Supporting Statement A for

United States and Global Human Influenza Surveillance in at-Risk Settings (NIAID)

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Name: Rich Gorman, MD
Address: 5601 Fishers Lane, Bethesda MD
Telephone: 240-627-3261
Email: gormanr@niaid.nih.gov

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SUPPORTING STATEMENT

United States and Global Human Influenza Surveillance in at-Risk Settings

A. JUSTIFICATION

In order to capture samples and information from the 2014-2015 influenza season, which featured a rare drift variant of influenza, we filed an emergency OMB paperwork reduction act clearance request for surveillance and information collection to be conducted at the Johns Hopkins University in a hospital setting. We received approval on 04/23/2015 under OMB control number 0925-0715, expiration date 10/31/2015. The hospital was able to collect some samples and information from the end of last influenza season, giving us critical information on an important new variant influenza strain. The study at Johns Hopkins University will need to continue to collect samples and information in the upcoming influenza seasons in order to identify if the draft variant from last season remains in circulation, to identify any additional novel circulating influenza strains, and to draw important conclusions on the risk to public health of circulating influenza viruses. We anticipate using the generic clearance we seek here to continue that study and capture information and samples from the upcoming 2015-2018 influenza season. We also anticipate future studies in other at-risk settings described below in section A.2.

A.1 CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY

The collection of the information required for the study "United States and Global Human Influenza Surveillance in at-Risk Settings" directly ties to the core mission of NIAID and NIH. The surveillance that will be conducted under this protocol (Attachment 1) will permit timely identification of Influenza viruses with pandemic potential, as well as variant seasonal influenza virus strains such as those resulting from antigenic drift; complementary clinical research will assess serologic and immunologic correlates of infection and disease severity. Sites will be located globally in at-risk settings for exposure to influenza, to include hospitals, farms, slaughterhouses, and within households at-risk individuals, and will provide the US government with capacities to respond appropriately to emerging and re-emerging influenza strains. These studies will provide information to better understand influenza in the human population, and the knowledge gained will be utilized to enhance health and reduce illness due to influenza infection.

Information collected through this study will be shared with the influenza community at large through public databases and with interested government parties, including the US Centers for Disease Control (CDC).

The clinical samples and data collected through this study will be used to accomplish the following objectives:

- Rapidly identify and genetically fingerprint influenza virus strains through surveillance and molecular triaging efforts
- Perform whole genome sequencing of influenza A virus strains to identify major and minor virus quasi-species variants
- Characterize virus isolates using novel approaches designed to assess viral pathogenic fitness, antiviral resistance and relatedness to influenza vaccine strains.
- Identify biomarkers associated with influenza transmission, pathogenesis, and disease severity
- Serology measuring the specificity, extent and magnitude of the antibody response to infection and past exposure to novel influenza viruses

Evaluation components for projects under this clearance include monthly reporting to NIAID which is used for program metrics evaluation. Additionally, investigators will internally and externally (through advisory board) review and evaluate information collection, analyses and outcomes.

The authority to collect this information is under 42 USC 285f National Institute of Allergy and Infectious Diseases (NIAID).

A.2 PURPOSE AND USE OF THE INFORMATION COLLECTION

This generic package is for conducting multi-center prospective observational cohort studies that recruit throughout the year to identify influenza in at-risk settings globally. At-risk settings include places where individuals are likely to be exposed to influenza-infected humans or animals or present with influenza infection such as hospitals, the households of influenza-positive individuals, farms, slaughterhouses and other locations with avian- and swine-human contact. Acquiring samples from these individuals will allow us to rapidly identify novel influenza viruses in the human population and characterize viruses to identify those of pandemic potential. Samples collected from influenza-infected individuals will help identify serologic and immunologic correlates of infection and disease severity, characterize cellular responses that are protective for influenza, and identify factors associated with human-to-human and interspecies transmission. Three similar types of collections will be performed using this generic; while the approaches and rationales will be similar, the frequency of collection and subjects will differ, as follows:

Hospital/Care setting surveillance: Approximately 1600 adult subjects (18-100 years) with and without influenza like illness each year, as well as subjects with laboratory confirmed influenza each year. Children, prisoners, and those unable to provide informed consent will be excluded. There are no exclusion criteria based on gender or race/ethnicity. Subjects will have an initial visit (enrollment) and up to four follow-up visits depending on the results of their initial influenza test. Attachments 3-8 are representative of what will be completed by subjects on the first visit; Attachment 10 is representative of what will be completed by subjects on follow-up visits. The 1600 subjects are estimated to include 1100 from the US, 500 from Taiwan total in the 3 years of this generic.

