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Privacy Impact Assessment Form

v 1.21

Status | Form Number | Form Date 02/14/20

	Question	Answer
1	OPDIV:	CDC
2	PIA Unique Identifier:	TBD
2a	Name:	Assessment of Potential Exposure from Private Wells for Drinkin
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: Environmental Epidemiologist POC Name: Johnni Daniel POC Organization: DEHSP POC Email: bez2@cdc.gov POC Phone: 770-488-3415
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 exposure study will utilize several CDC authorized systems for data collection, storage, and processing.	
10	Describe in further detail any changes to the system that have occurred since the last PIA.	N/A	
11	Describe the purpose of the system.	The purpose of this Generic ICR is to respond to state and local areas that request assistance with assessing potential exposure to contaminants in drinking water from private wells in their jurisdiction. An example of a prior study conducted by CDC that has yielded information used to reduce exposures is the Navajo study where NCEH provided technical assistance (OMB approval was not needed) to assess the health risks associated with drinking water from various sources used by the Navajo Nation (2007-2011). The investigation identified contaminants, including uranium, in these drinking water sources. Based on this information, the Navajo Nation Environmental Protection Agency (NNEPA) and Navajo Nation Division of Health (NNDOH) collaborated to develop a consumer awareness campaign to help people understand sources of drinking water contamination, learn where to get safe drinking water, and learn how to protect the quality of water stored at home. Having a generic mechanism in place will facilitate a faster processing and clearance of information collection approvals requested by NCEH and partners. This is an extension GenICR which is needed to continue the work conducted during the original ICR approval period. During the approval period, one GenIC has been generated to respond to three state health department (New Hampshire, New Mexico, and Connecticut) requests in assisting with assessing potential exposure to arsenic and uranium in residential private wells used for drinking water.	

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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.)	The study will collect, maintain, and store the information below: Participant Contact Information (name, mailing address, email, phone number) De-identified Demographic Data (date of birth, sex, height, weight) Laboratory Results (creatinine concentrations in urine, arsenic and uranium in urine, arsenic and uranium in water) Surveys (diet, drinking water, bathing, employment, lifestyle factors, and recreational activities) Other (StudyID) All information in the system will be stored for at least six years, but no longer than ten years after the end of the study depending on the program need for scientific, legal or business reference. The study will be sharing de-identified data with the requesting agency in areas in which the study is being conducted. The requesting agency will use the data to support response activities. Users will be authenticated via CDC's Secure Access Management System (SAMS) and CDC's Active Directory (AD). SAMS and AD are both authorized CDC information systems.

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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 enroll participants with potential exposure to drinking water contaminants in private wells. Participants will be members of the general public in affected areas that are at least 18 years of age, use private wells for drinking water, willing to receive and return a tap water sampling kit and urine specimen kit or to provide a blood specimen, and willing to answer survey questions. They will be enrolled from the geographic area of concern as defined by the requesting agency. The types of information that will be collected and maintained about these participants are participant contact information, demographic information, laboratory results, surveys and study ID. Any information shared about the participants with the requesting agency or other external entities will be de-identified. Information in the system will be regularly retrieved by the participant's name when participants contact the study for follow up appointments, at those appointments, or for the status of their labs. Users will be authenticated via CDC's Secure Access Management System (SAMS) and CDC's Active Directory (AD). SAMS and AD are both authorized CDC information systems. The study will collect, maintain, and store the information below: Participant Contact Information (name, mailing address, email, phone number) De-identified Demographic Data (date of birth, sex, height, weight) Laboratory Results (creatinine concentrations in urine, arsenic and uranium in urine, arsenic and uranium in water) Surveys (diet, drinking water, bathing, employment, lifestyle factors, and recreational activities) Other (StudyID)
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 Other... Surveys Other... Lab results included in medical notes 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?	To contact study participants with reminders and information about the study, 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)	None
20	Describe the function of the SSN.	The study will not collect, store, or share SSN.
20a	Cite the **legal authority** to use the SSN.	NA
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)
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:	SORN 09-20-0136 "Epidemiologic Studies and Su
		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.	0920-1173 and 03/31/2020	
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	
		☐ 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)).	De-identified information will be shared with requesting agencies. As part of the required "Data Management Plan," if sharing is required NCEH will share data sets with external entities via data use agreements (DUA) with each data recipient.	

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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.	Participants sign a consent form on order to participate in the study. The consent form notifies the individual that their information will be collected, for what purpose, and information they will receive back from the study.	
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.	
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.	NCEH will contact the study principal investigator (PI) (per consent form) via email, telephone, and/or mail when major changes to the study occur to obtain consent from the study participants.	
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 PI and data manager using contact information in the study's SORN or consent form. 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 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	To contact study participants during study activities and to provide
		☒ Administrators	To provide access to users as needed.
		☐ Developers	
		☐ Contractors	
		☐ Others	

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32	Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	The study PI will determine the level of access for each user depending on their role in the study.
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.	Due to the small number of study participants, all users with access to PII will have access to all study participants' PII.
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.	Study staff will all go through annual security awareness training.
35	Describe training system users receive (above and beyond general security and privacy awareness training).	We will provide instructions to users about how to manage data security and privacy protections and will require all study staff and direct contractors to receive training on their roles and responsibilities, as outlined in the study's Manual of Procedures. The study's 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.	Retention and destruction of PII in the study is determined using Records Control Schedule CDC RG-0442, Scientific and Research Project Records, Minor Research Records Authorized Disposition: Maintain at least six years, but no longer than ten years after the retirement of the system depending on the program need for scientific, legal or business reference, then delete/destroy.
38	Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.	PII will be secured using the following administrative controls: Rules of Behavior, Manual of Procedures, NDAs, and DUAs. PII will be secured using the following technical controls: file level and whole disk encryption, e-Auth Level 3, and access control lists in multiple authorized CDC IT systems. PII will be secured using the following physical controls: controlled physical access, guards, key card access, and locked rooms.

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: 2020.02.25 16:50:25 -05'00'	HHS Senior Agency Official for Privacy	