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Privacy Impact Assessment Form

v 1.21

Status | Form Number | Form Date 11/14/18

	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

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8c	Briefly explain why security authorization is not required	Not applicable.
10	Describe in further detail any changes to the system that have occurred since the last PIA.	Not applicable.
11	Describe the purpose of the system.	Per- and polyfluoroalkyl substances (PFAS) are a family of environmentally and biologically persistent chemicals used in industrial applications such as aqueous film-forming foam (AFFF), used to extinguish flammable liquid fires. Since the 1970s, military bases in the U.S. have used AFFF with PFAS constituents for firefighting training as well as to extinguish fires. At some military bases, AFFF use has resulted in the migration of PFAS chemicals through soils to ground water and/or surface water sources of drinking water for bases and/or surrounding communities. In 2016, the U.S. Environmental Protection Agency (USEPA) issued a lifetime health advisory level of 0.07 total micrograms of perfluorooctanoate (PFOA) and perfluorooctane sulfonate (PFOS) combined per liter of drinking water (µg/L). In response to growing awareness of the extent of PFAS contamination across the U.S., the Consolidated Appropriations Act of 2018 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. The Pease Study will serve as a proof-of-concept model for a national multi-site study of PFAS health effects. The existence of a large body of state and local environmental monitoring and population blood testing data makes the Pease community in Portsmouth, NH, particularly suitable as ATSDR's initial PFAS research study site. The main goals of the research study are to: 1) evaluate the study procedures and methods to identify any issues that need to be addressed before embarking on a national multi-site study; and 2) examine associations between health outcomes and measured and historically reconstructed serum levels of PFAS.
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.)	ATSDR will collect and maintain participant information including social security number, name, E-Mail address, phone numbers, medical notes, education records, military status, date of birth, mailing address, race, sex, and employment status; survey information and responses including consent forms, exposure routes, water consumption/source, medical history, education, and occupation; lab test results including PFAS concentration values in blood and urine, lipids, liver function test, kidney function test, thyroid hormones, sex hormones, immune function, and antibody response; special educational records; and medical records from study participants.

Save

13	Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.	The Pease Study will be cross-sectional in design, drawing from a convenience sample of people with and without exposure to PFAS-contaminated drinking water from Pease. ATSDR will collect information in several modes: (1) hard copy and then entered into databases (e.g., informed consent, update contact information, several forms to collect study data during the appointment, neurobehavioral test battery results, etc.); and (2) through electronic means using an approved survey/data-collection tool (e.g., eligibility screening scripts, appointment reminder telephone calls, adult and child questionnaires, 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.
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...
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?	500-4,999
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.

Save

19	Describe the secondary uses for which the PII will be used (e.g. testing, training or research)	ATSDR will keep participant PII for future studies, to include longitudinal data collections, to link participant study identity and results from Study A to Study B, B to A and/or C, etc.
20	Describe the function of the SSN.	SSN will be collected for linkage to medical records and school records. Once linkage has occurred, SSNs will be kept with other PII in a separate access-restricted and encrypted secure share site. ATSDR will use SSN for tracking and tracing Pease Study participants for enrollment in future longitudinal studies.
20a	Cite the **legal authority** to use the SSN.	Executive Order 9397
21	Identify **legal authorities** governing information use and disclosure specific to the system and program.	Consolidated Appropriation Act of 2018; Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA) and Superfund Amendments and Reauthorization Act of 1986 (SARA); Public Health Service Act
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
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

Save

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
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 (DUAs) with each data recipient. DUAs will be prepared, detailing the condition of use of the data and proposed analyses for each outside project. One of the Pease 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 the Pease study group is completed, secondary and/or other levels of 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 scientists and institutions.
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 (PAS) that will be part of the informed consent package. The PAS specifies the purpose for collecting PII. The informed consent information will be mailed in advance to willing participants as part of an Appointment Packet for them to read and keep for their records. In addition, ATSDR will use these forms and materials at enrollment during 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 participating in the study. Additionally, participants may opt out of potential recontact for future studies.
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 when major changes to the study occur to obtain consent from 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 should contact the study investigator (PI) and data manager using contact information in the study's SORN or consent form. They 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 Centers for Disease Control and Prevention (CDC) Security Incident Response Team and Privacy Officer. The data manager 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.	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	Users include study PIs and trained study staff to obtain informed consent
		☒ Administrators	Study PIs will be responsible for setting parameters allowing access to
		☐ Developers	
		☐ Contractors	
		☐ Others	
32	Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Per the Pease Study Rules of Behavior, the data manager, in consultation with the study PI, will determine which users will be able to access data-access 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 access is no longer needed, the data manager will be responsible for removing or terminating user 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.	
35	Describe training system users receive (above and beyond general security and privacy awareness training).	ATSDR will require all study staff and contractors to receive training on their roles and responsibilities, as outlined in the Pease 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 Pease Study Rules of Behavior will be signed and reviewed by all research staff.	

Save

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 CDC Records Control Schedule (B-321) and the ATSDR Comprehensive Records Control Schedule (B-371).
38	Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.	Administrative controls are specified in Rules of Behavior, Manual of Procedures, Non-Disclosure Agreements (NDAs), and DUAs. Technical controls include file level, column, and whole disk encryption; e-Auth Level 3 external file share with encryption; access control lists in multiple authorized CDC systems; and routine daily backup of study data. Physical controls include physical access checkpoints, guards, key card access, locked rooms, and locked cabinets for hard copy 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		
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		

Save

	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	12/1/18: PIA is approved; however the authority for collection of SSNs is awaiting approval.

OPDIV Senior Official for Privacy Signature	Jarell Oshodi -S Digitally signed by Jarell Oshodi -S Date: 2018.12.10 17:21:55 -05'00'	HHS Senior Agency Official for Privacy	