Household surveillance: Approximately 500 children and adult subjects (0 -100 years) with and without influenza like illness each year who live with an individual with a confirmed influenza positive test. There are no exclusion criteria based on gender or race/ethnicity. Subjects will have an initial visit (enrollment), up to five follow-up visits, and a final visit where nasal and throat swabs, nasal washes, and/or blood samples will be collected. Subjects under 6 months old will have a single throat swab taken. Attachments 3-8 are representative of what will be completed by subjects on the first visit; Attachment 10 is representative of what will be completed by subjects on follow-up visits. The 500 subjects are estimated to include 250 from Nicaragua and 250 from Egypt total in the 3 years of this generic.

Human-animal interface surveillance: Approximately 900 adult subjects (18-100 years) with and without influenza like illness each year who work in a setting with exposure to birds and/or swine. There are no exclusion criteria based on gender or race/ethnicity. Subjects will have an initial visit (enrollment) involving nasal/throat swab and blood collection and up to bi-weekly visits for nasal/throat swab collection and symptom assessment. Attachments 3-8 are representative of what will be completed by subjects on the first visit; Attachment 10 is representative of what will be completed by subjects on follow-up visits. The 900 patients are estimated to include 400 from the US, 300 from Bangladesh and 200 from China total in the 3 years of this generic.

Surveillance will occur in the at-risk setting. Following informed written consent, eligible, consented subjects whom enrolled will complete a questionnaire detailing the demographic information, current symptoms, and past medical history. Nasal/throat samples and blood will be collected, and the nasal/throat samples will be tested for influenza. All clinical information will be linked with stored samples via an anonymous study ID to create a database linking samples and detailed clinical, demographic and epidemiologic information.

The data collection is an incredibly important part of this study. The information will be used to inform clinicians and public health experts about variant seasonal strains of influenza and the associated medical and public health related consequences.

The data collected on the influenza viruses isolated will be reviewed by program staff at NIAID/NIH. This information will be used as part of the NIAID influenza pandemic

preparedness plan under the CEIRS program. Data will be used to help inform which influenza strains will be further evaluated through the risk assessment pipeline established. The data will also be shared with the US CDC and international health agencies, when relevant, for consideration in influenza vaccine strain selection activities and in outbreak monitoring and containment.

A.3 USE OF INFORMATION TECHNOLOGY AND BURDEN REDUCTION

For hospital/care setting patients, some patient information (that does not require explicit direct questions to patient and is otherwise available on the patient chart) described above will be collected via the Electronic Medical Record, which will reduce the burden of patient reported information.

Data will be reported and shared in an electronic format with the CEIRS investigators and NIAID/NIH, which will reduce the paper burden.

With regard to IT systems, this work will be conducted on IT systems owned, operated and controlled outside the NIH network by non-Government entities. PIA is not required for these Systems.

In accordance with HIPAA laws, studies performed under this clearance will seek a waiver of consent to screen patient's medical records prior to enrollment for eligibility criteria when appropriate. This will reduce the burden of the research coordinator and streamline the process for identifying eligible patients. This will also reduce the burden on the patients for patient reported information. After screening is completed, informed consent will be documented by all patients who participate in any of the studies within this collection.

A.4 EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION

NIAID staff have searched clinical trials.org to search for similar studies. In additional, NIAID staff has consulted with the US CDC to see if there are duplicative studies. No studies to our knowledge exist that include the robust research components tied to this surveillance activity.

Studies conducted under this generic clearance will not duplicate other studies because of unique at-risk settings being pursued. The geographic location of sites, interactions with various species of animals including swine and birds, and the high genetic diversity of influenza ensure that similar studies conducted in distinct areas on different human populations will yield different and complementary results. The combination of data from the diverse sites through these studies ensure rapid detection novel influenza strains in a more immediate manner which will trigger an immediate public health response for the protection of those that the CDC identifies as at increased risk for complications from influenza.

A.5 IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES

Study associated personnel will be hired and trained to provide appropriate informed consent, sample collection and data collection so that these tasks will not fall to the associated clinical staff. No small entities will be impacted by studies conducted under this protocol.

A.6 CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY

Capturing samples from each influenza season and from various human-animal interface settings is essential for understanding the public health implications that influenza viruses may have in the future, and discerning the reasons behind the severity of the disease it causes. Additionally, capturing the full diversity influenza viruses that humans become exposed to in at-risk settings is essential for identifying and characterizing viruses of pandemic potential.

