

**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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Attachments

- | | |
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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)

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

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.

PREVIOUS WATER TESTING		
Previous Sample Date:		
Who did the test:		
Parameters	MCL (mg/L)	Exceeded Health Criteria?
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		
OTHER:		

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

Yes 1
No 2

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



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

Parameter	MRL
Total coliform	Presence / Absence
Alkalinity	10 mg/L as CaCO ₃
Total Hardness	10 mg/L as CaCO ₃
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.

SENDER

cc:

CONTACTS