

# Information for Child Participant (Less Than 12 Years)





Michigan.gov/DEHbio

855-322-3037

MDHHS-PFAShealthstudy@Michigan.gov



## STATE OF MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES LANSING

ROBERT GORDON

Date SAMPLE PARTICIPANT SAMPLE ADDRESS

**GRETCHEN WHITMER** 

GOVERNOR

Dear SAMPLE PARTICIPANT:

Thank you for choosing to participate in the Michigan PFAS Exposure and Health Study (MiPEHS)! With your help, we may all gain a better understanding of how exposure to per- and polyfluoroalkyl substances (PFAS) affects the long-term health of all Michiganders.

#### Welcome to the study!

This welcome packet contains resources to prepare you for your study office appointment and other parts of the study. This includes details about your appointment, instructions for how to complete the survey, information on COVID-19 safety precautions, Frequently Asked Questions, and a study office visit fact sheet.

You can visit our website at Michigan.gov/DEHbio and click on "MiPEHS" to learn more.

As a reminder, taking part in MiPEHS is completely free and voluntary. If you have any questions, concerns, or need to reschedule your appointment for any reason, please call our research partners, RTI International (RTI) at 855-322-3037.

On behalf of the entire MiPEHS research team, thank you for joining us in this important study!

Sincerely,

Kory Groetsch, M.S.

Environmental Public Health Director and MiPEHS Principal Investigator Michigan Department of Health and Human Services

## **Study Office Visit Confirmation**

Thank you for choosing to participate in MiPEHS! This document confirms and provides details for your study office visit. Please read this carefully to make sure you have everything you need for your visit.

## Your appointment details SAMPLE PARTICIPANT

**Visit Date** 

**Visit Time** 

Study Office Location: 519 E. Division Street NE, Rockford, MI 49341.

- > PLEASE NOTE: Entering the above address in Google Maps will take you to the wrong location. The directions below and on the next page should help you find the study office.
- > The study office is located between Rite Aid Pharmacy and MVP Athletic Club. It is the first suite to your right as you enter the doors under the Life Beyond Barriers sign.
- > Parking is available at the office.

Study Office Phone Number: 800-848-4071

#### WHEN YOU ARRIVE AT THE STUDY OFFICE:



WAIT in your car.



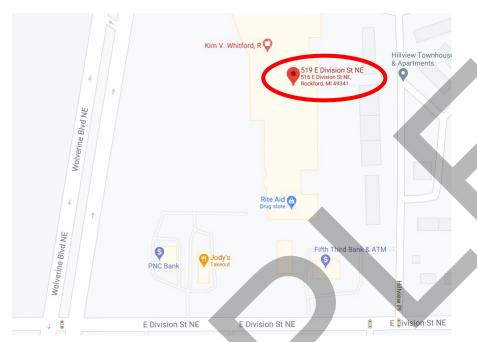
CALL 800-848-4071 from your car to let the staff know you have arrived and complete a COVID-19 screening.







#### Map to Study office



#### **Driving Directions**

From the North: Travel south on Northland Dr NE; At the Northland Dr-Wolverine Blvd split, continue south onto Wolverine Blvd NE; Continue south at the Wolverine Blvd- E Division St traffic light; at the next turn lane, make a left to head north on Wolverine Blvd; Turn right onto E Division St NE; Turn left into the second drive; the study office will be on your right (between Rite Aid Pharmacy and MVP Athletic Club).

From the East: Head west on 10 Mile Rd NE; Continue straight at the light at the 10 Mile Rd-Hillview PI intersection; Continue straight at the light at the 10 Mile Rd-Marcell Dr intersection; Turn right into the second drive after the light; the study office will be on your right (between Rite Aid Pharmacy and MVP Athletic Club).

**From the South**: Head north on Wolverine Blvd NE; Turn right onto E Division St NE; Turn left into the second drive; the study office will be on your right (between Rite Aid Pharmacy and MVP Athletic Club).

From the West: Head east on 10 Mile Rd NE/W Division St NE; Continue to Wolverine Blvd NE;

Continue straight onto E Division St NE; Turn left into the second drive; the study office will be on your right (between Rite Aid Pharmacy and MVP Athletic Club).







