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Privacy Impact Assessment Form

v 1.21

Status | Form Number | Form Date 11/13/18

	Question	Answer
1	OPDIV:	ATSDR
2	PIA Unique Identifier:	0923-13RT
2a	Name:	ATSDR Exposure Investigation - Extension
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.	Implementation
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: Environmental Health Scientist POC Name: Peter Kowalski POC Organization: ATSDR/DCHI/SSB POC Email: pek2@cdc.gov POC Phone: 770-488-0776
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	This data collection does not have a dedicated IT system. It uses various authorized Centers for Disease Control and Prevention (CDC) systems for the collection, processing, analysis, and storage of data .
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 OMB Generic Information Collection Request (ICR) extension
10	Describe in further detail any changes to the system that have occurred since the last PIA.	None. This assessment represents an extension information collection request.

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11 Describe the purpose of the system.	The Agency for Toxic Substances and Disease Registry (ATSDR) Division of Community Health and Investigation (DCHI) conducts public health assessments (PHAs) at sites when requested by the U.S. Environmental Protection Agency (EPA), states, organizations, or individual petitioners following the Public Health Assessment Guidance Manual. The purpose of the agency's PHA process is to ascertain whether a community has experienced environmental exposures of concerns or is now being exposed to hazardous substances, and if so whether conditions warrant additional sampling and to decide if intervention is needed to minimize or eliminate exposure. The process also serves as a mechanism through which the agency responds to specific community health concerns related to hazardous waste sites. ATSDR scientists review environmental data to see how much contamination is at a site, where it is, and how community residents might come into contact with it. Generally, ATSDR does not collect its own environmental sampling data but when adequate environmental or exposure information to assess human exposures and possible related health effects do not exist, ATSDR will perform an Exposure Investigation (EI). The EI team conducts point of human-contact sampling focused on geographic areas where exposures are expected to be high. EIs may include environmental (e.g, soil, drinking water, sediment, food sources, etc.), biological sampling (e.g., blood, urine, etc.), or both. An EI, using purposive convenience sampling, aims to identify the most highly exposed individuals and measure their exposure. The results of the investigation are site-specific and apply only to the participants from the site. An EI is not considered a health study or research, and any data gathered will thus not be disseminated as such. Furthermore, the EI is not designed to provide individual diagnoses, nor are participants' results intended to be generalized to other populations and other communities. No participants from external comparison groups are included in the data collection. As a public service and incentive to participate, EIs provide individual exposure information back to the participants. The Science Support Branch (SSB) also coordinates and lends technical assistance to states, tribal, and territorial health departments that conduct their own EIs as well as to states included in ATSDR's Partnership to Promote Localized Efforts to Reduce Environmental Exposure (APPLETREE) Program which sponsors state-led non-research EIs.

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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.)	Two primary types of information are collected during the EI process: collection of environmental and/or biological data and questionnaire data that will be used to better interpret the sampling results obtained during the EI. The results of the questionnaire will be recorded electronically in the field and the data will be transferred to a secure server. The questionnaire will include direct identifiers including name, mailing address, phone numbers, medical notes, date of birth, and E-Mail address; demographic information including gender, age, ethnicity, and race; household information including age of home and time of residency; and occupational information including occupations that may be related to a particular contaminant. Consent forms will be signed by participants and the hard copy forms will be secured in a locked cabinet at ATSDR. Appropriate information will be shared with federal and state partners, as appropriate. Participants may be asked to consent to their information being shared with federal and state partners. Users are authenticated to systems used in this information collection via CDC's Active Directory and security card credentials. PII collected from users and/or system administrators to access the system consists of user credentials like username, password, Personal Identity Verification (PIV) card, and user ID. Users and system administrators include CDC employees and badged contractors.

