

**Evaluation of Efficacy of Household Water Filtration/Treatment Devices  
in Households with Private Wells  
(OMB 0920-0670)**

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Request for Revision

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## A. JUSTIFICATION

### 1. Circumstances Making the Collection of Information Necessary

The most recent comprehensive study of domestic water sources (1995) reports that approximately 16% of the U.S. population or 42.4 million people are served by private wells.<sup>1</sup> Unlike community water systems (CWS), private wells are not regulated by the U.S. Environmental Protection Agency's (EPA) Safe Drinking Water Act (SDWA).

Groundwater quality can be affected by local land uses, geological factors and characteristics of the aquifer from which water is extracted. Contaminants in ground water include man-made contaminants (pesticides, fertilizers, and industrial chemicals), natural contaminants (arsenic, fluoride, radionuclides) and pathogens (coliform bacteria and viruses). In an analysis of data from well water quality surveys across the United States, the U.S. Geological Survey (USGS) reports detections exceeding Maximum Contaminant Levels (MCLs) for arsenic (11%), nitrate (8%), uranium (4%) and pesticides (2%).<sup>2</sup> In a study of 1,926 private wells, USGS detected volatile organic compounds (VOCs) in 12% of wells with 1.4% of wells tested having at least one VOC that exceeded an EPA or other health standard<sup>3</sup>. Following the 1993 Missouri and Mississippi River basin floods, CDC surveyed 5,520 households with domestic wells in nine Midwest states to measure levels of coliform bacteria, *Escherichia coli*, nitrate and atrazine. Coliform bacteria were present in 41% of samples and *E. coli* in 11.1% of samples. Nitrate was detected in 65.4% of samples, with 13.4% samples exceeding the EPA MCL of 10mg/L. Atrazine and related triazines were detected in 13.6% of samples with 0.2% samples exceeding the MCL of 3 ppb.<sup>4</sup> A 1997 U.S. General Accounting Office (GAO) report on drinking water reports coliform bacteria in 33.3% of Illinois wells and 44.6% of wells in Iowa. The same study also reported nitrate levels exceeding EPA's 10 ppm standard in 18.3% of Iowa wells and 28.2% of wells in Kansas.<sup>5</sup> The GAO report concluded that users of private wells may face higher exposure levels to groundwater contaminants than users of community water systems.

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1 USGS. 1998. Estimated Use of Water in the United States in 1995. <http://water.usgs.gov/watuse/pdf/1995/pdf/domestic.pdf>. United States Geological Survey, Denver, CO.

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? Focazio, Michael. October 2, 2003. "Ground-water Quality Data and Programs of the U.S. Geological Survey". Presentation at "Household Water Filtration Study Meeting". October 2, 2003. Sponsored by CDC. Decatur, GA.

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? Moran, M. and P. Hamilton. 2003. Volatile Organic Compounds in Ground Water from Rural Private Wells. *Well Water Journal*. March 2003. pp 32-35.

4

? CDC. 1998. A Survey of the Quality of Water Drawn from Domestic Wells in Nine Midwest States. <http://www.cdc.gov/nceh/emergency/WellWater/default.htm>. CDC, National Center for Environmental Health, Atlanta, GA. This study was funded through the 1993 Midwest Flood Supplemental Appropriation and performed by the U.S. Public Health Office of Emergency Preparedness. Money was provided to nine states affected by flooding. It is unknown if an IRB protocol or OMB package was prepared for this study due to its emergency nature. Persons involved with the study are no longer at CDC. Personal communication from Mike McGeehin, Director, NCEH Division of Environmental Hazards and Health Effects.

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? GAO. 1997. Information on the Quality of Water Found at Community Water Systems and Private Wells. GAO/RCED-97-123. U.S. General Accounting Office, Washington, DC.

The use of water treatment devices among the public rose from 27% in 1995 to 41% in 2001<sup>6</sup>. While the efficacy of water treatment devices is not regulated by the government, the American National Standards Institute (ANSI) and National Sanitation Foundation (NSF) developed ANSI/NSF consensus standards to certify health and aesthetic contaminant reduction claims for drinking water treatment units. Manufacturers whose products make claims to mitigate pathogens or contaminants routinely submit their products to several companies such as Underwriters Laboratories, Inc., or NSF to obtain ANSI/NSF certification. Implicit in certification of water treatment devices is that claims made for contaminant and pathogen removal are dependent on proper use, installation and maintenance of the devices.

While there are studies evaluating efficacy of point-of-use (POU) water treatment devices on removal of pathogens and other contaminants<sup>7-10</sup>, we are not aware of any studies evaluating how efficacy is impacted by homeowner behaviors. Furthermore, there is concern that homeowners may be using water treatment technologies that may be inappropriate for contaminants of concern in specific hydrogeological areas.

We plan to conduct a *pilot/scoping study* to assess how factors, such as information used to select a water treatment device, and behaviors around use, installation and maintenance of devices, affect treatment device efficacy and human exposure to contaminants of health concern. This is the first study of its kind to assess the efficacy of home water treatment devices from the perspective of proper selection of contaminant(s) of concern and maintenance by homeowners. In areas of known groundwater contamination, the study will determine if an intervention and/or education program is necessary to better inform at-risk populations about proper selection and maintenance of water treatment devices.

We are requesting a one year approval for this OMB renewal and revision package. Due to a one year delay in obtaining funding for the project (obtained in June 2005) and delays in synchronizing the study protocol for Institutional Review Boards at CDC and in four of the six study states, we were unable to complete this study during the original OMB approval period. Because of these delays the study is currently in the participant recruitment stage. That is, states

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6 WQA. 2001. 2001 National Consumer Water Quality Survey. Water Quality Association, Lisle, IL.

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? Daschner FD, Ruden H, Simon R, Clotten J. Microbiological contamination of drinking water in a commercial household water filter system. SO European Journal of Clinical Microbiology & Infectious Diseases. Vol. 15(3)(pp 233-237), 1996.

8 Lin TF, Hsiao HC, Wu JK, Hsiao HC, Yeh JC. Removal of arsenic from groundwater using point-of- use reverse osmosis and distilling devices. Environmental Technology 23:781-790 (2002).

9 Schlafer JL, Bicking M. Heterotrophic bacteria control in a residential reverse-osmosis drinking-water filter. Journal of Environmental Health 60:14-16 (1997).

10 Snyder JW, Mains CN, Anderson RE, Bissonnette GK. Effect of Point-Of-Use, Activated Carbon Filters on the Bacteriological Quality of Rural Groundwater Supplies. Applied and Environmental Microbiology 61:4291-4295 (1995).

are currently contacting potential participants and have not yet started household visits for questionnaire administration and water sampling (as of July 1, 2006).

The data collection authority for this study is Section 301 of the Public Health Service Act (42 USC 241) (Attachment 1).

## **2. Purpose and Use of Information Collection**

The purpose of this study is to collect data, through water sampling and questionnaires, to determine if people in households on private wells are being exposed to contaminants of health concern. Specifically, we are interested in how factors such as selection, installation, maintenance and use of treatment devices impact the efficacy of these devices. We know from data obtained through USGS, state groundwater sampling programs and EPA databases that about 6% of the U.S. population<sup>11</sup> does not have access to drinking water that meets federal standards. By targeting a sample of the population we believe most at risk (those households on private wells in hydrogeological areas suspected or known to be vulnerable to contamination), the study seeks to gather information about the use of and maintenance of water treatment devices that could be protective of public health. To that end we seek to answer the following questions with data obtained from the study:

1. Are people in homes with private wells being exposed to groundwater contaminants through improper selection of water treatment device technology?
2. Are households properly maintaining water treatment devices?
3. Are contaminants/pathogens aggregating in and being released from water treatment devices?
4. What kinds of information are people using to select treatment devices?
5. Are homeowners aware of possible contaminants in their well water?
6. Are homeowners having well water tested and using that information to determine the best water treatment device technology for mitigating contaminants?
7. What contaminants, if any, are in the wells being tested as part of the study?
8. What kind(s) of water are people using for drinking and cooking at home?
9. What reasons do people give for not drinking plain/untreated tap water?
10. What experiences have people had with illness due to drinking water?

