FISH Project Protocol and Procedures Manual

The FISH Project: Fish Are Important for Superior Health

January 2015



Cook County North Shore Hospital Grand Portage Health Service Grand Portage Trust Lands Minnesota Department of Health Sawtooth Mountain Clinic

Table of Contents

Acronyms	3
ntroduction	4
itaff Training	7
Project Promotion	8
/isit One	. 12
/isit Two	. 29
Appendices	.31

Acronyms

µg/L	micrograms per liter
CCNSH	Cook County North Shore Hospital
сос	chain of custody (form)
EHR/PM	Electronic Health Record/Practice Management
EPA	U.S. Environmental Protection Agency
FAQ	frequently asked questions
FISH	Fish are Important for Superior Health
GLRI	Great Lakes Restoration Initiative
GPHS	Grand Portage Health Services
ΙΑΤΑ	International Air Transport Association
MDH PHL	Minnesota Department of Health Public Health Laboratory
MDH	Minnesota Department of Health Fish Consumption Advisory Program
mL	Milliliter
Ppt.	participant
RfD	(EPA) reference dose
SMC	Sawtooth Mountain Clinic

Introduction

Background

The **Fish are Important for Superior Health (FISH) Project** (EPA title, "Reducing Mercury in Great Lakes Fish Consumers in Minnesota") is an intervention project to reduce mercury exposure in women aged 16 to 50 living in or near Cook County, Minnesota, on the North Shore of Lake Superior. The intervention will be implemented by health care providers at the Sawtooth Mountain Clinic in Grand Marais and the Grand Portage Health Service in Grand Portage, Minnesota, with assistance from laboratory staff at the Cook County North Shore Hospital.

Women who participate in FISH will learn about the risks and benefits of eating fish, and how to enjoy the health benefits of fish consumption while reducing their exposure to mercury. They will also learn their own mercury and fatty acids levels; this will help to inform their future fish choices. The Project will produce an in-clinic mercury screening tool and educational materials for health care providers and their patients. These intervention materials will be available for use in clinics throughout the Great Lakes Basin.

FISH was proposed and funded in response to the EPA-funded 2007-2011 <u>Mercury in Newborns in the</u> <u>Lake Superior Basin</u> study. Mercury in Newborns was conducted by MDH in collaboration with state newborn screening programs in Minnesota, Wisconsin, and Michigan. To be eligible for the study, the mother of the newborn had to live in one of the three participating states and in the Lake Superior Basin. Mercury in Newborns showed that ten percent of Minnesota newborns (three percent in Wisconsin, none of the Michigan newborns) who were tested had mercury levels above the reference dose for methylmercury (5.8 μ g/L) set by U.S. EPA. These data suggest that a significant number of northern Minnesota women were eating more high-mercury fish than was healthy for their babies.

The fetus and young children are most at risk from exposure to mercury, so FISH was designed to intervene with women of childbearing age. Because health care providers are considered a reliable source of health-related information, FISH was designed as an in-clinic intervention. MDH approached the Sawtooth Mountain Clinic and leadership of the Grand Portage Band of Chippewa Indians in Grand Portage. Both the tribe and the clinic agreed to partner with MDH.

Partners in the FISH project are:

- MDH, Division of Environmental Health, Fish Consumption Advisory Program, St. Paul
- Sawtooth Mountain Clinic (SMC), Grand Marais
- Grand Portage Health Services (GPHS), Grand Portage
- Grand Portage Trust Lands, Grand Portage
- Cook County North Shore Hospital (CCNSH), Grand Marais
- MDH Public Health Laboratory (MDH PHL), St. Paul

MDH will develop protocol, forms, and materials with input from partners, support clinic staff in implementing the intervention, analyze data, and write reports. The clinic and hospital will implement the intervention and be responsible for all participant contact and personal data.

FISH is a four-year (November 1, 2012 to September 30, 2016) project funded by a grant to the Minnesota Department of Health (MDH) from the U.S. Environmental Protection Agency (EPA) through the EPA Great Lakes Restoration Initiative.

This Manual provides procedural details of activities related to the FISH Project: staff training; promotion; recruitment and enrollment; clinic intervention visits; data management; and results communication and counseling.

FISH Project Components

Fish Consumption Risks and Benefits Training

In Year One of the Project, physicians and nurses from SMC and GPHS participated in several days of training on risks and benefits of fish consumption. MDH provided training programs developed by three different institutions (University of Illinois at Chicago, Michigan State University, and Stony Brook University). These staff completed the coursework, testing and evaluations for each of the programs, as well as an overall evaluation comparing and contrasting the three programs. The University of Illinois and Michigan State trainings were developed as part of previous Great Lakes Restoration Initiative (GLRI) grants.

A fish consumption risks and benefits refresher course – designed based on the results of those evaluations - will be provided for all participating staff prior to the first patient visits. That course will also be made available to other health care providers.

<u>Visit One</u>

MDH and FISH partners will work together to recruit 500 women to participate in Visit One. Visit One procedures include:

- Eligibility verification
- Informed consent
- Brief (three-question) mercury screening
- Blood draw: Blood to be tested for total mercury and omega-3 fatty acids; methymercury if total mercury is over the RfD (5.8 μg/L).
- Detailed (Fish Consumption) Questionnaire: Results used to supplement three-question mercury screen, for counseling purposes, and to improve fish consumption education for women of childbearing years.
- Fish consumption education: Participants learn to choose fish that are low in mercury and high in omega-3 fatty acids.

Results Notification and Counseling

Blood samples - identified by Participant IDs - will be analyzed by the MDH PHL. Lab results will be sent to CCNSH and electronically transferred into the joint SMC and GPHS electronic medical record (EMR).

Clinic staff will link Participant IDs with clinic-held personal information and send a result letter to each participant. The letter will explain her results and recommend an appropriate course of action. Participants with mercury over the EPA reference dose (RfD) of 5.8 μ g/L will be offered counseling by a clinic nurse or physician trained for this purpose. Counseling will also be available to participants with mercury results below the RfD who request it.

Follow-Up/Visit Two

All participants with mercury values over the RfD will be asked to return for a follow-up visit (Visit Two) in six months. Based on Mercury in Newborn findings (i.e., ten percent of babies tested in Minnesota had mercury over the RfD), it is estimated that approximately 50 women in FISH will fall into this range.

For each of the high-mercury follow-up participants, two women with mercury results under the RfD will also be asked to participate in the follow-up visit. Visit Two will be nearly identical to the first, including the mercury screen, blood draw, detailed questionnaire, and fish consumption education, followed by similar results notification and counseling. Additional information will be collected on participant reaction to the educational materials and the Project overall.

Report to the Community

MDH will analyze FISH data and present the results in a report to the community at the end of the Project. Partners will review and approve the report before it is shared with the community.

Staff Training

Training on risks and benefits of fish consumption was provided for staff in the first year of the Project. All Project staff at Sawtooth Mountain Clinic, Grand Portage Heath Services, and the Cook County North Shore Hospital will receive additional training on each aspect of the Project in which they will be involved. In addition, SMC staff are required to follow internal clinical practices and policies (found in Appendix 5).

Each of the trainings listed below will be provided by MDH staff with the exception of the Laboratory Procedures training, which will be provided by Cook County North Shore Hospital laboratory staff.

Refresher Fish Consumption Risk and Benefits Training

This one-to-two hour course will be provided for all staff involved in the Project. It is designed according to clinic staff preferences expressed in evaluations of the previous trainings. This refresher training is intended to provide clinic-ready information for patients in a busy clinic setting.

Protocol, Forms, and Visit One

Staff at SMC and GPHS who will recruit or enroll participants and conduct participant visits will receive FISH Protocol training. Topics include: Project objectives; purpose and value; data privacy; informed consent; incentive procedures; forms and data processing; and conducting Visit One/Two. Each SMC and GPHS staff member will learn how to correctly and uniformly deliver participant education and will practice doing so in the course of this training.

Laboratory Procedures

Venipuncture and lab protocols training will be provided by CCNSH for all SMC and GPHS staff who will be doing blood draws at either Visit One or the Follow-Up. Training will also be provided for those who will be processing or shipping lab samples.

Results Communication and Counseling

SMC and GPHS staff who provide the recommended results counseling for all participants with mercury >5.8 µg/L and respond to low-mercury participant questions and concerns related to their own lab results ("results counselors") will receive training on topics related to those results (e.g., 'desirable' fatty acid and Hg levels; what levels mean; what to do to reduce or increase levels; which fish to eat; what to do if Hg level is high).

Training will take place over a several-month period prior to the activities related to their content. MDH will provide refresher training as needed; new clinic and hospital staff will receive training for any aspect of the Project in which they will be involved.

Project Promotion

Promotion Plan

MDH and project staff will draft promotional materials based on input from Project partners, including Sawtooth Mountain Clinic (SMC), Cook County North Shore Hospital, Grand Portage Health Service (GPHS), Grand Portage Trust Lands (GPTL) and other stakeholders. SMC and GPHS staff will suggest what type of materials are needed; provide input on community standards and values to inform the design and content; and will review and comment on draft materials. MDH, GPHS, and SMC will sign-off on all final versions before they are distributed.

MDH staff will work with Project partners to promote the Project in their communities. Print and other materials will be created to **inform the public** about FISH; its purpose, procedures, and benefits. This group of materials will also serve to **promote participation** in FISH. They will not be designed to provide significant information about safe fish eating guidelines or the risks and benefits of eating fish. Education about fish consumption will be reserved for Project participant education.

In addition to creating promotional print materials for dissemination in North Shore communities, partners will engage a variety of local media and will attend local family and community events to promote the Project and increase participation, as needed. Promotional activities will take place throughout the clinic phase of the Project.

Community Partners

MDH and partners will work to engage and inform local stakeholders about the Project. These will include Grand Portage tribal officials and agency staff; Cook County and Grand Marais public health and other government officials and agencies; business owners and others in both communities whose support will enhance the implementation and success of the Project.

Promotional Venues

<u>Media</u>

Local media resources will be used periodically to promote the Project and increase participation and awareness. A potential list of local media outlets is below. Depending on participation, some media resources may not be used.

Print Media

- Cook County Co-op Newsletter, *Blueberry Jam* (every two months, online)
- Cook County News Herald (weekly, Saturday)
- Duluth News Tribune (daily, contact: John Meyer)
- Grand Portage Tribal Newsletter, *Moccasin Telegraph* (quarterly, print, contact: Mary Ann Gagnon, 218-475-0111)
- Grand Portage Trust Lands Newsletter (periodically, paper, contact: Amy Seitz)

- North Shore Journal (print and online, contact: 218-226-3335)
- Northern Wilds (monthly, print)
- North Shore Healthcare Foundation News (quarterly, online)
- Sawtooth Mountain Clinic News, *The Daily Apple* (quarterly, print and online)
- *Viking Voice*, Cook County Schools (annual online in August; monthly, print)

Radio

• WTIP North Shore Community Radio (90.7 FM)

WTIP is an important local partner. MDH has agreed to communicate regularly with WTIP staff about FISH. WTIP is interested in informing the community about the Project, its objectives, progress, and outcomes. In addition to other activities undertaken in collaboration with WTIP, Grand Portage's Dr. Seth Moore has a regular radio show and will provide updates as appropriate.

Internet

- Boreal Access mailing lists
- CCNSH internet and intranet
- SMC website The FISH promotional video and other information will be posted here.

Public Events and Locations

Promotional Events and "Special Clinics"

FISH will be promoted - beginning May 2014 - at a variety of public events where names and contact information for women who express an interest in Project participation will be collected (see *Pre-Enrollment* section below).

FISH Partners will also hold special Visit One clinics, in conjunction with scheduled community events or as stand-alone opportunities for participation. Some events for possible FISH tie-ins are:

- SMC women's health event, May 2014
- Grand Portage Mammobus event, May 2014
- North House Chowder Festival, Summer 2014
- Grand Portage Health Fair, Summer 2014
- Grand Portage women's softball, Summer 2014
- Cook County Schools Open House, August 2014
- Blood pressure clinics throughout enrollment period
- SMC Pappy Hours throughout enrollment period
- Pizza bake at the Birch Grove Community Center

Public Poster Locations

Project partners have compiled a list of community sites on the North Shore where they will request placement of FISH posters. Posters will initially be placed four to six weeks before the Project begins,

and will be refreshed as FISH progresses. Locations include but are not limited to churches, schools, and the following specific locations:

Grand Marais

- Arrowhead Center for the Arts
- Arrowhead Pharmacy
- Cook County Community Center
- Cook County Early Childhood Family Education (ECFE)
- Cook County Extension
- Cook County Family Planning
- Cook County North Shore Hospital
- Cook County Public Health
- Cook County Whole Foods Co-op
- Dockside Fish Market
- Drury Lane Books
- Gene's IGA
- Grand Marais Art Colony
- Grand Marais Public Library
- Java Moose
- Johnson's Foods
- Lake Superior Trading Post
- North House Folk School
- North Shore Car Wash & Laundromat
- Sawtooth Mountain Clinic
- The Garage
- U.S. Post Office

Grand Portage

- Grand Portage Community Center
- Grand Portage Head Start
- Grand Portage Health Service
- Grand Portage Human Services
- Grand Portage RTC
- Grand Portage Trading Post
- Grand Portage Trust Lands
- Oshki Ogimaag Community School
- Ryden's Border Store & 66
- U.S. Post Office
- WIC

Hovland

• Chicago Bay Store

• U.S. Post Office

Lutsen

- Clearview General Store
- Heavy Duty Sewing (Clearview)
- Lockport Marketplace
- Lutsen Resort
- Moondance Coffee Shop
- U.S. Post Office

Tofte

- Birchgrove Community Center (Patty Nordahl)
- North Shore Commercial Fishing Museum & Visitor Center
- North Shore Market
- Sawtooth Outfitters
- Tall Tale Yarn Shop
- U.S. Post Office

Other

- Churches
- Schools

Promotional Materials

Informational and promotional materials will include but are not limited to:

- Three-fold Promotional Flyer
 - briefly describes the Project; found in Appendix 1
- Posters for public locations
 - small posters distributed throughout North Shore communities
- Display boards
 - displayed at public events and SMC/ GPHS in between events; intended to introduce the Project and Project partners and to encourage participation
- Announcement letters
 - clinics may decide to send Project information to mailing lists or email lists held by SMC/GPHS
- Promotional video
 - developed by MDH with Project partners to inform the public about FISH and encourage participation; features staff and community members
- FISH Frequently Asked Questions (FAQs)
 - provides answers for questions that staff are likely to be asked by media, community members, and prospective participants during the promotion and recruitment phases; found in Appendix 3

Visit One

Eligibility, Pre-Enrollment, Recruitment, and Scheduling

Eligibility Criteria

Women aged 16 to 50 are eligible to participate in FISH if they meet the following conditions:

- Permanent residence must be in Cook County or the surrounding area.
- Live in the area at least nine months of the year; however, women who recently move to the area may also participate if they intend to be full-time residents.
- Must be willing to provide a blood sample to be tested for mercury and Omega-3 fatty acids.
- Able to take part in Visit Two six months after Visit One, if requested.

Pre-Enrollment

Women can indicate their willingness to participate in FISH by completing a **Pre-Enrollment Form** at a public event, FISH special clinic, regular clinic visit, or other venues. The **Pre-Enrollment Form** gives the clinic permission to contact the woman at a later date. The **Pre-Enrollment Form** is found in Appendix 1.

Recruitment

Staff will attempt to enroll women ages 16-50 in the Project area by:

- Checking clinic schedules weekly for eligible women and scheduling FISH visits back-to-back with clinic appointments.
- Promoting the Project through word-of-mouth, promotional materials, community events, social media, etc.
- Organizing special clinics to accommodate women unable to make appointments at the clinic during clinic hours.
- At their discretion, staff may choose to send a letter to encourage potential participants to contact the clinic to schedule a FISH appointment. An example of the **Upcoming Visit Letter** is in Appendix 2.

