

Attachment 6a. Consent Form for Licensed Anglers

**Wisconsin Department of Health Services
Milwaukee Angler Project
Participant Information and Consent Form
Licensed Anglers**

Title of the Project Biomonitoring Legacy and Emerging Great Lakes Contaminants in Susceptible Great Lakes Populations (“Milwaukee Angler Project”)

Principal Investigator: Jonathan Meiman, M.D. (phone: 608-266-1253)

OVERVIEW

The Wisconsin Department of Health Services (DHS) invites you to be in a project to measure chemicals in people who eat fish from certain lakes, rivers, and streams in or near Milwaukee. This project is funded by the Agency for Toxic Substances and Disease Registry (ATSDR).

You are being asked to participate in this project. Your participation is your choice. This consent form will tell you more about the project so you can decide if you want to participate. Please ask questions if there is anything you do not understand.

The purpose of this project is to measure the levels of chemicals in people who eat fish caught from the lakes, rivers, streams, and ponds in Milwaukee and the surrounding southeastern area of Wisconsin. We also want to know how people might be exposed to these chemicals. We can do this by looking at what types of fish and how much fish people eat, as well as hobbies, jobs and other food that might lead to exposures.

We will use the results of this project to guide actions that will protect people from exposure to chemicals in the environment.

WHY ARE YOU BEING ASKED TO BE IN THIS PROJECT?

You were chosen at random from the Wisconsin Department of Natural Resources license database and you completed a screening survey. In the screening survey you said that you have lived at the address on your license for at least one year; that you ate at least one fish caught from one of the lakes, rivers, or streams of interest in the past year, that you are age 18 years or older; and (if female) that you are not pregnant.

WHAT ARE WE ASKING YOU TO DO?

If you choose to be in this project:

- We will ask you to complete a questionnaire. You can complete the questionnaire online via secure web link or on paper before your appointment. Alternatively, you can complete the questionnaire at your appointment. The questionnaire will ask you about where you have lived, jobs you have had, your use of tobacco, your outdoor activities and hobbies, fish and other foods you eat, your education and income, your health, and (for women) the number of children you breastfed.
- We will collect a blood sample. A person trained to draw blood will make sure that it is safe for you to give blood, and will collect about 60 mL (about 4 tablespoons) of blood from a vein in your arm. You can refuse to give a blood sample and still be in this project.
- We will ask you to collect 50-100 ml (about a half cup) of urine in a cup. You will do this in a private restroom. You can refuse to give a urine sample and still be in this project.
- We will ask you to give a small hair sample (3 cm from the back of your head). The hair sample will not be tested for this project, but instead will be kept in a secure location by DHS for future testing. This hair sample may be tested for chemicals at a later date. There is a place at the end of this form for you to tell us if you want to give this sample or not. If you want to give a hair sample, you can choose to be asked again before DHS can test the sample. You can refuse to give a hair sample and still be in this project.
- We will measure your height, weight, and waist size.

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- We will measure your blood pressure.
- We will ask you to take a brief follow-up survey after you have received your blood and urine test results

HOW MUCH TIME WILL THIS TAKE?

It will take around a half hour to do the questionnaire. It will take a little more than a half hour to take your measurements, and collect blood and urine samples during your appointment.

WHAT WILL YOUR BLOOD AND URINE BE TESTED FOR?

Your blood and urine samples will be collected at the project appointment location. We will look for chemicals in your blood and urine that are often found in fish and soil near Milwaukee. These chemicals may harm your health. The chemicals are:

- Polychlorinated biphenyls (PCBs)
- Perfluorinated chemicals (PFCs)
- Metals (mercury, lead, cadmium, manganese, selenium)
- Persistent pesticides (hexachlorobenzene, beta- and gamma-hexachlorohexane, oxychlordane, trans-nonachlor, Mirex, dichlorodiphenyltrichloroethane (DDT), dichlorodiphenylchloroethylene (DDE))
- Polycyclic aromatic hydrocarbons (PAHs)

We will also measure lipids (cholesterol and triglycerides) in your blood. This will help us understand the results for chemicals found in the fat in the blood. We will also measure creatinine in your urine. This will help us understand the results for chemicals found in urine. Lipids and creatinine are normal substances found in your body.

We will also ask for your permission to keep your leftover blood and urine samples. The samples would be tested in the future if any new chemicals are found in the Great Lakes, or if new lab tests are developed to measure chemicals. We would keep your samples for up to 10 years. Samples would be kept in a locked freezer at the Wisconsin State Laboratory of Hygiene in Madison, Wisconsin. Your samples would only be identified by your project identification number. Only staff involved in this project will have access to them. You will be able to tell us at the end of this consent form if you give us permission to keep your samples, or if you would like them to be destroyed at the end of this project. If you give us permission to keep them, you can also let us know if you would like us to re-ask you before testing your stored samples in the future.