CDC will use information from this scoping study to determine if people using water treatment devices might be exposed to contaminants of health concern because of improper selection, use or maintenance of a water treatment system. The study design makes use of a convenience sample to obtain water quality samples and participants, so the results of both water samples and questionnaire data are not generalizable in regards to human populations or water quality. Depending on results of data analysis from the study, CDC may determine that a more rigorous evaluation of this issue is needed and that would entail a different kind of sampling plan and study design. Results from this study may be used to guide the development of the CDC

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<sup>11</sup> EPA. 2003. Analysis and Findings of the Gallup Organization's Drinking Water Customer Satisfaction Survey.

website, including information for the public and health messages that will encourage the public to properly select and maintain water treatment devices. State health and environmental quality agencies may use the information from this study (when published by CDC) to better inform the public about water treatment device selection and use.

EPA and USGS have requested well water sample analysis data from this study. The list of contaminants analyzed in this study is provided as Attachment 11. The contaminant list submitted with the original OMB package was substantially longer and more comprehensive. Due to budget constraints on water sample analysis costs we reduced the contaminant list to those priority contaminants of interest to the participating states and CDC. Reducing the list of contaminants does not affect respondent burden.

Because we have reduced the contaminant list, EPA has submitted a revised statement regarding their intended uses of the data CDC shares from this study. The USGS statement remains the same. These statements can be found as Attachments 9 and 10.

Since water quality data is of little value without a location, both EPA and USGS requested that we collect, where possible, georeference data associated with well water samples. To accommodate that request, we developed a second consent form for the study. EPA originally wanted to use the data to characterize results of exposure assessments through determination of the impact of agricultural and/or suburban and urban use of pesticides on groundwater quality. However, since we will not capture pesticides in the water sampling, EPA is interested in having data on arsenic and nitrate/nitrite occurrence. USGS will use the data to supplement other USGS monitoring data to better define the water-quality of the aquifer systems represented in the study. Neither EPA nor USGS will contact participants in this study for follow-up or future investigations.

### **3. Use of Improved Information Technology and Burden Reduction**

Study participants will not complete any kind of paperwork or forms. Study participants will provide oral responses to a trained interviewer who will conduct the interview and record the responses on the questionnaire form. The study instruments require collection of only the minimum information necessary for the purposes of the project. The data collection methodology will not utilize automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Data from questionnaires will be entered into a database by a CDC contractor at the conclusion of the study.

### **4. Efforts to Identify Duplication and Use of Similar Information**

An extensive review of the scientific literature, and discussion with consultants and experts in the field, were conducted to locate other studies associating water treatment device efficacy with human behaviors at the point of use. There are no such studies in publication or underway based on our literature queries and discussions with knowledgeable experts in the field.

**5. Impact on Small Businesses or Other Small Entities**

No small business will be involved in this study.

**6. Consequences of Collecting the Information Less Frequently**

Data collection will occur only one time for each respondent. There are no legal obstacles to reduce the burden of this data collection.

**7. Special Circumstances relating to the Guidelines of 5 CFR 1320.5**

This data collection fully complies with the guidelines of 5 CFR 1320.5.

**8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

8.A. A 60-day notice for renewal of this study was published in the *Federal Register* on February 26, 2006 (Vol. 71, No. 35, pp. 9134-9135) (Attachment 2). No comments were received in response to the renewal notice. The original 60-day notice was published April 23, 2004 (Vol. 69, No. 79, pp. 22047-22048). A summary of comments received in response to the original 60-day notice is provided as Attachment 3.

8.B. In October 2003, the Health Studies Branch of the National Center for Environmental Health convened a one-day workshop to discuss parameters for the study. We requested input from participating states, federal agencies, consultants, and an analytical laboratory on the availability of data, study design, study feasibility, objectives and desired outcomes.

The following individuals, as attendees at the October 2003 meeting, were consulted to obtain their views on the availability of data, the clarity of instructions, disclosure, and on the data elements to be recorded and reported. Study objectives, data collection and other study instruments were developed as a result of a one-day study scoping meeting in October 2003.

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**9. Explanation of Any Payment or Gift to Respondents**

Respondents will not receive gifts or payments for participating in this study.

**10. Assurance of Confidentiality Provided to Respondents**

The CDC Privacy Act Officer reviewed this submission and determined that the Privacy Act does not apply to this data collection. No sensitive information is being collected and no system of records will be established. While personal identifiers will be obtained by state-based health department representatives, the identifiers will be maintained only temporarily to support interview scheduling and to ensure that each participating household receives the results of the lab analysis of the water sample. All study-related data and forms will be maintained in a secure manner. Identifiers will not be stored as part of the study dataset or transmitted to CDC. Personal identifiers collected from households will be on pre-screening telephone solicitation records and the cover page and end page of questionnaires. Pre-screening telephone participation records will be destroyed after home visits are completed. The cover page of questionnaire will be retained at each state until the household can be notified of water sample results; this cover page will be destroyed as soon as the household has been notified of its results. Water samples and questionnaires will be assigned a participant ID code at the time of household interviews and sampling. The laboratory that conducts the water sample analysis will identify water samples only by the ID code and will not have access to personal identifiers. Water quality data and questionnaire data will be aggregated for analysis and no personal identifiers will be used in reporting study results.

We intend to solicit consent from households to collect georeference data (latitude and longitude) of well locations (See section B.2. for explanation of consent). The reason we are asking to collect georeference data is because some states, EPA and USGS have requested data from well water sample analysis. The data will be meaningless without georeference data. We intend to request signed consent to collect well latitude and longitude readings using a Global Positioning System unit. CDC will not keep GPS data. Once it provides the state, EPA and USGS with water quality data where consent from the study participants is obtained, CDC will destroy all GPS data.

Water quality data from well samples will be transmitted to EPA and USGS in an Excel spreadsheet. EPA and USGS will only receive data from wells where homeowners have provided consent to obtain latitude and longitude and share that data with EPA and USGS. CDC will enter the georeference data written at the bottom of the household questionnaires into the well water sampling analysis spreadsheet received from the laboratory conducting water quality analysis (no personal identifiers or georeference data will be provided to the analytical laboratory). Once georeference data has been copied from questionnaires into the well water quality data spreadsheet, CDC will destroy that portion of the questionnaire.

This data collection has been approved by CDC’s IRB (Attachment 12).

**11. Justification for Sensitive Questions**

None of the questions included in the study questionnaire or participant solicitation questionnaire are considered sensitive.

**12. Estimates of Annualized Burden Hours and Costs**

12.A. The response burden was estimated by testing the study instruments on fewer than 9 individuals who use water treatment devices at home. Because we are in the recruitment phase of this study, we have not observed any changes to the respondent burden hours.

<b>A.12-1 ESTIMATES OF ANNUALIZED BURDEN HOURS</b>				
Type of Respondent	Number of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Screening Questionnaire	1200	1	5/60	100
Household Survey Questionnaire	600	1	20/60	200
Total				300

12.B. The hourly wage rate is based on U.S. Department of Labor, Bureau of Labor Statistics for May 2006 found at: <http://www.bls.gov/news.release/empst.t17.htm>. Estimated hourly wage reported in table A.12-2 relates to earnings of production or nonsupervisory workers on private nonfarm payrolls.

