Jun 1, 2015, at 08:38, Pone, Laura (NIH/NIAID) [E] (b) (6) wrote:

Thank you for providing additional information. However, there are still some concerns related to the protections of human subjects proposed in this project that we ask that the PI address. Would the PI please address the following by close of business Tuesday, June 2nd:

- The PI mentioned recruiting participants at bat caves, wet markets etc., would the PI please discuss the method of recruitment on how participants would be approached to be involved in the study?
- In our previous set of questions we asked about maintaining the privacy of subjects, specifically we would like the PI to discuss how will be ensure and maintain privacy of participants during the one-on-one interviews, e.g., what is the location of the interviews?
- There is mentioned of focus group interviews, would the PI please explain which groups of participants are included and the location of the focus groups?
- Lastly, in addition to following up with participants who test positive for coronavirus in 6 months, what is the PI's plan for linking positive participants to treatment?

Laura Pone

Grants Management Specialist DHHS/NIH/NIAID/GMP 5601 Fishers Lane, Room 4E29, MSC 9824 Bethesda, MD 20892-9824

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

Email: (b) (6)



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Publications Reported for this Reporting Period

NIH Public Access Compliance	Citation
PMC Journal In Process	(b) (4)
Not applicable	Olival KJ, Weekley CC, Daszak P. Bats and Viruses. Wang L, editor. New York: John Wiley & Sons, Inc.; 2015. What we know and need to know

From: Aleksei Chmura

To: Pone, Laura (NIH/NIAID) [E]

Cc: Stemmy, Erik (NIH/NIAID) [F]; Peter Daszak

Subject: Fwd: (HD-43100) Unable to delete an My NCBI entry

Date: Tuesday, May 26, 2015 1:46:57 PM

Attachments: bib.pdf

ATT00001.htm

Dear Laura,

We have heard back from NCBI - see email response, below.

Please contact the My NCBI Helpdesk (<u>PublicAccess@nih.gov</u>) to confirm removal of the paper in review:

(b) (4)

In Review).

We sent the revised NCBI Award Compliance Report previously on 5th May; it is attached here for reference. Let me know, if you require any further details.

Many thanks!

-Aleksei

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

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From: tkt-helpdesk@ncbi.nlm.nih.gov <tkt-helpdesk@ncbi.nlm.nih.gov>

Sent: Wednesday, May 13, 2015 11:04 AM

To: Peter Daszak

Subject: (HD-43100) Unable to delete an My NCBI entry

Dear Colleague,

The silver lock on the grant association is preventing you from removing the grant

Publications Reported for this Reporting Period

NIH Public Access Compliance	Citation
PMC Journal In Process	(b) (4)
Not applicable	Olival KJ, Weekley CC, Daszak P. Bats and Viruses. Wang L, editor. New York: John Wiley & Sons, Inc.; 2015. What we know and need to know

from the citation, or the citation from your Bibliography. You will need to have the lock removed before you can do either of those things.

The silver padlock indicates that the paper has been reported to NIH on a progress report. To remove the lock, you have to effectively revise the progress report that listed the paper. Please contact your NIH program officer to let them know you wish to revise the report and have the paper removed. They can explain what documentation they will need from your institution to make the revision. Your program officer can then contact our help desk (PublicAccess@nih.gov) to confirm that NIH can remove the papers.

Please let me know if you have any questions.

Thank you!
David Brodsky
Summary: Unable to delete an My NCBI entry

Description:

Dear Help Desk, I uploaded the following reference to My NCBI (

(b) (4)

but it is currently IN REVIEW and not yet accepted for publication. This was an error on my part and I would like to delete this entry. It is associated with an award (R01 AII 10964), but I am unable to disassociate this via the "add or delete award" link. Also, when I select the journal article and click on the "delete" button under Display Settings, I receive a notice that the action cannot be undone and when I click "delete" the item remains in My Bibliography. I appreciate your help with this. Sincerely, - Peter Daszak

Please do not change the subject line when replying to this message.

Regards, NCBI Help Desk

From: Aleksei Chmura

To: Pone, Laura (NIH/NIAID) [E]

Cc: Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]

Subject: Re: Grant Number: 5R01AI110964 - 02 PI Name: DASZAK, PETER

Date: Wednesday, May 20, 2015 3:58:46 PM
Attachments: R01AI110964 IRB Approval Letter.pdf

ATT00001.htm

Dear Laura,

Attached is our IRB approval notice, which includes both our IRB protocol and our informed consent forms. The text (pages 4-5 in the PDF) details how we plan to recruit participants and ensure their privacy (consent forms in English and Chinese on pages 7-13 of the PDF).

We do not have formal plans to provide participants with information about minimizing risks of exposure to Coronavirus infection, but test-retest studies have shown that participants in surveys similar to ours do increase their knowledge about the survey topics. All participants will be allowed to ask questions and discuss any related topics.

Please call or email me anytime, if further information is required. We are still waiting on the FWA number from Wuhan University and I will keep you updated early next week with any progress.

Many thanks!

-Aleksei

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

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November 17, 2014

Peter Daszak Ph.D. EcoHealth Alliance 460 West 34th St., 17th Floor New York, NY 10001-2320

Protocol Title: Understanding the Risk of Bat Coronavirus Emergence

Hummingbird IRB #: 2014-23

Grant Number: 1R01AI110964-01

Sponsor: EcoHealth Alliance

Approval Period: November 14, 2014 - November 13, 2015

Dear Dr. Daszak:

At the convened board meeting of November 14, 2014, Hummingbird IRB approved the above referenced study for one year.

The following document was approved:

Protocol Date: May 27, 2014

We wish to acknowledge the approval from Wuhan University's IRB which approved the portion of the study for which there was human subject intervention. Hummingbird IRB's approval extends only to the data analysis which will take place for anonymized data transferred to Dr. Daszak.

Any changes made to the protocol must be submitted to the Hummingbird IRB. Approval from Hummingbird IRB must be secured prior to initiation of the revision(s). You will receive a reminder to renew approval of the study approximately 3 months prior to the end of the approval period.

Attached, you will find a summary of investigator commitments with which the Board requires each investigator to adhere to during the approval period.

(b) (6)

Sincerely,

Isaac M. Colbert, Ph.D. Chairman, Hummingbird IRB

Attachment

cc: Maureen Miller, EcoHealth Alliance

Hummingbird IRB File

Investigator Commitments

All Hummingbird IRB (HIRB) approved investigators are required to fulfill these commitments.

In granting approval to the investigator for the conduct of an investigational study, Hummingbird IRB requires the investigator to understand and agree to these commitments:

- 1. The investigator will conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol when necessary to protect the safety, rights, or welfare of subjects.
- 2. The investigator will personally conduct or supervise the described investigation(s).
- 3. The investigator will delegate tasks to only trained, experienced and appropriately credentialed individuals who are familiar with the protocol and understand the tasks required to conduct the study and protect human subjects during screening and while enrolled.
- 4. The investigator is obligated to inform Hummingbird IRB of any financial conflicts of interest which may exist through submitting appropriate forms on an annual basis. Should a conflict arise during the course of the study, this conflict will be promptly reported to the IRB.
- 5. The investigator will inform any patients involved in a study involving drugs, devices or biologics, or any persons used as controls, that the drugs, devices or biologics are being used for investigational purposes and will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.
- 6. The investigator will report to the sponsor and Hummingbird IRB (when applicable) adverse and unanticipated problems that occur in the course of the investigation(s). If after the study has concluded, new information is made available that is relevant to ongoing health or safety, the investigator will inform subjects of these results.
- 7. When applicable, the investigator will read and understand the information in the investigator's brochure, device manual and other scientific background that describes the potential risks and side effects of the drug, procedure or device.
- 8. The investigator will ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the commitments outlined in this document.
- 9. The investigator will maintain adequate and accurate records and make those records available for inspection.

Peter Daszak Ph.D. November 17, 2014 Page 3 of 3

- 10. The investigator will promptly report Hummingbird IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, the investigator will not make any changes in the research without Hummingbird IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.
- 11. The investigator will have in place at his or her site, a process by which the HIRB approved consent form is compared to the executed contract to ensure that consistency exists between documents in terms of procedures, study visits, payment to subjects and compensation for injury as well as other conditions effecting human subjects. The investigator and sponsor will resolve any difference and notify HIRB of any changes impacting the consent.
- 12. The investigator will provide referrals to any subject for whom a condition or potentially adverse information is uncovered during the study. This may include, for example, learning of suicidality or a previously unknown disease. This does not pertain to results of genetic testing unless sharing this information is part of the protocol.

PROTOCOL: Understanding the Risk of Bat Coronavirus Emergence

Protocol #: R01AI110964

Version Date and Number: 6/5/13 updated 10/21/14 Version #1

The behavioral component of this multidisciplinary study has been designed directly in concert with the novel work of zoonotic viral detection and the identification and characterization of spillover and further transmission risk from wildlife. The approach is iterative and begins with rapid and focused qualitative research conducted in natural settings at biological and ecological surveillance sites. The research includes observation and mapping of public spaces, as well as focus groups and ethnographic interviews conducted with two groups of individuals: those involved with the wildlife value chain (from hunter through market to consumer) and those highly exposed exposure to wildlife, particularly bats (eg, cave dwellers). The focus is on the type and frequency of animal contact, as well as the range of wildlife observed. Participants will also be asked about observed environmental/ecological changes and impact; travel with animals, animal responsibilities and how these are divided by age and gender, and animal taboo; daily life, seasonal changes, times of shortage and other socioeconomic factors; and finally the frequency, types, causes and understanding of illness. This information provides a framework to gain rapid understanding of humananimal interactions and the actions/meanings surrounding these interactions, as well as for the exploration of unanticipated knowledge, such as the presence and rationale for taboos on certain human-animal interactions. These data will directly inform the development of detailed behavioral surveys. Alignment of the behavioral studies will coincide with animal biological surveillance to maximize the understanding of risk and reconcile information gathered on transmission risk with the actual presence of potentially zoonotic pathogens.

Consistent with the original proposal, we will recruit volunteers for the qualitative research by word of mouth or by referral from key informants or other participants from the two target groups (ie, wildlife value chain participants and those highly exposed to wildlife, particularly bats) in Guangdong, Guangxi, Yunnan, and Fujian provinces in cooperation with local Bureaus of Public Health and CDCs. To recruit participants, we will identify local individuals influential with the target population, introduce the study in public community fora and identify volunteers through these mechanisms. We will identify three sites in each province for a total of 12 sites representing the range of settings where the target population may be found (eg, bat caves, wet markets; formal and informal wildlife trade posts; animal transport/travel routes and mechanisms including transport storage and exchange centers, and wildlife value chain supporting industries such as guesthouses, restaurants, medicinal/magical/material animal parts and animal by-product preparers, vendors and purchasers). It is anticipated that eight focus groups (two per province) of approximately 8-10 individuals each (ie, a total of 48-80) and 144 ethnographic interviews (12 per site) will be conducted. Therefore, a total of 192 to 224 individuals will participate in qualitative research. With participant permission, qualitative interviews and focus groups will be recorded.

For the behavioral survey, in each of the four provinces in southern China we will aim to include 10 markets and survey 20 vendors per market; an additional 420 individuals will be selected based on the results of qualitative data analysis. In each province, 620 people will be surveyed for a total of 2480 individuals. A sampling frame and recruitment materials for this quantitative research will be developed in Year 2. Participants in the survey will be asked to provide blood (no more than 550ml), sputum, and stool samples. We will screen sera for antibodies to SARS-CoV, other alpha & beta coronaviruses including MERS-CoV,

and novel bat-CoVs. We will screen stool from CoV seropositive participants for CoV nucleic acid. We will also develop specific bat-CoV serological assays and share these with our Chinese collaborators.

In recognition of the time and expertise offered by study participants, each person will be offered a small token of practical, emotional or social significance. The token will not cost a lot of money, nor will it be money.

Only adults 18 years or older will be invited to participate. At least one of the focus groups and an estimated 35-40% of the interviews and surveys will be conducted with women. Subjects will be enrolled in this study without regard to ethnicity. The primary enrollment criteria are related to occupational exposure to wildlife and residence near wildlife.

We currently have no plans to pursue the substudy in Shanghai mentioned in the text. There are also no current plans for follow up of any study participants. In addition, if SARS virus is identified in any human sample, it will be immediately reported to public health authorities because we will have identified an outbreak.

The original sources of this information are on p112 section C1b and p120 Human subjects in the grant proposal.

On May 18, 2015, at 13:49, Pone, Laura (NIH/NIAID) [E] (b) (6) wrote: Hi Aleksei,

Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.quested the following additional information. Please provide a response no later than **Wednesday**, **May 20th**.

- · Please have the PI discuss the recruitment of participants.
- Please have the PI discuss how privacy is ensured, particularly with face-to-face interviews.
- · Will participants be provided any information regarding minimizing their risks of Coronovirus infection?

NIH Instructions for Grant Applications may be found at:

http://grants.nih.gov/grants/funding/424/SF424 RR Guide General Adobe VerB.pdf, Part II onwards for requirements on the Protection of Human Subjects

Please also visit our public website for information on "Research Involving Human Subjects": http://grants.nih.gov/grants/policy/hs/index.htm

Thank you,

Laura

From: Aleksei Chmura

To: Pone, Laura (NIH/NIAID) [E]

Cc: Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]

Subject: Re: Grant Number: 5R01AI110964 - 02 PI Name: DASZAK, PETER

Date: Thursday, May 14, 2015 4:11:59 PM

Attachments: Wuhan IRB fin.pdf

ATT00001.htm

Dear Laura,

That is very good to hear!

Here is another update: attached is our IRB approval from Wuhan University.

In summary, we have IRB approval from US and China and are waiting on the FWA number for Wuhan University. I will let you know about the FWA as soon as possible.

Thanks again!

-Aleksei

Aleksei Chmura

Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

(b) (6) (direct) (b) (6) (mobile)

Aleksei MacDurian (Skype)

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WUHAN UNIVERSITY

299 Bayi Rd., Wuhan 430072, Hubei, P.R. China

Wuhan University Ethics Approval Board

Research Study US NIAID R01AI110964: Understanding the Risk of Bat Coronavirus Emergence

This multidisciplinary study will include human subjects research. The human subjects research is both qualitative and quantitative. The focus is on the type and frequency of animal contact, as well as the range of wildlife observed. The research provides a framework to gain rapid understanding of human-animal interactions. Alignment of the human subjects research will coincide with animal biological surveillance to maximize the understanding of transmission risk with the potentially zoonotic pathogens identified in animal populations.

Volunteers will be recruited by word of mouth or by referral from key informants or other participants from the two target groups (ie, wildlife value chain participants and those highly exposed to wildlife, particularly bats) in Guangdong, Guangxi, Yunnan, and Fujian provinces in cooperation with local Bureaus of Public Health and CDCs. We will identify three sites in each province for a total of 12 sites representing the range of settings where the target population may be found (eg, bat caves, wet markets; formal and informal wildlife trade posts; animal transport/travel routes and mechanisms including transport storage and exchange centers, and wildlife value chain supporting industries such as guesthouses, restaurants, medicinal/magical/material animal parts and animal by-product preparers, vendors and purchasers). It is anticipated that eight focus groups (two per province) of approximately 8-10 individuals each (ie, a total of 48-80) and 144 ethnographic interviews (12 per site) will be conducted. Therefore, a total of 192 to 224 individuals will participate in qualitative research. With participant permission, qualitative interviews and focus groups will be recorded.

For the behavioral survey, a sampling frame and recruitment materials for this quantitative research will be developed in Year 2. It is anticipated that approximately 2500 individuals will be interviewed and asked to provide blood (no more than 550ml), sputum, and stool samples. We will screen sera for antibodies to SARS-CoV, other alpha & beta coronaviruses including MERS-CoV, and novel bat-CoVs.

Only adults 18 years or older will be invited to participate. At least one of the focus groups and an estimated 35-40% of the interviews and surveys will be conducted with women. Subjects will be enrolled in this study without regard to ethnicity. The primary enrollment criteria are related to occupational exposure to wildlife and residence near wildlife. All participants will sign an informed consent approved by the Wuhan Ethics Approval Board. In recognition of the time and expertise offered by study participants, each person will be offered a small token of practical, emotional or social significance. The token will not



WUHAN UNIVERSITY

299 Bayi Rd., Wuhan 430072, Hubei, P.R. China

cost a lot of money, nor will it be money.

All data, including notes, recordings, questionnaires, and computer files will be will be coded to strictly preserve confidentiality. Paper files will be scanned electronically and then shredded. Biological samples will be coded to maintain anonymity of sample results. Identifying information such as consent forms and test results will be kept under lock and key in a file cabinet. All electronic data will be encrypted. Data access will be limited to investigators conducting analyses; data will have protections with data access codes required. Data collection is cross sectional and master list data will not be required for the analysis of data. Data will be presented in the aggregate. Original data will be stored for five years after the completion of the study. At that time, electronic files will be permanently deleted.

(b) (6)

Nov. 11, 2014

Chuanhua Yu, Ph.D

Director of Medical Ethics Committee

School of Public Health

Wuhan University

115 Donghu Rd.

Wuhan, Hubei 430071

Tel:

(b) (6)

Fax: (+8627)68758648

Email:

(b) (6)

On May 14, 2015, at 16:00, Pone, Laura (NIH/NIAID) [E]

(b) (6) wrote:

Hi Aleksei,

Evaluation Only, Created with Aspose HTML. Copyright 2013-2020 Aspose Pty Ltd.was responded to and have submitted that for review. Please let me know once Wuhan has the FWA.

Thank you!

Laura Pone **Grants Management Specialist** DHHS/NIH/NIAID/GMP 5601 Fishers Lane, Room 4E29, MSC 9824 Bethesda, MD 20892-9824 Phone: e-Fax: 301-493-0597 Email:

please consider the environment before printing this e-mail.

Disclaimer:

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(b) (6) From: Aleksei Chmura

Sent: Wednesday, May 13, 2015 4:36 PM

To: Pone, Laura (NIH/NIAID) [E]

Cc: Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]

Subject: Re: Grant Number: 5R01Al110964 - 02 PI Name: DASZAK, PETER

Importance: High

Dear Laura,

Apologies for any delays or confusion on my part, but I am not certain what summary statement concerns you are requesting. We provided details about protection of human subjects via our Just in Time Report in May of last year and sent our US IRB approval for our human research protocol under our award last month (attached here for reference). We expect to have an FWA for Wuhan University before the end of the month, but I will update you on our progress in the next week.

Can we have a quick chat about the summary statement concerns anytime that is good for you. Once we are clear on what is required, we will provide the requested details immediately.

Is the deleted reference with updated My NCBI report for Dr. Daszak ok as well? I have not yet had a response from the NCBI support re. removing and/or disassociating the reference.

Please call me anytime day/night at (b) (6)

Many thanks!

Aleksei Chmura Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

(b) (6) (direct) (b) (6) (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.

From: Williams, Barbara (NIH/OD) [C]
To: (b) (6).

Cc: (b) (6) : Pone, Laura (NIH/NIAID) [E]; OLAW Division of

Assurances (NIH/OD)

Subject: Animal Welfare Interinstitutional Assurance #A7941-02 - EcoHealth Alliance & Tufts University Cummings School

of Veterinary Medicine - 1R01AI110964-01

Date: Tuesday, May 20, 2014 9:40:52 AM
Attachments: Animal Welfare Assurance #A7941-02.pdf

Dear Dr. Chmura,

Attached is a copy of the signed, approved Animal Welfare Interinstitutional Assurance between EcoHealth Alliance and Tufts University Cummings School of Veterinary Medicine, needed for animal research to be conducted under grant 1R01A110964-01. The Assurance number is A7941-02 and became effective on 5/19/2014. I am also mailing this information to you. Thank you for your assistance.

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: OLAWdocs@mail.nih.gov

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC EALTH 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

May 19, 2014

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) 480-3117

Project #: 1 R01 A1 110964-01

Project Title: Understanding the Risk of Bat Coronavirus Emergence

Investigator: Dr. Peter Daszak

Animal Facility: Tufts University Cummings School

of Veterinary Medicine

Dr. Aleksel Chmura Program Coordinator 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 Human Care and Use of Laboratory Animals (Policy) revised August 2002.

The Assurance, with identification number A7941-02 became effective on 5/19/2014. The Assurance is good for the current period of support. Under your approved Assurance with Tufts University Cummings School of Veterinary Medicine, 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) (f)

Doreen H. Bartlett Senior Assurance Officer Division of Assurances Office of Laboratory Animal Welfare

Enclosure

cc:

Dr. Diane Souvaine Dr. Barry Goldin Ms. Laura Pone, NIAID

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

- 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>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).</u>
- 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: Tufts University Cummings School of Veterinary Medicine Address: (street address, city, state, zip code)
IACUC/Office of the Vice Provost for Research
136 Harrison Ave.
Boston, MA, 02111

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

Name of Awardee Institution: EcoHealth	Alliance		
Authorized Official: Aleksei Chmura			
Signature:	(b) (6) Date: 08 May 2014		
Title: Authorized Organizational Represe	■ □ → F NAS TAN, NAS JANA NAS JANA 12 12 12 12 12 12 12 1		
Address: (street address, city, state, zip 460 WEST 34 TH ST., 17 TH FL. NEW YORK, NY 10001, USA	code)		
Phone:+ (b) (6)	Fax:+1,212.380.4465		
E-mail: (b) (6)	V - 2. 000 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		
B. Endorsement of Assured Institu	tion		
Name of Assured Institution: Tufts Univer	ersity Cummings School of Veterinary Medicine		
Institutional Official: pr. Diane L. Souva			
Signature:	(b) (6) Date: May 14, 2014		
Title: Vice Provost for Research			
Address: (street address, city, state, zip 136 Harrison Avenue Boston, MA 02111	code)		
Phone: (b) (6)	Fax:617-636-8354		
E-mail: (b) (6)	Transaction activities		
IACUC Chairperson: Dr. Barry Goldin			
(6) (6)			
Signature:	Date: May 2014		
Title: Professor, Department of Public He	ealth and Community Medicine		
Address: (street address, city, state, zip			
136 Harrison Avenue, Boston, MA 02111			
Phone: (b) (6)	Fax: 617-636-8354		
E-mail: (b) (6)	A STATE OF THE PARTY OF THE PAR		
Date of IACUC Approval: (within 3 years,	, pending not acceptable) 05/08/2014		
PHS Approval (to be completed by C	D(AW)		
	(6)(6)		
Signature of OLAW Official	Date: 5/19/2014		
Doreen H. Bartlett - Senior Assurance Office of Laboratory Animal Welfan National Institutes of Health Bethesda, MD 20892-7982 (b) (6) Phone: (b) (6) FAX: 301-451-5672	ce Officer re		
Grant/Contract #:1R01AI110964-01	Animal Welfare Assurance #: A 1941-02		
Effective Date:	Expiration Date: (duration of project, up to 5 years)		

III.

VERTEBRATE ANIMALS:

1. Detailed description of animal use.

All work with vertebrate animals will be conducted in China.

Capture and sampling techniques for all wild animals described in this study have been approved by Tufts University IACUC. Experimental work using humanized mice will be conducted at the Center for Animal Experiment Biosafety 3 lab of Wuhan University at the School of Medicine in Wuhan, China. The Center is AAALAC accredited and has both an Institutional Biosafety Committee and an Institutional Animal Care and Use Committee and 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. Conditions for animal use are described below.

Note: The majority of wild animals captured and sampled will be done using nondestructive, techniques. In a small number of instances (~ 2 bats per species), where intestine and lung tissue is required to establish cell lines, animals will be humanely euthanized and a necropsy performed according to accepted protocols (see euthanasia section)

Bat capture. Free-ranging bats will be captured using either a mist net or harp trap. The net system is manned by two people during the entire capture period, and bats are removed from the net as soon as they become entangled to minimize stress and prevent injury. In the Co-PI's (Dr. Epstein) experience, a maximum of 20-30 bats can 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 six hours.

