## Attachment 7b – Informed Consent Packet Multi-site Study

#### **Attachment 7b1 – Privacy Act Statement**

#### **Attachment 7b2 – Parental Permission and Child Assent Forms**

#### **Attachment 7b3 – Parental Consent to Release Student Information**

#### **Attachment 7b4 – Adult Consent Form**

#### **Attachment 7b5 – Parent/Child/Adult Permission for Medical Record Abstraction**

Attachment 7b1 – Privacy Act Statement

**PRIVACY ACT STATEMENT**

**FOR THE**

**Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS): A multi-site cross-sectional study (The Multi-site Study)**

This statement provides the notice required by the Privacy Act of 1974 (5 USC § 552a(e)(3)).

* **Authority:** The Agency for Toxic Substances and Disease Registry (ATSDR) has the authority to collect this information under the Section 316(a) of the National Defense Authorization Act of 2018 (Public Law 115-91), as amended by Section 315(a) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232).
* **Purpose:** ATSDR is funding this research to study whether exposure to per- and polyfluoroalkyl substances (PFAS) from drinking water might be a public health concern. [Insert study investigators’ institution name] is collecting this information on you or your child for:
  + Adult consent, parental permission, and child assent to participate in surveys, tests, and blood and urine collections.
  + Consent for ATSDR and [institution name] to look at your child’s school records. This will help to compare study results to school records.
  + Consent for ATSDR and [institution name] to look at your or your child’s medical records. We will compare doctors’ notes to survey results. This will improve the quality of the study results.
  + Sending your or your child’s results back to you.
  + Contacting you for future studies.
* **Routine Uses:** 
  + ATSDR will share these records with the National Center for Environmental Health. NCEH may provide research or support staff, laboratory and statistical analysis, etc.
  + ATSDR and [institution name] may disclose these records to its contractors to locate individuals exposed or potentially exposed to PFAS, and to conduct interviews and other research activities. The contractor must also comply with the requirements of the Privacy Act to protect your or your child’s records.
  + Other routine uses as described in System of Records Notice (SORN) No. 09-19-0001 - ‘‘Records of Persons Exposed or Potentially Exposedto Toxic or Hazardous Substances.” See <https://www.gpo.gov/fdsys/pkg/FR-2011-01-25/pdf/2010-33004.pdf>.
* **Disclosure:** Providing this information is voluntary. ATSDR and [institution name] need this information for you or your child to take part in the study. Both institutions need up-to-date contact information to send your or your child’s study results. If you permit, ATSDR would like to keep your contact information for future studies.

Multi-site Study

Privacy Act Statement at Consent

Flesch-Kincaid Readability Score – 8.5 (deleting authority; NCEH spelled out; SORN)

Attachment 7b2.

Multi-site Study – Parental Permission/Child Assent

Flesch-Kincaid Readability Score –

KEY THINGS – 8.4

Overall – 7.9

Children – 4.5

**Parental Permission and Child Assent Form**

**TITLE OF RESEARCH:** *“****The Multi-site Study****” formally titled:*

*“Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS): A multi-site cross-sectional study “*

**[INSTITUTION NAME] PRINCIPAL INVESTIGATOR(S):** [investigator name(s)]

**ATSDR PRINCIPAL INVESTIGATORS:** Dr. Marian Pavuk, Dr. Frank Bove

**SPONSOR:** Agency for Toxic Substances and Disease Registry (ATSDR)

**CDC Protocol #**7207

**KEY THINGS TO KNOW ABOUT THIS RESEARCH**

**AUTHORITY:** Public Law 115-91, the “National Defense Authorization Act of 2018.”

**PURPOSE:** To see if PFAS exposure from drinking water is related to children’s health outcomes.

**WHO CAN TAKE PART:** About 2,000 eligible children, 4-17 years of age, and their parents or guardians.

* ATSDR and [institution name] are enrolling [300] children, 4-17 years of age, who were exposed to PFAS-contaminated water from the [insert site].
* ATSDR and its research partners plan to recruit at least 2,000 children for the Multi-site Study. Those children have 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. The birth mothers for children cannot have or had contact with PFAS chemicals at work.
* Eligible girls who are pregnant may enroll.
* People who are prisoners or under house arrest are not eligible to take part in this study.

Ideally, the parent should be the mother, who can best answer some survey questions about the child’s exposures and about the mother’s pregnancy and breastfeeding history. A parent can enroll with more than one child. In this case, ATSDR and [institution name] will enroll each child separately along with his or her parent. Parents, if eligible, may also enroll in the adult study.

ATSDR and [institution name] ask children and parents to come to our central study office. We will offer to meet some families at home, if they find travel difficult. They must live within a one-hour drive from the office.

Please be assured that ATSDR and [institution name] will take COVID-19 prevention measures at every step of our work in your community. The Multi-site study will be conducted following all state, local, and CDC guidelines in place at the time the study is conducted. Multi-site study team members will be monitored twice daily for fever and any COVID-19-related symptoms and will wear masks and gloves to ensure the protection of participants. Similarly, participants will be monitored for fever and COVID-19-related symptoms prior to their entry into the testing facility and will be asked to wear a face covering or mask. If you do not have a mask, one will be provided to you.

