

Attachment 7c.

Agency for Toxic Substances and Disease Registry (ATSDR)
[Insert Investigators' Institution Name]

Multi-site Study Fact Sheet

What is this new study about? The [institution name] and the Agency for Toxic Substances and Disease Registry (ATSDR) wants to learn how per- and polyfluoroalkyl substances (PFAS) in drinking water might have affected the health of people living in the [study sites].

Who is leading this study? Researchers from [institution name] and ATSDR (part of the U.S. Department of Health & Human Services, working with the Centers for Disease Control and Prevention [CDC]) are doing this study. The [institution name(s)] are helping to recruit people for this study.

Who can join this study? ATSDR is inviting adults ages 18 years and older, and children ages 4–17 years, with their parent or guardian, to take part in the Pease Study.

ATSDR and its research partners plan to recruit at least 6,000 adults and 2,000 children for the Multi-site Study. A target of about 1,000 adults and 300 children would need to be recruited from each site including the [study site]. Those persons had to reside in areas served by PFAS contaminated drinking water or were exposed in utero or during breastfeeding when the mother consumed the contaminated drinking water. Drinking water exposure must have occurred within 15 years of the start of the study. Persons who were ever employed as a firefighter, ever participated in fire training exercises using AFFF foam, or were ever employed at industrial facilities that used PFAS chemicals in the manufacturing process will be excluded.

It is best if the mother takes part with her child. That is because we will ask lots of questions about her child's exposures, especially about her pregnancy and breastfeeding. If another parent enrolls with his or her child, that is OK. We might need to ask a few more questions about the mother's history. You might be eligible to take part as both an adult and as a parent. As a parent, you also might be eligible to enroll with more than one child.

If I decide to take part in this study, how can I join? To join this study, call study investigators at [institution name] at [xxx-xxx-xxxx] to let us know you want to participate. Study staff will ask you a few questions to make sure you qualify. Because this is a study only about PFAS in drinking water, people who have worked with PFAS chemicals at their jobs cannot take part. Some workers who might not qualify for the study include firefighters, PFAS manufacturing workers, chrome plating workers, electronics manufacturing workers, pulp and paper mill workers, and automotive service technicians and mechanics. If you are eligible, study investigators will work with you to make an appointment. We will mail you an appointment information packet to help you get ready.

Will I be paid to take part? This study has multiple parts. We will give you a \$25 gift card if you complete the written questionnaire. We will give you another \$25 gift card if you complete your body and blood pressure measures and give blood and urine samples. If you are a parent with a child who completes all the tests, we will give you an additional \$25 gift card for each child who completes these tests. This is our way of thanking you for taking part in the study.

Where will I go to take part? We are offering appointments at our central study office at [insert address]. The appointment will take about 45 minutes for adults and about 2 hours for children.

It is hard for me to come to the office. Can I still take part? If your house is within a 1-hour drive from the study office, we can do a home visit.

How do I get ready for my appointment? We will send you instructions on how to prepare for the appointment.

- On the morning of the appointment, as soon as you get up, you will need to collect your urine in the sample cup provided in the packet you got, or help your child collect urine. After collecting the urine sample in the cup, cap the cup, write the date and time on the cup, and seal the cup in the provided plastic bag. Place the sample cup in the refrigerator until it is time to go to your appointment. When you are ready to leave for your appointment, put the sample cup in the cooler with the frozen ice pack that was given to you, and bring it with you to the appointment.
- Please DO NOT TO EAT at least 8 hours before your appointment so that we can collect a fasting blood sample at the appointment. This way the blood sample gives us better information.
- If you are taking any medications or dietary supplements, such as vitamins, herbs, or natural medicines, please bring them to the appointment or tell us about them.
- If your child is participating, we will ask about his or her most recent vaccinations. If you have your child's vaccination record card, please bring it.
- If you were a part of any PFAS Blood Testing Program, please bring your results.

How do I give permission to be in the study? You will need to sign a consent form to agree to be in this study. We are required to have your signed consent before you start any part of the study. This is for your protection.

Along with getting blood and urine samples from you or your child and having you complete a questionnaire, we might want to ask your doctor more questions about your health. Study investigators might also want to look at your child's school records. We will ask for your permission to get this additional information. The additional information could improve the quality of the study results.

What will happen at my appointment?

- We will measure your or your child's height, weight, waist-to-hip ratio, and blood pressure.
- We will take the urine sample that you collected that morning.
- We will collect a fasting blood sample. A trained phlebotomist (professionally trained and licensed person who can draw blood) will draw a few teaspoons of blood from a vein in your arm or your child's arm. We will label your samples with a study identification code only. To protect your privacy, your name will **not** be on the collection tubes.

