60-day FRN Publication Request for Information Collections (ICRs)

<Instructions: Fill every field, unless marked "if applicable". Attach FRN draft and primary data collection instrument(s). Delete all text in orange.>

Project Title ___ Aggregate Reports for Tuberculosis Program Evaluation_____
Requesting CIO ___ National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)____
Program Contact Person _____Tempest Hill mno8@cdc.gov_____

Extension: OMB No. 0920-0547 OMB Expiration 12/31/2022

Rationale for reinstatement (if applicable):

Requested Approval Period for proposed ICR (Select one):

_X_ Three years from approval date
__ Two years from approval date
__ One year from approval date
__ Six months from approval date
__ Other (specify _____)

Use of Information collection (Select one)
__ Application for Benefit
_X_ Program Evaluation
__ General Purpose Statistics
__ Regulatory/Compliance
__ Program Planning/Management
__ Public Health/Emergency Response
__ Research
__ Surveillance/Surveillance Core Functions
__ Service Delivery/Customer Feedback
__ Administrative
__ Audit
__ Other

Who will collect the data? (Select all that apply)
__ CDC
_X_ Grantees
__ Public Health Partners
__ Contractors
__ Other

Affected public (Select all that apply)
__ Individuals and Households
_X_ State, Local, or Tribal Governments
__ Federal Government
__ Private Sector - If affected Public is Private Sector, indicate if the following apply:
Is the proposed ICR related to the Affordable Care Act (PPACA, P.L. 111-148 &111-152)? Yes No
Does the proposed collection pose burdens on practicing physicians or their patients? Yes No

[Click here to enter submission date Month day, 20##]

SUMMARY

<Fill each item within the box. Try to keep the box to less than one page >

<Note: when you create Supporting Statement A for your full ICR, this section will map to the Summary box at the beginning of the document.>

Goal of the project: The extension request allows for programs to continue to address the change in the national strategies for TB control and prevention emphasizing treatment of individuals with latent TB infection (LTBI). The data collection allows programs to continue to assess high-risk populations served, and evaluate the adaptation and effectiveness of new diagnostic tests and drug regimens used in treating LTBI.

Intended use of the resulting data:
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 acid-fast bacilli 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").

Methods to be used to collect:
Data aggregation varies by site, with computerized methods becoming the norm. Respondents provide the data following the reporting format as outlined on the "Aggregate Reports for Tuberculosis Program Evaluation." The respondents enter and submit an aggregated summary report per reporting jurisdiction annually via NTIP, a web-based encrypted data system containing program evaluation data.

The subpopulation to be studied:
This report emphasizes treatment of individuals with latent TB infection (LTBI), and at high risk of progression to TB disease. The data that are reported to CDC are summed up for the U.S. national TB program statistics, which are sent to all the respondents annually.

How the data will be analyzed:
Simple tabulation and trend description are applied to the results of the reports. The indices that are used for program evaluation are unadjusted.

Circumstances Making the Collection of Information Necessary

<Begin by stating the type of information collection request (including any relevant OMB number) and the length of time requested, generally three years.>
<When justifying the reason to collect information, if there is a law/regulation requiring that CDC collect the info; state it.>

<Provide background information on the program and describe how the collection supports it.>

<Detail any specific public health problems you hope to resolve.>

<Try to keep the answer to one page or less. Cite relevant cooperative agreement or grant #s.>

<Note: when you create Supporting Statement A for your full ICR, this section will map to section A.1>

CDC requests a 3-year extension of the Aggregate Reports for Tuberculosis Program Evaluation, previously approved under OMB No. 0920–0457, for three years. To ensure the elimination of tuberculosis in the United States, CDC monitors indicators for key program activities, such as finding tuberculosis infections in recent contacts of cases and in other persons likely to be infected and providing therapy for latent tuberculosis infection. In 2000, CDC implemented two program evaluation reports for annual submission: Aggregate report of follow-up and treatment for contacts of tuberculosis cases and Aggregate report of targeted testing and treatment for latent tuberculosis infection (OMB No. 0920-0457). The respondents for these reports are the 67 state and local tuberculosis control programs receiving federal cooperative agreement funding through the CDC Division of Tuberculosis Elimination (DTBE). These reports emphasize treatment outcomes, high-priority target populations vulnerable to tuberculosis, and electronic report entry and submission to CDC through the National Tuberculosis Indicators Project (NTIP), a secure web-based system for program evaluation data.

