

Information Collection for Tuberculosis Data from Referring Entities to CureTB

Request for OMB approval of a Revision Information Collection (OMB Control No. 0920-1186)

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Supporting Statement A

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- **Goal of data collection:** To provide continuity of care for individuals affected by TB who enter US jurisdictions from foreign nations or who leave US jurisdictions bound for foreign nations.
- **Intended use of the resulting data:** To improve the continuous and appropriate care for individuals affected by TB as they move between the US and foreign nations.
- **Methods to be used to collect:** Review of medical and demographic information provided by referring entities. Follow up with treating physicians to determine treatment outcomes.
- **The subpopulation to be included as respondents:** Individuals affected by TB who are expected to leave or enter US jurisdictions and need ongoing TB care and follow-up.
- **How data will be analyzed:** Identify demographics, clinical features and outcomes of referred individuals for quality assurance and program management purposes.

PART A. JUSTIFICATION

CDC is requesting a revision of this information collection request. CDC requests this data collection approval for three years. CDC is making a small number of changes to the CureTB Transnational Notification information collection tool for ease of use by the respondents and adding two pieces of additional data important for clinical decision making and patient contact. Additionally, CDC is clarifying the specific burden attributable to individuals within Immigration and Customs Enforcement (ICE) custody by noting this in the tables in Section 12. Finally, CDC is updating the number of respondents and associated burden based on program operations over the last 12 months. No other changes are proposed.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration and Quarantine (DGMQ), requests approval for information collection from entities that partner with CureTB for continuity of care services.

The respondents are local health departments (LHD) and federal Immigration and Customs Enforcement (ICE) detention centers within the United States and physicians in healthcare facilities or public health departments in other countries who provide diagnostic and treatment services to individuals affected by TB. Individual TB patients may also be respondents if critical clinical or contact information is missing from their referral and CureTB follows-up with them to fill-in gaps to complete the referral service. All 50 US states and territories may refer TB patients to the CureTB program. To date, CureTB has also received referrals from Mexico and Guatemala.

This information has been provided to CureTB by these entities for over 20 years; however, the leadership and oversight of CureTB transitioned to CDC DGMQ in 2016, because the activities align with federal TB control priorities and several key CureTB management moved positions from San Diego County Public Health to CDC. CDC CureTB's mission is aligned with CDC DGMQ's public health goals to reduce the spread of disease in globally mobile populations and those populations living along the U.S. Mexico border.

CureTB started in the County of San Diego's TB Control Branch to assist with continuity of care for TB patients in the immediate California-Mexico border region. CureTB expanded its

services to TB programs throughout the US and for patients moving between countries beyond the Mexican border, and to immigration facilities. The program has now transitioned to CDC DGMQ to augment its mission of improving the health of migrating populations. CDC CureTB is able to leverage national health authority partners who are accustomed to working with national public health authorities. In addition, CDC CureTB staff can access the Quarantine Activity Reporting System (QARS) data system, which is a federal database used to follow patients with infectious diseases, such as TB, which pose a risk for travel. CDC CureTB information will assist federal partners in assuring patients do not travel back to the US until they have adequate treatment.

To achieve CDC/DGMQ's mission, CDC CureTB will continue its work with domestic and international programs to protect the U.S. public by preventing the global development of drug resistance and reducing disease transmission and importation of infectious TB. These goals are accomplished through CDC CureTB referral and continuity of care services for mobile TB patients. Throughout the world, nearly 500,000 individuals have newly diagnosed multi-drug resistant TB each year, a type of TB that is extremely costly and difficult to successfully treat. Lack of treatment adherence and inappropriate selection of medications are prime reasons for the continued emergence and spread of resistant strains. To combat this, CDC CureTB assures patients understand how to remain adherent despite moving between nations and provides information to the health care team that will be continuing care about each patient's TB strain and tailored medication regimen. CDC CureTB, through the referring partners, gathers demographic and clinical information for each patient, and connects that individual to care through provision of accurate information about how to locate the correct downstream provider and assurance that real-time information is given directly to medical providers and public health authorities in receiving nations. As stated above, within CDC DGMQ, CureTB is able to leverage health authority partners in countries around the world to better assure continuity of care and can expand the countries served to a global reach.