**EXPECTED TIME IN THE STUDY:** About 2 hours. To save time, your child can do some parts of the study while you do the parent’s parts.

**PROCEDURES:** Trained study staff will take your child’s body measures and list your child’s medications. You, as the parent, will answer survey questions and behavioral assessments about your child. At the same time, the child will complete his or her own assessments.

ATSDR and [institution name] will collect your child’s blood and urine biospecimens. ATSDR will try to analyze blood for PFAS and health tests right away. Urines will be stored until such time that lab methods are developed and scientific evidence shows which PFAS tests will yield useful results. After all tests are done, ATSDR would like to save your child’s leftover blood and urine for future studies, and only if you permit.

If you permit, ATSDR and [institution name] will ask the doctor to verify some of your child’s medical history. ATSDR will also look at your child’s school records to compare to the assessment results. If your child took part in any PFAS Blood Testing Program, ATSDR would like to get those results.

**RISKS:** The risks of taking part in this research are minimal. These risks are about the same as those your child would face in daily life. The risk of giving blood would be the same as in a doctor’s office. It may hurt a little when the blood is drawn. Your child may get a bruise where the blood is drawn. We will do our best to prevent these problems.

ATSDR will be taking precautions to minimize the risk associated with COVID-19 transmission for both participants and Multi-site Study team members.

**BENEFITS:** There are no direct benefits for your child to be in the study.We will give you the results of his or her 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 the [insert site] community better understand the connection between PFAS and health.

**CONFIDENTIALITY:** ATSDR and [institution name] has taken steps to protect your child’s privacy.A Certificate of Confidentiality covers this research.ATSDR, [institution name], and its contractors cannot be forced to release information that could identify you or your child even under a court order or subpoena (unless you consent to a release). You should know, however, that ATSDR may tell local authorities if harm to you, harm to others, or if child abuse or neglect becomes a concern.

**IT IS YOUR DECISION:** You and your child may freely choose to, or refuse to, take part in this research. During your appointment, you can stop at any time. You and your child can refuse to answer any questions or have your child’s blood drawn or urine collected. There is no penalty for refusing to take part or for leaving the study at any time.

**FOR QUESTIONS ABOUT THIS STUDY:** If you have any questions about the study, or if you and your child decide later that you do not want to take part, please contact [study investigators]at (xxx) xxx-xxxx. They can provide a phone number for a consultation with a health care provider at no cost to you if you would like to discuss your child’s results.

**FOR QUESTIONS ABOUT YOUR CHILD’S RIGHTS IN RESEARCH OR ABOUT A RESEARCH-RELATED INJURY:** For questions about your rights in taking part in this study, call the CDC/ATSDR Human Research Protection Helpline at (800) 584-8814. Be sure to say your call is about CDC Protocol No. 7207. Leave your name, contact information, and a description of your concern.

**DETAILS ABOUT THIS RESEARCH**

**STUDY OVERVIEW/PURPOSE:** ATSDR and [institution name] are inviting your child to take part in a research study to find out about the potential health effects of PFAS in the drinking water in your area.

**GETTING READY FOR YOUR APPOINTMENT:** When study staff screened and told you that your child was eligible, we scheduled your appointment and mailed you a packet with instructions on how to prepare for the appointment.

* On the morning of the appointment, we request that you help your child collect a clean first morning voided urine sample. Bring it to the appointment.
* We also request that your child not eat for at least 8 hours before his or her appointment so that we can collect a fasting blood sample.
* If your child is taking any medications or dietary supplements, we request that you bring them to the appointment. We also as that you note the dates of your child’s vaccinations for us to write down.
* If your child participated in a PFAS biomonitoring program in the past, we ask that you bring a copy of the results to the appointment.

**WHAT TO EXPECT AT YOUR APPOINTMENT:** The whole appointment will take about two hours.

* We will measure your child’s height, weight, waist, hip, and blood pressure.
* We will take in your child’s urine sample, which you will help your child collect that morning.
* We will collect a fasting blood sample from your child. A trained phlebotomist will draw a small amount of blood from a vein in your child’s arm (about 5 teaspoons). We will label your child’s samples with a study ID only.

Certain medical conditions might interfere with our drawing blood or might affect the results of our lab tests. If your child has of one of these conditions, he or she may not be able to take part in all parts of the study. However, he or she can still do the interviews and have a weight, height, waist, hip, and blood pressure measured.

* The questionnaire about your child’s exposure and medical history should take about 30 minutes to complete. Parents who also enroll as adults will take a shorter 15-minute questionnaire.
* 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 your child the behavioral assessments. Although some age groups will only need 30 to 60 minutes, the testing will take about 90 minutes for most children. The tests will be given at a relaxed pace and should not be tiring for your child.

We very much appreciate you and your child taking part in this study. If you complete all parts of the study, we will give you $75 in gift cards as our way of saying thank you. If you and your child complete parts of the appointment, we will provide the following gift cards:

* $25 for body and blood pressure measures, and for blood and urine collection;
* $25 for completed questionnaire; and
* $25 for child/parent completion of the neurobehavioral test battery

**QUESTIONS WE WILL ASK:** We will ask you questions about your child’s health, medications, vaccinations, drinking water habits, and daycare attendance. If you report that your child had certain health conditions, we would like to review your child’s medical records to confirm his or her health conditions. We will also ask you about his or her mother’s health, pregnancies, and work history. We would like to know more about her pregnancy and breastfeeding of your child.

