Request for OMB Review

Supporting Statement

Aggregate Reports for Tuberculosis Program Evaluation:

(1) Follow-up and Treatment of Contacts to Tuberculosis Cases

(2) Targeted Testing and Treatment for Latent Tuberculosis Infection

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A. Justification

This is a request for a revision of an approved data collection, OMB Control No. 0920-0457, which is in active use by tuberculosis (TB) control programs in health departments throughout the United States.

1. Circumstances Making the Collection of Information Necessary

The Division of Tuberculosis Elimination (DTBE), National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), leads the campaign for tuberculosis elimination in the United States. This includes administrating the federal tuberculosis cooperative agreements with the health departments of the 50 states, 10 large cities, and 8 trust territories and protectorates. CDC also provides ongoing technical consultation about tuberculosis control for these health departments. To assist CDC in these functions, health departments have been submitting tuberculosis program management reports since 1961. Two reports, the “Aggregate Reports for Tuberculosis Program Evaluation”, replaced several outdated reports and were implemented nationwide in 2000. The changes in these reports corresponded to the evolving national tuberculosis-control strategy and the new data-systems technology.

Fifteen years ago, the United States was challenged by an epidemic resurgence of tuberculosis. From 1986 through 1992, tuberculosis cases reported through CDC’s national surveillance system increased 20%, with a peak of 26,673 cases in 1992. Some state and local tuberculosis control programs experiences significant increases in rising case loads and the emergence of

highly fatal drug-resistant tuberculosis. The resurgence had multiples causes; one factor was the dwindling resources for tuberculosis control at many state and local health departments. In response, Congress appropriated additional base funding and special emergency funding for CDC to disburse to the state and local health departments.

The first priority for tuberculosis control programs is finding all the persons who have tuberculosis and making certain that they all complete curative treatment. By focusing on these activities, state and local health departments brought tuberculosis back under control, as shown by a steady decrease in tuberculosis cases since 1993. Now health departments are accelerating tuberculosis elimination by focusing on strategies for preventing tuberculosis: (1) evaluating all contacts to contagious tuberculosis and treating the contacts who are infected, and (2) carrying out targeted testing for latent tuberculosis infection in selected populations and treating the persons who are infected. Between these two, contact investigations have greater priority, consistent with guidance from the U.S. Institute of Medicine in *Ending Neglect: The Elimination of Tuberculosis in the United States*.[1] The two reports submitted here (attachments C and D), measure the extent, the efficiency, and the yield of these activities.

These reports superseded previous reports in "Tuberculosis Statistics and Program Evaluation Activity" (OMB Control No. 0920-0026) which were discontinued. The two newer report forms, the Aggregate Reports for Tuberculosis Program Evaluation, that were initiated in 2000 (OMB Control No. 0920-0457) have contents and methods that were updated for increased public

1Ending Neglect: The Elimination of Tuberculosis in the United States. Lawrence Geiter, Editor. Committee on the Elimination of Tuberculosis in the United States, Division of Health Promotion and Disease Prevention, Institute of Medicine, National Academy Press, Washington, D.C., 2000: pp 101-117.

health relevance. The first report in this OMB submission, “Follow-up and Treatment of Contacts to Tuberculosis Cases” (attachment C), puts the emphasis on the key public health outcome: treating the tuberculosis-infected contacts.

The second report in this submission is “Targeted Testing and Treatment for Latent Tuberculosis Infection” (attachment D). Targeted testing intensifies the search for latent tuberculosis infections in selected populations that have high prevalence rates of tuberculosis, such as immigrants who have come from countries where tuberculosis is endemic. It also focuses on preventing tuberculosis in groups who are especially susceptible to tuberculosis, such as persons infected with human immunodeficiency virus. The report focuses on the types of testing, the priorities for treatment, and the linkage between testing and treatment. In addition to targeted testing, this report counts some other types of tuberculosis testing that are already commonly in practice in many U.S. health care settings. It includes a special category for tuberculosis-infected persons who have been referred to health departments from other health care providers.

For tuberculosis control, 68 federal cooperative agreement sites encompass the United States, and they are the correspondents for the reports. These sites have adopted the Aggregate Reports for Tuberculosis Evaluation as their generic tool for assessing their tuberculosis prevention activities. They use the reports for generating indicators used in program evaluation as stipulated in the 2005 cooperative agreement, for monitoring the workload of tuberculosis prevention, and for estimating the epidemiological status of tuberculosis in their jurisdictions.

