Report of Verified Case of Tuberculosis (RVCT)
OMB No. 0920-0026 Exp. 5/31/2014

Supporting Statement Part A

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A. Justification

1. Circumstances Making the Collection of Information Necessary

CDC is requesting 3-year extension to current OMB approval of the Report of Verified Case of Tuberculosis (RVCT) information collection No. 0920-0026 (exp. 05/31/2014), for the National Tuberculosis (TB) Surveillance System (NTSS). TB is a reportable disease in every state. NTSS has been conducted and maintained by the U.S. Public Health Service through the cooperation of the states since 1953. Respondents are public health departments that receive annual federal funds for TB control and surveillance through CDC cooperative agreements. CDC conducts and maintains NTSS pursuant to the provisions of Section 301 of the Public Service Act [42 U.S.C. 241 (a)] and Section 306 of the Public Health Service Act [42 U.S.C. 242k] to avoid identification of any unique individual (**Attachment 1**). Data management procedures have not changed and the data instrument has not been revised since prior approval.

Since 2011 when OMB granted renewal for the RVCT, the information collected by NTSS has continued to be used to assist federal, state, and local public health officials and policy makers in program planning, evaluation, and resource allocation. Annual summaries of the surveillance data were used to monitor national trends of TB by demographic and risk conditions. These annual reports were published as a report for the agency. Annual reports were also disseminated to health department TB control officers, pulmonary and infectious disease experts, and others concerned with TB control. The annual surveillance report and accompanying summary slide set were posted on the DTBE web site: http://www.cdc.gov/tb/surv/default.htm each year. In addition, public use aggregate data were available at the Online Tuberculosis Information System (OTIS): http://www.cdc.gov/tb/surv/default.htm and the CDC ATLAS: http://www.cdc.gov/nchhstp/atlas/.

CDC periodically conducted 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 were 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. The clinician's reference and brochures for World TB Day were posted on the main DTBE web site: http://www.cdc.gov/tb/default.htm.

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 2012, the most recent year for which data are published, 9, 945 cases of TB were reported to NTSS. This represents a 5.4% decline compared to the 2011 case count, and a decrease of approximately 63% since the 1992 TB resurgence peak. The mission of the CDC Division of Tuberculosis Elimination (DTBE) is to provide leadership in preventing, controlling, and eventually eliminating TB from the United States in collaboration with partners at the community, state, and international levels. To accomplish this mission, DTBE key activities include supporting a nationwide framework for monitoring TB morbidity. NTSS continues to be critical for detecting risk factors for TB resurgence and providing the scientific basis to obtain resources to control and eliminate TB. CDC is requesting 3-year OMB

clearance extension approval for continued use of the NTSS data collection form, RVCT OMB No. 0920-0026.

2. Purpose of Use of the Information Collection

To accomplish the goal of TB elimination in the United States, DTBE maintains NTSS, initiated in 1953 and modified several times to better monitor and respond to changes in TB morbidity. This proposed extension involves no changes to the currently approved data collection instrument.

In 1985, NTSS changed from collecting aggregate data to collecting individual case reports using the Report of Verified Case of Tuberculosis (RVCT). In 1993, the RVCT was expanded in response to the TB epidemic of the late 1980s and early 1990s and incorporated into a CDC software package for electronic reporting of TB case reports to CDC. A modification was implemented in 2002, when race and ethnicity variables were modified to comply with OMB standards for federal data. Finally, a revision of variables was conducted in 2009 to reflect stakeholder requirements and changes in TB diagnostics, drugs, and epidemiology since 1993. This request reflects extension without changes to the current RVCT.

Data are collected by health departments in 60 reporting areas (the 50 states, the District of Columbia, New York City, Puerto Rico, and 7 jurisdictions in the Pacific and Caribbean). An RVCT is completed for each TB case and contains demographic, clinical, and laboratory information. Reporting areas review and analyze their RVCT data to monitor local TB trends, evaluate program success, and assist in focusing resources to eliminate tuberculosis. These data

are routinely collected in the operation of TB control programs. RVCT data are stripped of unique identifiers prior to transmission of reports to CDC.

The surveillance system also responds to special data requests to assist other government agencies and organizations in TB control and prevention activities. Specific examples include use by the Institute of Medicine (IOM) Committee on the Elimination of Tuberculosis in the United States in their 2000 report on TB control, “Ending Neglect: The Elimination of Tuberculosis in the United States,” and in CDC’s response to IOM’s TB elimination challenge. Similarly, the U.S. General Accounting Office report (GAO-01-82) focusing on MDR TB, “Trends in Tuberculosis in the United States,” is based on data from the national surveillance system. The collection of information on TB morbidity also helps to determine resources required for federal elimination efforts, including support of state and local TB programs.

Without extension of OMB approval for the NTSS data collection form, CDC will not be able to:

- Provide reliable and consistent information on the extent and distribution of the TB problem in the United States.
- Enable federal health officials to efficiently detect and respond to outbreaks or changes in morbidity patterns.
- Allow evaluation of federal, state, and local TB prevention and control efforts based on timely and standardized data.
- Help achieve the goal of TB elimination in the United States.

