

**Attachment 9b - Informed Consent Packet**

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Participant Initials: \_\_\_\_\_

**PRIVACY ACT STATEMENT  
FOR THE  
PEASE 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 § 8006 of the Consolidated Appropriations Act of 2018 (Public Law 115-141). ATSDR also conducts research under the “Comprehensive Environmental Response, Compensation, and Liability Act of 1980” (CERCLA) as amended by “Superfund Amendments and Reauthorization Act of 1986” (SARA) (42 U.S.C. 9601, 9604).
- **Purpose:** ATSDR is conducting this research to study whether exposure to per- and polyfluoroalkyl substances (PFAS) from drinking water might be a public health concern. ATSDR 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 to look at your child’s school records. This will help to compare study results to school records.
  - Consent for ATSDR to look at your or your child’s medical records. ATSDR 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 National Center for Environmental Health. NCEH may provide research or support staff, laboratory and statistical analysis, etc.
  - ATSDR 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 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 Exposed to 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 needs this information for you or your child to take part in the study. ATSDR needs 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.

Participant Initials: \_\_\_\_\_

Attachment 9b2.

**Parental Permission and Child Assent Form**

**TITLE OF RESEARCH:** *“The Pease Study”* formally titled:  
*“Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS) at Pease International Tradeport, Portsmouth, NH”*

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

**CO-INVESTIGATOR:** xxxxxxxx

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

**CDC Protocol #7161**

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**KEY THINGS TO KNOW ABOUT THIS RESEARCH**

**AUTHORITY:** Public Law 115-141, the “Consolidated Appropriations Act of 2018.”

**PURPOSE:** to see if per- and polyfluoroalkyl substances (PFAS) in drinking water might affect human health. Study methods will inform the design of future studies.

**WHO CAN TAKE PART:** About 525 eligible children, 4-17 years of age, and their parents or guardians.

- ATSDR is enrolling 350 children, 4-17 years of age, who were exposed to PFAS-contaminated water from the former Pease Air Force Base or the Pease International Tradeport. Pease water sources for children are likely at daycare, at work for older children with jobs, and from private wells in the area. Their exposure must have occurred between 2004 and May 2014.
- To compare, ATSDR is also enrolling 175 children who are not exposed to PFAS-contaminated water from the former Pease Air Force Base or the Pease International Tradeport. The birth mothers of these children cannot have any exposure to drinking water from Pease, as well.
- Except for drinking water for the exposure group, the birth mothers for children in either group cannot have 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 will enroll each child separately along with his or her parent. Parents, if eligible, may also enroll in the adult study.

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

Participant Initials: \_\_\_\_\_

Please be assured that ATSDR and its contractor, Abt Associates, will take all necessary steps to protect members of your community from COVID-19. The Pease Study will be conducted following all state, local, and CDC guidelines in place at the time the study is conducted. Pease 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, your child may do some parts of the study while you complete the parent's assessment about your child.

**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 will collect your child's blood and urine biospecimens. ATSDR will 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 will ask the doctor to verify some of your child's medical history and will also look at your child's school records to compare to the assessment results. If your child took part in the Pease PFC Blood Testing Program, ATSDR will ask you if we can 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 Pease 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 may help the Pease 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 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. There is no penalty for refusing to take part or for leaving the study at any time.

Participant Initials: \_\_\_\_\_

**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 Dr. Marian Pavuk or Dr. Frank Bove 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. 7161. Leave your name, contact information, and a description of your concern.

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## DETAILS ABOUT THIS RESEARCH

**STUDY OVERVIEW/PURPOSE:** ATSDR is inviting your child to take part in a research study to learn more about potential health effects of PFAS in the drinking water in your area.

In 2015-7, the New Hampshire Department of Health and Human Services (NH DHHS) conducted the Pease PFC Blood Testing Program. Because the Pease Study builds off the earlier NH program, NH DHHS is helping ATSDR recruit some people to take part in this study.

