Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-14-0888]

Proposed Data Collections Submitted for

Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to Kimberly Lane, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Persistence of Viable Influenza Virus in Aerosols (0920-0888, Expiration 05/31/2014) – Revision – National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC)

Background and Brief Description

The National Institute for Occupational Safety and Health (NIOSH) is authorized to conduct research to advance the health and safety of workers under Section 20(a)(1) of the 1970 Occupational Safety and Health Act. Influenza continues to be a major public health concern because of the substantial health burden from seasonal influenza and the potential for a severe pandemic. Although influenza is known to be transmitted by infectious secretions, these secretions can be transferred from person to person in many different ways, and the relative importance of the different pathways is not known. The likelihood of the transmission of influenza virus by small infectious airborne particles produced during coughing and

breathing is particularly unclear. The question of airborne transmission is especially important in healthcare facilities, where influenza patients tend to congregate during influenza season, because it directly impacts the infection control and personal protective measures that should be taken by healthcare workers. The purpose of this study is to measure the amount of viable influenza virus in airborne particles that are produced by patients when they cough, and the size and quantity of the particles carrying the virus. A better understanding of the amount of potentially infectious material released by patients and the size of the particles carrying the virus will assist in determining the possible role of airborne transmission in the spread of influenza and in devising measures to prevent it.

Volunteer adult participants will be recruited by a test coordinator using a poster and flyers describing the study. Interested potential participants will be screened verbally to verify that they have influenza-like symptoms and that they do not have any medical conditions that would preclude their participation. Qualified participants who agree to participate in the study will be asked to read and sign an informed consent form, and then to complete a short health questionnaire. After completing the forms, two nasopharyngeal swabs and one oropharyngeal swab will be collected from the participant. They

then will be asked to cough repeatedly into an aerosol particle collection system, and the airborne particles produced by the participant during coughing will be collected and tested. The sounds produced during coughing will also be recorded for analysis and comparison to the amount of virus expelled. The study will require 60 volunteer test subjects each year for 3 years, for a total of 180 test participants.

The following revisions have been made to the previous approved information collection request:

1) Initially, potential participants will be screened verbally rather than through the health questionnaire.
2) The number of potential participants has been increased from 132 to 360. In a previous similar study, the number of potential participants who agree to join the study was 50%, which was lower than anticipated. The increase will allow the study to recruit 180 participants.
3) The number of qualified participants has been increased from 120 to 180. This is necessary to provide a sufficient number of cough aerosol samples with detectable amounts of viable influenza and is based on a previous study, where 10% of aerosol samples had culturable virus.
4) The Informed consent form has been substantially revised to make it easier to read and understand. As a result of

the revisions, the burden per response for that form has been reduced from 20 to 15 minutes.

5) Because of the increases in the number of potential and qualified participants, the total burden hours has increased from 51 to 78 hours.

6) The title of the ICR has been changed to "Factors Influencing the Transmission of Influenza" in order to reflect the new focus of the project on influenza viability and to match the title of the human subjects protocol approved by the Institutional Review Board.

There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Potential participant	Initial verbal screening	360	1	3/60	18
Qualified participant	Informed consent form	180	1	15/60	45
Qualified participant	Health questionnaire	180	1	5/60	15
Total					78

Kimberly S. Lane, MBA
Deputy Director
Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

[FR Doc. 2013-26787 Filed 11/07/2013 at 8:45 am; Publication Date: 11/08/2013]