

**REQUEST FOR APPROVAL UNDER THE GENERIC CLEARANCE FOR
HEALTH RISKS FROM USING PRIVATE WELLS
FOR DRINKING WATER (0920-1173)**

Instruction: This form should be completed by the primary contact person from the CDC CIO that will be sponsoring the investigation.

DETERMINE IF YOUR INVESTIGATION IS APPROPRIATE FOR THIS GENERIC CLEARANCE MECHANISM: *Instruction: Before completing and submitting this form, determine first if the proposed investigation is appropriate for the Private Well Generic ICR mechanism. Complete the checklist below. If you select “yes” to all criteria, the Private Well Generic IR mechanism can be used.*

Criteria
CDC epidemiologic assistance is requested by one or more external partners (e.g., local, state, tribal, other federal agency, or other partner organization). [x] Yes [] No
The focus of the data collection is to assess the health risks associated with exposure to contaminants in drinking water from private wells or other issues associated with private wells in the U.S. [x] Yes [] No
Results from investigations will be used to improve the requesting agency’s public health activities. [x] Yes [] No
Investigations will be non-research public health activities designed to prevent or control disease and reduce risk in the requesting agency’s jurisdiction. [x] Yes [] No

Did you select “Yes” to all criteria?

If yes, the Private Well Generic ICR may be appropriate for your investigation. → You may proceed with this form.

If no, the Private Well Generic ICR is not appropriate for your investigation. → Stop completing this form now.

TITLE OF INFORMATION COLLECTION: Exposure to Arsenic and Uranium in Private Well Water in Connecticut, New Mexico, and New Hampshire

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Problem to be Investigated: The purpose of this GenIC is to respond to Connecticut, New Mexico, and New Hampshire's request for assistance to assess potential exposure to contaminants in drinking water from private wells in their jurisdiction. The new information obtained from this investigation will be the description of exposure to contaminants in drinking water from private wells within a well-defined time-period and geographic distribution. The requesting agencies will use this information to inform whether there is a need for public health intervention activities to reduce exposures.

OMB previously approved this GenIC on 08/27/2019, for 450 burden hours. Due to the COVID pandemic, the data collection never began. The PRA clearance expired on 08/31/2020.

This is a resubmission of the GenIC, with some protocol refinements based on recent feedback from partner health departments with the addition of COVID precautions. NCEH is updating its time burden request to 544 hours.

2. Contaminant of interest: arsenic, uranium
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3. Location of Investigation: *Instruction: Indicate location where investigation will occur. If multiple locations, specify each one.*

State: Connecticut

City/County (if applicable):

Region (if applicable):

Territory (if applicable):

State: New Mexico

City/County (if applicable):

Region (if applicable):

Territory (if applicable):

State: New Hampshire

City/County (if applicable):

Region (if applicable):

Territory (if applicable):

4. Agency Requesting Epidemiologic Assistance/Name and Position Title of Requestor

Agency: Connecticut Department of Health

Name: Suzanne Blancaflor, MPH, MS

Position Title: Section Chief, Environmental Health Section

Agency: New Mexico Department of Health

Name: Heidi Krapfl

Position Title: Deputy Division Director

Agency: New Hampshire Department of Health

Name: James V. Chithalen, PhD
Position Title: Chemistry Program Manager, Public Health Laboratory

Note: Attach the Letter of Invitation requesting support. The letter should include the following information: 1) background on the contaminant/issue; 2) steps already taken toward prevention and control, if any; 3) request for CDC assistance, including objectives of the investigation; and 4) how data will be used to improve public health activities in the requesting agency's jurisdiction. Sensitive information in the Letter of Invitation not appropriate for public dissemination should be redacted.

Attachment A (Letters of Collaboration) is attached.

5. Selection of Respondents: *Instruction: Provide a brief description of how respondents will be identified and selected. Use as much space as necessary for the description.*

We have added the statement below about COVID-19 precautions that is included in the invitation letter (Attachment B Invitation Letter Response Form), screening survey (Attachment C Screening Survey), and consent form (Attachment D Consent Form):

Please be assured that CDC will take all necessary steps to protect members of your community from COVID-19. The study will be conducted following all state, local, and CDC guidelines in place at the time the study is conducted. CDC team members will be monitored twice daily for fever and any COVID-19-related symptoms. Although we don't anticipate face-to-face contact with study participants, if this does occur (e.g., when a study team member picks up water samples and urine specimens), study team members will wear surgical masks and gloves to ensure the protection of participants. Again, although we do not anticipate face-to-face contact with study team members, if that occurs, participants will be asked to always wear a face covering or mask. If you do not have a mask, one will be provided to you before you enter the facility. If you are unable to wear a mask for medical reasons, please let us know.

Additional precautions: The Survey (Attachment G Survey) will be conducted by phone rather than in-person, study participants will collect the water sample from the tap inside their home and leave that, along with their signed consent form, the food log, the home tap water sample, and urine specimen outside for the study team to pick up.

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. 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 private wells within the selected cells and obtain contact information for private well owners.