<b>A.12-2 ANNUALIZED COST TO RESPONDENTS</b>					

Type of Respondent	Number of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Average Hourly Wage	Respondent Cost
Screening Questionnaire	1200	1	5/60	\$16.62	\$1,662
Household Survey Questionnaire	600	1	20/60	\$16.62	\$3,324
Total					\$4,986

**13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers**

There are no other costs to respondents or record keepers.

**14. Annualized Cost to the Government**

Costs for CDC personnel were estimated based on experience with previous surveillance activities. This is a one-year project.

The Team Leader is the supervisor of the Principal Investigator and will have a role in consultation and guidance on the study. The Principal Investigator will be in charge of supervising and monitoring the study in all six states. This includes travel to states to train staff in administration of questionnaires and water sampling as well as analysis and reporting of data obtained in the study. A data entry contractor will be hired to enter data from questionnaires (which are paper format) into a database.

<b>A.14 ANNUALIZED (ESTIMATED) COST TO THE FEDERAL GOVERNMENT</b>	
<b>Service</b>	<b>Annual Cost</b>
CDC Personnel	
Team Leader	\$8,000
Principal Investigator	\$25,000
Subtotal	\$33,000
Other Expenses	
Travel	\$12,000
Data Entry	\$12,000
Mailing Costs	\$800
Subtotal	\$24,800

<b>Total</b>	<b>\$57,800</b>
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Field personnel are supported by the participating states.

**15. Change in Burden Hours**

This is a revision of an existing data collection. We are currently in the study recruitment phase.

**16. Plans for tabulation and Publication and Project Time Schedule**

OMB approval is needed for only one year. In the table below, analyses and publication will occur after OMB approval expires.

<b>A.16 PROJECT TIME SCHEDULE</b>	
<b>Activity</b>	<b>Time Schedule</b>
Contact potential study participants for pre-screening questionnaire	ongoing
Household visits for administering questionnaires & water sampling	1-8 months after OMB approval

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

The OMB expiration date will be displayed on the data collection instrument.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There will be no exceptions to certification for Paperwork Reduction Act.

## **B. STATISTICAL METHODS**

### **11772. Respondent Universe and Sampling Methods**

The respondent universe for this study consists of households in Colorado, Maine, Nebraska, Missouri, Wisconsin, and North Carolina with private wells using water treatment devices to filter/treat water used in the household for drinking or cooking. Households with private wells and water treatment devices will be excluded from this study if they rely on bottled water for drinking and cooking.

States were selected as partners in the study based on their own interest in investigating if water treatment devices are being selected, used and maintained properly. New Jersey, a state that was initially supposed to participate, withdrew due to lack of personnel to assist with the study. CDC then contacted the North Carolina Department of Health and Human Services, which agreed to participate because they have an interest in knowing if people in that state are properly selecting, using and maintaining water treatment devices. All participating states are participating because of interest and not because of a significant problem related to what the study proposes to investigate.

This is a scoping study. The study population sample size is 600 households – approximately 100 households from each state listed above. One adult member of each household will be asked to respond to a questionnaire and two sets of water samples will be drawn at each household. The water sampling sets consist of one set of samples drawn directly from the well and a second set of samples drawn directly from the water treatment device.

## **2. Procedures for the Collection of Information**

A list of potential respondents will be developed in each participating state using well registration/permitting information, water treatment device sales, and other sources. Potential respondents will be contacted by telephone for solicitation to the study (estimated number of potential study candidates across Colorado, Maine, Nebraska, Missouri, Wisconsin, and North Carolina is 1,200). During the pre-enrollment screening telephone call, the study purpose and criteria for inclusion will be described (Attachment 4). Households agreeing to participate will then be scheduled for a home visit (Attachment 5)

During the home visit, an adult member of the household will be interviewed and the health department representative will personally obtain two sets of water samples using a standard sampling protocol. One sample set will be drawn directly from the well and the second set from the water treatment device.

The study questionnaire (Attachment 6) will be administered by the trained interviewer/health department representative. Prior to beginning the interview, the interviewer will review the consent document with the respondent and ask the respondent to sign the study

consent form (Attachment 7). The respondent will provide oral responses to the interviewer, who will be responsible for recording responses on a paper copy of the questionnaire. Well data questions (questions #19 - #29) in the study questionnaire can be answered with a visual inspection of the well and if the homeowner has a certificate or permit of well construction. Householders may not be able to answer any questions about well characteristics without well construction documentation so some responses will have to be left blank. We will attempt to obtain other information (well type, casing type) by visual inspection when well water is sampled. The questionnaires will be submitted to CDC and data from questionnaires entered into a database by the CDC principal investigator and data entry contractor.

A separate consent form (Attachment 8) will be used to obtain permission to collect georeference data (latitude and longitude) for the location of the well. Respondents will be made aware that saying 'no' to letting us obtain georeference data will not impact their participation in the rest of the study. A separate consent form is intended to fully inform respondents about the purpose of obtaining, and uses for, georeference data. We anticipate that some respondents may not wish to grant consent.

Georeference data is for EPA and USGS use only. CDC will not retain georeference data.

Water samples will be shipped to the contract laboratory for analysis by express mail, overnight delivery, on the same day samples are drawn from households.

### **3. Methods to Maximize Response Rates and Deal with Non-response**

Before soliciting participation in the study, each state will identify potential study households by using well permitting information, water treatment device sales information (as available) and other sources. Potential participants will be pre-screened by telephone to assure they meet study criteria and agree to be part of the study. A home visit will be scheduled with those who consent to participate, with a pre-arranged date and time. We will also suggest to participating states that they contact households again shortly before the scheduled visit to confirm the appointment.

With pre-arranged scheduled household visits, we anticipate the response rate to be 95%. We also anticipate that agreement to participate in the study will be high since participants will get 'free' water quality testing of their water source and the water coming out of treatment devices.

This is a scoping study. The study is intended to get information about how households are selecting, using and maintaining water treatment devices and the efficacy of these devices. The major outcome of interest is levels of pathogens and contaminants that exceed EPA MCLs or other health standards in water treated with a water treatment device. Statistical analysis will be performed to determine the association, if any, between questionnaire response categories and



success and/or failure of treatment devices to remove contaminants based on water sampling results.

Field personnel performing household visits for the purposes of administering questionnaires and obtaining water samples will receive training from CDC in interviewing and obtaining water samples. Data coding and preparation will be done by the principal investigator, with assistance from a data entry contractor within the Health Studies Branch, NCEH.

#### **4. Tests of Procedures or Methods to Be Undertaken**

The study materials (questionnaire) were evaluated in pilot tests with less than 9 respondents from CDC who use water treatment devices in their home.

#### **5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

The following individuals were consulted in reviewing statistical procedures for this study:

Lorraine Backer, Ph.D., M.P.H, Health Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, 1600 Clifton Road NE, MS F-46, Atlanta, GA 30333.

Stephanie Kieszak-Holloway, M.A., M.P.H., Statistician, Health Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, 1600 Clifton Road NE, MS F-46, Atlanta, GA 30333.

The following person is responsible for collecting and analyzing data:

Jane Horton, M.S., Health Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, 1600 Clifton Road NE, MS F-46, Atlanta, GA 30333.

