PROGRAM CONTACT:
Erik Stemmy
[redacted] (b) (6)

SUMMARY STATEMENT
(Privileged Communication)

Release Date: **01/02/2014**

Application Number: **1 R01 AI110964-01**

Principal Investigator

DASZAK, PETER PHD

Applicant Organization: ECOHEALTH ALLIANCE, INC.

Review Group: **CRFS**
Clinical Research and Field Studies of Infectious Diseases Study Section

Meeting Date: **12/18/2013**
Council: **JAN 2014**
Requested Start: **10/01/2013**

RFA/PA: **PA11-260**
PCC: **M51C**

Project Title: **Understanding the Risk of Bat Coronavirus Emergence**

SRG Action: **Impact Score:** (b) (5) [redacted] **Percentile:** (b) (5) [redacted]
Next Steps: **Visit http://grants.nih.gov/grants/next_steps.htm**
Human Subjects:
Animal Subjects:
Gender:
Minority:
Children:
[redacted] (b) (4), (b) (5)

Project Year	Direct Costs Requested	Estimated Total Cost
1	499,993	(b) (4), (b) (5) [redacted]
2	499,469	[redacted]
3	499,978	[redacted]
4	499,953	[redacted]
5	499,974	[redacted]
TOTAL	2,499,367	[redacted]

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

1R01AI110964-01 DASZAK, PETER

BUDGETARY OVERLAP
PROTECTIONS FOR HUMAN SUBJECTS UNACCEPTABLE

RESUME AND SUMMARY OF DISCUSSION: This impressive application proposes studies to determine factors that increase the risk of zoonotic coronavirus (CoV) emergence in people by studying CoV diversity in a critical zoonotic reservoir (bats), at sites of high risk for emergence (wildlife markets) in an emerging disease hotspot (China). Given the SARS outbreak and the current emergence of MERS in the Middle East, the significance relates to advancing the knowledge of zoonotic potential of coronaviruses. [redacted] (b) (5)

[redacted] (b) (5)

DESCRIPTION (provided by applicant): This project will examine the risk of future coronavirus (CoV) 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. Zoonotic CoVs are a significant threat to global health, as demonstrated with the emergence of pandemic severe acute respiratory syndrome coronavirus (SARS-CoV) in China in 2002, and the recent and ongoing emergence of Middle East Respiratory Syndrome (MERS-CoV). Bats appear to be the natural reservoir of these viruses, and hundreds of novel bat-CoVs have been discovered in the last two decades. Bats, and other wildlife species, are hunted, traded, butchered and consumed across Asia, creating a large scale human-wildlife interface, and high risk of future emergence of novel CoVs. This project aims to understand what factors increase the risk of the next CoV emerging in people by studying CoV diversity in a critical zoonotic reservoir (bats), at sites of high risk for emergence (wildlife markets) in an emerging disease hotspot (China). The three specific aims of this project are to: 1. Assess CoV spillover potential at high risk human-wildlife interfaces in China. This will include quantifying the nature and frequency of contact people have with bats and other wildlife; serological and molecular screening of people working in wet markets and highly exposed to wildlife; screening wild-caught and market sampled bats from 30+ species for CoVs using molecular assays; and genomic characterization and isolation of novel CoVs. 2. Develop predictive models of bat CoV emergence risk and host range. A combined modeling approach will include phylogenetic analyses of host receptors and novel CoV genes (including functional receptor binding domains); a fused ecological and evolutionary model to predict host-range and viral sharing; and mathematical matrix models to examine evolutionary and transmission dynamics. 3. Test predictions of CoV inter-species transmission. Predictive models of host range (i.e. emergence potential) will be tested experimentally using reverse genetics, pseudovirus and receptor binding assays, and virus infection experiments across a range of cell cultures from different species and humanized mice.

PUBLIC HEALTH RELEVANCE: Most emerging human viruses come from wildlife, and these represent a significant threat to global public health and biosecurity - as demonstrated by the SARS coronavirus pandemic of 2002-03 and an ongoing SARS-like epidemic in the Middle East. This project seeks to understand what factors allow animal Coronaviruses to evolve and jump into the human population by studying virus diversity in a critical group of animals (bats), at sites of high risk for emergence (wildlife markets) in an emerging disease hotspot (China).

