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Privacy Impact Assessment Form

v 1.21

Status | Form Number | Form Date

	Question	Answer
1	OPDIV:	ATSDR/NCEH
2	PIA Unique Identifier:	0923-18AJK
2a	Name:	PFAS Exposure Assessments
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.	Planning
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: Section Chief Exposure Investigat POC Name: Karen Scruton POC Organization: ATSDR/OCCHA POC Email: isg3@cdc.gov POC Phone: 770-488-1325
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	The study will use multiple CDC authorized systems for data collection and storage.
10	Describe in further detail any changes to the system that have occurred since the last PIA.	There is no previous PIA for this new electronic information collection.
11	Describe the purpose of the system.	The goal of this information collection is to address the requirements for completing exposure assessments (EAs) for per- or polyfluoroalkyl substances (PFAS). The Agency for Toxic Substances and Disease Registry and the National Center for Environmental Health (ATSDR/NCEH) will use statistical methods to recruit respondents at former domestic military installations or non-military installations known to have PFAS contamination in drinking water, groundwater or other water sources. Respondents may include both on-site and off-site residents. ATSDR will collect biological and environmental samples to evaluate exposure.
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.)	The types of information to be collected, maintained, and shared include: Contact information (name, mailing address, email address, phone numbers) Demographics information (date of birth, age, household demographic history, activity patterns, residential history, occupational history) Household information (drinking water source and household filtration system, household dust and tap water lab results) Basic Health Status Information (e.g., kidney disease, pregnancy status, medical notes) and blood and urine lab results.

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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.	The study will determine the level of PFAS exposure of participants at various sites. All information collected, maintained, and/or shared is needed to allow participants' blood results to be assessed and interpreted. It is also needed to share the information with federal and state partners, and for participants to be contacted after the EA for potential participation in a national multi-site study for PFAS. Results of the EA will be used to inform the multi-site study. Questionnaires will be administered in person to participants by the Centers for Disease Control and Prevention (CDC) and ATSDR personnel or their direct contractors. PII data will be retrieved routinely by respondents' names, mailing addresses, phone numbers, and/or Email addresses to allow CDC/ATSDR and its direct contractors to provide respondents with their individual sampling results. We require Contact Information in order to provide the participants their sampling results and to contact them for future PFAS studies, as appropriate. We require Demographics Information to allow us to better interpret blood and urine test results given that PFAS levels may be related to age, duration of residency, and occupational exposure. Date of birth is important to allow us to determine an age for children since we will only test children aged 3 and older. We require Household Information so we can determine how much water a person drinks, whether they have treatment systems and to collect the results of the PFAS sampling in dust and tap water. We require Basic Health Status Information because PFAS has been associated with pregnancy status and kidney disease and any appropriate medical notes. WE need to collect the results of the PFAS sampling in blood and urine.
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 Household dust and tap water results Blood and urine lab results Household demographics and information Occupational information Basic Health Status Information
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?	The primary purpose for collecting PII is to provide participants their individual biological and environmental sampling results.
19	Describe the secondary uses for which the PII will be used (e.g. testing, training or research)	The secondary use of PII will be to contact a select number of participants about involvement in a subsequent national multi-site study of PFAS.
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, in general, is authorized to conduct exposure assessments 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); and the 'Resource Conservation and Recovery Act of 1976'' as amended in 1984 (42 U.S.C. 6901).

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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: 09-19-001 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.	CDC ID No. 0923-18AJK; OMB Control No. 0923-0059 (exp 06/30/22 - 3 year extension in process)
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 the EAs. The agencies may use PII if ☒ State or Local Agency/Agencies: State Agencies may assist with the EA ☐ 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)).	An MOU with federal or state partners will be created for each specific EA location.

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24c	Describe the procedures for accounting for disclosures	As appropriate, PII will be shared with federal and state partners in accordance with the MOU(s). Disclosures are accounted for according to the SORN. Disclosures not accounted for in the SORN will be managed and the procedures established by the system manager. Typically, this procedure involves a manually updated tracking spreadsheet. Disclosure of PII to entities outside of CDC must be approved in writing and then logged in a spreadsheet. Disclosures should not be made without a fully executed data use agreement (DUA). The DUA and disclosure spreadsheet are maintained by a principal investigator and data manager. No data will be disclosed to an outside entity unless controls exist to protect the data in transit.
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 assent forms if a participant is younger than 18 years old. The forms have a provision that will request permission to allow CDC/ATSDR to share participants' PII with federal and state partners, as appropriate, as well as to be contacted after the EA for potential participation in a national multi-site study for PFAS. A Privacy Act Statement (PAS) is included as part of the consent information. The PAS also is mentioned to participants as part of an eligibility screener.
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.	Participants may opt-out of the study entirely by non-response, non-consent, or stated refusal. Also, the consent forms and parental permission/assent forms include a provision for individuals to opt-out of the sharing of their PII with partners.
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 a major change to the information collection occurs, 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.
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 reasonably identify the record, contact CDC/ATSDR personnel, specify the information being contested, state the corrective action sought, and state the reasons for requesting the correction. They also should provide supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant. If an individual is concerned that their PII has been used inappropriately and communicates that to the CDC, the matter will be reported to and evaluated by CDC/ATSDR personnel within 48 hours. Any inquiries from individuals related to their PII also will be reviewed by the PFAS Data Manager. The Data Manager will decide what action to take and communicate that decision to the individual within 60 days.

