

Attachment 2

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
DIVISION OF ENVIRONMENTAL HEALTH**

**Biomonitoring of Persistent Toxic Substances
in Michigan Urban Fisheaters**

Informed Consent

For Repeated Clinic Screening

Attachment 4c Revised July 8, 2014

NOTE TO REVIEWERS

Readability has been calculated using the Fry Readability Formula for determining grade level at the 7th grade level when sentences containing agency names are omitted.



Biomonitoring of People Who Eat Fish Caught in Michigan

Adult Consent Form

Purpose of the Study - The Michigan Department of Community Health (MDCH) is working on a fish eaters study. Some fish from this area contain chemicals that can be found in the people who eat them.

The purpose of this study is to find out the amount of these chemicals in people who often eat these fish. We will also look at other ways that people can be exposed to these chemicals such as on the job, through diet, or from hobbies.

We will use the results of this study to help people make choices about eating fish from the {AOC1/AOC2} that are lower in chemicals. We will also use the results of this study to protect public health by improving Michigan's fish testing program and the Michigan Fish Advisory.

Last year, you participated in the study by answering a questionnaire and providing blood and urine samples. There was a problem with the laboratory equipment and your blood sample was damaged. I'm calling to ask if you are willing to come to another clinic to provide blood and urine samples again. We would also like to ask you the questions on the questionnaire again. We are asking you to repeat the entire clinic process so that all of your information will be current.

The study is supported by the Agency for Toxic Substances and Disease Registry (ATSDR). ATSDR is also funding Great Lakes Biomonitoring studies in New York and Minnesota.

Public reporting burden of this collection of information is estimated to average 1 minute per response for total participation, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road, MS D-74, Atlanta, GA 30333, ATTN: PRA (0923-0044).

The Chemicals - We will test your blood for chemicals often found in fish and soil in the areas where you live and fish. The chemicals most often found in fish are mercury, polychlorinated biphenyls (also called PCBs), and dioxins. We will test your blood and urine for these chemicals as well as lead, cadmium, manganese, and the pesticides toxaphene, mirex, hexachlorobenzene, and DDT/DDE. Some of these chemicals are no longer used. Some are still in use.

What to Expect During Your Appointment - Your appointment will take about two hours. When you arrive, you will be asked some basic questions such as your name, address, and date of birth. We will also measure your weight, height, and your blood pressure to be sure that you can safely give blood.

You will be asked to complete a questionnaire with one of the study staff. You will be asked about fish and other foods that you eat, about jobs that you have had, and other ways that you could come into contact with chemicals. We will also ask you questions such as the age of the house you live in, your education, and your hobbies. You will be given a \$25 gift card as a thank you for answering the questions. You can refuse to answer any of the questions that you do not want to answer.

Next, a medical professional will take 83 ml (about 5 1/2 tablespoons) of blood from a vein in your arm. Then, you will be shown to a private room and asked to provide a urine sample in a cup. You will be given another \$25 gift card as a thank you for your blood and urine samples. Finally, you will receive another \$25 gift card for completing both parts of the study, for a total of up to \$75 in gift cards.

What We Will Do with Your Blood and Urine - Your blood and urine will only be tested for the chemicals listed above.

We WILL NOT use your blood and urine for any other tests, including alcohol, drug, or DNA testing. All blood and urine will be destroyed at the end of the study.

Your Test Results - You can choose whether or not you want to receive your test results. If you want your results, we will send you a letter explaining them. You will receive your letter after all of the tests from everyone in the study have been completed. The letter will have a number for you to call if you have any questions.

If you want your test results and we find any results that show health concerns, we will contact you as soon as possible. If there are health concerns or problems with your results, we may also contact you to ask more questions. You can decide whether or not you want us to contact you and if you want to answer more questions.

This study will tell us

1. The amount of these chemicals that you have in your blood and urine, if any.
2. How similar levels of PCBs, dioxins, or pesticides in your blood or urine is similar to people your age who live in the United States.
3. If the level of mercury, arsenic, lead, cadmium or manganese in your blood or urine suggests you should see your doctor.

This study will not tell us

1. Where the chemicals came from, if they are found.
2. About chemicals in your blood or urine that we are not testing for.
3. If the amount of any of these chemical is harming your health.

Risks - We will make you as comfortable as possible. Having your blood drawn will be like a blood test done at your doctor's office. You may feel a small amount of discomfort during the blood draw and may later have a small bruise where the blood was drawn from.

Benefits - There is no cost to you for the tests on your blood and urine. You will receive a copy of your test results, if you want them. If you'd like, a copy will also be sent to your doctor. You will receive information on the health benefits and risks of eating fish and learn how to best protect your health. Your participation will also help us make decisions about how to protect the people in your community from exposure to these chemicals.

It's Your Decision - You can choose whether or not to be part of this study. During your appointment, you can stop at any time by telling the study staff that you do not want to be part of the study. You can refuse to answer questions or to give a blood or urine sample. You can choose to be removed from the study even after your appointment by calling Linda Dykema, Michigan Department of Community Health, at 1-800-648-6942.

Privacy - All of the information that you give us is private to the extent it is protected by Michigan law. To protect your privacy, we will store your answers and test results using a code number instead of your name. We will keep your records in locked files at the MDCH office in Lansing. Any computer files with your information will be securely kept. Only study staff will have access to your information and your test results.

Reports or academic articles may be written about the study results. These reports or articles will be available to the public after the study is finished. Any reports or articles that are written about this study will only talk about group results. They WILL NOT include information that could identify you, such as your name or address.

Contact Person - If you have any questions about the study, or decide that you do not want to participate, please contact:

Susan Manente
Michigan Department of Community Health
P.O. Box 30195
Lansing, Michigan 48909
Direct: 517-335-9003
Toll-free: 1-800-648-6942

If you do not understand what we are asking you to do, please ask questions. If you have no questions and if you agree to be in this study, please sign the consent form below.

PARTICIPANT CONSENT

I have read and/or been told about the purpose of the study. I have been given a chance to ask questions and my questions have been answered. I have been given a copy of this form. I choose to take part in the study. By signing this consent form, I agree to take part in Biomonitoring of Persistent Toxic Substances in Michigan Urban Fisheaters Study.

May we contact you in the future if we have additional questions? At that time we will ask you for your consent again.

YES _____ NO _____

Participant Name (Print)

Participant's Signature _____ Date

If you do not want a written report of your exam results, check this box.

If you would like a copy of your test results to be sent to your doctor, please give us your doctor's name and address below:

Name: _____ Telephone Number: _____

Address: _____

Attached to Contact Information Sheet - Contact Information is verified after the Informed Consent form is signed by the participant and before the biomonitoring interview begins.

Script: I also need to verify we have the correct contact information for you. Would you look at this sheet to see if we need to make any changes in your phone, address, or email address?

*If information is correct, write "No corrections" on the Contact Information sheet and initial it. Attach it to the Participant Consent signature page. **Okay. Let's move on to the questionnaire.***

*If information is incorrect, write the corrections on the Contact Information sheet and initial it. Attach it to the Participant Consent signature page. **Okay. Let's move on to the questionnaire.***