Reading Level: 7.9

Appendix H – Adult Consent Form Copy

COPY OF CONSENT FORM TO KEEP

Evaluating the Association between Serum Concentrations of Per- and Polyfluoroalkyl Substances (PFAS) and Symptoms and Diagnoses of Selected Acute Viral Illnesses

Consent to Take Part in a Research Study
(Adult ≥ 18 years of age)

The Centers for Disease Control and Prevention's (CDC) National Center for Environmental Health (NCEH) and the Agency for Toxic Substances and Disease Registry (ATSDR) is conducting this research study. Recently, you took part in an ATSDR study that measured PFAS in your blood. You also agreed to hear about new ATSDR studies. This makes you eligible for this new research study.

KEY THINGS TO KNOW ABOUT THIS RESEARCH

AUTHORITY: 1980 Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended by the 1986 Superfund Amendments and Reauthorization Act (SARA) (42 U.S.C. 9601, 9604), and the Public Health Service Act Section 301 (42 U.S.C. 241) and Section 311 (42 U.S.C. 243)

PURPOSE: To see if a person's PFAS blood levels may be related to viral illnesses. This can include getting the COVID-19 virus.

WHO CAN TAKE PART: About 2,800 eligible adults (≥ 18 years of age) and 370 eligible children (4-17 years of age) who took part in an earlier ATSDR PFAS study.

- Eligible adults aged 18 years and older (including pregnant women) can enroll, with the exception noted below.
- People who are prisoners or under house arrest are not eligible to take part in this study.
- Eligible children aged 4-17 years can enroll with the permission of a parent or guardian (see parental permission form and child assent form).

You will not need any in-person contact with any CDC/ATSDR team members.

EXPECTED TIME IN THE STUDY: About 2-½ hours over a year-long period. You are asked to answer five 30-minute surveys at home. The five surveys will be spaced three months apart, and each follow-up survey will ask about the three-month time period since the previous survey was completed.

PROCEDURES: If you agree to take part, we ask you to sign this consent form. Next, we ask you to answer the first survey that is attached to this consent form. You are asked to mail them both back to CDC/ATSDR in the addressed pre-paid envelope. You can choose to complete the next four surveys through an online platform or by mail. CDC/ATSDR will link your new survey answers to your earlier blood PFAS measures and data. No new blood or urine will be collected for this study.

Between the surveys, we will ask you to keep track of certain things, such as symptoms that could indicate a viral infection, exposures to people who have or might have COVID-19, and vaccinations. Keeping track of these things will help you to be able to provide accurate information on the follow up surveys.

BENEFITS: There are no direct benefits for you to be in this study. Your taking part will help us learn if a person's PFAS blood measures may be related to viral illnesses. This can include the COVID-19 virus.

RISKS: The risks of taking part in this research are minimal. There is a small chance of an accidental breach of your private information. We want you to know that our study staff are trained to take all necessary steps to protect your private information to avoid this risk.

COSTS: You do not have to pay to be part of this study.

INCENTIVES: We very much appreciate your taking part in this study. You will receive a $10 gift card for each completed survey. If you complete all five surveys, you will receive an additional $25 gift card, for a total of $75 for completing all five surveys.

CONFIDENTIALITY: A Certificate of Confidentiality covers this research. CDC/ATSDR cannot be forced to release information that could identify you even under a court order or subpoena (unless you choose to release it). You should know, however, that CDC/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. You can stop at any time. You can refuse to answer any questions on any of the surveys. 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 to leave the study, please contact the Principal Investigator, Breanna Alman, at (xxx) xxx-xxxx or pfasviralstudy@cdc.gov.

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. 7360. Leave your name, contact information, and a description of your concern.

DETAILS ABOUT THIS RESEARCH

MORE ON WHAT TO EXPECT DURING THIS STUDY:

- This research is solely a survey-based study. It does not involve collecting any samples from you (like blood or urine) or your home (like tap water).
- We are providing you with two copies of this form, one to keep and one to sign and return.
- Once the consent form is signed, you are asked to complete the attached first survey.
- Next, you are asked to return both the consent form and the completed survey to us in the mail.

- The completed survey must be returned with the signed consent form. Otherwise, we will not be able to use the information from your survey.
- There is a section on the consent form to tell us how you want to receive the four follow-up surveys. You can choose a secure online platform called REDCap or a paper survey in the mail.
    - If you choose the REDCap option, you need to provide your personal e-mail address. We will email you with instructions and a link for each follow-up survey. Please note – each participant, including children, needs their own, unique email address.
    - If you choose the mail option, we will send a paper survey with an addressed pre-paid envelope for each follow-up survey.
- With your consent, CDC/ATSDR will link your new survey answers to your earlier blood PFAS measures and data.
- Between surveys, we ask you to keep track of things like symptoms, exposures to people who might have COVID-19, and vaccinations, using the Symptom Diary included in this packet.