**GETTING READY FOR YOUR APPOINTMENT:** When ATSDR 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 ask that you note the dates of your child's vaccinations for us to write down.
- If your child was a past participant, we request that you bring your child's Pease PFC Blood Testing Program results. If you arrive at your appointment, and do not bring the results, we will ask for permission to get your child's results directly from NH DHHS.

**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.

Participant Initials: \_\_\_\_\_

Certain medical conditions might interfere with our drawing blood or might affect the results of our lab tests. If your child has 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. If your child participated in the NH DHHS Pease PFC Blood Testing Program in 2015-7, we would like to compare your child's earlier results with his or her Pease Study results.

**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

Participant Initials: \_\_\_\_\_

response. Doctors often use these types of tests. They will help us learn more about how PFAS might affect health. For this study, ATSDR will not conduct genetic, HIV, or drug testing.

**PFAS MEASURED IN URINE:** Scientists are learning more about PFAS every day. If you consent, 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 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 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 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.

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 to release it.

ATSDR 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 child's name. We will keep his or her records in locked files at the study office in Pease. ATSDR and its contractors 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 try and get a picture of the health issues of people in Pease 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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Participant Initials: \_\_\_\_\_

## STORING RESIDUAL BIOSPECIMENS AND PEASE STUDY DATA FOR FUTURE USE:

ATSDR investigators 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.

Some children have also participated in the 2015-7 Pease PFC Blood Testing Program and have leftover blood stored at NH DHHS. We will ask you if you consent to have your child's samples stored by ATSDR to be used in future analyses related to PFAS research. If you do not consent, those samples will be discarded at the end of the Pease Study enrollment by the NH DHHS.

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 (including leftover blood from NH DHHS) 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 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.

With your permission, we will *keep your contact information for future studies*. We will **recontact you** to get additional consent for 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 would 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.
- **Future Studies using existing or additional biospecimens for genetic tests or whole genome sequencing.** Currently, ATSDR has 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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Participant Initials: \_\_\_\_\_



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

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|--|
| Pease Study - Parental Permission/Child Assent<br>Flesch-Kincaid Readability Score -<br>Children - 4.8 |
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## Child Assent Information about the Pease Study

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### THINGS TO KNOW ABOUT THIS STUDY

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

**PURPOSE:** In this study, ATSDR 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 looks at all the results together, we can try to see if any answers about children’s health might relate to their PFAS results.

**WHO CAN TAKE PART:** ATSDR wants to enroll about 525 eligible children, 4-17 years of age, and their parents or guardians. 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 its contractor, Abt Associates, will take all necessary steps to protect members of your community from COVID-19. The Pease Study will be conducted following all state, local, and CDC guidelines in place at the time the study is conducted.

Pease 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 and bring the sample with you.

**WHAT WILL YOU DO:** It will be a lot like going to the doctor’s. 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.

Participant Initials: \_\_\_\_\_

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

Participant Initials: \_\_\_\_\_

**PARENTAL PERMISSION AND CHILD ASSENT (SIGNATURE PAGE 1 OF 2)**

**TITLE OF RESEARCH:** *“The Pease Study”* formally titled:  
*“Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS) at Pease International Tradeport, Portsmouth, NH”*  
**CDC Protocol #7161**

|                             |         |
|-----------------------------|---------|
| FOR OFFICE USE ONLY         |         |
| Adult Study ID No.   _____  | (alias) |
| Parent Study ID No.   _____ |         |
| Child Study ID No.   _____  |         |

