

# Information for Youth Participant (12-17 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.



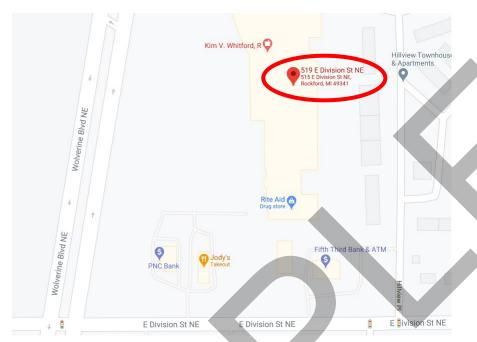
CALL 800-848-4071 from your car to let the staff know you have arrived and complete a COVID-19 screening.







#### 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:

SAMPLE PARTICIPANT
SAMPLE WEB ADDRESS

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 ever donate blood (whole blood, plasma, etc.), when was the last time you donated?
	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	





3.	Not	including this study, have you ever had your drinking water tested for PFAS?
		Yes No I don't know
4.	For v	water most often used in the house for drinking and cooking, do you currently use a
	filter	r for any reason? This does not include water softeners.
		Yes No I don't know
5.	•	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







## **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):	ne blood draw for this project is the following
☐ This patient can safely participate in the blo ☐ This patient cannot safely participate in the	

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 12-17

#### **KEY INFORMATION**

#### **OVERVIEW**

The Michigan Department of Health and Human Services (MDHHS) invites you, with permission of your parent or guardian, to participate in the Michigan PFAS Exposure and Health Study (MiPEHS). 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, with permission of your parent or guardian, agree to be part of this study, we will ask you 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. 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.

Before each of your appointments, we will ask you to fast (not eat) and drink only water for 8 hours before you arrive. We will also ask you to complete a health survey on the internet.

At each appointment, we will:

- 1. Measure your blood pressure, height, weight, and around your waist (waist circumference).
- 2. Take a blood sample from your arm.
- 3. Provide each participant a \$50 gift card for participating in the study, which means providing a blood sample from your arm and completing a survey.

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

At your first appointment only, we will take a blood sample from your finger. After the first appointment, you will also receive a \$5 gift card for providing a blood sample from your finger.

For selected households, we will ask your parent or guardian's 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 Newborn Blood Spot, samples of your blood collected at birth, and link to other existing health records as part of this study. By linking your 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 to participate. If you have a bleeding disorder, are taking blood thinners, have anemia, have cancer, are undergoing treatment for cancer, or are taking medications to lower your blood sugar, your parent or guardian should talk with your healthcare provider about giving a blood sample before you participate in the study. If you have these conditions or treatments, we will ask for your parent or guardian to have your healthcare provider fill out the "Healthcare Provider Authorization Form" prior to coming to the study office appointments. Having your blood taken may be uncomfortable, make you dizzy or faint, or, very rarely, cause infection. Also, sometimes answering questions about your health may be uncomfortable.

#### **POTENTIAL BENEFITS**

Most studies like this have benefits or reasons why you might want to participate. You may want to participate because you will get your blood PFAS and laboratory health test results. Also, you contribute to learning about your community's exposure to PFAS. Lastly, you may want 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 you, 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 you, such as your name or address.

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#### STUDY PARTICIPATION IS VOLUNTARY

Your participation is completely voluntary. Both you and your parent or guardian decide if you 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 parent or guardian to participate or to receive any of your study results.

#### QUESTIONS ABOUT YOUR RIGHTS

You or your parent or guardian may have questions about your 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:

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- Decreased chance of a woman getting pregnant.
- Increased chance of high blood pressure in pregnant women.
- Increased chance of thyroid disease.
- 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 <a href="https://www.michigan.gov/documents/pfasresponse/PFAS">https://www.michigan.gov/documents/pfasresponse/PFAS</a> 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 https://www.atsdr.cdc.gov/toxfaqs/tfacts17.pdf.

#### STUDY PARTICIPATION

You are invited to participate if you meet one of the following criteria:

- Currently live in the City of Parchment or Cooper Township study area and your well or municipal water supply was a source of your drinking water between 2005 and 2018
- Currently live in the Belmont/Rockford study area and have had your private drinking well water tested by or at the direction of a State of Michigan Agency and that well was a source of your 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 attend three appointments at a study office. 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 your parent or guardian to schedule three visits to your home where an MDHHS employee, a sanitarian, will collect sample(s) of your 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 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 your parent or guardian a confirmation package with information for your appointment. The first package will also include the informed consent paperwork (this form). We will ask your parent or guardian to complete survey about you as part of this study. We will ask questions about ways you might encounter PFAS such as the water you drink, the foods you eat, and the type of activities you do. We will also ask some questions about your health. We will also ask one participating adult household member (or your parent or legal guardian if no adults in your household participate), to complete an additional part of the survey on household water filters. Your confirmation package will include a code to complete these surveys on the internet. The confirmation package will also include a worksheet. The worksheet will help you and your parent or guardian gather some of the information that we will be asking about in the survey. The worksheet asks questions about medications you are currently taking.