Pre-appointment	checklist
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Please review all the materials in this Welcome Packet.
☐ Please complete the "MiPEHS Pre-Survey Worksheet." <b>This worksheet is </b> <i>not</i> <b>the survey, but it will ensure you have the information needed to complete the survey.</b>
☐ Please complete the online survey. Refer to the "Survey Instructions" in this Welcome Packet.
<ul> <li>Please review the "Healthcare Provider Blood Draw Authorization" form.</li> <li>Some health conditions or medical treatments, like bleeding disorders, anemia, or some cance treatments, may make it unsafe for you to provide a blood sample for this study.</li> <li>If you are 12 years old or older and have any of the listed health concerns, we ask that your healthcare provider sign this form agreeing that it is safe for you to give a blood sample; you will need to bring this form with you to your study office visit.</li> </ul>
<ul> <li>The following are common symptoms of COVID-19: fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea.</li> <li>If you have any symptoms of COVID-19 up to two weeks <u>before</u> the date of your appointment or <u>on</u> the date of your appointment, kindly call 855-322-3037 to reschedule. To ensure the safety of our participants and staff, we will find another time for you to come in.</li> </ul>
<ul> <li>□ If you are 12 years old or older, fast for 8 hours before your appointment.</li> <li>• Fasting means do not eat or drink anything besides water for 8 hours before your appointment.</li> </ul>

- It is okay to drink water and take any medications with water.
- If you must eat before your appointment because of a medical reason, eat fat-free or low-fat items. Write down what you ate and when you ate it. Bring this information with you.







#### Required for the appointment:

 $\square$ An ID with both your name and picture.

 Please see enclosed list of "Accepted Forms of ID". This applies to adult participants and parents/guardians accompanying a minor participant.

A mask or cloth face covering to wear during your study office appointment.

#### You may also need to bring:

☐ Your completed "MiPEHS Pre-Survey Worksheet."

Only if you were unable to complete the survey online before your appointment.

 $\Box$ A list of anything you ate in the 8 hours before your appointment and when you ate it.

• Only if you were unable to fast during that time.

☐ The signed Healthcare Provider Blood Draw Authorization form.

• Only if you have any of the health conditions that may result in problems with a blood draw.

#### For households with multiple appointments:

- Household members with appointments scheduled one after the other can plan to come to the study office together.
- Upon arrival, only one person needs to call to let the study team know you all have arrived.
- Please call 855-322-3037 if you have any questions about scheduling.

Have questions about your appointment or about the study? Need to reschedule or cancel? Please call 855-322-3037.

Need help with transportation to your appointment? Please call 844-464-7327.







## **MiPEHS Survey Instructions**

Each participant in this research study, or a participant's parent or legal guardian if the participant is a minor, is asked to complete a survey on health and behavior that may affect the amount of PFAS in their body. All the information you provide on the survey will be kept confidential and will be securely stored.

One adult participant from each household needs to complete an additional part of the survey about household water filters. Adults in the household should decide who should be the one to answer this part of the survey before beginning.

Please complete all parts of the survey before coming to your appointment if at all possible. Please let us know if you are unable to do this before your appointment so we can schedule extra time for you to complete this in our study office.

In this welcome packet, there is a Pre-Survey Worksheet. Doing this worksheet **first** will make it easier and faster to finish the online survey. When you are taking this survey, you will need to look at 2 maps included in this Welcome Packet. They are labeled Reference Map #1 and Reference Map #2.

Each participant in the study has their own, personalized web address for the survey. It is important to use the web address that has been assigned to you.

Here is **YOUR** unique web address for answering the survey:



If you are unable to complete the survey before your study office appointment, we will have space available for you to complete it at your appointment.

Please call us if you see something in the survey questions that does not look right to you or if you are confused by any question: **844-464-7327**. Our staff are here to help.

Our offices are open from 8 a.m. to 5 p.m., Monday through Friday.







### MiPEHS Pre-Survey Worksheet

Before starting the survey, we recommend you fill out this worksheet. You may need to look up information in your personal records or refer to your current medication(s) to finish this worksheet.

Filling this out may help you complete the survey faster.

We have study staff available to help you if you encounter any problems or questions when you are answering the questions on the online survey.

Please call us at **855-322-3037** during our open hours if you need help completing the survey. Our offices are open:

8 a.m. to 8 p.m., Monday through Friday 11 a.m. to 3 p.m. on Saturday

#### Health History

Gathering your answers to these questions may help you complete the survey faster. The survey has questions that will ask you about the following information.