## **Attachments**

<b>Attachment 1</b>	Authorizing Legislation – Section 301 of the Public Health Service Act (42 USC 241)
<b>Attachment 2</b>	<b>60-day</b> <i>Federal Register</i> Notice
<b>Attachment 3</b>	Comments from original 60-day Federal Register Notice
<b>Attachment 4</b>	Participant Screening Questionnaire
<b>Attachment 5</b>	Appointment Confirmation
<b>Attachment 6</b>	Study Questionnaire
<b>Attachment 7</b>	Study Consent Form
<b>Attachment 8</b>	Consent Form to Collect Georeference Data (#2)
<b>Attachment 9</b>	E-mail Correspondence from EPA Regarding Their Intended Use of Georeference Data
<b>Attachment 10</b>	E-mail Correspondence from USGS Regarding Their Intended Use of Georeference Data
<b>Attachment 11</b>	List of Contaminants for Water Sample Analysis
<b>Attachment 12</b>	CDC IRB Approval Letter

## Attachment 1

### Public Health Service Act Section 301 [241]

#### PART A. RESEARCH AND INVESTIGATION

##### IN GENERAL

SEC. 301 [241] (a) The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to -

- (1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;
- (2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;
- (3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;
- (4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;
- (5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;
- (6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;
- (7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under sections 2353 and 2354 of title 10, except that determination, approval, and certification required thereby shall be by the Secretary of Health and Human Services; and
- (8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section.

The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary

determines appropriate.

(b)(1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

(2)(a) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.

(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health and Human Services and shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

(4) The Secretary shall publish a biennial report which contains -

(A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and

(D) a description of (i) each request received during the year involved -

(I) from a Federal agency outside the Department of Health and Human Services for the Secretary, or

(II) from an entity within the Department of Health and Human Services to any other entity within the Department, to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph

(C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.

(5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

(c) The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.

(d) The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

**Attachment 2**

*Federal Register* Notice

### **Attachment 3**

#### **Comments on 60-Day Federal Register Notice Proposing the Study**

The 60-day notice published prior to the first OMB submission was published in the *Federal Register* on April 23, 2004, Volume 69, No. 79, Page(s) 22047-22048. Comments were received from the National Ground Water Association (NGWA) and the Water Quality Association (WQA) that did not pertain to cost and hour burden. A summary of comments received and our response to the comments are provided below. (No comments were received subsequent to the February 22, 2006 publication of the 60-Day FRN for this revision application, as described in Section A8.)

*Summary of NGWA Comments:* The NGWA provided 16 pages of comments to the proposed study compiled from comments received when the NGWA distributed the draft study protocol to multiple reviewers. The NGWA represents ground water professionals and is concerned, primarily, with assuring that the design of any study evaluating ground water contaminants/private household well water systems be valid. The NGWA identified a number of study limitations in their comments and requested changes to the study in the following general thematic areas to address those limitations: (1) Include well profile data in study; (2) Add additional water treatment options to questionnaire; (3) Change study design of using a targeted selection of participants to a random selection of study participants; (4) Revise water sampling protocol at wells and in households, and add an extra water sample per household, and; (5) Revise study analytes to include only those of concern in a specific hydrogeological area.

CDC responded by indicating that this proposed study is pilot in nature, with limited funding, and is not intended to assess ground water per se. For that reason, data gathering and sampling is limited. CDC is aware of study limitations and any reports of study results will address all study limitations. Further, to determine if populations most vulnerable to ground water contaminants are protected from exposure, the study purposefully targets populations in areas of known or suspected ground water contamination. We agreed to incorporate in the study, where appropriate, the following recommendations: (1) Addition of treatment options to the questionnaire; (2) NGWA sampling protocol suggestions, and; (3) Collection of information on well profiles.

*Summary of WQA Comments:* The WQA represents approximately 2,500 companies in the U.S. and internationally that manufacture, sell, service and consult on water treatment devices and water quality problems. The WQA comments address the following concerns: (1) The proposed study is outside the functions of the CDC; (2) The study has no practical utility; (3) The study is biased towards finding that water treatment devices do not work, and; (4) CDC seeks to influence private decision-making regarding use of water treatment devices. In addition the WQA requested minor language changes to the questionnaire.

CDC responded to the WQA by indicating that it would incorporate requested changes to the questionnaire. The CDC response further explains and clarifies that the study is not an evaluation of water treatment device efficacy per se, but rather seeks to evaluate if human

behavior is affecting device performance. The study targets populations most vulnerable to exposure of ground water contaminants to determine if people who are using water treatment devices to mitigate contaminants are adequately protected. CDC recognizes that the public selects water treatment devices for many reasons other than concerns about health and does not seek to influence those decisions.



## Attachment 4



Form Approved  
OMB No.: 0920-xxxx  
Expiration Date: xx/xx/xx

### **Participant Screening Questionnaire Household Water Filtration Study (HWFS)**

As part of the study on household water treatment systems we need to screen households based on source water and filtration systems. Study participants should include only those households on private wells using a water treatment device to treat drinking and cooking water. Households that meet this definition but use bottled water for drinking and cooking are not included in this study.

This questionnaire is to be used during initial contact (telephone) with households to determine if they meet the above criteria.

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road, MS D-74, Atlanta, GA 30333, ATTN: PRA (0920-xxxx).



## Participant Screening Questionnaire

Hello, I'm calling from (STATE AGENCY NAME). My agency, along with the Centers for Disease Control and Prevention, is conducting a research study of household drinking water. The purpose of this call is to find out if you might be interested in being a part of this study and have your water tested at no cost to you. Do you have a moment to talk?

We are looking for households that are on private wells and use a filter or water treatment system to treat water for drinking and cooking. This does not include water softeners.

If you are on a well and have a home water filtration system, would you be willing to participate?

As part of the study, we will come out to your house and complete a questionnaire about your water filtration system. We will also be taking samples of your water – one before treatment, the other after treatment – to see how well your water filtration system is working. You will receive the results from the water test.

I need to ask you a few questions about your tap water and water filtration system.

1. Do you get your tap water from a well?

Yes	1
No	2 – end survey, go to Remark B
DON'T KNOW	8
REFUSED	9

2. Are you on a private well that serves only your house?

Yes	1
No	2 – go to question 2a.
Other _____	
DON'T KNOW	8
REFUSED	9

2a. Please describe your well type and approximately how many households it serves.

Community well serving _____ households	1
Municipal well	2
DON'T KNOW	8

REFUSED

9

3. Do you have a water treatment or filtration device in your home?

- Yes 1 – go to question 4.
- No 2 – end survey, go to Remark C.
- DON'T KNOW 8 – end survey, go to Remark C.
- REFUSED 9

4. What type of water filtration or treatment system do you have? (Circle all that apply)

- Point-of-Entry treatment (whole-house) 1 - proceed to Question 4a.
- Point-of-Use treatment (single tap/site) 2 - proceed to Question 4b.
- DON'T KNOW 8
- REFUSED 9

**IF POINT-OF ENTRY (POE):**

4a. What type of Point-of-Entry treatment system? (Circle all that apply)

- Carbon Filter 1
- Ultraviolet Treatment 2
- Reverse Osmosis 3
- Distiller 4
- Water Softener 5
- Other \_\_\_\_\_
- DON'T KNOW 8
- REFUSED 9

**IF POINT-OF-USE (POU):**

4b. What kind of Point-of-Use treatment system? (Circle all that apply)

- Carafe Filter 1
- Faucet Mounted Filter 2
- Counter-top Filter 3
- Under-sink Filter 4
- Other \_\_\_\_\_
- DON'T KNOW 8
- REFUSED 9

5. Do you use mainly bottled water for drinking or cooking?

- Yes 1 – Go to Remark D
- No 2 - Go to Question 6

6. Do you use mainly your treated tap water for drinking or cooking at home?

Yes  
No

1 – Go to Remark A  
2 - Go to Remark D

**Remark A: FOR STUDY PARTICIPANTS:** Thanks for your time. You qualify for the study. Do you want to participate?

We are glad you can be part of this study. We will contact you soon about a convenient time to come to your home to do our survey of your water treatment system and take water samples. During our visit we will also be asking you questions about your reasons for having a water treatment system and upkeep of the system.

