Report of Verified Case of Tuberculosis (RVCT)
OMB No. 0920-0026 Exp. 3/31/2017

Supporting Statement Part A

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Goal of the study: To accomplish the goal of tuberculosis (TB) elimination in the United States, DTBE maintains the National TB Surveillance System (NTSS), initiated in 1953 and modified several times to better monitor and respond to changes in TB morbidity. This proposal is to extend without changes the currently approved data collection instrument, the Report of Verified Case of TB (RVCT).

Intended use of the resulting data: NTSS enables federal health officials to efficiently detect and respond to TB outbreaks or changes in morbidity patterns, and it facilitates evaluation of federal, state, and local TB prevention and control efforts through collection of timely and standardized data.

Methods to be used to collect: NTSS is a comprehensive infectious disease surveillance system. The intent is to conduct an actual enumeration of TB cases in the United States so no sampling methodology is necessary. The resulting dataset is analyzed using descriptive statistical methods as well as retrospective cohort and cross-sectional epidemiologic study methods.

The subpopulation to be studied: NTSS collects data on the population of persons diagnosed with TB disease in the United States.

How data will be analyzed: Data are analyzed using descriptive methods (e.g., averages, ranges, measures of dispersion) for general reporting purposes. Additional analyses in support of specific public health questions involve these descriptive methods as well as hypothesis testing using bivariate and multivariate methods such as regression models.

A. Justification

1. Circumstances Making the Collection of Information Necessary

CDC's Division of Tuberculosis Elimination (DTBE) is responsible for coordinating national efforts to eliminate tuberculosis (TB) from the United States. In order to track progress toward elimination and better understand the changing epidemiology of TB in the United States, comprehensive case-based surveillance for TB is necessary. The National TB Surveillance System (NTSS) has been operated by the U.S. Public Health Service in cooperation with state, local, and territorial reporting areas since 1953. NTSS's current data collection instrument, the Report of Verified Case of Tuberculosis (RVCT), is currently OMB-approved as information collection No. 0920-0026 (exp. 03/31/2017).

In the late 1980s and early 1990s, reported TB cases in the United States increased after decades of decline, reaching a peak of 26,673 in 1992. This resurgence was associated with the HIV/AIDS epidemic, immigration from TB-endemic countries, transmission in hospitals and prisons, deterioration of infrastructure for TB control programs, and development of difficult multidrug-resistant (MDR) TB cases. In 2014, the most recent year for which data are published, 9,421 cases of TB were reported to NTSS. This represents a 1.5% decline compared to the 2013 case count, and a decrease of approximately 65% since the 1992 TB resurgence peak. This success has been in part because of DTBE's ability to monitor trends in the epidemiology of TB through NTSS.

CDC and the Council of State and Territorial Epidemiologists have identified TB as a nationally notifiable disease, and TB is a reportable disease in every state. These measures have been taken because of the continued critical need to monitor and track cases of TB in the United States.

2. Purpose and Use of the Information Collection

The information collected via the RVCT (**Attachment** 3) is used to assist federal, state, and local public health officials and policy makers in TB program planning, evaluation, and resource allocation. Annual summaries of the surveillance data are used to monitor national trends of TB by demographic and risk conditions. These annual reports are made available for the use of federal, state, and local agencies and released to the public via the DTBE web site: http://www.cdc.gov/tb/surv/default.htm. In addition, public use aggregate data have been made available at the Online Tuberculosis Information System (OTIS): http://www.cdc.gov/tb/surv/default.htm and the NCHHSTP Atlas: http://www.cdc.gov/nchhstp/atlas/.

CDC periodically conducts special analyses for publication in peer-reviewed scientific journals to describe and interpret NTSS data to identify key trends and high-risk groups and assist in developing elimination strategies. The surveillance data are also used in DTBE materials for training and education of health care providers, the general public, and the media. Examples included a clinician's reference, the "Interactive Core Curriculum on Tuberculosis: What the Clinician Should Know," and materials for use by local health officials working with the media for the annual World TB Day. These materials are posted on the main DTBE web site: http://www.cdc.gov/tb/default.htm.