Wild rodent capture. Free-ranging rodents will be captured through pit traps and box traps; captive rodents, including resident free-ranging wild rats/rodents in markets, will be manually captured or captured through traps. Traps will be checked a minimum of once daily in the morning. If adverse weather (extreme heat, rain) is expected or researchers are working in areas where predation is common, traps will be checked more frequently, and closed during the adverse weather. Handling of rodents will involve morphometric measurements. Captive and wild rodent sampling procedures (including anesthesia if necessary), will involve manual restraint, venipuncture, mucosal swabs, fecal, urine, and external parasite collection. Following capture, small animals will be restrained with a fine mesh bag to minimize entanglement, taking precautions to ensure the animals are not traumatized by the hoop of the net or through net removal. Larger rodents will be restrained for sampling in specialized squeeze-cages, allowing adjustments appropriate to the size of the animal. Squeeze-cages consist of a wooden frame with a plasticized wire bottom and a Plexiglas shield used to press the animal, while ensuring visible communication between the field veterinarian and the animal. Once squeezed, a rod is inserted to keep the plastic shield in place. The box is then inverted, allowing sampling to be conducted through the open wire bottom and abdomen of the animal when the animal is safely immobilized. Anesthesia for small rodents will be conducted using plastic tubes, with the animals transferred directly from the traps to the tubes containing a cotton swab soaked in ether, isoflurane, or methoxyflurane for anesthetic induction. For larger rodents, chemical restraint and anesthesia (ketamine alone, or ketamine combined with xylazine) will be applied either through the squeeze cages by syringe if applicable.

Laboratory mice. Lab mice will be sourced commercially by the Wuhan Center for Animal Experiment at Wuhan University.

Sample Collection. Bats will be manually restrained during sampling.

Bats: Depending on the species and size of bat, swabs will be taken from the oropharynx, urogenital tract, and rectum. Fresh feces will be collected if available, in which case a rectal swab will not be collected. Blood will be collected from fruit bats either from the cephalic vein or from the radial artery or vein using a 25 gauge needle and 1cc syringe. Blood will be collected from bats weighing less than 100g according to published techniques (126).

Rodents: Rodents will be anesthetized prior to sampling. Once anesthetized a small blood sample will be collected using the submandibular vein or tail vein. Femoral or jugular venipuncture may be used for larger rodents (e.g. rats). In all rodents, blood volumes of no more than 1% of body weight will be withdrawn. (example 0.2 ml blood from a 20 gram rodent).

Civets and other small mammals: Anesthesia will be used to restrain small free ranging mammals according to published protocols. Animals will be monitored continuously while recovering from anesthesia. Animals that are sampled in the marketplace, and that may potentially be consumed, will not be anesthetized. Manual restraint will be used and blood will be drawn from the femoral artery or saphenous vein.

Laboratory Mice. Humanized mice will be bred at the University of Wuhan. Mice will be inoculated with a specific dose (e.g. 1x106 TCID50) of virus through different routes (intranasally and intraperitoneally). Mouse body temperature will be monitored with implanted temperature sensing microchips (LifeChip Bio-thermo, Destron Fearing), and mice will be weighed daily. Animals will be observed daily for clinical signs of illness. Moribund mice will be euthanized, according to AVMA recommendations. Live animals will be euthanized at three weeks post-inoculation and organs harvested. We will collect sera on days 10, 15 and 21 to test for neutralizing antibodies against bat CoVs. We will collect nasal washes, oral swabs, and rectal swabs, and urine every two days. These are minimally invasive procedures, and will be performed by experienced lab technicians under the supervision of a full-time veterinarian.

2. Justify use of animals, choice of species, numbers to be used. Species and number used in study:

The purpose of this study is to conduct multi-regional surveillance in large populations of animals 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. Because we don't have prevalence estimates for novel strains of coronaviruses, we assume a conservative estimate of 10% prevalence. SARS-like coronaviruses have been found in between 10% and 38% of bats studied (4, 25). A 10% in wild populations of bats would require a sample of 30 individuals per species in order to ensure detection of an infected individual with 95% confidence.

Wild bats: We will sample 30 individuals from 30 different species in each province in China (2 per species euthanized for organ tissue); representing but not limited to the following families: *Rhinolophidae, Hipposideridae, Vespertillionidae, Mollossidae,* and *Pteropodidae,* all of which are present in Southern China and potentially in the wildlife markets.

Bats in wet markets: We will opportunistically sample a wide variety of insectivorous and frugivorous bats according to what is present in markets. In addition to bats, we will sample civets, raccoon dogs, rats, bandicoots, bamboo rats, and other rodents present in the markets that may act as intermediate hosts. Numbers of animals sampled from markets will be limited to animal availability. 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 cases where feces are collected for testing, non-invasive techniques will be used. 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.

A small number of bats (maximum 2 per species) representing each of the species in this study may be euthanized in order to collect lung and intestinal tissue required for characterizing coronavirus receptors. Voucher specimens may also be collected at the discretion of the team leader for the accurate identification of species using molecular methodology.

Humanized mice for experimental infection for Specific Aim 3: In order to understand whether bat coronaviruses that utilize receptors found in people have the potential to infect people, we will use Swiss albino mice (standard breed at Wuhan University) that have been genetically modified to have human receptors. We'll infect them with cultured bat coronaviruses and determine which organs become infected and whether these mice are capable of shedding infectious virus. Humanized mice will be genetically modified to carry human ACE2 or DPP4 gene will be used to evaluate pathogenesis of CoVs. We cannot anticipate exactly how many viruses we will find that are candidates for experimental models, however we estimate that we will use four adult mice (2 male, 2 female) per virus and that we will identify approximately 20 viruses that will be used for mouse infection experiments. This will require a total of 80 mice over the study period.

3. Provide information on veterinary care. For wild caught animals, there is no specific veterinary care that is appropriate, nor will clinical veterinary facilities be available. Animals that are injured during the capture or sampling process will be assessed by an experienced team leader, and if the animal is determined to be unlikely to survive if released, it shall be euthanized humanely (see euthanasia section). Animals will be released within hours of capture. In the markets, animals will be sampled using manual restraint or anesthesia. Animals will be returned to vendors after sampling, or, if wild caught in the markets (e.g. rodents), they will be released in the area outside the marketplace.

Laboratory mice will be housed in the BSL-3 small animal facility Center for Animal Experiment at Wuhan Institute of Virology. Two senior Wuhan Institute of Virology veterinarians (Drs. An XueFang and Zhang Fan) will oversee the experiments. Experimental animals will be regularly monitored by experienced staff and a supervising veterinarian. The supervising veterinarian will have responsibility for the care and well-being of all mice used in the experimental studies. The animal facility operates 24 hours a day and has full-time veterinarians on staff. All animals will be provided with food and water ad libitum and will otherwise receive standard care. The Veterinarian in charge will notify the on-site Co-PI (Dr. Zhengli Shi) and the Principal Investigator (Dr. Daszak) by telephone and email if there are any issues regarding animal health and welfare.

4. Procedures for ensuring animal comfort, lack of distress, pain, or injury: Wild-caught animals: Animals will not be held longer than 6 hours. Co-Pls, Drs. Epstein and Olival have extensive experience in capture, anesthesia, and sampling wildlife, including bats. In our experience, bats and rodents tolerate the described procedure well. Mist nets will be attended continuously during capture periods, and bats will be extracted from the net as soon as they become entangled. This will minimize stress and injury from entanglement. Bats will be placed individually in cotton bags and hung from tree branches while awaiting processing and during recovery. The bags are sufficiently porous as to allow for ventilation and are designed for bat capture. The enclosed environment seems to calm the bats, as they do not struggle once

inside, but they hang quietly. Animals will be monitored by a veterinarian or experienced field team member during all stages of capture, processing, and release. Animals will be kept in a cool place while in the pillowcases. Rodent traps will be set overnight and all traps will be checked in the morning while it still cool outside. Rodents will be kept in a cool, shaded environment during sampling and will be released within 10 hours of capture. The procedures used in this experiment (blood draw, nasal, oral, and rectal swabs) are minimally invasive, however, mice that show signs of morbidity post-infection will be examined and euthanized according to AVMA standards (see below).

Market animals: Bats, rodents, and small mammals sampled in markets, sourced from vendors, will be manually restrained and sampled on-site, to minimize stress and discomfort. Because these animals are designated for human consumption, we will not use anesthetic agents if the animal is to be returned to the vendor following sampling. Manual restraint and sampling will be conducted by experienced members of the field team. Any animal that shows signs of distress (respiratory distress, pale mucous membranes) will be immediately released into a holding cage to recover. If the veterinarian or senior scientist in charge of sampling deems an individual animal to be fractious, or at risk for excessive stress and discomfort, anesthetic agents may be used for the safety of both animal and handler. Injectable tiletamine zolazepam (Telozol HCl) given intramuscularly, or isoflurane gas using a portable vaporizer may be used. Any animal that has been anesthetized for sampling will not be returned to the food chain due to possibility of human consumption of anesthetic drug. These animals will be purchased from the vendor and not returned to the market. Following sampling the animal will be euthanized according to AVMA standards and disposed of according to safe biohazard practices.

Experimental animals (mice): All experimental work will be conducted at Wuhan Institute of Virology under the supervision of senior veterinarians Drs. An XueFang and Zhang Fan. Animals will be observed daily for clinical signs of illness. All mice will be provided comfortable housing with regular access to water and food throughout the experiment. The experiments under this study do not include surgical procedures or use of experimental pharmacological agents. Mice will be anesthetized prior to sampling using isoflurane gas, which will reduce stress and discomfort. During experimental infections, mice will be monitored for signs of pain and discomfort. Moribund mice (e.g. mice showing depression, inappetance, respiratory distress, or severe fever) will be euthanized, according to AVMA recommendations.

5. Euthanasia: In the event of injury to an animal that results in pain and suffering, and reasonable veterinary care is unavailable, the animal will be euthanized by a veterinarian or trained field team member using ketamine injected intramuscularly 37.5mg/kg and sodium pentobarbital injected intravenously at a dose of 1.0ml per 5kg injected intravenously. This protocol is in accordance with the AVMA euthanasia report (2013). Any animal that is euthanized using a chemical agent will be disposed such that it will not be permitted to enter the food supply either through markets or hunting.

From: Aleksei Chmura

To: Pone, Laura (NIH/NIAID) [E]

Cc: Jon Epstein; Peter Daszak; Parkison Valerie

Subject: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER: Updated Vertebrate Animal Section

Date: Friday, May 16, 2014 12:16:02 PM
Attachments: response to VAS NIAID CoV updated.decx

Dear Laura,

Tufts has requested we provide you with an update to our Vertebrate Animal Section in accordance with the IACUC. Please see our updated form attached to this email. I have also cc'ed Valerie Parkison the IACUC/IBC Regulatory Director at Tufts on this email.

Many thanks!

Aleksei Chmura Program Coordinator EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

(b) (6) (direct) (b) (6) (mobile) (b) (6) (China)

Aleksei MacDurian (Skype)

www.ecohealthalliance.org

Visit our blog; www.ecohealthalliance.org/blog

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.

VERTEBRATE ANIMALS:

1. Detailed description of animal use.

All work with vertebrate animals will be conducted in China.

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Rodents: Rodents will be anesthetized prior to sampling. Once anesthetized a small blood sample will be collected using the submandibular vein or tail vein. Femoral or jugular venipuncture may be used for larger rodents (e.g. rats). In all rodents, blood volumes of no more than 1% of body weight will be withdrawn. (example 0.2 ml blood from a 20 gram rodent).

Civets and other small mammals: Anesthesia will be used to restrain small free ranging mammals according to published protocols. Animals will be monitored continuously while recovering from anesthesia. Animals that are sampled in the marketplace, and that may potentially be consumed, will not be anesthetized. Manual restraint will be used and blood will be drawn from the femoral artery or saphenous vein.

Laboratory Mice. Humanized mice will be bred at the University of Wuhan. Mice will be inoculated with a specific dose (e.g. 1x106 TCID50) of virus through different routes (intranasally and intraperitoneally). Mouse body temperature will be monitored with implanted temperature sensing microchips (LifeChip Bio-thermo, Destron Fearing), and mice will be weighed daily. Animals will be observed daily for clinical signs of illness. Moribund mice will be euthanized, according to AVMA recommendations. Live animals will be euthanized at three weeks post-inoculation and organs harvested. We will collect sera on days 10, 15 and 21 to test for neutralizing antibodies against bat CoVs. We will collect nasal washes, oral swabs, and rectal swabs, and urine every two days. These are minimally invasive procedures, and will be performed by experienced lab technicians under the supervision of a full-time veterinarian.

2. Justify use of animals, choice of species, numbers to be used. Species and number used in study:

The purpose of this study is to conduct multi-regional surveillance in large populations of animals 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. Because we don't have prevalence estimates for novel strains of coronaviruses, we assume a conservative estimate of 10% prevalence. SARS-like coronaviruses have been found in between 10% and 38% of bats studied (4, 25). A 10% in wild populations of bats would require a sample of 30 individuals per species in order to ensure detection of an infected individual with 95% confidence.

Wild bats: We will sample 30 individuals from 30 different species in each province in China (2 per species euthanized for organ tissue); representing but not limited to the following families: *Rhinolophidae, Hipposideridae, Vespertillionidae, Mollossidae,* and *Pteropodidae,* all of which are present in Southern China and potentially in the wildlife markets.

Bats in wet markets: We will opportunistically sample a wide variety of insectivorous and frugivorous bats according to what is present in markets. In addition to bats, we will sample civets, raccoon dogs, rats, bandicoots, bamboo rats, and other rodents present in the markets that may act as intermediate hosts. Numbers of animals sampled from markets will be limited to animal availability. 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 cases where feces are collected for testing, non-invasive techniques will be used. 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.

A small number of bats (maximum 2 per species) representing each of the species in this study may be euthanized in order to collect lung and intestinal tissue required for characterizing coronavirus receptors. Voucher specimens may also be collected at the discretion of the team leader for the accurate identification of species using molecular methodology.

Humanized mice for experimental infection for Specific Aim 3: In order to understand whether bat coronaviruses that utilize receptors found in people have the potential to infect people, we will use Swiss albino mice (standard breed at Wuhan University) that have been genetically modified to have human receptors. We'll infect them with cultured bat coronaviruses and determine which organs become infected and whether these mice are capable of shedding infectious virus. Humanized mice will be genetically modified to carry human ACE2 or DPP4 gene will be used to evaluate pathogenesis of CoVs. We cannot anticipate exactly how many viruses we will find that are candidates for experimental models, however we estimate that we will use four adult mice (2 male, 2 female) per virus and that we will identify approximately 20 viruses that will be used for mouse infection experiments. This will require a total of 80 mice over the study period.

3. Provide information on veterinary care. For wild caught animals, there is no specific veterinary care that is appropriate, nor will clinical veterinary facilities be available. Animals that are injured during the capture or sampling process will be assessed by an experienced team leader, and if the animal is determined to be unlikely to survive if released, it shall be euthanized humanely (see euthanasia section). Animals will be released within hours of capture. In the markets, animals will be sampled using manual restraint or anesthesia. Animals will be returned to vendors after sampling, or, if wild caught in the markets (e.g. rodents), they will be released in the area outside the marketplace.

Laboratory mice will be housed in the BSL-3 small animal facility Center for Animal Experiment at Wuhan Institute of Virology. Two senior Wuhan Institute of Virology veterinarians (Drs. An XueFang and Zhang Fan) will oversee the experiments. Experimental animals will be regularly monitored by experienced staff and a supervising veterinarian. The supervising veterinarian will have responsibility for the care and well-being of all mice used in the experimental studies. The animal facility operates 24 hours a day and has full-time veterinarians on staff. All animals will be provided with food and water ad libitum and will otherwise receive standard care. The Veterinarian in charge will notify the on-site Co-PI (Dr. Zhengli Shi) and the Principal Investigator (Dr. Daszak) by telephone and email if there are any issues regarding animal health and welfare.

4. Procedures for ensuring animal comfort, lack of distress, pain, or injury:
Wild-caught animals: Animals will not be held longer than 6 hours. Co-Pls, Drs. Epstein and Olival have extensive experience in capture, anesthesia, and sampling wildlife, including bats. In our experience, bats and rodents tolerate the described procedure well. Mist nets will be attended continuously during capture periods, and bats will be extracted from the net as soon as they become entangled. This will minimize stress and injury from entanglement. Bats will be placed individually in cotton bags and hung from tree branches while awaiting processing and during recovery. The bags are sufficiently porous as to allow for ventilation and are designed for bat capture. The enclosed environment seems to calm the bats, as they do not struggle once

inside, but they hang quietly. Animals will be monitored by a veterinarian or experienced field team member during all stages of capture, processing, and release. Animals will be kept in a cool place while in the pillowcases. Rodent traps will be set overnight and all traps will be checked in the morning while it still cool outside. Rodents will be kept in a cool, shaded environment during sampling and will be released within 10 hours of capture. The procedures used in this experiment (blood draw, nasal, oral, and rectal swabs) are minimally invasive, however, mice that show signs of morbidity post-infection will be examined and euthanized according to AVMA standards (see below).

Market animals: Bats, rodents, and small mammals sampled in markets, sourced from vendors, will be manually restrained and sampled on-site, to minimize stress and discomfort. Because these animals are designated for human consumption, we will not use anesthetic agents if the animal is to be returned to the vendor following sampling. Manual restraint and sampling will be conducted by experienced members of the field team. Any animal that shows signs of distress (respiratory distress, pale mucous membranes) will be immediately released into a holding cage to recover. If the veterinarian or senior scientist in charge of sampling deems an individual animal to be fractious, or at risk for excessive stress and discomfort, anesthetic agents may be used for the safety of both animal and handler. Injectable tiletamine zolazepam (Telozol HCl) given intramuscularly, or isoflurane gas using a portable vaporizer may be used. Any animal that has been anesthetized for sampling will not be returned to the food chain due to possibility of human consumption of anesthetic drug. These animals will be purchased from the vendor and not returned to the market. Following sampling the animal will be euthanized according to AVMA standards and disposed of according to safe biohazard practices.

Experimental animals (mice): All experimental work will be conducted at Wuhan Institute of Virology under the supervision of senior veterinarians Drs. An XueFang and Zhang Fan. Animals will be observed daily for clinical signs of illness. All mice will be provided comfortable housing with regular access to water and food throughout the experiment. The experiments under this study do not include surgical procedures or use of experimental pharmacological agents. Mice will be anesthetized prior to sampling using isoflurane gas, which will reduce stress and discomfort. During experimental infections, mice will be monitored for signs of pain and discomfort. Moribund mice (e.g. mice showing depression, inappetance, respiratory distress, or severe fever) will be euthanized, according to AVMA recommendations.

5. Euthanasia: In the event of injury to an animal that results in pain and suffering, and reasonable veterinary care is unavailable, the animal will be euthanized by a veterinarian or trained field team member using ketamine injected intramuscularly 37.5mg/kg and sodium pentobarbital injected intravenously at a dose of 1.0ml per 5kg injected intravenously. This protocol is in accordance with the AVMA euthanasia report (2013). Any animal that is euthanized using a chemical agent will be disposed such that it will not be permitted to enter the food supply either through markets or hunting.

From: Stemmy, Erik (NIH/NIAID) [E]
To: Pone, Laura (NIH/NIAID) [E]

Subject: RE: Grant Number: 1R01Al110964 - 01 PI Name: DASZAK, PETER: Updated Vertebrate Animal Section

Date: Friday, May 16, 2014 2:41:18 PM

Hí Laura,

Yes, the updates to the animal section look fine to me.

Thanks, Erik

Please note my updated contact information below:

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825

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

Getting ready to publish? Share the good news with your program officer asap! NIAID may be able to help publicize your article. And, remember to list your NIAID grant or contract number in the publication.

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----Original Message----

From: Pone, Laura (NIH/NIAID) [E] Sent: Friday, May 16, 2014 2:39 PM To: Stemmy, Erik (NIH/NIAID) [E]

Subject: FW: Grant Number: 1R01A1110964 - 01 PI Name: DASZAK, PETER: Updated Vertebrate Animal Section

Hi Dr. Stemmy,

Please let me know if you approve this revised VAS.

Thank you,

Laura Pone
Grants Management Specialist
DHHS/NIH/NIAID/GMP
6700B Rockledge Drive, Room 2240
Bethesda, MD 20892-7614 (Fed Ex zip 20817)

Phone: (b) (6) e-Fax: 301-493-0597 Email: (b) (6) please consider the environment before printing this e-mail.

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----Original Message----

From: Pone, Laura (NIH/NIAID) [E] Sent: Friday, May 16, 2014 2:38 PM To: Williams, Barbara (NIH/OD) [C]

Cc: OLAW Division of Assurances (NIH/OD); Stemmy, Erik (NIH/NIAID) [E]

Subject: FW: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER: Updated Vertebrate Animal Section

Hi Barbara,

Please see the attached revised VAS to accompany the IIA submitted for grant All 10964.

Thank you,

Laura Pone

Grants Management Specialist

DHHS/NIH/NIAID/GMP

6700B Rockledge Drive, Room 2240

Bethesda, MD 20892-7614 (Fed Ex zip 20817)

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

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----Original Message----

From: Aleksei Chmura (b) (6)

Sent: Friday, May 16, 2014 12:16 PM To: Pone, Laura (NIH/NIAID) [E]

Cc: Jon Epstein; Peter Daszak; Parkison Valerie

Subject: Grant Number: 1R01Al110964 - 01 PI Name: DASZAK, PETER: Updated Vertebrate Animal Section

Dear Laura,

Tufts has requested we provide you with an update to our Vertebrate Animal Section in accordance with the IACUC. Please see our updated form attached to this email. I have also cc'ed Valerie Parkison the IACUC/IBC Regulatory Director at Tufts on this email.

Many thanks!

Aleksei Chmura Program Coordinator EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

www.ecohealthalliance.org

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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.

From: Williams, Barbara (NIH/OD) [C]
To: (b) (6)

Cc: (b) (6) Pone, Laura (NIH/NIAID) [E]; OLAW Division of Assurances (NIH/OD)

Subject: Animal Welfare Interinstitutional Assurance #A7941-01 - EcoHealth Alliance & Wuahn Institute of Virology -

1R01Al110964-01

Date: Thursday, May 08, 2014 9:43:31 AM

Attachments: Animal Welfare Interinstitutional Assurance #A7941-01.pdf

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: OLAWdocs@mail.nih.gov

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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 Al 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.

Eileen Morgan
Director, Division of Assurances
Office of Laboratory Animal Welfare

Enclosure

CC:

Dr. Xinwen Chen Dr. Wuxiang Guan Ms. Laura Pone, NIAID

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

- 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>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).</u>
- 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

Name of Awar	dee Institution: Ecol	Health Alliance			
Authorized Off	ficial: Aleksei Chmur	а			
Signature:	· Control of the Control	(b) (6)	Da	te:20 March 2014	
Title: Authoriz	ed Organizational Re	epresentative			
Address: (stre 460 WEST 34 ^T NEW YORK, N	et address, city, sta ^H ST., 17 TH FL. Y 10001, USA	te, zip code)			
Phone:+	(b) (6)		Fax:+1.212.380.4465		
E-mail:	(1	6) (6)	* HIMMEN 100 CO.		
B. Endorser	nent of Assured I	stitution			
SCIENCES		20-2-3-2-	OF VIROLOGY, CHIN	ESE ACADEMY OF	
Institutional O Signature:	fficial: Xinwen Chen (b) (6)	Date: 30 April 2014			
HIII - COTTON - COTTO	of Wuhan Institute	of Virology, Ch	inese Academy of Sci	ences	
Phone:	(b) (6)		Fax: 86-27-87199106		
E-mail:	(b) (6)				
IACUC Chairpe	rson: Wuxiang Gua	n			
Signature:	(b) (6)		Date: 30 April 2014		
	n of Institutional An	imal Care and	Use Committee, Wuh	an Institute of Virology,	
Address: (stre Xiao Hong Sha Wuhan, 43007		te, zip code)			
Phone:	(b) (6)		Fax: 86-27-87197258		
E-mail:	(b) (6)				
Date of IACUC	Approval: (within 3	years, pendin	g not acceptable) 3/2	5/2014	
HS Approva	al (to be complete	d by OLAW)	The state of the s		
Signature of OLAW Officia			(b) (6) Da	ate: [10/2 =14/	
Signature of C	DLAW Officia		Do	ote: 5/1/2014	
Eileen M. I	Morgan		/1		

Signature of OLAW Officia 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 #:1R01Al110964-01 Effective Date: \$\int 1/1 \int 1/4 Expiration Date: (duration of project, up to 5 years)

III.