A.7 SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINES OF 5 CFR 1320.5

These data collections will be implemented in a manner fully consistent with 5 CFR 1320.5

A.8 COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE AND EFFORTS TO CONSULT INSIDE AND OUTSIDE AGENCY

The 60 day notice required in 5 CFR 1320.8(d) was published in the Federal Register on April 9, 2015 (Volume 80, Number 68, page 19090). One comment was received and it is attached along with the Notice (Attachment 19). However, it was not applicable to this data collection.

A.9 EXPLANATION OF ANY PAYMENT OF GIFT TO RESPONDENTS

Study participants will receive a standard nominal incentive, which is determined based on the cost of living in the country, number of follow-up visits required, and number of samples collected and the invasiveness of the collection. The decision to provide incentive and amount provided is in keeping with standard federal and institutional guidance.

There is extensive literature to support the use of incentives, primarily monetary incentives, as a supplement or complement to other efforts of persuasion to ensure recruitment of a representative

sample and maintain participation in longitudinal studies.[1,2] In studies for both commercial market research and social sciences, findings indicate that respondents who receive these tokens of appreciation provide valid input, and their inclusion makes for a more representative sample. The incentive will significantly increase the likelihood of reliable data based on the cited literature above and our research groups' extensive past experiences with similar studies. Incentive levels will vary between $15-100 USD per visit, in accordance with the invasiveness of procedures (swabs vs. blood draws), number of visits, and geographic location. Any incentive difference between countries will be based on standard cost of living differences and feedback from sites' IRBs. Incentives at the higher end of the range will only be used when the protocol requires that study participants to travel multiple times (e.g., to a clinic) to provide samples via invasive collection methods. Amount will be approved by the internal IRB of the institutions and NIAID. Each sub-study submitted under this generic umbrella will include a complete justification for the incentive proposed (e.g., travel to data collection site, blood draw), including relevant supporting evidence that the requested amount is necessary.

A.10 ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS

- Data capture will be ongoing throughout the period of the study.
- All data will be captured by fully trained research staff that have completed all required trainings by the site institution and NIAID/DMID.
- Additional laboratory updates will be entered within 30 days of the date of final laboratory result reporting.
- Data will be captured using paper DCFs and transcribed into a 21CFR11 compliant, secure, password-protected electronic database by trained study personnel.
- All data will be stored on encrypted servers and accessed via password protected, individual workstations with access logs.
- The investigators will maintain appropriate medical records and documentation related to the conduct of the research, in compliance with institutional requirements for confidentiality of subject information.
- These documents will be held at the study site in lockable cabinets under the control of the study staff and entered as coded data into a 21CRF11 compliant, secure, password-protected electronic database.
- Clinical samples will be de-identified before analysis
- All keys identifying subjects will be destroyed at study completion
- The Privacy Act applies to the information collection per Privacy Act System of Records Notice (SORN) #09-25-0200 http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm which covers clinical, basic and population-based research studies of the NIH.

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[1] Singer, Eleanor (2011) "Toward a Benefit-Cost Theory of Survey Participation: Evidence, Further Tests, and Implications" Journal of Official Statistics, Vol. 27, No. 2, pp. 379-392. http://www.jos.nu/Articles/abstract.asp?article=272379

[2] Rodgers, Willard (2011) "Effects of Increasing the Incentive Size in a Longitudinal Survey" Journal of Official Statistics, Vol. 27, No. 2, pp. 279-299. http://www.jos.nu/Articles/abstract.asp?article=272279

A.11 JUSTIFICATION FOR SENSITIVE QUESTIONS

- PII will be collected initially but all data will be fully and permanently de-identified upon study completion to mitigate risk of loss of patient privacy /confidentiality.
- Data will be captured using paper DCFs and transcribed into a 21CFR11 compliant, secure, password-protected electronic database by trained study personnel.
- All data will be stored on encrypted servers accessible only via password protected, individual workstations with access logs.
- The investigators will maintain appropriate medical records and documentation related to the conduct of the research, in compliance with institutional requirements for protecting the privacy of subjects and security of their information.
- These documents will be held at the study site in lockable cabinets under the control of the study staff and entered as coded data into a 21CRF11 compliant, secure, password-protected electronic database system.

Before any study procedures are performed, subjects must sign an informed consent form that complies with the requirements of 21 CFR Part 50 and 45 CFR 46 and the local IRB. Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continuing throughout the individual's study participation. At the time the study worker will seek informed consent, the study worker will ask the eligible candidate if he/she is literate. Subjects who are not literate are not eligible for these studies. If the study is conducted in a country where English is not the predominant language, medical professionals or translators and witnesses who are fluent in the native language of the study subject will be involved in the informed consent process.