Assurance of treatment completion is an important public health strategy for TB. Treatment length can span from 4-18 months, and protocols, drug availability, and healthcare infrastructure varies by country. Language and communication barriers also limit information sharing across nations. CDC CureTB provides up-to-date, accurate information between providers, as well as assisting patients to continue treatment as they transit between countries. One of CDC CureTB's key services is bridging the language divide that otherwise limits the ability of providers in different countries to communicate. Services are offered in all languages for patients and downstream providers. CDC CureTB has also been successful because of its strong partnerships with receiving countries, which streamlines the provision and receipt of information; critical in maintaining seamless continuity of care. The information collected by CDC CureTB provides documentation for successful patient follow-up and allows assessment of strategies for improving outcomes. This information is not reported in other systems, thereby preventing CDC from evaluating TB treatment completion outcomes in globally mobile populations and monitoring program effectiveness.

The information collection for which approval is sought is in accordance with CDC DGMQ's mission to reduce morbidity and mortality among immigrants, travelers, and other globally mobile populations, and to prevent the introduction, transmission, or spread of communicable

diseases from foreign countries into the U.S. This mission is supported by the Section 361 of the Public Health Service Act regulations found in 42 Code of Federal Regulations part 70 and 71 (Attachments A1, A2, and A3, respectively). It is also supported under general authorities provided by Sections 301 and 311 in the Public Health Service Act regulations (Attachments A4, and A5).

2. Purpose and Use of Information Collection

Information will be collected from local health departments and federal ICE detention centers, whenever these referring entities provide clinical services to an individual with TB who has imminent plans to relocate and needs continuity of care in their new location. The local health departments and federal ICE detention centers shares the information with CDC CureTB via fax, encrypted email, or phone so CDC CureTB can help coordinate care in the new location. TB patients may also be a respondent if critical clinical or contact data is missing and requires follow-up by CureTB to complete a patient's referral information set. The information collected is as follows:

- patient name, date of birth, sex
- contact information for patient
- expected location where patient will be moving to (e.g. country, state, municipality)
- tuberculosis laboratory results and other relevant clinical data
- tuberculosis treatment start date, medications
- contact information for referring entity

The request for CDC CureTB services comes from the referring entities and they supply the information at the time the patient is likely to leave their jurisdiction. The local health departments or ICE detention centers may update information only if relevant information to the patient's care becomes available to them after their first communication with CDC CureTB. Therefore, information is already largely collected by CDC CureTB only at one point in time, with subsequent information only collected if departure is delayed or when initially pending information becomes available and this is beyond the control of CDC.

CDC is notified of the date the patient will leave and sends the information they received to public health authorities in the new country via fax or encrypted email. That information is shared with the local physician that would provide care to the TB patient after they arrive.

Post relocation of the TB patient, data is also collected from the receiving physicians to determine patient outcomes. CDC Cure TB contacts the physician an average of every two months during the standard TB treatment process. The following data is collected:

- 1) Is patient still on treatment? Yes or No
- 2) If yes, what medications?
- 3) What is anticipated data of treatment completion?
- 4) If not, what is the final outcome?

Standard international outcomes:

- Lost

- Abandoned
- Died
- Stopped for medical reasons
- Completed treatment

The data provides valuable information on globally mobile populations and allows CDC to assist in continuity of TB care and monitor the effectiveness of the program. This data will be used to:

- Assure individuals are linked for follow-up care based on accurate and complete clinical information sharing between partnering countries.
- Estimate the impact of CDC CureTB in assuring TB patients who exit the US receive appropriate continuity of care services.
- Identify key countries where establishment of high-level continuity services will have the largest impact on morbidity in the US.
- Detect and resolve problems at domestic sites demonstrating lower than expected TB referral rates.

