Request for Project Determination & Approval – Division of Global Migration and Quarantine (DGMQ)

This form should be used to submit project protocols for any new research/non-research determination or HRPO/IRB review/approval.

Unique ID [user ID-year-project #]: DPL2-2017-1

***Project # is the number of projects you have submitted this year.**

Date of Submission: 12/29/2017

Project Title: Information Collection for
U.S. Tuberculosis Follow-up Worksheet for Newly-Arrived Persons with Overseas Tuberculosis Classifications

Project location (Country,State/Province,Town): Atlanta, GA

Principal investigator: Deborah Lee SEV#: 13461

Contact email: dpl2@cdc.gov

Project Officer*:

Project officer is required for larger projects that need administrative assistance, coordination with PGO/FMO, or extensive funding management

Proposed Project Dates Start: 12/28/2017 End: 12/28/2020 Branch/Unit: IRMH

Are there any CDC collaborator(s)?* ☐ Yes ☑ No If yes, please list.

*CDC collaborators: Any other CDC branch/unit, division or center outside DGMQ

Are there any non-CDC collaborator(s)?* ☐ Yes ☑ No If yes, list the organization(s) and lead investigator(s) for the organization(s).

*Non-CDC collaborators: Any collaborator outside CDC

DGMQ funding? ☐ Yes ☑ No If yes, please describe funding mechanism.

This information collection is already in process. Funding for the work is a part of normal operations.

Non-DGMQ funding? ☐ Yes ☑ No If yes, please describe funding mechanism.

Brief Project Summary (1-2 Sentences):

The purpose of this data collection is to follow-up with and assess newly arrived persons in the U.S. who received overseas tuberculosis classifications in order to assist in the national effort to prevent new transmission of TB.

Please check one appropriate category (and subcategories) from I-IV:

☑ **I. Activity is NOT human subjects research. Primary intent is public health practice or response i.e. disease control activity (Check one)**

- ☐ **A.** Public health response: Epidemic or endemic disease control activity; Epi-AID # if applicable:
- ☑ **B.** Surveillance activity (e.g., disease, adverse events, injuries)
- ☐ **C.** Program evaluation activity
- ☐ **D.** Analysis of surveillance data or data collected from a non-human subjects research protocol, not linking to another database
- ☐ **E.** Public health program activity e.g., service delivery, health education programs, social marketing campaigns, program monitoring, database construction or support, patient registries, needs assessments, data collection under regulation.

☐ **II. Activity is research but does NOT involve human subjects (Check one)**

- ☐ **A.** Activity is research involving collection or analysis of data about health facilities or other organizations or units (NOT persons).
- ☐ **B.** Activity is research involving data or specimens from deceased persons.
- ☐ **C.** Activity is research involving unlinked or anonymous data or specimens collected for another purpose.
- ☐ **D.** Activity is research involving linked data, but CDC non-disclosure form 0.1375B is signed.*
- ☐ **E.** Activity is research involving data or specimens from animal subjects or dead animals.**

*CDC investigators and the holder of the key linking the data to identifiable human subjects enter into an agreement prohibiting the release of the key to the investigators under any circumstances. It's important to note that use of the 1375B is at the discretion of the Center.

**Note: Approval by CDC Institutional Animal Care and Use Committee (IACUC) may be required for animal subjects.

☐ **III. Activity is research and activity involves human subjects but CDC investigators are "not engaged" in human subjects research (Check one)**

- ☐ **A.** This project is funded under a grant/cooperative agreement/contract award mechanism.

  Award #:

  ALL of the following 3 elements are required:

  1. CDC employees or agents will not intervene or interact with living individuals for research purposes.
  2. CDC employees or agents will not obtain individually identifiable private information.
  3. Supported institution must have a Federal wide Assurance (FWA) and project must be reviewed by a registered IRB (when supported institution is using an IRB other than CDC's).

- ☐ **B.** This project is not funded by CDC. CDC staff will provide technical support e.g., expert consultation, lab testing, data analysis, manuscript development. The following 2 elements are required:

  1. CDC employees or agents will not intervene or interact with living individuals for research purposes.
  2. CDC employees or agents will not obtain individually identifiable private information.

Note: Under this category, at the Center's discretion, the receipt of coded data under a non-disclosure agreement may satisfy criteria for being considered not individually identifiable.

☐ **IV. Activity is research involving human subjects that requires submission to CDC Human Research Protection Office (Check one)**

☐ A. Exemption Request (Use forms 0.1250X, 0.1379-Signatures, 0.1370-research partners) **(Check one)**

- ☐ 1. Research in established or commonly accepted educational settings, involving normal educational practices.
- ☐ 2. Research using anonymous educational tests, surveys, interview procedures or observation of public behavior.*
- ☐ 3. Research as in (B) but identified if subjects are elected or appointed officials.
- ☐ 4. Research involving existing data, documents, records, pathological specimens, or diagnostic specimens.*
- ☐ 5. Research conducted to evaluate public benefit or service programs, procedures, or alternatives.

☐ B. IRB Full Board Review (Use forms 0.1250, 0.1379-signature, 0.1370-research partners)

☐ C. Expedited IRB Board Review (Use same forms as above)

☐ D. Reliance

- ☐ 1. Request to allow CDC to rely on a non-CDC IRB (Use same form as A above, plus 0.1371)
- ☐ 2. Request to allow outside institution to rely on CDC IRB (Use same forms as A above, plus 0.1372)

*Information is recorded such that no PII linked to the subjects.

OMB determination

Has DGMQ Office of Policy and Regulatory Affairs (OPRA) been consulted regarding Paperwork Reduction Act (PRA) implications and OMB approval?

☑ Yes ☐ No

Date of Consultation: 12/28/2017

If yes, please include PRA Determination Form or an email from OPRA that outlines any PRA implications and a determination that PRA does or does not apply.

If OPRA was not consulted, please explain why?

Approvals/Signatures:	Date:	Remarks:
Investigator: Deborah Lee -S Digitally signed by Deborah Lee -S Date: 2017.12.28 09:59:42 -05'00'	12/28/2017	
Team Lead (if applicable):		
Branch/Unit Chief or designee: Nina Marano -S Digitally signed by Nina Marano -S Date: 2017.12.28 13:34:15 -05'00'	12/28/2017	

Please do not complete the "ADS Review and Determination" section, which will be done by DGMQ-OD

ADS Review and Determination

- ☑ Project does not require human subject research review beyond DGMQ
- ☐ Project requires NCEZID human subject review
- ☐ Project may constitute human subjects research and may be routed to CDC HRPO
- ☐ Project involves animals and may be routed to CDC IACUC

Comments/rationale for the determination:

The activities described in this information collection do not meet the regulatory definition of human subjects research under 45 CFR 56. Human subjects review for routine OMB packages has been delegated to the division by NCEZID.

Approvals/Signatures:	Date:	Remarks:
Division ADS/Designee Nicole J. Cohen -S Digitally signed by Nicole J. Cohen -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, 0.9.2342.19200300.100.1.1=1000484411, cn=Nicole J. Cohen -S Date: 2017.12.28 15:57:13 -05'00'	12/28/2017	