

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[30Day-22-0600]

**Agency Forms Undergoing Paperwork Reduction Act Review**

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “CDC Model Performance Evaluation Program (MPEP) for *Mycobacterium tuberculosis* Susceptibility testing” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on August 27, 2021 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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 submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

**Proposed Project**

CDC Model Performance Evaluation Program (MPEP) for *Mycobacterium tuberculosis* Susceptibility testing (OMB Control No. 0920-0600, Exp. 2/20/2022)—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

**Background and Brief Description**

The CDC is requesting a Revision to approved information collection from participants in the CDC Model Performance for *Mycobacterium tuberculosis* Drug Susceptibility Testing for a period of three years. Revision of this information will not require changes in the scope of the project. This Revision includes (a) modification of the Instructions to Participants Letter; (b) modification of the MPEP *Mycobacterium tuberculosis* Results Worksheet; (c) modification of online data collection instrument; (d) modification of the MPEP *Mycobacterium tuberculosis* Minimum

Inhibitory Concentration Results Worksheet; (e) removal of Reminder Telephone Script; and (f) modification of Aggregate Report Letter.

While the overall number of cases of TB in the U.S. has decreased, rates still remain high among foreign-born persons, corrections, homeless populations, and individuals infected with HIV in major metropolitan areas. To reach the goal of eliminating TB, the Model Performance Evaluation Program (MPEP) for *Mycobacterium tuberculosis* Susceptibility Testing is used to monitor and evaluate performance and practices among US laboratories performing *M. tuberculosis* susceptibility testing. Participation in this program is one way laboratories can ensure high-quality laboratory testing, resulting in accurate and reliable testing results.

By providing laboratories a self-assessment tool to test for drug resistant *M. tuberculosis* strains, the program aids laboratories in optimizing their skills in susceptibility testing. The information obtained from the laboratories on susceptibility practices and procedures is used to establish variables related to good performance, assessing training needs, and aid with the development of practice standards. Participants in this program include domestic clinical and public health laboratories. Data collection from laboratory participants occurs twice per year. The data collected in this program will include the susceptibility test results of primary and secondary drugs, drug concentrations, and test methods performed by laboratories on a set of performance evaluation (PE) isolates. The PE isolates are sent to participants twice a year. Participants also report demographic data such as laboratory type and the number of drug susceptibility tests performed annually.

CDC is requesting OMB approval for an estimated 129 annual burden hours. Participation of respondents is voluntary, and there is no cost to participants other than their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Domestic Laboratory .....	Participant Biosafety Compliance Letter of Agreement .....	80	1	5/60
	MPEP <i>Mycobacterium tuberculosis</i> Results Worksheet .....	80	2	30/60
	Online Survey Instrument .....	80	2	15/60
	MPEP <i>Mycobacterium tuberculosis</i> Minimum Inhibitory Concentration Results Form.	4	2	15/60

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30Day-22-0891]

#### Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “World Trade Center Health Program Enrollment, Petitions, Designated Representative/HIPAA Authorization, and Member Satisfaction” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on July 22, 2021 to obtain comments from the public and affected agencies. CDC received three comments related to the previous notice but were unrelated to the package. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570.

Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

#### Proposed Project

World Trade Center Health Program Enrollment, Petitions, Designated Representative/HIPAA Authorization, and Member Satisfaction (OMB Control No. 0920-0891, Exp. 12/31/2021)—Revision—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

NIOSH seeks to request OMB approval to revise the currently approved information collection activities that support the World Trade Center (WTC) Health Program. The James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347, as amended by Pub. L. 114-113) created the WTC Health Program to provide medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001, or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

Since its inception in 2011, the WTC Health Program has been approved to collect information from applicants and Program members concerning enrollment, appointment of a designated representative or third party, member satisfaction, and petitions regarding adding a new WTC-related health condition to determine coverage under the Program. The currently approved total estimated burden is 14,063 hours annually (see OMB Control No. 0920-

0891, Exp. 12/31/2021). The WTC Health Program has determined that some existing forms need to be updated and some need to be removed from the burden table.

For this revision, the burden hours on the WTC Health Program Applications for Enrollment increased due to an expected increase of application volume. The Program updated the enrollment applications for plain language and improved processing. We estimate 15,837 individuals will submit either a FDNY, General Responder, Pentagon/Shanksville Responder, or WTC Survivor application annually. The burden estimate for the applications is 7,919 hours. This is an increase from 2018 when the estimated annualized burden was 2,251. Of the Applications for Enrollment, we expect to receive per year, we estimate 3,830 of them are General Responder applications from the NY/NJ area and will have to select which clinic they would like to visit. It is expected that it will take the member 0.25 hours to complete the postcard. The burden hours for the General Responder Clinic Postcard are 958 hours.

The Program finds it necessary to update and add new forms to allow applicants and Program members to grant permission to share information with a designated representative or third person about an individual's application or case. We estimate that 1,300 applicants and members will submit a Designated Representative Appointment Form and Designated Representative HIPAA Authorization Form annually. These forms will take approximately 0.25 hours to complete. The burden estimate for these forms is 650 hours.

The Program proposes to extend this information collection to account for adding the WTCHP HIPAA Authorization for Deceased Individuals, WTCHP General HIPAA Authorization to Third Parties, and Designated Representative Revocation Form. The WTCHP HIPAA Authorization for Deceased Individuals was created so a family member and/or personal representative of a deceased applicant or member can request program documentation and/or medical records related to the deceased applicant/member. The WTCHP General HIPAA Authorization to Third Parties was created for members to give the Program permission to share information about their case with a third party, such as a lawyer. The Designated Representative Revocation Form was created for members who wish to remove or replace a currently appointed designated representative. We estimate that 30 applicants or members will submit a