Data will primarily be used to assist in continuity of TB care for mobile populations and will, therefore, be provided to specific downstream health entities and providers responsible for continuing care and management of the patient. Data will also be used internally to monitor program impact. Aggregated data may be shared with health authorities involved in TB control and dissemination may include abstract submission to scientific conferences, including the Union World Conference on Lung Health and the National TB Controllers Association.

3. Use of Improved Information Technology and Burden Reduction

The primary method of information collection is through completion of one-page referral forms that can be secure-faxed or emailed to CDC. The CDC CureTB form is adapted from one developed and already in widespread use by health departments, so the CDC CureTB form merely leverages standard practice by health departments. Federal correctional agencies developed their own form, which serves several purposes for their agency. CDC CureTB accepts their form and abstracts that data into the CDC CureTB form so, no additional burden is placed on those facilities.

The data elements collected during the referral process are the minimum required to elicit the necessary TB-related information. If a respondent leaves any critical elements described in section A2 incomplete on the form, which can happen when lab results are pending, CDC CureTB will contact the referring entity directly to gather any remaining critical information.

Particular emphasis will be placed on compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII. The data elements will be the same as the hard copy forms, but could be, for example, presented in a fillable PDF format.

CDC is considering further digitizing the submission of referrals to CDC, which would include the construction of a secure method of information collection and storage. Options for deployment of this system are still in development. Any change to submission of the CDC

CureTB forms to CDC will be sent to OMB for review and approval. If the changes are substantive, a revision will be submitted for public comment and OMB review and approval.

4. Efforts to Identify Duplication and Use of Similar Information

Because DGMQ's public health mission is dedicated to migrating populations and regulatory responsibilities limiting the spread of infectious diseases into and within the United States, it is not expected that the majority of the information collected under this proposed clearance is available through other systems maintained by the federal government. The CureTB information provides up-to-date clinical and exposure event information, which is not available through any existing CDC system. All of the functions of the CureTB management team have moved from San Diego County Public Health to the CDC. The collection of data is being directed and managed by CDC DGMQ staff.

5. Impact on Small Businesses or Other Small Entities

Health departments, correctional and immigration facilities are the majority providers of CureTB referrals and would be the only source of TB data for these specific populations. Small businesses are not involved. Health departments and federal correctional facilities already have standard forms and practices in place for trying to locate migrating patients. CDC CureTB leverages, but does not add to the standard practices.

6. Consequences of Collecting the Information Less Frequently

CDC notes that the majority of this information is already being collected by the referring entities. CDC is collecting this information in order to assist in coordinating continuity of care for individuals infected with TB. The majority of information that CDC collects from the initial referral is performed on a one time basis, with updates only performed if critical gaps are missing that would prohibit completion of the referral and appropriate medical treatment in the patients' new locations.

The consequences of not following up with the new treating physicians on a regular basis would be an absence of information on information on TB patient outcomes, patients who may be moving internationally. This would result in a reduction in the quality of care to the patient and reducing the confidence of referring health entities in the quality of CDC CureTB referral services. It would also negatively impact global TB elimination goals.

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

This request fully complies with the regulation 5 CFR 1320.5.

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 December 23, 2019, Vol. 84, No. 246, p. 70555. No comments were received. (Attachment B)

B. Consultation

A number of public health professionals involved in referrals to CureTB have been consulted over the years on the utility of the program. They are provided here:

Individuals	Title	Role
Ronelle Campbell, DO	Lead TB Clinician County of San Diego TB Branch	Consulted on the need for data collection, approved necessity of project
Maria Nunez	Deputy Director Yuma Health Department Yuma, Arizona	Consulted on the need for data collection, approved necessity of project
Maria Dalbey, RN	TB Nurse Consultant Kentucky TB Prevention and Control Program	Consulted on the need for data collection, approved necessity of project
Fátima Leticia Luna López, MD	Director Mexican National TB Program	Consulted on the need for data collection, approved necessity of project

9. Explanation of Any Payment or Gift to Respondents

DGMQ will not provide remuneration or incentives to participants.

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

CDC has determined that the Privacy Act does apply to this information collection. Individually identifiable data will be stored according to this system. The applicable system of record notice is Quarantine- and Traveler-Related Activities, Including Records for Contact Tracing Investigation and Notification under 42 CFR Parts 70 and 71.