From: Aleksei Chmura

To: Pone, Laura (NIH/NIAID) [E]

Cc: Peter Daszak; Stemmy, Erik (NIH/NIAID) [E1; Jon Epstein

Subject: Re: URGENT - RE: Grant Number: 1R01A1110964 - 01 PI Name: DASZAK, PETER

Date: Friday, March 21, 2014 9:50:56 AM

Importance: High

Dear Laura,

The techniques are the same across the board. There is no animal work being conducted at Guangdong CDC, East China Normal University, or Guangdong CDC. Members of the field team will be composed of personnel from EcoHealth Alliance Headquarters, Guangdong Entomological Institution, and Yunnan CDC. All animal work will occur in the field - excepting the experimental laboratory work done at the Wuhan Institute of Virology in China.

We have submitted two separate IACUC protocols: one at the Wuhan Institute of Virology which will cover the experimental work and the other via Tufts University for our fieldwork. We are waiting on committee review dates. These should be sent to us very soon and we will update you immediately.

If you have any further questions, please let me know anytime.

Sincerely,

-Aleksei

Aleksei Chmura

Program Coordinator & AOR EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

> (b) (6) (direct) (b) (6) (mobile)

> > (b) (6) (China)

Aleksel MacDurian (Skype)

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From: Pone, Laura (NIH/NIAID) [E] Sent: Monday, March 10, 2014 11:01 AM

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

(b) (6)

Subject: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER

Good Morning Aleksei,

Please provide a revised VAS including each of the sites listed below.

Guangdong Entomological Institute (ECNU)
 Zhongshanbei Rd
 Room 1707
 Building 622 3663
 Shanghai Putuo
 CHINA

- East China Normal University
 3663 Zhongshan
 Beilu Shanghai
 CHINA
- Center for Disease Control and Prevention of Guangdong 176 Xigang Xilu Guangzhou
 CHINA
- Yunnan Institute of Endemic Diseases Control and Prevention
 33 Wenhua Rd
 Dali
 CHINA

Thank you,

Laura Pone
Grants Management Specialist
DHHS/NIH/NIAID/GMP
6700B Rockledge Drive, Room 2240
Bethesda, MD 20892-7614 (Fed Ex zip 20817)
Phone: (b) (6)

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



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From: Aleksei Chmura

To: Pone, Laura (NIH/NIAID) [E]

Cc: Stemmy, Erik (NIH/NIAID) [E]; Peter Daszak

Subject: Re: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER

Date: Wednesday, February 26, 2014 12:35:14 PM

Importance: High

Dear Laura,

As per our proposed Timeline and Management Plan (Section D, page 119), our human sampling work would not commence until the 6th Quarter ~1.5 years after the commencement of the project, so definitely in Year 2.

Please call or email me, if you have further questions.

Many thanks!

Aleksei Chmura

Program Coordinator
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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On 26 Feb 2014, at 11:31:19, Pone, Laura (NIH/NIAID) [E] (b) (6) (7) wrote:

Hi Aleksei,

Dr. Stemmy mentioned that the human subject work begins in year 2. I could not find any correspondence from you stating that, so please let me know when the work is schedule to begin.

Thank you,

Laura Pone

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

Email: (b) (6)

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From: Aleksei Chmura (b) (6)

Sent: Monday, February 24, 2014 9:55 PM

To: Pone, Laura (NIH/NIAID) [E]

Cc: Stemmy, Erik (NIH/NIAID) [E]; Peter Daszak

Subject: Re: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER

Dear Laura,

We are in process of obtaining AWAs and FWAs for each site that does not already have these, but this process may take a month or more. Would this hold up an award or could an award be made with a block on human or animal work (until we have FWAs and/or AWAs)?

Many thanks most,

Sincerely,

Aleksei Chmura

Program Coordinator and AOR 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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On 24 Feb 2014, at 08:47:26, Pone, Laura (NIH/NIAID) [E] (b) (6) wrote:

Dear Aleksei,

It has come to my attention that animal and human subject work will be done at Guangdong Entomological Institute, Wuhan Institute of Virology, East China Normal

University, Center for Disease Control and Prevention of Guangdong, and Yunnan Institute of Endemic Diseases Control and Prevention. Please begin the process for obtaining AWA's and FWA's for each site that does not already have them.

- Confirmation of FWA for human subject work. If no FWA exists please establish one. http://ohrp.cit.nih.gov/efile/FwaStart.aspx
- Confirmation of AWA for animal subject work. If no AWA exists please establish one. http://grants.nih.gov/grants/olaw/obtain assurance.htm

Thank you,

Laura Pone
Grants Management Specialist
DHHS/NIH/NIAID/GMP
6700B Rockledge Drive, Room 2240
Bethesda, MD 20892-7614 (Fed Ex zip 20817)
Phone:
(b) (6)

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



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Just In Time Report

	Report submitted on :	01/24/2014 08:25 PM
IRB Confirmation:		
Human Subjects Assurance Number:		
Human Subjects Education:	No Human Subjects Education was provided	
IACUC Confirmation:		

CURRENT OTHER SUPPORT

DASZAK, PETER

ACTIVE

DEB-0955897 (Daszak) 07/01/10 - 06/30/15 (b) (4) (b) (6)

NSF \$497,121

EcoHealthNet: Ecology, Environmental Science and Health Research Network

Funding for student exchange and workshops to fuse veterinary science, ecology and human medical sciences.

Role: PI

5R01GM100471 (Perrings) 09/15/11 - 06/30/15 (6) (4), (6) (6)

NIGMS \$289,953 Modeling Anthropogenic Effects in the Spread of Infectious Disease

A collaborative international proposal using interdisciplinary approaches to address the links between globalization and emerging infectious disease risks.

Role: Co-Investigator

1R56TW009502 (Daszak) 09/17/12 - 04/30/14 (b) (4). (b) (6)

NIH Fogarty International Center \$300,000

Comparative Spillover Dynamics of Avian Influenza in Endemic Countries

Our research will advance the understanding of the long-term dynamics of H5N1 by relaxing the assumption of homogeneous mixing implicit in classical epidemiological models through fine-scale measurements of realistic contact networks in Bangladesh, China, and Egypt.

Role: PI

Emerging Pandemic Threats (Morse) 10/01/09 - 09/30/14 (b) (d) (d) (e) (e)

USAID \$18,000,000

PREDICT

Modeling hotspots for disease emergence and conducting surveillance in wildlife in hotspots for new emerging zoonoses.

Role: PI on Subcontract from UC Davis

2R01TW005869 09/01/08 - 06/30/14 (6) (4), (6) (6)

NIH Fogarty International Center \$2,498,829

The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh

To conduct mathematical modeling and fieldwork to understand the dynamics of Nipah virus in Bangladesh

Role: PI

PENDING

1R01Al110964 (Daszak) 07/01/2014 – 06/30/2019 (b) (4). (b) (6)

NIAID \$3,362,339

Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

Role: PI

SHI, ZHENG LI

ACTIVE

2011CB504700 (Shi) 01/01/2011-12/31/2015 (b) (4). (b) (6)

National Basic Research Program, China \$150,000

Mechanism of interspecies transmission of zoonotic viruses Study of the means of transmission of zoonotic viruses.

Role: PI

81290341 (Shi) 01/01/2013-12/31/2017 (b) (4), (b) (6

NSF China \$100,000

Genetic diversity, identification, and pathogenesis of bat viruses

Molecular characterization of viruses of bats in China.

Role: PI

PENDING

1R01AI110964 (Daszak) 07/01/2014 - 06/30/2019 (b) (4). (b) (6)

NIAID \$3,362,339

Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

Role: Co-Investigator

ZHANG, SHU-YI

ACTIVE

Emerging Pandemic Threats (Morse) 10/01/09 – 09/30/14 (b) (d) (d) (e) (e)

USAID \$18,000,000

PREDICT

Modeling hotspots for disease emergence and conducting surveillance in wildlife in hotspots for new emerging zoonoses.

Role: PI on Subcontract from EcoHealth Alliance

PENDING

1R01AI110964 (Daszak) 07/01/2014 - 06/30/2019 (b) (4), (b) (6)

NIAID \$3,362,339

Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

Role: Co-Investigator

KE, CHANG WEN

ACTIVE

2012ZX10004213-004 (Ke) 07/01/2012 - 06/30/2015

015 (b) (4), (b) (6)

Ministry of Science and Technology, PRC

National Major Projects of Major Infectious Disease Control and Prevention

Investigation of Disease Outbreaks in Guangdong Province

Role: PI

PENDING

1R01Al110964 (Daszak) 07/01/2014 - 06/30/2019 (b)(4),(b)(6)

NIAID \$3,362,339

Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

\$372,451

Role: Co-Investigator

EPSTEIN, JONATHAN H.

ACTIVE

DEB-0955897 (Daszak)

07/01/10 - 06/30/15

(b) (4), (b) (6)

NSF

\$497,121

EcoHealthNet: Ecology, Environmental Science and Health Research Network

Funding for student exchange and workshops to fuse veterinary science, ecology and human medical

sciences.

Role: Senior Scientist

Emerging Pandemic Threats (Morse)

10/01/09 - 09/30/14

(b) (4), (b) (6)

USAID

\$18,000,000

PREDICT

Modeling hotspots for disease emergence and conducting surveillance in wildlife in hotspots for new emerging zoonoses.

Role: Senior Scientist

2R01TW005869

09/01/08 - 06/30/14

(b) (4), (b) (6)

NIH Fogarty International Center

\$2,498,829

The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh

To conduct mathematical modeling and fieldwork to understand the dynamics of Nipah virus in Bangladesh

Role: Senior Scientist

4500036150 (Epstein)

07/01/14-06/30/19

(b) (4), (b) (6)

NIH

\$275,000

Risk of Zoonotic Transmission of Herpes B Virus from Wild Macaques in Bangladesh

Investigate causes of encephalitis for non-Nipah non-Japanese encephalitis in Bangladesh and determine the shedding prevalence of B Virus in macaques.

Role: PI

F12AP01117 (Epstein)

09/13/12 - 09/13/14

(b) (4), (b) (6)

USFW

\$35,000

Development of a Great Ape Health Unit in Sabah, Malaysia.

Develop a Great Ape Health unit to evaluate the health of rescued and translocated gibbons and

orangutans in Sabah, Malaysia.

Role: PI

PENDING

1R01Al110964 (Daszak)

07/01/2014 - 06/30/2019

(b) (4), (b) (6)

NIAID

\$3,362,339

Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

Role: Co-Investigator

OLIVAL, KEVIN J.

ACTIVE

Award GVSU 04152012 (Russell)

06/18/12 - 06/17/13

(b) (4). (b) (6)

USFWS/USGS

\$12,000

Genetic Approaches to Defining Taxonomic and conservation Units for the Hawaiian Hoary Bat Using molecular tools to date the origins and divergence of the endangered Hawaiian Hoary bat.

Role: Co-PI

4500036150 (Epstein)

07/01/12-06/30/14

(b) (4). (b) (6)

USFWS

\$197.950

Characterization of Climatic Parameters within Bat Hibernacula, their Influence on Environmental Loads of Geomyces destructans, and Implications for the Migration of White-Nose Syndrome in Bats.

Role: Co-PI

PENDING

1R01Al110964 (Daszak)

07/01/2014 - 06/30/2019

(b) (4), (b) (6)

NIAID

\$3,362,339

Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

Role: Co-Investigator

1 R21 Al113205-01 (Olival)

04/01/2014 - 03/31/2016

(b) (4), (b) (6)

NIAID

\$396,453

Understanding the Origin and Emergence of MERS-CoV

To investigate the ecology and animal origin of Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in the Kingdom of Saudi Arabia (KSA). A combination of field sampling and laboratory work to characterize KSA bat CoV diversity, seasonality of viral shedding, and identify ecological risk factors for transmission among bats, humans and livestock

HOSSEINI, PARVIEZ R.

ACTIVE

EF-1015791 (Mitchell) 07/01/10 - 6/30/15 (b) (4), (b) (6)

NSF \$745,295

The community ecology of viral pathogens

Causes and consequences of coinfection in hosts and vectors. To conduct mathematical modeling and fieldwork to understand implications in a wild grass, aphid-vectored disease system.

Role: Co-PI

PREDICT

Modeling hotspots for disease emergence and conducting surveillance in wildlife in hotspots for new emerging zoonoses.

Role: Hotspots Modeler

1R56TW009502 (Daszak) 09/17/12 – 04/30/14 (b) (4), (b) (6)

NIH Fogarty International Center \$300,000

Comparative Spillover Dynamics of Avian Influenza in Endemic Countries

Our research will advance the understanding of the long-term dynamics of H5N1 by relaxing the assumption of homogeneous mixing implicit in classical epidemiological models through fine-scale measurements of realistic contact networks in Bangladesh, China, and Egypt.

Role: Senior Scientist

PENDING

1R01AI110964 (Daszak) 07/01/2014 - 06/30/2019 (b) (4). (b) (6)

NIAID \$3,362,339

Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

Role: Co-Investigator

GE, XING YI ACTIVE: none

PENDING

1R01Al110964 (Daszak) 07/01/2014 - 06/30/2019 (b) (4), (b) (6)

NIAID \$3,362,339

Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

Role: Co-Investigator

ZHU, GUANG JIAN

ACTIVE: none

PENDING

1R01Al110964 (Daszak) 07/01/2014 - 06/30/2019 (b) (4), (b) (6)

NIAID \$3,362,339

Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

Role: Co-Investigator

ZHANG, YUN ZHI

ACTIVE:

(no number – Zhang) 01/01/2013- 12/01/2017 (b) (4). (b) (6)

Ministry of Science \$51,277

Yunnan region is an important natural reservoir

Pathogen survey of Yunnan province

Role: PI

81260437 (Zhang) 01/01/2013 -12/01/2016 (b) (4), (b) (6)

NSF, China \$108,561

Rat and mouse viral metagenome

Yunnan murine viral metagenome important viral epidemic status and related research

Role: PI

(no number – Zhang) 11/01/2012- 11/01/2015 (6) (4). (b) (6)

Talent Research Foundation \$87,000

Health Study Ecology

Yunnan Provincial Health Hall "Ten hundred" health study of the ecology of Yunnan province.

PENDING

1R01Al110964 (Daszak) 07/01/2014 - 06/30/2019 (b) (4), (b) (6)

NIAID \$3,362,339

Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

Role: Co-Investigator



January 15, 2014

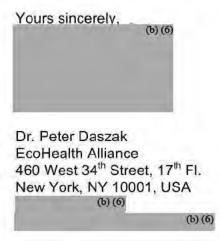
JUST IN TIME REQUESTED INFORMATION

1R01Al110964 Understanding the Risk of Bat Coronavirus Emergence (PI, Daszak)

Dear reviewers,

- Other current support: Our AOR/SRO has uploaded the other current support information for all senior/key personnel on our proposal via the eRA Commons' JIT page.
- 2) Budgeted effort for modeler/statistician: The only suggested critique for our proposal is: "Despite these strengths, it is noted that there is a limited effort for modeling and statistics." (summary statement, Resume and Summary of Discussion). As I suggested in a conversation with the Program Officer, Dr. Erik Stemmy on the 13th of January, should this proposal be awarded, we intend to modify our budget to increase effort (and corresponding salary support) for our modeler/statistician Hosseini by (b) (4), (6) (6) in each year of the proposed work. This would be achieved without increasing the overall proposed budget, and by reducing other costs on the award.
- 3) 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. Human subject education for all key personnel is being completed currently and all details will be provided at each step of approval.
- 4) IACUC: Our IACUC approval is also pending with Tufts University through our interinstitutional agreement with them. The OLAW Assurance number listed (A4059-01) is correct. Once we have an IACUC date, we will inform NIH immediately.

If you have any other questions, please contact me anytime. We are very appreciative of your consideration and look forward to further details.



Just In Time Report

	Report submitted on :	02/18/2014 12:49 PM
IRB Confirmation:		
Human Subjects Assurance Number:		
Human Subjects Education:	No Human Subjects Education was provided	
IACUC Confirmation:		

Last	First	Role	Training	Training URL	Date of Training
Daszak	Peter	PD/PI	COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)	https://www.citiprogram.org/index.cfm?pageID=22	12-Feb-14
Epstein	Jonathan H.	Co-Investigator	NIH Web based Training Protecting Human Subjects	http://phrp.nihtraining.com/users/login.php	04-Mar-09
Shi	Zheng Li	Co-Investigator	COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)	https://www.citiprogram.org/index.cfm?pageID=22	14-Feb-14
Zhang	Shu-Yi	Co-Investigator	COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)	https://www.citiprogram.org/index.cfm?pageID=22	14-Feb-14
Ke	Chang Wen	Co-Investigator	COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)	https://www.citiprogram.org/index.cfm?pageID=22	12-Feb-14
Zhang			COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)		12-Feb-14
Ge	Xing Yi	Co-Investigator	COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)	https://www.citiprogram.org/index.cfm?pageID=22	12-Feb-14
Olival	Kevin J.	Co-Investigator	COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)	https://www.citiprogram.org/index.cfm?pageID=22	12-Feb-14
Chmura	Aleksei	Admin	COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)	https://www.citiprogram.org/index.cfm?pageID=22	18-Feb-14

Just In Time Report

	Report submitted on:	02/12/2014 09:54 AM
IRB Confirmation:		
Human Subjects Assurance Number:		
Human Subjects Education:	No Human Subjects Education was provided	
IACUC Confirmation:		



February 11, 2014

JUST IN TIME REQUESTED INFORMATION

1R01Al110964 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.
- 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

b. Survey of cases of respiratory illness within the Shanghai CDC influenza-like illness surveillance program

[Study description from proposal with new material highlighted and in bold] Expanding on our work in Guangdong, we will develop a voluntary study of animal vendors and hunters in Guangxi, Yunnan, and Fujian provinces in cooperation with local Bureaus of Public Health and CDCs. We will develop a survey to identify people with high exposure to wildlife, particularly bats, and will recruit volunteers, collect blood, sputum, and stool sample from each enrolled participant. We will screen sera for antibodies to SARS-CoV, other alpha & beta coronaviruses including MERS-CoV, and novel bat-CoVs. We will screen stool from CoV seropositive participants for CoV nucleic acid. We will also develop specific bat-CoV serological assays and share these with our Chinese collaborators. In each province in southern China we will aim to include 10 markets and survey 20 vendors per market; 20 additional wildlife hunters per province (220 case subjects); 400 control subjects from the general population near the markets in each province (total of 620 people per province). For Shanghai, we will enroll 200 acute respiratory illness cases and 400 non-respiratory controls (600 total), The total number of human subjects will be 2460. The study will be conducted in Guangxi, Yunnan, Fujian and Shanghai provinces

HUMAN SUBJECTS RESEARCH

1. Risk to subjects: This project is a study of human exposure to animal coronaviruses in southern China. Subjects will be enrolled on a voluntary basis and a single interview and sample collection will be conducted. Informed consent will be obtained. People found to be infected with an animal coronavirus will be followed up after 6 months with a secondary interview and collection of biological specimens to determine whether infection is persistent and exposure is ongoing. Primary subjects will be male or female adults who are highly exposed to wildlife through hunting, butchering, or general handling in the context of live animal markets or restaurants that prepare and serve wild animals. The study population will be selected in Shanghai, Yunnan, Fujian, and Guangxi provinces, China, and will be open to people of all ethnicities that fit the subject criteria. We will target human subjects, comprising 220 subjects (market workers and hunters) and 400 controls from the general population in Yunnan, Fujian, and Guangxi provinces plus 600 subjects in Shanghai (total enrolled: 2460). The market types are defined in Specific Aim 1, Human exposure to CoVs. There are no data to suggest an ethnic bias for coronavirus exposure or infection, therefore subjects will be enrolled based on exposure criteria, though subjects will not be excluded based on ethnicity or gender. We will endeavor to have an equal number of men and women, if the composition of animal vendors in markets allows.

Sources of Materials: Samples to be collected and screened for coronaviruses include blood, saliva and stool samples. 10 mL of blood will be collected from each subject. Subjects will also be asked to provide saliva and stool in sterile containers. An initial sample collection and interview will be performed by trained medical personnel from the local CDC under the provincial Public Health Bureau. Sample collection will be done once in years 2-4 of the study. Samples will be screened for coronaviruses using PCR and an ELISA at the appropriate CDC microbiology lab or at the Wuhan Institute of Virology. Samples that test positive for coronavirus or antibodies to coronavirus will be followed up after 6 months with a secondary interview designed to determine the current level of

exposure to wild animals, and whether exposure at the current level was consistent between the first and subsequent interview. Repeated clinical samples will also be collected and tested for coronaviruses. In all instances, volunteers will be given a medical exam and informed of their test results.

Potential risks: The potential risks to study participants resulting from study participation are minimal. The volume of blood being collected is within normal safety limits. The interview questions will be designed to assess exposure risk, and may ask personal questions, but surveys will be done in private and anonymized to protect privacy. Some of the questions may include information about selling or trading animal species that are prohibited by local or federal laws. The participants may be reluctant to answer questions that implicate them in criminal activity and may become nervous following participation if their answers implicate them in potentially illegal activities. Participation in the survey and study is completely voluntary, and a participant may withdraw from the study at any time, or decline to participate in any aspect of the study, including declining to answer specific questions.

There may be information contained in the surveys that implicates an individual or place of business in illegal trade activities. This could potentially have real or perceived negative legal or financial impacts on the respondent, their place of business, or the larger marketplace from which the information was obtained.

There may be some stress to subjects who are informed that they have been exposed to an animal virus, but counseling will be available and options for medical care will be included in the discussion.

2. Adequacy of protection against risks: Recruitment and informed consent: Prospective study participants will be identified by the research team at each site in partnership with provincial CDC personnel. The team will be thoroughly trained on communicating the research objectives and will be able to address any questions that potential subjects may have. Both written and oral descriptions of the study will be provided in Chinese (in Mandarin or via an interpreter in local dialect if necessary) as part of the informed consent process. Contact details of the collaborators at local CDCs and the study PI will be provided to all subjects, and CDC personnel on the research team will be available on site to answer questions from the study subjects. Test results will be communicated to each subject and counseling offered to minimize stress.

Subjects will be informed, via written consent forms and oral explanation of the consent forms, that their participation is entirely voluntary and that they will have the right to decline to participate in any part of the study, and may decline to answer any questions in the survey. Further, the participant's identity will remain anonymous. They will be assigned a coded ID number that will link their responses to the questionnaire to their clinical specimens, but any identifying information will be kept separate from these data and held in a secure cabinet by the local investigator. For the purposes of achieving the aims of this study, data derived from questionnaires can be analyzed in aggregate by region within a province, without revealing the name or location of specific markets. This will serve to minimize the legal and economic risks to specific markets or vendors that may provide information about potentially unlawful actions.

The PI has entered into a confidentiality agreement with NIH to further protect study subjects from the release of any personally identifying information. Confidentiality for all participants will be protected to the greatest possible extent by law. Consent forms and the front page of the

questionnaire containing the name of the participants will be stored separately from the rest of the data and held by the Local Project Manager on site. Access to personal identifiers by the Project Coordinator is allowed only for the purposes of contacting the participant of their results and participation in follow-up studies if they desire. For research purposes and data analysis, test results and questionnaires will be linked by coded numbers, and only by code numbers. Researchers and investigators handling the data will not have access to participant names. The page containing identifiers will be separated from the rest of the questionnaire and stored separately in a locked facility on site. Only the Project Director and site Coordinators will have access to such information for follow-up, identification (such as photographs) and the offering of counseling services. Only unidentifiable-linked questionnaire data, accident report information, and corresponding test results will be made accessible to project investigators. The participants' identifiable data and contact information will be kept until the end of the study and then destroyed. Results given to the Ministry of Health will be reported in aggregate form only; no individual names will ever be reported or published. Results will not be included in the individual's general health record.