We will ask you to complete a parent’s assessment of your child’s attention and behaviors. We will ask your child to take assessment tests about his or her attention, memory, and behaviors. We will assess IQ for children older than 5 years of age. Education professionals have used these types of assessment tests for many years with thousands of children who often find them fun and enjoyable. We would like to compare your child’s school records to the assessment results.

**PFAS MEASURED IN BLOOD:** We will send your child’s blood sample for lab analysis. The lab will measure the levels of specific PFAS in your child’s blood.

**OTHER BLOOD TESTS:** We will send your child’s blood to the lab for health tests such as cholesterol, other lipids, liver enzymes, and thyroid hormones. We will also look at allergy markers and vaccine response. Doctors often use these types of tests. They will help us learn more about how PFAS might affect health. For this study, we will not conduct genetic, HIV, or drug testing.

**PFAS MEASURED IN URINE:** Scientists are learning more about PFAS every day. Your child’s urine specimen will be stored until lab methods are developed and the scientific evidence shows which PFAS tests will yield useful results. It might be a year or more before ATSDR decides if and which PFAS tests in urine should be done as part of this research study.

**YOUR CHILD’S TEST RESULTS**: We will send you a letter with your child’s blood PFAS and health test results. We think we will finish all of the lab tests in less than six months after we draw your child’s blood. If your child’s test results suggest a health problem, we will let you know before we mail the blood test results. Despite the anticipated time delay, ATSDR and [institution name] plans to send a report of your child’s urine PFAS.

**COSTS:** You do not have to pay to let your child be part of this study. The blood tests are free.

**MORE ABOUT CONFIDENTIALITY:** ATSDR and [institution name] has taken steps to protect your privacy. A Certificate of Confidentiality covers this research.ATSDR is required to protect the privacy of persons who are subjects of this research under subsection 301(d) of the Public Health Service Act (PHSA) [42 USC §241(d)]. ATSDR and its research partners cannot be forced to release information that could identify you or your child even under a court order or subpoena (unless you consent to a release). You should know, however, that ATSDR may tell local authorities if harm to you, harm to others, or if child abuse or neglect becomes a concern.

You should also know that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow ATSDR or [institution name] to release it.

ATSDR and its research partners are required to ensure that any investigator or institution not funded by ATSDR who receives a copy of identifiable, sensitive information protected by a Certificate, understand they are also subject to the requirements of subsection 301(d) of the PHSA.

We will store your answers and test results using a study number, not your child’s name. We will keep his or her records in locked files at the study office in [insert site]. ATSDR and its research partners will protect any computer files with your child’s information. Only study staff with a need-to-know will have access to his or her information and test results. All study staff will take training on how to protect the privacy of people who take part in this research.

**USE OF COLLECTED INFORMATION:** We will write reports or scientific articles about the study results. We will combine everyone’s responses to get a picture of the health issues of people across the sites as they may relate to PFAS. These reports or articles will be available to the public after the study is finished. The report results will not identify who took part in the study.

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**STORING RESIDUAL BIOSPECIMENS AND MULTI-SITE STUDY DATA FOR FUTURE USE:**

ATSDR will keep your and your child’s contact information and study ID number(s) in a restricted-access secure master dataset. All biospecimens and study data will be coded and stored only with study IDs for data analysis. If you change your mind later and decide not to let us use your biospecimens or data for other projects, you can contact us and we will remove you from the list.

We are ***seeking permission now and will not recontact*** you for the following activities:

* **Additional analyses of stored biospecimens related to this PFAS research:** After we test your child’s blood and urine, there may be some left over. Because new scientific knowledge, tests, or methods may arise, we would like to save this leftover blood and urine for additional analyses on exposures or health conditions related to PFAS. We do not plan to report the results of all of these additional or future research tests to you, but we will contact you if the results are clinically important to your child’s health.
* **Future analyses by outside investigators:** In addition, ATSDR/[institution name] may release your child’s **de-identified research datasets or de-identified blood and urine** samples for future studies related to PFAS to outside investigators under a data use agreement that will prohibit any attempt to identify you or your child as a research subject. In this case, your individual test results will not be reported to you.

We would like ***to keep your contact information for future studies*.** We would like **to recontact you** toget additional consentfor the following types of activities:

* **Studies that require collection of additional data or biospecimens.** After we complete this study, we may conduct new research studies. At that time, we may ask your consent to include your child, and your child’s data or leftover biospecimens from this current study. We’d like to contact you at that time. **For studies using existing or additional biospecimens for genetic test or whole genome sequencing.** Currently, we have no plans for such tests. However, if such studies are proposed in the future, we would recontact you to request consent for such tests.

Your stored biospecimens will not be used for any commercial activities for profit. All future analyses and studies must adhere to IRB review requirements.

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If you do not understand what we are asking you to do, feel free to ask questions now. If you have no further questions and agree to be in this study, please sign the permission and assent form below.

**Child Assent Information about the Multi-site Study**

Multi-site Study – Parental Permission/Child Assent

Flesch-Kincaid Readability Score –

Children – 4.8

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**THINGS TO KNOW ABOUT THIS STUDY**

**WHO IS DOING THIS STUDY:** ATSDR is a public health agency that does research at places like [insert site]. [Insert site] has a chemical that got into some of the drinking water. In [insert site], the chemical is called “PFAS.”

