[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day comment request

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

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on April 9, 2015, page 19090 and allowed 60-days for public comment. One comment was received. However, it was not applicable to this data collection. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, or request more

information on the proposed project, contact: Dr. Diane Post, Program Officer, Respiratory Diseases Branch, NIAID, NIH 5601 Fishers Lane, Bethesda, MD or call non-toll-free number at 240-627-3348 or email your request, including your address to: postd@niaid.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: United States and Global Human Influenza Surveillance in at-Risk Settings, 0925-NEW, National Institute of Allergies and Infectious Diseases (NIAID), National Institutes of Health (NIH).

Need and Use of Information Collection: These studies will identify individuals with or at risk for influenza through focused surveillance in at-risk settings within the United States and internationally, rapidly identify circulating influenza strains to identify those with pandemic potential and create an invaluable bank of human samples from influenza patients to allow the characterization of the determinants of influenza transmission to and among humans, the immune response to influenza, and the basis of severe disease - critical knowledge gaps impacting effectiveness of decision-making around patient care and pandemic preparedness. These studies will provide insight into viral and host determinants that may be contributing to the transmission of influenza, immune response to influenza, and severity of influenza and associated morbidity and mortality.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours for the entire 3 year request are 17334.

Estimated Annualized Burden Hours

	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	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	900	1	10/60	150
	Form 1a Screening and enrollment log (Attachment 3)		1	10/60	150
	Form 2a Eligibility Checklist (Attachment 4)		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	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		1	10/60	83

	(Attachment 6)				
	Form 5a Current Symptoms (Attachment 7)		6	10/60	500
	Form 6a Medical History (Attachment 8)		1	10/60	83
	Form 8a Follow Up Assessment (Attachment 10)		6	10/60	500
Study Staff	Informed Consent Form	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

Dated: September 10, /2015.

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Dione Washington,

Project Clearance Liaison, NIAID, NIH.

[FR Doc. 2015-23479 Filed: 9/17/2015 08:45 am; Publication Date: 9/18/2015]