

**Request for Extension to an Approved Information Collection**

***CDC Model Performance Evaluation Program (MPEP) for  
Mycobacterium tuberculosis Drug Susceptibility Testing  
(OMB Control No. 0920-0600)  
Exp. 02/20/2022***

**Supporting Statement B**

**November 16, 2021**

**Contact:**

Cortney Stafford  
Health Scientist  
Laboratory Branch  
Division of Tuberculosis Elimination  
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention  
Centers for Disease Control and Prevention  
1600 Clifton Road, N.E., MS H17-4  
Atlanta, Georgia 30333  
Phone: (404) 639-3420  
Fax: (404) 639-1287  
Email: fcx6@cdc.gov

Table of Contents

Section

B. Collections of Information Employing Statistical Method

1. Respondent Universe and Sampling Methods
2. Procedures for the Collection of Information
3. Methods to Maximize Response Rates and Deal with No Response
4. Tests of Procedures or Methods to be Undertaken
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

-

**B. Collections of Information Employing Statistical Methods**

This data collection does not use statistical methods but this section of the submission will be used to describe how the data are collected.

All information is filed and retrieved by using a Model Performance Evaluation Program (MPEP) identification number assigned to each participant. The number is linked to the name of the organization, which is a testing site. While the names of persons completing the forms are requested, no other personal identifiers are collected other than their title and email address. Respondents are speaking in their roles as staff knowledgeable of performance testing and laboratory practices at their testing site.

**1. Respondent Universe and Sampling Methods**

Data are collected from representatives of participating laboratories classified as public health, hospital, independent (non-hospital based), federal, or other to analyze the performance and practices of all known clinical and public health laboratories in the United States that perform drug susceptibility testing (DST) of isolates belonging to the *Mycobacterium tuberculosis* complex (MTBC). Since statistical methods are not utilized, no sampling is employed.

**2. Procedures for the Collection of Information**

Upon signing of the *Participant Biosafety Compliance Letter of Agreement (Attachment 4)* by an authorized representative, the laboratory will be enrolled in MPEP and assigned a MPEP number. The MPEP number is needed for participants to enter data online. Before survey isolates are mailed to the laboratory, *Pre-shipment Email (Attachment 5)* is sent to participants to

inform them of the expected date for receiving the isolates shipment. The *Pre-shipment Email* will also contain a request to notify CDC of any changes in laboratory contact information. Isolates are sent to the laboratories along with an *Instructions to Participants Letter* (**Attachment 6**), the *MPEP Mycobacterium tuberculosis Results Worksheet* (**Attachment 7**), and *MPEP Mycobacterium tuberculosis Minimum Inhibitory Concentration (MIC) Form* (**Attachment 9**). The *Instructions to Participants Letter* contains information on handling the isolates and for reporting DST results online using the survey instrument (**Attachment 8**). Background information concerning the classification of each participating laboratory and their DST methods will also be collected. Each participant will be sent a link to enter all information online using the *Survey Instrument* (**Attachment 8**). All testing results data must be entered online at <https://rdcp.cdc.gov/surveys/?s=TMKFMRNW4>.

### **3. Methods to Maximize Response Rates and Deal with No Response**

Participants who have not input their results two weeks prior to the collection deadline will be notified by *Reminder Email* (**Attachment 10**).

### **4. Tests of Procedures or Methods to be Undertaken**

Data collected for the DST results and the laboratory practices are stored as SAS files (or equivalent) data sets and imported into Excel files with a unique identifier. Information collected from participants is compiled, analyzed, and reported in an aggregate report that laboratories can use as a self-assessment tool to maintain the skills needed for DST of MTBC. The *Final Aggregate Report* (**Attachment 12**) is posted on the CDC MPEP Reports Page at <https://www.cdc.gov/tb/topic/laboratory/mpep/reports.htm> and an *Aggregate Report Letter* (**Attachment 11**) and is emailed to all enrollees with a link to the completed report. Data from this program will be used by CDC and other public health organizations to measure reproducibility of susceptibility test results performed with various test procedures in the U.S.

### **5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

Since this ICR does not employ statistical methods, no individuals were consulted on statistical aspects of either the data collection or analysis.