**PURPOSE:** In this study, ATSDR and [institution name] will ask you to tell us about your health, to take some assessment tests, and to get your blood tested for PFAS. This way, when ATSDR and [institution name] investigators look at all the results together, we can see if any answers about children’s health might relate with their PFAS results.

**WHO CAN TAKE PART:** ATSDR and [institution name] wants to enroll about 300eligible children, 4-17 years of age, and their parents. We think it is best if your mother comes with you. That is because we will ask a lot of questions about when you were a baby.

Please be assured that ATSDR and [institution name] will take COVID-19 prevention measures at every step of our work in your community. The Multi-site Study will be conducted following all state, local, and CDC guidelines in place at the time the study is conducted.

Multi-site Study team members will be monitored twice daily for fever and any COVID-19-related symptoms and will wear masks and gloves to ensure the protection of participants. Similarly, participants will be monitored for fever and COVID-19-related symptoms prior to their entry into the study office and will be asked to wear a face covering or mask. If you do not have a mask, one will be provided to you.

**EXPECTED TIME IN THE STUDY:** About 2 hours. To save time, you can do some parts of the study at the same time as your parent or guardian. Before you come to the study, we ask that you not eat for 8 hours. We also ask that you pee in a lab cup at home and bring the sample with you.

**WHAT WILL YOU DO:** It will be a lot like going to the doctors. We will measure how tall you are and how much you weigh. We will take your blood pressure and write down your medicines, if you take any. We will take your pee and draw a small blood sample. The blood draw might hurt a little, but for most children, it is not too bad.

Your parent or guardian will answer questions about you. At the same time, you will do the assessment tests. They are a lot like puzzles and thinking games that you might find fun to do.

**IT IS YOUR DECISION:** You are free to decide if you want to do the study. If you start, you can stop at any time. You can refuse to answer any questions. You can decide not to give a blood or urine sample. Nothing bad will happen to you or your parent if you don’t join the study.

**FUTURE STUDIES:** ATSDR and [institution name] may plan to do more studies in the future. Sometimes, ATSDR and [institution name] might want to let you know about a new study or to get your permission to include you, your study data, or your leftover blood and urine, for a new study. To do this, we’d like to contact you then.

**Parental Permission and Child Assent (SIGNATURE Page 1 of 2)**

**TITLE OF RESEARCH:** *“****The Multi-site Study****” formally titled:**“Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS): A multi-site cross-sectional study “*

**FOR OFFICE USE ONLY**

**Adult Study ID No.** |*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*| (alias)

**Parent Study ID No.** |*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*|

**Child Study ID No.** |*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*|

**CDC Protocol #**7207

I have read and/or have been told about the purpose of the study. I have been given a chance to ask questions and my questions have been answered. I have been given a copy of this form. I choose to take part in the study.

By signing below, I agree to the parts of the Multi-site Study that I have checked below:

[\_\_] Answer study questions about my child.

[\_\_] Complete a parent assessment of my child’s attention and behaviors.

[\_\_] Have my child take a test for attention and behaviors.

[\_\_] Have my child, who is > 5 years of age, take an IQ test; **or** [\_\_] My child is ≤ 5 years of age.

[\_\_] Allow ATSDR and [institution name] to review my child’s school records.

[\_\_] Allow ATSDR and [institution name] to review my child’s medical records.

[\_\_] Give ATSDR and [institution name] a copy of any PFAS Blood Testing Program results; if available; [\_\_] My child has not participated in a PFAS Blood Testing Program.

[\_\_] Have my child provide a blood sample and have it tested.

[\_\_] Have my child provide a urine sample and have it stored.

|  |  |
| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Parent or Guardian’s Name (Print)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Parent or Guardian’s Signature Date | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Child’s Name (Print) (≥ 7 years old)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Child’s Signature Date  |\_\_|\_\_|\_\_| - |\_\_|\_\_| - |\_\_|\_\_|\_\_|\_\_|  Child’s Social Security Number  |\_\_|\_\_| - |\_\_|\_\_| - |\_\_|\_\_|\_\_|\_\_|  MM DD YYYY  Child’s Date of Birth |

**Parental Permission and Child Assent (SIGNATURE Page 2 of 2)**

**TITLE OF RESEARCH:** *“****The Multi-site Study****” formally titled:**“Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS): A multi-site cross-sectional study “*

**FOR OFFICE USE ONLY**

**Adult Study ID No.** |*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*| (alias)

**Parent Study ID No.** |*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*|

**Child Study ID No.** |*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*|

**CDC Protocol #**7207

I have read and/or have been told about ATSDR’s plans for using my child’s study data and leftover biospecimens in the future. I have been given a chance to ask questions and my questions have been answered. I have been given a copy of this form. I understand that ATSDR will follow CDC IRB requirements for these new studies.

By signing below, I agree to the additional uses of my child’s Multi-site Study data and leftover biospecimens that I have checked below:

[\_\_] ATSDR and [institution name] can contact me about new studies.

[\_\_] ATSDR and [institution name] can use my child’s study data and his or her leftover blood and urine for new studies about PFAS.

