



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

Print Date: 11/17/20

Title: Exposure to arsenic and uranium from private wells in Connecticut, New Hampshire and New Mexico

Project Id: 0900f3eb81bd1920

Accession #: NCEH-HST-9/1/20-d1920

Project Contact: Backer_Lorraine (lfb9)

Organization: NCEH/ATSDR/DEHSP/EMRCB/HST

Status: Project In Progress

Intended Use: Project Determination

Estimated Start Date: 02/05/2021

Estimated Completion Date: 09/30/2022

CDC/ATSDR HRPO/IRB Protocol #: NA

OMB Control #: GenIC under: 0929-1173

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research / Other <i>45 CFR 46.102(l)</i> Non-Epi Aids Investigations	9/8/20	Davis_Stephanie I. (sgd8) CIO HSC
PRA: PRA Applies		9/9/20	Davis_Stephanie I. (sgd8) CIO OMB / PRA
ICRO: Returned with No Decision		9/9/20	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Urgent

Date Needed: 09/04/2020

Priority Justification: We need to get the approved protocol back to Connecticut so that their IRB can complete their review in September.

Determination Start Date: 09/01/20

Description: The purpose of this investigation is to respond to three states (Connecticut, New Hampshire, and New Mexico) that have requested assistance with assessing potential exposure to naturally-occurring arsenic and uranium in drinking water from private wells in areas (one area for each state) where there are no data about arsenic and uranium concentrations in ground water (Ayotte et al, 2017). The new information obtained from these investigations will be the description of exposure to contaminants in drinking water from private wells within a well-defined time period and geographic distribution. This information will be used by the requesting agencies to target their respective existing public health intervention activities to reduce exposures.

IMS/CIO/Epi-Aid/Chemical Exposure Submission: No

IMS Activation Name: Not selected

Primary Priority of the Project: Not selected

Secondary Priority(s) of the Project: Not selected

Task Force Associated with the Response: Not selected

CIO Emergency Response Name: Not selected

Epi-Aid Name: Not selected

Assessment of Chemical Exposure Name: Not selected

Goals/Purpose We will collect new data on the concentrations of arsenic and uranium in private well source water, household tap water, and urine as well as information from private well owners that will allow us to comprehensively assess exposures to these contaminants.

Objective: Collect new data on arsenic and uranium concentrations in private well water in areas where there are no data. Use biomonitoring and an individual exposure survey data to assess the association between concentrations of arsenic and uranium in drinking water obtained from a private well and levels of arsenic and uranium in urine. Use water quality testing, biomonitoring, and exposure survey results to support state-based outreach, education, and mitigation efforts.

Activities or Tasks: New Collection of Information, Data, or Biospecimens

Target Populations to be Included/Represented: General US Population

Tags/Keywords: Water quality, Arsenic, uranium, Drinking Water

CDC's Role: CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens, CDC employees will participate as co-authors in presentation(s) or publication(s). CDC employees will provide substantial technical assistance or oversight, CDC is providing funding

Method Categories: Convenience Sample

For this project, we will assess exposure to arsenic and uranium in private well water in areas of concern to our public health partners. We will collect new data on the concentrations of arsenic and uranium in private well source water, household tap water, and urine as well as obtain information about potential exposure to arsenic and uranium by asking participants to complete a food log and an exposure survey. Three public health partners (the state health/environmental protection agencies of Connecticut, New Hampshire, and New Mexico) have identified areas where there are no data describing the concentrations of arsenic and uranium in ground water that is the source for private wells (see Attachment A, Letters of Collaboration). We will create a grid across each area and randomly choose 100 cells from each grid. We will collaborate with our public health partners to identify households with private wells within the selected cells and obtain contact information for private well owners. If there are no households identified in a cell, we will skip the cell and add a household from the neighboring cell to supplement the absence of a household in the selected cell. A combination of Google & ESRI geolocation services & base maps, E-911 GIS files, and tax assessors' maps where available are used to identify household addresses. These are run inside of an ArcGIS program such as ArcMap and more currently ArcPro for a few reasons. First, the tool that is run to grid geographic areas and generate points within grid cells runs in ArcGIS. Second, most of the identification of homes is visual – more likely than not, the point that the program generates is not going to be sitting on the house. It is then up to the user to visually determine the nearest eligible household. The user must try to determine if the structure seen on the map is a household or a business, on public water or private, and abandoned or inhabited. An alternative approach would be to feed a fixed list of possible sites into the program, but this is generally not recommended because these lists are often incomplete and often have incorrectly geolocated points, which spatially biases the program. USGS reports that they recruit about 30% to 50% of people who receive notification of an upcoming water quality investigation like this. Thus, we will send out letters and prepaid postcards to a random sample of 200-300 households within the chosen cells in each state (see Attachment B, Invitation Letter) in order to enroll 100 households with private wells from each state (one household per cell). We will ask interested people to verify their name, address, and contact information and mail the prepaid postcard back to us. From the postcards, we will create a database to facilitate contacting potential recruits to conduct a brief telephone screening survey and, if appropriate, enroll them in the investigation. We will enroll 100 participants in each state (see Attachment C, Screening Survey). At enrollment, we will make arrangements to send participants a 3-day Food Log and materials to collect a urine specimen. We will also schedule appointments to visit the households where we will do the following: 1. Obtain a signed consent form 2. Collect well water and tap water samples 3. Collect the urine specimen 4. Review and collect the Food Log 5. Conduct the exposure survey with one adult in each household (see Attachments D, E, F, G: Consent Form, Food Log, Urine