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 Pease 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, > 5 years of age, take an IQ test; **or**  My child is ≤ 5 years of age.
- Allow ATSDR to review my child’s school records
- Allow ATSDR to review my child’s medical records
- Have my child provide a blood sample and have it tested
- Have my child provide a urine sample and have it stored
- Give ATSDR a copy of my child’s Pease PFC Blood Testing Program results; **or** give ATSDR permission to get my child’s results directly from NH DHHS
- Allow my child’s leftover blood from the 2015-7 Pease PFC Blood Testing Program to be stored at ATSDR for future testing

|   |   |
|---|---|
| <hr/> Parent or Guardian’s Name (Print)   | <hr/> Child’s Name (Print) (≥ 7 years old)                      |
| <hr/> Parent or Guardian’s Signature <span style="float: right;">Date</span>  | <hr/> Child’s Signature <span style="float: right;">Date</span> |
| <div style="border: 1px solid black; width: 100%; height: 20px; background-color: #e0e0e0; margin-bottom: 5px;"></div> Child’s Social Security Number |   |

Participant Initials: \_\_\_\_\_

**PARENTAL PERMISSION AND CHILD ASSENT (SIGNATURE PAGE 2 OF 2)**

**TITLE OF RESEARCH:** *“The Pease Study”* formally titled:

*“Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS) at Pease International Tradeport, Portsmouth, NH”*

**CDC Protocol #7161**

FOR OFFICE USE ONLY

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

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

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

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 future uses of my child’s Pease Study data and leftover blood and urine that I have checked below:

- ATSDR can contact me about new studies.
- ATSDR can use my child’s Pease Study data and his or her leftover blood and urine for new studies about PFAS and Pease.
- ATSDR can use my child’s data and his or her leftover blood from the 2015-7 Pease PFC Blood Testing Program for new studies about PFAS and Pease.
- ATSDR can use my child’s Pease Study data and his or her leftover blood and urine for new studies that are not about PFAS and Pease.
- ATSDR can use my child’s data and his or her leftover blood from the 2015-7 Pease PFC Blood Testing Program for new studies that are not about PFAS and Pease.

|   |   |
|---|---|
| <hr/> <p>Parent or Guardian’s Name (Print)</p><br><br><hr/> <p>Parent or Guardian’s Signature <span style="float: right;">Date</span></p> | <hr/> <p>Child’s Name (Print) (≥ 7 years old)</p><br><br><hr/> <p>Child’s Signature <span style="float: right;">Date</span></p> |
|---|---|

Participant Initials: \_\_\_\_\_

**Pease 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) is seeking parental consent for the release of your child’s school records. ATSDR will compare your child’s school records to some of his or her research test results from the Pease 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 plans 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 until the study is over.

By signing below, you permit:

Name of Official: \_\_\_\_\_ School: \_\_\_\_\_  
to release your child’s school records to the ATSDR Principal Investigators, Marian Pavuk, MD, PhD and Frank Bove, PhD. You may contact them with any questions at (603)292-3571.

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

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

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

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

Child’s SSN: |\_\_|\_\_|\_\_-|\_\_|\_\_|-|\_\_|\_\_|\_\_|\_\_|

Child’s Study ID No. |\_\_\_\_\_|

Participant Initials: \_\_\_\_\_

Attachment 9b4.

### Adult Consent Form

**TITLE OF RESEARCH:** *“The Pease Study”* formally titled:

*“Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS) at Pease International Tradeport, Portsmouth, NH”*

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

**CO-INVESTIGATOR:** xxxxxxxx

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

**CDC Protocol #7161**

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### KEY THINGS TO KNOW ABOUT THIS RESEARCH

**AUTHORITY:** Public Law 115-141, the “Consolidated Appropriations Act of 2018.”

**PURPOSE:** To see if PFAS exposure from drinking water might be related to people’s health. Study methods will inform the design of future studies.

**WHO CAN TAKE PART:** About 1,100 eligible adults, ≥ 18 years of age. ATSDR asks you to come to our central study office. ATSDR will offer to meet some adults at home, if they find travel difficult. They must live within a one-hour drive from the office.

- ATSDR is enrolling 1,000 adults, ≥ 18 years of age, who were exposed to PFAS-contaminated water from the former Pease Air Force Base or the Pease International Tradeport. Pease water sources for adults are likely at work, from private wells in the area, or perhaps from daycare for the younger adults. Their exposure must have occurred between 2004 and May 2014.
- To compare, ATSDR is also enrolling 100 adults who are not exposed to PFAS-contaminated water from the former Pease Air Force Base or the Pease International Tradeport.
- Except for drinking water for the exposure group, adults in either group cannot have contact with PFAS chemicals at work.
- 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 enroll as a parent or guardian of one or more eligible children.

