National Tuberculosis (TB) Laboratory Services Survey
Generic Information Collection under 0920-0840: Formative Research and Tool Development

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Request for Generic Collection Under the
Approved Generic ICR: Formative Research and Tool Development
OMB No. 0920-0840
National Tuberculosis (TB) Laboratory Services Survey
Supporting Statement Part A.

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Formative Research and Tool Development
National Tuberculosis (TB) Laboratory Services Survey
Supporting Statement

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

This is a generic information collection (generic IC) request under the umbrella collection: Formative Research and Tool Development (OMB No. 0920-0840).

The Centers for Disease Control and Prevention (CDC) requests approval to evaluate a survey instrument that captures information regarding tuberculosis (TB) laboratory services, testing volumes, turn-around times, referral strategies, and training needs from public health, commercial, and clinical laboratories that provide some level of TB testing in the United States.

Background

In 2002, the Association of Public Health Laboratories (APHL) and the CDC commissioned a *Task Force on the Future of TB Laboratory Services in order* to develop recommendations that assure continued availability of high-quality, cost-effective TB laboratory services. The Task Force formulated three key benchmarks of which one was a comprehensive assessment of available TB laboratory services in the public and private sector to fill gaps in knowledge about the capabilities and capacities of jurisdictional laboratory networks. The need to conduct this type of assessment was reiterated in the 2009 Federal TB Task Force *Plan to Combat XDR TB* (2).

CDC/ Mycobacteriology Laboratory Branch (MLB) are collaborating with APHL in the development of a new survey instrument . Data gathered from this comprehensive survey will be utilized for the formation of new programs by state and local public health laboratories and CDC/ MLB for the development and/or strengthening of laboratory systems through training, partnership building, and information exchange. The first step towards developing sound recommendations that improve laboratory performance with guidelines for TB laboratory services is a comprehensive assessment of the current state of TB laboratory services.

A.1.2 Privacy Impact Assessment

The data collection pertains to laboratory information, not information about individuals. The identity of the person responding on behalf of the laboratory will not be collected. Laboratory names and street addresses will be stripped from the

data base that is submitted to CDC. Neither APHL nor CDC will receive any information in individually identifiable form.

A.1.3 Overview of the Data Collection System

Information will be collected electronically via a web-based survey using the MRInterview Database system. The information collection activity in this application allows for usability and field testing of a technology-based instrument that will collect both qualitative and quantitative data from U.S. laboratories providing some level of TB diagnostic service. The purpose of this testing is to develop a web-based survey that can be used by CDC to quickly assess laboratory testing capacities and capabilities for establishment of interventions and relevant communications at the federal and local level in response to changes in the epidemiology of TB.

A.1.4 Items of Information to be Collected

APHL has received federal funds to implement the tool development project. The items of information that will be collected include: laboratory testing methodologies and volumes, referral strategies, turn-around times, reporting practices, laboratory staff and training, safety practices, proficiency testing, and future plans for expansion/ reduction of services (Attachment 1) (test link- http://research.aphl.org/mriweb/mriweb.dll?i.project=aphltb3).

Qualitative data will include awareness of CDC/ MLB and local public health laboratory programs, services, and training opportunities. Quantitative data includes testing volumes and turn-around times. Although the survey is comprehensive in scope, very few laboratories (estimated <15%) will answer all questions. Laboratories will be routed through sections of the instrument based on the level of TB laboratory testing service offered (e.g., AFB smear microscopy, culture, identification, drug susceptibility testing) as identified early in the survey.

A.1.5 Identification of Websites and Website Content Directed at Children Under 13 Years of Age

This information collection does not involve websites or website content directed at children less than 13 years of age.

A.2. Purpose and Use of Information Collection

A.2.1 Field testing of new methodologies and materials

The purpose of this information collection is to develop and field-test a new web-based survey. This survey instrument was

developed as a result of recommendations included in the 2002 APHL/CDC *Task Force on the Future of TB Laboratory Services* (1) and the 2009 Federal TB Task Force *Plan to Combat XDR TB* (2). Both of these documents stated that a comprehensive assessment of TB laboratory services in the US was needed to ensure continued progress in strengthening domestic laboratory capacity critical for TB elimination. The development and implementation of this survey instrument represents a new strategy by CDC/ MLB for improving existing CDC-funded programs and development of evidence-based recommendations aimed at enhancing US TB laboratory capacity. Data from the field testing will be used to improve the existing instrument and survey methodologies that would reduce the public burden of future data collections.

A.3. Use of Improved Information Technology and Burden Reduction

Testing will be conducted via a web-based survey designed using MRInterview Database software. Access to the web-based survey is provided via an individualized log-in and password that are embedded in a link distributed to each potential respondent in the letter of invitation. When a respondent clicks on the link, they will automatically be authenticated into the survey will not have to type in a 'user id' and 'password'.

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

NCHHSTP has verified that there are no other studies that duplicate the current effort.

A.5. Impact on Small Businesses and Other Small Entities

This research activity will involve data collection from small businesses (e.g., clinical and small commercial laboratories) and small public health laboratories. These entities will be asked to identify the most appropriate staff members to voluntarily complete the data collection instrument. Efforts will be made to limit the burden on these small businesses and entities by conducting the survey electronically and integrating routing and logic algorithms to minimize the number of questions that respondents will answer. Only a very small subset (estimated <15%) of respondents will answer all questions and most of these entities will be representative of large public health, clinical, and commercial laboratories because of the level of TB laboratory testing services offered. As such, participation in this survey will not affect the normal operation of these entities.