This data collection is authorized under Section 301 of the Public Health Service Act (42

U.S.C. 241) (attachment A).

2. Purpose and Use of Information Collection

CDC uses the data from these reports for monitoring local, state, and national tuberculosis control programs, for planning national tuberculosis control strategy, and in estimating funding needs. The results in these reports are compared to the national performance goals, and they indicate progress toward achieving tuberculosis elimination. These data address Government Performance Results Act (GPRA) section IIH, Tuberculosis Performance Goal 1 Item 3 ("Increase the percentage of contacts of infectious AFB smear-positive cases who are placed on treatment for latent tuberculosis infection and complete a treatment regimen") and Item 4 ("Increase the percentage of other high-risk infected persons who are placed on treatment for latent tuberculosis infection and complete a treatment regimen"). The Aggregate Reports for Tuberculosis Program Evaluation show that approximately 42% of contacts of infectious tuberculosis cases start and finish a treatment regimen, which informs CDC and the respondents that the current prevention activities are not at their full potential. This informs strategy and resource allocation.

CDC has disseminated the results from these reports in the following ways:

- An annual dear-colleague letter from the director of DTBE, for data years 2000–2004, to the respondents, who are the 68 state, territorial, and big city tuberculosis control officials. (The letter for data year-2005 will be sent in mid-2007, after all results for 2005 have been submitted.) This letter reiterates the purposes of the data collection and provides a national interpretation of the results for the year.

- A journal publication of the baseline data that some of the respondents submitted to CDC during the first year of the reporting cycle (Jereb J, Etkind S, Joglar O, Moore M, Taylor Z. Tuberculosis contact investigations: outcomes in selected areas of the United States, 1999. The International Journal of Tuberculosis and Lung Disease 2003;7:S384-S390).
- CDC poster presentations of the national summary results and interpretation, at the annual conference of the National Tuberculosis Controllers Association (NTCA, i.e., the official organization representing the report respondents), 2005 and 2006. Presentations in this forum will continue annually.

CDC uses the reports for assessing the effective use of federal tuberculosis cooperative agreement funds. Reports for program evaluation are stipulated in the cooperative agreements. The CDC tuberculosis program consultants, who use the reports as the standard measurement of workload and performance, visit the 68 cooperative agreement sites at least annually to review local progress toward tuberculosis elimination.

All state health departments have adapted the Aggregate Reports for Tuberculosis Program Evaluation for their own tuberculosis control programs. Most health departments use the identical reports that they submit to CDC, while a few, such as the health departments in California and Florida, have elaborated on the reports to meet their specialized needs. Health departments that have their own comprehensive data management systems for tuberculosis control, such as in New York State and Illinois, have designed their systems so that information for the Aggregate Reports for Tuberculosis Program Evaluation are generated automatically and

thus at no added burden for the respondents, who already were collecting the data for their own use.

CDC is not proposing revisions to the Aggregate Reports for Tuberculosis Program Evaluation. The majority of technical-support questions about the reports have been related to data definitions. CDC has addressed these questions by preparing extended on-line instructions that are linked to the DTBE web page (http://www.cdc.gov/nchstp/tb/pubs/PDF/ARPEs_manual.pdf). The on-line instructions include guidance about how the respondents (i.e., the state and local public health departments) can use the reports for monitoring the results of their own tuberculosis control programs.

Difficulties have been reported anecdotally for specific complex large tuberculosis outbreaks in institutional settings (e.g., prisons or homeless shelters) two or three times per year. The data structure required by these outbreaks is too complex for the Aggregate Reports for Tuberculosis Program Evaluation. These issues have been resolved collaboratively between the respondents and the CDC tuberculosis program consultants by collapsing the data into simpler formats that were compatible with the reports. CDC is not proposing revisions to the reports to accommodate more complex data because the current reports are sufficient for most data. If the reports were expanded for rare instances of complex data, this would increase the burden to the respondents without sufficient compensatory benefit to the respondents or to CDC.

State and local public health officials have cited improved convenience and usefulness of the current reports in comparison to the older CDC reports. The reports document that the scope of

prevention activities is large: according to the most recent final reports, at least 130,000 persons in the United States were listed as exposed to tuberculosis in 2003, and more than one-quarter of the persons who underwent diagnostic testing were found to have tuberculosis infection. The reports also have shown that approximately 10% of contagious tuberculosis patients in the United States do not have contacts listed, which demonstrates a particular need for improvements in tuberculosis prevention.