Extensive discussion of risks and possible benefits of participation in this study, including a detailed explanation of the proposed use and disclosure of their protected health information, including specifically their specimens, will be provided to the subjects and their families before any study procedures are performed, including pre-screening of subjects for eligibility. Consent forms describing in detail the study procedures and risks are given to the subject and written documentation of informed consent is required prior to enrolling in the study and prior to performing any study procedures. Consent forms (Attachment 2) will be IRB approved and the subject will be asked to read and review the document. Upon reviewing the document, the investigator will explain the research study to the subject and answer any questions that may arise. The subjects will sign the informed consent document prior to being enrolled in the study and prior to having any study procedures performed. The subjects should have the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. By signing the informed consent form, subjects agree to complete all procedures required by this study, unless the subject withdraws voluntarily, or is withdrawn or terminated from this study for any reason. The subjects may withdraw consent at any time throughout the course of the study. A copy of the informed consent document will be given to the subjects for their records and if they refuse to take it, the study staff should document it in the subject's records. The rights and welfare of the subjects will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

A.12 ESTIMATED ANNUAL HOURS OF BURDEN AND ANNUALIZED HOURLY COSTS

	ESTIMATES OF HOUR BURDEN				
Type of Respondents	**Form Name**	**Number of Respondents**	**Frequency of Response**	**Average Time per Response**	**Annual Hour Burden**
Hospital/care setting patients	Informed Consent Form (Attachment 2)	1600	1	10/60	267
	Form 1a Screening and enrollment log (Attachment 3)**		1	10/60	267
	Form 2a Eligibility Checklist (Attachment 4)		1	10/60	267
	Form 3a Subject Identification (Attachment 5)		1	10/60	267
	Form 4a Demographic and Exposure Information (Attachment 6)		1	10/60	267
	Form 5a Current Symptoms (Attachment 7)		1	10/60	267
	Form 6a Medical History (Attachment 8)		1	10/60	267
	Form 8a Follow Up Assessment (Attachment 10)*		4	10/60	1067
Human Animal-interface patients	Informed Consent Form (Attachment 2)		1	10/60	150
	Form 1a Screening and enrollment log (Attachment 3)**		1	10/60	150

	Form 2a Eligibility Checklist (Attachment 4)	900	1	10/60	150
	Form 3a Subject Identification (Attachment 5)		1	10/60	150
	Form 4a Demographic and Exposure Information (Attachment 6)		1	10/60	150
	Form 5a Current Symptoms (Attachment 7)		25	10/60	3750
	Form 6a Medical History (Attachment 8)		1	10/60	150
	Form 8a Follow Up Assessment (Attachment 10)		25	10/60	3750
Household Surveillance patients	Informed Consent Form (Attachment 2)	500	1	10/60	83
	Form 1a Screening and enrollment log (Attachment 3)**		1	10/60	83
	Form 2a Eligibility Checklist (Attachment 4)		1	10/60	83
	Form 3a Subject Identification (Attachment 5)		1	10/60	83
	Form 4a Demographic and Exposure Information (Attachment 6)		1	10/60	83
	Form 5a Current Symptoms (Attachment 7)		6	10/60	500
	Form 6a Medical History (Attachment 8)		1	10/60	83
	Form 8a Follow Up		6	10/60	500

	Assessment (Attachment 10)				
Study Staff	Informed Consent Form (Attachment 2)	5	600	10/60	500
	Form 7a Enrollment Specimen Collection (Attachment 9)		600	10/60	500
	Form9a ED Chart Review (Attachment 11)		600	10/60	500
	Form 10a Chart Review – Inpatient Hospitalization (Attachment 12)		600	10/60	500
	Form 11a Subject Withdrawal Form (Attachment 13)		600	10/60	500
	Form 12a Subject checklist (Attachment 14)		600	10/60	500
	Form 13A Enrollment Report (Attachment 15)		600	10/60	500
	Form 14A 10% Data accuracy report (Attachment 16)		600	10/60	500
	Form 15A – QC Checklist (Attachment 17)		600	10/60	500
Totals		3005			17334

* Some patients will not require the number of follow-up visits listed. Number is **not anticipated for all studies**.

** Forms 1a-6a (Attachments 3-8) are collected as a packet. The burden statement added to Form 1a reflects the total burden hours for the entire packet.

The burden was estimated by the time required to read and sign the consent form, to wait for the result of their Influenza test, and to complete the questions asked on the Data Collection Forms (Attachments 3-17). The burden for Form 8a (Attachment 10) reflects the time required for sample collection in the follow up visits.