DGMQ and contractors will follow procedures for ensuring and maintaining the security of the data. Contract staff for CureTB must comply with CDC security standards. Paper data forms will be stored in locked cabinets at CDC headquarters and CDC Quarantine stations which are located in a secure area of the airport, in this case in a secured building owned by the San Diego Public Health Department used by CDC to house CDC and its contracted staff. Entry of electronic information pertinent to travel may also be entered into QARS at CDC headquarters in Atlanta. The majority of the data will be stored at the CDC office in San Diego.

CDC and contractor employees who maintain records are instructed to check with the system manager prior to making disclosures of data. When individually identified data are being used in a room, admittance at either CDC or contractor sites is restricted to specifically authorized personnel. Privacy Act provisions are included in contracts, and the CDC Project Director, contract officers and project officers oversee compliance with these requirements. Upon completion of the contract, all data will be either returned to CDC or destroyed, as specified by the contract.

All patient data accumulated by CDC is kept secure and stored according to CDC's data security guidance and System of Records Notice. CDC conducted a Privacy Impact Assessment (Att. G).

Respondents send referrals to CDC CureTB voluntarily to enhance patient outcomes. The CDC will not require this activity. Respondents will be made aware that de-identified, aggregate data may be part of presentations or publications.

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

IRB Approval

Data collected will be only that which is required to maintain continuity of patient care and includes limited clinical data concerning the TB diagnosis and treatment, and contact information described in section A2. The collection of this data is consistent with public health practice, in particular, case management and quality management. The project description has been submitted to the National Center for Emerging and Zoonotic Infectious Disease and this collection has received a non-research determination. (Attachment F)

Justification for Sensitive Questions

There are no sensitive questions asked by CDC CureTB. Health entities will provide the information needed to assure clients get appropriate downstream care. While some content may be sensitive, TB control and continuity of care aims cannot be achieved without sharing with appropriate health authorities and healthcare providers.

12. Estimates of Annualized Burden Hours and Costs

A. Health departments submit CDC CureTB forms (Attachment C, CureTB Transnational Notification) to the CureTB program each time they request TB referral services. One referral is sent for each patient. On average, 70 health departments send approximately 4 referrals each year to the CureTB program, making a total of 280 referrals from health departments annually. The average time to complete and send a CureTB referral form is estimated at 30 minutes.

Therefore, the annual estimated burden to health departments to submit a CureTB Transnational Notification form is 140 hours.

Federal Immigration and Customs Enforcement (ICE) Detention Centers also send TB referrals to the CureTB program. On average, 22 ICE detention centers send approximately 40 referrals each year to the CureTB program, making a total of 880 referrals from ICE detention centers annually. Approximately 95% of them send forms that have already been filled out through the ICE system to reduce the burden of having to fill out an additional form and not duplicate federal efforts. An estimated 5% don't have access to the ICE TB forms and will use the CureTB form (Attachment C, CureTB Transnational Notification) to capture the necessary information of the TB case. As these requests come from federal employees at an agency that captures this information for its own purposes, we do not consider this as respondent burden and have not included it in the burden table.

In approximately 67% percent of referrals from health departments and ICE detention center referrals, CDC CureTB may need to follow up with an individual to complete missing data fields concerning clinical or contact information. This is done to ensure continuity of care. Because this missing data is not uniformly absent from the data sets, the amount of time needed to follow up with each patient differs.

CDC estimates it takes approximately 5 mins to complete the needed information from TB patients referred by health departments. CDC generally needs more information directly from the TB patients who are ICE detainees than it does from the TB patients referred by the health departments. Because of this, there is a higher level of burden of needing 45 mins to get complete information from TB patients referred by ICE detention centers. This results in an anticipated 16 total burden hours for follow up with approximately 187 (66.67% of 280) TB patients referred by health departments, and an anticipated 440 total burden hours for follow up with approximately 587 (66.67% of 880) TB patients referred by ICE detention centers.