- 3. <u>Potential benefits to Subjects and Others</u>: There are potential benefits to the study subjects including receiving a physical exam/health check from a medical officer and the potential benefit of identifying an occupational health hazard. At the conclusion of the study, we will deliver an educational workshop for high risk individuals (open to study subjects and non-study subjects) describing the health benefits of using PPE and hand-washing during animal handling activities throughout the day.
- 4. The importance of knowledge to be gained. There are valuable potential benefits to the general public from the knowledge to be gained by this study, as it may identify sources of zoonotic coronaviruses in the market system or which are commonly hunted. Avoidance of these animals or extra care when handling them may substantially reduce the risk of CoV (and other zoonotic pathogen) transmission.

Inclusion of Women: This proposal will enroll men and women as study subjects. Depending on local gender composition of animal vendors, we will make every effort to have men and women equally represented in this study.

Inclusion of minorities: Subjects will be enrolled in this study without regard to ethnicity. Occupational exposure to wildlife in a market, hunting, or butchering context will be the primary criteria for identifying subjects.

Inclusion of Children: Children (subjects below age 18) will not be included in this study. Children do not normally work in wildlife markets, and are not normally involved in the wildlife trade in China.

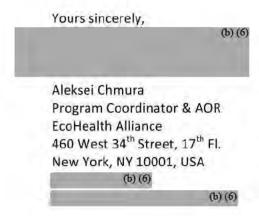
Total planned enrollment: See enrollment table

4) B: OVERLAP: The summary statement requested that: "[Budgetary] Overlap with PREDICT and other R01 funded projects should be better defined". The first (PREDICT) is a contract from USAID with the goal of building capacity in developing countries to identify and address new pandemic threats. The work funded by this contract covers 24 countries, and aims to 1) identify regions of high risk for viral spillover from wildlife to humans, conduct preliminary surveillance of wildlife, take blood samples, and conduct RT-PCR assays to identify new viruses present in them; and 2) to work with local agencies to

build laboratory capacity for viral work within the countries. The surveillance conducted in this project was used to build preliminary data for our proposal. However, this is primarily a capacity building project and is specifically defined as a non-research project so that none of the hypotheses in our current proposal are being tested. Furthermore, fieldwork for this project has been designated by USAID to end by June 2014 and the project completely ends on September 30th 2014. Work in China is now being conducted on birds, rats and primates only. Three other R01 projects were current at the time of submission:

- 1) <u>R01GM100471</u> ("Modeling anthropogenic effects in the spread of infectious diseases") is an economic modeling grant that uses mathematical equations to describe the economic impact of disease spread, and therefore has no overlap
- 2) <u>2R01TW005869</u> ("The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh") focuses the vast majority of its work on Nipah virus within Bangladesh, but some of the funding was used with permission from the Fogarty International Center to build collaborations with our Chinese partners by conducting bat testing within China. This grant is now in a 6th year no-cost extension to finish human survey work in Bangladesh and no further work in China is planned or budgeted. The no-cost extension year ends on June 1st 2014
- 3) 1R01Al079231 ("Risk of viral emergence from bats") was focused on detailed surveys of bat species in 10 countries globally and viral diversity analyses (PCR-based), as well as hotspot modeling for bat-origin viruses. The grant ended on 8/31/2013 and the final report has been filed. This award was also used to build preliminary data for our current proposal. No other grants have been applied for or awarded that have any other overlap with the current proposed work.
- 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.



Just In Time Report

	Report submitted on: 02/10/2014 04:38 PM
IRB Confirmation:	
Human Subjects Assurance Number:	
Human Subjects Education:	No Human Subjects Education was provided
IACUC Confirmation:	

NONPROFIT RATE AGREEMENT

EIN: 311726494

ORGANIZATION:

EcoHealth Alliance

460 West 34th St., 17th Fl. New York, NY 10001-2320 DATE: 04/03/2013

FILING REF .: The preceding

agreement was dated

03/23/2012

The rates approved in this agreement are for use on grants, contracts and other agreements with the Federal Government, subject to the conditions in Scction III.

SECTION I:	INDIRECT	COST RATES				
RATE TYPES:	FIXED	FINAL	PROV.	(PROVISIONAL)	PRED.	(PREDETERMINED)

EFFECTIVE PERIOD

TYPE	FROM	TO	RATE(%) LOCATION	APPLICABLE TO
FINAL	07/01/2011	06/30/2012	44.10 On-Site	All Programs
PROV.	07/01/2012	Until Amended		Use same rates and conditions as those cited for fiscal year ending June 30, 2012.

*BASE

Total direct costs excluding capital expenditures (buildings, individual items of equipment; alterations and renovations), that portion of each subaward in excess of \$25,000 and flow-through funds.

ORGANIZATION: EcoHealth Alliance

AGREEMENT DATE: 4/3/2013

SECTION	I: FRINGE BE	NEFIT RATES**		
TYPE	FROM	TO	RATE(%) LOCATION	APPLICABLE TO
FINAL	7/1/2011	6/30/2012	32.30 All	Full-Time Employees
PROV.	7/1/2012	Until amended		Use same rates and conditions as those cited for fiscal year ending June 30, 2012.

^{**} DESCRIPTION OF FRINGE BENEFITS RATE BASE: Salaries and wages.

ORGANIZATION: EcoHealth Alliance

AGREEMENT DATE: 4/3/2013

SECTION II: SPECIAL REMARKS

TREATMENT OF FRINGE BENEFITS:

The fringe benefits are charged using the rate(s) listed in the Fringe Benefits Section of this Agreement. The fringe benefits included in the rate(s) are listed below.

TREATMENT OF PAID ABSENCES

Vacation, holiday, sick leave pay and other paid absences are included in salaries and wages and are claimed on grants, contracts and other agreements as part of the normal cost for salaries and wages. Separate claims are not made for the cost of these paid absences.

Fringe benefits include FICA/Medicare, health insurance, life insurance, dental insurance, short/long term disability insurance, retirement, workers' compensation and unemployment and other.

Equipment means an article of n onexpendable, tangible personal property having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit.

ORGANIZATION: EcoHealth Alliance

AGREEMENT DATE: 4/3/2013

SECTION III: GENERAL

A. LINITATIONS:

The rates in this Agreement are subject to any statutory or administrative limitations and apply to a given grant, contract or other agreement only to the extent that funds are available. Acceptance of the rates is subject to the following conditions: (1) Only costs incurred by the organization were included in its indirect cost pool as finally accepted; such costs are legal obligations of the organization and are allowable under the governing cost principles; (2) The same costs that have been treated as indirect custs are not cloimed as direct costs; (3) Similar types of costs have been accorded consistent accounting treatment, and (4) The information provided by the organization which was used to establish the rates is not later found to be materially incomplete or inaccurate by the Federal Government. In such situations the rate(s) would be subject to renegotiation at the discretion of the Federal Government.

B. ACCOUNTING CHANGES:

This Agreement is based on the accounting system purported by the organization to be in effect during the Agreement period. Changes to the method of accounting for costs which affect the smount of reimbursement resulting from the use of this Agreement require prior approval of the authorized representative of the cognizant agency. Such changes include, but are not limited to, changes in the charging of a particular type of cost from indirect to direct. Failure to obtain approval may result in cost disallowances.

C. FIXED RATES:

If a fixed rate is in this Agreement, it is based on an estimate of the costs for the period covered by the rate. When the actual costs for this period are determined, an adjustment will be made to a rate of a future year(a) to compensate for the difference between the costs used to establish the fixed rate and actual costs.

D. USE BY OTHER PEDERAL AGENCIES:

The rates in this Agreement were approved in accordance with the authority in Office of Management and Budget Circular A-122, and should be applied to grants, contracts and other agreements covered by this Circular, subject to any limitations in A above. The organization may provide copies of the Agreement to other Federal Agencies to give them early notification of the Agreement.

E, OTHER:

If any Federal contract, grant or other agreement is reimbureing indirect costs by a means other than the approved rate(s) in this Agreement, the organization should (1) credit such costs to the affected programs, end (2) apply the approved rate(s) to the appropriate base to identify the proper amount of indirect costs allocable to these programs.

BY THE INSTITUTION:	ON BEHALF OF THE PROBRAL GOVERNMENT:	
EcoHealth Alliance	DEPARTMENT OF HEALTH AND HUMAN SERVI	CES
(institution) (b) (6)	(AGENCY) (b) (6)	
(SIGNATURE)	(SIGNATURE) U	_
HARVEY KASDAN	Darryl W. Mayes	
(NAME)	(NAME)	
Chif Finand Offen	Megional Director, Division of Cost	Allocation
(TITLE)	(TITE)	
7/8/2013	4/3/2013	
(DATE)	(GATR) 1227	
	HHS REPRESENTATIVE: Regina Dis	Sennaro
	Telephone (212) 264-	2069

From: Aleksei Chmura

To: Pone, Laura (NIH/NIAID) [E]

Cc: Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]

Subject: Re: Grant Number: 1R01AI110964 - 01 PI Name: DASZAK, PETER

Date: Wednesday, March 05, 2014 3:53:10 PM
Attachments: JIT Other Support 1R01Al110964 Updated.pdf

ATT00001.htm

Dear Laura,

Apologies for the discrepancies between the proposal budget and the JIT Other Support file. These were the result of copy-pasting errors. The budgeted amounts are correct and we have no changes to them. Please find a corrected and updated Other Support file attached. The efforts for the following senior personnel are as follows:

```
(b) (4), (b) (6)
Dr. ZL Shi -
                                       (b) (4), (b) (6)
Dr. SY Zhang -
Dr. JH Epstein -
                                        (b) (4), (b) (6)
                                      (b) (4), (b) (6)
Dr. KJ Olival -
Dr. PR Hosseini -
                                          (b) (4), (b) (6)
Dr. XY Ge -
                                  (b) (4), (b) (6)
                                  (b) (4), (b) (6)
Dr. GJ Zhu -
                                  (b) (4), (b) (6)
Dr. CW Ke -
                                       (b) (4), (b) (6)
Dr. YZ Zhang -
```

Please let me know, if you have any further questions most,

Sincerely,

Aleksei Chmura

Program Coordinator and 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)

www.ecohealthalliance.org

Visit our blog: www.ecohealthalliance.org/blog

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.

Principal Investigator: Daszak, Peter

CURRENT OTHER SUPPORT

DASZAK, PETER

ACTIVE

DEB-0955897 (Daszak) 07/01/10 - 06/30/15 (b) (4). (b) (6)

NSF \$497,121

EcoHealthNet: Ecology, Environmental Science and Health Research Network

Funding for student exchange and workshops to fuse veterinary science, ecology and human medical sciences.

Role: Pl

5R01GM100471 (Perrings) 09/15/11 – 06/30/15 (6) (4), (6) (6)

NIGMS \$289,953

Modeling Anthropogenic Effects in the Spread of Infectious Disease

A collaborative international proposal using interdisciplinary approaches to address the links between globalization and emerging infectious disease risks.

Role: Co-Investigator

1R56TW009502 (Daszak) 09/17/12 - 04/30/14 (b) (4). (b) (6)

NIH Fogarty International Center \$300,000

Comparative Spillover Dynamics of Avian Influenza in Endemic Countries

Our research will advance the understanding of the long-term dynamics of H5N1 by relaxing the assumption of homogeneous mixing implicit in classical epidemiological models through fine-scale measurements of realistic contact networks in Bangladesh, China, and Egypt.

Role: PI

Emerging Pandemic Threats (Morse) 10/01/09 – 09/30/14 (b) (4). (b) (6)

USAID \$18,000,000

PREDICT

Modeling hotspots for disease emergence and conducting surveillance in wildlife in hotspots for new emerging zoonoses.

Role: PI on Subcontract from UC Davis

2R01TW005869 09/01/08 - 06/30/14 (b) (4). (b) (6)

NIH Fogarty International Center \$2,498,829

The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh

To conduct mathematical modeling and fieldwork to understand the dynamics of Nipah virus in Bangladesh

Role: PI

PENDING

1R01Al110964 (Daszak) 07/01/2014 - 06/30/2019 (b) (4). (b) (6)

NIAID \$3,362,339

Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

Role: PI

SHI, ZHENG LI

ACTIVE

2011CB504700 (Shi) 01/01/2011-12/31/2015 (b) (4), (b) (6)

National Basic Research Program, China \$150,000

Mechanism of interspecies transmission of zoonotic viruses Study of the means of transmission of zoonotic viruses.

Role: PI

81290341 (Shi) 01/01/2013-12/31/2017 (b) (4). (b) (6)

NSF China \$100,000

Genetic diversity, identification, and pathogenesis of bat viruses

Molecular characterization of viruses of bats in China.

Role: Pl

PENDING

1R01Al110964 (Daszak) 07/01/2014 - 06/30/2019 (b) (4). (b) (6)

NIAID \$3,362,339

Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

Role: Co-Investigator

ZHANG, SHU-YI

ACTIVE

Emerging Pandemic Threats (Morse) 10/01/09 - 09/30/14 (b) (d) (b) (d)

USAID \$18,000,000

PREDICT

Modeling hotspots for disease emergence and conducting surveillance in wildlife in hotspots for new emerging zoonoses.

Role: PI on Subcontract from EcoHealth Alliance

PENDING

1R01Al110964 (Daszak) 07/01/2014 - 06/30/2019 (b) (4), (b) (6)

NIAID \$3,362,339

Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

Role: Co-Investigator

KE, CHANG WEN

ACTIVE

2012ZX10004213-004 (Ke) 07/01/2012 - 06/30/2015

(b) (4), (b) (6)

Ministry of Science and Technology, PRC

\$372,451

National Major Projects of Major Infectious Disease Control and Prevention

Investigation of Disease Outbreaks in Guangdong Province

Role: PI

PENDING

1R01Al110964 (Daszak)

07/01/2014 - 06/30/2019

(b) (4). (b) (6)

NIAID

\$3,362,339

Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

Role: Co-Investigator

EPSTEIN, JONATHAN H.

ACTIVE

DEB-0955897 (Daszak)

07/01/10 - 06/30/15

(b) (4), (b) (6)

NSF

\$497,121

EcoHealthNet: Ecology, Environmental Science and Health Research Network

Funding for student exchange and workshops to fuse veterinary science, ecology and human medical

sciences.

Role: Senior Scientist

Emerging Pandemic Threats (Morse)

10/01/09 - 09/30/14

(b) (4), (b) (6)

USAID

\$18,000,000

PREDICT

Modeling hotspots for disease emergence and conducting surveillance in wildlife in hotspots for new emerging zoonoses.

Role: Senior Scientist

2R01TW005869

09/01/08 - 06/30/14

(b) (4), (b) (6)

NIH Fogarty International Center

\$2,498,829

The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh

To conduct mathematical modeling and fieldwork to understand the dynamics of Nipah virus in Bangladesh

Role: Senior Scientist

4500036150 (Epstein)

07/01/14-06/30/19

(b) (4), (b) (6)

NIH

\$275,000

Risk of Zoonotic Transmission of Herpes B Virus from Wild Macaques in Bangladesh

Investigate causes of encephalitis for non-Nipah non-Japanese encephalitis in Bangladesh and determine the shedding prevalence of B Virus in macaques.

Role: PI

F12AP01117 (Epstein)

09/13/12 - 09/13/14

(b) (4), (b) (6)

USFW

\$35,000

Development of a Great Ape Health Unit in Sabah, Malaysia.

Develop a Great Ape Health unit to evaluate the health of rescued and translocated gibbons and

orangutans in Sabah, Malaysia.

Role: PI

PENDING

1R01Al110964 (Daszak)

07/01/2014 - 06/30/2019

(b) (4), (b) (6)

NIAID

\$3,362,339

Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

Role: Co-Investigator

OLIVAL, KEVIN J.

ACTIVE

Award GVSU 04152012 (Russell)

06/18/12 - 06/17/13

(b) (4), (b) (6)

USFWS/USGS

\$12,000

Genetic Approaches to Defining Taxonomic and conservation Units for the Hawaiian Hoary Bat Using molecular tools to date the origins and divergence of the endangered Hawaiian Hoary bat.

Role: Co-PI

4500036150 (Epstein)

07/01/12-06/30/14

(b) (4), (b) (6)

USFWS

\$197.950

Characterization of Climatic Parameters within Bat Hibernacula, their Influence on Environmental Loads of *Geomyces destructans*, and Implications for the Migration of White-Nose Syndrome in Bats.

Role: Co-PI

PENDING

1R01Al110964 (Daszak)

07/01/2014 - 06/30/2019

(b) (4), (b) (6)

NIAID

\$3,362,339

Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

Role: Co-Investigator

1 R21 Al113205-01 (Olival)

04/01/2014 - 03/31/2016

(b) (4), (b) (6)

NIAID

\$396,453

Understanding the Origin and Emergence of MERS-CoV

To investigate the ecology and animal origin of Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in the Kingdom of Saudi Arabia (KSA). A combination of field sampling and laboratory work to characterize KSA bat CoV diversity, seasonality of viral shedding, and identify ecological risk factors for transmission among bats, humans and livestock

HOSSEINI, PARVIEZ R.

ACTIVE

EF-1015791 (Mitchell) 07/01/10 - 6/30/15 (b) (4), (b) (6)

NSF \$745,295

The community ecology of viral pathogens

Causes and consequences of coinfection in hosts and vectors. To conduct mathematical modeling and fieldwork to understand implications in a wild grass, aphid-vectored disease system.

Role: Co-PI

PREDICT

Modeling hotspots for disease emergence and conducting surveillance in wildlife in hotspots for new emerging zoonoses.

Role: Hotspots Modeler

1R56TW009502 (Daszak) 09/17/12 – 04/30/14 (b) (4), (b) (6)

NIH Fogarty International Center \$300,000

Comparative Spillover Dynamics of Avian Influenza in Endemic Countries

Our research will advance the understanding of the long-term dynamics of H5N1 by relaxing the assumption of homogeneous mixing implicit in classical epidemiological models through fine-scale measurements of realistic contact networks in Bangladesh, China, and Egypt.

Role: Senior Scientist

PENDING

1R01Al110964 (Daszak) 07/01/2014 - 06/30/2019 (b) (4). (b) (6)

NIAID \$3,362,339

Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

Role: Co-Investigator

GE, XING YI ACTIVE: none

PENDING

1R01Al110964 (Daszak) 07/01/2014 - 06/30/2019

(b) (4), (b) (6)

NIAID
Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

\$3,362,339

Role: Co-Investigator

ZHU, GUANG JIAN

ACTIVE: none

PENDING

1R01Al110964 (Daszak) 07/01/2014 - 06/30/2019

(b) (4), (b) (6)

NIAID Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

\$3,362,339

Role: Co-Investigator

ZHANG, YUN ZHI

ACTIVE:

(no number – Zhang) 01/01/2013- 12/01/2017 (b) (4). (b) (6)

Ministry of Science \$51,277

Yunnan region is an important natural reservoir

Pathogen survey of Yunnan province

Role: PI

81260437 (Zhang) 01/01/2013 -12/01/2016 (b) (4), (b) (6)

NSF, China \$108,561

Rat and mouse viral metagenome

Yunnan murine viral metagenome important viral epidemic status and related research

Role: Pl

(no number – Zhang) 11/01/2012- 11/01/2015 (6) (4). (b) (6)

Talent Research Foundation \$87,000

Health Study Ecology

Yunnan Provincial Health Hall "Ten hundred" health study of the ecology of Yunnan province.

PENDING

1R01Al110964 (Daszak) 07/01/2014 - 06/30/2019 (b) (4). (b) (6)

NIAID \$3,362,339

Understanding the Risk of Bat Coronavirus Emergence

To examine risk of future coronavirus emergence from wildlife using in-depth field investigations across the human-wildlife interface in China, molecular characterization of novel CoVs, and host receptor binding domain genes, mathematical models of transmission and evolution, and in vitro and in vivo laboratory studies of host range.

Role: Co-Investigator

On 03 M	ar 2014, at 16:23:19, Pone, Laura (NIH/N	JIAID) [E]) (6) wrote:
Hi Aleksei	,		
Evaluation 5th is appr	n Only. Created with Aspose.HTML. Copyrigh reciated.	t 2013-2020 Aspose Pty Ltd. <u>Wed</u>	nesday, March
إدا	Please confirm effort for these individuals: O Zheng li Shi�s effort is listed as in the other support.	(b) (4), (b) (6) in the budget and (b) (4), (b) (6)
	 Shu-Yi Zhang�s effort is listed as in the other support. Jonathan Epstein�s effort is listed as in the other support. 	(b) (4), (b) (6) in the budget and (
	 ○ Kevin Olival�s effort is listed as in the other support. 	(b) (4), (b) (6) in the budget and	(b) (4), (b) (6)
	 Parviez Hosseini�s effort is listed as in the other support. Xing-Yi Ge�s effort is listed as 	(b) (4). (b) (6) in the budget and (b) (4). (b) (6) in the budget and	(b) (4), (b) (6) (b) (4), (b) (6)
	in the other support. Guang Jian Zhu�s effort is listed as	(b) (4). (b) (6) in the budget ar	
	in the other support. Chang Wen Ke�s effort is not provide in the other support.	d in the budget but is listed as	(b) (4), (b) (6)
	 Yun Zhi Zhang�s effort is not provided the other support. 	d in the budget but is listed as	(b) (4), (b) (6) in
Thank you			
Grants N	Ianagement Specialist IH/NIAID/GMP		
6700B R Bethesda	ockledge Drive, Room 2240 i, MD 20892-7614 (Fed Ex zip 20817)		
Phone: e-Fax: 3 Email:	(b) (6) 01-493-0597 (b) (6)		

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please consider the environment before printing this e-mail.

To: Pone, Laura (NIH/NIAID) [E]
Cc: Peter Daszak; Jon Epstein

Subject: Re: Grant Number: 1R01A1110964 - 01 PI Name: DASZAK, PETER

Date: Tuesday, April 15, 2014 7:08:24 PM

Importance: High

Dear Laura,

Apologies for the delayed response. Here are the justifications for Local Reimbursement and Driver:

LOCAL REIMBURSEMENT: Once all permits are in place in Years 2 to 4, technicianconsultants trained in phlebotomy and employed by EcoHealth Alliance partner institutions Yunnan Center for Disease Control, Wuhan Institute of Virology, or Guangdong Center for Disease Control will conduct interviews as part of the human wildlife contact survey as well as collect blood samples from volunteers in animal markets. No funds are requested to support these technician-consultants, since their respective institutions will support them. Each technician will be required to complete the Collaborative Institutional Training Initiative via the University of Miami. Shipping and maintenance of cold-chain from provincial areas to Wuhan Institute of Virology are already supported in the funding requests for our subwardees: East China Normal University and Wuhan Institute of Virology. We will provide reimbursement for the technician-consultant's allowable room/transportation/food costs that are expected to average monthly at food (\$24.50), room (\$25), and transportation (\$56): \$105.50 x 3 technicians x 3 months = \$950 per year. In year 5 sampling will have ended, but partial support is requested for only two technician-consultants at \$550.

DRIVER: In year 1, we have requested \$7,200 for driver (\$600 per month x 12 months). The driver will provide daily transportation for our field team from local lodging to field, market, and other locations including transport to/from local laboratories. The rates are estimated to remain constant, but the amount requested for the driver will be pro-rated to 8-months in year 2 (\$4,800), 6-months in year 3 (\$3,600), 4-months in year 4 (\$2,400), and 3-months in year 5 (\$1,800).

If you have further questions, please let me know.

Many thanks!

Aleksei Chmura

Program Coordinator
EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

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

www.ecohealthalliance.org

Visit our blog: www.ecohealthalliance.org/blog

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 15 Apr 2014, at 16:41:52, Pone, Laura (NIH/NIAID) [E] 6) (6).

Hi Aleksei,

I do not see a response to the email below. Please provide it as soon as possible.

