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Privacy Impact Assessment Form

v 1.21

Status | Form Number | Form Date

	Question	Answer
1	OPDIV:	CDC
2	PIA Unique Identifier:	0920-0600
2a	Name:	CDC Model Performance Evaluation Program (MPEP) for Mycoba
3	The subject of this PIA is which of the following?	○ General Support System (GSS) ○ Major Application ○ Minor Application (stand-alone) ○ Minor Application (child) ◉ Electronic Information Collection ○ Unknown
3a	Identify the Enterprise Performance Lifecycle Phase of the system.	Initiation
3b	Is this a FISMA-Reportable system?	○ Yes ◉ No
4	Does the system include a Website or online application available to and for the use of the general public?	○ Yes ◉ No
5	Identify the operator.	◉ Agency ○ Contractor
6	Point of Contact (POC):	POC Title: Project Officer POC Name: Cortney Stafford POC Organization: NCHHSTP/DTBE/LB POC Email: fcx6@cdc.gov POC Phone: (404) 639-3420
7	Is this a new or existing system?	○ New ◉ Existing
8	Does the system have Security Authorization (SA)?	○ Yes ◉ No
8b	Planned Date of Security Authorization	☒ Not Applicable

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8c	Briefly explain why security authorization is not required	N/A
9	Indicate the following reason(s) for updating this PIA. Choose from the following options.	☒ PIA Validation (PIA Refresh/Annual Review) ☐ Significant System Management Change ☐ Anonymous to Non-Anonymous ☐ Alteration in Character of Data ☐ New Public Access ☐ New Interagency Uses ☐ Internal Flow or Collection ☐ Conversion ☐ Commercial Sources Other...
10	Describe in further detail any changes to the system that have occurred since the last PIA.	Project will use an online instrument instead of the previous website to collect the MPEP results.
11	Describe the purpose of the system.	The purpose of the Centers for Disease Control and Prevention (CDC) Model Performance Evaluation Program (MPEP), a voluntary educational self-assessment information collection, is to collect and analyze the performance and practices of all known clinical and public health laboratories in the United States that perform drug susceptibility testing of isolates belonging to the Mycobacterium tuberculosis complex (MTBC), a genetically related group of Mycobacterium species that can cause tuberculosis in humans.
12	Describe the type of information the system will collect, maintain (store), or share. (Subsequent questions will identify if this information is PII and ask about the specific data elements.)	Data will be collected from a purposive sample of staff from public health laboratories performing drug susceptibility testing of MTBC. The "Participant Biosafety Compliance Letter of Agreement" collects the name, city and state of the facility, the name and business title of the person completing form, and because the person completing the form Emails the letter back to CDC, the responding Email address will be captured. Data collected from the online survey instrument will include the conventional drug susceptibility results and the molecular test results obtained from testing performed on the isolates the facility received from CDC. The pre-shipment Email will request contact and address information, which includes the name, participant site, mailing address, city, state, zip code, phone, fax number and Email address.

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13	Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.	MPEP is a voluntary educational self-assessment and non-statistical data collection program. The subsequent report reflects data received from participating laboratory personnel. Under MPEP, five isolates of MTBC are sent from CDC to participating laboratories bi-annually for staff to monitor their ability to determine drug resistance among the isolates. The report produced from testing information received from the participating MPEP sites includes results for a subset of laboratories performing drug susceptibility tests (DST) for MTBC in the United States. The aggregate report is prepared in a format that will allow laboratory personnel to compare their DST results with those obtained by other participants using the same methods and drugs, for each isolate. Contact and address information, which includes the name, participant site, mailing address, city, state, zip code, phone, fax number and Email address for the laboratory contact for "Participant Biosafety Compliance Letter of Agreement" is used by CDC to ship isolates to the participating laboratory. This information is used temporarily to conduct shipping and confirm receipt and is stored in CDC email records as part of routine CDC email records retention policy. Although the name of the individual who completes the form on behalf of the respondent laboratory is collected, the individual is responding in their role as an official contact for the laboratory, rather than via personal email or address. Drug susceptibility results submitted by the laboratory through the survey include conventional drug susceptibility results and molecular test results obtained from testing isolates the laboratory received from CDC. Drug susceptibility information based on tuberculosis isolates is retained for 10 years. The aggregate reports of drug susceptibility results are published and used to to monitor the quality and effectiveness of laboratory testing systems which support public health objectives of tuberculosis treatment programs. Aggregate information collected from participants is compiled, analyzed, and reported in a form laboratories can use as a self-assessment tool to maintain the skills for drug susceptibility testing of MTBC.
14	Does the system collect, maintain, use or share **PII**?	(•) Yes ( ) No