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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.	Under this information collection, the EI will be completed using an approved protocol. All collections are voluntary for respondents. The information collected may include environmental and/or biological samples and questionnaire results, which will be used to interpret the sampling results. PII information will be collected, including respondent's name, address, phone number and email address to allow ATSDR to provide respondents with their individual sampling results. PII information will be stored on a secure server and access will be limited to ATSDR personnel on the EI team. The information collected for the EI using the questionnaire may include information regarding demographic and residential history, household water use, occupational history, and age and activity patterns. Basic health status information (i.e., pregnancy status) may be obtained that will allow the sampling results to be assessed for each participant. The information collected will be used to better interpret the sampling results obtained during the EI. The questionnaire will be administered in person to participants by ATSDR personnel. Questionnaire results will be recorded in the field on a secure computer and transferred to a secured server. Access to the server will be limited to ATSDR personnel on the EI team. Appropriate information will be shared with federal and state partners. Participants will be asked to sign an adult consent form or a parental permission and/or assent form for children younger than 18 years old. The consent/parental permission/assent forms will include permission for ATSDR to share information with federal and state partners. Consent forms are hard copy and will be secured in a locked cabinet.
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 Participant biological testing results Participant environmental sampling results Household and Demographic Information Occupational Information 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
17	How many individuals' PII is in the system?	100-499
18	For what primary purpose is the PII used?	The primary purpose for collecting the PII for EIs is to provide participants their individual sampling results.
19	Describe the secondary uses for which the PII will be used (e.g. testing, training or research)	Not applicable.
20	Describe the function of the SSN.	Not applicable.
20a	Cite the **legal authority** to use the SSN.	Not applicable.
21	Identify **legal authorities** governing information use and disclosure specific to the system and program.	ATSDR is authorized under the 'Comprehensive Environmental Response, Compensation, and Liability Act of 1980'' as amended by ''Superfund Amendments and Reauthorization Act of 1986'' (42 U.S.C. 9601, 9604).
22	Are records on the system retrieved by one or more PII data elements?	◉ Yes ○ No

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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:	09-19-001 Records of Persons Exposed or Potent
		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.	OMB package in process; OMB Control No. 0923-0048 (Expiration Date: 03/31/2019)	
24	Is the PII shared with other organizations?	◉ Yes ○ No	
24a	Identify with whom the PII is shared or disclosed and for what purpose.	☐ Within HHS ☒ Other Federal Agency/Agencies: Federal Agencies may assist with EIs. The agencies may use PII if follow- ☒ State or Local Agency/Agencies: State Agencies may assist with EIs. ☐ 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)).	A Memorandum of Understanding (MOU) providing a data use agreement for state and federal partners will be implemented, as needed.	

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24c	Describe the procedures for accounting for disclosures	As appropriate, PII will be shared with federal and state partners. For instance, state agencies may obtain blood lead results at a reportable level or EPA may obtain results to assist with their remedial efforts at a site. All disclosures will be recorded on an excel spreadsheet and will include the dataset, who the dataset was disclosed to, and for what purpose.
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.	Participants will sign consent forms or parental permission forms/assent forms if participant is younger than 18 years old. The forms have a provision that will request permission from the participant to allow ATSDR to share their PII with federal and state partners, as appropriate.
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.	In the consent forms and parental permission/assent forms, there is a provision for individuals to opt-out of the sharing of their PII with partners. However, collection of PII will be required to participate in the study so ATSDR can share results of the testing with participants. They may also opt out of the EI entirely by not responding, consenting, or by stated refusal.
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.	Participants will be notified by phone, email and/or mail using information participants provided during the consent process. Participants will be asked to consent to the change in writing and the forms will be secured at ATSDR.
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.	Individuals should contact the system manager, identify the record and specify the information being contested, the corrective action sought, and the reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant. If an incident has occurred, the system manager will report the potential incident to the CDC Security Incident Response Team and Privacy Officer. The data manager in consultation with the principal investigator will serve as the point of contact to resolve concerns.
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.	ATSDR personnel will determine whether the PII collected via consent/parental permission/assent forms and questionnaires are accurate. Participants will be provided ATSDR contact information to allow them to inform ATSDR if their contact information changes. ATSDR will use obtained contact information to provide participants with biological testing results.