These data from the Aggregate Reports for Tuberculosis Program Evaluation continue to demonstrate the scope of the public health problem and the prevention activities for which CDC is jointly accountable, in collaboration with U.S. state and local health departments. Unless the Aggregate Reports for Tuberculosis Program Evaluation are continued, CDC cannot acquire these estimates of the public health impact caused by exposure to tuberculosis. Without the reports, CDC does not have a standard measurement of workload, yield, efficiency, and effectiveness of the prevention activities carried out by state and local tuberculosis control programs. National data about the transmission of tuberculosis infection and the prevention of tuberculosis cases will not be available. CDC needs a fair, standard assessment of the utilization of the funding disbursed through the federal tuberculosis cooperative agreements. Even if CDC could not collect the reports, state health departments would continue using them for monitoring the efforts of their own tuberculosis programs, because they have found the reports to be feasible and useful.

3. Use of Improved Information Technology and Burden Reduction

The federal tuberculosis cooperative agreements include funds for computer equipment and

support. Since 1997, all the project areas have been using the Tuberculosis Information Management System (TIMS), a software package developed at CDC for the electronic collection, storage, collation, and transmission of tuberculosis data. Tuberculosis cases were first reported through TIMS in 1998. As stipulated in the cooperative agreements, all project areas report their tuberculosis case data (OMB Control No. 0920-0026) through TIMS by transmitting the reports to CDC electronically. In 2000, CDC added the Aggregate Reports for Tuberculosis Program Evaluation to TIMS, which allows the respondents to enter, save, collate, and transmit the reports electronically and which CDC uses to store the reports. TIMS also calculates all process indicators automatically, which saves time for the correspondents and eliminates transcription errors in this step. CDC still accepts facsimile transmissions and paper copies for the reports from low-burden respondents who report so few data that the electronic format is not advantageous. CDC will continue to work with the respondents in adopting new technology. Some jurisdictions are transferring to the CDC-led National Electronic Disease Surveillance System (NEDSS) (OMB Control No. 0920-0728), where elements from the Aggregate Reports for Tuberculosis Program Evaluation will be integrated as soon as the tuberculosis-specific module for NEDSS is approved.

4. Efforts to Identify Duplication and Use of Similar Information

The Aggregate Reports for Tuberculosis Program Evaluation are a comprehensive standard summary of priority tasks for controlling and eliminating tuberculosis in the United States. Some state health departments (e.g., in California, New York, Illinois, and Florida) subsequently have designed their own similar reports for program evaluation, in accordance with their specific

programmatic needs. Their reports are compatible with the national reports, but they are either too specific or too complex for national adoption. No federal agency besides CDC collects uniform data on tuberculosis prevention nationwide. Through literature searches, attendance at national tuberculosis meetings and conferences, and ongoing consultations with tuberculosis experts nationwide, CDC has determined that the Aggregate Reports for Tuberculosis Program Evaluation are unique and that no other similar data are available within or outside the federal government.

5. Impact on Small Businesses or Other Small Entities

Data are requested from state, local, and territorial health departments. No small businesses are involved in this data collection. Data are collected only once a year and are kept to an absolute minimum to lessen the reporting burden.

6. Consequences if Information Collected Less Frequently

There are no legal obstacles to reducing the burden to the respondents.

The reporting frequency is once a year. The respondents collect the data for these reports continuously as part of standard public health practice. Annual reporting is linked to the annual funding cycle and program evaluation of the tuberculosis cooperative agreements. Less frequent reporting would delay feedback and technical consultation to the respondents and would leave CDC without current data for monitoring the national tuberculosis situation.

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

This request fully complies with the guidelines in 5 CFR 1320.5, and no special circumstances require the information to be collected in any other manner.

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

CDC published its proposal for extending these data collections in the May 24, 2006, (Volume 71, Number 100) Federal Register Notices, pages 29967-29968 (attachment B). CDC received no comments in response to this notice.