1.	If you eve	er donate blo	ood (whole blood	l, plasma, etc.	, when was th	e last time you do	nated?
	Month: _		_				
	Year:						

2. We will ask about certain health conditions you have been diagnosed with. It will be helpful to gather information about your health history as you prepare for the survey. We will ask about a variety of health conditions (like some cancers, preeclampsia, thyroid problems and more) and how old you were when you were diagnosed.







- 3. If you are currently taking any medications, please have a complete list available. Filling out the table below may help you organize your medication information, so it is ready for the survey questions. The survey will ask you about ALL current medications you are taking including prescription and over-the-counter medications. By "medications" we mean any of the following:
  - pills
  - liquid medications
  - skin patches
  - eye drops
  - salves, ointments and creams
- inhalers and injections
- hormonal birth control devices
- aspirin

- cold or allergy medications
- herbal remedies
- Tylenol<sup>®</sup> and Motrin<sup>®</sup>
- vitamin supplements
- any other prescription or over-the-counter medication

		How often do you take/use	Date you last took/used the
	Medicine name	the medicine?	medicine (MM/DD/YYYY)
1		☐ Every day	, ,
		3 or more days a week, but not every day	
		1 or 2 days a week	
		Every other week or less	
		☐ I don't know	
2		Every day	, ,
		3 or more days a week, but not every day	/
		1 or 2 days a week	
		☐ Every other week or less	
		I don't know	
3		Every day	, ,
		3 or more days a week, but not every day	/
		1 or 2 days a week	







	Every other week or less	
	☐ I don't know	
4	Every day	
	3 or more days a week, but not every day	
	1 or 2 days a week	
	☐ Every other week or less	
	☐ I don't know	
5	Every day	
	3 or more days a week, but not every day	
	1 or 2 days a week	
	Every other week or less	
	☐ I don't know	
6	☐ Every day	
	3 or more days a week, but not every day	/
	1 or 2 days a week	
	Every other week or less	
	☐ I don't know	
7	☐ Every day	
	3 or more days a week, but not every day	/
	1 or 2 days a week	
	☐ Every other week or less	
	☐ I don't know	
8	Every day	, ,
	3 or more days a week, but not every day	/
	1 or 2 days a week	







	Every other week or less	
	☐ I don't know	
9	Every day	
	3 or more days a week, but not every day	
	1 or 2 days a week	
	☐ Every other week or less	
	☐ I don't know	
10	Every day	
	3 or more days a week, but not every day	
	1 or 2 days a week	
	☐ Every other week or less	
	☐ I don't know	
11	☐ Every day	, ,
	3 or more days a week, but not every day	/
	1 or 2 days a week	
	☐ Every other week or less	
	☐ I don't know	
12	Every day	
	3 or more days a week, but not every day	/
	1 or 2 days a week	
	☐ Every other week or less	
	☐ I don't know	
13	Every day	, ,
	3 or more days a week, but not every day	/
	1 or 2 days a week	







	Every other week or less
	☐ I don't know
14	☐ Every day
	3 or more days a week, but not every day
	1 or 2 days a week
	☐ Every other week or less
	☐ I don't know
Drinking Water History	
related to drinking water. We only questions below are very similar t	e survey on behalf of the household will answer questions need this information from one person per household. The the ones we will ask on the survey and they might take a nswer. We are including them here so you know what kind of the survey.
this study – what is the water these people? 'Water source' city water, or bottled water.  Private well	r household who are over 12 years old and participating in source most used for drinking water in the house right now by means where your water comes from, either a private well, alled municipal water or public water)
In approximately what month drinking water in the house right.	and year did you start using the water source most used for the now?
Month:	
学 学 学	





NOT	including this study, have you ever had your drinking water tested for PFAS?
	Yes No I don't know
	water most often used in the house for drinking and cooking, do you currently use a
filter	for any reason? This does not include water softeners.
	Yes No I don't know
-	u use a filter for the water you use for drinking or cooking, what are the reasons that currently use a filter? Again, this does not include water softeners. Please select all that y.
	Water tastes bad Water is cloudy or has a bad color Water smells bad or has a bad odor Water has sediment or has particles that 'settle out' as it sits Water has dissolved minerals, commonly known as 'hard water' Water tested positive for lead Water tested positive for PFAS Water tested positive for another contaminant As a safety measure (precaution) for any contaminants that haven't been tested for Other, please specify: I don't know
	For v filter







## **Healthcare Provider Blood Draw Authorization Form**

<u>SAMPLE PARTICIPANT</u> is choosing to participate in the Michigan Department of Health and Human Services (MDHHS) Michigan PFAS Exposure and Health Study

(MiPEHS). This study is evaluating how PFAS exposure in drinking water relates to blood PFAS levels and how blood PFAS levels may be related to health.

