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SUMMARY STATEMENT
(Privileged Communication)

Release Date: 04/13/2012

Application Number: 1 R01 TW009502-01

Principal Investigator

DASZAK, PETER PHD

Applicant Organization: ECOHEALTH ALLIANCE, INC.

Review Group: ZRG1 IDM-U (55)
Center for Scientific Review Special Emphasis Panel
Ecology and Evolution of Infectious Diseases

Meeting Date: 02/22/2012 RFA/PA: PAR12-810
Council: MAY 2012 PCC: EEID
Requested Start: 09/01/2012 Dual PCC: G126IE
Dual IC(s): GM

Project Title: Comparative Spillover Dynamics of Avian Influenza in Endemic Countries

SRG Action: Impact/Priority Score: 30
Human Subjects: 44-Human subjects involved - SRG concerns
Animal Subjects: 30-Vertebrate animals involved - no SRG concerns noted
Gender: 1A-Both genders, scientifically acceptable
Minority: 1A-Minorities and non-minorities, scientifically acceptable
Children: 1A-Both Children and Adults, scientifically acceptable
Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested	Estimated Total Cost
1	349,998	468,648
2	349,998	468,648
3	349,997	468,647
4	349,996	468,646
5	349,997	468,647
<hr/> TOTAL	<hr/> 1,749,986	<hr/> 2,343,237

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.

1R01TW009502-01 DASZAK, PETER

PROTECTIONS FOR HUMAN SUBJECTS UNACCEPTABLE

RESUME AND SUMMARY OF DISCUSSION: This application on the Ecology and Evolution of Infectious Diseases was received and reviewed in accord with National Science Foundation Program Solicitation NSF 11-580 and National Institutes of Health Notice NOT-TW-12-001 (<http://grants.nih.gov/grants/guide/notice-files/NOT-TW-12-001.html>). The purpose of this study is to analyze the interactions among humans, domesticated fowl, and wild birds for their role in influenza virus A/(H5N1) transmission and persistence in Bangladesh, China, and Egypt while in Cameroon, the control region, this virus does not persist. Significance resides in the integration of sophisticated models at different geographic scales with surveillance, human contact, and environmental data that are used to develop predictive strategies of transmission risk and the strong need to control the spread of influenza virus among wild birds, domesticated animals, and humans.

The outstanding principal investigators, each of whom has an impressive record of productivity from previous awards, have formed an outstanding investigative team with good breadth and strong expertise that builds on existing research collaborations at all four sites and is highly capable of completing the proposed project.

Strengths of the proposal are the innovative use of different geographic scales, a variety of modeling approaches, the integration of social, biological, and physical data, and the use of a control site where A/(H5N1) has been detected in the past but has not become established. In addition, the approach and methods are appropriate and sound while the research environments build on extensive prior research in all four sites and local collaborations and adequate infrastructures are already in place.

Minor weaknesses that slightly reduce enthusiasm are questions regarding the general sampling design, as more details about how the sites were chosen would enhance clarity, and the rationale for why all four sites are truly needed to accomplish project goals is not well justified. In addition, there is a lack of integration of the data collection and modeling activities, the proposal lacks details on how the hypotheses will actually be tested, and there are grammar and spelling issues that are amenable to proofreading.

Broader impact strengths are that proposal activities will foster the continuance of multiple international collaborations, substantial effort will be devoted to student training at all levels and in all local areas, the appropriate postdoctoral mentoring plan is sufficiently detailed, and the proposed community outreach activities are substantial.

The data management plan is well designed, and the willingness to share data as soon as practicable and the strong focus on improving the ease of access through web-based services are both admirable. Overall, there is extremely high to very strong enthusiasm and confidence in the likelihood of this project's success and that the proposed work will lead to important insights about the persistence and spread of influenza virus A/(H5N1). These are important for developing predictive strategies of transmission risk, which may then be used to help control the spread of influenza virus among wild birds, domesticated animals, and humans.

CRITIQUE 1: Daszak and colleagues propose a complex study of the spatial and temporal dynamics of AH5N1 influenza. The specific objectives involve hypotheses about different types of poultry production-marketing, the factors that affect probability of contact between humans and poultry (and therefore spillover to humans), and modeling to synthesize these data to produce a comprehensive explanation of why H5N1 persists in certain places and never occurs in others.