[\_\_] ATSDR and [institution name] can use my child’s study data and his or her leftover blood and urine for new studies that are not about PFAS.

|  |  |
| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Parent or Guardian’s Name (Print)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Parent or Guardian’s Signature Date | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Child’s Name (Print) (≥ 7 years old)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Child’s Signature Date |

Attachment 7b3.

Multi-site Study

Parental Consent Release Student Info

Flesch-Kincaid Readability Score – 8.1

**Multi-site Study**

**PARENTAL CONSENT TO RELEASE STUDENT INFORMATION**

Under the Family Educational Rights and Privacy Act (FERPA), the Agency for Toxic Substances and Disease Registry (ATSDR) and [institution name] are seeking parental consent for the release of your child’s school records. ATSDR and [institution name] will compare your child’s school records to some of his or her research test results from the Multi-site Study.

The only type of information that is to be released under this consent is:

\_\_\_\_\_ Individualized Education Program (IEP)

\_\_\_\_\_ IEP Evaluation Report (“Full Individual Evaluation” or “FIE”)

\_\_\_\_\_ Independent Educational Evaluation (IEE)

ATSDR and [institution name] plan to send trained study staff to the school indicated on this form. The staff will perform school record abstractions limited to the above information. You have a right to inspect any written records released pursuant to this consent. You may revoke this consent upon providing written notice to the Education Official and School that you permitted to release you child’s school records. Until it is revoked, this consent shall remain in effect. Until such time, your child’s school records will be provided to ATSDR and [institution name] until the study is over.

By signing below, you permit:

Name of Official: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_School: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

to release your child’s school records to the study investigators [insert name(s)]. You may contact them with any questions at [study telephone number].

## Name of Student (print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Student ID No. \_\_\_\_\_\_\_\_\_\_\_\_\_

## Address of Student: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## City: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ State: \_\_\_\_\_\_\_\_\_\_\_ Zip Code: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Name of Parent or Guardian (print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Signature of Parent or Guardian: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date of Consent: |\_\_|\_\_|/|\_\_|\_\_|/|\_\_|\_\_|**

**Child’s Study ID No. |*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*|**

Attachment 7b4.

Multi-site Study – Adult Consent

Flesch-Kincaid Readability Score –

KEY THINGS – 8.2

Overall – 8.3

**Adult Consent Form**

**TITLE OF RESEARCH:** *““****The Multi-site Study****” formally titled:**“Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS): A multi-site cross-sectional study “*

**[INSTITUTION NAME] PRINCIPAL INVESTIGATOR(S):** [investigator name(s)]

**ATSDR PRINCIPAL INVESTIGATORS:** Dr. Marian Pavuk, Dr. Frank Bove

**SPONSOR:** Agency for Toxic Substances and Disease Registry (ATSDR)

**CDC Protocol #**7207

**KEY THINGS TO KNOW ABOUT THIS RESEARCH**

**AUTHORITY:** Public Law 115-91, the “National Defense Authorization Act of 2018.”

**PURPOSE:** To see if PFAS exposure from drinking water is related to adult health outcomes.

**WHO CAN TAKE PART:** Eligible adults, ≥ 18 years of age. ATSDR and [institution name] ask you to come to our central study office.

* ATSDR and [institution name] are enrolling 1,000 adults, ≥ 18 years of age who were exposed to PFAS-contaminated water from the [insert site].
* ATSDR and its research partners plan to recruit at least 6,000 adults for the Multi-site Study. 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.
* Eligible females who are pregnant may enroll.
* People who are prisoners or under house arrest are not eligible to take part in this study.
* An eligible adult can also enroll as a parent of one or more eligible children.

We will ask you to come to our central study office. We will offer to meet some adults at home, if they find travel difficult. They must live within a one-hour drive from the office.

Please be assured that ATSDR and [institution name] will take COVID-19 prevention measures at every step of our work in your community. The Multi-site Study will be conducted following all state, local, and CDC guidelines in place at the time the study is conducted.

Multi-site Study team members will be monitored twice daily for fever and any COVID-19-related symptoms and will wear masks and gloves to ensure the protection of participants. Similarly, participants will be monitored for fever and COVID-19-related symptoms prior to their entry into the study office and will be asked to wear a face covering or mask. If you do not have a mask, one will be provided to you.

**EXPECTED TIME IN THE STUDY:** About 45 minutes.

**PROCEDURES:** Trained study staff will take your body measures and list your medications. You will answer survey questions. During the screening for the study eligibility you will be offered the option to answer the survey questions over the phone.

ATSDR and [institution name] will collect your blood and urine biospecimens. ATSDR and [institution name] will try to analyze blood for PFAS and health tests right away. Urines will be stored until such time that lab methods are developed and scientific evidence shows which PFAS tests will yield useful results. After all tests are done, ATSDR and [institution name] would like to save your leftover blood and urine for future studies, and only if you permit.

If you permit, study staff will ask the doctor to verify some of your medical history. If you took part in any PFAS Blood Testing Program, ATSDR would like to get those results.

**RISKS:** The risks of taking part in this research are minimal. These risks are about the same as those you would face in daily life. The risk of giving blood would be the same as in a doctor’s office. It may hurt a little when the blood is drawn. You may get a bruise where the blood is drawn. We will do our best to prevent these problems.