Other strategies may be explored and implemented (as needed) throughout the recruitment period to increase participation, including active and passive recruitment methods. Some examples are:

- (active recruitment) Staff call the woman prior to her regular clinic visit to ask if she'd like to schedule a FISH appointment for the same day as her regular clinic appointment.
- (passive recruitment) Staff leave a stack of Three-fold Promotional Flyers at a local bank. A woman picks up a flyer and calls the clinic to learn more about the Project.

Once contacted (either through active or passive recruitment), women have the choice to take part in the Project. If the woman is not interested, staff will thank the woman for her time and add a note to

the EHR/PM so that she is not asked again to participate. However, the woman may contact the clinic in the future if she later decides she would like to take part.

If the woman expresses interest in participation, staff will do one or more of the following:

- Determine eligibility
- Enter participant information in the EHR/PM if appointment is scheduled at this time
- Discuss parental consent with minors
- Answer any questions the prospective participant has about the Project
- Proceed to Visit One steps

Scheduling

FISH visits will be scheduled by clinic scheduling staff or FISH Project staff using the EHR/PM.

Visit One Preparation

Visit One Folder

Prior to each scheduled Visit One, staff will assemble a **Visit One Folder** for the individual participant. This blue folder will contain the forms and materials for Visit One.

A unique **Participant ID** will be assigned to each participant after informed consent is obtained. This ID will be entered into the **EHR/PM** and a label added to each paper form used for the project. A picture of the **Participant ID label** is below.



Participant IDs will be assigned to participants as follows:

- Participant IDs F-001 to F-649: regular clinic visits at either SMC or GPHS.
- Participant IDs **F-650 F-999:** special clinic visits at any location.

For each visit, FISH staff will use the pre-filled **Visit One Folder**, **Lab Pack**, educational materials, and incentive items. Direct data entry into the **EHR/PM** will occur for some visit steps. When the **EHR/PM** is not available, a paper form for these steps will be added to the participant's folder for data entry at a later time.

The Visit One Folder contains the following paper forms:

- Visit One Checklist
- Contact Information/Pre-Enrollment Form (if EHR/PM not available)
- Eligibility Screening Form
- Adult Consent or Minor Assent with Parent/Guardian Consent
- Participant ID labels
- Mercury Screening Questions (if EHR/PM not available)
- Detailed Questionnaire, Part 1 (aka DQ, Part 1)

The Lab Pack contains:

- Blood collection labels (Specimen ID labels)
- Blood collection, processing, and storage supplies
 - Two Purple Top, 2 mL BD Vacutainer (K2 EDTA 3.6 mg) blood tubes (#367841: Plastic Tube, Hemogard[™] Closure, 13mm x 75mml). One 2 mL Vacutainer will be used for mercury and the other for fatty acids.
 - o One Pink Top, 2 mL cryovial for (fatty acid) plasma storage and transfer
- Lab Checklist
- Lab Verification Form
- Chain of Custody (COC) Form

Educational materials include:

- Three-fold brochure (SMC or GPHS version)
- Wallet card

The incentive items include:

- \$25 Visa gift cards (up to \$50 given to each participant if all visit steps are completed)
- Incentive Receipt Form
- MDH Incentive Log

These additional items may also be used for Visit One:

- Participant's Info Sheet (information about the FISH Project for potential participants)
- Lab Order (created through EHR/PM if participant consents and will have blood drawn by the lab)
- Detailed Questionnaire, Part 2 (individual fish forms based on participant's responses to DQ, Part 1; aka DQ, Part 2)

Visit One Steps

The FISH Visit steps are described in this section and will typically take place at Sawtooth Mountain Clinic (SMC) or Grand Portage Health Services (GPHS).

Electronic Records

The Centricity **EHR/PM** (Electronic Health Record/Practice Management) will be used to store and track appointment status, including no shows and rescheduled appointments. FISH Visit appointment status will be tracked thru the **EHR/PM** documentation and reports.

The **Visit One Checklist** (found in Appendix 1) will be used throughout the appointment to document each step. Staff will complete the paper Checklist form in the **Visit One Folder** and enter it into the **EHR/PM**. A screenshot of the **EHR/PM** is below for both Visit One and Visit Two.

FISH Visit #1 EHR/PM screenshot:

FISH Visit #1			
Eligibility Screening		T	Participant ID
	Informed Consent Patient	Γ	Informed Consent Parent/Guardian
C	Contact Information Verifie	d	
Mercury Screening Que	estions		
In the last 2 or 3 month	S:		
How many times a week	did you eat any kind of fish?		
How many times/month di	d you eat any of these fish? (Walleye, Nort	hern, Bass or Lake Trout from Lake Superior)
Did you eat either of these	e fish: Swordfish or Shark? (Yes	
	(No	
Referred to Lab	Lab Specimen ID:		
Detailed Question	naire Completed		
Education:			
Incentive Payment:			
Visit 1 Outcome:		V	
Contact again?		T	
Comments:			
Comments:			

FISH Visit #2 EHR/PM screenshot:

Participant ID	3		📃 Сог	tact Information Verit	fied
lercury Screening Qu	estions				
the last 2 or 3 month	ns:				
low many times a week	did you eat any kind of t	fish?			
low many times/month (did you eat any of these	fish (Walleye, North	nern, Bass or L	ake Trout from Lake	Superior?
Did you eat either of the	se fish: Swordfish or Sh	ark? 🚫 Yes			
Poterrad to Lab	Lob Specimen ID:	C No			
	Eab Specifiel ID.				
Detailed Questio	rinaire Completed				
Education:					1.1
					E
Incentive Payment:					
Visit 2 Outcome:		V			
Contact again?		V			
Comments:					~
					*
	n ferene and a second second	D -1			

Step 1: Introduce Project

When women arrive for their FISH visit, staff will briefly tell them about the Project, ask them to read the **Participant's Info Sheet**, and answer any questions they may have about FISH.

NOTE: Since much of the information in the **Participant's Info Sheet** is also on the consent forms, staff may choose instead to skip Step #1 and go through both the **Participant's Info Sheet** and the consent simultaneously at Step #3.

The Participant's Info Sheet is found in Appendix 1.

Step 2: Verify Eligibility

FISH staff will verify each woman meets the eligibility criteria to take part in FISH using the **Eligibility Screening Form**. Women who do not meet the Project's requirements will be informed they cannot take part in FISH and thanked for their time and interest in the Project.

The **Eligibility Screening Form** is found in Appendix 1.

Step 3: Obtain Consent

To take part, each participant must sign an informed consent form. FISH staff will go through the consent with the woman to make sure she understands what she will do as a participant and her rights. After all questions have been answered, the woman will be asked to sign and date the consent if she would like to take part. Her participation is voluntary; she can decide at any time to not continue with the Project.

Two copies of the consent will be completed by the participant and FISH staff. Adult women (ages 18-50) will be asked to sign and date the **Adult Consent**. Women ages 16-17 will sign and date a **Minor Assent** and must have a parent or guardian complete the **Parent/Guardian Consent Form** before the minor can take part. Each parent will also receive a copy of all assents/consents signed by minors. FISH staff will also complete their portion of the consent. The original consent will be scanned and entered into the **EHR/PM** and then kept in the participant's **Visit One Folder**. The second copy of the consent will be filled out and given to each participant for her records.

The Adult Consent, Minor Assent, and Parent/Guardian Consent forms are found in Appendix 1.

Step 4: Assign Participant ID

After the consent is signed, the woman becomes a participant and is assigned a **Participant ID** by FISH staff. This ID (pre-printed labels) will be used on all forms and her blood sample so that her identity will be protected. The **Participant ID** is also entered into the **EHR/PM**.

Step 5: Verify Contact Information

FISH staff will verify and update the contact information in the **EHR/PM** with each participant. Contact information includes: name, address, phone number, birthdate, and best method for future contact. If

the **EHR/PM** is not available (e.g. computer system is down or not available at a special event location), staff will use the **Pre-Enrollment/Contact Info Form** (paper form) to verify contact information. In these cases, the form will be entered into the **EHR/PM** at a later time.

The **Pre-Enrollment/Contact Info Form** is found in Appendix 1.

Step 6: Ask Mercury Screening Questions

Next, FISH staff will ask the participant 3 questions about the fish she has eaten in the past 2-3 months. Her answers to these questions will be compared to the mercury level in her blood.

- 1. How many times a <u>week</u> did you eat <u>any kind of fish</u>?
- 2. How many times a <u>month</u> did you eat any of these fish Walleye, Northern Pike, Bass, or Lake Trout from Lake Superior?
- 3. Did you eat Shark or Swordfish?

FISH staff will ask the screening questions word-for-word and enter responses directly into the **EHR/PM** (if available) or on the paper form (entered later into the **EHR/PM**).

Answers must be whole numbers. If any response is high (>10 meals per week or >30 meals per month), staff will verify the answer with the participant and make corrections as necessary. If a participant ate fish during the last 2-3 months but ate less than 1 meal per week/month (question 1 and 2 respectively), please enter "<1".

The Mercury Screening Questions Form is found in Appendix 1.

Step 7: Prep for Blood Sample Collection

Preparing for the blood collection includes two key items: printing the lab order and updating the **EHR/PM** with the **Specimen ID**.

Lab Order

The nurse will explain the blood collection and then print a Lab Visit Standard Order (aka Lab Order), which refers the participant for a blood draw. Once printed, the Lab Order will be labeled with a Participant ID (from the participant's Visit One Folder) and Specimen ID (from the Lab Pack). The nurse will also add Participant ID and Specimen ID labels (where indicated) to the rest of the forms in the Lab Pack: Laboratory Checklist, Lab Verification Form, and Chain of Custody Form (see Appendix 4 for lab forms).

A figure of the **Lab Pack** is below. Blood collection tubes have an expiration date. The expiration date for each **Lab Pack** will be noted on a sticker placed on the outside of the bag. **Lab Packs** should be used in the order they are received (First In, First Out). Expired **Lab Packs** must be discarded. Please notify MDH (<u>patricia.mccann@state.mn.us</u>, 651-201-4915 or <u>jill.korinek@state.mn.us</u>, 651-201-4913) to request additional **Lab Packs**.



Specimen ID into EHR/PM

Staff will data enter the Specimen ID into the EHR/PM. This links the Participant's ID with a unique Specimen ID and serves as the key or link for personal identifiers and results. An example of the Specimen ID label is below:

SPECIMEN ID LABELS (FOR FORMS)

MDH PHL will provide printed, adhesive **Specimen ID Labels** in each **Lab Pack** for FISH forms and packing lists. The **Specimen ID** is the bottom number on the label. A multi-digit MDH PHL work order number will be printed on the label above the **Specimen ID** but will not be used by FISH staff.



Step 8: Collect Blood Sample

The blood collection step includes drawing blood from the participant and completing the appropriate paperwork.

Blood Collection

Blood specimens will be collected to measure fatty acids and mercury in participants' blood. Staff will draw 4 mL of blood from the participant's arm, unless the blood draw is refused, interrupted, or the participant cannot be drawn. See Appendix 4 for a detailed description of blood collection, processing, storage, and shipping procedures.

Based on the participant's visit location, blood collection will take place as follows:

<u>SMC:</u> Lab Packs will be stored in the clinic. The nurse will insert Participant ID labels and label a Lab Order, Lab Checklist, Lab Verification Form, and Chain of Custody Form with the Participant ID and Specimen ID. The Lab Order and forms will be placed into the Lab Pack. Then participants will take the Lab Pack with them to the lab at Cook County North Shore Hospital (CCNSH) for the blood draw. Staff may also choose to send DQ, Part 1 with the participant to the blood draw or while labeling the lab forms.

<u>GPHS:</u> Participants will have their blood drawn at GPHS by the FISH nurse. **Lab Packs** will be stored in the clinic where both the blood draw and other Visit One procedures will be completed. GPHS staff will label a **Lab Order**, **Lab Checklist**, **Lab Verification Form**, and **Chain of Custody Form** with the **Participant ID** and **Specimen ID** and proceed with the blood draw.

<u>Special Clinics</u>: Participants at special events may either be drawn onsite or referred for a later blood draw at either CCNSH or GPHS.

Complete Lab Paperwork

After the blood draw, Project staff will enter the **Specimen ID** and lab outcome from the **Lab Verification Form** into the **EHR/PM** and then proceed with the rest of the Project steps (for completed blood samples), reschedule anyone who needs to return for a blood draw (no incentive given), or give out a \$25 incentive to those who are unable to give blood. Only women who complete the blood draw are Project participants.

Blood collection/lab forms are found in Appendix 4.

Step 9: Complete Detailed Questionnaire

After completing the blood draw, staff will ask each participant to fill out the **Detailed Questionnaire** (**DQ**). The purpose of the **DQ** is to more thoroughly screen participants for exposure to mercury and fatty acids by asking detailed questions about fish eating patterns and behaviors and supplemental sources of fatty acids.

The **DQ** consists of two parts: **DQ**, **Part 1** and **DQ**, **Part 2** (both found in Appendix 1). Questions include:

• **DQ, Part 1**: demographics, eating habits and preferences, consumption of Omega-3 supplements or enriched foods, fish species eaten in the past week and past year.

• **DQ, Part 2**: detailed information about consumption frequency, season, and source for each fish species the participant reported eating during the past year in **DQ, Part 1**.

First, staff will ask each participant to complete **DQ**, **Part 1**. When finished, staff will check **DQ**, **Part 1** for completeness. Some things to check are:

- Responses are legible.
- When the question directs the participant to "*Check only 1,"* there is only one response checked (e.g., there is only one response checked for the education question, **Q3**)
- When there is no direction to "Check only 1," the question has been answered completely.
- For **Q9**, the number of fish meals per week is a whole number from 00 to 99. Verify any response greater than 10 with the participant before they leave the appointment.

Second, staff will give the participant **DQ**, **Part 2**. An example page of **DQ**, **Part 2** will also be provided to the participant to demonstrate how to fill out the questionnaire. When finished, staff will check **DQ**, **Part 2**. Some things to check are:

- **DQ, Part 2** has been completed for each species the participant reported eating in the past year on **DQ, Part 1, Q9**.
- Either Yes or No are checked for each of the four seasons.
- For each season, the number of times is reported for Weeks or Months or Season.
- At least one response is checked for the source of the fish.

Staff will be available during the questionnaire to answer questions, read the questionnaire, or assist participants as needed. Staff may also choose to have the participant complete **DQ**, **Part 1** prior to the blood draw.

<u>Visit Two only</u>: After completing the DQ, Visit Two participants will complete the **Evaluation Form** (Appendix 1) and then continue to Step 10.

Step 10: Fish Consumption Risk and Benefits Education

After completing the **DQ**, the participant will meet with a trained member of the clinic staff to receive the education portion of the Project.

Staff will hand the participant a **Three-fold Brochure**. The **Three-fold Brochure** contains fish consumption information, such as serving size, meal frequency, and risks and benefits of eating fish. Staff will explain the **Three-fold Brochure** and discuss the participant's **DQ**, **Part 2** responses to show how the participant's current fish consumption fits into the **Three-fold Brochure** recommendations. After answering any questions regarding safe eating of fish that the participant may have, clinic staff can also provide additional materials (e.g., site-specific advice and references) that may be available. A **Wallet Card** (smaller version of the **Three-fold Brochure**) will also be given to the participant for easy reference away from home.

The Three-fold Brochure and the Wallet Card are found in Appendix 1.

Step 11: Incentives

At the end of the Project steps, staff will thank the participant for taking part, give her the appropriate incentive, and ask her to sign the **Incentive Receipt** to acknowledge receipt of the gift card(s). Staff will instruct participants to use the "tips" sheet or instructions provided with the gift cards. The **Incentive Receipt** is found in Appendix 1.

The incentive amount is determined by the participation level and is described in the table below.