#### In this project, MDHHS will be collecting a fasting blood sample.

This form is to be completed by a licensed healthcare provider who is involved in the study participant's care if:

• the participant identifies as having a bleeding disorder, anemia, cancer, or other condition that could make it unsafe to draw blood for this project

Or

 the participant is taking medication(s) or is undergoing treatment that makes it unsafe to draw blood for this project

The total amount of blood that will be drawn from the study participant for this project is:

- 53 milliliters (about five 10mL vials) for adults age 18 years or older.
- 33 milliliters (about three 10mL vials) for minors age 12 to 17 years.

Please select all that apply to this patient:  Bleeding disorder(s) (i.e. hemophilia)  Anemia Current diagnosis of cancer	☐ Taking blood thinners ☐ Taking antihyperglycemic medication(s) ☐ Other:
Determination for this patient's participation in th (select one):  This patient can safely participate in the bloom.	
☐ This patient cannot safely participate in the	e blood draw for this project.
This patient cannot safely participate in the	Date

For questions about this form, please call MDHHS at 844-464-7327 and ask to speak with MiPEHS staff. Thank you for your assistance.

TITLE OF RESEARCH: "Michigan PFAS Exposure and Health Study (MiPEHS): City of Parchment, Cooper Township, and Belmont/Rockford Area" PRINCIPAL INVESTIGATOR: Kory Groetsch

## MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF ENVIRONMENTAL HEALTH

# MINOR CONSENT FORM AGE 0-11

#### KFY INFORMATION

#### **OVERVIEW**

The Michigan Department of Health and Human Services (MDHHS) invites your child to participate in the Michigan PFAS Exposure and Health Study (MiPEHS). As the parent or guardian of this child, you and your child both decide if your child will participate or not participate. First, we want to learn how exposure to per-and polyfluoroalkyl substances (PFAS) in drinking water relates to the levels in people's blood. Second, we want to learn how PFAS levels in people's blood could be related to health. We are conducting this health study in three communities— Belmont/Rockford area (North Kent County), the City of Parchment, and Cooper Township. This health study is research, which is different from MDHHS' routine public health activities.

#### WHAT TO EXPECT

If you agree to your child being part of this study, we will ask you and your child to participate in three appointments at a study office (90-minutes each). This is an MDHHS study, but you may notice that staff at the study office will be from RTI International and Frontline National. These appointments will be spaced about two years apart.

Before each of your appointments, we will ask you to complete a health survey on the internet about your child.

At each appointment, we will:

- 1. Measure your child's blood pressure, height, weight, and around your child's waist (waist circumference).
- 2. Provide each participant a \$25 gift card for completing the survey and attending a study office appointment.

TITLE OF RESEARCH: "Michigan PFAS Exposure and Health Study (MiPEHS): City of Parchment, Cooper Township, and Belmont/Rockford Area" PRINCIPAL INVESTIGATOR: Kory Groetsch

For selected households, we will ask your permission for an MDHHS employee, a sanitarian, to collect sample(s) of your household's drinking water that will be tested for PFAS. These home visits will happen three times, spaced about two years apart.

At each home visit to collect water, we will:

- 1. Ask an adult resident questions about your drinking water and home water treatment systems.
- 2. Collect at least one sample of your drinking water.

We will also ask your permission to use your child's Newborn Blood Spot, samples of your child's blood collected at birth, and link to other existing health records as part of this study. By linking your child's data with other health records, we will be able to improve our understanding about PFAS and health outcomes.

#### POTENTIAL RISKS OR DISCOMFORT

Most studies like this have risks or reasons you might not want your child to participate. Sometimes answering questions about your child's health may be uncomfortable.

#### **POTENTIAL BENEFITS**

Most studies like this have benefits or reasons why you might want your child to participate. Your child's participation will contribute to learning about your community's exposure to PFAS. Lastly, you may want your child to participate because this study could help expand public knowledge about PFAS, including the relationship between blood PFAS levels and health.

#### CONFIDENTIALITY

We are collecting information about your child, so there is a small risk to the confidentiality of the information you give us. We will protect the information you share with us to the fullest extent allowed by law.

Any reports or articles that are written about the study will only talk about group results. These materials will not include information that could identify your child, such as their name or address.