Efforts to Identify Duplication and Use of Similar Information

<Describe your research and collaboration with other federal agencies and academic institutions/NGOs with related activities.>

<Explain 1) how you reviewed other government and institutional sources of data; 2) how other data sources relate or why they are not applicable; 3) any stakeholder feedback about the value of collection.>

<Look for opportunities to conduct collections in conjunction with other CIOs and gov agencies. If you have not yet conducted all the outreach you plan, detail your plans.>

<Note: when you create Supporting Statement A for your full ICR, this section will map to section A.4>

No other federal agency collects this type of national tuberculosis data and the aggregate report of follow-up and treatment for contacts of tuberculosis cases, and aggregate report of targeted testing and treatment for latent tuberculosis infection are the only data source about latent tuberculosis infection for monitoring national progress toward tuberculosis elimination with these activities. CDC provides ongoing assistance in the preparation and utilization of these reports at the

local and state levels of public health jurisdiction. CDC also provides respondents with technical support for the NTIP software.

In July 2018, in response to the recommendations from the Association Council for the Elimination of Tuberculosis (ACET), CDC reached out to the National Tuberculosis Controllers' Association (NTCA) for feedback. NTCA surveyed and conducted in-person focus groups with members in the 67 jurisdictions to assess the uses of ARPE data, the feasibility, and burden associated with collecting these recommended data elements. NTCA found that 76% of respondents reported ARPE data are useful to their programs.

Estimates of Annualized Burden Hours

<In a narrative above the burden table, describe how you arrived at the estimated annualized burden hours and costs associated with the time found in the tables, including, for example, piloting a formal pretest of the form with fewer than 10 respondents (this is not required). Remember to estimate in annual terms, over the total number of years of clearance requested, regardless of the length of the activity.

<Separate respondents into categories, including CoAg awardees. Write the total time of all respondents, use whole numbers and fractions of time only by ½ hour increments (e.g. 13.5 hours).>

<If you propose to screen respondents, including your screening instrument is optional; assume 100% response.>

<For totals, round figures.>

<Note: when you create Supporting Statement A for your full ICR, this section will map to section A.12>

Respondents are the 67 health departments (state, local, city, or similar jurisdiction) funded under the CDC cooperative agreement. On an annual basis, each respondent will submit 2 summary reports to CDC. The summary reports are compiled from information collected by the health department's TB control program during routine operations. Burden estimates are based on the time needed to compile each summary report from the respondent's record system. Burden estimates do not include activities conducted by health departments as primary tuberculosis care and follow-up.

Each respondent will submit the *Follow-up and Treatment of Contacts to Tuberculosis Cases Form* (Attachment 3a) to CDC once per year. The estimated burden per response is 2 hours and the estimated annualized burden for this information collection is 134 hours.

Each respondent will submit the *Targeted Testing and Treatment for Latent Tuberculosis Infection Form* (Attachment 3b) to CDC once per year. The estimated burden per response is 2 hours and the estimated annualized burden for this information collection is 134 hours.

All information collection is conducted electronically. The total estimated annualized burden is 268 hours, as summarized in Table A.12-1.

<Example Table>

Estimated Annualized Burden (Hours)

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Health Department Awardee (state, local, city, or other jurisdiction)	Follow-up and Treatment of Contacts to Tuberculosis Cases Form (3a)	67	1	2	134
	Targeted Testing and Treatment for Latent Tuberculosis Infection (3b)	67	1	2	134
Total					**268**

Explanation for Program Changes or Adjustments

<If this request is a new, extension, or an existing collection without approval, indicate that and stop.>

<For all others, explain briefly what is being revised from the last approval, including changes to the burden.>

<Note: when you create Supporting Statement A for your full ICR, this section will map to section A.15>

This is an extension request of the previously approved request under OMB No. 0920–0457

REQUIRED ATTACHMENTS

1. 60-day Federal Register Notice

<Use the 60-day FRN template on ICRO's intranet site.>

2. Main Data Collection Instrument(s)

<Include your draft instruments. You do not need to include multiple versions of the same instrument (e.g., translations, in-person plus phone versions, translations). You do not need to have final formatting, but the documents

must be clean enough to be shared with members of the public who request to review them in response to the 60-day FRN. >