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 electronic RVCT (eRVCT). 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.

There are no legal or technical obstacles to reducing burden.

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 1320.6. DTBE requests that reporting areas electronically transfer RVCT updates and new cases on a monthly basis as justified under section A.6.

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

A 60-day Federal Register notice was published on November 7, 2013, Vol. 78, No. 216, pages 66934-66935, (**Attachment 2**). There were no public comments.

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 Advisory Committee for the Elimination of Tuberculosis (http://www.nchhstp.cdc.gov/dtbe/acet/default.asp), the Council for State and Territorial Epidemiologists (http://www.cste.org), and the National Tuberculosis Controllers Association (http://tbcontrollers.org). The data collection instrument (**Attachment 3**) and instructions (**Attachment 4**) are attached. No changes to the currently approved data collection instrument are currently proposed in this OMB clearance extension request.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive payments or gifts.

10. Assurance of Confidentiality Provided to Respondents

In the review of this application, it has been determined that the Privacy Act is not applicable. The name and address information are retained by the respondents—the 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.

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. Justification for Sensitive Questions

The RVCT collects information on sensitive matters such as:

a) HIV status – The HIV/ADIS 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 non-adherence 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 63% in 2012. In addition, MDR TB cases reported in foreign-born persons increased from 25% of all primary multi-drug resistant TB cases in 1993 to 86% in 2012. 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 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 and results of the pilot RVCT orientation conducted described in section A.8 - B. 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 9,945 TB cases in 2012. Based on 2012 RVCT data, the total response burden hours for 60 reporting areas is 5,801.

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	166	35/60	5,801
Total					5,801

Reporting areas receive annual federal funds for TB control and surveillance through CDC cooperative agreements.

Table 12-B: Estimate of Annualized Cost to Respondents

Types of respondents	Total Burden Hours	Hourly Wage Rate*	Total Respondent Costs**
State Health Departments	5801	$19.72	$114,396
Totals	5801		$114,396

CDC's cooperative agreement for TB elimination program to state and local health departments provides salaries of data collection staff. We used the median hourly rate for occupational code 43-9111, statistical assistant, from the May 2012 National Occupational Employment and Wage Estimate, U.S. Department of Labor to estimate cost to the respondent http://www.bls.gov/oes/current/oes_nat.htm. Respondent costs are paid by CDC-DTBE through cooperative agreements with state and local health departments for completing the RVCT and are included in A14 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 May 2012 National Occupational Employment and Wage Estimate, U.S. Department of Labor: http://www.bls.gov/oes/current/oes_nat.htm.

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)	$ 108,320
	CDC Epidemiologist (GS-14, 1 FTE)	$ 108,320
	CDC Epidemiologist (GS-14, .50 FTE)	$54,160
	CDC Epidemiologist (GS-13, 1 FTE)	$ 84,140
	CDC Epidemiologist (GS-12, .50 FTE)	$37,060
	CDC Statistical Assistant (GS 9, .25 FTE)	$16,404
	CDC Data Manager/Analyst (GS-14, 1 FTE)	$ 103,670
	CDC Data Manager/Analyst (GS-13, 1 FTE)	$ 84,877
	CDC Software Engineer (GS-13, .75 FTE)	$50,926
	CDC Public Health Analyst (GS-13, 1 FTE)	$ 84,877
	CDC Computer Systems Analyst (GS-14, 0.75 FTE)	$50,926
	CDC Information Specialist (GS-11, 1 FTE)	$66,563
	CDC Information Specialist (GS-12, 0.5 FTE)	$37,060
	Office supplies and equipment	$5,000
	Printing of RVCT forms and annual reports	$10,500
	Travel	$10,000
	Subtotal, Direct Costs to the Government	$777,000
Cooperative Agreements	60 reporting areas	$114,396*
Benefits	25% overhead (FTE & cooperative agreement wages)	$194,250
	Subtotal, Indirect Costs to the Government	$308,646
	TOTAL ANNUALIZED ESTIMATED COST TO THE GOVERNMENT	$1,085,646

* Included as cost to respondent in A12

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 2011. The estimated decrease of 919 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	
	2014	2011
Number of respondents	60	60
Number of responses per respondent	166	192
Hours per response	35/60	35/60
Total burden (hours)	5801	6720
Change in burden from 2011 submission (hours)	-919	

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 2012 were provisionally published in March 2013 then finalized in July 2013, with the final report posted on the DTBE web site and distributed to TB control officers in September 2013. 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 2014 annual national TB surveillance data collection (January through December 2014), 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 (May 2014)
Complete/submit 2014 RVCT data	6 - 9 months after OMB extension approval
Provisional reporting of 2014 RVCT data	10 months after OMB extension approval
Final data validation for 2014 data	12 - 15 months after OMB extension approval
Final data analysis for 2014 data	15 - 18 months after OMB extension approval
Final annual report publication for 2014 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.