Would you please tell me your name, address, and phone number:

_____	_____	_____
Last Name	First Name	MI
_____	_____	_____
Street		Apt. No.
_____	_____	_____
City	State	Zip
Telephone Number:	_____	
	Daytime	
	_____	
	Evening	

**Remark B:** Thanks for your time. Because we can only include households that get their drinking water from a well, we won't be able to include you in the study.

**Remark C:** Thanks for your time. Because we can only include households that use a water filtration system, we won't be able to include you in the study.

**Remark D:** Thanks for your time. Because we can only include households that use treated water for drinking and cooking, we won't be able to include you in the study.

**Attachment 5**

**Household Water Filtration Study – Form for Scheduling Home Visits**

Hello, my name is \_\_\_\_\_ and I'm calling from (State agency name). A while back we contacted you about being in a study we are doing with the Centers for Disease Control and Prevention on household water treatment systems at homes with wells. At that time you agreed to be in the study so I'm calling today to schedule a visit to your house.

1. Suggest dates and times:

DATE: \_\_\_\_\_

TIME: \_\_\_\_\_

DATE: \_\_\_\_\_

TIME: \_\_\_\_\_

DATE: \_\_\_\_\_

TIME: \_\_\_\_\_

2. Directions:

When we come to your house we will take water samples from your well and from your treated tap water. We'll also ask you some questions about how you use and maintain your water treatment system.

We are also going to ask if your well has ever been tested before and if you have the report of those tests on hand. If you do have water test results, will you be willing to share them with us?

Also, if you have any information that came with your water treatment system, we'd like to look at it so we can get information about recommended maintenance of the system. Would you be willing to share that with us during our visit?

Thanks for your help and interest.

If you have any questions about the study or need to change the visit date, please contact me at \_\_\_\_\_.

## Attachment 6

### Questionnaire: Household Water Filtration System (HWFS) Study

First, I would like to thank you for being in our study.

We are doing a study about water treatment systems and how well they work. As part of the study, we would like to take a sample of your treated tap water and your well water. We are also going to ask you some questions about your water treatment device, the reasons you have it, how satisfied you are with it, and how it is maintained.

[Enter homeowner name, address, and phone number here:]

_____	_____	_____
Last Name	First Name	MI
_____		_____
Street		Apt. No.
_____	_____	_____
City	State	Zip
Telephone Number:	_____	
	Daytime	
	_____	
	Evening	

***NOTE: This page will be discarded when water sampling results have been transmitted to households.***

Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road, MS D-74, Atlanta, GA 30333, ATTN: PRA (0920-xxxx).

DATE: \_\_\_\_\_ TIME: \_\_\_\_\_

1. What type of water filtration system do you have? (Circle all that apply)

Point-of-Entry (whole-house)	Y	N - proceed to Question 1a if 'Y'
Point-of-Use (single tap/site)	Y	N - proceed to Question 1b if 'Y'
DON'T KNOW	Y	N - perform a visual inspection to answer questions 1a -1c
REFUSED	Y	N - proceed to Question 2 if 'Y'

**IF POINT-OF ENTRY (POE):**

1a. What type of Point-of-Entry treatment system? (Circle all that apply)

Carbon Filter	Y	N
Softener	Y	N
Ultraviolet Treatment	Y	N
Reverse Osmosis	Y	N
Distiller	Y	N
Ion Exchange	Y	N
Activated Alumina	Y	N
Other _____		
DON'T KNOW	Y	N - verify with visual inspection
REFUSED	Y	N

**IF POINT-OF-USE (POU):**

1b. What kind of Point-of-Use treatment system? (Circle all that apply)

Carafe Filter	Y	N
Faucet Mounted Filter	Y	N
Counter-Top Filter	Y	N
Under-Sink Filter	Y	N
Other _____		
DON'T KNOW	Y	N - verify with visual inspection
REFUSED	Y	N

1c. What type of treatment system in POU filter? (Circle all that apply)

Carbon Filter	Y	N
Ultraviolet Treatment	Y	N
Reverse Osmosis	Y	N

Distiller	Y	N
Ion Exchange	Y	N
Activated Alumina	Y	N
Other _____		
DON'T KNOW	Y	N - verify with visual inspection
REFUSED	Y	N

2. Can you tell me the brand name & model number of your filtration system?

*(verify by visual inspection of treatment unit)*

\_\_\_\_\_

\_\_\_\_\_

<b>2a. Does the filtration unit appear to be properly installed?</b>	
<i>Yes</i>	<b>1</b>
<i>No</i>	<b>2</b>
<i>DON'T KNOW</i>	<b>8</b>

3. Who provides maintenance to your filtration system including changing filters?

Homeowner	1	
Vendor		2
Other _____		
DON'T KNOW	8	
REFUSED	9	Name of Vendor: _____

3a. Do you have a service contract?

Yes	1
No	2
DON'T KNOW	8
REFUSED	9

4. When was the water filter installed? \_\_\_\_/\_\_\_\_/\_\_\_\_ (mm/dd/yy)

4a. When was the last time you changed or recharged the filter?



\_\_\_/\_\_\_/\_\_\_ (mm/dd/yy)

Never Changed	1
DON'T KNOW	8
REFUSED	9

(NOTE: HOMEOWNERS ARE LIKELY TO CHANGE/CLEAR ION EXCHANGE FILTERS, VENDORS LIKELY TO CHANGE REVERSE OSMOSIS CARTRIDGES OR MAIL CARTRIDGES TO HOMEOWNER WHEN THEY SHOULD BE REPLACED.)

4b. Who installed your water filter?

Homeowner	1
Vendor	2
DON'T KNOW	8
REFUSED	9

5. How often do you or your vendor change the water filter or cartridges?

Every _____month(s)	
Every _____year(s)_	
DON'T KNOW	8
REFUSED	9

5a. Can you tell me (show me) how frequently the filter or cartridges should be changed?

_____ Yes	1 - if yes write in response below
No	2
DON'T KNOW	8
REFUSED	9

Filter should be changed every: \_\_\_\_\_

6. Who bought your water treatment system?

Respondent	1 - proceed to Question 6a
Other Householder	2 - proceed to Question 6a
Came with House	3 - proceed to Question 7
DON'T KNOW	8 - proceed to Question 7

REFUSED

9 - proceed to Question 7

6a. Why did you buy the water filtration system? (Circle all that apply)

- Improve Taste Y N
- Remove Chemicals Y N
- Remove Bacteria/Germs Y N
- Health Concerns Y N
- Health Advisory on Water Quality Y N
- Sales Call Y N
- Advertisement Y N
- Other \_\_\_\_\_
- DON'T KNOW Y N
- REFUSED Y N

6b. Where did you get the information you used to select your filtration system? (Circle all that apply).

- Sales Representative Y N
- Recommendation from Neighbor, Friend, etc... Y N
- Local Water Authority Y N
- Internet Y N
- Advertisement Y N
- Health Department Y N
- Other \_\_\_\_\_
- DON'T KNOW Y N
- REFUSED Y N

7. Did you have your water tested before buying your filtration system?

- Yes 1 - proceed to Question 7a.
- No 2 - proceed to Question 8
- DON'T KNOW 8 - proceed to Question 8
- REFUSED 9 - proceed to Question 8

*[For question 7a, ask to see the paper copy of water sample results if available]*

7a. If well water was previously sampled, please note any results that exceeded an EPA Maximum Contaminant Level (MCL) or other health parameter. Under **“Exceeded Health Criteria”**, insert a response of

'Y' only if parameter exceeded an EPA Maximum Contaminant Level or other health criteria. Otherwise leave it blank.