Incentive Amount	Visit Steps Completed	Explanation
\$50	 Eligibility Screening Informed Consent Mercury Screening Questions 	Participants receive two \$25 Visa gift cards (total of \$50) for completing all parts of
	 Blood draw Detailed Questionnaire Fish Consumption Education 	the visit.
Delayed	 Eligibility Screening Informed Consent Mercury Screening Questions Attempted blood draw but no sample; participant will be rescheduled 	Participants whose blood draw will be rescheduled will not receive an incentive until after the blood draw is complete.
\$25	 Eligibility Screening Informed Consent Mercury Screening Questions Attempted blood draw but sample could not be drawn 	Participants who attempt the blood draw (poked) but are unable to give enough blood will be given one \$25 gift card.
\$0	 One or more steps may be completed: Eligibility Screening Informed Consent Mercury Screening Questions However, participant is unwilling to provide a blood sample. 	Women who refuse to have their blood drawn are not participants and will not receive an incentive.

Staff will also use the **MDH Incentive Log** (Appendix 1) to document gift card distribution. Staff will track each gift card that is given to participants by recording the date it was given and the **Participant ID** of the person who received it. A copy of the **MDH Incentive Log** will be given to MDH every quarter for financial recording keeping purposes.

When not in use, all incentives must be securely stored in locked cabinets. See Step 12 (page 23) for incentive recordkeeping.

Step 12: Post-Visit Tasks

Checking Forms and Data Entry

At the end of Visit One, staff will check the contents of each **Visit One Folder** and complete data entry into the **EHR/PM**, if needed.

Each Visit One Folder will hold the following Visit One forms and materials:

- Participant ID Labels remaining
- Visit One Checklist
- Pre-Enrollment/Contact Information Form (if paper form was used)
- Eligibility Screening Form
- Clinic copy, Adult Consent or Minor Assent
- Clinic copy, Parent/Guardian Consent, if applicable
- Mercury Screening Questions (If completed on paper)
- DQ, Part 1 and DQ, Part 2
- Lab Verification Form
- Lab Checklist (returned from lab at a later date)
- Incentive Receipt

The checklist below describes the post-appointment tasks for each item in the Visit One Folder.

				_											
Post-Appt Tasks for Forms	Let I	LOVE Parti	opantiple tone che	abels shist	NICONTECT	Info Form	nor Assent	entiquart	Jan Conse roury Screen	enine Que	on form	Part lan	o2 Recei	at	
Store in folder (if paper form is used)	~	~	>	~	~	~	~	~	~	4	1	~			
Participant ID (on form, if used)		~	~	~	~	1	~	~	~	4	1	~			
Specimen ID (on form)		~							✓	4					
Lab visit outcome indicated on form		~							1	1					
Verify responses make sense and are complete/legible		~	~	~	~	~	~	~	~	~	~				
Enter responses/status in EHR/EM		✓	1	1	1	~	✓	1	✓	1					
Update visit status in EMR/PM		✓							✓						
Verify participant age between 16-50				4											
Check ppt agreed to blood sample and Visit 2				✓	✓	✓	✓								
Sign and date form (participant/staff)					1	~	~					~			
Verify responses are whole numbers or <1								~							
Prep for MDH transfer (copy or scan)											✓				
Verify correct incentives distributed and last eight digits of card(s) recorded												~			

Visit Two post-visit tasks will be very similar to Visit One. One additional task is to scan and send the **Evaluation Forms** to MDH separately from the Visit Two DQs.

Handling of No Shows, Refusals/Declines, and Possible Mercury-Related Symptoms

No Shows

When a woman does not arrive for a scheduled visit, she should receive a re-scheduling call. If she does not return the phone call after two attempts or reschedules but "no shows" again, she will be considered no longer interested in the Project.

Refusals/Declines at Visit One

If participants arrive at Visit One but decide not to complete the mercury screening questions or the blood draw, the woman should be noted as a refusal/decline in the Visit 1 Outcome of the **EHR/PM**.

NOTE: Skipping one or more individual questions on the **Detailed Questionnaire** is not considered a decline.

Participants Who Report Mercury-Related Symptoms

If a participant reports to clinic staff during her visit that she believes she has symptoms related to mercury exposure, she can continue with the visit. Afterwards, an appointment will be scheduled with a physician. The physician will evaluate whether symptoms are likely related to mercury exposure and, if so, whether it is probable that the mercury is from fish consumption. The physician will provide advice on a case-by-case basis, according to the participant's reported levels of fish consumption, other potential exposures to mercury, pregnancy status, and other factors. The physician will also decide whether to handle the case personally or to consult with Dr. Beth Baker, FISH consultant and medical toxicologist.

Incentive Record Keeping

MDH will deliver the **MDH Incentive Log** and \$25.00 Visa gift cards to SMC and/or GPHS. SMC and GPHS staff will store incentive materials in locked cabinets when not in use. Each time incentives are needed, the clinic staff will record the appropriate information in the **MDH Incentive Log** and distribute the card(s).

At the end of each day, staff will: (1) check-in any cards removed at the beginning of the day that were not used, (2) verify that the **MDH Incentive Log** matches the **Incentive Receipts** in that day's participant folders , and (3) store cards and the log in the locked cabinet.

Staff are responsible for keeping an up-to-date inventory of cards and notifying MDH in advance when additional cards are needed. When every card from the **MDH Incentive Log** has been distributed, clinic staff will make one copy of the log sheet for their records. The original **MDH Incentive Log** will be given to MDH every quarter for financial recording keeping purposes.

Data Transfer Procedures

Forms Transfer

The following forms from the FISH visit will be transferred to MDH from staff at SMC, GPHS, or CCNSH:

- DQ, Part 1 and DQ, Part 2
- Evaluation Form (Visit 2 only)
- MDH Incentive Log
- Chain of Custody (COC) Form

Transfer of Detailed Questionnaires and Evaluation Forms

Completed **DQs** will be given to MDH staff or scanned and emailed to MDH individually or in batches along with a completed **DQ Batch Log** (found in Appendix 1). Visit 1 **DQs** and Visit Two **DQs** will be scanned and emailed separately to MDH. **Evaluation Forms** will be also scanned and emailed as a separate file.

Project staff at SMC and GPHS will:

- 1. Place a Participant ID Label for each DQ included in the batch on the DQ Batch Log.
- Clip the corresponding DQs to the DQ Batch Log. Complete a separate batch log for Visit One DQs, Visit Two DQs, and Visit Two Evaluation Forms.
- 3. Fill-in dates and shipping method information before shipping or scanning.
- 4. Save a copy of each **DQ Batch Log** in a binder kept for that purpose.

Transfer of Incentive Logs

Project staff at SMC and GPHS will send MDH a copy of the **MDH Incentive Log** at the end of each quarter and save the original for their records.

Transfer of Chain of Custody Forms

CCNSH staff will assemble and finalize **Chain of Custody (COC)** Forms from all blood draw locations (CCNSH, GPHS, outside locations for special clinics) and prepare blood specimens for shipment to MDH PHL. Before shipping, lab staff will make one copy of each **Chain of Custody (COC)** Form for each participant.

- The original will be shipped with specimens to MDH PHL.
- The copy will be retained at the CCNSH lab.

EHR/PM Data Transfer

SMC Project staff will transfer the following data for Visit One/Two electronically from the **EHR/PM** to MDH for each participant:

- Participant ID
- Specimen ID
- Age
- Zip Code
- Responses to Mercury Screening Questions
- Visit completion date and clinic location

MDH Data Handling Procedures

Laboratory Data

The MDH PHL will analyze blood specimens for total mercury and fatty acid content; specimens with mercury levels greater than 5.8 μ g/L will be reanalyzed to speciate mercury. The MDH PHL will provide results to the MDH Fish Consumption Advisory Program. MDH FISH staff will email the results as Excel data to CCNSH for entry into the CCNSH EMR.

Once entered into the CCNSH EMR, results will automatically transfer to the SMC **EHR/PM**, which will be used to generate results letters and document counseling calls as described in the Results Communication Section below.

Detailed Questionnaires

MDH staff will log-in **Detailed Questionnaires** by **Participant ID** and check those IDs against the **EHR/PM** visit outcome. Questionnaire data will be entered into an electronic database. All electronic entries will be checked against the paper or scanned copy.

MDH will analyze questionnaire data with blood mercury and fatty acids results, **Mercury Screening Question** responses, and demographic factors. Results will be used for participant results counseling, to refine **Mercury Screening Questions** (if indicated), and to improve communication materials and health care provider training throughout the Great Lakes Basin.

Results Communication and Counseling

Results Communication

Lab results for each participant will be sent by MDH PHL to CCNSH. CCNSH will enter lab results into the **EHR/PM** where they are accessible to SMC and GPHS staff. Then clinic staff will send a results letter to each participant.

Mercury Results

All participants will receive a mercury results letter from the clinic containing the following information:

- Personal blood mercury results
- Recommendation to follow fish consumption advice discussed at Visit One (eat fish low in mercury)
- Reminder that they MAY be asked to take part in Visit Two (if mercury <5.8 μg/L) or WILL be asked to take part (mercury >5.8 μg/L)
- Fatty acid results will be mailed in a separate letter at a later date

In addition, letters for participants whose mercury results are >5.8 μ g/L and ate fish will include:

- Notification that the mercury result is higher than the level of concern
- Recommendation to contact the nurse about their result or the nurse will contact them
- Individualized fish consumption recommendations, based on DQ responses
- On a case-by-case basis, the physician may also decide to contact these participants to discuss the high mercury result, or the letter may ask the participant to make an appointment to discuss the result with the doctor.
- The **FISH Project Meal Planning Infosheet** (see Appendix 2) gives examples of monthly fish meals within the fish consumption recommendations and will accompany each results letter.

Likewise, letters for participants whose mercury results are >2 but did not eat fish will include:

• Recommendation to contact the nurse, who will then refer the participant to MDH to discuss other possible mercury exposures

The **Mercury Result Letter Templates** are found in Appendix 2. MDH will inform clinic staff which template to use.

Fatty Acid Results

All participants will receive a fatty acids results letter and information sheet from the clinic containing the following information:

- Personal fatty acid results
- Meaning of fatty acid results and how this relates to their fish consumption
- Description of which fish are higher in fatty acids and recommendation to follow fish consumption advice discussed at Visit One (eat fish low in mercury)

The Fatty Acids Result Letter Templates and Fatty Acids Info Sheet are found in Appendix 2.

Results Counseling Materials

MDH will provide individualized counseling recommendations for each participant with high-mercury and/or for each participant with mercury > 2 μ g/L who reports eating little or no fish. MDH staff will complete the **Counseling Notes Template** (see Appendix 2) with lab values and fish eating information and provide individualized consumption advice based on all of the information collected at Visit One.

Clinic staff will also use the **Results Counseling Questions and Answers** (see Appendix 3) to assist them in responding to participant questions about their results.

Results Counseling

At least two nurses and one physician at SMC and at least one nurse at GPHS will receive extensive training on topics related to test results and be able to answer questions and provide counseling on a variety of topics.

All participants with **mercury levels** > 5.8 μ g/L will have the option to receive results counseling by either a clinic nurse or physician. In addition, participants with **mercury levels** >2 μ g/L but reported eating no fish will receive a recommendation to call the FISH Coordinator about their result.

On a case-by-case basis, some participants will receive a call from a nurse or physician or be advised to make an appointment with a physician. Calls and appointments will be documented in the EHR/PM.

The physician will also decide whether to handle the case personally or to do so in consultation with Dr. Beth Baker, FISH Project consultant and medical toxicologist.

Participants who do not respond to a counseling call may be sent a **Counsel Reminder Letter** (see Appendix 2) to encourage them to contact the clinic about their result.

All Participants with Mercury >5.8 µg/L

Counseling advice discussed during the call or appointment will be based on each participant mercury result, Mercury Screening Question responses, and DQ. The table below describes the key messages for participants with **mercury results >5.8 µg/L**.

Mercury >5.8 μg/L and Eats Fish	Mercury >5.8 μg/L and Pregnant/Planning Pregnancy
• Your exposure to mercury is higher than most people in the U.S.	 Your result does not mean there will be a health problem with you or your baby.
• Your result does not mean that you are sick or will become sick.	 Reducing mercury exposure is one of the many things you should pay attention to when pregnant.
• We excrete mercury so the level will come down if changes are made to your diet.	 Provide standard advice about mother and baby care or refer to a source of prenatal care.
• Discuss fish consumption and advice to reduce exposure and how to keep mercury exposure from fish low.	 If risk adverse, suggest eating only very low-mercury fish; provide list of fish to eat.
• It is important to eat fish low in mercury.	
• Discuss individualized fish consumption recommendations described in results letter.	
 Ask if they understand the fish consumption guidelines. 	
 If participant asks or thinks their exposure to mercury could be from other sources, nurse or physician can refer them to MDH to discuss. 	

Participants with Mercury > 2 μ g/L

It is not expected that there will be a large number of participants who have a mercury result >2 μ g/L and reported not eating fish, but it is possible. The *most* common way people in the U.S. are exposed to mercury is by eating fish. Unless the participant has misreported their fish consumption for some reason, the source or sources of mercury exposure for participants with levels > 2 μ g/L should be investigated.

Participants with mercury results > $2 \mu g/L$ and reported eating no fish will be given the recommendation to call the FISH Coordinator. The key messages are:

- (If >2 and \leq 5.8 µg/L) Your result is below the level of concern but it is higher than expected for someone who reports eating little or no fish.
- (> 5.8 µg/L) The result is above the level of concern and also higher than expected for someone who reports eating little or no fish.
- Your result does not mean that you are sick or will become sick.
- We should try to figure out how you are being exposed to mercury; we recommend that you contact MDH who can help to figure that out.
- Provide MDH referral to Carl Herbrandson (651-201-4906)
- Eat fish low in mercury and high in fatty acids to encourage fish consumption and getting the benefits of eating fish
- Ask if they understand the fish consumption guidelines.

Participants with Mercury \leq to 5.8 μ g/L

Participants with **mercury levels less than or equal to 5.8 µg/L** will not receive the <u>recommendation</u> for counseling. However, any participant who has concerns or questions can discuss them on the telephone with a nurse-counselor, who would go over the results letter, review the advice given at Visit One for eating fish low in mercury, and ask if the participant understands the fish consumption guidelines. The participant may also request an office visit to meet with a clinic physician.

Visit Two

All participants who have a blood mercury levels greater than 5.8 μ g/L (Highs) at Visit One will be asked to return for Visit Two about six months after their Visit One date. Based on the *Mercury in Newborns Study*, it is estimated that approximately 50 women in FISH will have blood mercury levels above the EPA RfD of 5.8 μ g/L. For every High, two participants from the below-RfD mercury population (Controls) will be chosen and asked to participate.

Selection of Controls

Controls will be roughly matched with Highs, based on the date of Visit One. MDH will provide a **Potential Controls List** (in preferential order) of approximately 15 potential Controls whose Visit One dates were within plus-or-minus two weeks of the High's Visit One date. (Controls are being date-matched with Highs because of seasonal differences in fish consumption.) In cases where multiple Controls make the list based on Visit One date, age will be used to determine the contact order for Visit Two. Out of this list of 15, two Controls will be scheduled for Visit Two.

Notification/Recruitment for Visit Two

Highs were informed they were selected for Visit Two in their Visit One mercury results letter. Staff will call Highs about 5 months after Visit One to schedule Visit Two.

All other participants were informed in their Visit One mercury results letter that they <u>may</u> be selected for Visit Two. Once identified by MDH on the **Potential Controls List**, staff will contact selected Controls to schedule Visit Two.

Scheduling Visit Two

When scheduling, Visit Two should be plus-or-minus 2 weeks of the 6-month mark of each participant's Visit One date. This Visit Two scheduling window will be provided by MDH for all potential Visit Two participants. Visit One location information will also be provided by MDH on the **Potential Controls List**, in case staff wish to contact participants based on location to schedule Visit Two.

Using the list, staff will begin calling each High to schedule Visit Two about 5 months after Visit One. At the same time, staff will call the top two Controls on the list and ask them to schedule Visit Two. Staff will attempt to contact Highs multiple times to schedule Visit Two. Staff will use their discretion for the number of follow-up calls to make to Controls; if they have not responded or scheduled within a reasonable time, they will be crossed off the list and the next Control on the list will be contacted for Visit Two.