ATSDR asks you to come to our central study office. ATSDR 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 its contractor, Abt Associates, will take all necessary steps to protect members of your community from COVID-19. The Pease Study will be conducted following all state, local, and CDC guidelines in place at the time the study is conducted.

Participant Initials: \_\_\_\_\_

Pease 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 will collect your blood and urine biospecimens at the study office. ATSDR will 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 leftover blood and urine for future studies, and only if you permit.

If you permit, ATSDR will ask the doctor to verify some of your medical history. If you took part in the Pease PFC 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 may help the Pease 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 contractors 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.

**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 Dr. Marian Pavuk or Dr. Frank Bove 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

Participant Initials: \_\_\_\_\_

Helpline at (800) 584-8814. Be sure to say your call is about CDC Protocol No. 7161. Leave your name, contact information, and a description of your concern.

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## DETAILS ABOUT THIS RESEARCH

**STUDY OVERVIEW/PURPOSE:** ATSDR is inviting you to take part in a research study to help us learn more about the potential health effects of PFAS in the drinking water in your area.

In 2015-7, the New Hampshire Department of Health and Human Services (NH DHHS) conducted the Pease PFC Blood Testing Program. Because the Pease Study builds off the earlier NH program, NH DHHS is helping ATSDR recruit some people to take part in this study.

**GETTING READY FOR YOUR APPOINTMENT:** When ATSDR 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 8 hours 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 were a past participant, we request that you bring your Pease PFC Blood Testing Program results. If you arrive at your appointment, and do not bring the results, we will ask for permission to get your results directly from NH DHHS.

**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 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.

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Certain medical conditions might interfere with our drawing blood or might affect the results of our lab tests. If you have 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 child's blood. If you participated in the NH DHHS Pease PFC Blood Testing Program in 2015-7, we would like to compare your earlier results with your Pease Study results.

**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 may help us learn more about how PFAS might affect health. For this study, ATSDR 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 once it is tested.

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

**MORE ABOUT CONFIDENTIALITY:** ATSDR 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 contractors 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

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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 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 Pease. ATSDR and its contractors 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 try to get a picture of the health issues of people in Pease 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 PEASE STUDY DATA FOR FUTURE USE:**

ATSDR investigators will keep your contact information and study ID number(s) in a restricted-access secure master dataset. All biospecimens and study data will 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.

Some of you have also participated in the 2015-7 Pease PFC Blood Testing Program and have leftover blood stored at NH DHHS. We will ask you if you consent to have those samples stored by ATSDR to be used in future analyses related to PFAS research. If you do not consent, those samples will be discarded at the end of the Pease Study enrollment by the NH DHHS.

We are ***seeking consent 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 (including leftover blood from NH DHHS) 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 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 may release your **de-identified research datasets or de-identified blood and urine** samples for future studies related to PFAS to

Participant Initials: \_\_\_\_\_

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.

With your consent, we will **keep your contact information for future studies**. We will **recontact you** to get additional consent for 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 would 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.
- **Future Studies using existing or additional biospecimens for genetic tests or whole genome sequencing.** Currently, ATSDR has 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 consent form below.

Participant Initials: \_\_\_\_\_



**ADULT INFORMED CONSENT (SIGNATURE PAGE 2 OF 2)**

**TITLE OF RESEARCH:** *"The Pease Study" formally titled:*

*"Human health effects of drinking water exposures to per- and polyfluoroalkyl substances (PFAS) at Pease International Tradeport, Portsmouth, NH"*

**CDC Protocol #7161**

|                             |         |
|-----------------------------|---------|
| FOR OFFICE USE ONLY         |         |
| Adult Study ID No.   _____  | (alias) |
| Parent Study ID No.   _____ |         |
| Child Study ID No.   _____  |         |

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 will follow CDC IRB requirements for these new studies.