At the June 12-16, 2006 meeting of the National Tuberculosis Controllers Association (NTCA, i.e., the official organization representing the report respondents), a convenience sample of state tuberculosis control program officials were consulted about the current utility of the reports and issues within their states. Summaries of the consultations follow:

> Kim Field, RN, State TB Program Director and past president of NTCA, and Lorena Jeske, State Regional Nurse Consultant, TB Control Services, Washington Department of Health, telephone 360-236-3447. Ms. Fields and Ms. Jeske stated that the more useful report (of the two Aggregate Reports) for Washington has been targeted testing, because most of the low-incidence jurisdictions do more targeted testing than they do contact investigations. The State program officials use the targeted testing report during annual on-site evaluations with county public health programs. The reports have been effective for focusing attention on resource allocation. The report on contact investigations has been more useful for comparing statewide activities to national objectives, which is part

of the federal tuberculosis cooperative agreement. Ms. Field and Ms. Jeske pointed out that the current aggregate reports cannot discriminate the contact-selection priorities as described in the 2005 NTCA guidelines for tuberculosis contact investigations. However, the current reports still successfully record the workload and efficiency of contact investigations as intended. (Adding additional stratification to the reports would increase their burden and complexity by at least two fold, without increasing their utility nationally. State program officials have the option of collecting stratified data, which can be merged for reporting to CDC.)

John Grabau, Assistant Director, and Steven Hughes, Program Epidemiologist, New York State Department of Health, Bureau of TB Control, telephone 518-474-7000. Dr. Grabau and Mr. Hughes described State-wide computerized collection of record-based data from contact investigations. Their resulting data exceed the requirements for reporting to CDC and are used in monitoring the New York county health department programs in tuberculosis contacts investigations, program evaluation, and epidemiology. The New York data are extracted automatically for reporting to CDC and for discussing with the CDC tuberculosis program consultant who administrates the federal tuberculosis cooperative agreement. The extent of data collected in New York would allow for more comprehensive reporting to CDC, but CDC is not requesting these additional data because it would increase the burden for other respondents. Dr. Grabau and Mr. Hughes stated that every year, one or more local jurisdictions in the State require technical assistance in assembling data that ultimately contribute to the report to CDC. The technical assistance is advantageous because it enables officials from the State program

to work more closely with county officials, and this is viewed as an asset of the process.

Michael Arbise, Section Chief [TB Control], Illinois Department of Public Health, telephone 217-785-5371. Before he became the chief of the Illinois tuberculosis control program, Mr. Arbise was the program epidemiologist. As such, he designed and implemented the State's computerized tracking system for tuberculosis contact investigations, which automatically generates the aggregated reports for sharing with CDC. Because the Illinois system is record based, it enables epidemiological analyses that are impossible with the aggregated data. The CDC aggregate reports have proven successful in monitoring the effectiveness of county health department tuberculosis control programs, which varies widely from site to site, and the reports have indicated where more assistance from the State office is needed. Mr. Arbise is not requesting changes to the CDC national reports, but he will continue using the more refined layers of analyses that the Illinois system is designed to support.

Jim Cobb, Chief, Bureau of TB & Refugee Health, Florida Department of Health, telephone 850-245-4350. Mr. Cobb employs a team of epidemiologists and evaluation specialists who implemented a comprehensive web-based system for monitoring tuberculosis control program data, including the CDC aggregate reports. The data are built into the State strategy for assisting tuberculosis control programs in all Florida county health departments. The Florida system is more inclusive than the CDC reports because it integrates multiple programmatic activities, evaluation, operational costs, and resource allocation. Mr. Cobb is not requesting modifications of the current CDC reports.

9. Explanation of Any Payment or Gift to Respondents

The respondents do not receive payments or gifts for providing the Aggregate Reports for Tuberculosis Program Evaluation.

10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer has reviewed this OMB application and has determined that the Privacy Act is not applicable. Respondents are state and local health departments that provide CDC with aggregate information on cases of tuberculosis disease or infection. Although health departments may collect identifiable information for local tuberculosis control purposes, consistent with state and local laws, this information is retained at those level, and health departments do not transmit person-level data or identifiable data to CDC. The data associated with this OMB clearance are submitted to CDC only in an aggregate format. The aggregate data are not stratified by age, sex, or specific medical conditions except for tuberculosis, and therefore the accidental identification of any patient who is counted in the reports is extremely unlikely. All data which are submitted electronically through TIMS are encrypted and files are password protected. Any reports that are transmitted by telephone facsimile are sent unencrypted, to the CDC office where the data are collected, under the privacy-statement cover sheet of the submitting agency as guided by state or local law. Any printed records from specific jurisdictions are kept in a locked file cabinet. The summary national reports contain no sensitive or private information.