Staff will document Visit Two scheduling calls and appointments in the EHR/PM.

Visit Two Steps

Visit Two will be very similar to Visit One. All Visit Two participants will:

- Verify current contact information with staff
- Answer the mercury screening questions
- Provide a blood sample to be tested for mercury and omega-3 fatty acids (Specimen IDs are unique to each blood draw so Visit Two participants will have 2 different Specimen IDs corresponding to each visit)
- Complete a detailed questionnaire and some additional evaluation questions
- Meet with staff for fish consumption education
- Receive up to \$50 in Visa gift cards for completing all parts of Visit Two

Visit Two participants will <u>not</u>:

- Sign another consent form (Visit One consent was previously signed and covered both Visit One and Two)
- Be assigned another Participant ID (the Participant ID assigned at Visit One will be used again for Visit Two)

For Visit Two step-by-step instructions, follow Visit One Steps #5 through #12 in the Visit One Steps section (Step #5 begins on page 16). Staff will also assemble and use a yellow **Visit Two Folder** for each returning participant.

Visit Two forms and materials are as follows:

- Visit Two Checklist
- Participant ID labels (leftover from Visit One or supplied by MDH)
- Mercury Screening Questions (if EHR/PM not available)
- Lab Order
- Lab Pack
- DQ Part 1 and DQ Part 2
- Evaluation
- Educational materials
- Incentive items
- Participant's Info Sheet

Visit Two forms and materials listed above are the same items used for Visit One, except for the **Visit Two Checklist** and **Evaluation** (found in Appendix 1). Likewise, results communication and counseling for Visit Two are the same as Visit One (see page 25).

Appendices

- Appendix 1: FISH Forms and Materials
- Appendix 2: Letters and Materials
- Appendix 3: FISH Frequently Asked Questions
- Appendix 4: CCNSH and GPHS Laboratory and Specimen Procedures
- Appendix 5: Sawtooth Mountain Clinic Policies

Appendix 1: FISH Forms and Materials

Three-fold Promotional Flyer Pre-Enrollment/Contact Information Form Visit One Checklist Participant's Infosheet **Eligibility Screening Form** Adult Consent Minor Assent Parental/Guardian Consent Mercury Screening Form Detailed Questionnaire, Part 1 Detailed Questionnaire, Part 2 Three-fold Brochure Wallet Card **Incentive Receipt MDH** Incentive Log DQ Batch Log Potential Controls List Visit Two Checklist Evaluation



Three-fold Promotional Flyer

Fish are Important for Superior Health (FISH) Project Why are we doing the FISH If I decide to take part, Is my information private? Project? what will I do? Yes. Your information will not be shared Participant names and personal results will You will answer questions about the kinds of fish you eat and how often you eat fish. A 2010 study showed that 10% of Northeast only be seen by some Sawtooth Mountain Clinic and Grand Portage Health Service Minnesota babies tested had mercury in their blood above the level considered safe. * You will have some blood drawn from clinic staff. We want women to choose to eat your arm. fish that are low in mercury. You will learn how to choose locally caught and purchased fish for healthy That way women and their families can have the health benefits of eating fish while lowering their exposure to mercury. eating. We will ... Who can participate in the Test your blood samples for mercury and healthful fatty acids found in fish. FISH Project? Women age 16 to 50 who live in or near Cook Send you your blood results and a nurse will be available to discuss them with you. County can take part in FISH. Why should I eat fish? Why should I participate? How long will it take? Fish are an important part of a healthy diet. Taking part will give you information to improve your health and the health of your family. Catching and eating fish are part of the history and culture of the Great Lakes region. The first visit will take about one hour. Women who complete Visit One will receive a \$50 Visa gift card. Fish are a great source of low-fat protein. The things we learn from the FISH Project We will ask some women to return for a second visit in 6 months. For completing the • Fish contain Omega-3 fatty acids that are will help your community and other communities where people catch and eat fish. important for the developing eyes and brains of a fetus. follow-up visit, women will receive a second \$50 card. Eating fish low in contaminants is good for the health of adults and children.

Pre-Enrollment/Contact Information Form

	Fish are Impor	and Contact In	(FISH) Project
To I	Pre-Enroll in the FISH Pr	oject:	
Fill o be se contr are	ut this form if you would like t een by staff at the Sawtooth / act you to make an appointmen available cach week. Completi	to be contacted about the FISH Mountain Clinic or the Grand Por t for the FISH Project. Only a ing this form does not mean you	Project. Your information will only tage Health Service. They will certain number of appointments have to take part in the project.
1.	Are you currently a patie Health Service?	ent at the Sawtooth Mountain	Clinic or Grand Portage
	Ves N	D	
2.	If you decide to take particular	rt in the FISH Project, when in Clinic	e would you like to be seen? age Health Services
3.	What is your full name?	(print, please)	
3.	What is your full name? 	(print, please) (Middle Initial)	(Last Name)
3. 4.	What is your full name? (First Name) What is your birthdate?	(print, please) (Middle Initial) /// (month) (day) (year,	(Last Name)

	IS IT OK TO CONTACT YOU BY EMAIL?	
	No	
6.	What is your phone number(s)?	
	Home Phone:	
	Work Phone:	-
	Cell Phone:	May we text you? Ves No
	Other:	Describe:
	When is the best time to call you?	□ Afternoon □ After 6:00 pm □ Work □ Cell □ Other
	Is it ok to leave a recorded message at this number	? □Yes □No
7.	What is your mailing address?	
	Post Office Box: or	
	Street: Unit City: State (or Province):	: ZIP (or Postal) Code:

Visit One Checklist

Nar	me	DOB
1.	Complete Eligibility Screening (Open EMR but don't assign Participant ID until after consent)	
	🗆 Eligible	
	□ Not eligible	
2.	Informed Consent(s)	
	Review participant information sheet	
	□ Sign Adult Consent (2 copies)	
	Sign Minor Consent and Parent/Guardian Consent (2 cop	ies each, if used)
	□ Give copy to patient	
	Give copy to medical records to scan into chart	
3.	Assign Participant ID	
	□ Attach labels to all forms (Note: participant IDs F650-F99	9 will be used for special clinics)
4.	Complete Contact Information (can use info from RS03 if in V1	packet)
	Verify or add contact information into EMR	
5.	Complete Mercury Screening Questions	
	Enter into EMR	
	Verify extreme values (initial if >30)	
7.	Assign Lab Specimen ID from Lab Kit assigned	
	Enter Specimen ID into EMR	pecimen ID: (attach here)
	Attach Specimen and Participant ID labels to Lab Checklin	st, Lab Verification, and Lab Order forms
	Attach Specimen ID label to COC form	
	Put 1 column of PPT ID labels in lab kit	
ISH Visit One Checklist		Participant ID: F
--	--------------------------------	-------------------
8. Send Participant to Lab (SMC only)		
Remind participant to bring back	Lab Verification Form after t	olood draw
(optional) Give DQ Part 1 to parti	cipant in case there is a wait	for blood draw
10. Blood Draw Outcome		
Blood draw complete		
Reschedule blood draw (talk to Page 1)	atty @printing off a report Q	(2wks)
Ineligible for blood draw; do not r	eschedule	
Participant declined		
11. Complete Detailed Questionnaire		
Check participant answered every	y question and answers make	e sense
Verify Part 2 fish pages match Part	rt 1 Q9 (table)	
12. Provide Education		
Discuss and give FISH brochure ar	nd wallet card to participant	
13. Incentives		
□ No incentive		
□1 st incentive (\$25)		
□ 2 nd incentive (\$25)		
14. Visit One Outcome		
Complete		
Closed by lab decision		
Closed by reason of decline		
		EISH Nurse

Participant's Infosheet

Fish Are Important for Superior Health (FISH) Project



FISH Participant Information

May 2014

Who can take part in the FISH Project?

Participants must be women age 16 to 50 and...

- Live in or near Cook County for at least 9 out of the last 12 months or at least 3 months if they recently moved to the area.
- Can come to the Sawtooth Mountain Clinic or the Grand Portage Health Service for a Visit One appointment.
- Are willing to provide a blood sample and, if asked, return for a follow-up visit in 6 months.



If I decide to take part, what will I do?

Visit One will take about 1 hour. You will...

- Answer 3 short questions about the kinds of fish that you eat and how often you eat fish.
- Have a blood sample taken from your arm.
 Fill out a paper questionnaire about fish and
- Omega-3 fatty acids in your diet.
- Talk with a nurse about the importance of including fish in your diet – particularly when you are pregnant.
- Learn how to get the healthy benefits of eating fish while reducing your exposure to mercury.
- Receive a \$50 Visa gift card.

About 1/3 of participants will be asked to return for a follow-up visit in 6 months.

Will I find out my blood results?

Yes. We will test your blood samples for healthful fatty acids found in fish and for mercury contamination from fish. The clinic will send you a letter with your results and what they mean.

If your mercury level is high or if you have other concerns, a nurse will be available to talk with you. The nurse will also be able to tell you what you can do to lower mercury in your blood and raise your levels of omega-3 fatty acids.

Who will be asked to return for a follow-up visit?

Any woman whose blood sample shows mercury above the level that is considered safe will be asked to return for a follow-up visit 6 months after Visit One.

For each woman with mercury above the safe level, we will also ask 2 women with lower mercury levels to return for a follow-up visit.

The second visit will be very much like the first. Participants will...

- Have a blood sample taken for mercury to see if the levels change over time.
- Complete questionnaires about their fisheating habits
- Receive another \$50 Visa gift card.

Why should I take part in FISH?

If you take part, you will...

- Find out the amount of mercury and fatty acids in your body.
- Encourage a wider community understanding of the risks and benefits of eating fish.
- Help people in other communities where people catch and eat fish.

Will my information be private?

Yes. All information gathered for the FISH Project will be kept safe and secure according to Minnesota law.

- All staff are trained in privacy laws and procedures.
- Only a few people from Grand Portage Health Service or Sawtooth Mountain Clinic will know your name and results.
- We will label all of your data collection forms and your blood sample with an ID number, not your name.
- We will send information from your questionnaire and blood sample to the Minnesota Department of Health using only your ID.

Who is sponsoring this Project?

The FISH Project partners are:

- Cook County North Shore Hospital
- Grand Portage Health Service
- Grand Portage Trust Lands
- Minnesota Department of Health
- Sawtooth Mountain Clinic

The Project is also supported by the Grand Portage Tribal Council.

Why do FISH partners think the Project is important?

Project partners believe the FISH Project is important because...

- Catching and eating fish are an important part of the history and culture of our communities.
- Mercury levels in Northeastern Minnesota waters are higher than in other parts of the state.
- Partners want families in their communities to continue to eat fish and to learn more about choosing fish that are low in contaminants.

Where can I get more information?

Please call and ask for a FISH Coordinator at one of our Project locations:

awtooth Mountain Clin (218) 387-2330

(218) 475-2235





(---) --- --



Eligibility Screening Form

	Eliaib	ility Screening	Form
-	ich ann Tennant	ant for Superior Healt	h (ETSH) Project
	ish are import	an for superior rican	((LON) MOJECI
First, I have to verify how old you are and who	that you are e ere you live.	ligible to participate. I	will ask you a few questions about
1. Are you currently	a patient at (S	MC or GPHS)?	
🗆 Yes			
□No → Ca	n we register	you as a patient at no	cost to you? 🗆 Yes 🔲 No
2. How old are you?	Yea	rs	
If age is less	than 16 years or	more than 50 years:	
I'm se Thank	you for your	icipants must be at leas time and interest in Fi	st 16 and no older than 50 years old. ISH.
(If 16 or 17 ye	ears):		
Do yo	u have or can	you get a signed paren	tal consent?
	U Yes		
	$\Box N_0 \longrightarrow$	If parental consent can	not be obtained
		I'm sorry, but we ha before we can ask yo the FISH project. (R	ve to get a signed parental consent ou questions or get a blood sample for eschedule)
3. What is your home	zip code (or (Canadian postal code)?	
U.S. Zip Code	2:	or Canadia	n Postal Code:/

<pre>s you lived in or near the Cook County area for more than three months? yes No → Recheck residential history in Project area for last 3 months. If still No I'm sorry. You cannot take part in FISH until you have lived in the area for more than 3 months. Would you like to schedule a visit in a few months? many months do you (or will you for new residents) live in the area each year?Months: If less than 9 months: I'm sorry. To be in FISH, participants must live in the area more than 9 months a year. Thank you for your time and interest in the Project. you willing to give a blood sample to be tested for mercury and omega-3 fatty acids? Yes No → I'm sorry. You cannot take part in FISH unless you are willing to give a blood sample. Thank you for your time and interest in the Project.</pre>
 you lived in or near the Cook County area for more than three months? yes No → Recheck residential history in Project area for last 3 months. If still No I'm sorry. You cannot take part in FISH until you have lived in the area for more than 3 months. Would you like to schedule a visit in a few months? many months do you (or will you for new residents) live in the area each year?Months: If less than 9 months: I'm sorry. To be in FISH, participants must live in the area more than 9 months a year. Thank you for your time and interest in the Project. you willing to give a blood sample to be tested for mercury and omega-3 fatty acids? Yes No → I'm sorry. You cannot take part in FISH unless you are willing to give a blood sample. Thank you for your time and interest in the Project.
 Yes No → Recheck residential history in Project area for last 3 months. If still No I'm sorry. You cannot take part in FISH until you have lived in the area for more than 3 months. Would you like to schedule a visit in a few months? many months do you (or will you for new residents) live in the area each year?Months: If less than 9 months: I'm sorry. To be in FISH, participants must live in the area more than 9 months a year. Thank you for your time and interest in the Project. you willing to give a blood sample to be tested for mercury and omega-3 fatty acids? Yes No → I'm sorry. You cannot take part in FISH unless you are willing to give a blood sample. Thank you for your time and interest in the Project.
 No → Recheck residential history in Project area for last 3 months. If still No I'm sorry. You cannot take part in FISH until you have lived in the area for more than 3 months. Would you like to schedule a visit in a few months? many months do you (or will you for new residents) live in the area each year?Months: If less than 9 months: I'm sorry. To be in FISH, participants must live in the area more than 9 months a year. Thank you for your time and interest in the Project. you willing to give a blood sample to be tested for mercury and omega-3 fatty acids? Yes No → I'm sorry. You cannot take part in FISH unless you are willing to give a blood sample. Thank you for your time and interest in the Project.
 I'm sorry. You cannot take part in FISH until you have lived in the area for more than 3 months. Would you like to schedule a visit in a few months? many months do you (or will you for new residents) live in the area each year?Months: If less than 9 months: I'm sorry. To be in FISH, participants must live in the area more than 9 months a year. Thank you for your time and interest in the Project. you willing to give a blood sample to be tested for mercury and omega-3 fatty acids? □ Yes □ No → I'm sorry. You cannot take part in FISH unless you are willing to give a blood sample. Thank you for your time and interest in the Project.
 many months do you (or will you for new residents) live in the area each year?Months: I'm sorry. To be in FISH, participants must live in the area more than 9 months a year. Thank you for your time and interest in the Project. you willing to give a blood sample to be tested for mercury and omega-3 fatty acids? Yes No → I'm sorry. You cannot take part in FISH unless you are willing to give a blood sample. Thank you for your time and interest in the Project.
If less than 9 months: I'm sorry. To be in FISH, participants must live in the area more than 9 months a year. Thank you for your time and interest in the Project. you willing to give a blood sample to be tested for mercury and omega-3 fatty acids? □ Yes □ No → I'm sorry. You cannot take part in FISH unless you are willing to give a blood sample. Thank you for your time and interest in the Project.
I'm sorry. To be in FISH, participants must live in the area more than 9 months a year. Thank you for your time and interest in the Project. you willing to give a blood sample to be tested for mercury and omega-3 fatty acids? □Yes □No → I'm sorry. You cannot take part in FISH unless you are willing to give a blood sample. Thank you for your time and interest in the Project.
you willing to give a blood sample to be tested for mercury and omega-3 fatty acids? □Yes □No → I'm sorry. You cannot take part in FISH unless you are willing to give a blood sample. Thank you for your time and interest in the Project.
□Yes □No → I'm sorry. You cannot take part in FISH unless you are willing to give a blood sample. Thank you for your time and interest in the Project.
□ No → I'm sorry. You cannot take part in FISH unless you are willing to give a blood sample. Thank you for your time and interest in the Project.
blood sample. Thank you for your time and interest in the Project.
e women will be asked to return for a second clinic visit in 6 months. Are you willing and to return in 6 months, if asked to do so?
□ Yes
$\square No \longrightarrow Recheck response. If still No$
I'm sorry. You cannot take part in FISH unless you are willing to come for a second visit in 6 months, if asked. Thank you for your time and
interest in the Project.
Thank you. You are eligible for FISH and can take part. Now, we will go through the