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

Please do not eat or drink anything other than water for 8 hours before each of your appointments. It is okay to take any medications with water. The reason you will need to fast is that eating and drinking anything besides water could affect the levels of what we are testing for in the blood.

If you have diabetes or have other medical needs, we will do our best to schedule your appointment as early in the morning as possible. If you must eat before your appointment because of a medical reason, please eat fat-free or low-fat foods. Please write down what you ate and the time that you ate it and bring this list to your appointment.

Your parent or guardian will be required to bring a picture ID to your 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, and any person you bring to the study office, to wear a face covering if you are medically able.
- 2. Measure your blood pressure, height, weight, and around your waist (waist circumference).
- 3. Take a blood sample from your arm. You will have 33 milliliters (mL), about 2.2 tablespoons, of blood taken from a vein in your arm. We will use this blood to measure the amount of certain PFAS in your blood. We will also use this blood to measure laboratory health tests, such as cholesterol and glucose levels. A full list of laboratory health tests is on the last page of this form.
  - We will not use your blood for alcohol, drug, or DNA testing.

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4. Provide you gift card(s) as a thank you for your time and participation. After each appointment, you will receive a \$50 gift card for participating in the study, which means providing a blood sample from your arm and completing a survey.

At your first appointment, we will also take a blood sample from your finger.

We will collect a few drops of blood from your finger and store them on a card. These cards will be stored at MDHHS's lab for up to 20 years. The blood spot samples will be used for MDHHS study purposes only. We will not use your blood for alcohol, drug, or DNA testing. We will collect this current blood spot for two reasons:

- We want to understand the difference between PFAS measured from whole blood, meaning cells and serum, taken from your finger and PFAS measured from a part of the blood, serum, taken from a vein in your arm. Different levels of PFAS may be found in whole blood compared to serum. By comparing these PFAS results, we will learn more about the ways to test for PFAS in future studies.
- To learn how the amount or type of PFAS in blood stored on a card may change over time. This will help us use PFAS testing results from blood collected at birth (newborn blood spots). See the "Michigan Newborn Blood Spot" section below for more detail.

After the first appointment, you will also receive a \$5 gift card for providing a blood sample from your finger.

#### After Your Study Office Appointment

We may contact your parent or guardian in the future if we have more questions or have information about the study to provide to you. If there is a public health need, MDHHS may ask you to participate in a new study, with permission from your parent or guardian.

#### 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 with your parent or guardian for a trained MDHHS sanitarian to collect sample(s) of your 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 an adult resident 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.

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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 Blood Test Results

You and your parent or guardian can choose to receive the results for PFAS measured in your blood. Your parent or guardian will receive the results for all your laboratory health tests (e.g., cholesterol, glucose, etc. measured in your blood).

For this study, PFAS results from your blood test can only tell you what the levels were at the time your blood was drawn.

MDHHS will not be able to tell you:

- All the sources of PFAS to your body or how much of the PFAS in your body is from PFAS-contaminated water.
- About chemicals we did not test for.
- If these chemicals are harming your health.
- If these chemicals could harm your health in the future.

Your results will be mailed to your parent or guardian at the address provided on the signature page. It may take up to 6 months to receive all of your blood test results. As soon as blood test results are available, we will send them. This could mean your parent or guardian receives several different result letters.

Based on your results for certain laboratory health tests, MDHHS may call your parent or guardian if we recommend that they speak to your healthcare provider right away. At the end of this consent form, please provide a phone number where we can reach your parent or guardian if needed. We will not leave your test results in a message or voicemail.

#### 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 your parent or guardian at the address provided 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 your parent or guardian to name one adult in your household at checkout to receive your household's water results (unless requested otherwise).

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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 your parent or guardian to provide recommendations based on your PFAS water results.

#### Linking with existing records and samples

MDHHS will use your personal information to link to other existing records as part of this study. By linking your 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 birth, other MDHHS databases, and the North Kent County Exposure Assessment (NKCEA) during 2018-2019 (if applicable).