CDC previously has not made any assurance of confidentiality to the respondents. Data from

specific respondents will be treated in a confidential manner and will not be disclosed unless otherwise compelled by law. The respondents requested in 1999, and CDC agreed, that local public health authorities will be notified before locality-specific data is published or shared outside CDC. CDC publishes the national data and shares the national summaries with the respondents routinely after aggregating the reports. This surveillance activity does not require IRB review and approval.

11. Justification for Sensitive Questions

As a part their routine public health practices, health department officials (i.e., the respondents) collect sensitive information (e.g., address, occupation, country of origin, infection with the human immunodeficiency virus and risk factors for it, and the use of alcohol or illegal drugs) from persons who have tuberculosis infection or who have been exposed to tuberculosis. For preparing the reports, the respondents interpret some of this sensitive information, but the sensitive information is not recorded per se in the reports, and it is not extractable from the reports. The aggregate format of the reports precludes linking any sensitive information to any individuals who are counted in the reports.

12. Estimates of Annualized Burden Hours and Costs

A. The data that the respondents need to prepare the Aggregate Reports for Tuberculosis Program Evaluation are accrued during the normal operations of a tuberculosis control program following standard accountability practices. Therefore the annualized burden-hour estimates are based on the time for studying the report instructions, searching the existing data sources, and tabulating and reviewing the results. The reports are submitted

annually. The annualized burden is estimated partly from the experience with older reports, the Tuberculosis Program Management Reports (formerly, portions of OMB No. 0920-0026). A series of pretests of the current report forms was done in 1999 with four volunteer respondents who tabulated their data for the report manually.

The respondents are the tuberculosis control officials of the 68 U.S. jurisdictions receiving federal tuberculosis cooperative agreement funding. The officials ideally assign the responsibilities for preparing and submitting these reports to administrative personnel, such as data clerks and program managers. CDC does not request data on who prepares or submits the reports.

The estimates for annualized burden hours are variable because some respondents use custom automated data management systems for tabulating results while other tabulate results manually and then either enter the results into computer spreadsheets or maintain paper files. The tuberculosis incidence at a site also influences the annualized burden hours, because greater numbers of cases generate greater amounts of data. The maximum estimate for annualized burden hours is shown in the table.

Table A 12-A. Estimated annualized burden hours for respondents using electronic data storage and transmissions or manual data entry and transmission by mail or facsimile. Nominal respondents are the tuberculosis control officials of the 68 U.S. jurisdictions.

Report Name	Respondents (State and Local TB	Response Format	No. Response per	Hrs per Response	Response Burden

	Control Programs)		Respondent		
Follow-up and Treatment of Contacts to Tuberculosis Cases	68 data clerks	50 Electronic	1	30/60	25
		18 Manual	1	3	54
	68 program managers	50 Electronic	1	30/60	25
		18 Manual	1	30/60	9
Targeted Testing and Treatment for Latent Tuberculosis Infection	68 data clerks	50 Electronic	1	30/60	25
		18 Manual	1	3	54
	68 program managers	50 Electronic	1	30/60	25
		18 Manual	1	30/60	9
Total					226

B. The annualized costs to the respondents are estimated here based on estimated savings from using electronic storage and transmission of reports. The entire costs are labor. Part of the reporting is be done by (1) the 22 CDC field-staff employees who are working in state and local health departments and (2) the health department personnel who work in positions funded by the federal tuberculosis cooperative agreements, which reduce direct costs to the correspondents, and therefore the costs that are shown probably represent an overestimation.

Table A 12-B. Estimated Annualized Costs to the Respondents

Report Name	Respondents	Response Format	Estimated Hours	Hourly Wage Rate	Estimated Respondent

					Cost
Follow-up and Treatment of Contacts to Tuberculosis Cases	68 data clerks	50 Electronic	30/60	$12	$300
		18 Manual	3	$12	$648
	68 program managers	50 Electronic	30/60	$25	$625
		18 Manual	30/60	$25	$225
Targeted Testing and Treatment for Latent Tuberculosis Infection	68 data clerks	50 Electronic	30/60	$12	$300
		18 Manual	3	$12	$648
	68 program managers	50 Electronic	30/60	$25	$625
		18 Manual	30/60	$25	$225
Total					$3,596

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

None. The reports do not cause additional capital and maintenance costs to the respondents. The systems that are used for data collection, collation, and storage are already in place for routine public health practice.