Adult Consent

	Adult Participant Consent Form
_	Fish are Important for Superior Health (FISH) Project
The	Sawtooth Mountain Clinic (SMC), Grand Portage Health Service (GPHS), and Minnesota
Dep	artment of Health (MDH) are partners in this Project. Funding is from the U.S.
Envi	ronmental Protection Agency (EPA).
Purp	oose: This project will help women of childbearing age to reduce their exposure to mercury
in fi	h.
Wha	at we will ask you to do: We will ask you to: (1) answer three questions about the kinds of
fish	that you eat; (2) have a small amount of blood taken from your arm; 3) complete a longer
que	stionnaire with more details about your fish eating habits; and (4) talk to a nurse about how
to g	at the health benefits of eating fish while lowering your exposure to mercury in fish.
	The entire visit will take about one hour.
Step	s for Visit One:
	Screening: The nurse will ask you 3 questions about fish you have eaten in the last 2-3
	months. Your answers will be compared to the mercury level found in your blood sample.
	Giving blood: Staff from GPHS or the Cook County North Shore Hospital lab will take a
	small amount of blood from your arm. The blood will only be tested for mercury and for
	healthy Omega-3 fatty acids.
	All blood will be destroyed at the end of the Project.
	Questionnaire: You will complete the questionnaire on your own or have it read to you, it
	you prefer. This should take about 20 minutes. You will answer questions about: 1) what
	kinds of fish you eat and at what times of the year you eat them; and 2) foods you eat that
	might contain Omega-3 fatty acids. We will also ask about your age and education. Your
	answers will help us to understand mercury exposure in women of childbearing age.
•	Health Education Information: A nurse will talk to you and give you a brochure about
	choosing which fish to eat and how often to eat fish.

Participant ID: F Return Visit: We will ask all of the participants with higher levels of mercury in their blood to return for a second visit in six months. We will also ask some of the participants with low levels of mercury in their blood to return. You should not agree to participate if you are not able to return for a second visit in six months. The return visit will be very similar to Visit One. Test Results: SMC and GPHS staff will send your results in a letter with information about what they mean and be available to discuss your results with you. A summary of Project results will be shared with the public. Participants will not be identified in this report. This will happen after SMC and GPHS have read and approved the report. Risks: You might feel a slight sting or "pinch" when we take your blood. You may get a small bruise. A small number of people may feel dizzy or faint. Benefits: Getting your own test results can be helpful. You will know more about the amount of mercury and fatty acids in your body. This Project will help you to plan healthier meals for yourself and your family. We will use what we learn from the FISH Project to help people in your area and other communities where people catch and eat fish. Privacy Protection: All information about you is private. Project records will be in locked files or password-protected computers at SMC, GPHS, and MDH. Only Project staff at SMC and GPHS will be able to see information about you. We will share test results and interview answers with EPA. We will not give them any information that could identify you. Personal information will not leave SMC and GPHS. Costs: The only costs to you are your time and any travel expense. To thank you, we will give you up to \$50 in Visa gift cards at the end of Visit One. If the North Shore Hospital Lab technician or GPHS clinic staff cannot take your blood, you will get a \$25 Visa gift card but cannot participate in the Project. People asked to participate in the Follow-Up visit will receive an additional \$50 Visa gift card. Taking part is your choice: You can choose to participate or not. You may refuse any part or quit at any time. Your choice will not affect your relationship with or services from SMC, GPHS, MDH, or the federal government. Questions: For more information or if you have questions about your rights as a participant,

you may call the Sawtooth Mountain Clinic at 218-387-2330 or Grand Portage Health Service at 218-475-2235 and ask for a FISH Coordinator. You may also contact the MDH Institutional Review Board at 651-201-5942.

FISH Adult Consent, V103, 2014_08_27

Page 2 of 3

	Con Fish	are Important for Sup	Adult Particip erior Health (FISH) P	ants roject
By marking about the Project sta keep a cop	g the boxes and Project and free ff to collect, sto y of this form.	d signing below, you a ely choose to take part ore, and share your Pro	re saying you had a cl in it. You are also say ject information as d	hance to ask questions ving that you will allow escribed above. You may
l have rea	d the consent	form (or have had it re	ad to me) and I unde	erstand the information.
	□ Yes	□ No		
l choose to	o complete the	e questionnaires and to	o give a sample of my	y blood.
	□ Yes	□ No		
l will parti	cipate in a sec	ond clinic visit in six m	onths, if I am asked t	to return.
	nt)			Birthdate
Name (pri	First name	Middle Initial	Last Name	
Name (pri	First name	Midale Initial	Last Name	Date
Name (pri Signature	First name First name	Midale Initial	Last Name ast Name	Date:
Name (pri Signature Staff Signa	First name First name sture	Midale Initial L Middle Initial L t name Middle Initi	ast Name al Last Name	Date:
Name (pri Signature Staff Signa	First name First name sture First	Middle Initial L Middle Initial L t name Middle Initi	ast Name ast Name al Last Name	Date:
Name (pri Signature Staff Signa	First name First name sture	Midale Initial L Middle Initial L t name Middle Initi	ast Name al Last Name	Date:
Name (pri Signature Staff Signa	First name First name sture First	Middle Initial L Middle Initial L	ast Name al Last Name	Date:

Minor Assent

t	
The	Sawtooth Mountain Clinic (SMC), Grand Portage Health Service (GPHS), and Minnesota
Dep	artment of Health (MDH) are partners in this Project. Funding is from the U.S.
Envi	ionmental Protection Agency (EPA).
Purp	ose: This project will help women of childbearing age to reduce their exposure to mercury
in fis	h.
Wha	t we will ask you to do: We will ask you to: (1) answer three questions about the kinds of
fish	that you eat; (2) have a small amount of blood taken from your arm; 3) complete a longer
ques	tionnaire with more details about your fish eating habits; and (4) talk to a nurse about how
to ge	t the health benefits of eating fish while reducing your exposure to mercury in fish.
	The entire visit will take about one hour.
Step	s for Visit One:
٠	Screening: The nurse will ask you 3 questions about fish you have eaten in the last 2-3
	months. Your answers will be compared to the mercury level found in your blood sample.
•	Giving blood: Staff from GPHS or the Cook County North Shore Hospital lab will take a
	small amount of blood from your arm. The blood will only be tested for mercury and for
	healthy Omega-3 fatty acids.
	All blood will be destroyed at the end of the Project.
•	Questionnaire: You will complete the questionnaire on your own or have it read to you, if
	you prefer. This should take about 20 minutes. You will answer questions about: 1) what
	kinds of fish you eat and at what times of the year you eat them; and 2) foods you eat that
	might contain Omega-3 fatty acids. We will also ask about your age and education. Your
	answers will help us to understand mercury exposure in women of childbearing age.
•	Health Education Information: A nurse will talk to you and give you a brochure about

Participant ID: F

Return Visit: We will ask all of the participants with higher levels of mercury in their blood to return for a second visit in six months. We will also ask some of the participants with low levels of mercury in their blood to return. You should not agree to participate if you are not able to return for a second visit in six months. The return visit will be very similar to Visit One.

Test Results: SMC and GPHS staff will send your results in a letter with information about what they mean and be available to discuss your results with you. A summary of Project results will be shared with the public. Participants will not be identified in this report. This will happen after SMC and GPHS have read and approved the report.

Risks: You might feel a slight sting or "pinch" when we take your blood. You may get a small bruise. A small number of people may feel dizzy or faint.

Benefits: Getting your own test results can be helpful. You will know more about the amount of mercury and fatty acids in your body. This Project will help you to plan healthier meals for yourself and your family. We will use what we learn from the FISH Project to help people in your area and other communities where people catch and eat fish.

Privacy Protection: All information about you is private. Project records will be in locked files or password-protected computers at SMC, GPHS, and MDH. Only Project staff at SMC and GPHS will be able to see information about you. We will share test results and interview answers with EPA. We will not give them any information that could identify you. Personal information will not leave SMC and GPHS.

Costs: The only costs to you are your time and any travel expense. To thank you, we will give you up to \$50 in Visa gift cards at the end of Visit One. If the North Shore Hospital Lab technician or GPHS clinic staff cannot take your blood, you will get a \$25 Visa gift card but cannot participate in the Project. People asked to participate in the Follow-Up Visit will receive an additional \$50 Visa gift card.

Taking part is your choice: You can choose to participate or not. You may refuse any part or quit at any time. Your choice will not affect your relationship with or services from SMC, GPHS, MDH, or the federal government.

Questions: For more information or if you have questions about your rights as a participant, you may call the Sawtooth Mountain Clinic at 218-387-2330 or Grand Portage Health Service at 218-475-2235 and ask for a FISH Coordinator. You may also contact the MDH Institutional Review Board at 651-201-5942.

FISH Minor Assent, V104, 2014_08_27

Page 2 of 3

	Assent	Form for Partic	ipants under	Age 18
	Fish a	re Important for Supe	rior Health (FISH) P	roject
By markin about the that you ha You are als informatio	g the boxes and Project and freel ave received perm to saying that yo n as described a	signing below, you are y choose to take part i nission from a parent o u will allow Project sta bove. You may keep a	e saying you had a c n it. You are saying t r guardian to particip ff to collect, store, a copy of this form.	hance to ask questions hat you are a minor and bate in the Fish Project. Ind share your Project
I have rea	d the consent fo	rm (or have had it rea	d to me) and I unde	erstand the information.
	□ Yes	No		
I have rece	eived permission	n from a parent or gua	rdian to participate	in the Project.
	□ Yes	No		
I choose to	complete the c	uestionnaires and to	give a sample of m	y blood.
	□ Yes	No		
l will parti	cipate <mark>in a seco</mark> r	nd clinic visit in six mo	nths, if I am asked t	to return.
	□ Yes	□ No		
Name (pri	nt)			Birthdate
	First name	Middle Initial	Last Name	MM/DD/YYYY
Signature	First name	Middle Initial La	st Name	Date:
Staff Signs	ture			
First name	Middle Initio	al Last Name		

Parental/Guardian Consent

	Participant ID: F
	Parent/Guardian Consent Form Fish are Important for Superior Health (FISH) Project
Your o Projec collab Enviro	daughter is being asked to participate in the Fish Are Important for Superior Health (FISH) ct conducted by the Sawtooth Mountain Clinic and Grand Portage Health Service in woration with the Minnesota Department of Health. Funding is from the U.S. commental Protection Agency (EPA).
lf you this co satisfa	decide to allow your daughter to participate in the FISH Project, you will be asked to sign onsent form once all your questions about the Project have been answered to your action.
Purpo in fish	ose: This project will help women of childbearing age to reduce their exposure to mercury
What about comp a nurs mercu	we will ask your daughter to do: We will ask participants to: (1) answer three questions the kinds of fish that they eat; (2) have a small amount of blood taken from their arm; 3) lete a longer questionnaire with more details about their fish eating habits; and (4) talk to se about how to get the health benefits of eating fish while lowering their exposure to ury in fish.
	The entire visit will take about one hour.
Steps •	for Visit One: <u>Screening</u> : The nurse will ask your daughter 3 questions about fish she has eaten in the last 2-3 months. Her answers will be compared to the mercury level found in her blood sample.
•	<u>Giving blood</u> : Staff from GPHS or the Cook County North Shore Hospital will take a small amount of blood from your daughter's arm. The blood will only be tested for mercury and for healthy Omega-3 fatty acids.
	All blood will be destroyed at the end of the Project.
•	<u>Questionnaire</u> : It will take your daughter about 20 minutes to complete the questionnaire. Questions will be about: 1) what kinds of fish she eats and at what times of the year she eats them; and 2) foods she eats that might contain Omega-3 fatty acids. We will also ask about her age and education. Her answers will help us to understand mercury exposure in women of childbearing age.

Participant ID: F
 <u>Health Education Information</u>: A nurse will talk to your daughter and give her a brochure about choosing which fish to eat and how often to eat fish.
Return Visit: We will ask all of the participants with higher levels of mercury in their blood to return for a second visit in six months. We will also ask some of the participants with low levels of mercury in their blood to return. You should not agree to your daughter's participation, if sh is not able to return for a second visit in six months. The return visit will be very similar to Visit One.
Test Results: SMC and GPHS staff will send your daughter's results in a letter to you and to her with information about what they mean. Staff will also be available to discuss those results with you and your daughter. A summary of Project results will be shared with the public. Participants will not be identified in this report. This will happen after SMC and GPHS have read and approved the report.
Risks: Your daughter might feel a slight sting or "pinch" when we take her blood. She may get a small bruise. A small number of people who give blood may feel dizzy or faint.
Benefits: Getting your daughter's test results can be helpful. She will know more about the amount of mercury and fatty acids in her body. This Project will help you to plan healthier meals for yoursel and your family. We will use what we learn from the FISH Project to help people in your area and other communities where people catch and eat fish.
Privacy Protection: All information about your daughter is private. Project records will be in locked files or password-protected computers at SMC, GPHS, and MDH. Only Project staff at SMC and GPHS will be able to see information about your daughter. We will share test results and interview answers with EPA. We will not give them any information that could identify your daughter. Personal information will not leave SMC and GPHS.
Costs: The only costs to your daughter are her time and any travel expense. To thank her, we will give her up to \$50 in Visa gift cards at the end of Visit One. If the North Shore Hospital Lab technician or GPHS clinic staff cannot take her blood, she will get a \$25 Visa gift card but cannot participate in the Project. People asked to participate in the Follow-Up Visit will receive an additional \$50 Visa gift card.
Taking part is her choice and yours: You can choose to allow your daughter to participate or not. She can refuse any part of the Project or quit at any time. That choice will not affect your relationship or that of your daughter with or services from SMC, GPHS, MDH, or the federal government.
Questions: For more information or if you have questions about your daughter's rights as a participant, you may call the Sawtooth Mountain Clinic at 218-387-2330 or Grand Portage Health Service at 218-475-2235 and ask for a FISH Coordinator. You may also contact the MDH Institutiona Review Board at 651-201-5942.