#### 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 you and your parent or guardian permission to access your newborn dried blood spot sample. We will also measure two thyroid hormones, fT4 and TSH, in your newborn dried blood spot sample. This only applies if you were born in the State of Michigan on or after October 1, 1987. We will not use your 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 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 <a href="http://www.michigan.gov/biotrust">http://www.michigan.gov/biotrust</a>.

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 newborn blood spot, we will ask you to provide:

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

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#### **RISKS AND BENEFITS**

#### Potential Risks or Discomfort

Most studies like this have some risk. Risks could be reasons you might not want 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.

If you have a bleeding disorder, are taking blood thinners, have anemia, have cancer, are undergoing treatment for cancer, or are taking medications to lower your blood sugar, your parent or guardian should talk with your doctor about having your blood taken before participating in the study. If you have these conditions or treatments, we will ask for your parent or guardian to have your healthcare provider fill out the "Healthcare Provider Authorization Form" prior to coming to the study office appointments.

The blood draw will be like a blood test done at your doctor's office or a medical lab. You may feel a small amount of discomfort, feel dizzy or faint during the blood draw, and may later have a small bruise on your arm where the blood was taken. You may, although it's very rare, develop an infection where the blood was drawn. To reduce these risks, trained professionals will draw your blood.

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

We will protect the information you share with us and your results to the fullest extent of the 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 include getting your blood results following each of your study office appointments. Your parent or guardian may want to share these results with your doctor. The results might help your doctor monitor your health in the future.

Another benefit may be learning about your exposure to PFAS and 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.

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#### CONFIDENTIALITY

#### **Protecting Your Privacy**

MDHHS will keep a copy of your survey answers, blood test results, water test results (if tested), and contact information. Your 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 your household's water PFAS results. In this unlikely event, we will share your 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 or blood test results will be shared.

To protect your privacy, we will store your answers and test results using codes instead of your name. Your name and contact information will be kept separate from your answers and 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 information will be kept secure following MDHHS data storage protocols. Only a limited number of study staff at MDHHS will have access to your information and 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.

After testing your blood, there may be some of the blood sample remaining. We will store the remaining sample securely at the MDHHS Laboratory until the study is over, at which point it will be destroyed. We are keeping the remaining sample in case it needs to be re-tested. Access to the MDHHS Laboratory building is restricted and only certain staff can enter the laboratory.

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.

#### 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 and your parent or guardian want to allow permission for sharing your parent or guardian's contact information, your de-identified survey answers and test results, and your de-identified samples (if requested prior to the end of the study).

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If both you and your parent or guardian give permission, MDHHS will remove all information that could identify you from your survey answers and 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 parent or guardian's contact information, your de-identified survey answers and test results, and/or your de-identified samples from this study.

Some researchers may want to ask for survey answers and tests results that are connected to your name and your parent or guardian's contact information. MDHHS plans on having survey answers and test results connected to your name and your parent or guardian's name and contact information available after the study has ended. However, both you and your parent or guardian will have the opportunity to decide if you want MDHHS to share identifiable information (survey answers, test results, and/or samples) with a researcher outside of MDHHS. We will not share your identifiable information and/or samples without your and your parent or guardian's 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 identifiable information and/or samples.

#### STUDY PARTICIPATION IS VOLUNTARY

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

To withdraw from the study, your parent or guardian needs to contact the study staff and let them know that you do not want 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. Your parent or guardian 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 you before you stopped participating. If you wish for your information and any samples to be destroyed, your parent or guardian should 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 you to participate in this study. There is no cost to receive your blood or water 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 THIS STUDY

If you or your parent or guardian 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 RIGHTS

For any questions about your rights if you 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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#### ASSENT AND CONSENT SIGNATURE PAGE

#### Minor Assent

By signing this form, you agree that you both have read this form or had someone read it to you and you agree to participate in this study. You have been told about the purpose of the Michigan PFAS Exposure and Health Study: Parchment, Cooper Township, and Belmont/Rockford area (North Kent County). You have been given a chance to ask questions and your questions have been answered.

