Revision of Report of Verified Case of Tuberculosis (RVCT) Form
Current OMB No. 0920-0026 Expiring 11/30/2008

Part A

Carla Winston, PhD
Epidemiologist, Surveillance Team
Surveillance, Epidemiology and Outbreak Investigations Branch
Division of Tuberculosis Elimination
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
Mailstop E-10
1600 Clifton Road NE
Atlanta, GA 30333
Phone: (404) 639-6063
Fax: (404) 639-8959
cwinston@cdc.gov

2/5/2021

Table of Contents

A. Justification

1. Circumstances Making the Collection of Information Necessary

CDC is requesting 3-year OMB approval of a revision of the currently approved Report of Verified Case of Tuberculosis (RVCT) information collection No. 0920-0026 for the National Tuberculosis (TB) Surveillance System. TB is a reportable disease in every state. National TB surveillance has been conducted and maintained by the U.S. Public Health Service through the cooperation of the states since 1953. CDC conducts and maintains the surveillance system 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] (Attachment 1). This request updates the approved RVCT information collection to reflect stakeholder requirements and changes in TB diagnostics, drugs, and epidemiology since 1993.

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 1993, the RVCT was approved to collect information to monitor factors essential to the reversal of the epidemic, including drug resistance, risk factors such as HIV coinfection or living in congregate settings such as prisons, and TB drug therapy.

In 2006, 13,767 cases of TB were provisionally reported to the national TB surveillance system. 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. The national TB surveillance system continues to be critical for detecting TB resurgence and providing the scientific basis to obtain resources to control TB. Updating this system to include recent advances in diagnosis and treatment is required to detect the emergence of extensively drug-resistant (XDR) TB strains, to identify high-risk populations, and to assist in program planning, evaluation, and resource allocation to meet the national goal of TB elimination. CDC is requesting 3-year OMB clearance approval for use of the national TB surveillance system's revised 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 the national TB surveillance system, initiated in 1953 and modified several times to better monitor and respond to changes in TB morbidity. This proposed revision to the data collection instrument captures results from the latest rapid diagnostic tests and treatment modalities. In 1985, the national TB surveillance system 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. The most recent modification was implemented in 2002, when race and ethnicity variables were modified to comply with OMB standards for federal data.

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 tuberculosis control programs. RVCT data are stripped of unique identifiers prior to transmission of reports to CDC.

The information collected by the National TB surveillance system will be used to assists federal, state, and local public health officials and policy makers in 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 published as a

report for the agency. Annual reports are 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 are posted on the DTBE web site: http://www.cdc.gov/tb/surv/default.htm each year. In addition, public use aggregate data are available at the Online Tuberculosis Information System (OTIS): http://www.cdc.gov/tb/surv/default.htm.

CDC periodically conducts special analyses for publication in peer-reviewed scientific journals to describe and interpret national TB surveillance data to describe key trends, identify 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 include 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 are posted on the main DTBE web site: http://www.cdc.gov/tb/default.htm.

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 updating the national TB surveillance system data collection instrument, 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 will 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 is currently developing two software products that will 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. Next steps include coding, testing, and deployment of these tools in collaboration with state and local TB program stakeholders. Currently, states and local health jurisdictions use a CDC software package distributed by DTBE, the Tuberculosis Information Management System (TIMS), to collect and manage TB surveillance data from the RVCT. TIMS is a comprehensive software for surveillance, patient management, and program evaluation. The surveillance module contains electronic duplicates of the RVCT, which are electronically sent to DTBE via modem and compiled to create the national TB surveillance database. TIMS will be retired for each reporting area in a planned approach based on that area's TB surveillance reporting needs and its progress towards converting to the new NEDSS/PHIN environment. TIMS will not be completely retired until all sites have transitioned from that system.

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 the national TB surveillance system 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. 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. A 60-day Federal Register notice was published on 08/01/2007, Volume 72, Number 147, Pages 42096-42097 (Attachment 2). There were no public comments.

B. DTBE has closely collaborated with its partners and stakeholders concerning the RVCT and national TB surveillance system to obtain their views and any suggested improvements. In 2001, DTBE arranged for consultations with territorial, state, and local TB control officers and surveillance coordinators to obtain input on a future RVCT revision. The RVCT Revision Workgroup was created, consisting of nearly 30 members from 15 TB programs and CDC and the National TB Controllers Association (NTCA). The RVCT Revision Workgroup convened a series of 26 conference calls to draft the next revision to the RVCT. The group collaborated to consider variable additions, deletions, and revisions based on surveillance significance, ease of data collection, and ability to yield meaningful and useful data. The Workgroup produced a final draft of the revision in December 2006. The revision was accepted by DTBE and shared with TB control officers and surveillance coordinators in March 2007. The revision was also shared with DTBE partner organizations including the Advisory Committee for the Elimination of Tuberculosis (ACET), the Council for State and Territorial Epidemiologists (CTSE), and NTCA. The data collection instrument (Attachment 3) and instructions (Attachment 4) are attached. All partner organizations provided letters of support for the RVCT revision (Attachment 5).

