

Appendix B2: Adult Consent Form

Respondent ID No:

Form Approved
OMB No. 0923-xxxx
Exp. Date

PFAS Exposure Assessment, Biological Sampling Adult Consent Form (≥ 18 years of age) Reading Level: 8.7

ATSDR estimates the average public reporting burden for this collection of information as 10 minutes per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information 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 Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0923-xxxx).

We are doing an exposure assessment (EA) on chemicals called PFAS. PFAS stands for Per- and Polyfluoroalkyl Substances. We want to give you some information so you can decide whether you want to take part.

PFAS have been found in the drinking water supply in (*insert name of city/town/place here*). Scientists and doctors don't yet know how PFAS may affect people's health. A first step in figuring that out is measuring the amount of PFAS in the bodies of people who may have come into contact with this contaminated water.

PFAS are chemicals that were used in a wide range of ways in the United States, such as in personal care and cleaning products; oil, stain and grease-repelling coatings on carpet, textiles, leather and paper; and in fire-fighting foams. PFAS are found in the environment (in the air, soil, and water). And they can stay in the human body for years.

The main goal for this assessment is to find out how much PFAS are in the blood and urine of people in (*Insert name of city/town/place here*) who may have been exposed to contaminated drinking water. We will conduct this assessment from (*insert dates here*).

We hope you will agree to be part of this exposure assessment. If you have any questions about this form while filling it out, please don't hesitate to ask. Thank you for considering being in this assessment.

Follow these instructions: This form tells you about the assessment. It also says what will happen if you decide to take part. If you agree to take part in this assessment, please sign at the end of the form.

Procedures for the Exposure Assessment

First, we will ask you to answer a few questions.

A few weeks ago, we mailed you a container for a urine collection and instructions on how to collect the sample. After you sign this consent form, we will ask for the urine sample you collected first thing this morning. We will also ask you to give us a blood sample today. A phlebotomist will draw a small amount of your blood for testing. We will label your blood and urine samples with a code only. Only the project coordinator will be able to identify who gave the blood and urine samples. The questionnaire should take about 30 minutes to complete.

We will send your blood to the National Center for Environmental Health (NCEH) laboratory in Atlanta, GA, for analysis. Your urine sample will be sent to [*insert name and location of bio-specimen repository*]. Only recently

have scientists been able to measure PFAS in urine. Because the method for measuring PFAS in urine is developing, not all urine samples collected will be analyzed for PFAS. Instead, ATSDR will randomly chose a percentage of urine samples for PFAS analysis. All of the blood and urine samples will be stored and may be analyzed in the future. If your urine or blood samples are analyzed in the future, we will give you the results.

Your blood and urine will not be tested for HIV, or for the presence of alcohol or drugs and your DNA will not be used for any purpose. There will be no charge to you for the sample collection or the laboratory analysis.

At the end of the exposure assessment, we will mail your test results to you at the address you provide today. If you would like to talk with a doctor about your results, you can talk to one working on the exposure assessment free of charge.

ATSDR will also use your PFAS level results (but not any information that would identify you personally) to better understand PFAS exposure in your community.

Scientists are not sure how PFAS levels in the blood can affect a person's health. However, our main purpose for this assessment is to see if people in your community are exposed to unusual levels of PFAS. It is possible that new tests will be developed in the future that will increase our understanding about PFAS. We would like to keep your blood and urine samples so that scientists can test for more things if new tests are developed. To do this, we need your permission.

The Benefits of Taking Part in Our Exposure Assessment

Your participation in this assessment will help us understand the range of PFAS exposure and possible exposure sources in your community. Scientists are not sure how PFAS levels in the body can affect a person's health. More work is needed to clarify the risks posed by PFAS exposure. Your participation in this assessment will help advance this knowledge.

