

Information Collection for US Tuberculosis Follow-Up Worksheet for Newly Arrived Persons with Overseas Tuberculosis Classifications

OMB Control No. 0920-1238

Expires 06/30/2021

Request for Reinstatement with Change of a Data Collection

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Supporting Statement A

Reviewed by ICRO

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- **Goal of the study:** The purpose of this data collection is to follow-up with and assess newly-arrived persons in the United States who received overseas tuberculosis classifications in order to assist in the national effort to prevent new transmission of TB.
- **Intended use of the resulting data:** The information collected by The EDN Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications, also commonly known as the TB Follow-Up Worksheet, will provide outcomes for improving national TB prevention programs. The Division of Global Migration and Quarantine (DGMQ) staff, along with other federal partners will use this information to assess overseas panel physician performance, overseas prevention activities, and TB control program performance in the United States. Specifically, to improve overseas panel physician performance and TB prevention activities, CDC needs information on the U.S. domestic chest x-rays, chest x-ray comparison sputum smear and culture, and diagnosis results along with U.S. domestic reviews of overseas treatment. To monitor and assess U.S. domestic TB program performance, CDC needs to collect data on all elements of TB U.S. domestic follow-up evaluations, including chest x-rays, diagnosis, and U.S. treatment outcomes.
- **Methods to be used to collect:** Prospective cohort design
- **The subpopulation to be studied:** Persons requiring overseas medical examinations, including, but not limited to, immigrants and refugees newly arriving to the United States with noted Class A or B TB classification recommended follow up by state/local health departments.
- **How data will be analyzed:** CDC will analyze patient outcome data on a quarterly basis and share aggregate reports with state and local health departments.

1. Circumstances Making the Collection of Information Necessary

This Information Collection Request (ICR) is composed of a reinstatement with change to US Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications. The Centers for Disease Control and Prevention is requesting 36 months of clearance for this ICR.

The Secretary of Health and Human Services has the legal authority and delegates that authority to the CDC director to establish regulations outlining the requirements for the medical examination of persons before they may be admitted into the United States. This authority is provided under Section 212(a)(1) (A) of the Immigration and Nationality Act (8 U.S.C. § 1182(a)(1)(A)) (Attachment 1A) and Section 325 of the Public Health Service Act 42 U.S.C. 252 (Attachment 1B). These regulations are codified in 42 CFR Part 34 (Attachment 1C), which establishes requirements that determine whether persons can be admitted into the United States, which includes health examinations when persons attempt to adjust status to lawful permanent residents. In addition, the Public Health Service Act, Section 325 “Examination of Alien’s” (42 U.S.C. 252), the “Immigration and Nationality Act,” Section 212(g), and the “Application for Waiver of Grounds of Inadmissibility” (8 U.S.C. 1182(g)) authorizes CDC to maintain a system for the surveillance and periodic medical evaluation of immigrant persons with tuberculosis.

The EDN Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications (Attachment 3), is needed to ensure that newly arriving persons who have undergone the required medical screening examinations prior to coming to the United States are examined and further assessed in the United States.

In order to be compliant with regulations regarding the Office of Management and Budget's (OMB) collection and use of data, the data collection instrument was submitted as a "Request for OMB Approval of an Information Collection in Use without an OMB Control Number" in 2018. CDC will continue to submit the proper documentation requested from OMB to ensure that the data collection instrument is always in compliance with OMB guidelines. Since the last OMB approval in 2018, CDC has made changes to the collection instrument to enhance quality of data collection, provide consistency throughout all data fields in terms of wording, and provide additional options for respondents to select in certain data fields based on how they used the collection instrument currently in use.

Due to the highly infectious nature of TB, it is imperative to implement measures of preventing new transmission from recently arrived persons to the general US population. According to CDC, the 2019 TB case rate was 14.2 per 100,000 for foreign-born persons compared to 0.9 per 100,000 for US-born persons.¹ The proportion of TB cases occurring in the foreign-born population was found to be approximately 70.9% of the national case total.¹ Given the high-case rate of TB in the US foreign-born population, it is essential to provide domestic follow-up examinations for TB in persons within thirty days of their arrival to help reduce the risk of transmitting TB to the general US population.

