

Attachment 5c. Minnesota Informed Consent Brochure and Form



Fond du Lac Community Biomonitoring Study

Fond du Lac Public Health Nursing Department
Fond du Lac Human Services Division



INFORMED CONSENT BROCHURE

This brochure gives information about the Fond du Lac (FDL) Community Biomonitoring Study. If you are interested in being in the study, you should read this information before deciding whether or not to participate.

This brochure describes the study purpose, what you will be asked to do, and the chemicals your blood and urine will be tested for. You will read about your rights and privacy, risks and benefits of being in the study, and how study results will be used.

This information is summarized in the Individual Consent Form for the study.

WHAT IS THE PURPOSE OF THIS STUDY?

We are surrounded by chemicals that enter our bodies through food, air, water, soil and dust. The purpose of the biomonitoring study is to measure some of these chemicals in FDL Community members. "Biomonitoring" is one way to do this.

Other biomonitoring studies have shown that most people have small amounts of chemicals that might be harmful in their bodies. Some people may have more contact with certain chemicals because of where they live or what they eat. For example, fish and wild game may contain more mercury than other foods.

This study will identify:

- 1) the amount of certain environmental chemicals in the blood and urine of the FDL Community;

BIOMONITORING IS MEASURING CHEMICALS IN PEOPLE. WE WILL TEST BLOOD AND URINE IN THIS STUDY.

It is a tool that can tell people about their exposures to chemicals in the environment that may be harmful.

By taking part in this study, you can help the FDL Community learn about their exposures to chemicals in the environment.

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- 2) how the amounts of these chemicals in the FDL Community compare with amounts found in other communities; and
- 3) how FDL Community members may have contacted the chemicals through food, jobs, or where they live.

Study results will tell people about their exposures to chemicals in the environment. Summary results will provide a baseline “snapshot” for the FDL Community.

FDL Public Health Nursing and the Minnesota Department of Health (MDH) will do this study with funding from the federal Agency for Toxic Substances and Disease Registry (ATSDR).

WHO CAN TAKE PART?

Randomly chosen members of the FDL Community will be invited to be in the study. Anyone who used FDL Human Services between (yyyy) and (yyyy) and meets the requirements shown below has an equal chance of being asked to take part:

- Native American
- 18 years or older
- Not pregnant
- Has lived in the study area for the past 12 months; and
- Medically able and willing to give a blood and urine sample for testing of environmental chemicals.

The goal is to have 500 people in the study. The more people who agree to participate, the more useful study findings will be to the whole FDL Community.

WHAT WILL I HAVE TO DO?

If you decide to be in the study, an appointment will be made at Min No Aya Win. At the clinic, staff will:

- ❖ Explain the study and what you will be asked to do.
- ❖ Answer your questions so you feel satisfied that you know enough about the study to take part.
- ❖ Ask you to sign an Individual Consent Form (a copy is provided with this brochure) to show that you understand what you will do and agree to take part.

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- ❖ Measure your height, weight, waist, and blood pressure.
- ❖ Take about 3 tablespoons (1 ½ ounces) of blood from your arm and ask you to collect some urine in a cup.
- ❖ Ask you some questions that may help explain the amounts of the chemicals present in your body. You can refuse to answer any question that makes you uncomfortable.

HOW MUCH TIME IS NEEDED TO BE IN THE STUDY?

You will have to travel to Min No Aya Win for one appointment. For most people, the appointment will take about 1½ to 2 hours.

WHAT WILL BE TESTED FOR IN MY BLOOD AND URINE?

Blood or urine will only be tested for the environmental chemicals listed in Table 1 (next page). These were chosen because of their presence in the area around Lake Superior and northern Minnesota.

ONLY THE CHEMICALS SHOWN IN TABLE 1 (PAGE 4) will be measured. We will not measure controlled or illegal substances or drugs. We will not do any genetic (DNA) testing.

At the bottom of Table 1 are a few other measures related to general health. Blood will be tested for selenium and omega-3 fatty acids. We will measure blood pressure, cholesterol, and hemoglobin A1C to see if you are at risk for diabetes or cardiovascular disease. No other tests will be done on blood or urine. Any left-over blood and urine will be destroyed.