Thank you,

Laura Pone Grants Management Specialist DHHS/NIH/NIAID/GMP 6700B Rockledge Drive, Room 2240 Bethesda, MD 20892-7614 (Fed Ex zip 20817)

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

Email: (b) (6)



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

Cc: Peter Daszak; 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]; Alison Andre

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

Date: Monday, April 27, 2020 11:58:11 PM

Importance: High

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

www.econcattraniance.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]

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]" (9) (6)

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

Obtained via FOIA by White Coat Waste Project

2R01Al110964-06

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

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

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)

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]"

കര, "Erbelding, Emily (NIH/NIAID) [E]" രേത **Subject:** RE: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06

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

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

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

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

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

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

Yours sincerely,

Peter Daszak

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

(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] 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 2R01Al110964-06 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) (b) (6) Email: 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) (b) (6) Subject: Re: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06 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.
- 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) (b) (6) (mobile)

1.212.380.4465 (fax)

www.ecohealthalliance.org

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

On Apr 20, 2020, at 2:16 PM, Lauer, Michael (NIH/OD) [E]

Many thanks Naomi – it would be helpful for us to know about all China-based participants in this work since the Type 1 grant started in 2014 – who they were and how much money they received. The sooner you can get us that information, the better.

Best, Mike

From: Naomi Schrag (b) (6)

Date: Sunday, April 19, 2020 at 11:59 AM

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

കര്, കര് കര്, Naomi Schrag കര്

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

Subject: RE: Please read and acknowledge receipt --

Actions needed regarding 2R01Al110964-06

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] Sent: Sunday, April 19, 2020 11:00 AM To: (b) (6); Naomi Schrag (b) (6) Cc: Black, Jodi (NIH/OD) [E] Subject: Please read and acknowledge receipt -- Actions needed regarding 2R01Al110964-06 Importance: High Dear Dr. Olival and Ms. Schrag Please see attached. Many thanks, Mike Michael S Lauer, MD NIH Deputy Director for Extramural Research 1 Center Drive, Building 1, Room 144 Bethesda, MD 2089Z Phone: (b) (6) (b) (6) Email: <EcoHealth Alliance re Al grant 4 19 20.pdf>

<EcoHealth Alliance re Al grant 4 19 20[2].pdf><NoA R01Al110964-06.pdf><NoA R01Al110964-01.pdf>

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

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

Cc: Peter Daszak; Black, Jodi (NIH/OD) [E]; Stemmy, Erik (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]

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

Date: Thursday, April 23, 2020 1:50:57 PM

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

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

On Apr 21, 2020, at 19:28, Lauer, Michael (NIH/OD) [E]

Many thanks Peter for your response.

We note that:

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

We appreciate your working with us.

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

Phone: (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 2R01Al110964-06

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

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

However, I can categorically state that no funds form 2R01Al110964-06 have been sent to Wuhan Institute of Virology, nor has any contract been signed. <u>Furthermore</u>, 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 2R01Al110964-06 Importance: High Thank you Kevin We need to work with a senior responsible business official – usually Pl'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) (b) (6) From: Kevin Olival Date: Monday, April 20, 2020 at 4:14 PM To: "Lauer, Michael (NIH/OD) [E]" (b)(6)(b) (б), "Black, Jodi (NIH/OD) [E]" Cc: Naomi Schrag (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 460 West 34th Street, Suite 1701 New York, NY 10001 (b) (6) (direct) (b) (6) (mobile) 1.212.380.4465 (fax) www.ecohealthalliance.org EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation On Apr 20, 2020, at 2:16 PM, Lauer, Michael (NIH/OD) [E] (b) (6) wrote: Many thanks Naomi – it would be helpful for us to know about all Chinabased participants in this work since the Type 1 grant started in 2014 – who they were and how much money they received. The sooner you can get us that information, the better. Best, Mike From: Naomi Schrag (b) (6) Date: Sunday, April 19, 2020 at 11:59 AM To: "Lauer, Michael (NIH/OD) [E]" (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 2R01Al110964-06 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 (b) (6); Naomi Schrag (b) (6) Cc: Black, Jodi (NIH/OD) [E] (b) (6)

Subject: Please read and acknowledge receipt -- Actions needed regarding

2R01Al110964-06 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) (b) (6)

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

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

Girma, Tseday (NIH/NIAID) [E] To:

Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]

Subject: Re: Grant Number: 2R01AI110964 - 06 PI Name: DASZAK, PETER

Date: Wednesday, July 24, 2019 8:56:24 AM

Dear Tseday,

We just received our NOA in the wee hours of this morning! Many thanks for all your help and support during the application and JIT processes. 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 duedate?
- 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?

Many thanks!

-Aleksei

Aleksei Chmura, PhD

Chief of Staff

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

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

EcoHealth Alliance leads cutting-edge scientific 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.

On Jul 24, 2019, at 08:06, Girma, Tseday (NIH/NIAID) [E] (b) (6) wrote:

Good morning,

It was released last week. You should receive it by today. Thanks,
Tseday
Tseday Girma, MPA
Grants Management Specialist
National Institutes of Allergy and Infectious Diseases
5601 Fishers Lane, Room 4E49
Rockville, MD 20852

Phone: (b) (6)

Email: (b) (6)

NIAID, National Institutes of Health, DHHS

Effective January 1, 2017, NIH closeout documentation policy has changed (see <u>NOT-OD-17-022</u>). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the <u>NIH RPPR Page</u>.

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From: Aleksei Chmura (6) (6)

Sent: Tuesday, July 23, 2019 9:48 PM

To: Girma, Tseday (NIH/NIAID) [E] (b) (6)

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

(b) (6)

Subject: Re: Grant Number: 2R01Al110964 - 06 PI Name: DASZAK, PETER Dear Tseday,

I am just checking-in with you to see if there were any additional outstanding items requested for our proposal - and for which we may have missed an email. Peter and I looked through our spam folders and inboxes and saw no emails. I checked eRA Commons as well and saw no pending notices.

I realize you are dealing with many proposals and grants, so do not mean to pester. Just confirming that all is in order at this stage.

Cheers!

-Aleksei

Aleksei Chmura, PhD Chief of Staff

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

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

EcoHealth Alliance leads cutting-edge scientific 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.

On Jul 17, 2019, at 16:07, Girma, Tse	day (NIH/NIAID) [E]
(b) (6) wrote:	
Thank you.	
Tseday Girma, MPA	
Grants Management Specialist	
National Institutes of Allergy and Infe	ectious Diseases
5601 Fishers Lane, Room 4E49	
Rockville, MD 20852	
Phone: (b) (6)	
Email: (b) (6)	
NIAID, National Institutes of Health,	DHHS
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(see NOT-OD-17-022). NIH is no lor	nger accepting Final Progress Reports
(FPR). Grantees must now report fina	I project outcomes using the new F-
RPPR. For instructions on how to sub	omit the new F-RPPR please see
instructions on the NIH RPPR Page.	
*** The information in this email and any	
may contain sensitive information. It shou	
the originally intended recipient. If you har inform the sender and delete it from your	
The National Institute of Allergy and Infe	
liability for any statements made that are the	
made on behalf of NIAID by one of its re	epresentatives.***
From: Aleksei Chmura	(6) (6)
Sent: Wednesday, July 17, 2019 3:52	PM
To: Girma, Tseday (NIH/NIAID) [E]	(b) (6)
Cc: Peter Daszak	(b) (6); Stemmy, Erik
	0) (6)
Subject: Re: Grant Number: 2R01Al1	and the second s
Tseday,	10504 OUT Name. DASZAK, I ETEK
VC-CAMP	(b) -id to do
Attached is our provisional rate of	- signed today.
Many thanks!	
-Aleksei	
On Jul 17, 2019, at 15:38, Girm	na Tseday (NIH/NIAID) [F]
(b) (6) wrot	e.
Thank you.	
Tseday Girma, MPA	
Grants Management Specialist	II C . D
National Institutes of Allergy at	
5601 Fishers Lane, Room 4E49	
Rockville, MD 20852	
Phone: (b) (6)	

Email: (b) (6)

NIAID, National Institutes of Health, DHHS

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From: Aleksei Chmura (b) (6)

Sent: Wednesday, July 17, 2019 3:11 PM

To: Girma, Tseday (NIH/NIAID) [E] (b) (6)

Cc: Peter Daszak (b) (6); Stemmy,

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

Subject: Re: Grant Number: 2R01Al110964 - 06 Pl Name:

DASZAK, PETER

Dear Tseday,

We are still waiting on our cognisant agency (DoD) to issue a provisional rate or other notice. We will do all possible to get this to you today or before 5pm tomorrow.

Cheers.

-Aleksei

Aleksei Chmura, PhD

Chief of Staff

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

(b) (6) (office) (b) (6) (mobile)

www.ecohealthalliance.org

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On Jul 17, 2019, at 12:07, Girma, Tseday (NIH/NIAID) [E] (b) (6) wrote: Good afternoon,

The F&A rate agreement submitted in the JIT for ECHOHealth Alliance, Inc. dated 11/14/2018 has expired on 06/30/2017. Do you have any documentation that you can send us that shows you could use the expired rate. Pending the establishment of a negotiated facilities and administrative (F&A) rate, we will restrict the amount of F&A funds in excess of 10% salaries and wages exclusive of fringe benefits and may not be expended until the new F&A rate agreement is issued and you receive a revised Notice of award from NIH.

Please send us the requested information ASAP but no later than 07/18/2019.

Thanks,

Tseday

Tseday Girma, MPA

Grants Management Specialist

National Institutes of Allergy and Infectious

Diseases

5601 Fishers Lane, Room 4E49

Rockville, MD 20852

Phone:

(b) (6)

Email:

(b) (6)

NIAID, National Institutes of Health, DHHS
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To: Girma, Tseday (NIH/NIAID) [E]

Cc: Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]

Subject: Re: Grant Number: 2R01AI110964 - 06 PI Name: DASZAK, PETER

Date: Monday, July 8, 2019 3:04:13 PM

Tseday,

I am just checking back with you about our FWA number. Let me know, if I should contact OHRP to get a confirmation or any necessary documentation.

Cheers!

-Aleksei

On Jul 8, 2019, at 07:58, Girma, Tseday (NIH/NIAID) [E] (6) (6) wrote:

Thanks for sending me this. I will look into why its showing as none on my screen.

Thanks,

Tseday

From: Aleksei Chmura (6) (6)

Sent: Monday, July 8, 2019 7:39 AM

To: Girma, Tseday (NIH/NIAID) [E] (b) (6)

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

(b) (6)

Subject: Re: Grant Number: 2R01Al110964 - 06 PI Name: DASZAK, PETER

Tseday,

This is via our current, active R01Al110964 - 05 award IRB with Hummingbird (IRB00009289).

Please see attached screen shot from OHRP. Should I get them to email you to confirm?

Cheers!

-Aleksei

<image001.png>

Aleksei Chmura, PhD

Chief of Staff

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

(b) (6) (office) (b) (6) (mobile)

www.ecohealthalliance.org

EcoHealth Alliance leads cutting-edge scientific 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.

On Jul 8, 2019, at 07:33, Girma, Tseday	(NIH/NIAID) [E]
(b) (6) wrote:	
Good morning,	
No - I couldn't find any record associate	ed with that FWA in OHRP website
Please follow up with them and let me k	know the status.
Thanks,	
Tseday	
From: Aleksei Chmura	(b) (6)
Sent: Monday, July 8, 2019 7:23 AM	
To: Girma, Tseday (NIH/NIAID) [E]	(b) (6)
Cc: Peter Daszak	(b) (6); Stemmy, Erik
(NIH/NIAID) [E] (b) (6)	
Subject: Re: Grant Number: 2R01AI110	964 - 06 PI Name: DASZAK, PETER
Dear Tseday,	
Can you find our number as follows: FW	A00022431?
Cheers!	
-Aleksei	

On Jul 8, 2019, at 07:21, Girma, Tseday (NIH/NIAID) [E] (b) (6) wrote:

Good morning,

Thank you for submitting the IIA document for North Carolina performance site. While reviewing your application, I noticed that you entered 'None' in eRA commons for Human subjects Federal Wide Assurance (FWA). Per policy, "Institutions that are awarded funds for human subjects research are considered to be engaged in human subjects research and must have an approved FWA even if

another institution performs the human subjects activities through a subaward." For the full list of certification and assurance requirements, go to the <u>Human Subjects Research Requirements SOP</u>. I also check the OHRP website, I wasn't able to look up your FWA info.

Please let us know if you established FWA with OHRP, if not, you will have to do it ASAP. We are not able to issue an award without an FWA.

Thank you,

Tseday Girma

Tseday Girma, MPA

Grants Management Specialist

National Institutes of Allergy and Infectious Diseases

5601 Fishers Lane, Room 4E24

Rockville, MD 20852

Phone: (b) (6)

Email: (b) (6)

NIAID, National Institutes of Health, DHHS

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To: Soto, Tiffani (NIH/OD) [C]

Cc: Peter Daszak; OLAW Division of Assurances (NIH/OD); Girma, Tsedav (NIH/NIAID) [E]; 李泓萤; Stemmy, Erik

(NIH/NIAID) [E]; Alison Andre

Subject: Fwd: 2R01AI110964-06 EcoHealth Alliance, Inc.

Date: Friday, July 5, 2019 4:18:56 PM

Attachments: IIA - Baric, R. 19-1777 - EcoHealth [UNC final].pdf

Dear Tiffani,

Please find attached to this email a PDF of our signed Interinstitutional Assurance letter from the University of North Carolina at Chapel Hill.

Many thanks most,

Sincerely,

-Aleksei

Aleksei Chmura, PhD

Chief of Staff

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

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

EcoHealth Alliance leads cutting-edge scientific 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.

On Jun 12, 2019, at 10:28, Soto, Tiffani (NIH/OD) [C] (b) (6) wrote:

Good Morning Dr. Chmura,

Please find enclosed a copy of the request letter for the required Interinstitutional *Assurance*. If your company has any type of written agreement with the institution where the animal work will take place this does not replace our requirement for the IA. The IA is a document that is required by OLAW.

<u>No other type of documentation</u>, other than the requested interinstitutional assurance is acceptable. For example, a copy of a Protocol is not a replacement for our required interinstitutional assurance, neither is a type of agreement that might already be in place between the grantee and the animal sites.

ScInterinstitutional 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, Suite 1701, New York, NY 10001, USA

Project Title: (from grant application/contract proposal)

Understanding the Risk of Bat Coronavirus Emergence

Grant/Contract Number: 2-R01-AI110946-06

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

- 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: University of North Carolina at Chapel Hill

Office of Sponsored Research 104 Airport Dr. CB# 1350 Chapel Hill, NC 27599

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.

Name of Awardee Institution:	EcoHealth Alliance	
Authorized Official: Dr. Aleks	ei Chmura	0.75
Signature:	(b) (6)	Date: 21 June 2019
Title: Authorized Organization	nal Representative	
Address: (street address, cit) 460 West 34th Street, Suite 1		.0001, USA
Phone: (b) (6)	1	Fax: +1.212.380.4465
E-mail:	(6) (6)	
B. Endorsement of Assur	ed Institution	
Name of Assured Institution:	University of North	Carolina at Chapel Hill
Institutional Official: Terry Ma	agnuson, PhD	010
Signature:	(b) (6)	Date: 7/5/2019
Title: Vice Chancellor for Res	earch	1
Address: (street address, city 312 South Bldg- Office of the Chapel Hill NC, 27599-4000	v, state, zip code) VCR CB #4000	
Phone: (b) (6)		Fax: 919-962-1476
E-mail: (b) (6	0	
IACUC Chairperson: Roland	sch, PhD	
Signature:	(ъ) (б	Date: 7/05/19
Title: IACUC Chair		
Address: (street address, cit) UNC - Department of Microbi Chapel Hill, NC 27599-7290		gy CB #7290
		Fax: 919-966-8429
Phone: (b) (6)		M-71

III. PHS Approval (to be completed by OLAW)

Signature of OLAW Official:	Date:
Office of Laboratory Ani National Institutes of He 6705 Rockledge Drive RKL1, Suite 360, MSC 7 Bethesda, MD 20892-79 Phone: (301) 496-7163	ealth 1982 1982 (express mail zip code 20817)
Grant/Contract #:	Animal Welfare Assurance #:

The IA is available on our web site see the link below.

http://grants.nih.gov/grants/olaw/sampledoc/interinstitutional_assurance.htm
The following signatures are required by Wuhan University in Wuhan China: Page 2 of the interinstitutional Assurance, Section II.B., needs to be signed by the Institutional Official (or an individual with signature authority as reported in the Animal Welfare Assurance), and by the IACUC Chairperson, (or an IACUC designee verifying IACUC review and approval of this proposal). The IACUC approval date will also needs to be furnished by the IACUC Chairperson. he following signatures are required by The University of North Carolina at Chapel Hill: Page 2 of the interinstitutional Assurance, Section II.B., needs to be signed by the Institutional Official, Terry Magnuson, PhD (or an individual with signature authority as reported in the Animal Welfare Assurance), and by the IACUC Chairperson, Roland Tisch, PhD (or an IACUC designee verifying IACUC review and approval of this proposal). The IACUC approval date will also needs to be furnished by the IACUC Chairperson.

Upon completion, the interinstitutional assurance should be sent to the OLAW Division of Assurances mailbox. olawdoa@mail.nih.gov

Kind Regards.

Tiffani T. Solo

Program Assistant

Office of Laboratory Animal Welfare (OLAW)

National Institutes of Health

6700 B Rockledge Drive

Suite 2500, MSC 6910 Bethesda, Maryland 20892

Phone: (b) (6) (Main)

Phone: (b) (6) (Direct)

Email: (b) (6)

Division of Assurances E-Fax (301) 451-5672

Email: OLAWdoa@mail.nih.gov

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. Quote:

Tell me and I forget, Teach me and I remember, Involve me and I learn. Benjamin Franklin

<interinstitutional_assurance.doc><EcoHealth 1 IIA Request letter.doc><EcoHealth 2 IIA
Request letter.doc>

To: Stemmy, Erik (NIH/NIAID) [E]; Soto, Tiffani (NIH/OD) [C]

Cc: Baric, Ralph; Amy Sims; Graham, Rachel; Peter Daszak; Girma, Tseday (NIH/NIAID) [E]; Alison Andre

Subject: Re: 2R01AI110964-06 (PI: Daszak. Understanding the Risk of Bat Coronavirus Emergence) EcoHealth Alliance,

Inc.

Date: Thursday, June 20, 2019 3:46:55 PM

Attachments: Baric pending approval pdf

Dear Erik and Tiffani,

We will have our Interinstitutional Assurance from Wuhan University in China next week and send that to you immediately upon receipt.

Attached, please find a letter from the University of North Carolina-Chapel Hill OACU Director. The letter indicates that our protocol as submitted by Co-Investigator (Dr. Ralph Baric) from our proposal Understanding the Risk of Bat Coronavirus Emergence (2R01AII 10964-06) has been received and will be reviewed.

Many thanks most,

Sincerely,

-Aleksei

Aleksei Chmura, PhD

Chief of Staff

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

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

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On Jun 12, 2019, at 10:28, Soto, Tiffani (NIH/OD) [C] 60 60 wrote: Good Morning Dr. Chmura,

Please find enclosed a copy of the request letter for the required Interinstitutional



UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF ANIMAL CARE AND USE

SUITE 1140 BIOINFORMATICS BUILDING T 919-966-5569 CAMPUS BOX 7193 CHAPEL HILL, NC 27599-7115

F 919-966-8429 hence/med me edu

To Erik Stemmy, Ph.D., National Institutes of Health,

The Office of Animal Care and Use (OACU) at the University of North Carolina at Chapel Hill has received an animal protocol submission for Principle Investigator Dr. Ralph Baric titled "Understanding the Risk of Bat Coronavirus Emergence". The IACUC committee will meet on July 12th and this animal protocol will be reviewed at that meeting. Once the animal protocol is approved, the approval page be available.

(b) (6) Tracy Heenan, DVM, CPIA Professor Director, Office of Animal Care & Use UNC-Chapel Hill, Campus Box #7193 Chapel Hill, NC 27599

(b) (6)

(b) (6)

6/20/19

Assurance.

If your company has any type of written agreement with the institution where the animal work will take place this does not replace our requirement for the IA. The IA is a document that is required by OLAW.

No other type of documentation, other than the requested interinstitutional assurance is acceptable. For example, a copy of a Protocol is not a replacement for our required interinstitutional assurance, neither is a type of agreement that might already be in place between the grantee and the animal sites.

The IA is available on our web site see the link below.

http://grants.nih.gov/grants/olaw/sampledoc/interinstitutional_assurance.htm
The following signatures are required by Wuhan University in Wuhan China:
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he following signatures are required by **The University of North Carolina at Chapel Hill:** Page 2 of the interinstitutional Assurance, Section II.B., needs to be signed by the **Institutional Official**, **Terry Magnuson**, **PhD** (or an individual with signature authority as reported in the Animal Welfare Assurance), and by the **IACUC Chairperson**, **Roland Tisch**, **PhD** (or an IACUC designee verifying IACUC review and approval of this proposal). The IACUC approval date will also needs to be furnished by the IACUC Chairperson.

Upon completion, the interinstitutional assurance should be sent to the OLAW Division of Assurances mailbox. <u>olawdoa@mail.nih.gov</u>

Kind Regards.

Tiffani T. Solo Program Assistant

Office of Laboratory Animal Welfare (OLAW)

National Institutes of Health

6700 B Rockledge Drive

Suite 2500, MSC 6910

Bethesda, Maryland 20892

Phone: (b) (6) (Main)
Phone: (b) (6) (Direct)
Email: (b) (6)

Division of Assurances E-Fax (301) 451-5672

Email: OLAWdoa@mail.nih.gov

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Benjamin Franklin

<interinstitutional_assurance.doc><EcoHealth 1 IIA Request letter.doc><EcoHealth 2 IIA Request letter.doc>

To: Stemmy, Erik (NIH/NIAID) [E]; Girma, Tseday (NIH/NIAID) [E]

Cc: Peter Daszak

Subject: Re: Grant Number: 2R01AI110964 - 06 PI Name: DASZAK, PETER

Date: Thursday, June 20, 2019 12:55:47 PM

Dear Tseday,

We are doing all possible to push UNC IACUC for expedited review.

Would it be acceptable if UNC IACUC provides a letter signed by their IACUC Chair stating that we have a protocol pending review with the date of review and the likely timeline of approval?

Cheers,

-Aleksei

Aleksei Chmura, PhD

Chief of Staff

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

(b) (6) (direct) (b) (6) (mobile)

Aleksei MacDurian (Skype)

www.ecohealthalliance.org

Visit our blog: www.ecohealthalliance.org/blog

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On Jun 17, 2019, at 16:56, Aleksei Chmura

(b) (6) wrote:

Dear Erik and Tseday,

Our University of North Carolina IACUC committee will not reconvene until 12th of July, which means we should be able to have our interinstitutional assurance forms signed and completed no later than end-of-July.

On Jun 13, 2019, at 15:11, Aleksei Chmura (6) (6) wrote:

Thanks, Erik! Exactly right. Peter actually is travelling this week!

I responded to the OLAW person this morning with CC to Tseday. Our University of North Carolina POC is out until Monday and Wuhan is on this already. We should have these submitted by early next week. I will let you both know as well.

Cheers.

-Aleksei

Aleksei Chmura, PhD

Chief of Staff

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

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On Jun 13, 2019, at 15:07, Stemmy, Erik (NIH/NIAID) (b) (6) wrote: [E] Hello Aleksei, Forwarding you this message as well to loop you in, in case Peter is traveling. Best, Erik Erik J. Stemmy, Ph.D. Program Officer Respiratory Diseases Branch Division of Microbiology and Infectious Diseases NIAID/NIH/HHS 5601 Fishers Lane, Room 8E18 Bethesda, MD 20892-9825 Phone: (b) (6) (b) (6) Email: Getting ready to publish? Share the good news with your program officer asap! NIAID may be able to help publicize

your article. And, remember to list your NIAID grant or contract number in the publication.