ATSDR will be taking precautions to minimize the risk associated with COVID-19 transmission for both participants and the study staff members.

**BENEFITS:** There are no direct benefits for you to be 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 doctor. We also think that the study will help the [insert site] community better understand the connection between PFAS and health.

**CONFIDENTIALITY:** ATSDR has taken steps to protect your privacy.A Certificate of Confidentiality covers this research*.* ATSDR and its research partners cannot be forced to release information that could identify you even under a court order or subpoena (unless you choose to a release). You should know, however, that ATSDR may tell local authorities if harm to you, harm to others, or if child abuse or neglect becomes a concern.

**IT IS YOUR DECISION:** You may freely choose to, or refuse to, take part in this research. During your appointment, you can stop at any time. You can refuse to answer any questions or have your blood drawn. There is no penalty for refusing to take part or for leaving the study at any time.

**FUTURE STUDIES:** ATSDR and [institution name] may plan to do more studies in the future. Sometimes, ATSDR and [institution name] might want to let you know about a new study or to get your permission to include you, your study data, or your leftover blood and urine, for a new study. To do this, we’d like to contact you then.

**FOR QUESTIONS ABOUT THIS STUDY:** If you have any questions about the study, or if you decide later that you do not want to take part, please contact [study investigators] at (xxx) xxx-xxxx. They can provide a phone number for a consultation with a health care provider at no cost to you if you would like to discuss your results.

**FOR QUESTIONS ABOUT YOUR RIGHTS IN RESEARCH OR ABOUT A RESEARCH-RELATED INJURY:** For questions about your rights in taking part in this study, call the CDC/ATSDR Human Research Protection Helpline at (800) 584-8814. Be sure to say your call is about CDC Protocol No. 7207. Leave your name, contact information, and a description of your concern.

**DETAILS ABOUT THIS RESEARCH**

**STUDY OVERVIEW/PURPOSE:** ATSDR and [institution name] are inviting you to take part in a research study to find out about the potential health effects of PFAS in the drinking water in your area.

**GETTING READY FOR YOUR APPOINTMENT:** When study staff screened and told you that you were eligible, we scheduled your appointment and mailed you a packet with instructions on how to prepare for the appointment.

* On the morning of the appointment, we request that you collect a clean first morning voided urine sample. Bring it to the appointment.
* We also request that you not eat for at least 8hours before your appointment so that we can collect a fasting blood sample.
* If you are taking any medications or dietary supplements, we request that you bring them to the appointment.
* If you participated in a PFAS biomonitoring program in the past, we ask that you bring a copy of the results to the appointment.

**WHAT TO EXPECT AT YOUR APPOINTMENT:** The whole appointment will take about 45 minutes.

* Upon entering the study office, the staff will check if you are a wearing a mask (will provide one if not) and take your temperature using no-touch thermometer.
* If temperature is below 100.4 ˚F, we will ask if you have experienced any symptoms related to COVID-19.
* If you have a temperature above 100.4 ˚F and/or have any COVID-19 related symptoms, we will reschedule your appointment for you. CDC guidance recommends you self-isolate at home for a minimum of 14 days. Seek immediate medical attention if you have serious symptoms. Always call before visiting your doctor or health facility.
* We will measure your height, weight, waist, hip, and blood pressure.
* We will take in your urine sample, which you will collect that morning.
* We will collect a fasting blood sample. A trained phlebotomist will draw a small amount of blood from a vein in your arm (about 8 teaspoons). We will label your samples with a study ID only.

Certain medical conditions might interfere with our drawing blood or might affect the results of our lab tests. If you have of one of these conditions, you may not be able to take part in all parts of the study. However, you can still do the interviews and have a weight, height, waist, hip, and blood pressure measured.

* The questionnaire about your exposure and medical history should take about 30 minutes to complete.

We very much appreciate you taking part in this study. If you complete all parts of the study, we will give you $50 in gift cards as our way of saying thank you. If you complete parts of the appointment, we will provide the following gift cards:

* $25 for body and blood pressure measures, and for blood and urine collection; and
* $25 for completed questionnaire.

**QUESTIONS WE WILL ASK:** We will ask you questions about your health, medications, drinking water habits, and work history. If you report that you had certain health conditions, we would like to review your medical records to confirm these health conditions. For women, we will also ask your reproductive and breastfeeding history.

**PFAS MEASURED IN BLOOD:** We will send your blood sample for lab analysis. The lab will measure the levels of specific PFAS in your blood.

**OTHER BLOOD TESTS:** We will send your blood to the lab for health tests such as cholesterol, other lipids, liver enzymes, and thyroid hormones. We will also look at allergy markers. Doctors often use these types of tests. They will help us learn more about how PFAS might affect health. For this study, we will not conduct genetic, HIV, or drug testing.

**PFAS MEASURED IN URINE:** Scientists are learning more about PFAS every day. Your urine specimen will be stored until lab methods are developed and the scientific evidence shows which PFAS tests will yield useful results. It might be a year or more before ATSDR decides if and which PFAS tests in urine should be done as part of this research study.

**YOUR TEST RESULTS**: We will send you a letter with your blood PFAS and health test results. We think we will finish all of the lab tests in less than six months after we draw your blood. If your test results suggest a health problem, we will let you know before we mail the blood test results. Despite the anticipated time delay, ATSDR plans to send a report of your urine PFAS.