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15	Indicate the type of PII that the system will collect or maintain.	☐ Social Security Number ☐ Date of Birth ☒ Name ☐ Photographic Identifiers ☐ Driver's License Number ☐ Biometric Identifiers ☐ Mother's Maiden Name ☐ Vehicle Identifiers ☒ E-Mail Address ☒ Mailing Address ☒ Phone Numbers ☐ Medical Records Number ☐ Medical Notes ☐ Financial Account Info ☐ Certificates ☐ Legal Documents ☐ Education Records ☐ Device Identifiers ☐ Military Status ☐ Employment Status ☐ Foreign Activities ☐ Passport Number ☐ Taxpayer ID Unique Identifier: Facility MPEP Number Business related contact information Other... Other... Other...
16	Indicate the categories of individuals about whom PII is collected, maintained or shared.	☐ Employees ☐ Public Citizens ☐ Business Partners/Contacts (Federal, state, local agencies) ☐ Vendors/Suppliers/Contractors ☐ Patients Other: Employees of clinical and public health laboratories
17	How many individuals' PII is in the system?	<100
18	For what primary purpose is the PII used?	The primary purpose of the PII is to document the contact information of persons completing and submitting the "Participant Biosafety Compliance Letter of Agreement," used to prepare shipments of MTBC isolates to institutions participating in MPEP.
19	Describe the secondary uses for which the PII will be used (e.g. testing, training or research)	The name and business email address will be used to send a final MPEP report to each MPEP participating site where they can compare their DST results to expected results.
20	Describe the function of the SSN.	N/A
20a	Cite the **legal authority** to use the SSN.	N/A

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21	Identify **legal authorities** governing information use and disclosure specific to the system and program.	Public Health Service Act, Section 301, "Research and Investigation," (42 U.S.C. 241); and Sections 304, 306 and 308(d) which discuss authority to maintain data and provide assurances of confidentiality for health research and related activities (42 U.S.C. 242 b, k, and m(d)).Information use and disclosure is governed under Departmental regulations, 5 USC 301. OMB #0920-0136, Epidemiologic Studies and Surveillance of Disease Problems includes authorities for the System of Records Notice (SORN) that covers laboratory assessments for tuberculosis.
22	Are records on the system retrieved by one or more PII data elements?	○ Yes ◉ No
22a	Identify the number and title of the Privacy Act System of Records Notice (SORN) that is being used to cover the system or identify if a SORN is being developed.	Published: Published: Published: ☐ In Progress
23	Identify the sources of PII in the system.	Directly from an individual about whom the information pertains ☐ In-Person ☐ Hard Copy: Mail/Fax ☒ Email ☐ Online ☐ Other Government Sources ☐ Within the OPDIV ☐ Other HHS OPDIV ☒ State/Local/Tribal ☐ Foreign ☐ Other Federal Entities ☐ Other Non-Government Sources ☐ Members of the Public ☐ Commercial Data Broker ☐ Public Media/Internet ☒ Private Sector ☐ Other
23a	Identify the OMB information collection approval number and expiration date.	0920-0600
24	Is the PII shared with other organizations?	○ Yes ◉ No

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24a	Identify with whom the PII is shared or disclosed and for what purpose.	☐ Within HHS ☐ Other Federal Agency/Agencies ☐ State or Local Agency/Agencies ☐ Private Sector
24b	Describe any agreements in place that authorizes the information sharing or disclosure (e.g. Computer Matching Agreement, Memorandum of Understanding (MOU), or Information Sharing Agreement (ISA)).	
24c	Describe the procedures for accounting for disclosures	
25	Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason.	Participant Biosafety Compliance Letter of Agreement is completed by the laboratory employee. The pre-shipment Email is sent to the employee based on contact information provided by the laboratory. Therefore, participating laboratories are aware that the contact information is required in order to participate in the MPEP program, to receive cultures from CDC to test, and to return the results to CDC. If individuals do not want to be the contact person, the facility or lab will identify another individual.
26	Is the submission of PII by individuals voluntary or mandatory?	◉ Voluntary ○ Mandatory
27	Describe the method for individuals to opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason.	Individuals may omit their contact information from the forms. If individuals do not want to be the contact person, the facility or lab will identify a replacement individual.
28	Describe the process to notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of original collection). Alternatively, describe why they cannot be notified or have their consent obtained.	If there are any changes to the system, individuals will be notified by Email, mailing address, or phone number.
29	Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate. If no process exists, explain why not.	No process exists to resolve an individual's concern because they provide the contact information as the laboratory representative. Nonetheless, the Participant Biosafety Compliance Letter of Agreement provides contact information for the system.
30	Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy. If no processes are in place, explain why not.	MPEP participants must submit a Participant Biosafety Compliance Letter of Agreement annually containing PII contact information, allowing CDC program staff to update it as needed.