#### STUDY PARTICIPATION IS VOLUNTARY

Your child's participation is completely voluntary. As the parent or guardian of this child you and your child both decide if your child will participate. If you decide to participate, you can change your mind and stop participation at any time. There is no cost to you or your child to participate or to receive any of your study results.

TITLE OF RESEARCH: "Michigan PFAS Exposure and Health Study (MiPEHS): City of Parchment, Cooper Township, and Belmont/Rockford Area" PRINCIPAL INVESTIGATOR: Kory Groetsch

#### QUESTIONS ABOUT YOUR RIGHTS

You may have questions about your child's rights as a study participant. MDHHS Institutional Review Board (IRB) protects people who take part in health studies like this. You may contact the IRB by phone: (517) 241-1928 or email: MDHHS-IRB@michigan.gov.

#### QUESTIONS ABOUT THE STUDY

You may have questions about this study. If so, please call 844-464-7327 and ask for the MiPEHS study team.

#### DETAILED INFORMATION

#### STUDY PURPOSE

There are many things we can learn about from this study:

- How exposure to per-and polyfluoroalkyl substances (PFAS) in drinking water relates to the levels in people's blood.
- How PFAS levels in people's blood could be related to health.
- If a blood sample taken from your arm and a blood sample taken from your finger have similar PFAS
  test results.
- If PFAS exposure during pregnancy is related to birth outcomes, like low birth weight.
- If people's polychlorinated biphenyls (PCBs) in blood changes the relationship between PFAS levels and health.

#### **BACKGROUND**

PFAS are a large group of man-made chemicals that are fire-resistant and repel oil, stains, grease, and water. They are used in fire-fighting foams, stain repellants, nonstick cookware, waterproof clothing and shoes, fast food wrappers, personal care products, and many other consumer goods. Most of these chemicals do not break down easily in the environment.

Research is ongoing to understand the effects PFAS might have on health. Having PFAS exposure or PFAS in your body does not mean you will necessarily have health problems now or in the future. Most people in health studies do not have health effects, even when exposed to high amounts of PFAS. Some health studies have found health effects linked to some PFAS such as:

- Decreased chance of a woman getting pregnant.
- Increased chance of high blood pressure in pregnant women.
- Increased chance of thyroid disease.

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- Changed immune response.
- Increased cholesterol levels.
- Increased chance of cancer, especially kidney and testicular cancers.

For more information on PFAS, please see the fact sheet "Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water" included in your invitation packet. This fact sheet can also be found at https://www.michigan.gov/documents/pfasresponse/PFAS in Drinking Water 624844 7.pdf.

PCBs are a mixture of chemicals that were used in electrical equipment like transformers and were also found in hydraulic oils. PCBs are no longer produced in the USA, but PCBs are still found in the environment.

Some health effects linked to PCB exposure are the same as health effects linked to PFAS exposure. For more information on PCBs please see the ATSDR's fact sheet at <a href="https://www.atsdr.cdc.gov/toxfaqs/tfacts17.pdf">https://www.atsdr.cdc.gov/toxfaqs/tfacts17.pdf</a>.

#### STUDY PARTICIPATION

Your child is invited to participate if they meet one of the following criteria:

- Currently live in the City of Parchment or Cooper Township study area and a well or municipal water supply was a source of their drinking water between 2005 and 2018
- Currently live in the Belmont/Rockford study area, have had a private drinking well water tested by or at the direction of a State of Michigan Agency, and that well was a source of their drinking water between 2005 and 2018
- Are a current or former dependent of an adult that lives at an eligible household, and you drank that household's water between 2005 and 2018

#### WHAT TO EXPECT

We are asking you to complete three surveys and attend three appointments at a study office with your child. The appointments will begin in 2020 and future appointments will be about two years apart. Each appointment will be up to 90-minutes.

For selected households, we ask you to schedule three visits to your child's home where an MDHHS employee, a sanitarian, will collect sample(s) of the household's drinking water for PFAS. These home visits will happen soon after each of your study office appointments. That means the home visit, like the study office appointments, will be about two years apart.

Your child's study participation will end after the third visit to the study office (or third home visit, if selected).

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#### Before Each Appointment at the Study Office

We will mail you a confirmation package with information for your child's appointment. The first package will also include the informed consent paperwork (this form). You will be asked to complete a survey for your child as part of this study. We will ask questions about ways your child might encounter PFAS, such as the water they drink, the foods they eat, and the type of activities they do. We will also ask some questions about your child's health. One participating adult from your household, or you if there are no participating adults, will be asked to complete an additional part of the survey on household water filters. The confirmation package will include a code to complete this survey on the internet. The confirmation package will also include a worksheet. The worksheet will help you gather some of the information about your child that we will be asking about in the survey. The worksheet asks questions about medications your child is currently taking.