We will **not** be able to tell you if the PFAS levels in your blood or urine will make you sick now or later in life. You will be able to call project staff during and after the exposure assessment if you have any questions about your results. If your doctor has questions about PFAS, he or she may also call project staff or the physician working on the exposure assessment. The names and phone numbers of people to call are listed below.

The Risks of Taking Part in Our Exposure Assessment

This exposure assessment requires approximately 6 milliliters of blood (which is about 1 teaspoon). You may feel a sharp sting from the needle used to draw your blood. Sometimes a bruise or small blood clot appears at the site. These bruises or clots usually go away on their own. Putting heat on the site can also help the bruise or clot to go away. Although it is not common, the needle could irritate a nerve. This irritation may cause temporary numbness in part of the arm.

Risk of injury from the blood draw is higher for people with bleeding disorders, such as aplastic anemia, and for anyone on blood thinning medications (such as Coumadin) and other therapies. If you have such a bleeding disorder or are taking blood thinning medication, we recommend that you talk to your doctor before joining this exposure assessment. Also, infection could also develop as a result of the puncture through the skin. You or your health insurance company would be responsible for any follow-up care if you are injured as a result of the blood draw.

Additional Information:

- **Results:** We will send you a letter with your PFAS test results along with how they compare to levels in other people in the United States. All participants will receive blood testing results and a percentage of participants will receive urine testing results. We do not yet know enough to say whether there are levels in the blood or urine that are safe or unsafe. This assessment will only tell you how much PFAS are currently in your body. It will not tell you when or for how long you were exposed.
- **Privacy:** All personally identifiable information (PII) (such as name, address, date of birth) gathered during the exposure assessment is private and will not be publically released. This information is protected to the extent possible by (*insert name of state here*) and federal laws and regulations related to privacy protection. Only trained and authorized project staff will have access to information that can identify you, and we will keep all of the information in a secure, locked database or file at all times. Aside from the exposure assessment team, you are the only one who will receive your individual results. In accordance with CDC/ATSDR's policy regarding data access, sampling results that do not include PII may be used by public health researchers for approved research purposes.
- **Voluntary Participation:** Participation in this exposure assessment is completely voluntary. Your choice will not affect your current or future relationships with groups that are part of the exposure assessment. Even if you decide to participate, you are free to quit the exposure assessment at any time. If project staff decide it is in your best interest, or if you fail to meet the exposure assessment qualifications, you may be removed from the exposure assessment without your consent. If at any time in the future, you would like to have your blood or urine sample destroyed or removed from the assessment, please call (*insert name and phone number of Study coordinator*).

Adult Consent

By marking the check boxes below and signing this form, you are confirming that you understand the goals of the exposure assessment, and that you agree, of your own free will, to participate. You are also confirming you will allow the project staff to collect, store, and share the information gathered for the exposure assessment as described above. You will receive a copy of this form for your records.

I agree to participate in this Exposure Assessment and provide a blood and urine sample.

Yes No

I understand that I will receive my PFAS test results by mail. I will be able to compare some of my test results with national levels.

Yes No

I understand that project staff will not be able to determine if the PFAS levels in my body will impact my health.

Yes No

I agree that my PFAS test results may be shared with other federal, state, and local environmental and health agencies. Your identifying information will be protected to the extent possible by law should you choose to allow ATSDR to share your results with other federal, state or local agencies.

Yes No

I understand that my PFAS test results and questionnaire data may be used for additional analysis in the future.

Yes No

I agree to allow my blood and urine samples to be saved and used for other PFAS-related tests. If your blood and urine are analyzed in the future, we will send you the results.

Yes No

I agree to let ATSDR/NCEH keep my contact information and contact me in the future for possible follow-up studies (may be research or non-research studies).

Yes No

Participant's Name: _____
(Printed)

Participant's Signature: _____

Date Signed: _____

Street Address: _____

City: _____ State: _____ Zip: _____

Phone number (area code): _____

Project Representative's Name: _____
(Printed)

Project Representative's Signature: _____