CDC staff in the CureTB program also contact the new treating physicians in the new country to determine patient outcomes using the CureTB Clinician Public Health Department Follow-up Script (Attachment E) for approximately 870 patients (75% of the 1,160 patient referrals made by health departments and ICE detention centers). The physicians are generally contacted every two months over the course of the standard 6 month TB treatment, for a total of 3 follow-up contacts per patient. This totals to 2,610 follow-up contacts. CDC estimates that each follow-up contact requires approximately 10 minutes resulting in an estimated annual burden for follow-up contacts of hours.

CDC's CureTB program helps health departments in the United States notify contacts of TB cases who may have been exposed in the new country (Attachment D, CureTB Contact/Source Investigation (CI/SI) Notification). This is a lesser used function of CureTB but burden is included below. These respondents are only the health departments as ICE detention centers do not do contact investigations. Of the approximately 280 responses a year, 20 health departments submit approximately five notifications per year. CDC estimates it takes about 30 min to fill out this form, making a total annual burden of approximately 50 hours.

Table 12.A: Estimated Annualized Burden to Respondents

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Local Health Departments (LHD) in the United States	CureTB Transnational Notification	70	4	30/60	140
TB patients referred by LHD	CureTB Transnational Notification	187	1	5/60	16
TB patients referred by ICE*	CureTB Transnational Notification	587	1	45/60	440
TB treating physicians in new country	Clinician Public Health Department Follow-up Script	870	3	10/60	435
LHD in the United States	CureTB Contact/Source Investigation (CI/SI) Notification	20	5	30/60	50
TOTAL	1,081				

*ICE captures information about patient for its own purposes. CDC does not consider this as respondent burden and have not included it in the burden table.

B. Most of the respondents will be nurses in the public health field (RNs and NPs). Table 12.B presents the calculations for cost of respondents' time using one category of mean hourly wages for a nurse in the U.S. Hourly mean wage information is from the U.S. Department of Labor's Bureau of Labor Statistics website (https://www.bls.gov/oes/current/oes_nat.htm). Based on BLS wage category 29-1141 Registered Nurses, average hourly wage of \$36.30 and 29-1171 Nurse Practitioners, average hourly wage of \$52.90; an average overall is estimated at \$44.60 for all respondents.

TB patients come from a variety of occupations, so CDC is using the All Occupations category from the BLS to calculate annualized cost to respondents. That mean wage is \$24.98 per hour.

TB treating physicians' wages were estimated from data published by the Mexico Secretary of Health. These data were used because a large majority of the referrals are made to Mexico. The category of physician used for this estimate is a Médico General "A", which commonly serves as a TB controller. The salary data is available on a monthly basis, and approximately 35,463 Mexican pesos per month gross. Using PPP data from the World Bank¹, this equates to approximately \$3,780. We assume that these physicians work 40 hours per week, which result in an hour wage of approximately \$23.63 per hour.

Table A.12-B shows estimated burden and cost information. The total estimated annualized respondent cost is \$30,139.

Table 12.B: Estimated Annualized Cost to Respondents

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response	Hourly Wage Rate	TotalCost
Local Health Departments (LHD) in the United States	CureTB Transnational Notification	70	4	30/60	\$44.60	\$6,244
TB patients referred by LHD	CureTB Transnational Notification	187	1	5/60	\$24.98	\$389
TB patients referred by ICE*	CureTB Transnational Notification	587	1	45/60	\$24.98	\$10,997
TB treating physicians in new country	Clinician Public Health Department Follow-up Script	870	3	10/60	\$23.63	\$10,279
LHDs in the United States	CureTB Contact/Source Investigation (CI/SI) Notification	20	5	30/60	\$44.60	\$2,230

¹ <https://data.worldbank.org/indicator/PA.NUS.PPP?locations=MX>

TOTAL						\$30,139
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13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no direct costs to the respondents other than their time to complete the CureTB Transnational Notification or CureTB Contact/Source Investigation (CI/SI) Notification forms, and to respond to CDC requests for follow up with the treating physicians abroad.