Due to its length, the list of persons consulted outside DTBE during 2001-2007 is included as Attachment 6. The RVCT Revision effort was facilitated within DTBE from

2001-2005 by Eileen Schneider, MD [Medical Officer, (404) 639-5345, eschneider@cdc.gov], supported in 2006 by Philip Spradling, MD [Medical Officer/Epidemiologist, (404) 718-8566, pspradling@cdc.gov] and finalized in 2006-2007 by Carla Winston, PhD, MA [Epidemiologist, (404) 639-6063, cwinston@cdc.gov]. A pilot orientation to the RVCT revision was conducted in Atlanta by DTBE on April 12, 2007 with 7 representatives from state and local TB programs (see Attachment 6 for list of participants). On June 12, 2007, the DTBE lead of the RVCT Revision, Carla Winston, PhD, MA [Epidemiologist, (404) 639-6063, cwinston@cdc.gov] provided an update to the NTCA membership on the RVCT revision process during the annual meeting of TB controllers. On June 13, 2007, discussion of the proposed RVCT revision was conducted at the NTCA meeting (see Attachment 6 for list of participants). The RVCT revision was sent forward to the Federal Register for publication on August 1, 2007.

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, date of birth). 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.”

(Attachment 1). 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, date of birth). 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 57% in 2006. In addition, MDR TB cases reported in foreign-born persons increased from approximately 26% of all multi-drug resistant TB cases in 1993 to approximately 73% of all MDR cases in 1999, continuing at this proportion through 2006. 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 are 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. In 2006, 13,767 cases of TB were provisionally reported to CDC. Based on 2006 RVCT data, the total response burden for 60 reporting areas is 8050 hours.

CDC's cooperative agreement for TB elimination program to state and local health departments provides salaries of data collection staff at GS-7 step 5.We used the hourly rates from the Office of Personnel Management to estimate cost to the respondent (http://www.opm.gov/oca/07tables/html/atl_h.asp). Respondent costs shown in Table A 12. 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..

Table A. 12Estimated Annualized Burden Hours and Costs

Types of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden hours	Hourly Wage Rate	Total Respondent Costs
Local, state, and territorial health departments	CDC form 72.9 series	60	230	35/60	8050	$20.00*	$161,000 **
Total					8050		$161,000**

*

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

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 OPM pay scales with locality adjustments from (http://www.opm.gov/oca/07tables/html/atl_h.asp)

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)	$103,910
	CDC Epidemiologist (GS-14, 1 FTE)	$103,910
	CDC Epidemiologist (GS-14, .50 FTE)	$51,955
	CDC Epidemiologist (GS-13, 1 FTE)	$87,936
	CDC Epidemiologist (GS-12, .50 FTE)	$36,974
	CDC Statistical Assistant (GS 9, .25 FTE)	$50,992
	CDC Data Manager/Analyst (GS-14, 1 FTE)	$103,910
	CDC Data Manager/Analyst (GS-13, 1 FTE)	$87,936
	CDC Software Engineer (GS-13, .75 FTE)	$65,952
	CDC Public Health Analyst (GS-13, 1 FTE)	$87,936
	CDC Computer Systems Analyst (GS-14, 0.75 FTE)	$77,933
	CDC Information Specialist (GS-11, 1 FTE)	$61,698
	CDC Information Specialist (GS-12, 0.5 FTE)	$36,974
	Office supplies and equipment	$5,000
	Printing of RVCT forms and annual reports	$22,500
	Travel	$10,000
	Subtotal, Direct Costs to the Government	$985,526
Cooperative Agreements	60 reporting areas	$161,000*
Benefits	25% overhead (FTE & cooperative agreement wages)	$277,257
	Subtotal, Indirect Costs to the Government	$438,257
	TOTAL ANNUALIZED ESTIMATED COST TO THE GOVERNMENT	$1,146,526

* Included as cost to respondent in A12

15. Explanation for Program Changes or Adjustments

The changes incorporated into the updated RVCT form are in response to requests by stakeholders as described in section A.8 Proposed changes are described in detail in the 60 day Federal Register posting (Attachment 2). In brief, revisions to the currently approved RVCT include ability to capture TB risk factors such as diabetes, end-stage renal disease, anti-tumor necrosis factor alpha therapy, and contact with an infectious TB case. Revisions to the data collections will improve TB monitoring in the U.S. and particularly for pediatric TB patients. The revisions to the data collection will now reveal the primary reason for TB disease evaluation, whether the patient moved during TB treatment, immigration status for TB screening purposes, reason TB therapy extended if more than one year, and susceptibility testing for newer TB drugs. Enhancements to the RVCT will also accommodate changes in diagnostic technology since 1993, such as nucleic acid amplification tests, interferon gamma release assays, computerized tomography, and genotyping. The proposed revision modifies the RVCT case number to include year and jurisdictional code to allow each TB case to be allocated a "linking state case number" field to record source cases or prior TB disease episodes.

The table below summarizes the changes of response burden from the previous OMB submission in 2005. The estimated increase of 490 burden hours is due to the addition of information on new clinical diagnostic tests and factors to identify high-risk patients in the revised RVCT.

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

	Year	
	2007	2005
Number of respondents	60	60
Number of responses per respondent	230	252

Hours per response	35/60	30/60
Total burden (hours)	8050	7560
Change in burden from 2005 submission (hours)	490	

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 5 months after the data are finalized. For example, the national TB surveillance data for 2006 were provisionally published in March 2007 then finalized in early May 2007, with the final report posted on the DTBE web site and distributed to TB control officers in October 2007. 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 2009 annual national TB surveillance data collection (January through December 2009) using the revised RVCT form, the following time schedule has been estimated based on timelines from the previous five years of tuberculosis data collection, analyses, and publication.

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

Activity	Time Schedule
Pilot testing of RVCT orientation materials	1 – 3 months after OMB approval
Training on the RVCT revision	3 – 6 months after OMB approval
Complete/submit 2009 RVCTs	6 – 18 months after OMB approval
Final data validation for 2009 data	18 – 21 months after OMB approval
Final data analysis for 2009 data	22 – 26 months after OMB approval
Final annual report publication for 2009 data	27 months after OMB 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.