	Parent/	Guardian (Consent F	orm
	Fish are import	ant for superio	r nealul (rish	rioject
By marking the boxe the Project and freely allow Project staff to above. You may keep	s and signing bel choose to allow collect, store, an a copy of this fo	ow, you are sayi your daughter t d share your dau rm.	ng you had a c o take part in it ghter's Project	hance to ask questions about . You are saying that you will information as described
I have read the cons	sent form (or ha	ve had it read t	o me) and I u	nderstand the information.
Ves Yes	No			
My daughter may co	omplete the que	estionnaires and	t give a sampl	e of her blood.
🗆 Yes	□ No			
I agree my daughter return. □ Yes	r may participat D No	e in a second cl	inic visit in six	months, if she is asked to
Minor's Name (print)			Birthdate
Minor's Name (print) First name	Middle Initial	Last Nam	Birthdate e
Minor's Name (print Parent Name (print)) First name First name	Middle Initial Middle I	Last Nam	e Birthdate
Minor's Name (print Parent Name (print)) First name First name	Middle Initial Middle II	Last Nam nitial	e Birthdate
Minor's Name (print Parent Name (print) Parent Signature) First name First name First name	Middle Initial Middle In Middle Initial	Last Nam nitial Last Name	e Birthdate e Last NameDate:
Minor's Name (print) Parent Name (print) Parent Signature Staff Signature) First name First name First name	Middle Initial Middle In Middle Initial	Last Nam hitial Last Name	e Birthdate e Last NameDate:

Mercury Screening Form

	Mercury Screening Form				
	Fish are Important for Superior Health (FISH) Project				
Now, I a months	am going to ask you three questions about the fish you have eaten in the past two to three s. We will compare your answers to the mercury level in your blood.				
When a the last	nswering these questions, please keep in mind how much fish you ate, on average, <u>during</u> two to three months.				
1.	How many times a <u>week</u> did you eat <u>any kind of fish</u> ?				
	(Think of all the different kinds of fish you eat. Include canned tuna, fish sticks or patties at				
	home or in a restaurant, fast food fish sandwiches, pickled herring, or canned sardines – any				
	fresh, frozen, or packaged fish at home or away from home.				
	Examples: (1) If you have eaten herring or purchased salmon or canned tung about once a				
	week over the last two or three months, answer one time a week. (2) If you eat canned tuna				
	once every week and herring or shrimp about once a week, answer two times a week.)				
	times a <u>week</u>				
2.	How many times a <u>month</u> did you eat any of these fish – Walleye, Northern Pike, Bass, or Lake Trout from Lake Superior?				
	(Example: if you have eaten walleye about two times and lake trout about three times a month over the last two or three months, answer five times a month.)				
	times a month				
3.	Did you eat Shark or Swordfish?				
	🗆 Yes 🗆 No				
	FISH Nurse				
	Initials:				

Detailed Questionnaire, Part 1

	The FTSH YOU FAT SURVEY
lea	se answer the following questions as best as you can. Ask a FISH Project nurse if one of the stions does not make sense to you, or if you are not sure how to answer it.
1.	How old are you? Years
2.	What is your home zip code (or Canadian postal code)?
	U.S. Zip Code: or Canadian Postal Code: /
3.	What is the highest level of education you have completed? (Check only 1)
	□ High school diploma or GED
	□ Vocational/technical school or some college after high school
	□ College degree (e.g., Bachelor's or Associate degree)
	□ Some post-graduate work
	Post-graduate degree (e.g., Master's, PhD, JD, MD, etc.)
4.	Have you changed your eating habits because you have learned about contaminants in fish?
	□Yes
	□ No
	FISH Nurse Initials:
	Date://

D .	When you eat	locally caught fish, do you know what size fish you are eating?	(Check only 1)
		□ Yes	
		\Box No, I usually don't know what size fish I am eating	
6.	How many piece meal? (Check of	ces of fish, the size of the palm of your hand, do you <u>usually</u> e any 1)	at at <u>one</u>
	I usually cat:	□ Less than 1 piece	
		2 pieces	
		3 pieces	
		14 or more pieces	
		□ I never eat fish	
7.	On average ov supplements?	□ I never eat fish ver the past 3 months, how often have you taken any Omega-3 (Check only 1)	
7.	On average ov supplements?	 A or more pieces I never eat fish ver the past 3 months, how often have you taken any Omega-3 (Check only 1) Never 	
7.	On average ov supplements?	 4 or more pieces I never eat fish ver the past 3 months, how often have you taken any Omega-3 (Check only 1) Never Daily (most days of the week) 	
7.	On average ov supplements?	 4 or more pieces I never eat fish ver the past 3 months, how often have you taken any Omega-3 (Check only 1) Never Daily (most days of the week) Weekly (1-2 times per week) 	
7.	On average ov supplements?	 4 or more pieces I never eat fish ver the past 3 months, how often have you taken any Omega-3 (Check only 1) Never Daily (most days of the week) Weekly (1-2 times per week) Occasionally (less than 1 time per week) 	
8.	On average ov supplements? On average ov fatty acids <u>ad</u>	 4 or more pieces I never eat fish ver the past 3 months, how often have you taken any Omega-3 (Check only 1) Never Daily (most days of the week) Weekly (1-2 times per week) Occasionally (less than 1 time per week) ver the past 3 months, how often have you caten foods that hadded to them? (Check only 1) 	ve Omega-3
8.	On average ov supplements? On average ov fatty acids <u>ad</u>	 4 or more pieces I never eat fish ver the past 3 months, how often have you taken any Omega-3 (Check only 1) Never Daily (most days of the week) Weekly (1-2 times per week) Occasionally (less than 1 time per week) ver the past 3 months, how often have you caten foods that hadded to them? (Check only 1) Never 	ve Omega-3
8.	On average ov supplements? On average ov fatty acids <u>ad</u>	 4 or more pieces I never eat fish ver the past 3 months, how often have you taken any Omega-3 (Check only 1) Never Daily (most days of the week) Weekly (1-2 times per week) Occasionally (less than 1 time per week) ver the past 3 months, how often have you caten foods that hadded to them? (Check only 1) Never Daily (most days of the week) 	ve Omega-3
8.	On average ov supplements? On average ov fatty acids <u>ad</u>	 4 or more pieces I never eat fish ver the past 3 months, how often have you taken any Omega-3 (Check only 1) Never Daily (most days of the week) Weekly (1-2 times per week) Occasionally (less than 1 time per week) ver the past 3 months, how often have you caten foods that hadded to them? (Check only 1) Never Daily (most days of the week) Weekly (1-2 times per week) 	ve Omega-3

Participant ID:	F		

9. Which fish did you eat in the past year, and how many times did you eat those fish in the <u>last week</u>?

Please put a 🗸 in front of all the fish you have eaten in the past year. Remember to include all fresh, canned, frozen, smoked, cooked, or pickled fish. If you did not eat a certain fish (e.g. sushi), please leave the box blank.

For each fish you ate in the past week, write the number of times you have eaten that fish. Telling us what fish you ate in the last week will help us and you understand your blood tests.

Check here if you ate this fish in <u>past year</u>	Fish Species	Number of times you ate this fish in the <u>last week</u>
	Lake Herring (Cisco)	
	Whitefish, Menominee	
	Walleye	
	Lake Trout	
	Perch	
	Salmon (canned or not canned)	
	Northern Pike	
	Bass (Smallmouth, Largemouth, Rock)	
	Panfish (Bluegill, Sunfish, Crappie, etc.)	
	Stream Trout (Brook, Splake, Rainbow, Brown)	
	Shrimp and Shellfish (Clams, Mussels, Oysters, Scallops, Crab)	
	Tilapia	
	Tuna (canned)	
	Tuna steak or sushi	
	Cod	
	Halibut	
	Fish sticks or fish sandwiches	
	Other, write species name here:	
	Other, write species name here:	
	Other, write species name here:	
	I did not eat fish in the past year.	

Thank you! Please give the FISH nurse your survey.

Page 3 of 3

Detailed Questionnaire, Part 2

FISH YOU EAT	Survey, Part 2 Participant ID: F
1. Fish Specie	s: Lake Herring (Cisco)
Which seasons did you eat <i>Herring</i> during the last year? Mark Yes or No.	 Do your best to complete the questions in this column: Enter either times per week or month or season – however it is easiest for you. Check all of the places that your fish came from that season.
Spring Yes No	In the Spring, I ate Herring times each
Summer Yes No	In the Summer, I ate Herringtimes each
Fall □Yes □No	In the Fall, I ate Herring times each
Winter Ves No	In the Winter, I ate Herringtimes each

FISH YOU EAT Survey, Part 2



2. Fish Species: Whitefish, Menominee

Which seasons did you eat <i>Whitefish</i> during the last year? Mark Yes or No.	 Do your best to complete the questions in this column: Enter either times per week or month or season – however it is easiest for you. Check all of the places that your fish came from that season.
Spring Yes No	In the Spring, I ate Whitefish times each
Summer Yes No	In the Summer, I ate Whitefish times each
Fall □Yes □No	In the Fall, I ate Whitefishtimes each
Winter Yes No	In the Winter, I ate Whitefish times each

FISH YOU EAT Survey, Part 2 Participant ID: F		
3. Fish Specie	es: Walleye	
Which seasons did you eat <i>Walleye</i> during the last year? Mark Yes or <i>No</i> .	Do your best to complete the questions in this column: Enter either times per week or month or season – Check all of the places that your fish came from the	however it is easiest for you. Nat season.
Spring	In the Spring, I ate Walleye times each UWeek or D	Month or Season
C Yes	Check all of the places that the Walleve came fromRestaurant, grocery store, or market Lake Superior	
🗆 No	Local inland lake, specify: Local inland stream or river, specify: Non-local waters, specify if possible: I don't know where it came from	
Summer □Yes □No	In the Summer, I ate <i>Walleye</i> times each	□ Month or □ Season
Fall □Yes □No	In the Fall, I ate Walleye times each	Nonth or □Season
Winter Yes No	In the Winter, I ate Walleye times each	□ Month or □ Season

FISH YOU EAT	Survey, Part 2	Participant ID: F
4. Fish Specie	es: Lake Trout	
Which seasons did you eat <i>Lake</i> <i>Trout</i> during the last year? Mark Yes or <i>No</i> .	Do your best to complete the questions in this column: • Enter either times per week or month or season – how • Check all of the places that your fish came from that s	vever it is easiest for you. eason.
Spring Yes No	In the Spring, I ate Lake Trout times each	Month or 🗆 Season
Summer Yes No	In the Summer, I ate Lake Trout times each	□ Month or □ Season
Fall □Yes □No	In the Fall, I ate Lake Trouttimes each	onth or 🗆 Season
Winter □Yes □No	In the Winter, I ate Lake Trout times each	Month or Season

5. Fish Species: Perch		
Which seasons did you eat <i>Perch</i> during the last year? Mark Yes or <i>No</i> .	 Do your best to complete the questions in this column: Enter either times per week or month or season – however it is easiest for you. Check all of the places that your fish came from that season. 	
Spring Yes No	In the Spring, I ate Perch times each	
Summer Yes No	In the Summer, I ate Perch times each	
Fall □Yes □No	In the Fall, I ate Perchtimes each	
Winter Ves No	In the Winter, I ate Perch times each	

6. Fish Species: Salmon (canned or not canned)		
Which seasons did you eat <i>Salmon</i> during the last year? Mark Yes or <i>No</i> .	 Do your best to complete the questions in this column: Enter either times per week or month or season – however it is easiest for you. Check all of the places that your fish came from that season. 	
Spring □Yes □No	In the Spring, I ate Salmon times each	
Summer Yes No	In the Summer, I ate Salmon times each	
Fall □Yes □No	In the Fall, I ate Salmontimes each	
Winter Ves No	In the Winter, I ate Salmon times each	

FISH YOU EAT Survey, Part 2 Participant ID: F	
Which seasons did you eat <i>Northern</i> during the last year? Mark Yes or No.	Do your best to complete the questions in this column: Enter either times per week or month or season – however it is easiest for you. Check all of the places that your fish came from that season.
Spring Yes No	In the Spring, I ate Northern times each
Summer Yes No	In the Summer, I ate Northern times each
Fall □Yes □No	In the Fall, I ate Northern times each
Winter Yes No	In the Winter, I ate Northern times each

FISH YOU EAT Survey, Part 2 Participant ID: F 8. Fish Species: Bass (Smallmouth, Largemouth, Rock) Which seasons did you eat Bass Do your best to complete the questions in this column: during the last Enter either times per week or month or season – however it is easiest for you. year? Check all of the places that your fish came from that season. Mark Yes or No. Spring Check all of the places that the Bass came from. T Yes Restaurant, grocery store, or market Local inland lake, specify: Local inland stream or river, specify: Non-local waters, specify if possible: I don't know where it came from In the Summer, I ate Bass times each Week or Month or Season Summer Check all of the places that the Bass came from. Yes Restaurant, grocery store, or market Local inland lake, specify: Local inland stream or river, specify: Non-local waters, specify if possible: I don't know where it came from Fall Check all of the places that the Bass came from. C Yes Restaurant, grocery store, or market Local inland lake, specify: Local inland stream or river, specify: Non-local waters, specify if possible: I don't know where it came from In the Winter, I ate Bass _____ times each 🗆 Week or 🗆 Month or 🗆 Season Winter Check all of the places that the Bass came from. C Yes Restaurant, grocery store, or market Local inland lake, specify: Local inland stream or river, specify: Non-local waters, specify if possible: I don't know where it came from

Participant ID: F FISH YOU EAT Survey, Part 2 9. Fish Species: Panfish (Bluegill, Sunfish, Crappie, etc.) Which seasons did you eat Do your best to complete the questions in this column: Panfish during Enter either times per week or month or season – however it is easiest for you. the last year? Check all of the places that your fish came from that season. ٠ Mark Yes or No. In the Spring, I ate Panfish _____ times each 🗆 Week or 🗆 Month or 🗆 Season Spring Check all of the places that the Panfish came from. Yes Restaurant, grocery store, or market Local inland lake, specify: Local inland stream or river, specify: Non-local waters, specify if possible: I don't know where it came from In the Summer, I ate Panfish _____ times each 🗆 Week or 🗆 Month or 🗆 Season Summer Check all of the places that the Panfish came from. C Yes Restaurant, grocery store, or market Local inland lake, specify: Local inland stream or river, specify: Non-local waters, specify if possible: I don't know where it came from Fall Check all of the places that the Panfish came from. Yes Restaurant, grocery store, or market Local inland lake, specify: Local inland stream or river, specify: Non-local waters, specify if possible: I don't know where it came from In the Winter, I ate Panfish _____ times each 🛛 Week or 🗆 Month or 🗆 Season Winter Check all of the places that the Panfish came from. Yes Restaurant, grocery store, or market Local inland lake, specify: Local inland stream or river, specify: Non-local waters, specify if possible: I don't know where it came from

FISH YOU EAT Survey, Part 2 F Participant ID: 10. Fish Species: Stream Trout (Brook, Splake, Rainbow, Brown) Which seasons did you eat Do your best to complete the questions in this column: Stream Trout · Enter either times per week or month or season - however it is easiest for you. during the last Check all of the places that your fish came from that season. year? Mark Yes or No. In the Spring, I ate Stream Trout _____ times each UWeek or Month or Season Spring Check all of the places that the Stream Trout came from. Yes Restaurant, grocery store, or market Local inland lake, specify: Local inland stream or river, specify: Non-local waters, specify if possible: I don't know where it came from In the Summer, I ate Stream Trout ______ times each __ Week or __ Month or __ Season Summer Check all of the places that the Stream Trout came from. Yes Restaurant, grocery store, or market Local inland lake, specify: □ No Local inland stream or river, specify: Non-local waters, specify if possible: I don't know where it came from Fall Check all of the places that the Stream Trout came from. Yes Restaurant, grocery store, or market Local inland lake, specify: Local inland stream or river, specify: Non-local waters, specify if possible: I don't know where it came from In the Winter, I ate Stream Trout _____ times each 🛛 Week or 🖾 Month or 🗆 Season Winter Check all of the places that the Stream Trout came from. Yes Restaurant, grocery store, or market Local inland lake, specify: Local inland stream or river, specify: Non-local waters, specify if possible: I don't know where it came from

11. Fish Species: St	rrimp and shellfish (Clams, Mussels, Oysters, Scallops, Crab)
Which seasons did you eat <i>Shrimp/Shellfish</i> during the last year? Mark Yes or <i>No</i> .	Do your best to complete the questions in this column: • Enter either times per week or month or season – however it is easiest for you.
Spring Ves No	In the Spring, I ate <i>Shrimp/Shellfish</i> times each
Summer Yes No	In the Summer, I ate Shrimp/Shellfish times each UWeek or UMonth or Season
Fall □ Yes □ No	In the Fall, I ate Shrimp/Shellfishtimes each
Winter Ves No	In the Winter, I ate Shrimp/Shellfish times each

