Survey Reading Level: 7.4

Appendix A – Consent Form and Initial Survey – Adult

Form Approved
OMB No. 0923-0064
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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 and Initial Survey (Adult ≥ 18 years of age)

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.

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STUDY ID: _____

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. If you opt in to receive surveys digitally in the future, then you will receive the gift card through your provided email address, otherwise it will be sent in the mail.

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.

FOR OFFICE USE ONLY:
STUDY ID: _____

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 study participant who would like to receive the follow-up surveys online must have their own, unique e-mail 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**

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STUDY ID: _____

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, each study participant who would like to receive the follow-up surveys online must have their own, unique e-mail 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.

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☐ **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): _____

FOR OFFICE USE ONLY:
STUDY ID: _____

Adult (≥ 18 years of age) Initial Survey

Introduction

We are conducting a study to improve our understanding of the relationship between the amount of PFAS in a person's blood and susceptibility to acute (short-term) viral illnesses. This includes the COVID-19 virus as well as other viral illnesses. Since you took part in a previous ATSDR-funded study that measured PFAS in your blood, we would like to invite you to complete this survey. Before starting, please be sure that you have completed and signed the consent form.

Section 1. Instructions for completion and submission

This first survey is divided into sections and should take about 30 minutes to complete. As you go through each section, read each question carefully and answer as best as you can. If you have questions and would like to speak with a member of the study team, please call xxx-xxx-xxxx or send an email with your question to pfasviralstudy@cdc.gov.

Please return the signed consent form and this completed survey by mail in the addressed, stamped envelope provided by (date). If you did not receive or misplaced the return envelope, forms can be mailed to (add return address). Keep in mind, if we receive a completed survey without the signed consent form, we will not be able to use the information from the survey in this study. Thank you for taking part this study.

Section 2. Demographic and health information

Name (Last, First): _____

Date of Birth (month/day/year): __ __ /__ __ /__ __ __ __ (example 01/01/2010)

Height ____ feet ____ inches Weight _____ lbs.

Has your address changed since you had your blood drawn to measure PFAS?

___ YES ___ NO

Did you get the Influenza vaccine (Flu shot) in the 2020-2021 flu season (September 2020 – April 2021)?

___ YES ___ NO

If yes, what was the date (month/year)? _____ Don't know _____

Did you get the Influenza vaccine (Flu shot) in the 2021-2022 flu season (September 2021 – April 2022)?

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___ YES ___ NO

If yes, what was the date (month/year)? _____ Don't know _____

Did you get the Influenza vaccine (Flu shot) in the 2022-2023 flu season (September 2022 – April 2023)?

___ YES ___ NO

If yes, what was the date (month/year)? _____ Don't know _____

During the past year, was the primary drinking water source in your home a private well?

___ YES ___ NO

If yes, was that well ever found to have been contaminated with PFAS?

___ YES ___ NO

If yes, did you make any changes to reduce exposure to PFAS from drinking water? (A change could include using bottled water for drinking, adding a filter, or connecting to a community water source)

___ YES ___ NO

If yes, when did you first make a change to reduce your exposure to PFAS through drinking water?

_____(Month/Year)

Have you smoked at least 100 cigarettes in your life? ___ YES ___ NO

Do you currently smoke cigarettes? ___ Everyday ___ Some days ___ Not at all

If yes, how many cigarettes do you usually smoke per day? _____

Do you smoke electronic or e-cigarettes (also known as vaping)? ___ YES ___ NO

If yes, for how long? _____ years _____ months

During the past 30 days, on how many days did you have at least one drink of alcohol?

___0 ___1-2 ___3-5 ___6-9 ___10-19 ___20-29 ___All 30 ___Prefer not to answer/Don't know

During the past 30 days, on how many days did you have 4 or more drinks in a row if you are a woman or 5 or more drinks in a row if you are a man, that is, within a couple of hours?

___0 ___1 ___2 ___3-5 ___6-9 ___10-19 ___20 or more ___Prefer not to answer/Don't know

Do you currently have any of the following health conditions (identified by a doctor or another health professional)? Mark YES or NO for all conditions listed. If you mark YES for a condition, please indicate how old you were at the time of diagnosis (when the medical condition was identified by a doctor or other healthcare professional).

HEALTH CONDITION	NO	Don't know	YES	Age (in years) at time of diagnosis
Lung Disease				
Asthma				
Chronic Obstructive Pulmonary Disease (COPD)				
Cystic Fibrosis				
Other Chronic Lung Disease (please specify below)				
Heart / Cardiovascular Disease				
Hypertension (High Blood Pressure)				
Congenital (since birth) Heart Disease				
Chronic Heart Failure				
Coronary Artery Disease				
Cardiomyopathy				
Other Heart/Cardiovascular Disease (please specify below)				
Diabetes (type 1 or type 2)				
Chronic Kidney Disease				
Liver Disease				
Seasonal Allergies				
Cancer				
Currently on Chemotherapy				
History of Bone Marrow / Stem Cell Transplant				
History of Organ Transplant				
Immunocompromised State (weakened immune system)				
Sickle Cell Disease (Sickle Cell Anemia)				
Inherited Metabolic Disorders				
Neurological Disease (epilepsy / seizure disorder)				
Intellectual Disability				
Down Syndrome				
Cerebral Palsy				
Dementia				

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HEALTH CONDITION	NO	Don't know	YES	Age (in years) at time of diagnosis
Other Developmental Disability (please specify below)				
Depression				
Anxiety				

If you selected "Other Chronic Lung Disease" above, please specify:_____
_____

If you selected "Other Heart/Cardiovascular Disease" above, please specify: _____
_____

If you selected "Other Developmental Disability" above, please specify:_____
_____

Section 3. The questions in this section relate to situations that may increase your risk of exposure to viruses through close contact with other people (e.g., working in an office outside your home or attending school in person).

