Survey Reading Level: 7.0

Appendix B - Parental Permission, Child Assent, and Initial Survey (paper) - Child

Form Approved OMB No. 0923-0064 Exp. Date 9/30/2025

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

Parental Permission Form (<18 years of age), Child Assent Form (7 to <18 years), and Initial Child Survey (<18 years of age)

ATSDR estimates the average public reporting burden for this collection of information as 30 minutes per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB Control Number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0923-0064).

Parental Permission Form (< 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, your child took part in an ATSDR study that measured PFAS in your child's blood. You and your child agreed to hear about new ATSDR studies. This makes your child 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 children 4-17 years (including pregnant girls) 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 adults aged 18 years and older (including pregnant women) can enroll (see adult consent form). A parent can enroll more than one child. In this case, ATSDR will enroll each child separately. Parents, if eligible, may also enroll in the adult study.

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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 and your child 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 for your child to take part, we ask you to sign this permission form. Next, if your child is 7-17 years of age, they should sign the assent form. Then, we ask you (with your child's help) to answer the first survey that is attached to this permission 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 new survey answers to your child's 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 your child to be in this study. Your child 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. These risks are about the same as those your child would face in daily life. There is a small chance of an accidental breach of your child's private information. We want you to know that our study staff are trained to take all necessary steps to protect your child's private information to avoid this risk.

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

INCENTIVES: We very much appreciate you and your child taking part in this study. Your child will receive a \$10 gift card for each completed survey. If you (with help from your child) complete all five surveys, your child 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 your child will receive the gift card through the 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 your child 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 and your child may freely choose to, or refuse to, take part in this research. You can stop at any time. You and your child 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.

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FOR QUESTIONS ABOUT THIS STUDY: If you have any questions about the study, or if you and your child decide to leave this 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 or your child (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 this permission form is signed, you and your child are asked to complete the attached first survey.
- If your child is 7-17 years of age, they will also need to sign the attached assent form.
- Next, you are asked to return both the permission and assent (if applicable) forms and the completed survey to us in the mail.
- The completed survey must be returned with the signed permission and assent (if applicable) forms. Otherwise, we will not be able to use the information from your child's survey.
- There is a section on the consent form to tell us how you want to receive your child's four follow-up surveys. You can choose a secure online platform called REDCap or a paper survey in the mail.
 - o If you choose the REDCap option, you need to provide us your child's personal e-mail address. We will email you with instructions and a link for each follow-up survey. Please note Please note, if you want to receive your child's follow-up surveys online, your child must have their own, unique email address.
 - O 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 child's new survey answers to your child's 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 child's 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 child's 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

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Health Service Act (PHSA) [42 USC §241(d)]. CDC/ATSDR and their 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 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 your child or his/her involvement in this research. If you want your child's 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 child's answers and test results using a study number, not his/her name. We will keep your child' records in locked files at CDC/ATSDR. CDC/ATSDR and their contractors will protect any computer files with your child's information. Only study staff with a need-to-know will have access to your child's 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 for your child to be in this study, please sign the permission form below.

Permission / Consent Form

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 let your child 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 this permission/consent form

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included in this introductory package; you should sign and return one and keep one copy for your records.

For your	child to t	ake part	t in this	stuc	ly, you r	nust s	select	'Yes' t	o all th	ree of	these ques	tions:

_	w my child to take part in this research study, and I agree to assist my child in completing the best of my ability. \square No
from the earlie in this study.	w CDC/ATSDR study staff to access my child's survey data and PFAS blood sample results er ATSDR PFAS study and to allow them to link that earlier data to the new data collected
☐ Yes	□ No
-	y child's results (with no personal identifying information) can be included in publications dy in aggregate (in other words, at the population-level not individual-level). \square No
Below are foll	ow-up questions that provide options for how you can participate.
, .	let your child take part in this study, how would you like to receive and submit your up surveys? (choose one)
	ould like to receive my child's follow-up surveys in paper form by mail and return them in paid, addressed envelope provided by CDC/ATSDR.
platfo	ould like to receive and complete my child's follow-up surveys using the REDCap online rm that was described above. e send the link to my email address:
_	e note, if you want to receive your child's follow-up surveys online, your child must have own, unique email address).
	allow your child to take part in this study, can study staff contact you with reminders to submit your child's follow-up surveys?
information for please select a	I Yes , how would you like to receive the reminders? Please provide your personal contact or the option you choose. If you would like to be contacted by more than one method, all that apply.
	one call/ voice message: ()
	xt message: () ail:
□ I d	o not want reminders