NOTE: This material is intended for the individual or entity to which it is addressed. It may contain privileged, confidential information that is protected from disclosure under applicable laws. If you are not the addressee, or a person authorized to deliver the document to the addressee, please note that you are strictly prohibited from reviewing, copying, disclosing, disseminating or distributing this material or any other action based on the contents of this material. If you have received this communication in error, please permanently delete this from your system immediately. Thank you.

From: Girma, Tseday (NIH/NIAID) [E]

(b) (6)

Sent: Tuesday, June 11, 2019 4:50 PM

To: (b) (6)

(b) (6)

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

Subject: Grant Number: 2R01Al110964 - 06 Pl Name:

DASZAK, PETER Good afternoon,

This is to give you a heads up that I submitted a request to OLAW for the negotiation of an interinstitutional assurance (IIA) for the activities described your VAS. You will receive a request from OLAW to submit you IIA documentation — please respond ASAP as we need this to process this award. Thanks,

Tseday

m 1 0

Tseday Girma, MPA

Grants Management Specialist

National Institutes of Allergy and Infectious Diseases

5601 Fishers Lane, Room 4E49

Rockville, MD 20852

Phone: (b) (6)

Email: (b) (6)

NIAID, National Institutes of Health, DHHS

Effective January 1, 2017, NIH closeout documentation policy has changed (see NOT-OD-17-022). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the NIH RPPR Page.

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be used by anyone who is not the originally intended recipient. If you have received this email in error, please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of NIAID by one of its representatives.***

To: Stemmy, Erik (NIH/NIAID) [E]; Girma, Tseday (NIH/NIAID) [E]

Cc: Peter Daszak

Subject: Re: Grant Number: 2R01AI110964 - 06 PI Name: DASZAK, PETER

Date: Wednesday, June 19, 2019 3:13:22 PM
Attachments: EHAL FY19 Prov Rates Agrmt.pdf

EHA- rates FY2020.pdf

Dear Tseday and Erik,

Please find our latest provisional rate agreement for FY'19 and our FY'20 rate proposal as well. We are expecting DOD/USN to come back to us with our new next month.

Many thanks!

-Aleksei

Aleksei Chmura, PhD

Chief of Staff

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From: "Girma, Tseday (NIH/NIAID) [E]" (b) (6)

Date: June 18, 2019 at 4:25:14 PM EDT

To: (b) (6)

(b) (6)

(b) (6)

Good afternoon,

Thank you for your recent JIT submissions. The most recent F&A Rate Agreement that was provided is dated 11/14/2018 and the F&A rate of (b) (4) expired on 06/30/17.

Did you have any documentation that you can send us that shows you could use the expired rate. Otherwise, we will have to put a restriction on the award until we receive a new F&A Rate Agreement.

Please send this information ASAP but no later than 06/20/2019

Subject: Grant Number: 2R01Al110964 - 06 PI Name: DASZAK, PETER

Please let me know

Thanks,

Tseday

DEPARTMENT OF THE NAVY

OFFICE OF NAVAL RESEARCH 875 NORTH RANDOLPH STREET SUITE 1425 ARLINGTON, VA 22203-1995

IN REPLY REFER TO:

Agreement Date: July 9, 2018

NEGOTIATION AGREEMENT

INSTITUTION:

ECOHEALTH ALLIANCE, INC. 460 WEST 34TH ST. 17TH FLR NEW YORK, NY 10001-2320

The Indirect Cost and Fringe Benefits rates contained herein are for use on grants, contracts and/or other agreements issued or awarded to EcoHealth Alliance, Inc. by all Federal Agencies of the United States of America, in accordance with the provisions and cost principles mandated by 2 CFR Part 200. These rates shall be used for forward pricing and billing purposes for EcoHealth Alliance, Inc. for Fiscal Year 2019.

Section I: RATES - TYPE: PROVISIONAL (PROV)

Indirect Rates:

<u>TYPE</u> <u>FROM</u> <u>TO</u> <u>RATE</u> <u>BASE</u> <u>APPLICABLE TO</u> <u>LOCATION</u> Prov. 07/01/18 06/30/19 (b) (4) (a) All All

Fringe Benefits Rates:

<u>TYPE</u> <u>FROM</u> <u>TO</u> <u>RATE</u> <u>BASE</u> <u>APPLICABLE TO</u> <u>LOCATION</u> Prov. 07/01/18 06/30/19 (b) (b) All All

DISTRIBUTION BASES

- (a) Total direct costs excluding capital expenditures (buildings, individual items of equipment; alterations and renovations), the portion of each subaward in excess of \$25,000, participant support costs, and flow-through funds.
- (b) Salaries and Wages.

SECTION II - GENERAL TERMS AND CONDITIONS

A. LIMITATIONS: Use of the rates set forth under Section I is subject to any statutory or administrative limitations and is applicable to a given grant, contract or other agreement only to the extent that funds are available and consistent with any and all limitations of cost clauses or provisions, if any, contained therein. Acceptance of any or all of the rates agreed to herein is predicated upon all the following conditions: (1) that no costs other than those incurred by the recipient\contractor were included in its indirect cost pool as finally accepted and that all such costs are legal obligations of the recipient\contractor and allowable under governing cost principles; (2) that the same costs that have been treated as indirect costs are not claimed as direct costs; (3) that similar types of costs, in like circumstances, have been accorded consistent accounting treatment;

- (4) that the information provided by the recipient\contractor, which was used as the basis for the acceptance of the rates agreed to herein and expressly relied upon by the Government in negotiating the said rates, is not subsequently found to be materially incomplete or inaccurate.
- B. ACCOUNTING CHANGES: The rates contained in Section I of this agreement are based on the accounting system in effect at the time this agreement was negotiated. Changes to the method(s) of accounting for costs, which affects the amount of reimbursement resulting from the use of these rates, require the written approval of the authorized representative of the cognizant negotiating agency for the Government prior to implementation of any such changes. Such changes include but are not limited to changes in the charging of a particular type of cost from indirect to direct. Failure to obtain such approval may result in subsequent cost disallowances.
- C. PROVISIONAL RATES: The provisional rates contained in this agreement are subject to unilateral amendment by the Government or bilateral amendment by the contracting parties at any time.
- D. USE BY OTHER FEDERAL AGENCIES: The rates set forth in Section I hereof were negotiated in accordance with and under the authority set forth in 2 CFR Part 200. Accordingly, such rates shall be applied to the extent provided in such regulations to grants, contracts, and/or other agreements to which 2 CFR Part 200 is applicable, subject to any limitations in part A of this section. Copies of this document may be provided by either party to other Federal agencies to provide such agencies with documentary notice of this agreement and its terms and conditions.
- E. SPECIAL REMARKS: The Government's agreement with the rates set forth in Section I is not an acceptance of the EcoHealth Alliance, Inc.'s accounting practices or methodologies. Any reliance by the Government on cost data or methodologies submitted by EcoHealth Alliance, Inc. is on a non-precedence-setting basis and does not imply Government acceptance.

FOR ECOHEALTH ALLIANCE, INC.: FOR THE U.S. GOVERNMENT: KERSEY.SHEA.DE Digitally signed by KERSEY.SHEA.DELORES.1049331149 LORES.104933111 DN: c-US, 0=US, Government, ou=Dob, ou=PKI, ou=USN, cn=KERSEY.SHEA.DELORES.1049331149 49 Date: 2018.07.24 16:59:32 -04'00 ARMINE ARUSTAMYAN SHEAD, KERSEY Chief Financial Officer Contracting Officer 7-11-2018 July 24, 2018 Date For information concerning this agreement contact: Shea Kersey Phone: (b) (6) Office of Naval Research E-mail: (b) (6)

Accepted:

See indipendent auditor's report

Schedule of Indirect Costs and Calculation of indirect Costs Rate

Schedule A

		Inc	direct Costs
Salaries			836,247
Payroll taxes and emloyees benefits			311,491
Total salaries and related expenses			1,147,738
Professional Fees			191,643
Field Work Costs			502
Meetings and Conferences			66,653
Travel Expense			33,891
Occupancy & Insurance			666,153
Printing			20,855
Postage			2,576
Supplies			34,981
Telephone			30,545
Memberships/Subscriptions			21,576
Miscellaneous Expenses			218
Depreciation			20,681
Information Technology			37,952
Total Other than salaries and related expenses			1,128,226
Total Expenses	A	\$	2,275,964
Distribution Base	В	\$	6,915,741
Indirect Costs Rate	A/B		(b) (4)

Obtained via FOIA by White Coat Waste Project
The accompanying notes are integral part of these notes

ECOHEALTH ALLIANCE, INC AND WILDLIFE PRESERVATION TRUST INTERNATIONAL, INC.

CONSOLIDATED STATEMENT OF FUNCTIONAL EXPENSES

YEAR ENDED JUNE 30, 2018

Schedule B

		Audited TOTAL	Exclusions	Notes	Adj	usted Total Cc I	Indirect	Fund Raising	Program
Salaries	- \$	4,521,242			\$	4,521,242 \$	8 836,247	\$ 46,905	\$ 3,638,090
Payroll taxes and emloyees benefits		1,606,748				1,606,748	311,491	27,521	1,267,736
Total salaries and related expenses	35	6,127,991	2			6,127,991	1,147,738	74,426	4,905,826
Professional Fees		541,460	22,438	1		519,022	191,643	83,504	243,875
Grant to Other Organizations		50,000	50,000	2		10=0			
Subcontracts		6,768,985	6,768,985	2		-			9 - 8
Field Work Costs		455,548	188,734	3		266,814	502	3,246	263,066
Meetings and Conferences		271,374	35,515	4		235,859	66,653	5,132	164,074
Travel Expense		869,470				869,470	33,891	37,661	797,918
Occupancy & Insurance		666,153				666,153	666,153		0
Printing		63,931				63,931	20,855	18,371	24,706
Postage		20,116				20,116	2,576	3,905	13,636
Supplies		37,742				37,742	34,981	1211	2,762
Telephone		70,633				70,633	30,545	923	40,088
Memberships/Subscriptions		50,082				50,082	21,576	6,893	21,613
Miscellaneous Expenses		6,495	4,294	5		2,200	218		1,982
Depreciation		22,335				22,335	20,681	18.0	1,654
Catering and Faculity Rental		99,748	30,686	6		69,062		69,062	· ·
Information Technology		194,270	23,978	3		170,292	37,952	28,398	103,942
Investment Fees		16,765	16,765	7		1.50			-
Total Other than salaries and related expenses		10,205,109	7,141,395			3,063,715	1,128,226	256,173	1,679,316
Total Expenses	-\$	16,333,100	\$ 7,141,395		\$	9,191,705	\$ 2,275,964	\$ 330,599	\$ 6,585,142

Notes - Excluded from indirect and direct costs

- 1. In-Kind and Donated Services
- 2. Sub-Receipent exceeding \$25,000 and Pass-through to Partners over \$25,000
- 3. Equipment over \$5,000
- 4. Particpants Costs
- 5. Bad Debt expense
- 6. Rental expenses
- 7. Investment Fees

See indipendent auditor's report

Obtained via FOIA by White Coat Waste Project

The accompanying notes are integral part of these notes

Summary Fringe Benefits Allocations

Schedule C-2

Federal Agency	Program	Federal Contract Number	Reference	Number	Salaries and Wages		Fringe Benefits
Federal Awards							
National Science Foundation (NSF)	Pass-through from Arizona State University	141374	7015	067	\$ 4,5	.5 S	\$ 1,0:
National Science Foundation (NSF)	EcoHealth Net	DEB-08010000	7022	851	18,3	0	7,15
DoD - Defense Threat Reduction Agency - DTRA	Global Rapid Identification System	HDTRA1-15C-0041	7096	068	181,2	4	63,2
DoD - Defense Threat Reduction Agency - DTRA	Spillover of Henipaviruses and Filoviruses at Agricultural	HDTRA1-14-1-0037	7096	103	34,0	3	13,3
DoD - Defense Threat Reduction Agency - DTRA	Understanding the Risk of Bat-Borne Zoonotic Disease Emergence	HDTRA1-17-1-0064	7096	105	119,6	.8	44,7
DoD - Defense Threat Reduction Agency - DTRA	Rift Valley Fever in South Africa	HDTRA1-14-1-0029	7096	294	182,6	1	56,9
U.S. Department of Health and Human Services (DHHS - NIH)	Bat Coronavirus in China	1R01AI110964-01	7012	049	163,5	5	55,5
U.S. Department of Health and Human Services (DHHS)	Columbia University Center for Excellence	5U19AI109761-05	7023	262	35,9	5	9,17
United States Agency for International Development (USAID)	Land Use Change	AID-486-A-13-00005	7129	302	94,7	9	36,0
United States Agency for International Development (USAID)	Pass Through UC Davis Emerging Pandemic Threat Program	AID-OAA-A-14- 00102	711X	306	2,377,6	4	846,1
U. S Department of Homeland Security (DHS)	Ground Truth	HSHQDC-16-C- 00113	7137	097	129,4	5	47,9
U. S Department of Homeland Security (DHS)	IBIS: Inbound Bio-event Information System	HSHQDC-17-C- B0031	7138	099	84,3	0	23,9
Sub-Total Federal					\$ 3,426,19	9 9	\$ 1,205,2
Non-Federal Awards Non-Federal Awards	Predict and Prevent pandemics		7138	107	67,4	31	17.8
Non-Federal Awards	Predict and Prevent pandemics		7092	850	26,2		10,1
Non-Federal Awards	Predict and Prevent pandemics		7098	850	2,68		1.0
Non-Federal Awards	Predict and Prevent pandemics		7143	104	10,9		4,29
Non-Federal Awards	Predict and Prevent pandemics		7144	106	28,4		8,2
Sub-Total Non-Federal					\$ 135,8	1 9	\$ 41,5
EcoHealth Alliance - General Funds	Global Rapid Identification System		7100	068	32,4	5	4,70
EcoHealth Alliance - General Funds	Land Use Change		7100	302	4,05		2,38
EcoHealth Alliance - General Funds	Predict and Prevent pandemics		7100	306	39,5		13,7
Sub-Total General Funds					\$ 76,0	0 5	\$ 20,9
				0.60	44.0	ve.	27,5
EcoHealth Alliance - General Funds	Fund Raising		7100	860	46.9	1)	4/
	Fund Raising in the Coat Via FOIA by White Coat V	Vaste Project		860 860	46,96 836,24		311,4

Summary Fringe Benefits

Schedule C-1 - Summary

Account Description	Frin	nge Beenfits, USD	ess Direct Charges to Grants	Net Fringe Benefits	
Health Insurance		783,091		783,091	Ī
Health Insurance payments in lieu of benefit		8,917		8,917	7
COBRA Recovery (Exp Red)		(13,528)		(13,528))
Vision Care		2,713		2,713	3
Washington Unemployment Insurance		60		60)
Life Insurance ST/LT Disability/Dental		129,606		129,606	5
NYS Unemployment Ins (NYSUI)		13,538		13,538	3
Alaska Unempolyment Insurance Expense		0		0)
NYS Disability Insurance		1,016		1,016	5
Pension Expense		312,180		312,180)
Tuition Reimbursement expense		18,062	7,656	10,406	5
NYS Commuter Tax		17,500		17,500)
Social Security Employor Expense		306,788		306,788	3
Workers Compensation		26,340		26,340)
FSA Fees		466		466	5
Total Benefits	\$	1,606,749	\$ 7,656	\$ 1,599,093	-

Schedule of Federal Awards

Schedule E

Schedule F Reference	Federal Agency	Direct Federal / Pass- Through	Type of Award	Award Amount	Award Period	Federal Contract Number	Control of the state of the sta	Indirect Costs Limitations
	National Science Foundation (NSF)							
A	EcoHealth Net	Direct Federal	Research Subaward Agreement	\$499,897	9-1-2016 to 8-31-2021	DEB-08010000		No
В	Pass-through from Arizona State University U.S. Department of Defense (DOD) Defense Threat Reduction Agency - DTRA	Pass- Through Direct Federal	Grant	\$162,024	9-1-2014 to 8-31-2017	141374	15-588	No
C	Global Rapid Identification System		DOD Contract (FAR)	\$4,479,678	4-9-2015 to 9-30-2017	HDTRA1-15C-0041		No
D	Rift Valley Fever in South Africa	Direct Federal	Grant	\$4,936,359	5-28-2014 to 5-27-2019	HDTRA1-14-1-0029		No
E	Henipaviruses and Filoviruses at Agricultural and Hunting Human- Animal Interfaces in Malaysia	Direct Federal	Grant	\$2,408,373	5-1-2017 to 4-30-2020	HDTRA1-14-1-0037		No
F	Understanding the Risk of Bat-Borne Zoonotic Disease Emergence in Western Asia	Direct Federal	Grant	\$2,881,913	10-1-2017 to 9-30-2022	HDTRA1-17-1-0064		No
	U.S. Department of Health and Human Services (DHHS) National Institute of Health							
G	Bat Coronavirus in China	Direct Federal	Grant (Research)	\$3,086,735	6-1-2014 to 5-31-2019	1R01AI110964-01		No
н	Pass-through from Columbia University Center for Excellence	Pass- Through	Research Subaward Agreement	\$345,003	3-7-2014 to 2-28-2019	5U19AI109761-05	6(GG008377-39)	No
	United States Agency for International Development (USAID)							
1	Land Use Change		Cooperative Agreement	\$2,499,147	10-15-2013 to 5-30-2018	AID-486-A-13-00005		No
J	Emerging Pandemic Threat Program	Pass- Through	Cooperative Agreement	\$47,651,611	10-1-2014 to 9-30-2019		AID-OAA-A-14- 00102	No
	U. S Department of Homeland Security (DHS)							
K	IBIS: Inbound Bio-event Information System	Direct Federal	Contract	\$413,761	10-30-2017 to 10-28-2018	HSHQDC-17-C- B0031		No
L	Ground Truth	Direct Federal	Fixed Fee Contract	\$271,272	9-30-2016 to 9-29-2018	HSHQDC-16-C-00113		N/A

Schedule of Direct Costs by Awards and Applied Indirect

Schedule F			A	В	C	Ð	E	F	G	н	1	J	K	E				
			NSF - Grant	NSF- Grant	DOD- Cost Reimbursemen t Contract	DOD- Grant	DOD- Grant	DOD- Grant	DHHS-Grant	DHHS-Grant	USAID -Grant	USAID - Grant	DHS- Cost Reimbursement Contract	DHS- Fixed Fee	Total Fedeal			1045 1028850
	Total Audited	Indirect	DEB-08010000	141374	HDTRA1-15C- 0041	HDTRA1-14-1- 0029	HDTRA1-14-1- 0037	HDTRA1-17-1- 0064	1R01AI110964- : 01	5U19AI109761- 05	AID-486-A-13- 00005	AID-OAA-A- 14-00102	HSHQDC-17-C- B0031	HSHQDC-16- C-00113	Grants	Total Non- Federal Grants	EHA Internal Funds	Fund Raising - EHA Internal Funds
Salaries	S 4,521,242 S	836,247	S 18,350	\$ 4,525	\$ 181,234	5 182,691	S 34,083	\$ 119,628	\$ 163,575	S 35,935	S 94,709	5 2,377,644	\$ 129,445	\$ 84,380	\$ 3,426,199	S 135,831	\$ 76,060	\$ 46,905
Payroll taxes and emloyees benefits	1,606,748	311,491	7,156	1,054	63,277	56,971	13,323	44,715	55,511	9,173	36,030	846,137	47,907	23,996	1,205,251	41,582	20,903	27,521
Total salaries and related expenses	6,127,991	1,147,738	25,506	5,579	244,511	239,662	47,406	164,343	219,086	45,108	130,739	3,223,781	177,352	108,376	4,631,450	177,413	96,963	74,426
Professional Fees	541,460	191,643	120		5,000	5,104	44	2,996	37,512		10,669	185,969			262,419	1,279	2,615	83,504
Grant to Other Organizations	50,000	-													15	50,000		
Subcontracts	6,768,985	- 0				555,964	445,916	54,293	258,575		55,435	5,398,803			6,768,985		(0)	
Field Work Costs	455,548	502				13,911	169,935	39,387	214		519	227,497			451,464		336	3,246
Meetings and Conferences	271,374	66,653	24,651		9	9,658		11,780	13	108	306	115,219	45	14	161,803	23,110	14,676	5,132
Travel Expense	869,470	33,891	1,402	2,347		32,829	5,976	41,655	13,592	90	39,629	601,993	612	2,579	742,704	43,488	11,726	37,661
Occupancy & Insurance	666,153	666,153													170300000		0	
Printing	63,931	20,855				3,939	24	127	1,375		232	17,252	198		23,147	389	1,169	18,371
Postage	20,116	2,576	2,260			158	20		63			8,144			10,644		2,992	3,905
Supplies	37,742	34,981							2,762						2,762		(0)	
Telephone	70,633	30,545	70			5,031	220	111	8,548	1,969	7,387	15,736		61	39,134	954	0	1061
Memberships/Subscriptions	50,082	21,576				491		27	1,096		2,464	2,218		4,684	10,979	322	10,312	6,893
Miscellaneous Expenses	6,495	218															6,276	
Depreciation	22,335	20,681													(3		1,654	
Catering and Faculity Rental	99,748														10		12	99,748
Information Technology	194,270	37,952	239		6,824	1,432	333	308	30,016	2,113	5,271	39,726	17,173	185	103,621	321	23,978	28,398
Investment Fees	16,765		Wiles			1000000	E-Carlo	2000	A12246-1	6,000,000	9,0386	425-000-00	F2355-3-5	1000	***************************************	CAY	16,765	3.6
Total Other than salaries and related expenses	10,205,109	1,128,226	28,742	2,347	11,834	628,516	622,469	150,684	353,767	4,280	121,912	6,612,556	18,034	22,523	8,577,663	119,864	92,499	286,859
Total expenses	S 16,333,100 S	2,275,964	\$ 54,249	s 7,926	\$ 256,344	S 868,179	S 669,875	S 315,027	S 572,853	S 49,388	S 252,651	\$ 9,836,337	S 195,385	\$ 130,899	S 13,209,113	S 297,276	S 189,462	S 361,285
Direct Costs Base			S 29,598	\$ 7,926	\$ 256,344	s 312,215	s 54,023	\$ 241,882	S 314,278	s 49,388	\$ 197,216	\$ 4,437,534	\$ 195,385	\$ 130,899	\$ 6,226,689	S 223,299	S 135,155	S 330,599
Indirect Costs Allocation			s 9,741	s 2,608	S 84,363	\$ 102,750	S 17,779	s 79,603	S 103,429	S 16,254	S 64,904	s 1,460,392	s 64,301	5 43,079	s 2,049,203	S 73,488	s 44,479	S 108,800

GOVERNMENT PARTICIPATION IN INDIRECT COST POOLS

Schedule G

Awards	Inc	% of Base	
Federal Grants	\$	1,857,460	82%
Federal Contracts - Cost Reimbursements	\$	148,664	7%
Federal - Fixed Fee	\$	43,079	2%
Sub-Total Federal	\$	2,049,203	90%
Non-Federal Awards	\$	73,488	3%
Internal Funds	\$	153,280	7%
Sub-Total Non-Federal	\$	226,767	10%
Total Indirect Costs	\$	2,275,964	100%

RECONCILIATION OF TOTAL PAYROLL TO IRS 941 FORMS

Schedule H

Direct Salaries a	and Wages	3	3,684,995
Indirect Salaries	s and Wages		836,247
Total Salaries an	nd Wages	\$ 4	1,521,242
941 Reporting			
	July 1 - September 30, 2017	1	1,158,912
	October 1 - December 31, 2017	1	1,078,878
	January 1 - March 31, 2018	j	1,074,560
	April 1 - June 30, 2018	1	1,064,332
Total Salaries re	eported at 941	\$ 4	4,376,682
Adjustments to	Reconcile		
	Stipents Paid by Check		3,500
	Health Insurance payments in lieu of benefits		(661)
	Non-Taxable FSA, Dependent Care and Transit		141,721
Total Adjusmen	ts	\$	144,560
Total Adjusted		\$ 4	1,521,242

Tseday Girma, MPA
Grants Management Specialist
National Institutes of Allergy and Infectious Diseases
5601 Fishers Lane, Room 4E49
Rockville, MD 20852
Phone: (6) (6)

Email: (b) (6)

NIAID, National Institutes of Health, DHHS

Effective January 1, 2017, NIH closeout documentation policy has changed (see NOT-OD-17-022). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For instructions on how to submit the new F-RPPR please see instructions on the NIH RPPR Page.