We will never do any tests for diseases or genetics with your samples.

WILL YOU GET THE RESULTS FROM THE BLOOD AND URINE TESTS?

You will receive your blood and urine results by mail 6 to 9 months after your appointment. These will include results for all the chemicals listed above: PCBs, PFCs, metals, persistent pesticides, PAHs, lipids and creatinine. You may also receive information to help you make choices about eating fish from Wisconsin lakes and rivers.

If we find that certain chemical levels, such as lead, are very high, we will send you a separate letter as soon as possible. The letter will have your results and tell what you can do to bring your level down or keep it from getting higher.

ARE THERE ANY RISKS TO BEING IN THIS PROJECT?

You may feel a slight sting or "pinch" in your arm when the blood is drawn. You may also get a small bruise that should go away after 2 or 3 days. Some people may faint, but this is uncommon.

Filling out the questionnaire may be stressful if you have to remember events that are upsetting to you. You are free to skip any question for any reason.

There are no risks from giving urine or having your weight, height, waist, and blood pressure measured.

Emergency care will be available if you are physically injured as a result of participating in this project. You will be responsible for the cost of the emergency care. There is no commitment to provide any compensation for project-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the investigator, Dr. Jon Meiman at 608-266-1253 if you are injured or for further information.

WHO WILL SEE THE INFORMATION YOU GIVE TO THE PROJECT TEAM?

All your information (including your name and address, this form, your interview answers, and your blood and urine test results) will be secure. We keep track of your information using a code number, instead of your name. Paper records are stored in locked cabinets. Electronic records are stored on password-protected computers. Only project staff will be allowed to look at the paper and electronic records. Project records will be shared with ATSDR, but your name and personal information (like your address) will be removed. Any reports or presentations using information from this project will be grouped so that no one can be identified.

If project staff witness illegal activities such as child abuse, they will disclose this information without your consent as required by law.

ARE THERE ANY BENEFITS TO BEING IN THIS PROJECT?

You will get the results of your blood and urine tests and learn what they mean. There will be no other direct benefits to you. Participating in projects like this can help researchers better understand your community.

WHAT IS THE COST TO YOU AND WHAT WILL YOU RECEIVE?

The only cost to you is your time and effort to take part. We will give you up to \$60 in gift cards as a “thank you” if you complete the questionnaire, body measurements, and give blood and urine samples. If you do not complete all of these activities we will give you a lesser amount based on the activities you do complete. Your choice to give a hair sample does not change the value of the gift cards you receive.

WHO SHOULD YOU CONTACT IF YOU HAVE QUESTIONS?

You may ask any questions about the project at any time. If you have questions about the project, contact the Project Manager, Brooke Thompson, at 608-261-9325.

If your questions still aren’t answered or you want to talk with someone about your rights as a participant, call the UW Hospital and Clinics Patient Relations Representative at 608-263-8009, or the University of Wisconsin Medical Foundation Patient Relations Representative at 800-552-4255 or 608-821-4819.

WHAT SHOULD YOU DO AFTER READING THIS INFORMATION?

If you do not understand what we are asking you to do, please ask questions. After all your questions have been answered and if you want to be in this project, please sign the consent form on the next page. You will receive a copy of this form for your records.

Your participation is your choice. If you start the project and change your mind later, you can stop at any time without penalty. You may ask us to destroy any unused or stored blood, urine, or hair.

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WISCONSIN DEPARTMENT OF HEALTH SERVICES

Consent to Participate

I have read the above information about the Milwaukee Angler Project. I have been allowed to ask questions and I had all my questions answered. I have been given a copy of this consent form.

1. I would like to participate in the project.

(check one box)

Yes

No

2. I give Wisconsin DHS permission to store any leftover blood and urine samples for future testing.

(check one box)

Yes, and I do not need to be contacted before testing my stored blood or urine for other chemicals.

Yes, but contact me before testing my stored blood and urine for other chemicals.

No, please destroy all of my leftover blood and urine samples.

3. I will provide a hair sample and give Wisconsin DHS permission to store my hair sample for future testing.

(check one box)

Yes, and I do not need to be contacted before testing my stored hair sample for other chemicals.

Yes, but contact me before testing my stored hair sample for other chemicals.

No, I will not provide a hair sample.

4. I give Wisconsin DHS permission to contact me if future project opportunities arise.

(check one box)

Yes

No

Name of Participant (*please print*): _____

Signature: _____ Date: _____

Person Obtaining Informed Consent (*please print*): _____

Signature: _____ Date: _____