14. Annualized Cost to the Government

The reporting is recurrent and ongoing. The costs that are estimated here reflect a public health system that is assumed to be stable. Travel for training in Atlanta no longer is included in the costs because CDC provides comprehensive instructions for reporting on the internet. The upkeep for TIMS is minimal because programming is complete. Routine checks on the functionality of the reporting system are part of routine annual site visits made by CDC tuberculosis program consultants for the federal cooperative agreements, and the costs of these visits are not shown because the visits would be made regardless of the Aggregate Reports for Tuberculosis Program Evaluation.

3 years of operation costs:

TIMS programming, 4 hr/yr @ $70/hr (contract).....$840

Quarter-time medical epidemiologist GS-14 @ $80,000/yr.....$60,000

Quarter-time data clerk GS-7 @ $24,734/yr $18,551

Costs for 3 years of operations, totaled: $79,391

Total 3 years cost – government: $79,391

Annualized cost – government: $26,464

15. Explanation for Program Changes or Adjustments

This is a request for a revision of OMB approval. Increased automation through computer storage of source data has decreased burden hours for respondents in high-morbidity states, where the data already is being collected and stored for purposes besides the Aggregate Reports for Tuberculosis Program Evaluation. Maturity of computer systems and internet-available instructions for reporting have decreased the annualized cost to the government, although a cost-of-living wage adjustment offsets this somewhat.

16. Plans for Tabulation and Publication and Project Time Schedule

The data accumulation is intermittent, it represents continuous public health practice throughout the United States, and the reporting is annual and recurrent. A 3-year clearance cycle is requested.

No analytical methods beyond simple tabulation and trend description are applied to the results of the two reports. The indices that are used for program evaluation are unadjusted. The interpretation of the results from each reporting area is discussed between the respondents and their CDC tuberculosis program consultants. Specific data from one respondent are not shared with other respondents by CDC without prior notification because data ownership (i.e., intellectual property) remains with the respondents as per general agreement between CDC and the Council of State and Territorial Epidemiologists.

The data that are reported to CDC are summed up for the U.S. national tuberculosis program statistics, which are sent to all the respondents annually. At least annually, the program

consultants from CDC use the data that are reported by their tuberculosis cooperative agreement project sites for reviewing the effectiveness of existing tuberculosis control programs and for planning new local strategies for tuberculosis control.

A.16 Project Time Schedule	
Activity	**Schedule (after OMB approval)**
Notification of respondents	1 week
Earliest data collection by respondents	2 months
Earliest reports submitted to CDC	18 months
Published summary report by CDC	24 months

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

No exemption is sought.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are included in this request. Paper forms generally are not used for this report, because the respondents either send the report electronically or print the form from TIMS, where CDC can update the form certification easily.

B. Collection of Information Employing Statistical Methods

1. No sampling, stratification, or estimation procedures are used in this data collection. The data are entirely in an aggregate format. For summing the U.S. national tuberculosis program statistics, the data are left unadjusted.

2. The source data for the Aggregate Reports for Tuberculosis Evaluation are gathered as part of standard public health practice for tuberculosis control under the authority of state and local health departments. Data aggregation varies by site, with computerized methods becoming the norm at large jurisdictions. The respondents have a choice of submitting their aggregated data to CDC by encrypted computer transmission in TIMS, by facsimile copy, or by mail. No respondents submit these data with individual patient records to CDC.

3. The CDC tuberculosis program consultants routinely work with the respondents in all types of data reporting. When reports to CDC are delayed, the CDC tuberculosis program consultants meet with the respondents to determine the programmatic needs and to assist in the reporting process.

4. CDC tested the Aggregate Reports for Tuberculosis Program Evaluation (OMB Control No. 0920-0457) as part of the design and implementation strategy in 1999 by visiting four state and local health departments and entering sample data. Computer systems (i.e., TIMS) were tested in 2003 for the completion of automated report transmission.

5. Consultation on statistical aspects is not applicable. The public health officials who tested the trial reports (see item #4, directly above) were experts in tuberculosis control, and they were consulted on the data collection methods in 1999.

List of Attachments

Attachment A	Section 301 (a)-Public Health Service Act [42 U.S.C. 241 (a)]
Attachment B	May 24, 2006, (Volume 71, Number 100) Federal Register Notices, pages 29967-29968
Attachment C	Follow-up and Treatment of Contacts to Tuberculosis Cases, form and instructions (OMB No. 0920-0457)
Attachment D	Targeted Testing and Treatment for Latent Tuberculosis Infection, form and instructions (OMB No. 0920-0457)