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31	Identify who will have access to the PII in the system and the reason why they require access.	☒ Users	ATSDR personnel will have access to PII to provide participants with their test
		☒ Administrators	ATSDR administrators will be responsible for setting parameters
		☐ Developers	
		☒ Contractors	ATSDR may use contractors for some EIs and contractors will have access to
		☐ Others	
32	Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	PII access will be limited to that needed to notify participants of their testing results. ATSDR administrators will have access to PII as they set up and maintain permissions and access to the server that will house the PII data for the EI.	
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.	ATSDR personnel will access PII data when they are recruiting participants and providing sampling results to participants. System managers will implement role based access controls on share drives such that only designated staff may access PII. All other staff may have access to de-identified data only.	
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 users will be required to complete CDC's annual security and privacy training. All users with access to the study data will be required to only access PII for the purpose of recruitment or reporting testing results to participants. System managers continuously monitor system activities to ensure compliance with security requirements. A rules of behavior document for EIs will be signed by the EI team and then implemented at each site.	
35	Describe training system users receive (above and beyond general security and privacy awareness training).	All EA personnel handling PII will complete appropriate privacy training and obtain a Scientific Ethics Verification (SEV) number.	
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.	Records are retained and disposed of in accordance with the ATSDR Comprehensive Records Control Schedule (B-371). Final EI reports are permanent records. Site files generated in support of the final report will be maintained in the Records and Information Management Branch and transferred to a Federal Records Center 5 years after the final report is published. Site records will be destroyed 30 years after the report is published. Disposal methods include the paper recycling process, burning or shredding hard copy records, and erasing computer files. Registry records will be actively maintained as long as funding is provided for by legislation.	

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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 Controls ATSDR who maintain records are instructed in specific procedures to protect the security of records, and are to check with the system manager prior to making disclosure of data. When individually identified data are being used in a room, admittance is restricted to specifically authorized personnel. Appropriate Privacy Act provisions will be adhered to for the EI. Technical Controls Protection for computerized records includes programmed verification of valid user identification code and password prior to logging on to the system, mandatory password changes, limited log-ins, virus protection, user rights/file attribute restrictions and use of encrypted files. Password protection imposes user name and password log-in requirements to prevent unauthorized access. Each user name is assigned limited access rights to files and directories at varying levels to control file sharing. There are routine daily backup procedures and secure off-site storage is available for backup files. Knowledge of passwords is required to access systems which are limited to users obtaining prior supervisory approval. When possible, a backup copy of data is stored at an offsite location and a log kept of all changes to each file and all persons reviewing the file. Selected safeguards will be applicable to specific elements of the system, as appropriate. Additional safeguards may also be built into the program by the system analyst as warranted by the sensitivity of the specific data set. Study data files with PII will use file level encryption and databases will employ column level encryption for PII. Physical Controls Questionnaires, log books, and other source data are maintained in locked cabinets in locked rooms, and security guard service in buildings provide personnel screening of visitors. Access to facilities is controlled by a card key system. Access to computer rooms is controlled by a card key and security code system. Computer rooms are protected by an automatic sprinkler system, numerous automatic sensors are installed, and a proper mix of portable fire extinguishers is located throughout the computer room. The system is backed up on a nightly basis with copies of the files stored off site in a secure fireproof safe. Computer workstations, lockable personal computers, and automated records are located in secured areas.

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		

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	Reviewer Questions	Answer
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		
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

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Reviewer Questions		Answer
Reviewer Notes		
General Comments		
OPDIV Senior Official for Privacy Signature	Jarell Oshodi -S Digitally signed by Jarell Oshodi -S Date: 2018.12.18 13:49:15 -05'00'	HHS Senior Agency Official for Privacy