3. Use of Improved Information Technology and Burden Reduction

DTBE has been an active participant in the CDC development of the National Electronic Disease Surveillance System (NEDSS) and the Public Health Information Network (PHIN), a national initiative to improve the capacity of public health to use and exchange information electronically by promoting the use of standards, defining functional and technical requirements. PHIN strives to improve public health through best practices related to efficient, effective, and interoperable public health information systems. The adoption of PHIN standards continues to reduce the burden of reporting areas by providing ready access to electronic laboratory data (thus reducing double data entry) and by enhancing the timeliness and ease of reporting. DTBE has developed two software products that use NEDSS/PHIN standards: 1) a TB module integrated within the CDC-developed NEDSS Base System, a system of web-based modules that support state notifiable disease surveillance, and 2) a PHIN-compliant messaging platform for state and local users who do not plan to use the NEDSS Base System, which is known as the NTSS Case Report. These tools have been tested and deployed in collaboration with state and local TB program stakeholders. States also have the option to use either the CDC associated TB modules or their own TB surveillance application to collect and report RVCT data to CDC.

4. Efforts to Identify Duplication and Use of Similar Information

Through literature searches, attendance at national TB meetings/conferences, and ongoing consultations with TB experts nationwide, DTBE has determined that RVCT data are unique and not available from any other source within the federal government or from non-federal sources. The RVCT data collected by NTSS provide the sole source of comprehensive, complete national TB statistics collected in a timely and standardized manner.

5. Impact on Small Business or Other Small Entities

Data collection (i.e., RVCT) and electronic submission to CDC from the reporting areas is done by TB control programs in the public health sector. No small businesses or small entities are part of the respondent universe.

6. Consequences of Collecting the Information Less Frequently

CDC requests that reporting areas send electronic transfers on a monthly basis. Monthly transmissions have been the norm since initiation of electronic RVCT reporting in 1993. Due to improvements in information technology now being web-based, many TB programs are transmitting data more frequently, such as weekly or even daily. To minimize reporting burden, areas that have only a few cases per year send transfers on a quarterly basis, or less frequently if no cases have been reported. The goal of this transfer schedule is to finalize annual data within several months after the close of the calendar year. This transfer schedule has facilitated keeping reporting area and CDC databases up to date, to ensure timely and accurate assessments of trends. This process has also enabled DTBE to evaluate data quality on an ongoing basis in order to efficiently detect, investigate, and resolve data issues with the reporting areas. DTBE periodically discusses the frequency of electronic data transmission with reporting areas to determine the optimum frequency in order to keep respondent burden low while still allowing prompt identification of changes in TB trends. Less frequent collection would impede the ability of CDC to maintain an accurate and timely database that is finalized each year within the first quarter following the end of the calendar year.

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

Collection of RVCT data is conducted in a manner consistent with the guidelines in 5 CFR 1320.5. DTBE requests that reporting areas electronically transfer RVCT updates and new cases on a monthly basis as justified under section 7.

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

A 60-day Federal Register notice was published in Vol. 81, No. 163, Tuesday, August 23, 2016 on page 57588 (**Attachment 2**). No public comments were received during the 60 day comment period.

DTBE has closely collaborated with its partners and stakeholders concerning the RVCT and NTSS to obtain their views and any suggested improvements. The RVCT data collection instrument was developed with TB control officers and surveillance coordinators and was vetted and endorsed by DTBE partner organizations including the Council for State and Territorial Epidemiologists (CSTE), address: 2872 Woodcock Blvd, Ste-250, Atlanta, GA 30341, Office: 770-458-3811,website: http://www.cste.org; and the National Tuberculosis Controllers Association (NTCA), address: 2452 Spring Road, SE, Smyrna, GA 3080; Office: 678-503-0503; Email: ntca@tbcontrollers.org; Website: http://tbcontrollers.org.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive payments or gifts.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CDC NCHHSTP Associate Director of Science Office reviewed this submission and has determined that the information collected under this request will include personally identifiable information (PII) covered by the Privacy Act such as the name and address information, which are retained by the respondents/reporting areas. CDC receives only a state case number, and a city/county case number. State and city/county case numbers do not include names or other personal identifiers (e.g., Social Security number). The electronic RVCT data files for submission to CDC are encrypted and password protected, with only authorized staff having access to the files. Because the data shared with CDC will not contain PII to be stored in any information system at CDC, a System of Records Notice (SORN) for a CDC information system is not required to support the information collection request.
Routine disease surveillance activities, such as the ongoing national TB surveillance system since 1953, are excluded from 45 CFR 46, Regulations for the Protection of Human Subjects. An assurance of confidentiality is provided to all respondents according to section 308(d) of the Public Health Service Act (42 USC 242m) which states:

"No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section...306 (NCHS legislation),...may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose and (1) in the case of information obtained in the course of health statistical or epidemiological activities under section...306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form,..."