Some people cannot have their blood drawn for medical reasons. These people might still be able to be a part of the study. They can still do the interviews and have their weight, height, waist, hip, and blood pressure measured.

- You will be asked to complete paperwork about your exposure to the water, as well as your medical history. This might take about 30 minutes to complete. If you are a parent who also enrolled as an adult, study staff will give you another set of paperwork to fill out about your child that might take about 15 minutes.
- If you are a parent or guardian, we will also ask you to complete an assessment of your child's attention and behaviors. It should take about 15 minutes.
- Trained professionals will give child participants a behavioral assessment. These tests can take about 90 minutes or less. The tests are designed especially for children, are done at the child's pace, and should not make the child too tired.

Can I do the interview by telephone? No. You must do all parts of the study face-to-face. To keep the study results the most accurate, we need to interview everyone the same way.

Can someone else interview for me? No. It is important that we interview only people who are eligible. Of course, study staff will ask parents or guardians to answer questions about their children. If you are having trouble speaking, a household member may assist you.

What questions will I be asked? We will ask about your health in general, your family's health history, your job, and about other ways that you might be exposed to PFAS. For adults, we will also ask about health behaviors such as the use of alcohol and tobacco.

Is my personal information protected? We will keep your personal information private and confidential. The research staff will combine your answers with those of all other participants; no single person's information is ever released. We want to know if the health status and blood PFAS are different between groups of people.

What if I don't know how to answer the questions? If you do not know or do not remember an answer, you can simply say so.

Will you measure PFAS in my blood? Yes. We will test your blood for PFAS. We will let you know what your PFAS levels are. If you were part of any other PFAS Blood Testing Program, we will compare those results to the Multi-site Study results, if possible.

Will you do other blood tests? Yes. We will test your blood for cholesterol, liver enzymes, kidney function, and hormones. These results may help us learn more about how PFAS affect health. Doctors use most of these tests to assess health.

Will you measure PFAS in my urine? Because scientists are learning more about PFAS every day, your urine sample will be stored for the future until we have better PFAS tests that use urine. It might be a year or more

before ATSDR uses the urine samples collected in this study, but this way the scientists already have them if additional tests become available.

How will I learn about my test results? We will mail your test results to you. We think it will be up to 2 years from the time of your blood draw before we finish all of the tests and send a letter about your PFAS test results.

What if a test result for a health marker such as cholesterol is high and could be a health problem?

If one of your health marker test results means you might have a health problem, we will contact you as soon as possible after the laboratory sends us the result. Please work with your own doctor or nurse to go over any problematic test results you get back.

How are you going to use my information? We will combine everyone's results to get a picture of the health issues of people in Pease and how the results might relate to PFAS exposures. We will write reports or scientific articles about the study results and how we analyzed the results. You will be able to see these reports or articles after the study is finished.

What are the risks of taking part in the study? Your only risk from taking part in the study is from having your blood drawn. It might hurt a little when we take the sample. You might have some bruising afterward where the blood is drawn. We will do our best to avoid these problems.

Are there any costs to my taking part? You do not have to pay to be part of this study. All tests are free.

What benefit do I get for taking part? While there are no direct benefits for taking part in the study, we will give you the results of your blood PFAS and health tests that you may find helpful to share with your child's doctor. We also think that the study will help your community better understand the connection between PFAS and health.

Can I change my mind about taking part after I start? You can always choose whether you want to be part of this study or not. You can stop at any time by telling the study staff that you do not want to continue. You also can refuse to answer *any question* or choose not to have your blood drawn or give a urine sample. There is no penalty for refusal or withdrawal from the study.

Are you trying to sell me something? No. This study does not have anything to sell or buy. This is a study paid by ATSDR, a federal government agency, at no charge to you.

How will you protect information I provided? Your privacy and confidentiality are protected. We will keep all of the information that you give us private to the level required by law. We will use a code number instead of your name for your answers and test results. We will keep your records as confidential files at the office. [**Institution name**] and ATSDR will protect any computer files with your information and keep them secure. Only study staff with a need to know will have access to your information and test results. Other scientists might ask for information from this study. If we share the information with them, we will first make sure that you cannot be identified.

This research is covered under a certificate of confidentiality. That means that courts cannot make ATSDR reveal your identity, unless you agree to it.

How can I get more information about the study? To ask questions about the study, call study investigators at [xxx-xxx-xxxx]. To learn more about PFAS, you can also call 1-800-CDC-INFO (1-800-232-4636) or send an email to the PFAS mailbox at PFAS@CDC.gov.

For questions about your rights related to this study, contact the CDC/ATSDR Human Research Protection Helpline at 1-800-584-8814. Leave a message about CDC Protocol No. 7207 and a brief message about your concern or question.