12. Fish Species: Tilapia		
Which seasons did you eat <i>Tilapia</i> during the last year? Mark Yes or <i>No</i> .	Do your best to complete the questions in this column: • Enter either times per week or month or season – however it is easiest for you.	
Spring Yes No	In the Spring, I ate <i>Tilapia</i> times each UWeek or UMonth or Season	
Summer Yes No	In the Summer, I ate <i>Tilapia</i> times each	
Fall □ Yes □ No	In the Fall, I ate <i>Tilapia</i> times each	
Winter Yes No	In the Winter, I ate <i>Tilapia</i> times each UWeek or UMonth or USeason	

FISH YOU EAT Survey, Part 2



13. Fish Species: Tuna (canned only)

Which seasons did you eat <i>Canned Tuna</i> during the last year? Mark Yes or No.	Do your best to complete the questions in this column: • Enter either times per week or month or season – however it is easiest for you.		
Spring Ves No	In the Spring, I ate Canned Tuna times each		
Summer Yes No	In the Summer, I ate Canned Tuna times each		
Fall Yes In the Fall, I ate Canned Tunatimes each Uweek or Month or No			
Winter □Yes □No	In the Winter, I ate Canned Tuna times each		

FISH YOU EAT Survey, Part 2

Participant ID: F

14. Fish Species: Tuna steak or Sushi



Which seasons did you eat <i>Tuna</i> <i>Steak or Sushi</i> during the last year? Mark Yes or No.	 Do your best to complete the questions in this column: Enter either times per week or month or season – however it is easiest for you. Check all of the places that your fish came from that season. 		
Spring Yes No	In the Spring, I ate Tuna steak or Sushi times each		
Summer Yes No	In the Summer, I ate Tuna steak or Sushi times each		
Fall □ Yes □ No	In the Fall, I ate <i>Tuna steak or Sushi</i> times each		
Winter Yes No	In the Winter, I ate Tuna steak or Sushi times each		

15. Fish Species: (Cod
Which seasons did you eat <i>Cod</i> during the last year? Mark Yes or <i>No</i> .	Do your best to complete the questions in this column: • Enter either times per week or month or season – however it is easiest for you.
Spring Ves No	In the Spring, I ate Cod times each
Summer Ves No	In the Summer, I ate Cod times each
Fall Yes No	In the Fall, I ate Cod times each
Winter Yes No	In the Winter, I ate Cod times each 🗆 Week or 🗆 Month or 🗆 Season
	1

16. Fish Spe	ecies: Halibut
Which seasons did you eat Halibut during the last year? Mark Yes or No.	 Do your best to complete the questions in this column: Enter either times per week or month or season – however it is easiest for you. Check all of the places that your fish came from that season.
Spring	In the Spring, I ate Halibut times each 🗆 Week or 🗆 Month or 🗆 Season
C Yes	Check all of the places that the Halibut came from. Restaurant, grocery store, or market
□ No	Non-local waters, specify if possible: I don't know where it came from
Summer	In the Summer, I ate Halibut times each
C Yes	Check all of the places that the Halibut came from. Restaurant, procerv store, or market
□ No	Non-local waters, specify if possible:
Fall	In the Fall, I ate Halibut times each
□ Yes	Check all of the places that the Halibut came from.
- N-	Restaurant, grocery store, or market Non-local waters specify if possible:
L NO	I don't know where it came from
Winter	In the Winter, I ate Halibut times each 🗆 Week or 🗆 Month or 🗆 Season
□ Yes	Check all of the places that the Halibut came from.
	Restaurant, grocery store, or market

FISH YOU EAT Sur	vey, Part 2

17. Fish Category: Fish sticks or fish sandwiches



Which seasons did you eat Fish sticks or fish sondwiches during the last year? Mark Yes or No.	Do your best to complete the questions in this column: • Enter either <i>times per week</i> or <i>month</i> or <i>season</i> – however it is easiest for you.		
Spring Ves No	In the Spring, I ate Fish sticks/Sandwiches times each 🗆 Week or 🗆 Month or 🗆 Season		
Summer Ves No	In Summer, I ate Fish sticks/Sandwiches times each		
Fall □Yes □No	In the Fall, I ate Fish sticks/Sandwiches times each		
Winter Ves No	In the Winter, I ate Fish sticks/Sandwiches times each		

	FISH Y	YOU	EAT	Survey	, Part 2
--	--------	-----	-----	--------	----------



18. Other Fish Species: (Write name here)

Which seasons did you eat Other Fish during the last year? Mark Yes or No.	 Do your best to complete the questions in this column: Enter either times per week or month or season – however it is easiest for you. Check all of the places that your fish came from that season.
Spring	In the Spring, I ate this Other Fish times each 🗆 Week or 🗆 Month or 🗆 Season
Yes	Check all of the places that this Other Fish came from. Restaurant, grocery store, or market
□ No	Lake Superior Local inland lake, specify: Local inland stream or river, specify: Non-local waters, specify if possible:
	I don't know where it came from In the Summer, I ate this Other Fish times each Week or Month or Season
Summer	Check all of the places that this Other Fish came from.
Yes	Restaurant, grocery store, or market
□ No	Lake Superior Local inland lake, specify:
	Local inland stream or river, specify:
Fall	In the Fall, I ate this Other Fish times each
E Ver	Check all of the places that this Other Fish came from.
L res	Restaurant, grocery store, or market
D No	Lake Superior
	Local inland lake, specify:
	Local mand stream or river, specify:
	Non-local waters, specify it possible:I don't know where it came from
Winter	In the Winter, I ate this Other Fish times each UWeek or Month or Season
Yes	Check all of the places that this Other Fish came fromRestaurant, grocery store, or market
C No	Lake Superior
	Local inland lake, specify:
	Local Inland stream or river, specify:
	NOT-tocal waters, specify it possible:

Three-fold Brochure

Brochure used at Grand Portage Health Service only




Brochure used at Sawtooth Mountain Clinic and other North Shore locations





to get these fatty acids.

- DHA is a building block of the brain and eyes.

store-bought or locally-caught, may contain contaminants such as mercury that can harm human health - especially the development of children and fetuses. Too much mercury can affect a child's ability to learn and process information.

۲

NS Fish Is

mercury in fish won't build up to harmful amounts in your body.

have the highest levels.

Wallet Card





Incentive Receipt

FISH Project Incentive Receipt	Participant ID: F
I have received a gift card or cards in the amount	nt of
for my participation in the FISH Project.	
This signed receipt will remain in my private pati	ent file.
Print Name:	
Sign Here:	
Date:	-
Card #:	- (878)
	Participant ID: F
FISH Project Incentive Receipt I have received a gift card or cards in the amoun	Participant ID: F
FISH Project Incentive Receipt I have received a gift card or cards in the amoun for my participation in the FISH Project.	Participant ID: F
FISH Project Incentive Receipt I have received a gift card or cards in the amoun for my participation in the FISH Project. This signed receipt will remain in my private patie	Participant ID: F
FISH Project Incentive Receipt I have received a gift card or cards in the amoun for my participation in the FISH Project. This signed receipt will remain in my private patie Print Name:	Participant ID: F
FISH Project Incentive Receipt I have received a gift card or cards in the amoun for my participation in the FISH Project. This signed receipt will remain in my private patie Print Name:	Participant ID: F
FISH Project Incentive Receipt I have received a gift card or cards in the amoun for my participation in the FISH Project. This signed receipt will remain in my private patie Print Name:	Participant ID: F

MDH Incentive Log

	Min	nesota [Department of	Health Incent	ive Rec	onciliati	on Repo	ort: Fisca	al Year (July 1-June 30)	2014
				FISH Project In	centive L	og - <ins< th=""><th>ert clinic I</th><th>name></th><th></th><th></th><th></th></ins<>	ert clinic I	name>			
Batch N	umber: <inse< td=""><td>rt batch #>,</td><td>Page Number: <ins< td=""><td>ert page #></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></ins<></td></inse<>	rt batch #>,	Page Number: <ins< td=""><td>ert page #></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></ins<>	ert page #>							
Delivere	d to <clinic n<="" th=""><th>ame>:</th><th>//</th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th></clinic>	ame>:	//								
Receive	d by Staff Init	ials:	-								
No.	FM Dist.	Denom.	Card No.	Card	Card in	Date	Card	Card in	Date	FISH Dist. Date	Recipient ID
004	Date	635.00		out to:	from:	<u> </u>	out to:	from:			
001		\$25.00									
002		\$25.00									
003		\$25.00		_				<u> </u>			
005		\$25.00					<u> </u>	<u> </u>	<u> </u>		
006		\$25.00									
007		\$25.00									
006		\$25.00									
009		\$25.00									
010		\$25.00									
011		\$25.00									
012		\$25.00									
013		\$25.00									
014		\$25.00									
015		\$25.00									
016		\$25.00									
017		\$25.00									
018		\$25.00									
019		\$25.00									
		4		-			-				

FISH Incentive Log, V118, 2014_04_22

DQ Batch Log

Date Batched:/ month d Date Shipped:/ month d	ay year			
Shipping method				
1		11		
2		12.		
3		13		
4		14.		
5		15		
6		16		
7		17.		
8		18		
9		19.		
10.		20.		
1) Place a Participant ID label for ea 2) Clip the corresponding Questionr 3) Fill-in dates and courier informat 4) Save a copy of this Batch Log. 5) Incomplete batches (<20) can be	ch Detailed Questionnairr naires to this Batch Log an ion before shipping (if apj shipped if it is convenient	e to be included in d hold for shipme liicable). to do so.	this batch on one of th nt or scanning.	ne numbered lines.
	Page	1 of 1	Initials:	FISH Nurse

Potential Controls List

Example of Potential Controls List

Participant ID:	Visit 1 Date	Visit 1 Location	Visit 2 Open Date	Visit 2 Close Date	Visit 2 Appointment	Comments
ligh Mercury P	articipant					
X123	5/1/2014	SMC	10/16/2014	11/13/2014		
Senerated Pote	ential Controls	; 10/27/2014	; Listed in ord	ler of date differ	ence, age difference.	
Participant ID:	Visit 1 Date	Visit 1 Location	Visit 2 Open Date	Visit 2 Close Date	Visit 2 Appointment	Notes Comments
X234	5/2/2014	SMC	10/17/2014	11/14/2014		
X345	5/2/2014	SMC	10/17/2014	11/14/2014		
					es Participant ID.	X123 rptHigh Mercu
			onana i ontag		es Participant ID.	. X123 rptHigh_Mercu
					es Participant ID.	: <u>X123</u> rptHigh_Mercu
					es Participant ID.	: <u>X123</u> rptHigh_Mercu
		, or rio -			es Participant ID.	: <u>X123</u> rptHigh_Mercu
		, or rio -			rs Parucipant ID.	: <u>X123</u> rptHigh_Mercu

Visit Two Checklist

FIS	H Visit Two Checklist	Participant ID: F
Nan	ne	DOB
1.	Attach Participant ID	
	□ Attach labels to all forms	
2.	Verify Contact Information	
	Verify or add contact information into EMR	
3.	Complete Mercury Screening Questions	
	Enter into EMR	
	□ Verify extreme values (initial if >30)	
4.	Assign Lab Specimen ID from Lab Kit assigned	
	Enter Specimen ID into EMR	Specimen ID: (attach here)
	Attach Specimen and Participant ID labels to Lab Cl	hecklist, Lab Verification, and Lab Order forms
	□ Attach Specimen ID label to COC form	
	Put 1 column of PPT ID labels in lab kit	
5.	Send Participant to Lab (SMC only)	
	□ Remind participant to bring back Lab Verification Fe	orm after blood draw
	(optional) Give DQ Part 1 to participant in case the	re is a wait for blood draw
6.	Blood Draw Outcome	
	Blood draw complete	
	Reschedule blood draw (talk to Patty @printing off	a report Q 2wks)
	Ineligible for blood draw; do not reschedule	
	Participant declined	

FISH Visit Two Check	list	Participant ID: F
7. Complete Detailed Question	naire	
Check participant ans	wered every question and answer	rs make sense
Verify Part 2 fish page	s match Part 1 Q9 (table)	
8. Complete Evaluation		
Check participant ans	wered every question	
9. Provide Education		
Discuss FISH brochure	and wallet card to participant	
Offer copy of FISH bro	chure and wallet card	
10. Incentives		
□ No incentive		
□ 1 st incentive (\$25)		
□ 2 nd incentive (\$25)		
11. Visit One Outcome		
Complete		
Closed by lab decision	(I	
Closed by reason of de	ecline	
15H V1 Checklist 2014 11 03	Page 7 of 7	<u>FISH Nurse</u>
ant a concruit, 2014_11_02	rage z ur z	

Evaluation

1. Have you used the Brochure since your first FISH □ Ves □ No 2. When you were not at home, did you use the Wallet □ Ves □ No Card? If yes, where did you use it? □ Ves □ No 3. Can you find information about the recommended amount of fish to eat per week in the Brochure/Wallet Card? □ Ves □ No 4. Can you find which fish are low in mercury in the Brochure/Wallet Card? □ Ves □ No 5. Did you find the fish consumption advice easier to understand the way it was presented in the Brochure □ Brochure or in the Wallet Card? □ Wallet Card 6. Was the information below easy to find and to understand in the Brochure? Image: Please choose one answer for each row. I sow this and understand it this in the Brochure?	Fish are Important for Superior Health: Evaluation of the FISH St	[tudy	Participant ID:
3. Can you find information about the recommended amount of fish to eat per week in the Brochure/Wallet Card? □ Yes □ No 4. Can you find which fish are low in mercury in the Brochure/Wallet Card? □ Yes □ No 5. Did you find the fish consumption advice easier to understand the way it was presented in the Brochure or in the Wallet Card? □ Brochure □ Brochure 6. Was the information below easy to find and to understand in the Brochure? I saw this and Understand in the Brochure? I saw this and Understand it below the same for each row. I saw this and Understand it Brochure?	 Have you used the Brochure since your first FISH visit? When you were not at home, did you use the Wallet Card? If yes, where did you use it? 	□ Yes □ Yes	□ No □ No
 4. Can you find which fish are low in mercury in the Brochure/Wallet Card? 5. Did you find the fish consumption advice easier to understand the way it was presented in the Brochure or in the Wallet Card? 6. Was the information below easy to find and to understand in the Brochure? 6. Was the information below easy to find and to understand in the Brochure? Please choose one answer for each row. I saw this and understand it is an did not see this in the Brochure? 	3. Can you find information about the recommended amount of fish to eat per week in the Brochure/Wallet Card?	🗆 Yes	□ No
 5. Did you find the fish consumption advice easier to understand the way it was presented in the Brochure or in the Wallet Card? 6. Was the information below easy to find and to understand in the Brochure? ✓ Please choose one answer for each row. ✓ I saw this and understood it ✓ I saw this but I did not see this in the Brochure? 	4. Can you find which fish are low in mercury in the Brochure/Wallet Card?	Ves	□ No
6. Was the information below easy to find and to understand in the Brochure? Please choose one answer for each row. I saw this and understood it I did not this in the Brochu	5. Did you find the fish consumption advice easier to understand the way it was presented in the Brochure or in the Wallet Card?	□ Brochure □ Wallet Card	d
	6. Was the information below easy to find and to understand Please choose one answer for each row. I saw this and understood it	I saw this but did not understand it	e? I did not see this in the Brochu



Appendix 2: Letters and Materials

Upcoming Visit Letter FISH Project Meal Planning Infosheet Mercury Results Letter Templates Fatty Acids Results Letter Templates Fatty Acids Infosheet Counseling Notes Template Counsel Reminder Letter Template

Upcoming Visit Letter

Example

FISH Project Meal Planning Infosheet



Mercury Results Letter Templates

Visit One: Letter for women who reported eating fish and have a mercury result above 17.4 mcg/L

Visit One: Letter for women who reported eating fish and have a mercury result above 5.8 mcg/L but less than 17.4 mcg/L

Visit One: Letter for women who reported eating fish and have a mercury result below 5.8 mcg/L

Visit One: Letter for women who reported eating little or no fish and have a mercury result above 5.8 mcg/L

Visit One: Letter for women who reported eating little or no fish and have a mercury result above 2.0 mcg/L