QUESTIONS WE WILL ASK: On the first survey, we will ask questions about your medical history, flu vaccines, school or work-related situations, COVID-19 exposures, and COVID-19 vaccinations. On the follow-up surveys, we will ask about any changes in your medical history, updates in vaccinations, changes in school or work situations, viral symptoms and testing, and COVID-19 exposures since the previous survey.

MORE ABOUT CONFIDENTIALITY: A Certificate of Confidentiality covers this research. CDC/ATSDR must 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)]. CDC/ATSDR and their contractors cannot be forced to release information that could identify you even under a court order or subpoena (unless you choose to such a release). You should know, however, that CDC/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 CDC/ATSDR to release it.

CDC/ATSDR and their contractors are required to ensure that any investigator or institution not funded by CDC/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.

YOUR PRIVATE INFORMATION: We will store your answers and test results using a study number, not your name. We will keep your records in locked files at CDC/ATSDR. CDC/ATSDR and their 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.

CDC/ATSDR might remove your identifiers to make datasets to share with other investigators for future research. To do this, CDC/ATSDR will not seek additional informed consent from you.

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

If you do not understand what we are asking you to do, please ask all of your questions now. You may contact the Principal Investigator, Breanna Alman, at (xxx) xxx-xxxx or pfasviralstudy@cdc.gov.

If you have no further questions and agree to be in this study, please sign the consent form below.

Adult Informed Consent

By marking the check boxes below and signing this form, you confirm that you understand the goals of the ***Evaluating the Association between Serum Concentrations of Per- and Polyfluoroalkyl Substances (PFAS) and Symptoms and Diagnoses of Selected Acute Viral Illnesses Study***. You freely agree to take part. You also confirm that you will allow the project staff to collect, store, and share the information gathered, as described above. There are two copies of the consent form included in this introductory package; you should sign and return one and keep one copy for your records.

To take part in this study, you must select 'Yes' to all three of these questions:

I agree to take part in this research study, and I agree to complete surveys to the best of my ability.
¨ **Yes** ¨ **No**

I agree to allow CDC/ATSDR study staff to access my survey data and PFAS blood sample results from the earlier ATSDR PFAS study, and to allow them to link that earlier data to the new data collected in this study.
¨ **Yes** ¨ **No**

I agree that my results (with no personal identifying information) can be included in publications about this study in aggregate (in other words, at the population-level not individual-level).
¨ **Yes** ¨ **No**

Below are follow-up questions that provide options for how you can participate.

If you agree to take part in this study, how would you like to receive and submit your follow-up surveys? (choose one)

¨ I would like to receive my follow-up surveys in paper form by mail and return them in a pre-paid, addressed envelope provided by CDC/ATSDR.

¨ I would like to receive and complete my follow-up surveys using the REDCap online platform that was described above.
Please send the link to my email address: _____

(Please note, if you want to receive the follow-up surveys online, your child must have their own, unique email address).

If you agree to take part in this study, can study staff contact you with reminders to complete and submit your follow-up surveys?

¨ **Yes**
¨ **No**

If you selected **Yes**, how would you like to receive the reminders? Please provide your personal contact information for the option you choose. If you would like to be contacted by more than one method, please select all that apply.

☐ Email: _____
☐ Phone call/ voice message: (____) - _____ - _____
☐ Text message: (____) -_____ - _____
☐ Mail: _____
☐ I do not want reminders

The following questions are optional. You can select 'Yes' or 'No' and still take part in the study:

I agree that CDC/ATSDR may share my survey data along with my identifying information with other federal, state, and local environmental and health agencies. My identifying information will be protected to the extent possible by law if I allow CDC/ATSDR to share my data with these agencies. [CDC/ATSDR/The other agencies] will seek my informed consent for such uses.
¨ **Yes** ¨ **No**

I agree that CDC/ATSDR may share my survey data without my identifying information with other investigators for future studies. CDC/ATSDR will not seek my informed consent for such uses.
¨ **Yes** ¨ **No**

I agree to allow CDC/ATSDR to save and use my survey data (with no personal identifying information) for additional analysis in the future. CDC/ATSDR will not seek my informed consent for such uses.
¨ **Yes** ¨ **No**

I agree to allow CDC/ATSDR to save and use my survey data (with no personal identifying information) for other PFAS-related studies. CDC/ATSDR will not seek my informed consent for such uses.
¨ **Yes** ¨ **No**

I agree to let CDC/ATSDR keep my contact information and contact me in the future for possible follow-up studies for up to 5 years after this study (may be research or non-research studies).
¨ **Yes** ¨ **No**

Participant's Name:_____
(Printed)

Participant's Signature:_____

Date Signed:_____

Street Address: _____

City: _____ State: _____ Zip: _____

Phone number (area code): _____