<b>PREVIOUS WATER TESTING</b>		
Previous Sample Date:		
Who did the test:		
<b>Parameters</b>	<b>MCL (mg/L)</b>	<b>Exceeded Health Criteria?</b>
Total Coliform	zero	
Arsenic	0.01	
Copper	1.3 (action level)	
Lead	15 (action level)	
Nitrate	10	
Nitrite	1	
Organic compounds (pesticides, etc..)		
pH		
Volatile Organic Compounds		
<b>OTHER:</b>		

**7b.** Was a copy of the water test results available for you to review to fill in sample results on the table above?

<b>Yes</b>	<b>1</b>
<b>No</b>	<b>2</b>

**8.** How satisfied are you with your filtration system?

Very Satisfied	1
Somewhat Satisfied	2

Somewhat Dissatisfied	3
Very Dissatisfied	4
DON'T KNOW	8
REFUSED	9

Now, I'd like to ask you about the water you use for cooking and drinking.

9. When you cook, what kind of water do you use? (Circle all that apply)

Plain Tap Water	Y	N
Filtered Tap Water	Y	N - if 'Y' go to 9a.
Bottled Water	Y	N - if 'Y' go to 9a.
Other _____		
DON'T KNOW	Y	N - if 'Y' go to Question 10
REFUSED	Y	N - if 'Y' go to Question 10

9a. Why don't you use the plain tap water? (Circle all that apply)

Tastes Bad	Y	N
Smells Bad	Y	N
Has or might have germs in it	Y	N
Has or might have chemicals in it	Y	N
Other _____		
DON'T KNOW	Y	N
REFUSED	Y	N

10. When you prepare drinks with water at home, such as coffee, tea or drinks from concentrate what kind of water do you use? (Circle all that apply)

Plain Tap Water	Y	N
Filtered Tap Water	Y	N - if 'Y' go to 10a.
Bottled Water	Y	N - if 'Y' go to 10a.
Other _____		
DON'T KNOW	Y	N - if 'Y' go to Question 11
REFUSED	Y	N - if 'Y' go to Question 11

10a. Why don't you use the plain tap water? (Circle all that apply)

Tastes Bad	Y	N
Smells Bad	Y	N
Has or might have germs in it	Y	N

Has or might have chemicals in it	Y	N
Other _____		
DON'T KNOW	Y	N
REFUSED	Y	N

11. When you drink water at home, what kind of water do you drink?  
(Circle all that apply)

Plain Tap Water	Y	N
Filtered Tap Water	Y	N - if 'Y' go to 11a.
Bottled Water	T	N - if 'Y' go to 11a.
Other _____		
DON'T KNOW	Y	N - if 'Y' go to Question 12
REFUSED	Y	N - if 'Y' go to Question 12

11a. Why don't you use the plain tap water? (Circle all that apply)

Tastes Bad	Y	N
Smells Bad	Y	N
Has or might have germs in it	Y	N
Has or might have chemicals in it	Y	N
Other _____		
DON'T KNOW	Y	N
REFUSED	Y	N

12. Have you or someone in you household ever experienced an illness from drinking water from your tap?

Yes	1 - proceed to Question 12a
No	2 - proceed to Question 13
DON'T KNOW	8 - proceed to Question 13
REFUSED	9 - proceed to Question 13

12a. Did the illness require that you see a health care professional?

Yes	1 - proceed to Question 12b
No	2 - proceed to Question 13
DON'T KNOW	8 - proceed to Question 13
REFUSED	9 - proceed to Question 13

Now, I have a few questions about you.

13. How old are you?

\_\_\_\_\_ Years

REFUSED 9

14. What is your occupation?

Agriculture/Forestry/Fisheries/Landscaping		Y	N
Food Service	Y	N	
Construction/Repair/Mechanics	Y	N	
Manufacturing	Y	N	
Transportation/Communications/Public Utilities	Y	N	
Waste Management/Hazardous Materials Handlers		Y	N
Business/Finance/Customer Service	Y	N	
Service Professional (Health Care, Teachers)	Y	N	
Public Administration/Government/Military/Law Enforcement	Y	N	
Homemaker/Work from home/Unemployed		Y	N
Other _____			
REFUSED		Y	N

15. SEX

FEMALE 1  
MALE 2

16. Are you of Hispanic of Latino origin?

Yes 1  
No 2  
DON'T KNOW 8  
REFUSED 9

17. With which ethnic/racial group do you most closely identify (choose all that apply):

American Indian or Alaska Native 1  
Asian 2  
Black or African American 3  
Native Hawaiian or other Pacific Islander 4

White  
DON'T KNOW  
REFUSED

5  
8  
9

Place Well Water  
Sample Tracking Label  
Here

Place Treated Water  
Sample Tracking Label  
Here

WELL DATA

18. Date & time of well sample collection:     /    /     Time      -      (24 hr time)  
Mo Day Yr Hr Min

19. Person collecting sample: \_\_\_\_\_

20. Well Depth (feet) \_\_\_\_\_

21. Age of Well in years \_\_\_\_\_ (well construction date)

22. Date of Last Chlorination     /    /     Within last six months Y N  
Mo Day Yr

23. Type of Well: (check one)

\_\_\_\_\_ Sandpoint (Sa) \_\_\_\_\_ Buried slab (Bu) \_\_\_\_\_ Drilled (Dr) \_\_\_\_\_ Dug (Du)

\_\_\_\_\_ Other: (type) \_\_\_\_\_

24. Type of Casing: (check one)

\_\_\_\_\_ Steel (St) \_\_\_\_\_ Concrete or clay tile (Ct) \_\_\_\_\_ Brick or rock (Br) \_\_\_\_\_ Plastic (Pl)

\_\_\_\_\_ Wood (Wo) \_\_\_\_\_ Other: (type) \_\_\_\_\_

25. Depth of casing: (feet) \_\_\_\_\_

26. Well Diameter in inches: \_\_\_\_\_

27. Depth to Water (feet): \_\_\_\_\_

28. Depth of pump intake or well screen \_\_\_\_\_

29. Depth to bedrock (feet): \_\_\_\_\_

-----  
CDC to tear off and discard this portion of page (latitude and longitude) after data is provided to EPA and USGS. Take measurements of latitude and longitude only with signed consent of household member.

Latitude/Longitude

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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## Household Water Filtration System Study

### Consent Form

Centers for Disease Control and Prevention, Atlanta, Georgia  
(*State Agency name and logo inserted here*)

#### Introduction

We are asking you to join us in a research study. The Centers for Disease Control and Prevention (CDC) and the (*State Agency name inserted here*) are doing a study of homes that use water treatment systems on well water. Some well water may have harmful germs or chemicals in it that can affect your health. We want to know if your water treatment system is protecting you from any germs or chemicals that might be in your well water.

We are asking you to be in this study because you get your water from a well and use a water treatment system for your drinking and cooking water.

#### Purpose of the Research

The purpose of this study is to find out how well your water treatment system is working. We will take a sample of water from your well and a sample of treated water. We're also going to ask you about your treatment system and its upkeep. The water samples we take will be tested for germs and chemicals. We'll send you a copy of the test results. We'll be able to tell if your water treatment system is working properly by what, if any, chemicals or germs we find in the treated water sample. We want to know if people using water treatment systems are using the right kind of system and maintaining them in order to protect their health.