14. Annualized Cost to the Government

Costs of the collection to the federal government are a combination of personnel and information technology costs. The personnel costs are estimated using the San Diego – Carlsbad, CA locality adjustment, as the program is based in that location. Total cost for the collection is \$234,343 a year.

San Diego, CA locality.

Table 14: Estimated Annualized Cost to the Federal Government

Contract and Personnel	Role	Cost
Personnel Costs:		Total Personnel Costs
Contractor (GS 12 equivalent – 100% of time)	Program administration and management	\$83,063
Contractor (GS 12 equivalent – 80% of time)		\$66,450
Contractor (GS 13 equivalent – 75% of time)		\$74,080
FTE GS15 – 5% of time		\$10,750
Total Costs		\$234,343

15. Explanation for Program Changes or Adjustments

CDC is requesting a limited number of changes and adjustments to this information collection. These changes and adjustments are requests both to improve information collection, to better reflect the number of referrals received on an annual basis, and to update and be more explicit of the process for receiving the information.

Changes:

- 1) CDC requests the following changes to the CureTB Transnational Notification form:
 - a. Add space for 2 emails, one for the patient and one for the contact person in the U.S. for more complete contact information to enhance follow up success.
 - b. Make the form text larger for ease of completion and legibility.

Adjustments:

- 1) In the first row of the burden table, CDC has changed the type of respondent from Registered Nurses/Nurse Practitioners to Health Departments to clarify the entity responsible for the reporting. CDC has also updated the number of health department respondents referring TB cases to CureTB from 100 to 70, and the number of responses from 5 to 4 responses per respondent. The burden per response however has not changed. The decreases in the number of respondents and how many responses per respondent result in a decrease from 250 to 140 total burden hours for health departments using the CureTB Transnational Notification form.
- 2) While there was a decrease in number of respondents from health departments in row one, the number of TB patient respondents to provide missing information from the health department referrals for row two increased from 100 to 187. This results in a total estimated annual burden increase for the second row from 8 to 16 burden hours annually.
- 3) CDC does not consider the time it takes for the ICE detention facilities to fill out forms and share them with the CureTB as part of this information collection request because collecting the information is part of the federal ICE program already. However, the follow up with the TB patients who are referred by the ICE program is considered as part of this request in the third row and is separate from the health department TB patient follow-up in row two to more explicitly show the different average burden time per response. This new third row also demonstrates an increase in the number of referrals CureTB received from ICE detention centers in the last year. While it does add 440 more burden hours, it is necessary to get complete information to ensure TB patient's continuity of care by new healthcare providers in the new country.
- 4) The fourth row has been updated to reflect needing more physicians in the new country to treat the increase in TB patients. CDC estimates approximately 75% of the 1,160 total referred TB patients have follow up treatment of physicians in their new location. This means the number of respondents has increased from 500 to 870 but the burden per response has not changed. The total estimated respondent burden for the treating physicians abroad has increased from 250 to 435 hours. This is due primarily to the increase in referrals from ICE detention centers.
- 5) There is no increased burden in the fifth row, as this estimate has stayed approximately the same from the last information collection and is only done by health departments.
- 6) Given these adjustments, the total burden hours for this information has increased from 558 to 1,081, mostly due to the increase in referrals from ICE detention centers.

16. Plans for Tabulation and Publication and Project Time Schedule

Data is entered on an ongoing manner as collected. Reports of CDC aggregate outcomes will be provided to CDC DGMQ leadership annually. There are currently no plans for scheduled or routine peer-review publication; however, publication may be warranted as CDC DGMQ demonstrates continued impact on domestic and foreign TB-control efforts.

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

No exemption is being requested. The display of the expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

ATTACHMENTS

A1: Section 361 of the Public Health Service Act

A2: 42 CFR Part 70

A3: 42 CFR Part 71

A4: Section 301 of the Public Health Service Act

A5: Section 311 of the Public Health Service Act

B: Published 60-Day FRN Notice

C: CureTB Transnational Notification

D: CureTB Contact/Source Investigation (CI/SI) Notification

E: CureTB Physician Public Health Department Follow-Up Script

F: IRB Determination

G: Privacy Impact Assessment