**COSTS:** You do not have to pay to be part of this study. The blood tests are free.

**MORE ABOUT CONFIDENTIALITY:** ATSDR and [institution name] have taken steps to protect your privacy. A Certificate of Confidentiality covers this research.ATSDR is required to protect the privacy of persons who are subjects of this research under subsection 301(d) of the Public Health Service Act (PHSA) [42 USC §241(d)].ATSDR and its research partners cannot be forced to release information that could identify you or your child even under a court order or subpoena (unless you choose to such a release). You should know, however, that ATSDR may tell local authorities if harm to you, harm to others, or if child abuse or neglect becomes a concern.

You should know that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow ATSDR to release it.

ATSDR, [institution name], and its contractors are required to ensure that any investigator or institution not funded by ATSDR who receives a copy of identifiable, sensitive information protected by a Certificate, understand they are also subject to the requirements of Subsection 301(d) of the PHSA.

We will store your answers and test results using a study number, not your name. We will keep your records in locked files at the study office in [insert site]. ATSDR and its research partners will protect any computer files with your information. Only study staff with a need-to-know will have access to your information and test results. All study staff will take training on how to protect the privacy of people who take part in this research.

**USE OF COLLECTED INFORMATION:** We will write reports or scientific articles about the study results. We will combine everyone’s responses to get a picture of the health issues of people in [insert site] as they may relate to PFAS. These reports or articles will be available to the public after the study is finished. The report results will not identify who took part in the study.

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**STORING RESIDUAL BIOSPECIMENS AND MULTI-SITE STUDY DATA FOR FUTURE USE:**

ATSDR will keep your contact information and study ID number(s) in a restricted-access secure master dataset. All biospecimens and study data will be coded and stored only with study IDs for data analysis. If you change your mind later and decide not to let us use your biospecimens or data for other projects, you can contact us and we will remove you from the list.

We are ***seeking permission now and will not recontact*** you for the following activities:

* **Additional analyses of stored biospecimens related to this PFAS research:** After we test your blood and urine, there may be some left over. Because new scientific knowledge, tests, or methods may arise, we would like to save this leftover blood and urine for additional analyses on exposures or health conditions related to PFAS. We do not plan to report the results of all of these additional or future research tests to you, but we will contact you if the results are clinically important to your health.
* **Future analyses by outside investigators:** In addition, ATSDR/[institution name] may release your **de-identified research datasets or de-identified blood and urine** samples for future studies related to PFAS to outside investigators under a data use agreement that will prohibit any attempt to identify you as a research subject. In this case, your individual test results will not be reported to you.

We would like ***to keep your contact information for future studies*.** We would like to recontact you toget additional consentfor the following types of activities:

* **Studies that require collection of additional data or biospecimens.** After we complete this study, we may conduct new research studies. At that time, we may ask your consent to include you, and your data or leftover biospecimens from this current study. We’d like to contact you at that time.
* **For studies using existing or additional biospecimens for genetic test or whole genome sequencing.** Currently, we have no plans for such tests. However, if such studies are proposed in the future, we would recontact you to request consent for such tests.

Your stored biospecimens will not be used for any commercial activities for profit. All future analyses and studies must adhere to IRB review requirements.

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If you do not understand what we are asking you to do, feel free to ask questions now. If you have no further questions and agree to be in this study, please sign the permission and assent form below.

**ADULT INFORMED CONSENT (SIGNATURE Page 1 of 2)**

**TITLE OF RESEARCH:** *“****The Multi-site Study****” formally titled:*

**FOR OFFICE USE ONLY**

**Adult Study ID No.** |*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*|

**Parent Study ID No.** |*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*| (alias)

**Child Study ID No.** |*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*|

*“Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS): a multi-site cross-sectional study.”*

I have read and/or have been told about the purpose of the study. I have been given a chance to ask questions and my questions have been answered. I have been given a copy of this form. I choose to take part in the study.

By signing below, I agree to the parts of the Multi-site Study that I have checked below:

[\_\_] Answer study questions.

[\_\_] Allow ATSDR and[institution name] to review my medical records.

[\_\_] Give ATSDR and[institution name] a copy of my PFAS Blood Testing Program results if available; **or** give ATSDR and [institution name] permission to get my results (if available); [\_\_] I have not participated in a PFAS Blood Testing Program.

[\_\_] Provide a blood sample and have it tested.

[\_\_] Provide a urine sample and have it stored.

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Adult’s Name (Print)

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Adult’s Signature Date

|\_\_|\_\_|\_\_| - |\_\_|\_\_| - |\_\_|\_\_|\_\_|\_\_|

Adult’s Social Security Number

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MM DD YYYY

Adult’s Date of Birth

**ADULT INFORMED CONSENT (SIGNATURE Page 2 of 2)**

**TITLE OF RESEARCH:** *“****The Multi-site Study****” formally titled:*

**FOR OFFICE USE ONLY**

**Adult Study ID No.** |*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*|

**Parent Study ID No.** |*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*| (alias)

**Child Study ID No.** |*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*|

*“Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS): a multi-site cross-sectional study.”*

**CDC Protocol #**7207

I have read and/or have been told about ATSDR’s plans for using my study data and leftover biospecimens in the future. I have been given a chance to ask questions and my questions have been answered. I have been given a copy of this form. I understand that ATSDR and [institution name] will follow CDC IRB requirements for these new studies.

