TB Elimination and Laboratory Services: Input on Developing New Funding Opportunity Announcement

OSTLTS Generic Information Collection Request

Supporting Statement – Section A

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Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS Survey Center (OSC) – OMB No. 0920-0879. The respondent universe for this data collection aligns with that of the OSC. Data will be collected from state and local TB Controllers in 62 U.S. health department jurisdictions which includes the 50 states, 9 major U.S. Cities (Baltimore, Chicago, Detroit, Houston, Philadelphia, Los Angeles, New York City, San Diego, San Francisco), the District of Columbia, and two U.S. Territories. Data will also be collected from public health laboratory representatives from58 of the 62 programs –which includes the 50 states, 6 major U.S. cities (Houston, Philadelphia, Los Angeles, New York City, San Diego, and San Francisco), the District of Columbia, and Puerto Rico acting in their official capacities. This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241).

The Centers for Disease Control and Prevention (CDC) awards funds to the above state and local health departments, and to public health laboratories for laboratory services through a cooperative agreement to assist their efforts to prevent, control and with a goal of eliminating TB in the United States. Financial assistance is provided to TB Control programs and public health laboratories to augment current local contributions to core TB Control program activities and ensure that these activities are implemented to meet the needs of TB control and prevention.

TB Control Programs have a mission of carrying out programs to prevent, control, and eventually eliminate TB. The roles and responsibilities of these programs are complex and must be carried out at national, state, and local levels. The state and local public health departments have the primary responsibilities for preventing and controlling TB. TB patients often receive care in a variety of settings, including public and private sectors, which must report all TB cases to the health department in that jurisdiction. Regardless if a patient is being cared for in a public or private setting, state and local health departments must coordinate with the healthcare providers and facilities to ensure prevention and control strategies are being met. TB Control programs must work closely with laboratories to ensure the rapid delivery of specimens or isolates to the state or local public health laboratories for prompt reporting of AFB smear results, culture results, and drug-susceptibility test results to the clinician and health department.

TB Control programs and public health laboratories are awarded funds to augment their program activities based on applications submitted under the Funding Opportunity Announcement (FOA) for the TB Elimination and Laboratory Services Cooperative Agreement. The previous FOA was the starting point for developing the questions to gain insights into the success and challenges TB programs and public health laboratories experienced in meeting the requirements and following the guidance in the current cooperative agreement. The purpose of engaging the representatives of those TB Control programs and laboratory service for input in developing the guidance and requirements in the FOA is a critical component in developing the FOA.

This is the first attempt in gaining this level of insight into their experiences under the current cooperative agreement as part of the development process for the new FOA.

Privacy Impact Assessment

Overview of the Data Collection System – The data collection will be conducted using Adobe Fillable PDF (**see Attachment A –Data Collection Instrument: MS Word version and Attachment B– Data Collection Instrument: Online version**) designed to assess responses from the TB Control program and public health laboratory services that receive awards through the CDC TB Elimination Cooperative Agreement. The data collection instrument will be administered as a web-based assessment using Adobe® Fillable PDF. An email with an HTML link will be sent to respondents. The email will also contain instructions for completing and submitting the data collection instrument.

A pilot study was completed by three subject matter experts. An email with instructions and the html link to the assessment was sent. Participants were asked to record the amount of time to complete and note any technical errors or difficulties. Feedback from this group was used to refine questions as needed and establish the estimated time required to complete the instrument. The average time to complete the instrument was 10 minutes, with a range of 6-15 minutes, including time spent on instructions.

Items of Information to be Collected – The assessment consists of eight questions for which respondents will be informed to respond with narrative in bullet format. The assessment will collect information on the following:

a. Please describe your experience implementing activities required under the current Cooperative Agreement (CoAg, 2010-2014)
b. What challenges did your program experience meeting the expectations under the core components in the current Funding Opportunity Announcement (FOA)?
c. What challenges did your program experience meeting the reporting requirements in the current FOA?
d. What changes in expectations for program activities should be considered that would improve your program's ability to meet essential components of TB prevention and control?
e. What changes in expectations for reporting requirements should be considered that would improve your program's ability to meet national TB program objectives?
f. What additional ideas should be considered for inclusion in the FOA that would address current challenges?
g. How could the FOA better strengthen control and laboratory program interaction and joint effectiveness?
h. How could the FOA improve the timeliness and usefulness of genotyping information in the national surveillance system?

No individually identifiable information is being collected.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age –No website content will be directed at children.

2. Purpose and Use of the Information Collection

The purpose of this data collection is to gain a better understanding of the respondents' experiences in interpreting and meeting the expectations for performing TB services under the current TB Elimination and Laboratory Services Cooperative Agreement for project period 2010 to 2014.

The data collection is necessary because the information gathered will provide insights in those areas of both success and challenges programs had in meeting the requirements and following guidance in the previous FOA. Engaging the representatives of those TB Control programs and laboratory service for input in developing the guidance and requirements in the FOA is an important component in developing the FOA.

The resulting data will be used to determine lessons learned from respondents' experiences, which will assist in providing greater flexibility in the guidance to TB Control programs and public health laboratories in meeting expectations or acting on recommendations in the new TB Elimination and Laboratory Services Cooperative Agreement for project period 2015 to 2019.

Privacy Impact Assessment

CDC will not receive any personally identifiable information. Information will be collected electronically and all data will be entered into secure data bases.