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From: Peter Daszak

To: Girma, Tseday (NIH/NIAID) [E]

Cc: Stemmy, Erik (NIH/NIAID) [E]; Aleksei Chmura

Subject: RE: Grant Number: 2R01AI110964 - 06 PI Name: DASZAK, PETER

Date: Tuesday, June 11, 2019 2:47:34 PM

Importance: High

Thanks Tseday,

I'm cc'ing Aleksei Chmura in on this email and we will work on the issue rapidly.

Cheers,

Peter

Peter Daszak

President

EcoHealth Alliance

460 West 34th Street - 17th Floor

New York, NY 10001 Tel. (b) (6)

Website: www.ecohealthalliance.org

Twitter: @PeterDaszak

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: Girma, Tseday (NIH/NIAID) [E] (b) (6)

Sent: Tuesday, June 11, 2019 2:24 PM To: Peter Daszak; Peter Daszak Cc: Stemmy, Erik (NIH/NIAID) [E]

Subject: Grant Number: 2R01AI110964 - 06 PI Name: DASZAK, PETER

Good afternoon,

Thank you for submitting the JIT for the above mentioned grant. Regarding the other support submitted for Amy Sims, Peng Zhou and Ben Hu, When I add the efforts of all the grants in the other support (including some of the grants listed under pending that have a to be paid status), the total active support will be higher than (b) (4). (b) (6) including the effort for the above mentioned grant. While an individual may be affiliated with a number of organizations, the combination of appointments can be no higher than (b) (4). (b) (6).

Please indicate how much effort will be taken from which grants. We need specifics that shows the individuals will not go over (6) (6) at the time award. Please send revised other support.

Please send me the information ASAP but no later than Wednesday, 06/12/2019

Thanks,

Tseday

Tseday Girma, MPA

Grants Management Specialist

National Institutes of Allergy and Infectious Diseases

5601 Fishers Lane, Room 4E49

Rockville, MD 20852

Phone:

(b) (6)

Email:

(b) (6)

NIAID, National Institutes of Health, DHHS

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From: Aleksei Chmura

To: Timmerman, Michelle (NIH/CSR) [E]

 Cc:
 Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]; 季泓亩

 Subject:
 Re: NIH Pre-approval needed for 2R01AI110964-06

 Date:
 Wednesday, November 14, 2018 1:55:53 PM

Dear Michelle,

Many thanks to you and Erik!

-Aleksei

Aleksei Chmura, PhD

Chief of Staff

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

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

EcoHealth Alliance leads cutting-edge scientific 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.

On Nov 14, 2018, at 13:53, Timmerman, Michelle (NIH/CSR) [E] (b) (6) wrote:

NIAID has provided permission to submit this application to CSR. The application is now compliant with the \$500K policy. It is being assigned for additional administrative review and peer review

From: Timmerman, Michelle (NIH/CSR) [E] Sent: Friday, November 09, 2018 2:14 PM

To: (b) (6)
Cc: (b) (6)

Subject: NIH Pre-approval needed for 2R01Al110964-06

Dear Dr. Daszak:

Your application to PA-18-484 entitled "Understanding the Risk of Bat Coronavirus Emergence" (2R01AI110964-06) has been received by the Division of Receipt and Referral in the Center for Scientific Review at the NIH. This application is subject to the NIH's policy regarding applications requesting \$500,000 or more in subtotal direct costs for any year. Please see the Application

Guide instructions for the R&R Budget Form (https://go.usa.gov/xPTR9), part 2.3.7.2 of the Grants Policy Statement it references (https://go.usa.gov/xPNCA) and the original announcement NOT-OD-02-004 (https://go.usa.gov/xPTRX). Please also see Section IV.7 "Requests of \$500,000 or more for direct costs in any year" in the Funding Opportunity Announcement.

The policy has the following requirements:

- The PD/PI must contact and obtain agreement from an appropriate Institute/Center to accept assignment of the application, at least six weeks in advance of submission.
- The PD/PI must include a cover letter identifying the program staff member or the Institute/Center that has agreed to accept the assignment of the application.
- The Institute or Center that is willing to accept the application must notify the Center for Scientific Review (CSR), Division of Receipt and Referral (DRR) directly, that the application is acceptable.

Your application does not meet these requirements. Please see Total Direct Costs less Consortium F&A" in your application, which shows the requested budget of \$515,358 in each year. Please also see the warning in your Commons account that states "ESubmission warning:Direct cost requests of \$500k or more a year need approval to accept assignment from Institute/Center staff, except for RFAs or PAs with budgetary limits. Applications without such approval may be delayed or not accepted for review. (020.52.2)".

In order for your application to be considered for the current receipt cycle, we must receive notification of acceptance from an NIH Institute/Center by the end of the day November 16, 2018. If notification has not been received by then, your application will be withdrawn without review.

NIH policies on post-submission materials (NOT-OD-15-039) and late applications (NOT-OD-17-066) prohibit changing or correcting the budget or submitting budget forms on this application at this point.

Please acknowledge the receipt of this email. If you have questions about this policy, do not hesitate to contact me.

Sincerely,

Michelle M. Timmerman, Ph.D.

Associate Director

Division of Receipt and Referral

Center for Scientific Review/NIH/DHHS

(b) (6)

(b) (6)

From: Peter Daszak

To: Stemmy, Erik (NIH/NIAID) [E]; Aleksei Chmura
Cc: Hongying Li; Graham, Adam (NIH/NIAID) [E]
Subject: RE: NIH Pre-approval needed for 2R01AI110964-06
Date: Wednesday, November 14, 2018 1:27:53 PM

Thanks for your help with this Erik, it's really much appreciated!

Cheers,

Peter

Peter Daszak

President

EcoHealth Alliance

460 West 34th Street - 17th Floor

New York, NY 10001

Tel. (b) (6

Website: www.ecohealthalliance.org

Twitter: @PeterDaszak

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

Sent: Wednesday, November 14, 2018 1:21 PM

To: Aleksei Chmura

Cc: Peter Daszak; Hongying Li; Graham, Adam (NIH/NIAID) [E] Subject: Re: NIH Pre-approval needed for 2R01AI110964-06

Thank you! I'll route it to our Fanta folks and let you know if we need anything else.

Erik

Sent from my iPhone

On Nov 14, 2018, at 1:17 PM, Aleksei Chmura

(b) (6) wrote:

Dear Erik.

Please view the attached letter (PDF). Let me know, if it will be correct.

Many thanks!

-Aleksei

Aleksei Chmura, PhD

Chief of Staff

EcoHealth Alliance

460 West 34th Street, Suite 1701

New York, NY 10001

(b) (6) (office) (b) (6) (mobile)

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Obtained via FOIA by White Coat Waste Project

On Nov 14, 2018, at 12:17, Stemmy, Erik (NIH/NIAID) [E]

Hi Aleksei,

In looking in to this further, I will need you to write a letter stating the original budget submission was in error and that if the application receives a fundable score you will reduce the budget to be below the \$500k cap for all 5 years of the award. Please also include the new estimated total DC budgets for all years of the award.

The letter should be signed by the PI and the business official for EcoHealth. I'll need this ASAP. Would you be able to get it to me this afternoon? Erik

Sent from my iPhone

On Nov 13, 2018, at 11:06 AM, Aleksei Chmura
(b) (6) wrote:

Erik.

Just to clarify, Michelle is telling us that she needs your approval for us to upload our under-\$500k-per-year budget.

Cheers!

-Aleksei

On Nov 13, 2018, at 10:17, Aleksei Chmura

(b) (6) wrote:

Hi, Erik,

Thanks for this, Erik! I just left you a voice message and if you would please contact Michelle Timmerman

(b) (6); + (b) (6)), we are at the

ready to upload and/or submit our budget.

Cheers,

-Aleksei

On Nov 13, 2018, at 10:01, Stemmy, Erik (NIH/NIAID) [E]

Thanks Aleksei. Let me know if you need my help with anything else.

Erik

Sent from my iPhone

On Nov 11, 2018, at 7:08 PM, Aleksei Chmura (b) (6) wrote:

Dear Erik.

I have responded to Michelle from DRR and asked about the process to upload or submit our revised budget.

Obtained via FOIA by White Coat Waste Project

ASSIST does not currently permit me to modify our submitted budget, so I will await her instructions. We have modified our renewal proposal budget below the \$500k per year cap and have it at the ready.

Many thanks!

-Aleksei

Aleksei Chmura, PhD

Chief of Staff &

Authorized Organizational Representative

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

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

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Begin forwarded message:

From: "Timmerman, Michelle (NIH/CSR) [E]"

(b) (6)

(b) (6)

Subject: RE: NIH Pre-approval needed for

2R01AI110964-06

Date: November 9, 2018 at 17:17:52 EST

To: Aleksei Chmura (b)(6) Cc: Peter Daszak (b)(6), 李

Dear Aleksei:

泓萤

Unfortunately, this type of change is prohibited by NIH's policies about post submission materials and late submission. I also don't see a reason NIH's late submission policy accepts, like recent review service of the PD/PI. Unfortunately, if an IC does not provide the pre-approval this application will be withdrawn. You may also wish to view the NIH Guide (https://grants.nih.gov/funding/searchguide/index.html) to see if NIAID participates in other R01 funding opportunity announcements with an upcoming due date and May 2019 Advisory Council.

Sincerely, Michelle

From: Aleksei Chmura (b) (6)

Sent: Friday, November 09, 2018 4:19 PM

To: Timmerman, Michelle (NIH/CSR) [E]

(b) (6)

Cc: Peter Daszak (b)(6); 李泓萤

(b) (6)

Subject: Re: NIH Pre-approval needed for 2R01Al110964-06 Dear Michelle,

Thank you for your help earlier. We since spoke with Erik Stemmy our Program Officer at NIAID. Though he said he would have approved it, it would take 6-weeks through NIAID internal approval processes. Unfortunately, we had not realized that we were required to notify them of our intention to increase our renewal budget above the \$500 per year cap in advance of submission. Therefore, NIAID will be unable to make the 18th November deadline.

Is there any way to extend the due-date to accommodate the NIAID 6-week timeline?

the NIAID 6-week timeline?

If not, then we as per Erik's recommendation, we will proceed with updating our budget to \$500k in direct costs

per year. How may we do this in ASSIST or otherwise? Sincerely,

-Aleksei

Aleksei Chmura, PhD

Chief of Staff &

Authorized Organizational Representative

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

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On Nov 9, 2018, at 14:14, Timmerman, Michelle (NIH/CSR) [E]

(b) (6) wrote:

Dear Dr. Daszak:

Your application to PA-18-484 entitled "Understanding the Risk of Bat Coronavirus Emergence" (2R01AI110964-06) has been received by the Division of Receipt and Referral in the Center for Scientific Review

at the NIH. This application is subject to the NIH's policy regarding applications requesting \$500,000 or more in subtotal direct costs for any year. Please see the Application Guide instructions for the R&R Budget Form (https://go.usa.gov/xPTR9), part 2.3.7.2 of the Grants Policy Statement it references (https://go.usa.gov/xPNCA) and the original announcement NOT-OD-02-004 (https://go.usa.gov/xPTRX). Please also see Section IV.7 "Requests of \$500,000 or more for direct costs in any year" in the Funding Opportunity Announcement.

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- The PD/PI must include a cover letter identifying the program staff member or the Institute/Center that has agreed to accept the assignment of the application.
- The Institute or Center that is willing to accept the application must notify the Center for Scientific Review (CSR), Division of Receipt and Referral (DRR) directly, that the application is acceptable.

Your application does not meet these requirements. Please see Total Direct Costs less Consortium F&A" in your application, which shows the requested budget of \$515,358 in each year. Please also see the warning in your Commons account that states "ESubmission warning:Direct cost requests of \$500k or more a year need approval to accept assignment from Institute/Center staff, except for RFAs or PAs with budgetary limits. Applications without such approval may be delayed or not accepted for review. (020.52.2)". In order for your application to be considered for the current receipt cycle, we must receive notification of acceptance from an NIH Institute/Center by the end of the day November 16, 2018. If notification has not been received by then, your application will be withdrawn without review.

NIH policies on post-submission materials (NOT-OD-15-039) and late applications (NOT-OD-17-066) prohibit changing or correcting the budget or submitting budget forms on this application at this point. Please acknowledge the receipt of this email. If you have questions about this policy, do not hesitate to contact me. Sincerely, Michelle M. Timmerman, Ph.D. Associate Director Division of Receipt and Referral Center for Scientific Review/NIH/DHHS

(b) (6)

<NIAID COV 2019 Budget Letter 2R01AI110964-06.pdf>

From: Aleksei Chmura

To: Stemmy, Erik (NIH/NIAID) [E]

Cc: Peter Daszak; Graham, Adam (NIH/NIAID) [E]; 李泓葷; Alison Andre

Subject: Re: NIH Pre-approval needed for ZR01AI110964-06

Date: Friday, November 9, 2018 3:56:58 PM

Ok. Will do.

Cheers!

-Aleksei

On Nov 9, 2018, at 15:55, Stemmy, Erik (NIH/NIAID) [E] (b) (6) wrote:

I think the best thing is to check back in with Michelle Timmerman at R&R. I'm not sure if you need to withdraw and resubmit the application, or if you can edit the budget after submission. On the program side we don't have access to those systems. Erik

(b) (6) **Subject:** Re: NIH Pre-approval needed for 2R01Al110964-06

Dear Erik,

I am sorry that we did not realize that. We would like to proceed with having our application reviewed this round and will modify our Direct Costs to \$500k per year. Should we modify our budget in ASSIST or via another method? Many thanks for the rapid reply!

-Aleksei

On Nov 9, 2018, at 14:58, Stemmy, Erik (NIH/NIAID) [E]

(b) (6) wrote:

Hi Aleksei,

I didn't know that your group was planning to request a budget over \$500k for the renewal. Unfortunately, it won't be possible to get that approved before Nov 18th. There is a lengthy internal review process, and we require at least 6 weeks to process it. I've pasted a link below to NIAID's Big Grant SOP that has some additional information. If you would still like your application to be reviewed this round, the only option would be to reduce the budget to be below the cap, even through the out years

of the award.

Let me know how you'd like to proceed. If you want to pursue the large budget we can work to get it reviewed before the next receipt date.

Big Grant SOP: https://www.niaid.nih.gov/research/big-grants-sop

Erik J. Stemmy, Ph.D.

Program Officer

Respiratory Diseases Branch

Division of Microbiology and Infectious Diseases NIAID/NIH/HHS

5601 Fishers Lane, Room 8E18

Bethesda, MD 20892-9825

Getting ready to publish? Share the good news with your program officer asap! NIAID may be able to help publicize your article. And, remember to list your NIAID grant or contract number in the publication.

NOTE: This material is intended for the individual or entity to which it is addressed. It may contain privileged, confidential information that is protected from disclosure under applicable laws. If you are not the addressee, or a person authorized to deliver the document to the addressee, please note that you are strictly prohibited from reviewing, copying, disclosing, disseminating or distributing this material or any other action based on the contents of this material. If you have received this communication in error, please permanently delete this from your system immediately. Thank you.

From: Aleksei Chmura (b) (6)

Sent: Friday, November 9, 2018 2:50 PM

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

Cc: Peter Daszak (b) (6); Graham, Adam (NIH/NIAID) [E] (b) (6); 李

弘董 (b) (6); Alison Andre

Subject: Re: NIH Pre-approval needed for 2R01Al110964-06 Dear Erik,

We just spoke with Michelle Timmerman from the Department of Receipt and Referral. She said that as Program Officer at NIAID, you will need to fill out an "awaiting receipt of application form" to approve our renewal request in excess of the \$500 per year budget cap. She also mentioned that we should update her as to the progress through NIAID internal approval and that ultimately it will be send over to her at DRR.

Apologies if I have the incorrect terms here. Please let me know, if there is anything further that we may do.

Sincerely,

-Aleksei Chmura, PhD Chief of Staff

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

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

EcoHealth Alliance leads cutting-edge scientific 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.

On Nov 9, 2018, at 14:14, Timmerman, Michelle (NIH/CSR)
[E] 6) (6) wrote:

Dear Dr. Daszak:

Your application to PA-18-484 entitled "Understanding the Risk of Bat Coronavirus Emergence" (2R01AI110964-06) has been received by the Division of Receipt and Referral in the Center for Scientific Review at the NIH. This application is subject to the NIH's policy regarding applications requesting \$500,000 or more in subtotal direct costs for any year. Please see the Application Guide instructions for the R&R Budget Form (https://go.usa.gov/xPTR9), part 2.3.7.2 of the Grants Policy Statement it references (https://go.usa.gov/xPNCA) and the original announcement NOT-OD-02-004 (https://go.usa.gov/xPTRX). Please also see Section IV.7 "Requests of \$500,000 or more for direct costs in any year" in the Funding Opportunity Announcement. The policy has the following requirements:

- The PD/PI must contact and obtain agreement from an appropriate Institute/Center to accept assignment of the application, at least six weeks in advance of submission.
- The PD/PI must include a cover letter identifying the program staff member or the Institute/Center that has agreed to accept the assignment of the application.
- The Institute or Center that is willing to accept the application must notify the Center for Scientific Review (CSR), Division of Receipt and Referral

(DRR) directly, that the application is acceptable. Your application does not meet these requirements. Please see Total Direct Costs less Consortium F&A" in your application, which shows the requested budget of \$515,358 in each year. Please also see the warning in your Commons account that states "ESubmission warning:Direct cost requests of \$500k or more a year need approval to accept assignment from Institute/Center staff, except for RFAs or PAs with budgetary limits. Applications without such approval may be delayed or

In order for your application to be considered for the current receipt cycle, we must receive notification of acceptance from an NIH Institute/Center by the end of the day November 16, 2018. If notification has not been received by then, your application will be withdrawn without review.

NIH policies on post-submission materials (NOT-OD-15-039) and late applications (NOT-OD-17-066) prohibit changing or correcting the budget or submitting budget forms on this application at this point.

Please acknowledge the receipt of this email. If you have questions about this policy, do not hesitate to contact me. Sincerely,

Michelle M. Timmerman, Ph.D. Associate Director Division of Receipt and Referral Center for Scientific Review/NIH/DHHS

not accepted for review. (020.52.2)".

(b) (6)

(b) (6)

From: Peter Daszak

Sent: Thu, 5 Jul 2018 20:24:50 +0000

To: Graham, Adam (NIH/NIAID) [E];Stemmy, Erik (NIH/NIAID) [E];Aleksei Chmura
Cc: Linde, Emily (NIH/NIAID) [E];Glowinski, Irene (NIH/NIAID) [E];Erbelding, Emily

(NIH/NIAID) [E];Ford, Andrew (NIH/NIAID) [E];Khurana, Dhana (NIH/NIAID) [E]

Subject: RE: Grant Number: 5R01Al110964 - 05 PI Name: DASZAK , PETER

Importance: High

Dear Adam,

Thank you very much for this letter.

We will comply with the details and inform you immediately if any of our work results in the conditions laid out in the letter.

Thank you again for your oversight and we look forward to another fruitful year of work under this award!

Cheers,

Peter

Peter Daszak

EcoHealth Alliance 460 West 34th Street – 17th Floor New York, NY 10001

Tel (b) (b) 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: Graham, Adam (NIH/NIAID) [E] (b) (6)

Sent: Thursday, July 5, 2018 3:25 PM

To: Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]; Aleksei Chmura

Cc: Linde, Emily (NIH/NIAID) [E]; Glowinski, Irene (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E];

Ford, Andrew (NIH/NIAID) [E]; Khurana, Dhana (NIH/NIAID) [E]

Subject: Grant Number: 5R01AI110964 - 05 PI Name: DASZAK , PETER

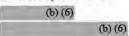
Good afternoon,

Attached is a letter notifying you that the GoF Research Funding Pause has been lifted via the HHS P3CO Framework and that the GoF term-of-award was removed when the next last Type 5 notice-of-award was issued.

Please let us know if you have any questions.

Adam Graham

Grants Management Specialist DHHS, NIH, NIAID, GMP Room 4E40, MSC 9833 5601 Fishers Lane Bethesda, MD 20892



Effective January 1, 2017, NIH closeout policy has changed (see <u>NOT-OD-17-022</u>). NIH is no longer accepting Final Progress Reports (FPR). Grantees must now report final project outcomes using the new F-RPPR. For Instructions on how to submit the new F-RPPR please see instructions on the <u>NIH RPPR Page</u>.



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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

July 05, 2018

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

RE: 5R01Al110964-05

Dear Mr. Chmura:

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

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

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

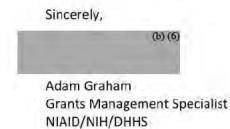
In accordance with the HHS P3CO Framework, research involving an enhanced PPP is subject to additional HHS department-level review. NIAID re-reviewed the grant application and other information provided by you, and made the following assessment:

The experiments to generate MERS-like or SARS-like chimeric coronaviruses, are not subject to the HHS P3CO Framework. The terms and conditions of the award have been revised to indicate that should experiments proposed in this award result in a virus with enhanced growth by more than 1 log compared to wild type strains, you must notify your NIAID Program Officer and

Grants Management Specialist immediately and that further research involving the resulting virus(es) may require review by the DHHS in accordance with the HHS P3CO Framework.

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

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





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

CC: Dr. Peter Daszak

Ms. Emily Linde

Dr. Emily Erbelding

Dr. Irene Glowinski

Dr. Andrew Ford

 From:
 Ford, Andrew (NIH/NIAID) [E]

 Sent:
 Mon, 25 Jun 2018 19:43:07 +0000

 To:
 Graham, Adam (NIH/NIAID) [E]

Cc: Ford, Andrew (NIH/NIAID) [E]; Khurana, Dhana (NIH/NIAID) [E]; Strickler-

Dinglasan, Patricia (NIH/NIAID) [C]; Stemmy, Erik (NIH/NIAID) [E]

Subject: 5R01Al110964 - Revising Terms and Conditions of Award

Attachments: R01Al110964 - Daszak 6-25-18.docx

Dear Adam,

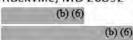
Thank you for your patience regarding the award referenced above. As you know, on December 19, 2017, HHS released the <u>Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens</u> (HHS P3CO Framework). The HHS P3CO Framework lifts the GoF Research Funding Pause and establishes a review mechanism for research the funding agency determines meets the scope of the HHS P3CO Framework. Attached is a letter to EcoHealth Alliance, regarding 5R01Al110964, notifying them that the pause has been lifted and that the terms and conditions of the award have been revised.

In accordance with past practices, please review, insert the date, and sign the attached letter and send it via email to the institution, copying those listed.

Should you have any questions please let me know.

Thanks, andrew

Andrew Q. Ford, Ph.D.
Office of Scientific Coordination and Program Operations
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
5601 Fishers Lane Room 7G64
Rockville, MD 20892



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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

June XX, 2018

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

RE: 5R01Al110964-05

Dear Mr. Chmura:

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

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

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

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

The experiments to generate MERS-like or SARS-like chimeric coronaviruses, are not subject to the HHS P3CO Framework. The terms and conditions of the award have been revised to indicate that should experiments proposed in this award result in a virus with enhanced growth by more than 1 log compared to wild type strains, you must notify your NIAID Program Officer and

Grants Management Specialist immediately and that further research involving the resulting virus(es) may require review by the DHHS in accordance with the HHS P3CO Framework.