Please complete the survey before your child's study office appointment. This survey will take about 30 minutes to complete.

You will be required to bring a picture ID to your child's appointment. Please see the attached sheet: "Acceptable Forms of ID".

#### At Each Appointment

#### We will:

- 1. MDHHS will take all needed precautions following CDC guidelines to protect you, your family, and staff at the study office from exposure to infectious disease, including COVID-19. This will include asking you, your child, and any person you bring to the study office, to wear a face covering if you are medically able.
- 2. Measure your child's blood pressure, height, weight, and around your child's waist (waist circumference).
- 3. Provide you a gift card as a thank you for both you and your child's time and participation. After each appointment, you will receive a \$25 gift card for completing the survey and coming to the study office appointments.

#### After Your Study Office Appointment

We may contact you in the future if we have more questions about your child or have information about the study to provide to you. If there is a public health need, MDHHS may ask you about your child participating in a new study.

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#### Collection of water samples

Not every household in the study will have sample(s) of their drinking water collected.

For selected households, we will schedule a home visit for a trained MDHHS sanitarian to collect sample(s) the household's drinking water for PFAS testing. This will happen three times, one home visit after each of your study office appointments. Each home visit will take about 30 minutes. An adult (18 years of age or older) must be present at this visit.

During this visit, the MDHHS sanitarian will:

- 1. Ask questions about your water filters and record information (including photos, if needed) about the plumbing and water treatment systems in your home
- 2. Collect a water sample or samples to test for PFAS

For homes with filters, a water sample will be collected of the water before it is filtered and after each filter. For homes without a filter, one water sample will be collected.

#### Your test results:

Your Water Test Results

PFAS water results will only tell you how much PFAS was in the water the day your water sample(s) was collected.

MDHHS will mail your water results to the address you provide on the signature page; this will be confirmed at checkout at your appointment. For multiple participants at the same address, we will send one water result letter per household. We will ask you to name one adult in your household at checkout to receive your household's water results (unless requested otherwise).

Results will be mailed when they are available, typically within 6 months. MDHHS will not provide you a water filter as part of this study. However, MDHHS may call you to provide recommendations based on your PFAS water results.

#### Linking with existing records and samples

MDHHS will use your child's personal information to link to other existing records as part of this study. By linking your child's data with other health records, we will be able to improve our understanding about PFAS and health outcomes. The other health records include those contained in the Michigan Care and Improvement Registry (MCIR), newborn screening records, birth certificate records, hospitalization billing records from the time of your child's birth, other MDHHS databases, and the North Kent County Exposure Assessment (NKCEA) during 2018-2019 (if applicable).

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#### Michigan Newborn Blood Spot

We want to understand how prenatal exposure to PFAS could affect health. To measure PFAS in blood at the time of birth, we are asking permission to access your child's newborn dried blood spot sample. We will also measure two thyroid hormones, fT4 and TSH, in your child's newborn dried blood spot sample. This only applies if your child was born in the State of Michigan on or after October 1, 1987. We will not use your child's blood for alcohol, drug, or DNA testing.

The State of Michigan requires newborn dried blood samples be collected at birth. These are used to learn if infants have rare diseases needing special care very early in life. Blood spots leftover after the screening are stored for quality assurance and can be made available for research through the Michigan BioTrust for Health (BioTrust). With your permission, we will use some of your child's newborn blood spots for this study. The newborn screening program keeps one blood spot for use only by you or your family in case of health reasons which cannot be used for research. You can learn more about the BioTrust at http://www.michigan.gov/biotrust.

A copy of your signed consent form will be shared with the BioTrust for approval to access your newborn blood spot. To access and locate your child's newborn blood spot, we will ask you to provide:

- Your child's name that was given at the time of birth (name on your child's birth certificate).
- The sex your child was assigned at birth.
- Your child's date of birth.
- Your child's birth mother's name at the time of your child's birth.
- Your child's birth mother's date of birth.
- The name and address of the hospital or birth center where your child was born.

#### **RISKS AND BENEFITS**

#### Potential Risks or Discomfort

Most studies like this have some risk. Risks could be reasons you might not want your child to take part in this study. MDHHS will take all needed precautions following CDC guidelines to protect you, your family, and staff at the study office from exposure to infectious disease, including COVID-19. This will include asking you, and any person you bring to the study office, to wear a face covering if you are medically able.