The research team is skilled, experienced, and international. Records of productivity from previous NSF support are outstanding for all those with previous grants; this is a very talented group of PIs.

The proposed approach is to focus on several areas where H5N1 has been problematic and persistent and one area where, apparently, it has not become established. Intensive surveillance, environmental

sampling, human contact data will be inputs to an unusually complex spatially explicit model of disease dynamics. The proposed research is ambitious in its goals and has good potential to enhance understanding about the dynamics of a pathogen that has already caused problems and could be devastating under certain scenarios.

One concern is the general sampling design. First, are the focal "persistence" sites a reasonable representation of where persistence has occurred? This question is linked to spatial scale and I suspect the answer is "yes," but more information on how the sites were chosen (or, whether there even was a choice of focal sites) would have been helpful. Yes, the history of the disease (incidence) in the focal regions is well-known, but the information presented seemed rather anecdotal without establishing general patterns.

More concerning is the use of a single site as a "control." Cameroon may be all you need, but why it was selected (one PI has a long research history there)? Apologies if I overlooked something, but would it be possible to sample where the pathogen has been known to occur and where it has NOT persisted?

The discussion of metapopulation dynamics partially addresses the possibility of persistence versus periodic reintroduction, but more discussion of finer scale spatio-temporal dynamics (e.g., sources-sinks, rescue effects, etc.) seems warranted.

A modeling effort as complex and multivariate as that proposed makes it difficult to offer specific predictions, but we are asked to take it on faith that results will have reasonable precision and generality. This reviewer has little experience with network models and this issue may be an irrelevant, but better development of a priori hypotheses would have strengthened the science a bit. This is a proposal where the complexity of the modeling effort cuts both ways for evaluating expected results. (Broader Impacts) The integrative approach (of social-biological-and physical data), the international cooperation, training opportunities and the public health/economic implications make for an unusually strong proposal. The track records of the PIs on outreach and the proposed data dissemination plan are excellent.

(Summary) This is an ambitious proposal from a team with the skills and experience to take it on. More detail on sampling design and a clearer accounting of what will emerge from the modeling process would have strengthened an otherwise very strong proposal.

CRITIQUE 2: This is an every exciting study that will link two local scale models of transmission risk and spillover risk into a comprehensive regional scale model. While this work will be very important in terms of avian flu research, the approach is important for epidemiology and environmental health in general. I find the focus on the behavioral surveys and understanding on transmission particularly transformative.

The fact that this team has been collaborating for 3 years and has preliminary data adds strength to their proposal and the likelihood of success.

(Broader Impacts) In addition to H5N1, being of public interest the PIs have developed a plan to communicate their research at multiple educational levels from K-12 to graduate students. They have relationships with NGO's and government agencies. Additionally, they have set up a portal at the University of Oklahoma that will share research and data with the public.

(Summary) This proposal has strong intellectual merit and broader impacts and in this case, both are excellent. I put more weight on the intellectual merit (75%) than broader impacts (25%).

CRITIQUE 3: This is an interesting project that involves a close examination of the interactions among humans, domesticated animals (especially poultry), and wild birds and their importance for the transmission of H5N1. The project combines several different modeling techniques that are appropriate at different spatial scales, including dynamical, network, and GIS-based spatial models. The research team is well qualified to do the work and they will draw on existing collaborations with local organizations in Bangladesh, China, Egypt, and Cameroon. The primary goal of the project, to integrate

models at different spatial scales in order to provide better predictions of future influenza risk, is laudable and success at achieving this goal is likely to lead to major advances in the utility of models to study infectious disease risks. The investigators have a well-structured plan for their work and they possess the necessary expertise to attack this ambitious problem. The project combines sophisticated modeling with the collection of essential data among both humans and the primary animal species implicated in the transmission of influenza viruses. It is not totally clear, however, how the two sides of the project (data collection and modeling) will be integrated. Sufficient details are presented about the types of data needed for each level of model, and it is clear how those data will be collected in the field, but more details are needed on how the collected data will be analyzed and put into a form that can be used by the proposed models. In addition, there is not enough discussion of how the specific hypotheses will actually be tested.