CRITIQUE 1:

(b) (5)

[redacted]

(b) (5)

[redacted]

[redacted]

(b) (5)

Protections for Human Subjects:

[redacted]

(b) (5)

Inclusion of Women, Minorities and Children:

[redacted]

(b) (5)

Vertebrate Animals:

[redacted]

(b) (5)

Biohazards:

[redacted]

(b) (5)

Select Agents:

[redacted]

(b) (5)

Resource Sharing Plans:

[redacted]

(b) (5)

Budget and Period of Support:

[redacted]

(b) (5)

CRITIQUE 2:

(b) (5)

[redacted]

(b) (5)

[redacted]

Protections for Human Subjects:

(b) (5)

[redacted]

Inclusion of Women, Minorities and Children:

(b) (5)

[redacted]

Vertebrate Animals:

(b) (5)

[redacted]

Budget and Period of Support:

(b) (5)

[redacted]

CRITIQUE 3:

(b) (5)

[redacted]

(b) (5)

[redacted]

Protections for Human Subjects:

(b) (5)

[redacted]

Inclusion of Women, Minorities and Children:

(b) (5)

[redacted]

Vertebrate Animals:

(b) (5)

[redacted]

Biohazards:

(b) (5)

[redacted]

Budget and Period of Support:

(b) (5)

[redacted]

[redacted] (b) (5)

THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS (Resume): [redacted] (b) (5)

PROTECTIONS FOR HUMAN SUBJECTS (Resume): [redacted] (b) (5)

[redacted] (b) (5)

INCLUSION OF WOMEN PLAN (Resume): [redacted] (b) (5)

INCLUSION OF MINORITIES PLAN (Resume): [redacted] (b) (5)

INCLUSION OF CHILDREN PLAN (Resume): [redacted] (b) (5)

VERTEBRATE ANIMALS (Resume): [redacted] (b) (5)

BUDGETARY OVERLAP:

[redacted] (b) (5)

COMMITTEE BUDGET RECOMMENDATIONS: [redacted] (b) (5)

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-10-080 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-080.html.

The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

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December 18, 2013

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* Temporary Member. For grant applications, temporary members may participate in the entire meeting or may review only selected applications as needed.

Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.

SUMMARY STATEMENT
(Privileged Communication)

PROGRAM CONTACT:
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(b) (6)

Release Date: 03/06/2019
Revised Date:

Application Number: **2 R01 AI110964-06**

Principal Investigator

DASZAK, PETER

Applicant Organization: ECOHEALTH ALLIANCE, INC.

Review Group: **CRFS**
Clinical Research and Field Studies of Infectious Diseases Study Section

Meeting Date: **02/14/2019**
Council: **MAY 2019**
Requested Start: **06/01/2019**

RFA/PA: **PA18-484**
PCC: **M51C**

Project Title: **Understanding the Risk of Bat Coronavirus Emergence**

SRG Action: **Impact Score:** (b) (5) **Percentile:** (b) (5)
Next Steps: **Visit https://grants.nih.gov/grants/next_steps.htm**
Human Subjects:
Animal Subjects:
Gender:
Minority:
Children:
(b) (4), (b) (5)

Project Year	Direct Costs Requested	Estimated
6	515,358	(b) (4), (b) (5)
7	515,358	
8	515,358	
9	515,358	
10	515,358	
TOTAL	2,576,790	

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

2R01AI110964-06 DASZAK, PETER

RESUME AND SUMMARY OF DISCUSSION: This outstanding application seeks to understand what factors allow coronaviruses, including close relatives to SARS, to evolve and emerge in the human population by studying viral diversity in their animal reservoirs (bats), surveying people that live in high-risk communities in China for evidence of bat-coronavirus infection, and conducting laboratory experiments to analyze and predict which newly-discovered viruses pose the greatest threat to human health. The renewal application follows a [redacted] (b) (5) (b) (5)

DESCRIPTION (provided by applicant): Understanding the Risk of Bat Coronavirus Emergence Novel zoonotic, bat-origin CoVs are a significant threat to global health and food security, as the cause of SARS in China in 2002, the ongoing outbreak of MERS, and of a newly emerged Swine Acute Diarrhea Syndrome in China. In a previous R01 we found that bats in southern China harbor an extraordinary diversity of SARSr-CoVs, some of which can use human ACE2 to enter cells, infect humanized mouse models causing SARS-like illness, and evade available therapies or vaccines. We found that people living close to bat habitats are the primary risk groups for spillover, that at one site diverse SARSr-CoVs exist that contain every genetic element of the SARS-CoV genome, and identified serological evidence of human exposure among people living nearby. These findings have led to 18 published peer-reviewed papers, including two papers in Nature, and a review in Cell. Yet salient questions remain on the origin, diversity, capacity to cause illness, and risk of spillover of these viruses. In this R01 renewal we will address these issues through 3 specific aims: Aim 1. Characterize the diversity and distribution of high spillover-risk SARSr-CoVs in bats in southern China. We will use phylogeographic and viral discovery curve analyses to target additional bat sample collection and molecular CoV screening to fill in gaps in our previous sampling and fully characterize natural SARSr-CoV diversity in southern China. We will sequence receptor binding domains (spike proteins) to identify viruses with the highest potential for spillover which we will include in our experimental investigations (Aim 3). Aim 2. Community, and clinic-based syndromic, surveillance to capture SARSr-CoV spillover, routes of exposure and potential public health consequences. We will conduct biological-behavioral surveillance in high-risk populations, with known bat contact, in community and clinical settings to 1) identify risk factors for serological and PCR evidence of bat SARSr-CoVs; & 2) assess possible health effects of SARSr-CoVs infection in people. We will analyze bat-CoV serology against human-wildlife contact and exposure data to quantify risk factors and health impacts of SARSr-CoV spillover. Aim 3. In vitro and in vivo characterization of SARSr-CoV spillover risk, coupled with spatial and phylogenetic analyses to identify the regions and viruses of public health concern. We will use S protein sequence data, infectious clone technology, in vitro and in vivo infection experiments and analysis of receptor binding to test the hypothesis that % divergence thresholds in S protein sequences predict spillover potential. We will combine these data with bat host distribution, viral diversity and phylogeny, human survey of risk behaviors and illness, and serology to identify SARSr-CoV spillover risk hotspots across southern China. Together these data and analyses will be critical for the future development of public health interventions and enhanced surveillance to prevent the re-emergence of SARS or the emergence of a novel SARSr-CoV.