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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.	For each EA, CDC/ATSDR personnel will determine whether the PII data are accurate in a periodic manner, including when appointments are being made, when consent forms and questionnaires are being administered or when results are being provided to participants. Participants will be provided CDC/ATSDR contact information to allow them to inform CDC/ATSDR if their contact information changes.	
31	Identify who will have access to the PII in the system and the reason why they require access.	☒ Users	CDC/ATSDR personnel will have access to PII to report individual results to
		☒ Administrators	CDC/ATSDR administrators will be responsible for allowing access to PII
		☐ Developers	
		☒ Contractors	ATSDR will use direct contractors to collect PII, perform testing during the
		☐ Others	
32	Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Access to PII will be limited to those with a need to know the data; individuals will be assigned roles based on their function in the study. Roles will determine the type and amount of PII individuals will be able to access. Additionally, roles and accesses will be reassessed periodically by CDC/ATSDR administrators, reestablishing permissions accordingly.	
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.	CDC/ATSDR personnel and contractors will access PII when they are recruiting participants and providing biological and environmental sampling results to participants. Field data collectors will only have access to the information they are collecting. They will not have permissions to access any IT resources from the study other than the laptops they use for data collection. Once data have been collected, system managers will implement role-based access controls on share drives such that only designated staff may access PII. Data aggregators and de-identifiers will be the only users with access to aggregated PII. Access to the de-identified data will be handled by the National Environmental Public Health Tracking Network (NEPHTN).	
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 EA personnel handling PII will have completed appropriate privacy training and CITI Human Subjects Training Certification as required by June 2022.	
35	Describe training system users receive (above and beyond general security and privacy awareness training).	All users must read and sign PFAS EA Rules of Behavior for Data Access and Use, a document that provides guidance for data access. System managers continuously monitor system activities to ensure compliance with security requirements.	
36	Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?	◉ Yes ○ No	

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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 Scientific and Research Project Records Schedule, under the Significant and or Secondary Research Records Schedule. The schedule for these records apply to datasets, field records, and other information necessary to understand a research project. They may also be connected to other data through metadata, indices, or other means. Research records that do not meet the criteria for permanently significant records but may be appropriate for long-term retention are those that: ☒ Have implications or usefulness for future scientific investigations. ☒ Might benefit from the passage of time for determining their value. Records may also include background materials maintained by individual researchers used to understand scientific advances, learn new techniques, or to prepare for a new project. Master file, system or databases of significant interest, and long-term value but not precedent-setting, not complete, have limited evidentiary and information value in terms of health data, and/or documenting CDC programs and accomplishments. Authorized Disposition: Maintain at least eleven years, but no longer than twenty years, after the retirement of the system—depending upon program need for scientific, legal, or business reference. Transfer to FRC is authorized in accordance with CFR storage regulations of electronic records.

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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: All users with access to study data will be required to read, agree to, and sign the PFAS EA Rules of Behavior for Data Access and Use. CDC/ATSDR and contractors who maintain records are instructed to protect the security of records, and are to check with the system manager prior to making disclosure of data. CDC/ATSDR and contractor sites are restricted to authorized personnel only. Appropriate Privacy Act provisions are included in contracts, and CDC/ATSDR 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/ATSDR or destroyed, as specified by the contract. PII and non-PII will be stored separately; a unique study ID will be used to link data when necessary (i.e., to provide participants their results). Technical: PII will be collected on computers lacking Internet access. The disclosure spreadsheet, DUA, and any related disclosure documentation will be stored in an encrypted administrator folder for this study. Protection for computerized records includes programmed verification of valid user identification code and password, periodic password changes, limited log-ins, virus protection, and user rights/file attribute restrictions. Each user name is assigned limited access rights to files and directories at varying levels to control file sharing. A log will be kept of all changes to each file and all persons reviewing files. Additional safeguards may also be built into the program by the system analyst as warranted by the sensitivity of the specific data set (i.e., encryption). Questionnaire and laboratory results will be recorded electronically, and its data will be securely transferred via CDC's Secure Access Management System (SAMS) server(s). SAMS has its own Privacy Impact Assessment. Physical: Consent and assent forms, log books, and other source data are maintained in locked cabinets in locked rooms. Site security guards screen personnel and visitors. Access to facilities and computer rooms is controlled by a card key system. 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		
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		

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	Reviewer Questions	Answer
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
Reviewer Notes		

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General Comments			
OPDIV Senior Official for Privacy Signature	Jarell Oshodi -S Digitally signed by Jarell Oshodi -S Date: 2022.05.09 14:58:27 -04'00'	HHS Senior Agency Official for Privacy	