You may feel stress from participating in this study. You may find it stressful answering health questions about your child, having someone come into your home to collect a water sample, or receiving your water results. If you experience this, you or your child may find it helpful to be in touch with a doctor, a counselor, or a mental healthcare provider. You or your health insurance company are normally responsible for the costs of healthcare.

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We will protect the information you share with us to the fullest extent allowed by law. You can read more about this in the CONFIDENTIALITY section below.

#### **Potential Benefits**

Most studies like this have some benefits. Benefits could be reasons you might want to take part in this study.

A benefit may be learning about your child's exposure to PFAS and contributing to public knowledge about your community's exposure to PFAS. We may learn more about how people could decrease PFAS exposure from sources other than drinking water. This study could help us learn more about how PFAS blood levels could be related to health. Your participation will advance PFAS research in Michigan and nationwide.

#### CONFIDENTIALITY

#### **Protecting Your Privacy**

MDHHS will keep a copy of the survey answers, water test results (if tested), and contact information. Your child's information will be protected to the fullest extent allowed by law. However, we may be required to report things like abuse or neglect to the appropriate authorities, e.g., abuse of a child seen during the home visit.

While unlikely, MDHHS may need to take public health action due to the household's water PFAS results. In this unlikely event, we will share your child's home address with others in the MDHHS Division of Environmental Health; the local health department; the Michigan Department of Environment, Great Lakes, and Energy; and other state or federal agencies as needed. No survey answers will be shared.

To protect your child's privacy, we will store survey answers and water test results using codes instead of your child's name. Your child's name and your contact information will be kept separate from your child's answers and water test results. We will keep any paper records in locked files at the study office. When we transport paper records, they will be placed in a lockbox, transported by a trained MDHHS employee, and then will be stored in locked files at the MDHHS office in Lansing, Michigan. Any electronic files with your child's information will be kept secure following MDHHS data storage protocols. Only a limited number of study staff at MDHHS will have access to your child's information and water test results. As required by law, study staff cannot give your information and results to anyone without your permission. The only exception would be a need for MDHHS to take public health action as described above.

Any reports or articles that are written about the study will only talk about group results. These materials will not include information that could identify you, such as your name or address.

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#### Researchers outside of MDHHS

We expect other researchers will request data and/or samples from this study to answer other questions about PFAS. We will ask you at the end of this form to select whether you want to allow permission for sharing your contact information, and your de-identified survey answers and water test results.

If you give permission, MDHHS will remove all information that could identify your child from the survey answers and water test results. MDHHS would not need to obtain another consent from you before sharing this type of unidentifiable ("de-identified") information. Then, researchers that have an MDHHS IRB-approved study protocol and have completed a Data Use Agreement (meet MDHHS privacy and security requirements) will be able to get your contact information, your child's de-identified survey answers, and de-identified water test results,.

Some researchers may want to ask for survey answers that are connected to your child's name and your contact information. MDHHS plans on having survey answers and test results connected to your name and contact information and your child's name available after the study has ended. However, you will have the opportunity to decide if you want MDHHS to share identifiable information (survey answers) with a researcher outside of MDHHS. We will not share your child's identifiable information without your written permission. After you have given your permission, researchers that have an MDHHS IRB-approved study protocol and have completed a Data Use Agreement (meet MDHHS privacy and security requirements) will be provided your child's identifiable information.

#### STUDY PARTICIPATION IS VOLUNTARY

Your child's participation is voluntary. You decide if you would like your child to participate or not. Even if you agree to have your child participate, you or your child can change your mind and stop participating at any time. Your and child's choice will not harm your relationship with MDHHS. Deciding not to participate or choosing to stop your child's participation will not result in a loss of you or your child's current benefits or services either of you may receive.

To withdraw from the study, you need to contact the study staff and let them know that you do not want your child to be part of the study from that point onward. Study staff may be reached by calling the Michigan PFAS Exposure and Health Study: Parchment, Cooper Township, and Belmont/Rockford area (North Kent County) at 844-464-7327. A study staff member will document the request to withdraw from the study and ask if you would share your reason for withdrawing. Once you have withdrawn from the study, the study staff will not obtain any additional information about you or contact you about this study. You may be contacted to tell you about other MDHHS studies.