#### Procedure

You are free to join the study or not. If you decide to be in this study, we will ask you for several things:

- Let us collect a sample of your well water
- Let us collect some water from inside your house
- Let us ask you about your water treatment system

We'll also ask to see paperwork you might have on the filter. If you have had your well water tested before, we would also like to see those results. We will collect the water samples and the samples will be shipped to Underwriter's Laboratories for testing.

***The questions will take about 20 minutes. You may choose not to answer any question for any reason.***

## **Risks or Discomforts**

None of the questions we will ask will be about touchy matters. So none of them should make you uneasy. But as we said, you can choose not to answer any question, for any reason.

## **Benefits**

By being part of this study you will find out about the quality of your well water and the treated water in your house. If we find that your treated water has chemicals or germs in it, you will also receive advice about what to do. Helping us with the study will let us know if we need to educate the public or companies that make water treatment devices about choosing and using the right kind of treatment system.

## **Confidentiality**

What we talk about and the results of water tests will be kept private to the extent allowed by law. We would like to keep your name and address only until we can send you your water test results. After we send you the test results, we will throw out your name and address. To protect your privacy, we will keep our final records under a code number rather than by name. We will keep the records in locked files and only study staff will be allowed to look at them. Your name and your answers will not appear when we present this study or publish its results.

## **Reporting of Results**

We will send you the results of your water tests by letter. If we find dangerous levels of anything in your drinking water we may contact you directly.

## **Cost/Payment**

The only cost to you for being in our study is the time you must spend.

## **Compensation**

We will not pay you for being part of our study.

## **Right to Refuse or Withdraw**

As we said before, you are free to join the study or not. If you do not join, it will not affect any services that you might expect to get in the future. Even if you agree to be in the project and sign this form, you can drop out at any time without any negative effect for you. You may refuse to answer any of the questions on the survey.

## **Persons to Contact**

If you have any questions about how the study will work, you may call Jane Horton, the chief study person from CDC, at 1- 770-488-3434 or (*insert state contact name, agency and number here*). If you have questions about your rights in this research study, please contact CDC's Deputy Associate Director for Science at 1-800/584-8814. Please leave a brief message

including your name, phone number, and say that you are calling about CDC study # (*insert study number here*). Someone will return your call as soon as possible.

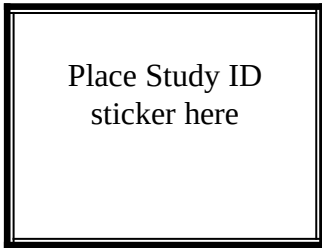
**Consent**

I have read this consent form and have received a copy of it. I have been given a chance to ask questions and I feel that all of my questions have been answered. I know that being in the study is my choice. I agree to be in the study.

\_\_\_\_\_  
Participant Signature

\_\_\_\_/\_\_\_\_/\_\_\_\_  
Date

\_\_\_\_\_  
Name of Participant (printed)



## Attachment 8

# Household Water Filtration System Study Collecting Latitude and Longitude Data on Wells



## Consent Form #2

Centers for Disease Control and Prevention, Atlanta, Georgia  
(*State Agency name and logo inserted here*)

### Introduction

#### Introduction

In this study we are taking a sample of your well water and asking you questions about your well. Knowing what is in your well water is important for you to protect your health. If your well water has any germs or chemicals in it, it might mean that other wells in your area also have problems.

The U.S. Environmental Protection Agency (EPA) and the U.S. Geological Survey (USGS) and the (insert state agency name) want to know about germs and chemicals we may find in well water. We plan to give them the results of tests on wells in this study. But we will not give them your name or address. They will not know where those results came from. Without a way to know where a well is, the results of well water tests are of little use.

We would like your permission to take a latitude and longitude reading of your well and give it to (the state agency), EPA and USGS. To do that we will use a tool that can pinpoint the exact location of your well. That information will not be connected to your name and address. But the well sample results we give to (the state agency), EPA and USGS will be identified by latitude and longitude. That means your well can be located using a map.

#### Purpose of the Research

The (insert state agency name), EPA and USGS monitor water for germs and chemicals. They can not take water samples in all places across the United States. That is why they have asked CDC to give them well water data from this study. They do not want your name or address, just the latitude and longitude of your well. USGS has water quality information from thousands of wells around the country so it can keep track of the health of our groundwater. It would like information about your well water so it can add this to a national water quality database. EPA will also add your well water information to a large national database. The (insert state agency name) also keeps water quality information about the state groundwater quality.

## **Procedure**

You are free to say ‘no’ to us taking latitude and longitude readings. It will not affect the rest of the study on your well water and treated tap water. If you give us permission to take a location reading, here is what will happen:

- o We will use a tool to measure your latitude and longitude
- o We will record that information on the Well Data sheet
- o We will give the (insert state agency name), EPA and USGS well water test results
- o We will also give the (insert state agency name), EPA and USGS your latitude and longitude reading and information about your well

You will not be contacted by the (insert state agency name), EPA and USGS. All they want is the results of your water sample and your well location. They will keep this information for as long as they keep a data base on water quality. That means they will have your well location information for many years.

## **Risks or Discomforts**

None of the questions we will ask will be about touchy matters. So none of them should make you uneasy. But as we said, you can choose not to answer any question, for any reason.

## **Benefits**

Giving your well water tests and well location to the EPA and USGS lets them add your well water quality information to a large national database. The more information we have about where germs and chemicals are located in wells, the better we can manage those germs and chemicals and protect health.

## **Confidentiality**

The results of water tests and your well location will be kept private to the extent allowed by law. CDC will not keep your latitude and longitude readings. That will be provided only to the state of (insert name), EPA and USGS. To protect your privacy, we will keep our final records under a code number rather than by name, address or location. We will keep the records in locked files and only study staff will be allowed to look at them. Your name, address, well location and your answers will not appear when we present this study or publish its results.

## **Reporting of Results**

We will send you the results of your water tests by letter. If we find dangerous levels of anything in your drinking water we may contact you directly.

## **Cost/Payment**

The only cost to you for being in our study is the time you must spend.

## **Compensation**

We will not pay you for being part of our study.

**Right to Refuse or Withdraw**

As we said before, you are free to not let us take latitude and longitude readings on your well. If you do not want us to take readings, it will not affect the rest of the study or any services that you might expect to get in the future. Even if you agree to be in this project and sign this form, you can drop out at any time without any negative effect for you.

**Persons to Contact**

If you have any questions about how the study will work, you may call Jane Horton, the chief study person from CDC, at 1- 770-488-3434 or (*insert state contact name, agency and number here*). If you have questions about your rights in this research study, please contact CDC’s Deputy Associate Director for Science at 1-800/584-8814. Please leave a brief message including your name, phone number, and say that you are calling about CDC study # (*insert study number here*). Someone will return your call as soon as possible.

**Consent**

I have read this consent form and have received a copy of it. I have been given a chance to ask questions and I feel that all of my questions have been answered. I know that allowing the taking of latitude and longitude readings is my choice. I agree to allow these readings to be taken.