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

other federal, s	C/ATSDR may share my child's survey data along with his/her identifying information with tate, and local environmental and health agencies. My child's identifying information will the extent possible by law if I allow CDC/ATSDR to share my child's data with these
-	/ATSDR/The other agencies] will seek my informed consent for such uses. □ No
_	C/ATSDR may share my child's survey data without my child's identifying information stigators for future studies. CDC/ATSDR will not seek my informed consent for such uses.
information) fo	CDC/ATSDR to save and use my child's survey data (with no personal identifying r additional analysis in the future. CDC/ATSDR will not seek my informed consent for such
uses. Yes	□ No
-	CDC/ATSDR to save and use my child's survey data (with no personal identifying r other PFAS-related studies. CDC/ATSDR will not seek my informed consent for such
□ Yes	□ No
_	DC/ATSDR keep my contact information and contact me in the future for possible follow-up to 5 years after this study (may be research or non-research studies).
Parent/Guardia	ın's Name:
	(Printed)
Parent/Guardia	n's Signature:
Child/ Name ar	nd Age:
Date Signed:	
Street Address:	
City:	State: Zip:
Phone number	(area code):

Child Assent Form (7 to <18 years of age)

Scientists at 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) are doing a research study. Because you helped us with another study, we would like to know if you want to help with this one too. This form will describe the study so you can decide if you want to be in it. We hope that you will be a part of this study.

THINGS TO KNOW ABOUT THIS STUDY

WHO IS DOING THIS STUDY: CDC/ATSDR are public health agencies that do research. A research study is when people like scientists, doctors, and teachers collect information to try and answer questions about certain things. If you have any questions about the study, your parents can help answer them, and you can also ask us.

PURPOSE: We are doing this study to try to find out if some things that may be found in people's bodies could make it easier for them get a virus infection (like a cold or the flu) or make the virus infection worse.

We sent your parents a letter asking if we have their permission for you to be a part of the study. Even if they said it was ok, it is still your choice to make and you can say yes or no.

WHO CAN TAKE PART: ATSDR wants to enroll 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. You will not need any inperson contact with any CDC/ATSDR team members.

EXPECTED TIME IN THE STUDY: About 2-½ hours over a year-long period. Your parent (with your help) is asked to answer five 30-minute surveys at home. The five surveys will be spaced three months apart.

WHAT WILL YOU DO: If you agree and your parents give permission, we ask your parents to answer some questions about you. You can help your parents answer the questions. The questions are on a paper that came in the mail with this letter. If you or your parents need help answering the questions, they can ask us by calling xxx-xxx-xxxx or sending an email with your question to xxx@cdc.gov.

In about 3 months, we will send the next set of questions to answer. There will be three more sets of questions after that. Remember, you can help your parents answer any of the questions.

IT IS YOUR DECISION: You may freely choose to take part in the study. If you start, you can stop at any time. You can refuse to answer any questions. Nothing bad will happen to you or your parent if you don't join the study.

We'd like to thank you and your parents for taking the time to read this letter and thinking about being in our research study.

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Child Assent (7 to <18 years)

Please mark one of the boxes below.

I agree to take best of my abil ☐ Yes	•	my parents comple	te the surveys to the
	o be a part of this study, and your parents agre Il be able to look at this form any time you war		copy of this form for
Child's Name: _			
	ure:		
Date Signed:			
Street Address	::		
City:		State:	Zip:
Phone number	· (area code):		

Child (< 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 your child took part in a previous ATSDR-funded study that measured PFAS in your child's blood, we would like to invite you to complete this survey about your child. Before starting, please be sure that you have completed and signed the permission form. If your child is 7 years of age or older, please also be sure that your child has signed the assent form.

Section 1. Instructions for completion and submission

Section 2. Demographic and health information

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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 permission form (and assent form, if applicable), 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 permission form (and assent form, if applicable), we will not be able to use the survey in this study. Thank you for allowing your child to take part in this study.