In addition, legislation covering confidentiality is provided according to section 513 of the Confidential Information Protection and Statistical Efficiency Act (PL 107-347) which states:

"Whoever, being an officer, employee, or agent of an agency acquiring information for exclusively statistical purposes, having taken and subscribed the oath of office, or having sworn to observe the limitations imposed by section 512, comes into possession of such information by reason of his or her being an officer, employee, or agent and, knowing that the disclosure of the specific information is prohibited under the provisions of this title, willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a class E felony and imprisoned for not more than 5 years, or fined not more than $250,000, or both."

Under the assurance, information that would permit identification of any individual on whom a record is maintained by CDC is collected with a guarantee to the agency providing the information that it will be held in strict confidence, will be used only for purposes stated in the assurance statement, and will not otherwise be disclosed or released without the consent of the individual.

Reporting areas completing the RVCT retain name and address information for treatment and follow-up of TB cases. CDC receives only a state case number, and a city/county case number. State and city/county case numbers do not include names or other personal identifiers (e.g., Social Security number). The state case number is the official identification number for the case and is used to facilitate communication between CDC and a reporting area when data issues are identified. Respondents are adding to their already existing record systems and data are maintained for a minimum of three years. Data or information retained by state or local health officials is protected in accordance with state law.

The electronic RVCT data files for submission to CDC are encrypted and password-protected, with only authorized staff having access to the files. Line-listed data in hard copy form, when temporarily needed for data management purposes, are kept in locked files in the DTBE surveillance offices when not in use. Incoming electronic transmissions are added to the previous data to enable annual summaries of trends in TB morbidity. Under the assurance of confidentiality, no CDC TB surveillance data that could be used to identify any individual whether directly or indirectly will be made available to anyone for non-public health purposes.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

NCHHSTP scientific review has determined that the information collection is not research involving human subjects, thus IRB approval is not required. (**Attachment 5)**

Sensitive Questions

The RVCT collects information on sensitive matters such as:

a) HIV status – The HIV/AIDS epidemic was one of the primary factors contributing to the resurgence of TB in the late 1980s and early 1990s. This is because people with HIV infection

are at extremely high risk for developing TB once infected with *Mycobacterium tuberculosis*. The HIV/AIDS epidemic has had an impact on TB morbidity and extent of drug-resistance, and is therefore extremely important to monitor.

b) Drug use (injecting, non-injecting) and excess alcohol use – One of the major reasons for acquiring drug-resistant TB is nonadherence to the prescribed regimen of medications. Behaviors that place TB patients at risk for non-adherence include drug use and excess alcohol use. In addition, injecting drug use is an important HIV risk factor.

c) Race/Ethnicity – In compliance with the 1997 Department of Health and Human Services Secretarial Initiative, CDC routinely collects race/ethnicity data whenever appropriate, including surveillance reports. The race/ethnicity categories in this information collection conform to OMB Directive 15.

d) Immigration status at entry to the United States – The percentage of TB cases accounted for by foreign-born persons has steadily increased from 22% in 1986 to 66% in 2014. In addition, multidrug-resistant (MDR) TB cases reported in foreign-born persons increased from 25% of all primary MDR TB cases in 1993 to 85% in 2014. As a result of disproportionately high TB and drug-resistant TB burden among foreign-born persons, immigration characteristics of foreign-born persons with TB are important to assess the impact of immigration screening guidelines.

12. Estimates of Annualized Burden Hours and Costs

A. The total number of respondents is the 60 reporting areas (50 states, the District of Columbia, New York City, Puerto Rico, and 7 U.S.-affiliated jurisdictions in the Pacific and Caribbean). Estimates of time to complete the RVCT (CDC form 72.9 series), are based on reports from the 60 respondents. For burden hours, we consider the RVCT as a single form because health jurisdictions complete all three parts and submit them to CDC as a single record comprised of the Initial Case Report (72.9A), Initial Drug Susceptibility Report (72.9B), and Case Completion report (72.9C).

The respondent burden is estimated to average 35 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The number of responses per respondent is calculated as the total number of annual TB cases reported to CDC divided by 60 respondents. CDC received reports of 9,421 TB cases in 2014. Based on 2014 RVCT data, the total response burden hours for 60 reporting areas is 5,495.

Table 12-A. Estimated Annualized Burden Hours

Types of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden hours

Local, state, and territorial health departments	Report Of Verified Case Of Tuberculosis	60	157	35/60	5,495
Total					5,495

Table 12-B: Estimate of Annualized Cost to Respondents

Types of respondents	Total Burden Hours	Hourly Wage Rate*	Total Respondent Costs**
State Health Departments	5,495	$19.72	$108,361
Totals	5,495		$108,361

CDC's cooperative agreement for TB elimination program to state and local health departments provides salaries of data collection staff. We used the median (step 5) from the 2016 General Schedule (GS) Locality Pay Table: Salary & Wages Table to estimate cost to the respondent https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/ATL.pdf. Respondent costs are paid by CDC DTBE through cooperative agreements with state and local health departments for completing the RVCT and are included in section 14 as Cost to the Government.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers
There are no costs to respondents other than their time.