3. Use of Improved Information Technology and Burden Reduction

Data collection will be conducted by using Adobe® Fillable PDF form. Web tools reduce respondent burden by enabling easy access and completion at a convenient time and location. The online data collection instrument will consist of embedded text boxes. Open-ended questions will be used in response to the guidance from the Office of the Associate Director for Programs (OADPG). It was recommended that discussion with potential recipients during the engagement process should not indicate specific strategies or requirements being considered during the development of the FOA. Rather, the discussions should aim at getting a general sense of their experience interpreting and meeting the guidance and expectations under the current FOA, in an effort to assist in the development of the structure and content of the new FOA. Open-ended questions will encourage critical reflection process, collegial feedback, and greater engagement of the respondents. The instrument was designed to collect the minimum information necessary for the purposes of this project. (i.e., limited to eight questions).

4. **Efforts to Identify Duplication and Use of Similar Information**

The information being collected is specific to the CDC TB Elimination and Laboratory Services Cooperative Agreement. The Division of TB Elimination is solely responsible for developing the FOA for the TB Elimination and Laboratory Services Cooperative Agreement, therefore, there is no other entity collecting the information for this purpose. This is the first attempt in using this data

collection instrument to gain this level of insight into the respondents' experiences in interpreting and meeting the expectations for performing activities to prevent, control, and eliminate TB under the current TB Elimination and Laboratory Services Cooperative Agreement for project period 2010 to 2014.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

This request is for a one time data collection. There are no legal obstacles to reduce the burden.

The consequence for not collecting this information would be:

- Developing an FOA for the TB Elimination and Laboratory Services Cooperative Agreement without valuable input to ensure the guidance and requirement in the announcement is grounded in field wisdom.
- Failure to gather the information from TB Control programs and public health laboratories during the development of the new FOA could result in guidance and requirements that do not best support meeting objectives in the elimination of TB.
- Providing guidance and stating requirements in the new FOA without the input from the TB Control programs and public health laboratories could lead to inefficiencies in the services provided by the programs.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS Survey Center (OSC) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on October 22, 2010, Vol. 75, No. 204; pp. 65353-54. Two comments were received from the Association of State and Territorial Health Officials (ASTHO), and the National Association of County and City Health Officials (NACCHO).

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act does not apply to this data collection. Employees of state and local public health agencies will be speaking from their official roles and will not be asked, nor will they provide individually identifiable information.

This data collection is not research involving human subjects.

11. Justification for Sensitive Questions

No information will be collected that are of personal or sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours is based on 62 state and local TB program representatives from the 50 states, 9 major U.S. Cities (Baltimore, Chicago, Detroit, Houston, Philadelphia, Los Angeles, New York City, San Diego, San Francisco), the District of Columbia, and two U.S. Territories; and 58 public health laboratory representatives including the 50 states, 6 major U.S. cities (Houston, Philadelphia, Los Angeles, New York City, San Diego, and San Francisco), the District of Columbia, and Puerto Rico. In the pilot test, the average time to complete including time for reviewing instructions, gathering needed information and completing the assessment, was approximately 10 minutes, with a range of 6-15 minutes. For the purposes of estimating burden hours, the upper limit of this range (i.e., 15 minutes) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations – medical and health services managers in state government (http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf). Based on DOL data, an average hourly wage of $57.11 is estimated for all 120 respondents. Table A-12 shows estimated burden and cost information.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
State and Local TB Controllers and public health laboratory representatives	120	1	15/60	30	$57.11	$1713.30
TOTALS	**120**	**1**		**30**		**$1713.30**

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no direct costs to the respondents.

14. Annualized Cost to the Government

There are no equipment or overhead costs. Contractors are not being used to support this data collection. The only cost to the federal government would be the salary of CDC staff supporting the data collection activities and associated tasks. The lead staff from the Division of Tuberculosis Elimination, CDC for this project consists of a Lead Public Health Advisor, Supervisory Health Scientist, and Public Health Analyst from the Field Service and Evaluation Branch; and a Microbiologist (Team leader) from the Laboratory Services Branch. The lead staff will collect the data; code, enter, and prepare the data for analysis; conduct data analyses and prepare the evaluation report. Hourly rates of $39.00 for GS-11 (step 3), $52.00 for 3 GS-14 staff were used to estimate staff costs. The estimated cost to the federal government is $14,040. Table A-14 describes how this cost estimate was calculated.

Table A-14: Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Public Health Analyst (GS-9) Instrument development, pilot testing, OMB package preparation, data collection, data coding and entry, quality control, data analysis, report preparation	200	$39.00	$7800.00
Microbiologist (GS-14), Team lead, Laboratory Capacity Team Instrument development, pilot testing, OMB package preparation, report preparation	40	$52.00	$2080.00
Program Evaluation Team Lead (GS-14) Instrument development, OMB package preparation	40	$52.00	$2080.00
Lead Public Health Advisor (GS-14) Instrument development, communications with respondent universe, data analysis	40	$52.00	$2080.00
Estimated Total Cost of Information Collection			**$14,040**

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish the results of this data collection. CDC lead staff will share the results with the workgroup developing the FOA and during any stakeholder engagement meeting or discussion scheduled as part of the FOA development process.

Project Time Schedule

- ✓ Design questionnaire.....(COMPLETE)
- ✓ Develop protocol, instructions, and analysis plan.....(COMPLETE)
- ✓ Pilot test questionnaire.....(COMPLETE)
- ✓ Prepare OMB package.....(COMPLETE)
- ✓ Submit OMB package.....(COMPLETE)
- ❑ OMB approval.....(TBD)
- ❑ Conduct assessment.....(open 3 weeks)
- ❑ Collect, code, enter, quality control, and analyze data.....(1 week)
- ❑ Prepare report.....(1 week)
- ❑ Disseminate results/reports.....(TBD)

17. Reason(s) Display of OMB Expiration Date is Inappropriate
We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions
There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

LIST OF ATTACHMENTS – Section A

Attachment A –Data Collection Instrument – Word Version

Attachment B –Data Collection Instrument-Online Version