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Table 1: What We Will Measure in Blood and Urine (table has 7.2 reading level)

| Environmental Chemical | What is it? How are we exposed? |
|---|--|
| Cadmium | A metal. Most exposure occurs through food or cigarette smoking. |
| Mercury | A metal. Most likely to be exposed by eating fish. |
| Lead | A metal. People may be exposed through air, soil, house dust, food, drinking water, and consumer products. |
| Mirex | A pesticide and flame retardant (currently banned). Most likely to be exposed by eating fish. |
| Hexachlorobenzene | A pesticide (currently banned). Also a waste product from some industries and trash burning. Most exposure is through food, especially fish. |
| DDT and DDE | A pesticide and its breakdown product (currently banned). Most exposure is through food, especially meat and dairy. |
| Toxaphene | A pesticide (currently banned). Exposure is mainly through food, particularly fish. |
| Polychlorinated biphenyls (PCBs) | A group of industrial chemicals (currently banned). Most exposure occurs through food. |
| Hydroxypyrene | One in a group of chemicals called polycyclic aromatic hydrocarbons (PAHs). Exposure may occur from tobacco smoking, breathing indoor and outdoor air, and eating char-broiled meats and fish. PAHs are also contaminants of concern at local Superfund sites. |
| Perfluorinated compounds | A group of chemicals used in products to resist heat, stains, or moisture. Exposure may occur through food, drinking water, and contact with consumer products. |
| Bisphenol A | A chemical found in plastics and food/beverage can linings. Most exposure likely occurs through food. May be present in Minnesota surface water. |
| Triclosan | A chemical found in consumer and personal care products. |
| Cotinine | Formed when body breaks down nicotine. Used to determine if PAHs, cadmium, and other chemicals in the body are from the environment or tobacco products. |
| Used by Doctors to Check Your Health or Diet | |
| Selenium | Essential mineral in our diet. Fish are high in selenium. |
| Polyunsaturated fatty acids | Beneficial chemicals in fish and plant/seed/nut oils. Essential for brain function and normal growth and development. Important for cardiovascular health. |
| Creatinine | A natural by-product in the body, used to interpret the level of chemicals in urine. |
| Glycohemoglobin (A1C) | Used to determine if you are at risk for diabetes. |
| Total cholesterol | Used to determine if you are at risk for heart disease. |

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WHAT ARE THE RISKS OF BEING IN THE STUDY?

Clinic staff will use a needle to take blood. This can cause discomfort for some people. Some people may feel faint or dizzy. A person will quickly replace the amount of blood that will be taken. Sometimes, a bruise or small blood clot appears at the place where the needle entered the skin.

If you have a bleeding disorder, are undergoing chemotherapy, or are taking a blood thinner, you should talk to your health care provider before taking part.

You are responsible for any follow-up care if you are injured in this study. FDL Public Health Nursing, MDH, or ATSDR cannot provide compensation to a person injured while taking part in the study.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

We will send you the results of your body measurements and blood and urine tests, unless you tell us not to. Your results will tell you the amount of chemicals in your body and how they compare to others.

WHEN WILL I GET MY RESULTS?

As soon as possible, you will find out:

- ❖ If your blood pressure, cholesterol, or hemoglobin A1C results show you may be at risk for diabetes or cardiovascular disease.
- ❖ If mercury, cadmium, or lead levels in your blood indicate a potential concern for your health.

If you choose to, at the end of the study you will learn:

- ❖ The amounts of all chemicals measured in your blood and urine. If you have questions about your results, you can talk to a nurse working with the study.
- ❖ Ways to help keep chemicals out of your body and protect your health.

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WHAT ARE THE COSTS TO ME?

The only cost to you for being in the study is the cost of getting to Min No Aya Win and the time you spend there. As a thanks for taking part, you will receive \$25 in gift cards for the blood and urine collection. You will receive another \$25 in gift cards for the interview and body measures. You will be offered another \$25 in gift cards if you complete all parts of this study. The gift cards can be used anywhere. If staff at the clinic decide you cannot give blood, we will give you a \$25 gift card to thank you for your interest but you won't be in the study.