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31	Identify who will have access to the PII in the system and the reason why they require access.	☐ Users	
		☐ Administrators	
		☐ Developers	
		☐ Contractors	
		☒ Others	Only CDC program staff
32	Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Only CDC program staff with administrative privileges can access the shared drive containing contact PII for MPEP. Supervisory staff submit names of staff members to IT personnel to allow permission to access shared drive.	
33	Describe the methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job.	Only PII needed to conduct MPEP is available to CDC program staff with administrative privileges. Other CDC program staff will be denied access.	
34	Identify training and awareness provided to personnel (system owners, managers, operators, contractors and/or program managers) using the system to make them aware of their responsibilities for protecting the information being collected and maintained.	All CDC program staff are required to complete Annual Security and Privacy Awareness Training.	
35	Describe training system users receive (above and beyond general security and privacy awareness training).	Additional training includes Office of Safety, Security, and Asset Management (OSSAM) Insider Threat and Counter Intelligence and annual refreshers for Records Management.	
36	Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?	○ Yes ◉ No	
37	Describe the process and guidelines in place with regard to the retention and destruction of PII. Cite specific records retention schedules.	CDC uses the CDC Records Control Schedule for determining retention and destruction of PII, specifically, section 04-4-40 Surveillance Report of STD Activity, which prescribes that records be retained and destroyed when no longer needed for administrative or research purposes or when 30 years old, whichever comes first.	

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38	Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.	Administrative: The CDC study team have defined that roles and responsibilities to access PII, which is limited to only study investigators will have access to recruitment, retention, survey, and interview data. CDC personnel are required to complete the annual OCISO Security Awareness Training to make them aware of their responsibilities for protecting the information being collected and maintained. Technical: Access to the server is controlled using individual access controls and only authorized users will have access to the data. Physical: PII for MPEP is kept in a secure drive accessible only to CDC program staff. The CDC campus is protected by armed guards. Building and room access requires a Personal Identification Verification (PIV) access card. A PIV card and password are required to access computer systems, and computer systems log off automatically according to timed schedules.

REVIEWER QUESTIONS: The following section contains Reviewer Questions which are not to be filled out unless the user is an OPDIV Senior Officer for Privacy.

	Reviewer Questions	Answer
1	Are the questions on the PIA answered correctly, accurately, and completely?	◯ Yes ◯ No
Reviewer Notes		
2	Does the PIA appropriately communicate the purpose of PII in the system and is the purpose justified by appropriate legal authorities?	◯ Yes ◯ No
Reviewer Notes		
3	Do system owners demonstrate appropriate understanding of the impact of the PII in the system and provide sufficient oversight to employees and contractors?	◯ Yes ◯ No
Reviewer Notes		
4	Does the PIA appropriately describe the PII quality and integrity of the data?	◯ Yes ◯ No
Reviewer Notes		
5	Is this a candidate for PII minimization?	◯ Yes ◯ No
Reviewer Notes		
6	Does the PIA accurately identify data retention procedures and records retention schedules?	◯ Yes ◯ No
Reviewer Notes		

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	Reviewer Questions	Answer
7	Are the individuals whose PII is in the system provided appropriate participation?	◯ Yes ◯ No
Reviewer Notes		
8	Does the PIA raise any concerns about the security of the PII?	◯ Yes ◯ No
Reviewer Notes		
9	Is applicability of the Privacy Act captured correctly and is a SORN published or does it need to be?	◯ Yes ◯ No
Reviewer Notes		
10	Is the PII appropriately limited for use internally and with third parties?	◯ Yes ◯ No
Reviewer Notes		
11	Does the PIA demonstrate compliance with all Web privacy requirements?	◯ Yes ◯ No
Reviewer Notes		
12	Were any changes made to the system because of the completion of this PIA?	◯ Yes ◯ No
Reviewer Notes		

General Comments	

OPDIV Senior Official for Privacy Signature	Jarell Oshodi -S Digitally signed by Jarell Oshodi -S Date: 2021.11.03 16:15:32 -04'00'	HHS Senior Agency Official for Privacy	