Minor points:

1) On pp. 2, the investigators imply that compartmental models with nonrandom mixing are rare. This is not the case, as there is a long history of the use of nonrandom mixing in compartmental models.

2) It is not clear whether the investigators will be selecting 10 sites total for sampling in each country or whether they will select 10 sites of each type (intensive poultry production, backyard production, mixed) [pp. 9].

3) What is involved in the movement logs mentioned on p. 10?

4) The IRB and vertebrate boxes are not checked on cover sheet, but were discussed in the proposal.

(Broader Impacts): The collaboration involves multiple US organizations as well as local infrastructure in four different countries. The researchers have already made the connections with scientists in these other countries and they have ongoing collaborations that are related to the proposed project.

Substantial effort will be devoted to the training of students at all levels and in all institutions/organizations involved and substantial outreach activities are planned in both the US and abroad.

(Summary) This is an interesting project that focuses on the interactions among humans, domesticated animals, and wild birds and how those interactions influence the transmission of the H5N1 influenza virus. The project integrates three different modeling approaches to effectively model the transmission of the virus at different geographic scales. The investigators are well qualified to do the work and they have ongoing collaborations with local groups in the four countries included in the project. The project has substantial broader impacts including training of students at all levels and planned outreach in the US and abroad. The proposal suffers from a lack of detail on how the data collection and modeling activities will be integrated and how the specific hypotheses will actually be tested.

CRITIQUE 3: This project is interested in considering what factors lead to endemicity of A/H5N1 (avian influenza), testing three hypotheses: (1) the pattern, size and distribution of poultry farms drives H5N1 endemism; (2) the frequency and intensity of intraspecific contact influences the risk of spillover from domestic and wild birds to people; and (3) integrating dynamical, network and spatial models across scales provides a strategy to better predict influenza-A transmission risk. This will be assessed through adaption of social network modeling to understand the dynamics of poultry markets and human-avian contact in three endemic countries and a control country, and will collect data on high-risk activities using a common questionnaire already developed and field tested. The work is based on existing collaborations and preliminary work already undertaken in the countries. Methods appear sound, although it is not quite clear how the survey questionnaire data will be utilized. It is a good team.

My only remark would be the relevance of continued research in to H5N1 - it is not clear that this will be the next major pandemic, and recent outbreaks have been very confined (and the economic impacts overstated). They already have funding for this work from Fogarty, and one is tempted to suggest that much of what they propose to do will be undertaken in any case, or could be largely achieved at a lower

scale in one country and 2-3 years rather than 4 countries and 5 years. I think there is a 'value for money' issue here.

(Broader Impacts) It is suggested that the work will offer a cost-effective way to identify areas of high risk, helping to prioritize influenza surveillance in order to detect outbreaks events quickly and prevent spread, but I am not clear quite how it will do this. In terms of training, there are two post-docs and two graduate students in the US, and various post-docs, graduate students and field assistants in-country. There will be dissemination to countries as well as internationally. There is nothing very exciting in what is proposed here I'm afraid.

(Summary) There is nothing especially wrong with this proposal, but I question the merit in funding it to such an extent of time, space and resource given the topic area and other research on this topic. It strikes me as quite worthy, but not very exciting and seeking too much input.

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:

PROTECTIONS FOR HUMAN SUBJECTS (Resume): Unacceptable: The risks to subjects by responding to questionnaires are not clearly described (point 1). The process of obtaining informed consent is not clearly described (point 2).

INCLUSION OF CHILDREN PLAN (Resume): Acceptable

INCLUSION OF MINORITIES PLAN (Resume): Acceptable

INCLUSION OF WOMEN PLAN (Resume): Acceptable

VERTEBRATE ANIMAL (Resume): Acceptable

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

MEETING ROSTER

The roster for this review meeting is displayed as an aggregated roster that includes reviewers from multiple National Science Foundation Review Panels and Center for Scientific Review Special Emphasis Panels for the 2010/05, 2011/05, and 2012/05 council rounds.

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. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

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CENTER FOR SCIENTIFIC REVIEW
Ecology and Evolution of Infectious Diseases
ZRG1 IDM-U (55) R
February 22, 2012 - February 24, 2012**

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