By signing below, I agree to the future uses of my study data and leftover blood and urine that I have checked below:

- ATSDR can contact me about new studies.
- ATSDR can use my Pease Study data and my leftover blood and urine for new studies about PFAS and Pease.
- ATSDR can use my Pease Study data and my leftover blood and urine for new studies that are not about PFAS and Pease.
- ATSDR can use my data and my leftover blood from the 2015-7 Pease PFC Blood Testing Program for new studies about PFAS and Pease.
- ATSDR can use my data and my leftover blood from the 2015-7 Pease PFC Blood Testing Program for new studies that are not about PFAS and Pease.

\_\_\_\_\_  
Adult's Name (Print)

\_\_\_\_\_  
Adult's Signature

\_\_\_\_\_  
Date

Participant Initials: \_\_\_\_\_

**Parent/Child/Adult Permission for Medical Record Abstraction**  
**AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR)**  
**PEASE STUDY**

|  |   |
|--|---|
| I authorize this health care provider or organization to release protected health information (PHI) for the uses listed below:   |   |
| <b>Information to be released by:</b><br><hr/> (Name of health care provider, health plan, or health care clearing house)<br><hr/><br><hr/> (Address)<br><hr/><br><hr/> (Phone number)   | <b>Information to be released to:</b><br><hr/> (Name of person or organization)<br>ATSDR Division of Toxicology and Human Health Sciences (DTHHS)<br><hr/><br>1600 Clifton Road, NE Mail Stop -S102-1<br><hr/> (Address)<br>Atlanta, Georgia 30341<br><hr/><br><hr/> (Phone number) |
| <b>The information is released for the following uses:</b><br>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.  |   |
| <b>By signing below, I understand that:</b> <ul style="list-style-type: none"> <li>• I do not have to sign this authorization.</li> <li>• My authorization will automatically end at the end of the study; or</li> <li>• I have the right to end my authorization at any time by writing a letter to this office.</li> <li>• Ending my authorization will not affect any earlier release of PHI.</li> <li>• Ending my authorization will not bar me from taking part in the study.</li> <li>• Under my authorization, I have a right to look at or copy any release of PHI.</li> <li>• I have a right to a copy of this authorization.</li> <li>• No study reports will reveal my identity.</li> </ul> |   |
| <hr/> (Signature of Individual or Authorized Representative)<br><hr/> (Representative's Legal Authority to Individual)<br><hr/> (Today's Date)<br><hr/> (Phone Number)<br><hr/> (Date of Birth of Individual)  | <hr/> (Print Name of Individual)<br><hr/> (Print Name of Authorized Representative)<br><hr/> (Address)<br><hr/><br> _ _ _ _  -  _ _ _ _  -  _ _ _ _ _ <br>(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.

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ATSDR 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 is seeking information on the date of diagnosis or first treatment for the following health conditions (except as shown on Page 1). ATSDR is also seeking information if the individual is currently receiving treatment for these health conditions. We are not sure if any of these conditions is related to PFAS exposure.

| <i>Diagnosis or Treatment of Health Conditions</i>   | <i>Adult</i> | <i>Child</i> |
|--|--------------|--------------|
| Osteoarthritis   | √            | --           |
| Osteopenia and osteoporosis  | √            | --           |
| Endometriosis  | √            | --           |
| Heart Disease  | √            | --           |
| Hypertension (including pregnancy-induced hypertension)  | √            | √            |
| 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)  | --           | √            |
| Antibody responses to rubella, mumps, and diphtheria vaccines  | --           | √            |
| Sex hormones, growth, and maturation   | --           | √            |
| Neurodevelopmental outcomes (lower intelligence quotient (full scale IQ), attention-deficit and hyperactivity disorder (ADHD). | --           | √            |

Participant Initials: \_\_\_\_\_