By signing below, I agree to the additional uses of my Multi-site Study data and leftover biospecimens that I have checked below:

[\_\_] ATSDR and [institution name] can contact me about new studies.

[\_\_] ATSDR and [institution name] can use my study data and leftover blood and urine for new studies about PFAS.

[\_\_] ATSDR and [institution name] can use my study data and leftover blood and urine for new studies that are not about PFAS.

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Adult’s Name (Print)

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Adult’s Signature Date

Attachment 7b5.

Multi-site Study Permission for Medical Record Abstraction

Flesch-Kincaid Readability Score – 11.7

**Parent/Child/Adult Permission for Medical Record Abstraction**

**FOR OFFICE USE ONLY**

**Adult Study ID No.** |*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*|

**Parent Study ID No.** |*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*|

**Child Study ID No.** |*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*|

**AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR)**

**MULTI-SITE STUDY**

|  |  |  |
| --- | --- | --- |
| I authorize this health care provider or organization to release protected health information (PHI) for the uses listed below: | | |
| **Information to be released by:**  (Name of health care provider, health plan, or health care clearing house)  (Address)  (Phone number) | | **Information to be released to:**  [study investigator]  (Name of person or organization)  [institution name]  (Address)  (Phone number) |
| **The information is released for the following uses:**  ATSDR is asking providers to verify diagnosis or treatment of certain health conditions and outcomes for the named individual. ATSDR lists the conditions on the back of this form. | | |
| ATSDR will not ask for the release of PHI about alcohol or drug abuse treatment, genetics, and about reportable diseases, including sexually transmitted diseases and HIV-AIDS. | | |
| **By signing below, I understand that:**   * I do not have to sign this authorization. * My authorization will automatically end at the end of the study; or * I have the right to end my authorization at any time by writing a letter to this office. * Ending my authorization will not affect any earlier release of PHI. * Ending my authorization will not bar me from taking part in the study. * Under my authorization, I have a right to look at or copy any release of PHI. * I have a right to a copy of this authorization. * No study reports will reveal my identity. | | |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **(Signature of Individual or Authorized Representative)**  **(Representative’s Legal Authority to Individual)**  **(Today’s Date)**  **(Phone Number)**  **(Date of Birth of Individual)** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **(Print Name of Individual)**  **(Print Name of Authorized Representative)**    **(Address)**    **|\_\_\_|\_\_\_|\_\_\_| - |\_\_\_|\_\_\_| - |\_\_\_|\_\_\_|\_\_\_|\_\_\_|**  **(Social Security Number of Individual)** | |

The Privacy Rule issued under Health Insurance Portability and Accountability Act (HIPAA) is a regulation that provides protection for the privacy of certain individually identifiable health data (“protected health information”). HIPAA applies to covered entities, including health care providers who conduct electronic transactions, health plans (both public and private), and healthcare clearinghouses. CDC is generally not a covered entity; it is a public health authority. CDC/ATSDR may receive protected health information from covered entities, because CDC is a public health authority authorized by law to receive such information for public health purposes. Covered entities may, but are not required to, provide protected health information to CDC.

**MULTI-SITE STUDY** (Authorization for Release or Use of PHI) Page 2

ATSDR or [institution name] may send a medical record abstraction form to be completed by the health care provider, health plan, or health care clearing house that you indicate on this form. Alternatively, ATSDR and NCEH staff or contractors may perform the medical record abstraction.

ATSDR and [institution name] are seeking information on the date of diagnosis or first treatment for the following health conditions (except as shown on Page 1). ATSDR and [institution name] are also seeking information if the individual is currently receiving treatment for these health conditions:

|  |  |  |
| --- | --- | --- |
| ***Diagnosis or Treatment of Health Conditions*** | ***Adult*** | ***Child*** |
| Osteoarthritis | √ | -- |
| Osteopenia and osteoporosis | √ | -- |
| Endometriosis | √ | -- |
| Heart Disease | √ | -- |
| Hypertension (including pregnancy-induced hypertension, preeclamsia) | √ | √ |
| Autoimmune diseases (including ulcerative colitis, rheumatoid arthritis, lupus, and multiple sclerosis) | √ | √ |
| Diabetes (including gestational diabetes) | √ | √ |
| Kidney Function (including kidney disease) | √ | √ |
| Lipid Disorder (including high cholesterol) | √ | √ |
| Thyroid Hormones | √ | √ |
| Liver Function (including liver disease) | √ | √ |
| Immune Response and Inflammation | √ | √ |
| Hypersensitivity-related outcomes (including asthma, atopic dermatitis/eczema) | -- | √ |
| Antibody responses to rubella, mumps, and diphtheria vaccines | -- | √ |
| Sex hormones, growth, and maturation | -- | √ |
| Neurodevelopmental outcomes (lower intelligence quotient (full scale IQ), attention-deficit, autism, and hyperactivity disorder (ADHD). | -- | √ |
| Parkinson disease | √ |  |
| Allergies | √ | √ |
| Infertility | √ |  |