There is no other federal level surveillance system that collects data on TB follow-up outcomes for newly-arriving individuals. The closest surveillance system, the Report of Verified Case of Tuberculosis (RVCT) surveillance reporting form (OMB Control No. 0920-0026), only collects information on TB cases, not those diagnosed with other TB conditions such as latent TB infection (LTBI) or no TB exposure or infection. Due to staffing changes and heavy involvement from many CDC staff on the Novel Coronavirus 2019 Response, the renewal of this particular data collection instrument was delayed in regards to more timely submission. To ensure that this type of delay does not happen again, CDC will initiate the package renewal process much earlier and ensure that the renewal of the data collection is made a priority among project queues. Plans for formal evaluations of US panel physicians are contingent upon the approval of the TB Follow-Up Worksheet.

2. Purpose and Use of Information Collection

A VISA medical examination is one means of evaluating the health of persons applying for entry into the United States. Through this examination, individuals are classified as: *Class A*; *B*; or *No Class*. *Class A* individuals are not granted a visa unless they have a signed treatment agreement with a receiving physician in the United States. Only under these circumstances are these individuals granted a waiver for visa approval. Those assigned a *Class B* for TB classification have received treatment prior to arrival in the United States and are highly recommended to receive US domestic follow-up evaluations to prevent new transmission of TB. *No class* individuals are defined as applicants without clinical

¹ Schwartz NG, Price SF, Pratt RH, Langer AJ. Tuberculosis — United States, 2019. MMWR Morb Mortal Wkly Rep 2020;69:286–289. DOI: <http://dx.doi.org/10.15585/mmwr.mm6911a3>

findings of TB disease and do not require follow-up evaluations after arrival in the United States. The recommendation for US domestic follow-up evaluations of *Class B* arrivals is the primary rationale for collecting US domestic TB follow-up information.

The Division of Global Migration and Quarantine (DGMQ) collaborated with the Division of TB Elimination (DTBE) to develop The EDN Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications which captures follow-up evaluation information.

The TB Follow-up Worksheet (attachment 3) captures domestic TB examination data of persons arriving to the US with overseas TB classifications. The information collected provides methods used to perform several of the TB prevention activities. DGMQ staff, along with other federal partners, will use this information to assess overseas panel physician's performance; overseas prevention activities, and assess the US domestic TB Program performance. The TB Follow-up Worksheet assesses panel physician performance, overseas TB prevention activities, and information from domestic medical examination follow-up conducted on persons arriving in the US with TB classifications through analysis of data captured on the Worksheet, which includes information on US domestic chest x-rays, chest x-ray comparisons, sputum smears and cultures, and diagnosis results along with US domestic reviews of overseas treatment. CDC staff review the information provided in the follow-up form to ensure that states are reaching goals for follow up and offering treatment to individuals with latent infection or history of TB disease. Timely follow-up reports to CDC will provide CDC staff with means to effectively and efficiently assess overseas panel physicians' performance.

Indicators will be assessed to measure US domestic TB program performance, including the percentage of persons with class B TB classifications with complete US evaluations. This program performance monitoring activity will be ongoing throughout the year. State and local health departments will voluntarily report evaluation outcome findings on a continuous basis once evaluation results for an individual become available.

The proposed worksheet contains sections that allow US physicians to review overseas chest x-rays and treatment and indicate any concerns or errors. A negative consequence of not collecting this information is that DGMQ will not be able to quickly analyze data to determine which panel physicians have inaccuracies. Plans for formal evaluation of panel physicians are contingent on OMB approval of The EDN Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications.