A.6. Consequences of Collecting the Information Less Frequently

The activities involve a one-time collection of data. There are no legal obstacles to reducing the burden.

A.7. Special Circumstances Relating to Guidelines of 5 CFR 1320.5
This request fully complies with the regulation 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agencies
For sub-collection requests under a generic approval, federal register notices are not required and none were published.

A.9. Explanation of Any Payment or Gift to Respondents
No payment or gift will be given to respondents.

A.10. Assurances of Confidentiality Provided to Respondents
IIF will not be collected as part of this study.

The grantee, APHL, will make efforts to securely maintain data. Data will be maintained on a local server at APHL and backed-up nightly to a server located off site. Access to data will be limited to APHL personnel directly involved in the information collection and will be password protected. Neither the identity of the participating laboratory nor that of the person responding on behalf of the laboratory will be known to CDC. Laboratory identifiable information will be removed prior to the transmission of data from APHL to CDC/ MLB. IRB approval is not required for this project (Attachment 4). The voluntary nature of the survey is described to potential respondents in the letter of invitation and the introductory paragraph of the survey instrument.

A.11. Justification for Sensitive Questions
This survey collects information from laboratories concerning organizational policies, turn-around time performance data, and work practices. A portion of potential respondents may view these questions as sensitive. However, identifiable information regarding specific laboratories will not be disclosed to CDC and only aggregate data will be publicly available from APHL. Therefore, participation in this study should not result in liability or competitive advantage. These potentially sensitive questions are necessary to identify opportunities to strengthen TB systems nationally and in local jurisdictions.

A.12. Estimates of Annualized Burden Hours and Costs

A.12.A. Estimated Annualized Burden Hours
CDC/ MLB estimates that a total of 1,588 potential respondents would spend on average, one hour in the collection, management,

and reporting of information for this project. Time estimates are based on the experience of APHL in conducting surveys of similar complexity.

Exhibit A.12.A Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response	Total Response Burden (Hours)
Mycobacteriology laboratory staff	Survey of Individual laboratory	1588	1	1	1588
Total					**1588**

A.12.B. Estimated Annualized Costs

The collection described here-in is funded through a cooperative agreement to the APHL. The survey will be completed primarily by medical and clinical laboratory technologists on behalf of the participating laboratories. Approximately 87% of potential respondent laboratories will be hospital-based clinical laboratories. As such, the annualized cost to the respondent is based on The United States Department of Labor, Bureau of Labor Statistics hourly wage rate for hospital-based clinical laboratory technologists (http://www.bls.gov/oco/ocos096.htm).

Exhibit A.12.B. Annualized Cost to Respondents

Activity	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Cost**
Surveys	1588	$23.45	$37238.60
Total	**1588**		$37238.60

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

None. CDC does not anticipate providing start up or other related costs to private entities.

A.14.Annualized Costs to the Federal Government

The National TB Laboratory Services Survey is funded as a supplement to the APHL cooperative agreement for two years in the amount of $240,590. This amount includes salary support, travel, and supplies for development and distribution of the survey instrument. The cooperative agreement monies also support data management, analysis, and a development of a final report of the survey data. Direct costs to the government include the salary for the CDC project officer and co-investigators providing statistical support.

Expense Type	**Expense Explanation**	**Annual Costs (dollars)**
Direct Costs to the Federal Government		
	CDC Project Officer (GS-13, 0.5 FTE)	$45,600
	CDC Co-investigator (GS-12, 0.1 FTE)	$7,190
	CDC Data Manager (GS-13, 0.2 FTE)	$18,240
	CDC Travel (2 trips)	$8,000
	Subtotal, Direct costs	**$79,030**
Cooperative Agreement	Cooperative Agreements with APHL for implementation and information management	$240,590
	TOTAL COST TO THE GOVERNMENT	**$319,620**

A.15.Explanation for Program Changes or Adjustments

Not applicable – request is for a sub-collection under a generic approval.

A.16.Plans for Tabulation and Publication and Project Time Schedule

Activity	Time Schedule
Distribute initial notification of survey (1 week before survey goes live)	Within 1 month after OMB approval
Send letter of invitation with link to survey	1 month after OMB approval
Email reminders to increase response rate (at 2, 4, and 5 weeks)	1 ½ month- 3 months after OMB approval

Data management and validation	4-5 months after OMB approval
Initial analyses by APHL and transfer of de-identified data to CDC	5-7 months after OMB approval
Final data analysis and review of results with expert consultants	7-9 months after OMB approval
Dissemination of APHL aggregate report to survey participants and public	9 months after OMB approval
In-person meeting of survey working group and development of recommendations to improve instrument and CDC/ MLB programs	10-12 months after OMB approval

A.17.Reason(s) Display of OMB Expiration Date is Inappropriate
OMB Expiration Date will be displayed.

A.18.Exceptions to Certification for Paperwork Reduction Act Submissions
There are no exceptions to the certification.

References

1. The Future of TB Laboratory Services. Association of Public Health Laboratories. 2004. http://www.aphl.org/aphlprograms/infectious/tuberculosis/Documents/TB_Task_Force_Future_2004.pdf

2. Plan to Combat Extensively Drug-Resistant Tuberculosis: Recommendations of the Federal Tuberculosis Task Force. Morbidity and Mortality Weekly Report. February 13, 2009 / Vol. 58 / No. RR-3. http://www.cdc.gov/mmWR/PDF/rr/rr5803.pdf