USGS reports that they recruit about 30% to 50% of people who receive notification of an upcoming water quality study like this (personal communication, Joe Ayotte, May 2018). Thus, we will send out letters and prepaid postcards to the identified households in the 100 cells (approximately 200 – 333 households) in each area to recruit one household per cell for a total of 100 households per state. We will ask interested people to verify their name, address, and contact

information and mail the response form back to us in a pre-paid and pre-addressed envelope.. From the response forms, we will create a database to facilitate contacting them to conduct a brief phone screening survey and, if appropriate, enroll them in the study. At enrollment, we will make appointments to visit the households to collect well water and tap water samples as well as urine specimens as well as an appointment to conduct telephone-based exposure survey responses from one adult per household. We will not ask questions about symptoms or health status. We will provide study participants with their well water sample and urine specimen test results and state partners will provide information about exposure reduction when appropriate.

6. Data Collection Mode: *Instruction: Select all that apply. For each data collection mode planned, provide a brief description. Use as much space as necessary for the description.*

Screening survey mode:

Face-to-face Interview (describe):

Telephone Interview (describe):

The Screening Survey comprises questions about home and household water source, whether their well water is used for drinking and cooking, whether there are water treatment systems in the home, and the inclusion criteria to participate in the study (see Attachment C Screening Survey).

Self-administered Paper-and-Pencil Questionnaire (describe):

Self-administered Internet Questionnaire (describe):

Other (describe):

Response Form mode:

Face-to-face Interview (describe):

Telephone Interview (describe):

Self-administered Paper-and-Pencil Questionnaire (describe):

The Response Form comprises questions about contact information so that the study team can contact interested individuals to make appointments to collect study materials.

Self-administered Internet Questionnaire (describe):

Other (describe):

Food log mode:

Face-to-face Interview (describe):

Telephone Interview (describe):

Self-administered Paper-and-Pencil Questionnaire (describe):

The Food Log comprises questions about what the study participant consumed during the three days before collecting their urine specimen to assess exposures to arsenic and uranium.

Self-administered Internet Questionnaire (describe):

Other (describe):

Survey mode (indicate which mode(s) below):

Face-to-face Interview (describe):

Telephone Interview (describe):

The survey will be conducted by telephone and comprises 44 questions that include personal information (date of birth, height, weight, race), home and household water source, other possible exposures to arsenic or uranium.

Self-administered Paper-and-Pencil Questionnaire (describe):

Self-administered Internet Questionnaire (describe):

Other (describe):

7. Type of Information to be Collected: *Instruction: Select all that apply. For each type of information to be collected, provide a brief description. Use as much space as necessary for the description.*

General information (describe):

Socio-demographic information (describe): Name, contact information so that we can make appointments for the telephone survey, to collect a well water sample, and to pick up a tap water sample and urine specimen.

Household water source(s) to ensure that participants are drinking their tap water.

Household water use to ensure that participants are using their private well water for household activities.

Environmental exposures not related to drinking water from private wells (confounders)

Perceptions and practices that might affect an individual's exposure level

Other (describe):

8. Duration of Data Collection (number of weeks): 9 weeks overall, approximately 3 weeks per site.

INVESTIGATION LEAD:

Name: Lorraine Backer

Title: Epidemiologist

Affiliation: CDC

CDC SPONSORING PROGRAM AND PRIMARY CONTACT PERSON:

CIO/Division/Branch: NCEH/DEHPS/EMRCB

Name of CDC Sponsoring Program Primary Contact Person: Lorraine Backer

Title of CDC Sponsoring Program Primary Contact Person: Epidemiologist

Contact Information: *Provide complete contact information. Check box for preferred method(s) of contact during the OMB approval process.*

Office phone: 770-488-3426

Home phone:

Cell phone/Blackberry: 404-840-3538

E-mail: lfb9@cdc.gov

Other:

CERTIFICATION: *Please read the certification carefully. Type your name to validate that you are providing certification. Note: If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved. Certification should be signed by the CDC Primary Contact Person for this Investigation.*

I, Lorraine Backer, certify the following to be true:

1. The collection is voluntary.
2. Respondents will not be personally identified in any published reports of the study.
3. Information gathered will be primarily used to inform effective prevention and control measures.

CDC Sponsoring Program Primary Contact Name: Lorraine Backer

Date of Certification: 11-10-2020

REQUESTED APPROVAL DATE (MM/DD/YYYY): 12/14/2020

DATE SUBMITTED TO INFORMATION COLLECTION REQUEST LIAISON (MM/DD/YYYY): 11-19-2020

E-mail the completed form to the Information Collection Request Liaison (ICRL), Stephanie Davis, at NCEHOMB@cdc.gov or submit completed request via the CDC STARS System as appropriate.

Attachments:

- A. Letters of Collaboration
- B. Invitation Letter and Response Form
- C. Screening Survey
- D. Consent Form
- E. Food Log
- F. Urine Collection Directions and Water Collection Log
- G. Survey
- H. Participant Results Letter
- I. STARS Determination Form