If instructions for TB diagnosis and treatment are followed properly overseas, immigrants and refugees with class B TB classifications should not have TB disease during their US follow-up examinations. According to CDC, the 2015 TB case rate was 14.6 cases per 100,000 for foreign-born persons and 1.1 cases per 100,000 for US-born persons.² The decrease in TB case rates from 2015 to 2019 among foreign-born persons and US-born persons can be further examined through utilization of the TB follow-up worksheet. The form will help DGMQ understand what factors may contribute to a US domestic diagnosis of TB. The worksheet contains a section that collects patient diagnoses and treatment

² Schmit KM, Wansaula Z, Pratt R, Price SF, Langer AJ. Tuberculosis — United States, 2016. MMWR Morb Mortal Wkly Rep 2017;66:289–294. DOI: <http://dx.doi.org/10.15585/mmwr.mm6611a2External>

recommendations. Without this information, DGMQ staff will not be able to accurately pinpoint what factors contributed to a TB disease diagnosis domestically. This form of monitoring would be ongoing and will occur with every instance a person is diagnosed with TB disease during follow-up examinations.

3. Use of Improved Information Technology and Burden Reduction

All (100%) responses will be collected electronically through the secure EDN website to reduce the burden at the state and local level in accordance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII. The information in the follow-up worksheet will be collected by state and local health departments from their respective local health clinicians. Follow-up outcome information will be collected either in-person, fax, or over the telephone by the state or local health departments. Once the state and local health departments receive information regarding domestic examination results, their designated EDN data entry staff will report data electronically in the secure EDN system.

4. Efforts to Identify Duplication and Use of Similar Information

There is no other federal level surveillance system that collects data on TB follow-up outcomes for this distinct population.

The CDC Division of Tuberculosis Elimination (DTBE) uses several data collection systems to obtain TB information from state and local health departments. Although DTBE collects information regarding TB cases in the US population through their Report of Verified Case of Tuberculosis (RVCT), it does not collect information on non-TB cases or LTBI cases. Information of a similar nature may be collected by state and local health departments using their own reporting tools; however, there has been no national level data collection on US domestic TB follow-up examinations of all class A or B persons. The follow-up worksheet not only collects information on persons who become TB cases in the United States but persons with other diagnoses as well. Essentially, the form will be used to collect information on persons who are diagnosed as LTBI; no TB exposure or infection; active TB disease; old, healed TB; and inactive TB disease.

DGMQ understands that there may be minimal duplication of reporting data for TB cases. However, DGMQ collaborates with DTBE to alleviate the burden of duplication at the state and local levels. DGMQ anticipates that the probability of a person being diagnosed with TB disease domestically is generally low considering persons cannot enter the United States with active TB unless a waiver is acquired.

5. Impact on Small Businesses or Other Small Entities

The follow-up worksheet should not have a direct impact on small businesses or other small entities given that data is collected directly from state and local health departments.

6. Consequences of Collecting the Information Less Frequently

The frequency of data collection will be ongoing and would occur when a person with an overseas Class A or B TB classification receives a US domestic medical evaluation for TB. As soon as US domestic examination results become available, state and local health departments should report results to CDC in a timely manner. There are several consequences of not obtaining information from state and local health departments in a routine manner. CDC staff directly involved with evaluating overseas panel physicians will not be able to effectively monitor panel physician performance. It is important for CDC to immediately target underperforming state and local TB programs to ensure that no new transmission of TB occurs. There are no legal obstacles to reducing burden. Collecting information on an ongoing basis for state and local health departments will prove to be less burdensome because it allows them to methodologically collect and report information rather than waiting to report semi-annually, which would result in an excessive backlog.

Respondents—EDN data entry staff at state and local health departments—will complete the TB follow-up worksheet, on average, 4 times per year.

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

This request fully complies with the regulation 5 CFR 1320.5.

Frequency of data collection is not inconsistent with the guidelines, as discussed in Section A6. The frequency of data collection is determined by the frequency that a person with an overseas TB classification is assessed in the United States which occurs on a continual basis.

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 in the *Federal Register* on 03-19-2021, vol. 86, No. 50, pp. 14921 (Attachment 2).

There was one public comment (Attachment 2a). It has been responded to via email.

B. No consultations outside of CDC occurred.

9. There Explanation of Any Payment or Gift to Respondents

No payment or gift will be provide to respondents.