Including yourself, how many people live in your household? Please include individuals who sleep in the home at least 2 nights per week; please do not include those who are living away from home for school. Enter number _____

How many children **less than 5 years old** live in your household? _____

How many children aged **5-11 years** live in your household? _____

How many children aged **12-17 years** live in your household? _____

How many adults aged **18-64 years** live in your household? _____

How many adults aged **65 years and older** live in your household? _____

Please answer the questions in the next three tables based on your average experience in the **two-weeks prior to receiving this initial survey.**

	Number of hours per week	Does not apply	Don't know/Prefer not to answer
On average, how many hours per week do you work in an **indoor** location that is **not** your home?			
On average, how many hours per week do you attend school in-person in an **indoor** classroom setting?			
On average, how many hours per week are you in a situation **indoors** that requires regular close contact			

FOR OFFICE USE ONLY:
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	Number of hours per week	Does not apply	Don't know/Prefer not to answer
(within 6 feet for a total of 15 minutes or more) with people who do **not** live with you? Please do not include transportation here; it will be asked in the next table.			

	Number of times per week	Does not apply	Don't know/Prefer not to answer
On average, how many times per week do you travel by bus or train in which the trip takes 15 minutes or longer?			
On average, how many times per week do you carpool with people who do not live with you?			

	NO	YES	Don't know/Prefer not to answer
Do you have children or adults living with you who are attending in-person daycare, school, college, or technical/trade school? Please do not include those who are living away from home for school.			
Are there other people living with you that work in-person at an indoor location that is not your home? If yes, how many? _____			

Section 4. Questions specific to COVID-19

This section relates to COVID-19 or a COVID-19-like illness. The items listed below could have happened more than once. For each item, list, to the best of your recollection, the number of times it occurred since **January 1, 2020** and use the date columns to list the approximate date(s), starting with the earliest occurrence. If the event occurred more than twice, please list the remaining dates together in the last column. Enter the dates using 2 digits for the month and 4 digits for the year (example: 01/2020)

<u>For questions below that ask about COVID-19 testing, please note</u>:

There are different types of COVID-19 tests available. Some test for current infection and some test for past infection.

- An **<u>antibody test</u>** (also known as a serology test) is a blood test that might tell you if you had a past infection. Antibody tests are not used to diagnose a current infection.

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STUDY ID: _____

A **viral test** tells you if you have a current infection. Two types of viral tests can be used: nucleic acid amplification tests (often called PCR tests) and antigen tests. The viral test involves collecting a specimen with a swab from the nose, nasopharynx, mouth, or throat; or collecting saliva.

Since January 1, 2020:	NO	YES	If YES, number of times	First time (month/year)	Second time (month/year)	Other approx. dates (month/year)
Have you had an antibody (blood) test for COVID-19 (either positive or negative)?						
If yes, was that test positive (indicating that you had antibodies to COVID-19)?						
Have you had a viral test for COVID-19?						
If yes, have you had a positive viral test for COVID-19 while having no symptoms?						
If yes, have you had a positive viral test for COVID-19 while having symptoms?						
If yes, did you seek medical care for your symptoms? If you answered YES to this question, please answer the remaining questions in this table. If you answered NO, skip the rest of this table.						
Did you receive in-person care at a Physician's or other healthcare provider's Office?						
Did you receive care from a Physician's or other healthcare provider's Office using Telehealth (by phone or computer)?						
Did you receive care at a Pharmacy (testing or treatment by a pharmacist or at a clinic located within a pharmacy)?						
Did you receive care at an Urgent Care Clinic?						
Did you receive care at a Hospital Emergency Department (ER)?						
Were you hospitalized overnight for your symptoms? (not including an emergency room visit?						

Did you get a COVID-19 vaccine? ___ YES

___ NO

FOR OFFICE USE ONLY:
STUDY ID: _____

___ Prefer not to answer

If yes, please complete the following table:

	Date (month/year)	Brand
1st dose	__ __ /__ __ __ __	☐ Pfizer ☐ Moderna ☐ Johnson & Johnson ☐ Other
2nd dose	__ __ /__ __ __ __	☐ Pfizer ☐ Moderna ☐ Johnson & Johnson ☐ Other
3rd dose	__ __ /__ __ __ __	☐ Pfizer ☐ Moderna ☐ Johnson & Johnson ☐ Other
4th dose	__ __ /__ __ __ __	☐ Pfizer ☐ Moderna ☐ Johnson & Johnson ☐ Other
5th dose	__ __ /__ __ __ __	☐ Pfizer ☐ Moderna ☐ Johnson & Johnson ☐ Other

Date on which survey was completed(month/day/year): __ __ /__ __ /__ __ __ __

Important note before you go:

Please take a moment to look at the symptom diary that is in the packet with this survey. Please write today's date at the top of that symptom diary to help you remember when you completed this survey. Please use the symptom diary to help you track your symptoms between now and the time when you receive the next survey.

Thank you for completing this survey! Be on the lookout for the next survey coming in about 3 months. Using the symptom diary in between the surveys will help you complete the next survey more easily.

*** THANK YOU ***

FOR OFFICE USE ONLY:
STUDY ID: _____