Save

Privacy Impact Assessment Form

v 1.21

Status | Form Number | Form Date 07/25/19

	Question	Answer
1	OPDIV:	ATSDR
2	PIA Unique Identifier:	CDC ID No. 0923-18AUZ
2a	Name:	Human health effects of drinking water exposures to per- and p
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.	Test
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: Principal Investigator POC Name: Marian Pavuk POC Organization: ATSDR Division of Toxicology and POC Email: fsh8@cdc.gov POC Phone: 770-488-3671
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

Save

8c	Briefly explain why security authorization is not required	This data collection does not have a single dedicated IT system. It uses various authorized CDC IT systems for the collection, processing, analysis, and storage of the data .	
10	Describe in further detail any changes to the system that have occurred since the last PIA.	Not applicable.	

Save

11 Describe the purpose of the system.	Per- and polyfluoroalkyl substances (PFAS) are a family of chemicals used in industrial applications and consumer products. PFAS contamination of drinking water is widespread in the U.S. Some estimates indicate that at least sixty million residents were served by 66 public water supplies that had at least one sample at or above the US Environmental Protection Agency (EPA) Lifetime Health Advisory for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) (individually or combined), which is 70 nanograms per liter (ng/L) of water. Industrial facilities that manufacture or use PFAS have contaminated drinking water in surrounding communities in several states. In addition, PFOS, PFOA, perfluorohexane sulfonic acid (PFHxS) and other PFAS chemicals are constituents in aqueous film-forming foam (AFFF), used to extinguish flammable liquid fires. The use of AFFF at military bases and other sites may have resulted in the migration of PFAS chemicals through soils to ground water and/or surface water sources of drinking water for the bases and/or surrounding communities around the country. In response to growing awareness of the extent of PFAS contamination across the U.S., the Section 316(a) of the 2018 National Defense Authorization Act (P.L. 115-91) as amended by Section 315 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) authorized the Agency for Toxic Substances and Disease Registry (ATSDR) to conduct a study on the human health effects of PFAS contamination in drinking water. Consequently, ATSDR is requesting a three-year Paperwork Reduction Act (PRA) clearance for the Multi-site Study. The Multi-site Study will build on the preceding proof-of-concept study at the Pease International Tradeport in Portsmouth, New Hampshire (OMB Control No. 0923-xxxx; expiration date mm/dd/yyyy). ATSDR will conduct this research using a cooperative agreement titled “Multi-site Study of the Health Implications of Exposure to PFAS-Contaminated Drinking Water” (Notice of Funding Opportunity [NOFO] No. CDC-RFA-TS-19-002). The expected number of research recipients (e.g., entities selected for funding) is six. The program will be administered by the CDC Extramural Research Program Office (ERPO) at the National Center for Injury Prevention and Control (NCIPC). The research under this cooperative agreement will be a two-part program. First, a mandatory core research protocol for all recipients is designed to aggregate data across all sites and designed to compare data between sites. Next, each recipient will have the option to propose additional investigator-initiated research questions and hypotheses related to the overall goals of this NOFO. The main goal of this cross-sectional multi-site study is to evaluate associations between measured and reconstructed historic serum levels of PFAS including PFOA, PFOS, and PFHxS, and selected health outcomes.

Save

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.)	Study recipients will collect participant information, survey responses, special educational records, and medical records from the study participants and transfer them them to CDC to be aggregated. Categories of data and examples of the data elements to be collected are: Participant Information (name, Social Security Number [SSN], date of birth, race, sex, address, email, phone number, etc.) Survey Information (consent forms, exposure routes, water consumption/source, medial history, education, occupation, etc.) Lab Test Results (per- and polyfluoroalkyl substances [PFAS] concentration values in blood and urine, lipids, liver function test, kidney function test, thyroid hormones, sex hormones, immune function, anti-body response, etc.) Children's schools will complete a form about diagnosed learning disabilities and behavioral problems. Medical providers will complete a form about conditions the participants have been diagnosed with. CDC will provide recipients with all lab test data to provide the results to study participants. Recipient will maintain collected information on site-specific participants for contact information for result reporting and future contact. CDC will maintain all-site aggregated data and share with the study recipients for statistical analyses of multi-site outcomes. All systems used by this study at CDC will authenticate users via CDC's Active Directory or Secure Access Management System (SAMS). Both are systems with their own PIA.

Save

13	Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.	The Multi-site Study will be cross-sectional in design. Statistical sampling methods (e.g., a two-stage cluster sample) may be used for recruitment of study participants if all the affected households can be enumerated. If enumeration of all households is not feasible, or if participation rates are expected to be low, then the recipient can consider non-probabilistic sampling approaches such as "judgment" and "snowball" sampling approaches. ATSDR and recipients will collect information in several modes: (1) hardcopy and then entered into data bases (informed consent, update contact information, several forms to collect study data during the appointment, neurobehavioral test battery results); and (2) through electronic means using an approved survey/data collection tool - eligibility screening scripts, appointment reminder telephone calls, adult and child questionnaires. Data collected, shared and stored about adults will be participant information, surveys, and lab test results. In addition, the study will collect educational records about school age children. This data will be shared outside CDC using approved data use agreements with outside investigators for approved research purposes.
14	Does the system collect, maintain, use or share **PII**?	(•) Yes ( ) No
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 Other... Lab Test Results Other... Other...