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

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

Sincerely,

Adam Graham Grants Management Specialist NIAID/NIH/DHHS

(b) (6)

Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Peter Daszak

Ms. Emily Linde

Dr. Emily Erbelding

Dr. Irene Glowinski

Dr. Andrew Ford

 From:
 Stemmy, Erik (NIH/NIAID) [E]

 Sent:
 Fri, 3 Mar 2017 13:32:48 -0500

To: Hauguel, Teresa (NIH/NIAID) [E];Erbelding, Emily (NIH/NIAID) [E];Glowinski, Irene (NIH/NIAID) [E];Dixon, Dennis M. (NIH/NIAID) [E];Lambert, Linda (NIH/NIAID) [E];Post, Diane (NIH/NIAID) [E];Brown, Liliana (NIH/NIAID) [E];Degrace, Marciela (NIH/NIAID) [E];Mulach, Barbara (NIH/NIAID) [E];Ford, Andrew (NIH/NIAID) [E];Strickler-Dinglasan, Patricia (NIH/NIAID) [C];Hanson, Christopher (NIH/NIAID) [E];Santora, Kenneth (NIH/NIAID) [E];Taylor, Travis (NIH/NIAID) [E]

Subject: RE: Additional agenda item for today's DURC/GoF Meeting

Attachments: MERS SARS Overview 3-3-2017.ppt

Hi Everyone,

For those planning to call in I'm attached a few slides here for agenda item.

Erik

From: Hauguel, Teresa (NIH/NIAID) [E] Sent: Friday, March 03, 2017 11:42 AM (b) (6); Glowinski, Irene (NIH/NIAID) [E] To: Erbelding, Emily (NIH/NIAID) [E] (b) (6); Lambert, (b) (6); Dixon, Dennis M. (NIH/NIAID) [E] Linda (NIH/NIAID) [E] (b) (6); Post, Diane (NIH/NIAID) [E] (b) (6): Stemmy, Erik (NIH/NIAID) [E] (b) (6); Brown, Liliana (NIH/NIAID) [E] (b) (6); Degrace, Marciela (NIH/NIAID) [E] (b) (6); Mulach, Barbara (NIH/NIAID) [E] (b) (6); Ford, Andrew (NIH/NIAID) [E] (b) (6); Strickler-Dinglasan, Patricia (NIH/NIAID) [C] (b) (6); Hanson, Christopher (NIH/NIAID) [E] (b) (6); Santora, Kenneth (NIH/NIAID) [E] (b) (6); Taylor, Travis (NIH/NIAID) [E] Subject: Additional agenda item for today's DURC/GoF Meeting

See below – one more agenda item for this afternoon's meeting (time-permitting)

Teresa M. Hauguel, Ph.D.

Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
5601 Fishers Lane, Room 8E19
Rockville, MD 20852

Phone: (b)

Email: (b) (6)

Getting ready to publish? Share the good news with your Program Officer asap! NIAID may be able to help publicize your article. And, remember to list your NIAID grant or contract number in the publication.

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mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases (NIAID) shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of the NIAID by one of its representatives.

Sent: Friday, March 03, 2017 9:59 AM	(b) (6)
bent: Friday, March 05, 2017 5.35 AM	284.003.0020.000.00 AS
ro: Shaw, Michael (CDC/OID/OD)	6) (6); Lambert, Linda (NIH/NIAID) [E]
(b) (6)	
Cc: Donis, Ruben (OS/ASPR/BARDA)	(b) (6); Huynh, Chuong (OS/ASPR/BARDA)
(b) (6); Castellino, Flora	
redericksen, Brenda (OS/ASPR/BARDA)	(b) (6)
subject: RE: Process for the evaluation of po	tential pandemic pathogens care and oversight at BARDA
The all the second of the seco	(b) (5)
Thank you Mike.	(0)(3)
	(5) (5) p.l.
	(b) (5) Please
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et us know if you have further inte provide a complete update or inclu	
	rest in this development effort. (b) (5) We'd be pleased to
Provide a complete update or incluses regards, Armen From: Shaw, Michael (CDC/OID/OD)	rest in this development effort. (b) (5) We'd be pleased to
Provide a complete update or incluses regards, Armen From: Shaw, Michael (CDC/OID/OD) Sent: Friday, March 03, 2017 8:58 AM	rest in this development effort. We'd be pleased to de you when there is a comprehensive review.
Provide a complete update or incluses regards, Armen From: Shaw, Michael (CDC/OID/OD) Sent: Friday, March 03, 2017 8:58 AM To: Donabedian, Armen (OS/ASPR/BARDA);	rest in this development effort. We'd be pleased to de you when there is a comprehensive review. (b) (6) (b) (6) Lambert, Linda (NIH/NIAID) [E]
Provide a complete update or incluses regards, Armen From: Shaw, Michael (CDC/OID/OD) Sent: Friday, March 03, 2017 8:58 AM Fo: Donabedian, Armen (OS/ASPR/BARDA); Cc: Donis, Ruben (OS/ASPR/BARDA); Huynh,	we'd be pleased to de you when there is a comprehensive review. (b) (5) We'd be pleased to de you when there is a comprehensive review. (b) (6) Lambert, Linda (NIH/NIAID) [E] , Chuong (OS/ASPR/BARDA); Castellino, Flora
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Provide a complete update or incluses regards, Armen From: Shaw, Michael (CDC/OID/OD) Sent: Friday, March 03, 2017 8:58 AM Fo: Donabedian, Armen (OS/ASPR/BARDA); Cc: Donis, Ruben (OS/ASPR/BARDA); Huynh, OS/ASPR/BARDA); Fredericksen, Brenda (OS/ASPR/BARDA)	we'd be pleased to de you when there is a comprehensive review. (b) (5) We'd be pleased to de you when there is a comprehensive review. (b) (6) Lambert, Linda (NIH/NIAID) [E] , Chuong (OS/ASPR/BARDA); Castellino, Flora
Best regards, Armen From: Shaw, Michael (CDC/OID/OD) Sent: Friday, March 03, 2017 8:58 AM To: Donabedian, Armen (OS/ASPR/BARDA); Cc: Donis, Ruben (OS/ASPR/BARDA); Huynh, OS/ASPR/BARDA); Fredericksen, Brenda (OS Subject: RE: Process for the evaluation of positions of positions and positions are considered.	(b) (5) We'd be pleased to de you when there is a comprehensive review. (b) (6) Lambert, Linda (NIH/NIAID) [E] , Chuong (OS/ASPR/BARDA); Castellino, Flora (S/ASPR/BARDA)
Provide a complete update or incluses regards, Armen From: Shaw, Michael (CDC/OID/OD) For: Friday, March 03, 2017 8:58 AM For: Donabedian, Armen (OS/ASPR/BARDA); Cc: Donis, Ruben (OS/ASPR/BARDA); Huynh, OS/ASPR/BARDA); Fredericksen, Brenda (OS/ASPR/BARDA)	(b)(5) We'd be pleased to de you when there is a comprehensive review. (b)(6) Lambert, Linda (NIH/NIAID) [E] , Chuong (OS/ASPR/BARDA); Castellino, Flora

SARS vs MERS

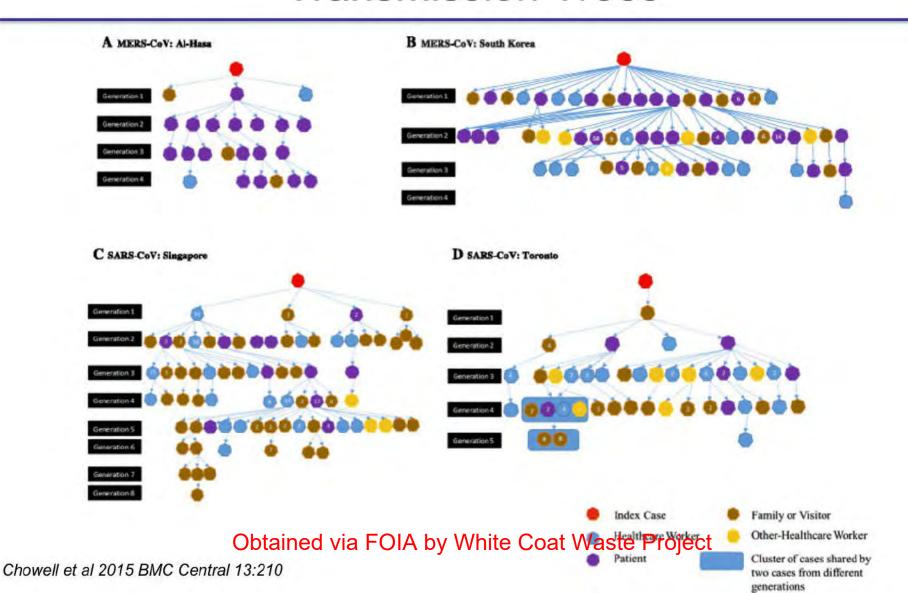
by the numbers

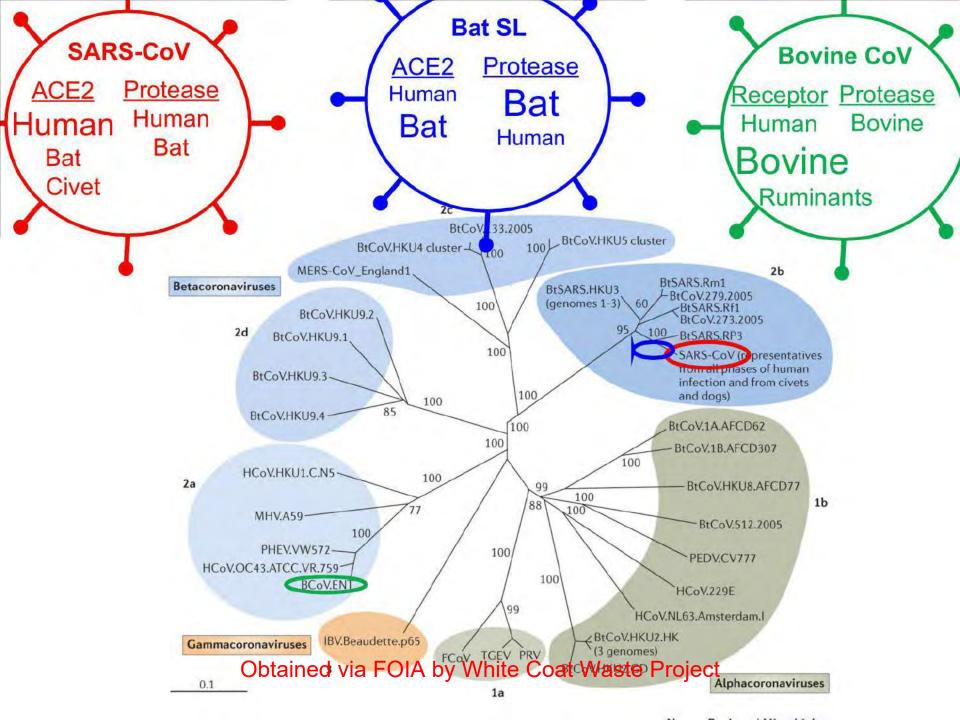
	SARS	MERS
Cases	8,096	1,905
Deaths	774	677
CFR	9.6%	35.5%
Countries	29	27
R_0	2-3*	<1
Duration	9 months	52 months (ongoing)

^{*} Before interventions

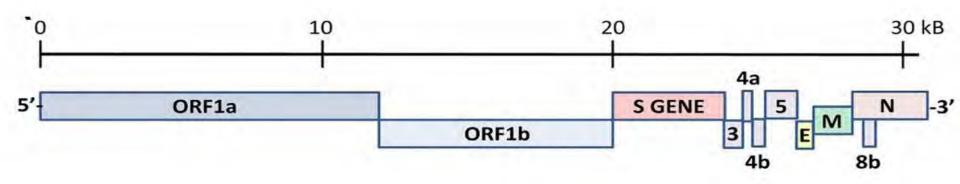
SARS vs MERS

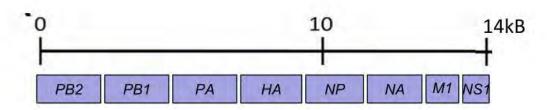
Transmission Trees





CoV vs Influenza Genome





From: Hauguel, Teresa (NIH/NIAID) [E]
Sent: Tue, 31 Jan 2017 09:35:46 -0500

To: Post, Diane (NIH/NIAID) [E];Stemmy, Erik (NIH/NIAID) [E];Brown, Liliana (NIH/NIAID) [E];Degrace, Marciela (NIH/NIAID) [E];Ford, Andrew (NIH/NIAID) [E];Hanson, Christopher

(NIH/NIAID) [E]

Subject: Call for agenda items - 2/3 DURC/GoF meeting

Hi All,

Below is the draft agenda for this Friday's DURC/GoF meeting. We are aiming to finish the review of paused projects and Erik will give a short overview of MERS/SARS epi data. If we have time, we will begin to discuss the format for the HHG P3CO review packages.

If you have any other urgent agenda items that need to be discussed this week please let me know by noon tomorrow.

Reminder to POs – once you have revised your assessment spreadsheets please send the information for currently paused projects to Andrew as he is keeping the master list.

Weekly DURC/GoF Meeting Agenda

Friday, February 3, 2017 2:00-3:00pm

5601/7F100

Skype Number: (b) (6)
Conference ID: (b) (6)

- 1. Review of Paused Projects
 - a. CEIRS Portfolio Diane
- MERS/SARS Overview Erik
- 3. Discuss HHG P3CO Review Package Format Teresa
- 4. Round Robin/Other Items

Thanks, Teresa

Teresa M. Hauguel, Ph.D.

Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
5601 Fishers Lane, Room 8E19
Bethesda, MD 20892
Phone: (b) (6)

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

Getting ready to publish? Share the good news with your Program Officer asap! NIAID may be able to help publicize your article. And, remember to list your NIAID grant or contract number in the publication.

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From: Hauguel, Teresa (NIH/NIAID) [E]
Sent: Tue, 10 Jan 2017 12:57:28 -0500

To: Post, Diane (NIH/NIAID) [E];Stemmy, Erik (NIH/NIAID) [E];Brown, Liliana

(NIH/NIAID) [E];Ford, Andrew (NIH/NIAID) [E];Hanson, Christopher (NIH/NIAID) [E]

Subject: Call for agenda items - 1/13 DURC/GoF meeting

Hi All,

The plan for this Friday's DURC/GoF meeting is to review the paused projects in Erik and my portfolios in light of the new P3CO policy guidance. If we have time we will also continue our discussions on implementing the policy guidance.

I doubt we will have time for much else given that we now only have a one hour time slot, but I wanted to check with you all to see if there is anything pressing that must be discussed this Friday. Keep in mind that the following Friday we will not have a meeting due to the Inauguration Day holiday. If you have anything pressing, please let me know by <u>COB tomorrow</u>.

Thanks, Teresa

Teresa M. Hauguel, Ph.D.

Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
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From: Peter Daszak

Sent: Mon, 11 Jul 2016 14:28:11 +0000

To: Greer, Jenny (NIH/NIAID) [E]; Aleksei Chmura

Cc: Stemmy, Erik (NIH/NIAID) [E];Kirker, Mary (NIH/NIAID) [E];Glowinski, Irene

(NIH/NIAID) [E];Ford, Andrew (NIH/NIAID) [E];Joseph Riccardi

Subject: Re: Grant Number: 5R01Al110964 - 03 PI Name: DASZAK, PETER

Dear Jenny,

This is terrific! We are very happy to hear that our Gain of Function research funding pause has been lifted.

Cheers,

Peter

Peter Daszak

President

EcoHealth Alliance 460 West 34th Street – 17th Floor New York, NY 10001

(b) (6) (direct) (b) (6) (fax)

www.ecohealthalliance.org

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.

From: Greer, Jenny (NIH/NIAID) [E] (b) (6)

Sent: Thursday, July 7, 2016 10:00 AM To: Aleksei Chmura; Peter Daszak

Cc: Stemmy, Erik (NIH/NIAID) [E]; Kirker, Mary (NIH/NIAID) [E]; Glowinski, Irene (NIH/NIAID) [E]; Ford,

Andrew (NIH/NIAID) [E]

Subject: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Aleksei and Peter,

Please find attached a determination regarding your grant.

As always, don't hesitate to contact us with any questions.

All the best,

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824

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

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

July 7, 2016

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

RE: 5 R01AI110964-03

Dear Mr. Chmura:

Thank you for your correspondence of June 28th, 2016, regarding the October 17, 2014 White House announcement of a U.S. Government-wide pause on certain gain-of-function (GoF) experiments and its potential impact on your research (http://www.whitehouse.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research). The research funding pause pertains to GoF research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the resulting virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.

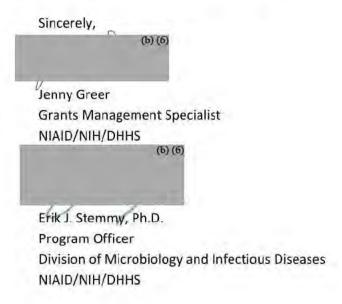
NIAID reviewed the original grant application, and the additional information provided by you, and made the following assessments regarding Aim 3 of the above-referenced grant:

- NIAID is in agreement that the work proposed under Aim 3 to generate MERS-like or SARS-like chimeric coronaviruses (CoVs) is <u>not</u> subject to the GoF research funding pause. This determination is based on the following: (1) the chimeras will contain only S glycoprotein genes from phylogenetically distant bat CoVs; and (2) recently published work demonstrating that similar chimeric viruses exhibited reduced pathogenicity. Therefore it is <u>not</u> reasonably anticipated that these chimeric viruses will have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.
- NIAID acknowledges that if any of the MERS-like or SARS-like chimeras generated under this
 grant show evidence of enhanced virus growth greater than 1 log over the parental backbone
 strain, Dr. Daszak will immediately stop all experiments with these viruses and provide the NIAID
 Program Officer and Grants Management Specialist, and Wuhan Institute of Virology
 Institutional Biosafety Committee, with the relevant data and information related to these
 unanticipated outcomes.

Please remember that the institution must comply in full with all terms and conditions placed on this grant. As indicated above, NIAID determinations are based on information from multiple sources, but primarily on our communication with you about the details of your proposed experiments and your research results. Should NIAID's determination change based on information obtained through the U.S. Government GoF deliberative process, described here

http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf, you will be notified; however, until such time, or until the GoF research funding pause is lifted, NIAID's determination, indicated above, is final.

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



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

From: Hauguel, Teresa (NIH/NIAID) [E]
Sent: Wed, 15 Jun 2016 12:54:49 -0400

To: Glowinski, Irene (NIH/NIAID) [E];Dixon, Dennis M. (NIH/NIAID) [E];Lambert, Linda (NIH/NIAID) [E];Spiro, David (NIH/NIAID) [E];Hauguel, Teresa (NIH/NIAID) [E];Post, Diane (NIH/NIAID) [E];Stemmy, Erik (NIH/NIAID) [E];Brown, Liliana (NIH/NIAID) [E];Mulach, Barbara (NIH/NIAID) [E];Ford, Andrew (NIH/NIAID) [E];Strickler-Dinglasan, Patricia (NIH/NIAID) [E];Hanson, Christopher (NIH/NIAID) [E];Delarosa, Patricia (NIH/NIAID) [E];Santora, Kenneth (NIH/NIAID) [E]

Subject: 6/17 DURC/GoF Meeting Agenda

Attachments: 1a-Response to GoF letter, 5R01Al110964 - 03 DASZAK, PETER.pdf

Hello Everyone,

Below is the agenda for Friday's DURC/GoF meeting.

Attached is the document for agenda item 1.

Weekly DURC/Gof Meeting Agenda

Friday, June 17, 2016 2:00-3:30pm 5601/7G31

Call in number: (b) (6)

Passcode: (b) (6)

- 1. Project for GoF Review
 - a. Daszak (RO1) MERS Erik
- 2. Updates
 - a. ISARG Dennis/Ken/Tricia
 - b. Erasmus RMP Diane/Ken/Tricia
- Round Robin/Other Items

Teresa M. Hauguel, Ph.D.

Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
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mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases (NIAID) shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of the NIAID by one of its representatives.

From:

Aleksei Chmura

Sent:

Thu, 9 Jun 2016 17:42:58 -0400 Greer, Jenny (NIH/NIAID) [E]

To:

Dr. Peter Daszak; Stemmy, Erik (NIH/NIAID) [E]; Kirker, Mary (NIH/NIAID)

[E];Glowinski, Irene (NIH/NIAID) [E];Ford, Andrew (NIH/NIAID) [E]

Subject:

Re: Grant Number: 5R01Al110964 - 03 PI Name: DASZAK, PETER

Dear Jenny,

I concur with the detailed response that Dr. Daszak just sent to you in response to the Gain of Function questions in your email from 28th May. Please let me know anytime, if you require any further information.

Many thanks!

Aleksei Chmura

Authorized Organizational Representative & Senior Coordinator of Operations

EcoHealth Alliance 460 West 34th Street – 17th floor New York, NY 10001

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

www.ecohealthalliance.org

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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 Jun 9, 2016, at 17:37, Greer, Jenny (NIH/NIAID) [E]

(b) (6) wrote:

Peter,

Thank you for providing this response. We will review it shortly. In the meantime, I look forward to receiving concurrence from your authorized business official.

Thanks again

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824

Phone:

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Email: (b) (6)

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From: Peter Daszak (b) (6) Sent: Thursday, June 09, 2016 5:23 PM To: Greer, Jenny (NIH/NIAID) [E] (b) (6); Aleksei Chmura Cc: Stemmy, Erik (NIH/NIAID) [E] (b) (6); Kirker, Mary (NIH/NIAID) [E] (b) (6); Ford, Andrew (b) (6); Glowinski, Irene (NIH/NIAID) [E] (b) (6) (NIH/NIAID) [E] Subject: RE: Grant Number: 5R01Al110964 - 03 PI Name: DASZAK, PETER Importance: High

Dear Jenny and Erik,

Please find our response letter to your email below, attached. I really appreciate you giving us the chance to clarify these details and look forward to your decision on our proposed work. As stated clearly in the letter, we will not (of course) move forward with any of the proposed work in Specific Aim #3 until we hear back from you with directions.

Cheers,

Peter

Peter Daszak

President

EcoHealth Alliance 460 West 34th Street - 17th Floor New York, NY 10001

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

From: Greer, Jenny (NIH/NIAID) [E] (b) (6)

Sent: Saturday, May 28, 2016 5:15 PM

To: Aleksei Chmura

Cc: Stemmy, Erik (NIH/NIAID) [E]; Peter Daszak; Kirker, Mary (NIH/NIAID) [E]; Glowinski, Irene

(NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]

Subject: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Dear Mr. Chmura,

Please find attached an important message about this grant. Your immediate response will be much appreciated.

All the best,

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824

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

"Effective October 1, 2014, NIH closeout policy has changed (see NOT-OD-14-084). In order to avoid unilateral closeout, final reports must be submitted in a timely manner. Failure to submit accurate final reports could result in enforcement actions such as revisions to NOA funding levels, or delay in future funding."

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Dear Drs. Greer and Stemmy,

June 8, 2016

We appreciate your rapid review of our proposed work for year 3 of our R01 (5R01Al110964-03). 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 UNC 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



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 UNC 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
- Remove the specific aims and experiments that are subject to the pause from the Research Plan and request to have the award budget renegotiated.





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,

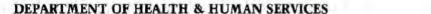


Dr. Peter Daszak

PI

President and Chief Scientist EcoHealth Alliance

Tel: (b) (6) e-mail: (b) (6)





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

May 28, 2016

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

RE: 5R01AI110964-03

Dear Mr. Chmura:

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

Aim 3: Testing predictions of CoV inter-species transmission

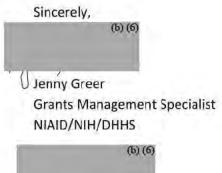
As per the funding pause announcement, new USG funding will <u>not</u> be released for GoF research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route. Therefore, the next non-competing segment of the award that starts June 1, 2016 cannot be released until a determination is reached based on the receipt and review of the information requested below. The research funding pause would not apply to characterization or testing of naturally occurring influenza, MERS, or SARS viruses, unless the tests are reasonably anticipated to increase transmissibility and/or pathogenicity.

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

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

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

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



Erik J. Stemmy, Ph.D.

Program Officer

Division of Microbiology and Infectious Diseases

NIAID/NIH/DHHS

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