14. Annualized Cost to the Federal Government

The national TB surveillance system collects information via the RVCT. Management of the system includes personnel such as epidemiologists, data managers, information specialists, and computer programmers/analysts. DTBE personnel provide technical support in-house and to the field for data collection and CDC reporting software. Estimated annualized cost for the RVCT includes, in part, the cost of the national TB surveillance system, the cooperative agreements with the state and local health departments and the salaries of the full-time staff that are involved in data analyses and report preparations. Costs were derived from the 2016 General Schedule (GS) Locality Pay Table: Salary & Wages Table to estimate cost to the respondent https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/ATL.pdf.

Table 14A: Estimates of Annualized Costs to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs		
	CDC Surveillance Supervisor (GS-14, 1 FTE)	$118,263
	CDC Epidemiologist (GS-14, 1 FTE)	$118,263
	CDC Epidemiologist (GS-14, .50 FTE)	$59,131
	CDC Epidemiologist (GS-13, 1 FTE)	$100,081
	CDC Epidemiologist (GS-12, .50 FTE)	$42,081
	CDC Statistical Assistant (GS 9, .25 FTE)	$14,508
	CDC Data Manager/Analyst (GS-14, 1 FTE)	$118,263
	CDC Data Manager/Analyst (GS-13, 1 FTE)	$100,081
	CDC Software Engineer (GS-13, .75 FTE)	$75,061
	CDC Public Health Analyst (GS-13, 1 FTE)	$100,081
	CDC Computer Systems Analyst (GS-14, 0.75 FTE)	$88,697
	CDC Information Specialist (GS-11, 1 FTE)	$66,563
	CDC Information Specialist (GS-12, 0.5 FTE)	$70,216
	Office supplies and equipment	$5,000
	Printing of RVCT forms and annual reports	$10,500
	Travel	$10,000
	Subtotal, Direct Costs to the Government	$1,096,789
Cooperative Agreements	60 reporting areas	$108,361*
Benefits	25% overhead (FTE & cooperative agreement wages)	$274,197.25
	Subtotal, Indirect Costs to the Government	$382,578
	TOTAL ANNUALIZED ESTIMATED COST TO THE GOVERNMENT	$1,479,347

* Included as cost to respondent in Table 12B

15. Explanation for Program Changes or Adjustments

This extension request includes no changes to the currently approved data collection form. The table below summarizes the changes of response burden from the previous OMB submission in 2014. The estimated decrease of 315 burden hours is due to having fewer TB cases reported in the United States as we continue progress towards TB elimination.

Table 15A: Program Changes to Current OMB No. 0920-0026

	Year	
	2016	2014
Number of respondents	60	60
Number of responses per respondent	157	166
Hours per response	35/60	35/60
Total burden (hours)	5496	5810
Change in burden from 2014 submission (hours)	-315	

16. Plans for Tabulation and Publication and Project Time Schedule

Collected RVCT data are analyzed and published annually in the report, "Reported Tuberculosis in the United States," and its accompanying slide set. This report is completed approximately 4 months after the data are finalized. For example, the national TB surveillance data for 2015 were provisionally published in March 2016 then finalized in July 2016, with the final report to be posted on the DTBE web site and distributed to TB control officers in October 2016. The short time between data finalization and publication provides prompt dissemination of current TB morbidity trends and timely evidence for decision makers related to program planning, evaluation, and resource allocation.

For the 2016 annual national TB surveillance data collection (January through December 2016), the following time schedule has been estimated based on timelines from the previous five years of TB data collection, analyses, and publication.

Table 16A. Project Time Schedule (Include activities from 27-36 months)

Activity	Time Schedule
Reporting health departments continue using the RVCT for data collection	Ongoing for 36 months after OMB extension approval (March 2017)
Complete/submit 2016 RVCT data	6-9 months after OMB extension approval
Provisional reporting of 2016 RVCT data	10 months after OMB extension approval
Final data validation for 2016 data	12 - 15 months after OMB extension approval
Final data analysis for 2016 data	15 - 18 months after OMB extension approval
Final annual report publication for 2016 data	20 months after OMB extension approval

17. Reason(s) Display of OMB Expiration Date is Inappropriate

CDC is not seeking exemption of display of the expiration date for OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions

No exceptions to certification are requested.