Save

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?	5,000-9,999
18	For what primary purpose is the PII used?	ATSDR needs up-to-date PII for the informed consent process and to send participants' their lab testing results.
19	Describe the secondary uses for which the PII will be used (e.g. testing, training or research)	ATSDR will keep participant PII, including SSN, for future studies, which will include longitudinal data collections. This will require the linking of participant study identity and results from Study A to Study B, etc.
20	Describe the function of the SSN.	SSN will be collected at enrollment for linkage to medical records and school records. Once the linkage has occurred, the SSN will be kept with other PII in a separate access-restricted and encrypted secure share site. ATSDR will use SSN for tracking and tracing Multi-site Study participants for enrollment in future longitudinal studies.
20a	Cite the **legal authority** to use the SSN.	Superfund Amendments and Reauthorization Act of 1986 (SARA).
21	Identify **legal authorities** governing information use and disclosure specific to the system and program.	Section 316(a) of the 2018 National Defense Authorization Act (P.L. 115-91).
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: 09-19-0001 ATSDR "Records of Persons Exposed Published: Published: ☐ In Progress

Save

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.	CDC ID No. is 0923-18AUZ; OMB Control No. 0923-NEW
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 ☒ State or Local Agency/Agencies: ATSDR will obtain consent to retrieve ☒ Private Sector: ATSDR will obtain consent to ~~retrieve medical records information~~

Save

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)).	As part of the required "Data Management Plan," ATSDR will share data sets with external entities via data use agreements (DUA) with each data recipient. The data use agreement (DUA) will be prepared, detailing the condition of use of the data and proposed analyses for each outside project. One of the Multi-site study investigators must be a co-investigator on any outside research project to guarantee adherence to the agreed conditions of use. After the approved project with the researchers outside of Multi-site study group is completed, further or secondary analyses of electronic datasets can only be undertaken with additional approval(s) from ATSDR. Written confirmation of understanding the conditions of use will be required from the lead scientist and institution.
24c	Describe the procedures for accounting for disclosures	Procedures for accounting for disclosures are detailed in the study's manual of procedures. Typically, this will be a manual process where the program keeps track of disclosures in a spreadsheet.
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.	ATSDR has a Privacy Act Statement that will be part of the informed consent package. The Privacy Act Statement specifies the ATSDR purpose for collecting PII, including SSN. The informed consent information will be mailed in advance to persons who are willing to take part in an Appointment Packet for them to read in advance and to keep for their records. In addition, ATSDR will use these forms and materials at enrollment during their actual informed consent to obtain signatures.
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 who wish to opt out may decline taking part in the study. Additionally, if participants decide at a later date that they would like to opt out of potential recontact for future studies, they can contact the Principal Investigators at the number provided on the consent form.
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.	ATSDR will contact individuals via email, telephone, and/or mail (if available) when major changes to the study occur to obtain consent from the study participants.

Save

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 that have a concern that their PII has been inappropriately used, obtained, or disclosed, OR that their PII is inaccurate should contact the study Principal Investigator (PI) and data manager using contact information in the study's consent form or System of Records Notice (SORN). The individual may be directed to contact the PI or data manager to 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 PI or data manager will report the potential incident to the CDC Security Incident Response Team and the Privacy Officer. The data manager will serve as the point of contact (POC) to resolve the individual's 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.	There is no process in place for periodic reviews of the PII. Once laboratory results are reported to the study participants, data will be de-identified and used for analysis.	
31	Identify who will have access to the PII in the system and the reason why they require access.	☒ Users ☒ Administrators ☐ Developers ☐ Contractors ☐ Others	Study PIs and trained study staff to obtain informed consent and to relink Study PIs will be responsible for setting parameters allowing access to
32	Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Per the Multi-site Study Rules of Behavior, the data manager, in consultation with the study PI, will determine which users will be able to access the data and the specific data they will need based on their role and research goals/priorities. Procedures for PII access are documented in detail in the study Manual of Procedures.	
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.	The data access request will be approved by the PI on a need to know basis. When the access is no longer needed, the data manager will be responsible for removing or terminating user's access. Least privilege access will be employed, and users will only be given access to the minimum data required for their particular analysis. The study data manager will make this determination.	
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.	Personnel are required to complete CDC security awareness training.	

Save

35	Describe training system users receive (above and beyond general security and privacy awareness training).	ATSDR will require all study staff and direct contractors to receive training on their roles and responsibilities, as outlined in the Multi-site Study Manual of Procedures. All research staff must have ethics training and possess certification of such training. All research staff must sign an agreement acknowledging their responsibilities to protect participants' privacy and confidentiality. The Multi-site Study Rules of Behavior will be signed and reviewed by all research staff.
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.	PII data files collected in this study will be stored in a dedicated CDC encrypted multi-user share with file level encryption. The study will use a CDC approved software tool (currently it is PGP Shredder) to dispose the PII data files when directed by the PI and according to the appropriate records control schedule. The approved records control schedule for this study is CDC/ ATSDR Records Control Schedule, Part 7: ATSDR, 5-13. Any records sent to the Federal Records Center (FRC) will be de-identified as per the consent form. No PII will be disclosed to the FRC.
38	Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.	The PII will be secure in the system using: 1. Administrative controls such as Rules of Behavior, Manual of Procedures, Non-disclosure Agreements (NDA), and Data User Agreements (DUA); 2. Technical controls including the file level, column, and whole disk encryption, e-Auth Level 3 external file share with encryption, access control lists in multiple authorized CDC IT systems, and routine daily backup of study data; and 3. Physical controls including controlled physical access, guards, key card access, locked rooms, as well as locked cabinets for hardcopy of documents with PII.

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		

Save

	Reviewer Questions	Answer
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
Reviewer Notes		
General Comments		

Save

OPDIV Senior Official for Privacy Signature	Jarell Oshodi -S Digitally signed by Jarell Oshodi -S Date: 2019.07.29 07:14:53 -04'00'	HHS Senior Agency Official for Privacy	