Unless you ask, the study staff will continue to use the information that was already obtained about your child before stopped your child's participation. If you wish for you and your child's information to be destroyed,

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please tell this to study staff and we will destroy anything that we have. It will not be possible for MDHHS to destroy information that has already been shared with other researchers.

There is no cost for your child to participate in this study. There is no cost to receive the water results.

#### QUESTIONS ABOUT THIS STUDY

If you have any questions about this study, please ask the staff at the study office. MDHHS has contracted with RTI International and Frontline National to operate the study office. You may also contact the MiPEHS study staff at:

Michigan Department of Health and Human Services Division of Environmental Health P.O. Box 30195 Lansing, Michigan 48909 Toll-free: 844-464-7327

#### QUESTIONS ABOUT YOUR CHILD'S RIGHTS

For any questions about your child's rights if they participate in this study or about the oversight of this study, please contact the MDHHS Institutional Review Board (IRB). The IRB helps protect people who volunteer for studies like this. You can reach them at:

Institutional Review Board
Michigan Department of Health and Human Services
333 S. Grand Ave., P.O. Box 30195
Lansing, MI 48909
517-241-1928
MDHHS-IRB@michigan.gov

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#### **CONSENT SIGNATURE PAGE**

Name of minor participant (Please print)	
By signing this form, you agree that you have read, and ur understand the purpose of the Michigan PFAS Exposure a Belmont/Rockford area (North Kent County). You have had study answered by the study staff. You agree to your child	nd Health Study: <i>Parchment, Cooper Township and</i> d all your questions about your child's participation in the
If you do not agree to allow your child to participate do no	ot sign this form.
The assent script was read to my child and my child as	sents to participate.
Name of legal guardian (Please Print)  S  Date	ignature of legal guardian

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Parent or Guardian Street address		
Parent or Guardian Apartment or Unit		
Parent or Guardian City		
Parent or Guardian State	MI	
Parent or Guardian Zip		
Parent or Guardian name		
Parent or Guardian Phone number	( )	Home Mobile
Parent or Guardian Email		

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#### Plea

ase	answer each question below.
A.	Researchers outside of MDHHS interested in furthering PFAS research may want to contact you because your child was part of this study. Researchers would need to have an IRB-approved study protocol and completed a Data Use Agreement before MDHHS would share you or your child's information with them.  May we share your contact information (name, address, phone number, email address) with outside researchers who meet these standards?
	□ YES
	□ NO
B.	Researchers outside of MDHHS interested in furthering PFAS research may request de-identified data (information that does not have any identifying information connected to it) that was collected by MDHHS. Researchers would need to have an IRB-approved study protocol and completed a Data Use Agreement before MDHHS would share your information with them.  May we share your child's de-identified data with outside researchers who meet these standards?
	□ YES
	□ NO

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## Access and use of your child's newborn blood spot from the Michigan BioTrust Health Program This only applies if your child was born in the State of Michigan on or after October 1, 1987. ☐ YES, I permit MDHHS to access my child's newborn blood spot from the Michigan BioTrust for the MiPEHS study. □ NO, I do not permit MDHHS to access my child's newborn blood spot from the Michigan BioTrust for the MiPEHS study. If you check NO, please do not sign or complete anything else on this form. Complete ONLY if you answered "YES" above and permit MDHHS to access your newborn blood spot. First and Last Name of Participant at Time of Birth Participant's birth date (month/day/year) Participant's Sex Assigned at Birth Participant's Birth Mother's First and Last Name at time of birth Participant's Birth Mother's birth date (month/day/year) Name of Birth Hospital /Center Street Address of Birth Hospital/Center City of Birth Hospital/Center ZIP Code of Birth Hospital/Center By signing this form, I authorize the release of my child's newborn blood spot and accompanying data to the MDHHS MiPEHS study team. Name of legal guardian (sign) Date Name of **legal guardian** (Print)

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For staff use only:

By signing below, I am agreeing that I have:

- ✓ Confirmed, to the best of my ability, that the participant has an understanding of the purpose and what to expect from their participation in the Michigan PFAS Exposure and Health Study: Parchment, Cooper Township and Belmont/Rockford area (North Kent County).
- ✓ Offered an opportunity to answer the participant's questions and have answered, as best as I could, any questions the participant asked.
- ✓ Read the form in its entirety to them, if needed.
- ✓ Verified the signature on this form and that the form is completely filled out.

Staff Member Verifying Consent (Signature)	Date
Staff Member Verifying Consent (Print)	