\_\_\_\_\_  
Participant Signature

\_\_\_/\_\_\_/\_\_\_  
Date

\_\_\_\_\_  
Participants Name (PRINTED)

## Attachment 9 – E-mail Correspondence from EPA Regarding Their Intended Use of Georeference Data



**DATE:** June 22, 2006

**SUBJECT:** Endorsement of the Centers for Disease Control Study “Evaluation of Efficacy of Household Water Filtration/Treatment Devices in Households with Private Wells”

**TO:** Jane Horton, Ph.D.  
National Centers for Environmental Health  
Division of Environmental Hazards and Health Effects  
Centers for Disease Control and Prevention

**FROM:** Sid Abel, Associate Director  
Environmental Fate and Effects Division (7507C)  
Office of Pesticide Programs

The U.S. EPA’s Office of Pesticide Programs’ (OPP) Environmental Fate and Effects Division (EFED) draws upon information from a wide range of federal, state and local programs to assist its understanding of potential exposures, effects and use of pesticides in the marketplace. Related to potential exposure is the effectiveness of various water treatment methods to remove pesticides from drinking water. OPP has partnered with the Office of Water, Office of Research and Development, the American Water Works Association, states and other constituents to better understand the effectiveness of treatment methods at community water supply systems. OPP is equally interested in the effectiveness of filtration/treatment devices purchased by consumers for household use who derive their water from private wells. OPP/EFED would like to express its support for the Centers for Disease Control’s (CDC) program to study the efficacy of household water treatment devices used by consumers obtaining water from private wells. Use of household water treatment devices has gained greater use in the U.S. as an important consumer tool for reliable safe drinking water. As such, OPP is interested in better understanding how consumers are deploying these devices in their homes and how effective they are in meeting their needs. Effective and proper selection, use, and maintenance of these devices by consumers are important to know in order to facilitate public education at the federal, state and local level.

EPA's OPP requested access to the data from the CDC study titled, "Evaluation of Efficacy of Household Water Filtration/Treatment Devices in Households with Private Well". During the development of the study, OPP discussed the study with CDC scientists and we understood the limited scope of the study and that results obtained would not be representative of a systematic evaluation of the potential exposure over large populations nor would they be indicative of the nation's ground water quality in the region or in general. We intend to explore the use of these data to evaluate the effectiveness of the filtration/treatment devices identified in the study to remove compounds listed and especially arsenic, the only pesticide related compound to be analyzed. More importantly, we are interested in how and why consumers select household treatment devices, how they are deployed in homes (e.g., whole house treatment or at the faucet), and how well they are maintained. Such information could be used to educate consumers about the proper selection, installation and maintenance of filtration/treatment devices depending on the concern they have about drinking water quality. Information gained from this study may also serve to inform educational campaigns within OPP's voluntary stewardship programs.



## **Attachment 10 – E-mail Correspondence from USGS Regarding Their Intended Use of Georeference Data**

**From:** David J Wangsness [wangsn@usgs.gov]

**Sent:** Friday, July 30, 2004 12:49 PM

**To:** Horton, Jane

**Cc:** Abel.Sid@epamail.epa.gov; Hetrick.James@epamail.epa.gov; wangsn@usgs.gov; Wangsn.David@epamail.epa.gov

**Subject:** Re: CDC study - Efficacy of water treatment devices in households with wells

Jane,

Thanks for your willingness to go the extra step on this. The additional information on the wells/aquifers and the locational information will contribute to a number of programs within USGS. Some suggestions:

What is GIS data? -- We probably don't have to get into descriptions of GIS if it may cause the homeowner some confusion because we wouldn't ask you to provide a GIS coverage but, rather, just the latitude/longitude, which we can then use to georeference the site and make our own coverage. If the person doing the sampling/interview has access to a GPS system and just explains to the homeowner that he wants approval to estimate a lat/long so that we can map the location, then it doesn't require any additional work on the part of the homeowner and doesn't require that they know anything about GIS. If they would rather put a point on a map and provide us a copy we can calculate a lat/long.

Why does USGS want well data and locational information? -- Our mission is to assess the quality and quantity of the nation's surface- and ground-water resources and provide knowledge and understanding about the resources to local, state, and federal water-resource managers, and to the public. We collect considerable amounts of data to help us meet our mission, but also rely on data from other sources to supplement our own. We view this as an opportunity to obtain high-quality data for an additional 600 wells. Locational information is critical to be able to georeference (locate) the well on a map, and to identify the aquifer system from which the sample is drawn, so that we can combine and compare the test results with other existing information for that specific area. The data cannot be used for an assessment of the quality of the resource (aquifer system) without being able to locate the well in reference to other wells in the area of study.

What will the data be used for? -- The data will be combined with USGS monitoring data to better define the water-quality of the aquifer systems represented.

Will water quality data and locational information be available to the public? -- The short answer is probably yes, if someone submitted a FOIA request. However, we typically do not put data from non-USGS sources into our publicly assessable databases (like NAWQA's data warehouse or the USGS NWIS database - both of which are accessible on the web) but, rather would keep the data in an internal data system for internal use only. Through a FOIA, someone would have

to specifically ask for those data, in which case our first response would generally be that we are not the owners of the data and refer the request to CDC. We would not analyze or interpret these data as a stand-alone dataset but, rather, would combine the data with other data for the same aquifer system and publish summary statistics rather than individual values for individual wells. The locational data (lat/long) and raw chemical data generally are not published just because of the sheer magnitude of the data tables, but the individual wells will likely be plotted on a map for locational purposes. However, it would be very difficult to link a specific well to a homeowner, and no way to link to the specific data.

USGS does not need any personal information from the homeowner (name and address) but if the homeowner would like to have any information we currently have on the aquifer system they draw water from, or would like a copy of any future report(s) that may incorporate information from their well, they could submit their request through CDC and we could respond back through CDC. In some cases, we may have an interest in approaching the homeowner about doing some additional sampling and analyses but can work through CDC to make that contact and gain approval.

Hope this answers your questions and helps you put together the appropriate wording. If not, let me know and I'll try again.

Dave

David J. Wangsness

Cell: (770) 318-3569

USGS -- Atlanta (770) 903-9156

EPA -- Washington (703) 305-5028 or (202) 566-1170

**Attachment 11: List of contaminants for water sample analysis**

<b>Parameter</b>	<b>MRL</b>
Total coliform	Presence / Absence
Alkalinity	10 mg/L as CaCO <sub>3</sub>
Total Hardness	10 mg/L as CaCO <sub>3</sub>
Nitrate	1 mg/L
Nitrite	0.1 mg/L
pH	N/A
Turbidity	0.1 NTU
Arsenic	5 ug/L
Iron	0.1 mg/L
Lead	5 ug/L
Manganese	5 ug/L
Sodium	100 ug/L
Uranium 238	5 ug/L
Sulfate	10 mg/L
Fluoride	0.1 mg/L

## Attachment 12: CDC IRB Approval Letter

DATE: 5/31/2006

FROM: IRB Administrator  
Human Research Protection Office  
  
Office of the Chief Science Officer, OD/CDC

SUBJECT: IRB Approval of Continuation of Protocol #4245, "Evaluation of Efficacy of Household Water Filtration/Treatment Devices in Households with Private Wells" (Expedited)

TO: JANE HORTON [AUX9]  
NCEH/EHH

CDC's IRB "G" has reviewed and approved your request to continue protocol #4245 for the maximum allowable period of one year and it will expire on 5/30/2007. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), Category(ies)((7)).

If other institutions involved in this protocol are being awarded CDC funds through the CDC Procurement and Grants Office (PGO), you are required to send a copy of this IRB approval to the CDC PGO award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided PGO with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

As a reminder, the IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk, but not less than once per year. There is no grace period beyond one year from the last IRB approval date. It is ultimately your responsibility to submit your research protocol for continuation review and approval by the IRB. Please keep this approval in your protocol file as proof of IRB approval and as a reminder of the expiration date. To avoid lapses in approval of your research and the possible suspension of subject enrollment and/or termination of the protocol, please submit your continuation request at least six weeks before the protocol's expiration date of 5/30/2007.

Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for IRB approval before they are implemented.

If you have any questions, please contact the Human Research Protection Office at (404) 371-5980 or e-mail: [huma@cdc.gov](mailto:huma@cdc.gov).

SENDER

cc:

## CONTACTS