A.12 - 2 ANNUALIZED COST TO RESPONDENTS

The annualized cost to respondents will vary by the location where influenza surveillance is performed – studies are expected to be conducted within the US at sites in Maryland, New York, Georgia, or Tennessee and international sites such as Taiwan, Vietnam, Cambodia, Bangladesh, Egypt, Chile, Argentina, Nicaragua and China. Sites have been established in all of these locations, but projects performed under this generic clearance will be dependent on the extent and severity of the influenza seen in these regions. Each site will be submitted as a separate project. The estimated annualized cost based on protocols we anticipate for research in the US, Taiwan, China, Nicaragua, Bangladesh and Egypt are shown below. As listed in the Bureau of Labor Statistics, the mean hourly wage for the state of Maryland is $25.41. The mean hourly wage for agricultural workers in the US (human-animal interface) is $9.37. The Bureau of Labor Statistics lists the hourly compensation for China in urban settings at $2.85 USD. The Taiwan hourly wage is $9.10 according to their state website. According to their country websites, Nicaragua's minimum wage for the agricultural sector is $99.32 USD/month, Bangladesh's minimum wage is $19 USD/month, and Egypt's average hourly wage is $6.30 USD. Study staff respondent costs are included in the Labor category under A.14, cost to the federal government.

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Respondents	Hourly Wage Rate	Respondent Cost
Hospital/care setting patients- US	1100	5	30/60	25.41 USD	$69877.50
Human Animal-interface patients - US	400	26	30/60	9.37 USD	$48,724
Household Surveillance patients- Nicaragua	250	7	30/60	.65 USD	$568.75
Hospital/care setting patients - Taiwan	500	5	30/60	9.10 USD	$11,375
Human Animal-interface patients - Bangladesh	300	26	30/60	.12 USD	$468
Human Animal-	200	26	30/60	2.85 USD	$7,410

interface patients - China					
Household Surveillance patients - Egypt	250	7	30/60	$6.30 USD	$5512.50
Totals across sites	3000				$143,935.75

A.13 ESTIMATE OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORD KEEPERS

There are no additional costs to the respondents other than their time.

A.14 ANNUALIZED COST TO THE FEDERAL GOVERNMENT

The anticipated cost to the Federal Government is approximately $715,551 annually per protocol. We anticipate no more than 4 distinct protocols under this generic clearance per year. An annualized Cost Table is below

Line Item	**Grade/Step**	**Salary**	**% of Effort**	**Fringe**	**Annual Cost to Gov't**		
Federal Oversight							
Clinical Project Manager	GS-14	$131,053	5%		$6553		
Scientific Lead/COR	GS-14	$138,136	2%		$2763		
Health Specialist	GS-13	$90,823	2%		$1816		
Contractor Cost							
Labor		$343,083		$99,384	$442,467		
Patient Remuneration					$11,905		
Materials and Supplies					$27,115		
Shipping					$29,280		
Indirect Costs					$145,955		
Travel					$3,526		
Other (IRB fees, service core fees)					$44,171	**Anticipated Studies per year**	**Anticipated Annual Cost to Gov't**

Subtotal – Annual Cost per study					$715,551	4	**$2,844,204**

A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS

This is a new generic Information Collection request.

A.16 PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE

The example protocol (Attachment 1) obtains the necessary data and samples to fulfill the objectives of the CEIRS network. Studies also will evaluate epidemiologic data from the surveillance studies, which will include molecular characterization and detailed sequence analysis. Data will be summarized using descriptive statistics and be published in relevant scientific journals. In addition studies conducted under this clearance may assess virus virulence and replication using a relevant, model system and assess effects of virus infection on differentiated epithelial cells and repair processes integral for cellular recovery from virus infection. We may also conduct studies to assess serologic and immunologic correlates of disease and disease severity. There will be multiple scientific publications each year (at least two per year per study) resulting from the data and samples obtained. Each study performed under this generic clearance may have differing timelines depending on the length and severity of the influenza seasons. A project time schedule for all studies is below:

A.16 - 1 Project Time Schedule

Activity	Time Schedule
Data collection and sample collection	October 2015 – October 2018
Sample testing and validation	December 2015 – December 2018
Analyses	April 2016- April 2018
Publications	August 2016 - June 2018

A.17 REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE

No exemption is being requested.

A.18 EXCEPTIONS TO CERTIFICATION FOR REDUCTION ACT SUBMISSIONS

This collection of information involves no exceptions to the Certification for Paperwork Reduction Act Submissions.