

Appendix 5c (MN 6.7). Individual Consent Form

5.4 reading level without Table 1 and burden statement

6.5 reading level with Table 1 and burden statement

Study ID

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Form Approved

OMB No. 0923-XXXX

Exp. Date xx/xx/20xx

NAME TBD

Fond du Lac Community Biomonitoring Study

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 Clinic; 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 1-2 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 the FDL HSD approves.

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 \$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 **NAME** at Min No Aya Win at **XXX-XXX-XXXX**, Mon.-Fri., **H:MM AM-H:MM PM**. You may also call Dr. Deanna Scher of MDH at **1-800-XXX-XXXX**, Mon.-Fri., **H:MM AM-H:MM PM**. This is a toll-free call.

If you have questions about your rights, call the Institutional Review Board at FDL (218-878-2134) or MDH (651-201-5942). Leave your name and phone number. Say the call is about the Fond du Lac Biomonitoring Study. Someone will call you as soon as possible.

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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 Lead Mercury Mirex Perfluorinated chemicals (PFCs) Polychlorinated biphenyls (PCBs) Selenium Triclosan	Cholesterol Hemoglobin A1C Omega-3 fatty acids
	Chemical used to understand urine results
	Creatinine