Child's Name (Last, First):	
Child's Date of Birth (month/day/year):// (example 01/01/2010)	
Height feet inches Weight lbs.	
Has your child's address changed since they had their blood drawn to measure PFAS? YES NO	
Did your child get the Influenza vaccine (Flu shot) in the 2020-2021 flu season (September 2020 – Ap 2021)? YESNO	ril

	If yes, what was the date (month/year)?	Don't know
Did you 2022)?	r child get the Influenza vaccine (Flu shot) in the 2021-2022	flu season (September 2021 – April
	YES NO	
	If yes, what was the date (month/year)?	Don't know
Did you 2023)?	r child get the Influenza vaccine (Flu shot) in the 2022-2023	flu season (September 2022 – April
	YES NO	
	If yes, what was the date (month/year)?	Don't know
During	the past year, was the primary drinking water source in you	r child's home a private well?
	YES NO	
	If yes, was that well ever found to have been contaminated	d with PFAS?
	YES NO	
	If yes, did you make any changes to reduce exposu change could include using bottled water for drinki community water source)	
	YESNO	
	If yes, when did you first make a change to reduce through drinking water?	your exposure to PFAS
	(Month/Year)	

Does your child 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 your child was at the time of diagnosis (when the medical condition was first 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				
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:					
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If you selected "Other Developmental Disability" above, please specify:	

Section 3. The questions in this section relate to situations that may increase your child's risk of exposure to viruses through close contact with other people (e.g., working in an indoor location that is not your home or attending school in person).

<u>Please remember:</u> If you are a parent filling this survey out for your child, questions about "anyone else in the household" refers to anyone besides the child you are answering the questions for (including yourself). If your child lives in more than one home, please answer the next questions based on the household that qualified the child for the previous ATSDR-funded study (i.e., Exposure Assessment, PEATT Study, or Pease Study). If the child lives in more than one home that qualified for these previous studies, please answer the questions based on the household with the most people.

ncluding your child, how many people live in your child's 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 nome for school. Enter number
How many children less than 5 years old live in your child's household?
How many children aged 5-11 years live in your child's household?
How many children aged 12-17 years live in your child's household?
How many adults aged 18-64 years live in your child's household?
How many adults aged 65 years and older live in your child's household?

Please answer the questions in the next three tables based on your child's 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 does your child work or play in an indoor location that is not your child's home? Please do not include school hours – this is asked for in the next question			
On average, how many hours per week does your child attend school or daycare in-person in an indoor classroom setting?			
On average, how many hours per week is your child in a situation indoors that requires regular close contact (within 6 feet for a total of 15 minutes or more) with people who do not live with your child? Please do not include transportation			

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

	NO	YES	Don't know/Prefer not to answer
Does your child have siblings or other children living with him/her that are regularly attending in-person school, daycare or camp? Please do not include siblings that are living away from your child's home for school.			
Are there other people living with your child that work in- person at an indoor location that is not your child's 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, please 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)

For questions below that ask about COVID-19 testing, please note:

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.

A <u>viral test</u> 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.

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<u>Please remember:</u> If you are a parent filling this survey out for your child, questions about "anyone else in the household" refers to anyone besides the child you are answering the questions for (including yourself).

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

test for COVID-19 while having symptoms?			
If yes, did you seek medical care for your			
child's symptoms? If you answered YES to			
this question, please answer the remaining			
questions in this table. If you answered			
NO, skip to the next table.			
If yes, did your child receive in-person care			
at a Physician's or other healthcare			
provider's office?			
Did your child receive care from a			
Physician's or other healthcare provider's			
office using Telehealth (by phone or			
computer)?			
Did your child receive care at a Pharmacy			
(testing or treatment by a pharmacist or at			
a clinic located at/within a pharmacy)?			
Did your child receive care at an Urgent			
Care Clinic?			
Did your child receive care at a Hospital			
Emergency Department (ER)?			
Was your child hospitalized overnight for			
his/her symptoms? (not ER)?			
Did your shild set a COVID 10 years - 2	/FC		
Did your child get a COVID-19 vaccine? Y	'ES		

___ NO

FOR OFFICE USE ONLY: STUDY ID:	

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

Important note before you go:

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

☐ Other

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: