

Informed Consent Form for Bhutanese and Burmese
New York State Department of Health
The Healthy Fishing Community Project in Syracuse, NY

October 21, 2014

Revised June 1, 2015

Readability, calculated using the Flesch-Kinkaid Readability Option in Microsoft Word, has been determined at the 7th grade level without chemical names

Overview

The New York State Department of Health (NYS DOH) in cooperation with the Agency for Toxic Substances and Disease Registry (ATSDR) invite you to be in a project to measure pollutants in people who eat fish from Onondaga Lake and its tributaries, Seneca River, Oswego River and Lake Ontario.

You are being asked to participate in this project. Your participation is voluntary. After you read about the project and before you decide to participate, please ask questions if there is anything that you do not understand.

What is the purpose of this project?

The purpose is to measure the levels of contaminants in people who eat fish caught from New York Great Lakes and rivers. The areas of interest are Onondaga Lake and its tributaries, Seneca River, Oswego River and Lake Ontario. To help us understand the results, we want to know what types of fish and how much fish people eat and other ways that people can be exposed to these pollutants, such as at their jobs and from eating other foods.

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

Why are you being asked to be in this project?

You are being invited to participate because you are from Burma, Bhutan or Nepal or are related to someone from one of these countries, you have received a referral coupon from someone you know, you have lived in or near Syracuse for at least one year, and you eat fish caught in certain lakes, rivers, and creeks. NYS DOH hopes to get about 300 people from Burma, Bhutan or Nepal who eat fish.

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-XXXX).

What are we asking you to do?

If you choose to be in this project:

- We will ask you a few questions to be sure that you can safely give blood. A person trained to draw blood will collect about 30 ml (about 2 tablespoons) of blood from a vein in your arm.
- You will be asked to provide 50-100 ml (about ½ cup) of urine in a cup. You will do this in private in a restroom.
- We will measure your height and weight.
- We will interview you. The interview will take about 45 minutes. During the interview we will ask you questions 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, and (for women) the number of children you breastfed.
- At the end of the interview we will ask you if you want to help find three more people from Burma, Bhutan or Nepal to be in the project. If you want to do this, we will teach you what you need to know.

How long will this take?

It will take about 1 hour to finish everything.

What will my blood and urine be tested for?

We will look for contaminants in your blood and urine that are often found in fish and soil in and around the areas that we are looking at. If you participate, laboratories at NYS DOH will test your blood and urine samples for the following contaminants:

- Polychlorinated biphenyls (PCBs)
- Polybrominated diphenyl ethers (PBDEs)
- Perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS)
- DDT, DDE, Mirex, hexachlorobenzene, toxaphene, chlordane, oxychlordane and trans-nonachlor (these two are chemicals produced by the body as it gets rid of chlordane)
- Mercury, lead, cadmium

Since some contaminants are found in the fat in blood, we will also measure the lipids (cholesterol and triglycerides) in your blood. For chemicals that are measured in urine, we will measure the creatinine in your urine. Lipids and creatinine are normal substances found in your body.

We would like your permission to store your leftover blood and urine and to test your blood for two contaminants (dieldrin and Dechlorane Plus) and one nutrient (omega-3 fatty acids). These tests are still being developed. We will not use your stored blood or urine for genetic testing.

New contaminants may be found in Great Lakes water bodies and new tests may be developed to measure Great Lakes contaminants. We need to know if we may use your blood and urine to test for additional Great Lakes contaminants in the future.

Are there any risks or discomforts to you if you decide to be 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. Some people may faint, but this is rare.

The interview may be stressful if you have to recall 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 and height measured.

Are there any benefits to you from being in this project?

You will be sent the results of some of your blood and urine tests and what they mean. There will be no other direct benefits to you from being in this project.

Who will see the information you give the study team?

All information about you (including your name and address, this form, your interview answers, and your blood and urine test results) will be kept secure. We keep track of your information using a code number rather than your name. We will keep paper records in locked files and electronic records are stored on password protected computers at the NYS DOH. Only staff working on the project will be allowed to identify you if NYS DOH needs to contact you. We can also share your results with your doctor if you ask us to. When the information is shared with ATSDR, your name and other information that may point to you will be removed. Any reports or presentations using the information from this project will be grouped so that no one can be identified.

What is the cost to you and what will you receive?

The only cost to you for being in our project is your time and effort to take part. We will give you a \$75 gift card as a thank you for your participation. If you want to help find up to three more people to be in the project, people now living in this area who are originally from Burma, Bhutan or Nepal and who eat fish from nearby waters, you will also get a \$15 gift card for each person who takes part in the study.

Will you get the results from your blood and urine tests?

We will send you the results from some of your blood and urine tests. We cannot send you the results for some of the tests because there is little or no information right now about what the results mean.

You will get results for the following tests: polychlorinated biphenyls (PCBs), DDT, DDE, hexachlorobenzene, toxaphene, oxychlorane, trans-nonachlor, mercury, lead, cadmium, cholesterol and triglycerides.

We can also send a copy to your doctor if you ask us to. The letter will have the numbers you can call if you have any questions.

If your levels require follow up, someone from the Department of Health will call you. We will also talk to you to help you figure out why your levels might be higher than average, and give

you advice about what to do. You may receive some information that will help you make choices about eating fish from New York lakes and rivers.

What are your choices about participating?

Your participation in this project is voluntary. You are free to be a part of it or not. You can refuse to have your blood drawn, give a urine sample, or answer any interview questions. You can choose to leave at any time, even after you have signed the consent form. You may ask us to destroy any unused or stored blood or urine. If you don't participate or if you drop out, nothing else will be affected (such as your medical care).

Who should you contact if you have questions later on?

If you have any question about the project or wish to drop out, please contact:

Sana Savadatti
Project Coordinator
New York State Department of Health
Center for Environmental Health
518-402-7950

For questions about your rights as a study participant, please contact:

Tony Watson
New York State Department of Health
Institutional Review Board
518-474-8539

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 to your satisfaction and if you want to be in this project, please sign the consent form on the next page.

I have read the above information about the Healthy Fishing Community Project in Syracuse, NY 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.

If you could not read any of the translated consent forms: Signing this document means that the project, including all the above information, has been described to you orally, and that you voluntarily agree to participate. You have been allowed to ask questions and had all your questions answered. You have been given a copy of this consent form.

1. I would like to participate in the project.

(Check one box.)

Yes Go to #2.

No

2. Two contaminants and one nutrient listed above can't be tested right away because the laboratory test is still being developed. I give NYS DOH permission to store my leftover blood and urine to do these tests later.

(Check one box.)

Yes Go to #3.

No Sign this form.

3. In the future, other contaminants may be found in Great Lakes water bodies and new tests may be developed to measure Great Lakes contaminants. I give NYS DOH permission to store my blood and urine to test for additional Great Lakes contaminants in the future. Your stored blood or urine would only be used for the purpose of measuring levels of contaminants in people who eat fish caught from New York Great Lakes and rivers.

(Check one box.)

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

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

No

Participant's name (Print)

Participant's signature

Date

I read this consent form to the prospective participant in a language which he/she understands. The prospective participant was given a chance to ask questions, appeared to accept the answers, and signed to enroll in the study.

Signature of interpreter/ person obtaining consent

Date