If you need transportation to and from your appointment, please contact Rebecca Provost at Min No Aya Win (218) 879-1227.

HOW WILL STUDY FINDINGS BE USED?

By taking part in this study, you will improve knowledge about exposures to chemicals in the area around Lake Superior and northern Minnesota. Your participation will benefit the FDL Community by adding current information about environmental chemicals in people.

Your results from blood and urine testing will be shared with you. Besides FDL study staff, no one will be able to link your name with your study results or interview answers. At the end of the study, your results and interview answers will be shared with ATSDR but not your name or any personal information.

Everyone has some amount of these chemicals in their bodies. For some chemicals, we know if the amount measured could be harmful to your health. For others, we will not be able to say much about what your results mean for your health because, at this time, there is not enough information to know whether certain levels in the body are safe.

The Fond du Lac Human Services Division owns the data it collects on you. Summary results will be shared with the FDL Community, who will use them to:

- ❖ Learn how chemicals in people may be related to food and activities in the environment.
- ❖ Create a community Public Health Action Plan to provide guidance on how to keep chemicals (if found) out of people's bodies.

Summary results may be reported in journals, at scientific meetings, or through other media. No information that could identify any single person will ever be released.

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PRIVACY OF RECORDS/DATA

Study staff respect the privacy of all people in the study. By law, all information gathered for this study must be kept safe and secure. No personal information will be attached to blood or urine samples, testing results, body measurements, or your interview answers. Only FDL study staff will be able to match people's identities with their answers or results. They will do this only to communicate with participants and give them their results. Unless you give FDL permission to contact you in the future (see below), we will permanently break all links between your name and your results when the study ends.

You will be asked to sign the Individual Consent Form -- a copy is attached with this brochure -- so you can read it before your appointment. Please let study staff know if you have any questions about the Consent Form or the information in this brochure.

Other than study staff at FDL Public Health Nursing, no one will know how you answered the interview questions or what your personal results were.

VOLUNTARY PARTICIPATION

It is up to you whether or not you take part in the study. You may leave the study at any time without loss of any benefits to which you may be entitled. Your choice whether to participate or to quit the study at any time will not affect your current or future relationships with Fond du Lac, MDH, or the federal government.

PERMISSION FOR FUTURE CONTACT

FDL Human Services staff may want to ask you to be part of future studies. We can only do this if you say we can contact you. If you would like to hear about future studies, check "Yes" to the statement "I agree to be contacted by FDL HSD for future studies" on the Consent Form. If you check "No," we will remove all your personal information from study records when the study ends.

CONTACTS AND QUESTIONS

If you have questions or concerns about the study, please contact:

Rebecca Provost

Attachment 5c (MN Appendix 6.6). Informed Consent Brochure and Form

7.8 reading level

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Biomonitoring Project Manager

218-879-1227

RebeccaProvost@FDLREZ.com

If you would like to talk to someone about your results, you can call Bonnie LaFromboise, the Public Health Nurse Consultant for the study. She will answer your questions and let you know if you should follow up with your health care provider.

Bonnie LaFromboise

Public Health Nurse Consultant

218-878-2132

BonnieLaFromboise@FDLREZ.com

If you have questions about your rights, call Crystal Greensky, Research Supervisor/Assistant Clinic Administrator at Fond du Lac Human Services Division (218-878-3759).

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Study ID

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Form Approved

OMB No. 0923-XXXX

Exp. Date xx/xx/20xx

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INDIVIDUAL CONSENT FORM

Fond du Lac (FDL) Human Services Division (HSD) and the Minnesota Department of Health (MDH) are partners on this study. Funding is from the federal Agency for Toxic Substances and Disease Registry (ATSDR).

Purpose – This study will measure some chemicals in people’s blood and urine. These chemicals could be in air, water, dust, soil, or food.