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

CDC's Office of the Chief Information Security Officer (OCISO) reviewed this submission and determined that the Privacy Act does apply. The applicable System of Records Notice is 09-20-0103 Alien Tuberculosis Follow-Up Program.

Through Title 8 and 42 of the US Code and the Refugee Act of 1980 [Immigration and Nationality Act, Section 412. (8 U.S.C. 1522)(b)(4)], DHHS/CDC has regulatory authority for the medical examination of refugees and is responsible for providing notifications about persons with class A (such as active

tuberculosis) or class B medical classifications. Care is taken to protect the personal information of newly arrived persons. The Privacy Impact Assessment for EDN is attached (Attachment 4).

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

Institutional Review Board (IRB)

NCEZID’s Human Subjects Advisor has determined that information collection is not research involving human subjects. IRB approval is not required (Attachment 5).

Justification for Sensitive Questions

The EDN Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications will collect information on US evaluation outcomes, overseas and domestic treatment recommendations, and domestic TB diagnoses. Demographic information will be pre-populated by the EDN system to help state and local health departments locate recently arrived persons. These data elements are important but limited to those critical to implementing measures to reduce the risk of TB transmission in the United States.

Data will be used to assess US TB program performance. Health departments will be assessed based on attempts to reduce the risk of TB transmissions by locating persons, coordinating medical follow-up for TB, and reporting follow-up outcome data. Without this information, there will be no way to ensure health departments are successfully assessing recently arrived persons on a national level.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

There were approximately 11,067 arrivals with TB class classifications in 2021. Given the National TB Program Objectives and Performance Target for 2025’s goal of an 87% treatment initiation rate for immigrants and refugees³, the estimated target number of individuals for follow-up annually is 9,628. There are currently 2,262 EDN users. By dividing the target number of individuals needing follow-up by the number of EDN users, we estimate approximately 4 responses per respondent. The estimated time to complete a follow-up form is approximately thirty minutes for each worksheet. These approximations yielded 4,524 total burden hours.

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
EDN data entry staff at state and local health departments	US Tuberculosis Follow-up Worksheet for Newly-Arrived Persons with	2,262	4	30/60	4,524

³ <https://www.cdc.gov/tb/programs/evaluation/indicators/default.htm>

	Overseas Tuberculosis Classifications				
Total					4,524

B. Estimated Annualized Burden Costs

Based on the 2019 national occupational employment and wages data from the Bureau of Labor Statistics, we assumed that EDN data entry staff located at state and local health departments fell under the epidemiologist category under the state government classification in the Life, Physical, and Social Science Occupation category (<http://www.bls.gov/oes/current/oes191041.htm>). The mean income for an epidemiologist at the state level was calculated to be \$ 32.58 hourly. Total respondent costs were calculated to be \$75,650.76 per year.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
EDN data entry staff at state and local health departments	The EDN Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications	2,322	\$32.58	\$75,650.76
Total				\$75,650.76

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

There are no costs to respondents other than their time to participate.

14. Annualized Cost to the Government

The estimated annual cost to the federal government for this project specifically was calculated to be \$137,417 per year.

Required Staff	GS Level/GS Level Equivalent	Cost (per hour)	No. of personnel	% dedicated to project (total hours per week)	Estimated Annual Cost	Comments
Public Health Advisor	13	\$46.52	1	8% (3.2)	\$7,741	In charge of oversight and analyses
Epidemiologist	13	\$46.52	1	5% (2)	\$4,838	Supervises project

Information Technology Staff	13	\$46,52	1	5% (2)	\$4,438	In charge of managing database and generating system report
Information Technology System					\$120,000	Estimated annual running costs of EDN system
Total					\$137,417	

15. Explanation for Program Changes or Adjustments

The number of respondents has increased due to more applicants requesting access to the EDN system since 2017. Due to the increase in the number of respondents and significant decrease in the number of US arrivals with TB classifications in 2021, the number of responses per respondent is expected to significantly decrease as well.