Name of <b>minor participant</b> (P	lease print)	Signature of minor participant	
Date			
Parent or Guardian Con	sent		
your child's participation in and Health Study: Parchme	this study. You have bent, Cooper Township, a questions and your qu	d this form or had someone read it to you and you agree been told about the purpose of the Michigan PFAS Expos- and Belmont/Rockford area (North Kent County). You ha destions have been answered. Please questions A-D on the this study.	ure ave
If you do not agree to allow y	our child to participate, o	do not sign this form.	
Name of <b>legal guardian</b> (Pleas	se print)	Signature of <b>legal guardian</b>	
Date			
Parent or Guardian Street address			
Parent or Guardian Apartment or Unit			
Parent or Guardian City			

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Parent or Guardian State			
	MI		
Parent or Guardian Zip			
Parent or Guardian name			
Parent or Guardian Phone	/		
number	( )		Home
			Mobile
Parent or Guardian Email			
Please answer each questi	on below.		
A. Would you like to re	eceive vour child's PFAS	S blood results (capillary, venou	s, and newborn bloodspot, if
		letermine if these chemicals wil	
			·
		results (capillary, venous, and n	•
applicable).	I understand these resu	ults will be mailed to the addres	ss provided on the Signature
Page.			
☐ NO, I do not war	it my child's results. I do	o not want them mailed to me.	
		in furthering PFAS research ma	•
		Researchers would need to have	• • • • • • • • • • • • • • • • • • • •
protocol and compl	eted a Data Use Agreen	nent before MDHHS would sha	re your information with
them.			
May we share your	contact information (na	ame, address, phone number, e	email address) with outside
researchers who me	eet these standards?		
	7		
☐ YES			
□ NO			

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C.	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			
D. Researchers outside of MDHHS interested in furthering PFAS research may request remaining blood samples (if any are still available when study is completed). These samples will be de-identified, whi means that they will not have any identifying information connected to them. Researchers would not have an IRB-approved study protocol and completed Data Use Agreement before MDHHS would give them any remaining blood samples.  May we share your child's remaining blood samples that have been de-identified with outside researchers who meet these standards?				
	□ YES			

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

#### Access and use of your child's newborn blood spot from the Michigan BioTrust Health Program

This only applies if your child was l	born in the State of Michigan on or after October 1, 1987.
$\square$ YES, I permit MDHHS to access MiPEHS study.	my child's newborn blood spot from the Michigan BioTrust for the
•	access my child's newborn blood spot from the Michigan BioTrust for neck NO, please do not sign or complete anything else on this form.
Complete ONLY if you answered "YES" al	bove 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 MDHHS MiPEHS study team.	se of my child's newborn blood spot and accompanying data to the
Name of <b>legal guardian</b> (sign)	Date
Name of <b>legal guardian</b> (Print)	<del></del>

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

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)	

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

Health Tests						
Lipids Thyroid hormones		Blood sugar/Glycemic	Sex hormones			
- Total cholesterol - Triglycerides - Low-density lipoprotein (LDL) - High-Density Lipoprotein	<ul> <li>Thyroid     Stimulating     Hormone (TSH)</li> <li>Free Total     Thyroxine (Free     T4)</li> <li>Total Thyroxine     (TT4)</li> <li>Total     Triiodothyronine     (TT3)</li> </ul>	parameters  - Glycosylated hemoglobin (HbA1c)  - Glucose, fasting, 8-hour  - Insulin  - Glutamate Decarboxylase -65 (Anti-GAD 65)  - Tyrosine Phosphatase-like Protein Autoantibodies (Anti-IA2)	<ul> <li>Testosterone</li> <li>Estradiol</li> <li>Sex hormone-binding globulin (SHBG)</li> <li>Follicle Stimulating Hormone (FSH)</li> <li>Insulin Growth Factor (IGF-1)</li> </ul>			
Liver Tests						
<ul> <li>Alanine transaminase (ALT)</li> <li>Alkaline phosphatase (ALP)</li> <li>Gamma-glutamyl transferase (GGT)</li> <li>Non-alcoholic fatty liver disease: CK-18 M30 &amp; CK-18 M65</li> </ul>		- Aspartate transaminase - Albumin (Alb) - Total bilirubin (TBIL) - Direct bilirubin (Conjuga				

#### **Kidney Tests**

- Uric Acid
- Creatinine (to estimate glomerular filtration rate {eGFR})
  - E. Antibody/Autoimmune Titers Researchers outside of MDHHS interested in furthering PFAS research may request remaining blood samples (if any are still available when study is completed). These samples will be de-identified, which means that they will not have any identifying information connected to them. Researchers would need to have an IRB-approved study protocol and completed Data Use Agreement before MDHHS would give them any remaining blood samples.

May we share your child's remaining blood samples that have been de-identified with outside researchers who meet these standards?

Ig A, Ig G, Ig M, Ig E

For minors only: antibodies to measles, mumps, rubella, tetanus and diphtheria

Adults only: Rheumatoid factor (RF), Antinuclear Antibody (ANA) screen, Antinuclear Antibody (ANA)

titer