Methods:

We will collect new data on the concentrations of arsenic and uranium in private well source water, household tap water, and urine as well as information from private well owners that will allow us to comprehensively assess exposures to these contaminants. At enrollment, we will make arrangements to send participants a 3-day Food Log and materials to collect a urine specimen. We will also schedule appointments to visit the households where we will do the following: 1. Obtain a signed consent form 2. Collect well water and tap water samples 3. Collect the urine specimen 4. Review and collect the Food Log 5. Conduct the exposure survey with one adult in each household see Attachments D, E, F, G: Consent Form, Food Log, Urine Collection Directions, and Exposure Survey, respectively). We will not ask questions about symptoms or health status. We will ask you about medications you take because that is important in helping us interpret exposure information. Project staff will provide investigation participants with their well water sample and urine specimen test results and information about exposure reduction when appropriate.

Collection of Info, Data or Biospecimen:

The primary audience for the results of this project is state public health partners responsible for private wells in their own jurisdictions. They will use their data to inform decisions about ongoing and future efforts in outreach, education, and mitigation for private well owners. We will share the protocol and associated documents for their review and comment.

Expected Use of Findings/Results:

Could Individuals potentially be identified based on Information Collected? Yes

Will PII be captured (including coded data)? Yes

Does CDC have access to the identifiers? Yes

Is an assurance of confidentiality in place or planned? No

Is a certificate of confidentiality in place or planned? No

Is there a formal written agreement prohibiting the release of identifiers? No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award
Other-Interagency agreement	14FED406345-001	\$99,035.00	2020	2

HSC Review**HSC Attributes**

Non-Epi Aids Investigations Yes

Additional Ethical Considerations

This activity is non-research. The methods described are systematic, yet the results for each site are not intended to be generalizable beyond the geographic boundaries of the investigation area of private wells identified by each state health department. Data will be analyzed for each state, and will not be aggregated across the three states.

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office No

Estimated number of study participants

Population - Children

Population - Minors

Population - Prisoners

Population - Pregnant Women

Population - Emancipated Minors

Suggested level of risk to subjects Do you anticipate this project will be exempt research or non-exempt research

Requested consent process wavier

Informed consent for adults No Selection

Children capable of providing assent No Selection

Parental permission No Selection

Alteration of authorization under HIPPA Privacy Rule No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults No Selection

Children capable of providing assent No Selection

Parental permission No Selection

Consent process shown in an understandable language

Reading level has been estimated No Selection

Comprehension tool is provided No Selection

Short form is provided No Selection

Translation planned or performed No Selection

Certified translation / translator No Selection

Translation and back-translation to/from target language(s) No Selection

Other method No Selection

Clinical Trial

Involves human participants No Selection

Assigned to an intervention No Selection

Evaluate the effect of the intervention No Selection

Evaluation of a health related biomedical or behavioral outcome No Selection

Registerable clinical trial No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus No Selection

Human genetic testing is planned now or in the future No Selection

Involves long-term storage of identifiable biological specimens No Selection

Involves a drug, biologic, or device No Selection

Conducted under an Investigational New Drug exemption or Investigational Device Exemption No Selection

Institutions & Staff

Institutions

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
USGS					\$99,035.00

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Diana Diaz	09/02/2023				Co-Investigator	prz4@cdc.gov	404-498-3060	HEALTH STUDIES
Kristin Marks	07/16/2023	08/29/2022	02/04/2023	08/29/2022	Co-Investigator	kma8@cdc.gov	770-488-3414	HEALTH STUDIES
Lorraine Backer	05/18/2021	04/12/2020	12/21/2021	04/13/2020	Principal Investigator	lfb9@cdc.gov	770-488-6	HEALTH STUDIES

Data

DMP

Proposed Data Collection Start Date: 2/5/21

Proposed Data Collection End Date: 9/30/22

Proposed Public Access Level: Public

Public Access Justification: Private well water analysis results will be made available by USGS on their website. Well locations will be masked using GIS to ensure that wells and well owners cannot be identified.

How Access Will Be Provided for Data: Private well water analysis results will be made available by USGS on their website. Well locations will be masked using GIS to ensure that wells and well owners cannot be identified. Data including study participant survey responses will only be available in aggregated form in a peer-reviewed publication.

Plans for Archival and Long Term Preservation: We will use only investigation IDs when communicating with laboratories for water testing and biomonitoring results. The ID key will be kept separately from the investigation data and will be destroyed once all the data have been analyzed, or by December 31, 2030.

Spatiality

Country	State/Province	County/Region
United States	Connecticut	
United States	New Hampshire	
United States	New Mexico	

Dataset

Dataset Title	Dataset Description	Data Publisher/Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									



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