



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-21-0888; Docket No. CDC-2020-0102]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Factors Influencing the Transmission of Influenza. This proposed collection is intended to further our understanding of how respiratory viruses like influenza are transmitted from person to person.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2020-0102 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7118; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of

information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of

information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Factors Influencing the Transmission of Influenza (OMB Control No. 0920-0888, Exp. 2/28/2021) - Extension - 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. NIOSH is requesting an extension to an existing ICR (expiring February 28, 2021) because the ongoing COVID-19 pandemic has temporarily halted the study due to staff safety concerns and an inability to access healthcare facilities in order to recruit test subjects.

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 gain a better understanding of the production of infectious aerosols by patients with influenza, and to compare this to the levels of biomarkers of influenza infection in the blood of these patients. To do this, airborne particles produced by volunteer subjects with influenza will be collected and tested for influenza virus, and the levels of influenza infection-associated biomarkers will be measured in blood samples from these subjects.

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. A matching number of healthy control participants will also be recruited. 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, the participant's oral temperature will be measured, and two nasopharyngeal mucus samples and five ml of blood will be collected. The participant then will be asked to don an elastomeric mask and breathe and cough normally for 40 minutes into an aerosol particle collection system. The total time from initial verbal screening to completion will be about 95 minutes. The study will require 90 volunteer test subjects each year for three years, for a total of 270 test participants. 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 | 180 | 1 | 3/60 | 9 |
| Qualified participant | Informed consent form | 90 | 1 | 15/60 | 23 |

| | | | | | |
|-----------------------|----------------------|----|---|-------|-----|
| Qualified participant | Health questionnaire | 90 | 1 | 5/60 | 8 |
| Qualified participant | Medical testing | 90 | 1 | 72/60 | 108 |
| | Total | | | | 148 |

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[FR Doc. 2020-22489 Filed: 10/9/2020 8:45 am; Publication Date: 10/13/2020]