CDC is requesting approval of adjustments made for this information collection in order to provide more clarity through enhancement of particular fields.

Field of Revision	Revision Made	Reason for Revision
C3a	<ul style="list-style-type: none"> Added “in the U.S.” after “Was IGRA performed” 	<ul style="list-style-type: none"> To make the language consistent with C2a “Was TST administered in the U.S.?”
C3c	<ul style="list-style-type: none"> Changed "other, (specify):" to "Other, specify:" 	<ul style="list-style-type: none"> To make the language consistent throughout the data collection instrument each time “Other, specify” is listed
C9b	<ul style="list-style-type: none"> Changed “At designated DOT site” to “At DGMQ-designated-DOT site” and “At non-DGMQ-designated DOT site” 	<ul style="list-style-type: none"> To make the language consistent with other Department of State overseas medical forms that are in use
C9f	<ul style="list-style-type: none"> Changed check boxes from "Yes" and "No" to "Standard TB treatment" and "Non-standard TB treatment." Moved C9f to the top of the right-side column. 	<ul style="list-style-type: none"> To provide more clarity regarding what “Yes” and “No” mean
C11b	<ul style="list-style-type: none"> Added “Undocumented/unverified treatment” checkbox option. 	<ul style="list-style-type: none"> Based on data analysis of how respondents

	<ul style="list-style-type: none"> • Changed “Other, please specify” to “Other, specify” 	<p>answered C11b since this data collection instrument’s use after the last OMB approval, this check box is added to reflect a commonly typed in response in the “other, specify” field.</p> <ul style="list-style-type: none"> • “Other, please specify” is changed to “Other, specify” to make the language consistent throughout the data collection instrument each time “other, specify” is listed.
D3	<ul style="list-style-type: none"> • Added “Culture confirmed Yes/No” field underneath “Class 3 – TB, TB disease” check box options 	<ul style="list-style-type: none"> • To enhance the quality of data collection by requesting additional data
E5a	<ul style="list-style-type: none"> • Changed “U.S. treatment completed” to "U.S. treatment completion status and dates" • Changed check box options from “Yes” and “No” to “Completed” and “Treatment discontinued/stopped” with date fields. Added “Treatment ongoing” checkbox option. 	<ul style="list-style-type: none"> • To enhance the quality of data collection by requesting additional data and listing possibilities to clarify treatment ending options
E5b	<ul style="list-style-type: none"> • Changed “If No” to “If treatment discontinued/stopped” 	<ul style="list-style-type: none"> • To match the check box option selection in E5a.
E6	<ul style="list-style-type: none"> • Removed E6 “Date therapy stopped” and removed "Specify reason therapy stopped" (open text field). 	<ul style="list-style-type: none"> • The addition of “Treatment discontinued/stopped” in E5a replaces “Date therapy stopped.” • “Specify reason therapy stopped” is removed as it is repetitive of E5b.

16. Plans for Tabulation and Publication and Project Time Schedule

This collection is ongoing and the frequency of submission to CDC would depend on the number of arrivals with Class A or B TB classifications. Annual reports summarizing aggregate patient outcome data will be provided to CDC staff. Aggregate reports for state and local health departments will be generated as needed through the EDN system. Aggregated reports will not contain personal identifiable information to protect the privacy of persons receiving US domestic follow-up. These aggregated reports will help federal, state, and local programs directly involved with TB follow-up determine their program's performance.

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

CDC requests an exemption to the expiration data display on the EDN Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications because state and local health departments will be collecting data for CDC.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

Attachment 1A – Immigration and Nationality Act 8 U.S.C. § 1182

Attachment 1B – Public Health Service Act 42 U.S.C. 252

Attachment 1C – 42 CFR Part 34

Attachment 2 – 60-day Federal Register Notice

Attachment 3 – The EDN Tuberculosis Follow-Up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications

Attachment 3A – Detailed Changes to Collection Instrument

Attachment 4 – Electronic Disease Notification System Privacy Impact Assessment

Attachment 5 – CDC Non-Research Determination