PUBLIC HEALTH RELEVANCE: Most emerging human viruses come from wildlife, and these represent a significant threat to public health and biosecurity in the US and globally, as was demonstrated by the SARS coronavirus pandemic of 2002-03. This project seeks to understand what factors allow coronaviruses, including close relatives to SARS, to evolve and jump into the human population by studying viral diversity in their animal reservoirs (bats), surveying people that live in high-risk communities in China for evidence of bat-coronavirus infection, and conducting laboratory experiments to analyze and predict which newly-discovered viruses pose the greatest threat to human health.

CRITIQUE 1

(b) (5)

[redacted]

(b) (5)

[redacted]

[redacted]

(b) (5)

Protections for Human Subjects:

[redacted]

(b) (5)

Inclusion of Women, Minorities and Children:

[redacted]

(b) (5)

Vertebrate Animals:

[redacted]

(b) (5)

Biohazards:

[redacted]

(b) (5)

Renewal:

(b) (5)

[redacted]

Resource Sharing Plans:

(b) (5)

[redacted]

Authentication of Key Biological and/or Chemical Resources:

Acceptable

Budget and Period of Support:

Recommend as Requested

CRITIQUE 2

(b) (5)

[redacted]

(b) (5)

[redacted]

(b) (5)

[redacted]

[redacted] (b) (5)

Protections for Human Subjects:

[redacted] (b) (5)

Inclusion of Women, Minorities and Children:

[redacted] (b) (5)

Vertebrate Animals:

[redacted] (b) (5)

Biohazards:

[redacted] (b) (5)

Renewal:

[redacted] (b) (5)

Select Agents:

[redacted] (b) (5)

Resource Sharing Plans:

[redacted] (b) (5)

Authentication of Key Biological and/or Chemical Resources:

[redacted] (b) (5)

Budget and Period of Support:

[redacted] (b) (5)

CRITIQUE 3

[redacted] (b) (5)

(b) (5)

[redacted]

Protections for Human Subjects:

(b) (5)

[redacted]

Inclusion of Women, Minorities and Children:

(b) (5)

[redacted]

Vertebrate Animals:

(b) (5)

[redacted]

Biohazards:

(b) (5)

[redacted]

Select Agents:

(b) (5)

[redacted]

Resource Sharing Plans:

(b) (5)

[redacted]

Authentication of Key Biological and/or Chemical Resources:
[redacted] (b) (5)

Budget and Period of Support:
[redacted] (b) (5)

THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS: [redacted] (b) (5)

INCLUSION OF WOMEN PLAN: [redacted] (b) (5)

INCLUSION OF MINORITIES PLAN: [redacted] (b) (5)

INCLUSION OF CHILDREN PLAN: [redacted] (b) (5)

VERTEBRATE ANIMALS: [redacted] (b) (5)

COMMITTEE BUDGET RECOMMENDATIONS: [redacted] (b) (5)

Footnotes for 2 R01 AI110964-06; PI Name: DASZAK, PETER

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

Clinical Research and Field Studies of Infectious Diseases Study Section
Infectious Diseases and Microbiology Integrated Review Group
CENTER FOR SCIENTIFIC REVIEW
CRFS
02/14/2019 - 02/15/2019

Notice of NIH Policy to All Applicants: Meeting rosters are provided for information purposes only. Applicant investigators and institutional officials must not communicate directly with study section members about an application before or after the review. Failure to observe this policy will create a serious breach of integrity in the peer review process, and may lead to actions outlined in NOT-OD-14-073 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-073.html and NOT-OD-15-106 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-106.html, including removal of the application from immediate review.

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