What we will ask you to do – We will ask you to: 1) come to Min No Aya Win; 2) let staff take your height, weight, waist size, and blood pressure; 3) give blood and urine samples; and 4) answer interview questions. It will take 1½ -2 hours.

Giving blood and urine – Clinic staff will take about 3 tablespoons of blood from your arm. You will go to a private restroom to give some urine in a cup.

Interview – The interview will last about a half hour. We will ask about: where you have lived; recent jobs; hobbies; fish and other foods you eat. We will ask about education and income. We will ask women if they gave birth or nursed in the last year. Your answers will tell us many things. We want to know if people are in contact with these chemicals from the environment.

Tests – We will test your blood and urine for chemicals that may be in air, water, dust, soil, or food. We will also test for a few measures of general health. Table 1 (page 4) lists these tests.

Blood and urine will NOT be tested for drugs or alcohol. No genetic (DNA) testing will be done. All blood and urine will be destroyed at the end of the study.

Sharing results – We will mail all your results to you, unless you tell us not to. You will get your results for diabetes and heart health within a few weeks. If mercury, lead, or cadmium are high, you will get these results quickly too. We will send you the rest of your own results after everyone’s samples have been tested.

A summary of study results will be shared with the public. This will only happen after FDL HSD approval.

Public reporting burden of this collection of information is estimated to average 3 minutes per response, 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 a 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 Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0923-XXXX).

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Risks - You might feel a slight sting or "pinch" when we take your blood. You may get a small bruise. Some people may feel dizzy or faint.

Benefits - Getting your own results can be helpful. You will know more about the amount of chemical in your body. You can compare your results to others. For some chemicals, we know if the level we find could harm your health. For others, we cannot say if your results are good or bad for your health. At this time, we don't know if some amounts in the body are safe.

Privacy protection - All information about you is private. Study records will be in locked files or password-protected computers at FDL HSD and MDH. Only study staff at FDL-HSD will be able to see information about you.

We will share test results and interview answers with ATSDR. We will not give them any information that could identify you. Personal information will not leave FDL HSD.

FDL HSD may want to tell you about future studies. If you give permission, FDL will keep your contact information in a secure file. If you do not, we will remove all your personal information from study records when the study ends.

Costs - The only costs are your time and any travel expense. To thank you, we will give you up to \$75 in gift cards if you do all parts of the study. If clinic staff cannot take your blood, you will get a \$25 gift card, but cannot be in the study.

Taking part is your choice - You choose to be in the study or not. You may refuse any part or quit at any time. You will not lose benefits if you do not take part or quit the study. Your choice will not affect your relationship with or services from FDL HSD, MDH, or the federal government.

Questions- For more information, you may call Rebecca Provost at Min No Aya Win at 218-879-1227. You may also call Dr. Deanna Scher of MDH at 651-201-4922 or toll free 1-800-657-3908.

If you have questions about your rights, call Crystal Greensky, Research Supervisor/Assistant Clinic Administrator at Fond du Lac Human Services Division (218-878-3759).

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INDIVIDUAL CONSENT FORM

By marking the boxes and signing below, you are saying you had a chance to ask questions about the study and freely choose to take part in it. You are also saying that you will allow study staff to collect, store, and share your study information as described above. You may keep a copy of this form.

I have read and understand the information in the Consent Form. Yes No

I choose to give body measurements, blood and urine samples, and answer interview questions. Yes No

I agree to be contacted by FDL HSD for future studies. Yes No

If you do NOT want a written report of your lab results, check here.

Name (print) _____

First *Middle* *Last*

Signature *Date*

Study staff

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Table 1: List of what will be tested in blood and urine.
 (also in Consent Brochure)

| Chemical in the Environment | Tests for General Health |
|---|--|
| 1-Hydroxypyrene Bisphenol A (BPA) Cadmium Cotinine DDT and DDE Hexachlorobenzene | Cholesterol Hemoglobin A1C |
| Lead Mercury Mirex Perfluorinated chemicals (PFCs) Polychlorinated biphenyls (PCBs) | Nutrients Selenium Polyunsaturated fatty acids |
| Toxaphene Triclosan | Chemical used to understand urine results Creatinine |