Visit Two: Letter for women who reported eating fish, have a mercury result above 5.8 mcg/L at Visit Two, and a mercury result above 5.8 mcg/L at Visit One; we are concerned in case the woman gets pregnant

Visit Two: Letter for women who reported eating fish, have a mercury result above 5.8 mcg/L at Visit Two, and a mercury result above 5.8 mcg/L at Visit One; we are not concerned because the women indicated no future pregnancies

Visit Two: Letter for women who reported eating fish, have a mercury result below 5.8 mcg/L at Visit Two, and a mercury result above 5.8 mcg/L at Visit One

Visit Two: Letter for women who reported eating fish, have a mercury result above 5.8 mcg/L at Visit Two, and a mercury result below 5.8 mcg/L at Visit One

Visit Two: Letter for women who reported eating fish, have a mercury result below 5.8 mcg/L at Visit Two, and a mercury result below 5.8 mcg/L at Visit One

Fatty Acids Results Letter Templates

Visit One: Letter for women who reported eating fish

Visit One: Letter for women who reported eating no fish

Visit Two: Letter for women who reported eating fish

Visit Two: Letter for women who reported eating no fish

Visit One and Two: Letter for women who do not have fatty acids results

Fatty Acids Infosheet

Counseling Notes Template

 Participant ID: F Total mercury result: (Methylmercury result to follow) DHA result: Values range found in NHANES survey participants: EPA result: Values range found in NHANES survey participants: EPA result: Values range found in NHANES survey participants: Does the participant report eating fish? Yes No Mercury Screening Responses a. How many times a week did you eat any kind of fish? b. How many times a month did you eat any of these fish - walleye, northern, bass, or lake trout from Lake Superior? c. Did you eat shark or swordfish? Yes No Do we suspect that the major sources of mercury are non-fish? Yes No Individualized consumption advice based on responses to Mercury Screen and Detailed Questionnaire: a. Of the fish she reported eating these are the species to eat more of (to replace highmercury with low-mercury fish): b. Species to eat less of (to reduce mercury):		Fish are Important for Superior Health (FISH) Project
 Participant ID: F Total mercury result: (Methylmercury result to follow) DHA result: Values range found in NHANES survey participants: EPA result: Values range found in NHANES survey participants: EPA result: Values range found in NHANES survey participants: Does the participant report eating fish? Yes No Mercury Screening Responses a. How many times a week did you eat any kind of fish? b. How many times a month did you eat any of these fish - walleye, northern, bass, or lake troot from Lake Superior? c. Did you eat shark or swordfish? Yes No Do we suspect that the major sources of mercury are non-fish? Yes No Individualized consumption advice based on responses to Mercury Screen and Detailed Questionnaire: a. Of the fish she reported eating these are the species to eat more of (to replace highmercury with low-mercury fish): b. Species to eat less of (to reduce mercury): Counseling recommendation: a		This are important to superior reacting for the
 Total mercury result: (Methylmercury result to follow) DHA result: Values range found in NHANES survey participants: EPA result: Values range found in NHANES survey participants: EPA result: Values range found in NHANES survey participants: Does the participant report eating fish? Yes No Mercury Screening Responses a. How many times a week did you eat any kind of fish? b. How many times a month did you eat any of these fish - walleye, northern, bass, or lake trout from Lake Superior? c. Did you eat shark or swordfish? Yes No Do we suspect that the major sources of mercury are non-fish? Yes No Individualized consumption advice based on responses to Mercury Screen and Detailed Questionnaire: a. Of the fish she reported eating these are the species to eat more of (to replace highmercury with low-mercury fish): b. Species to eat less of (to reduce mercury): Counseling recommendation: a Include in results letters the recommendation for a nurse counseling call or b Include in results letters the recommendation for counseling by a physician, either of the telephone or at an in-clinic call, at the physician's discretion (MD will also consider additional factors know to them such as participant pregnancy or planning pregnancy; other medical conditions) 	1.	Participant ID: F
 3. DHA result: Values range found in NHANES survey participants:	2.	Total mercury result: (Methylmercury result to follow)
 4. EPA result: Values range found in NHANES survey participants:	3.	DHA result: Values range found in NHANES survey participants:
 5. Does the participant report eating fish?YesNo 6. Mercury Screening Responses a. How many times a week did you eat any kind of fish? b. How many times a month did you eat any of these fish - walleye, northern, bass, or lake trout from Lake Superior? c. Did you eat shark or swordfish?YesNo 7. Do we suspect that the major sources of mercury are non-fish?YesNo 8. Individualized consumption advice based on responses to Mercury Screen and Detailed Questionnaire: a. Of the fish she reported eating these are the species to eat more of (to replace highmercury with low-mercury fish): b. Species to eat less of (to reduce mercury):	4.	EPA result: Values range found in NHANES survey participants:
 6. Mercury Screening Responses a. How many times a week did you eat any kind of fish? b. How many times a month did you eat any of these fish - walleye, northern, bass, or lake trout from Lake Superior? c. Did you eat shark or swordfish?YesNo 7. Do we suspect that the major sources of mercury are non-fish?YesNo 8. Individualized consumption advice based on responses to Mercury Screen and Detailed Questionnaire: a. Of the fish she reported eating these are the species to eat more of (to replace highmercury with low-mercury fish): b. Species to eat less of (to reduce mercury):	5.	Does the participant report eating fish?YesNo
 a. How many times a week did you eat any kind of fish? b. How many times a month did you eat any of these fish - walleye, northern, bass, or lake trout from Lake Superior?	6.	Mercury Screening Responses
 b. How many times a month did you eat any of these fish – walleye, northern, bass, or lake trout from Lake Superior?		a. How many times a week did you eat any kind of fish?
 c. Did you eat shark or swordfish?YesNo 7. Do we suspect that the major sources of mercury are non-fish?YesNo 8. Individualized consumption advice based on responses to Mercury Screen and Detailed Questionnaire: a. Of the fish she reported eating these are the species to eat more of (to replace highmercury with low-mercury fish): b. Species to eat less of (to reduce mercury):		b. How many times a month did you eat any of these fish – walleye, northern, bass, or lake trout from Lake Superior?
 Do we suspect that the major sources of mercury are non-fish?YesNo Individualized consumption advice based on responses to Mercury Screen and Detailed Questionnaire: a. Of the fish she reported eating these are the species to eat more of (to replace highmercury with low-mercury fish): b. Species to eat less of (to reduce mercury): Counseling recommendation: aInclude in results letter the recommendation for a nurse counseling call or bInclude in results letters the recommendation for counseling by a physician, either of the telephone or at an in-clinic call, at the physician's discretion (MD will also consider additional factors know to them such as participant pregnancy or planning pregnancy; other medical conditions) 		c. Did you eat shark or swordfish?YesNo
 8. Individualized consumption advice based on responses to Mercury Screen and Detailed Questionnaire: a. Of the fish she reported eating these are the species to eat more of (to replace highmercury with low-mercury fish):	7.	Do we suspect that the major sources of mercury are non-fish? Yes No
 a. Of the fish she reported eating these are the species to eat more of (to replace high-mercury with low-mercury fish):	8.	Individualized consumption advice based on responses to Mercury Screen and Detailed Questionnaire:
 b. Species to eat less of {to reduce mercury}:		 Of the fish she reported eating these are the species to eat more of (to replace high- mercury with low-mercury fish):
 9. Counseling recommendation: a Include in results letter the recommendation for a nurse counseling call or b Include in results letters the recommendation for counseling by a physician, either of the telephone or at an in-clinic call, at the physician's discretion 10. (MD will also consider additional factors know to them such as participant pregnancy or planning pregnancy; other medical conditions) 		b. Species to eat less of (to reduce mercury):
 a Include in results letter the recommendation for a nurse counseling call or b Include in results letters the recommendation for counseling by a physician, either of the telephone or at an in-clinic call, at the physician's discretion 10. (MD will also consider additional factors know to them such as participant pregnancy or planning pregnancy; other medical conditions) 	9.	Counseling recommendation:
 b Include in results letters the recommendation for counseling by a physician, either of the telephone or at an in-clinic call, at the physician's discretion 10. (MD will also consider additional factors know to them such as participant pregnancy or planning pregnancy; other medical conditions) 		a Include in results letter the recommendation for a nurse counseling call or
the telephone or at an in-clinic call, at the physician's discretion 10. (MD will also consider additional factors know to them such as participant pregnancy or planning pregnancy; other medical conditions)		b Include in results letters the recommendation for counseling by a physician, either or
10. (MD will also consider additional factors know to them such as participant pregnancy or planning pregnancy; other medical conditions)		the telephone or at an in-clinic call, at the physician's discretion
pregnancy; other medical conditions)	10	. (MD will also consider additional factors know to them such as participant pregnancy or planning
		pregnancy; other medical conditions)

Counsel Reminder Letter Template



Appendix 3: FISH Frequently Asked Questions (FAQs)

FISH Frequently Asked Questions (FAQs)

Results Counseling Questions and Answers (Q & A)

FISH Frequently Asked Questions (FAQs)



What is the FISH Project?

Purpose:

- Reduce mercury exposure in women who are or may become pregnant to lower the exposure in babies
 - Integrate communication of fish consumption advice into clinical practice
 - Train healthcare providers about the risks and benefits of eating fish
 - Evaluate if 3 mercury screening questions predict a women's exposure to mercury in fish

Kev Messages:

- Encourage women who eat fish now to continue eating fish but focus on eating fish low in mercury.
- Encourage women who eat little or no fish to increase their consumption of fish low in mercury.
- Pregnant women: Eating fish is good for developing babies

Who are the Project partners?

- Cook County North Shore Hospital
- Grand Portage Health Service
- Grand Portage Trust Lands
- Minnesota Department of Health
- Sawtooth Mountain Clinic
- Supported by Grand Portage Tribal Council and other local agencies and organizations

Why did Project partners agree to support this Project?

Partners see a need to reduce mercury exposure in some women on the North Shore because

- A recent study showed that 10% of Northeast Minnesota babies tested had mercury in their blood above the level considered safe.
- The benefits of eating fish outweigh the risks if people eat fish low in mercury and other contaminants.
- People living along the North Shore of Lake Superior may eat more fish than many other people in Minnesota.
- Fish and fishing are an important part of the history and culture of Grand Marais and Grand Portage communities.
- We want people to continue fishing and eating fish... but to be better informed about the fish they choose to eat.

What do Project partners (MDH, clinics, hospital, and tribe) hope to achieve with this Project?

Educate women on the importance of eating fish low in mercury, particularly during pregnancy.
 Participants will learn...

1

- How much mercury and omega-3 fatty acids they have in their blood
- What they can do to reduce methylmercury and increase omega-3s by eating fish
- o Education will have a positive impact on families and friends of participants.
- Impact other communities by implementing healthcare provider Risks and Benefits Training and the Project's mercury screening questions in clinics throughout the Great Lakes region.
Eligibility FAQs

Who is eligible?

- Women ages 16 to 50.
- Must live in or near Cook County as full-time residents for at least 9 months of past year. If new to area, must have lived here for at least 3 months.
- Must be willing to provide a blood sample and take part in a follow-up visit 6 months after Visit One, if asked.

Why is participation limited to women of childbearing age-- 16 to 50?

 Mercury and other contaminants in fish are most harmful to the developing fetus and small children.

Men eat a lot of fish. Why can't they be tested?

- EPA funded this Project only for women of child-bearing age because of findings from the study, Mercury in Newborns in the Lake Superior Basin.
- If future funding becomes available, we may propose a similar project to include other community members (children, men, or older women).

Why did you choose age 50 as the upper limit?

- Our objective is to reach women who are pregnant or who may become pregnant to protect the developing fetus.
- Babies are less likely to be born to women over age 50.

Isn't age 16 young to include with "pregnant women and those who could become pregnant"?

- Women age 16 and 17 may be mothers one day.
- They are old enough to learn about eating wisely during their future/current pregnancies.
- They will learn their fatty acid and mercury levels and whether they need to alter their fisheating habits to improve and protect their own health.

Do participants have to be US citizens? Do they have to be from Minnesota?

No, they do not have to be U.S. citizens.

Can I participate if I don't have insurance?

 Yes. Eligible women who are not current patients at Sawtooth Mountain Clinic or the Grand Portage Health Service can take part in this Project at no expense to them.

Participation FAQs

Why should I participate?

You will:

- Get results for mercury and Omega-3 fatty acids in your body
- Receive individual advice from a nurse on how to choose fish low in mercury to improve your health and the health of your family
- · Help your community and other communities where people catch and eat fish

Can I participate even if I don't eat fish (or eat very little fish)?

Yes. All women aged 16-50 are welcome to participate.

I'm not planning to get pregnant. Why should I take part? Why do women who aren't pregnant have to be careful about the fish they eat?

- The Project is open to all women between ages 16 to 50, whether or not you are or plan to become pregnant.
- All participants will receive information about choosing healthy fish to eat. This knowledge
 enables you to make educated meal choices for you and your family.
- Every pregnancy isn't planned, and impact to the fetus can occur in the early stages of pregnancy before a women knows she is pregnant.
- Any woman who might become pregnant should follow the fish consumption advice developed for women who are or may become pregnant.

What do I have to do?

You will:

- Answer 3 questions about the kinds of fish you eat and how often you eat fish
- Answer a longer questionnaire about your fish-eating habits
- Have blood drawn from your arm
- Learn how to choose the best locally caught and purchased fish for healthy eating

How long will the visit take?

- Visit One will take about 1 hour.
- Some women will be asked to return for a second visit in 6 months. The second visit will also take about 1 hour.

Why will some women be asked to return for a second visit?

All women with blood mercury levels above the level considered safe will be asked to return for
a second visit. At the second visit, participant's blood will be tested again to find out if the levels
of mercury and/or fatty acids changed.

 For every high-mercury participant, 2 participants below the level considered safe will be chosen for the second visit. These participants must have completed Visit One within 2 weeks of a highmercury participant's Visit One.

Are there any risks to me or my family if I participate?

- No. However, you may feel slight discomfort when we take your blood.
- Everything you tell us is private; there is no risk that your personal information could be made public.

Are there any benefits to me or my family?

- You will know more about the amount of mercury and fatty acids in your body.
- Information about choosing healthy fish will help you plan healthier meals for yourself and your family.
- Your participation will help people in your community and other communities where people catch and eat fish.

Blood Sample and Results FAQs

What will my blood be tested for?

Your blood will only be tested for mercury and healthful fatty acids found in fish.

Do I get my blood results? When will I get them?

- Yes. You will receive a letter from Sawtooth Mountain Clinic or the Grand Portage Health Service about 2 months after your Visit One. Only members of the clinic staff will see your results.
- A nurse will be available to discuss results with participants.

What if I find out that my mercury level is high? Is there something I can do?

- You will receive personalized advice from clinic staff about what you can do to lower mercury in your body and continue to eat fish safely.
- If you reported eating very little fish on your questionnaire, a clinic physician will work with you
 to figure out how you may have been exposed to mercury from another source.

I am pregnant. What if I find out that I have high mercury in my blood? Is there something I can do to keep my baby from being harmed?

- A high level of mercury in your blood doesn't mean that your baby will be harmed.
- · Changing fish consumption choices will bring your mercury level down.
- If you have a high level of mercury, a clinic physician will tell you what to do to get your mercury level down.

What will happen if I have my blood tested again and I still have too much mercury in my blood?

- If you reported eating high-mercury fish in excess of recommendations, clinic staff will be available again to provide advice to lower the mercury level and plan healthy fish meals.
- If you reported eating very little fish but have a high mercury level, a clinic physician will work
 with you to figure out how you may have been exposed to mercury from another source.

Data Privacy FAQs

Who will know I am a participant? Will my name or personal information be used?

- Only a few staff at Sawtooth Mountain Clinic or Grand Portage Health Service will know who is in the study.
- Your information will be protected the same way staff protect other private and personal information of clinic patients.
- Only clinic staff have access to your personal information. All Project forms will be labeled with a
 Participant ID. Records linking participants' names and IDs will be stored in a secure database
 accessible only to clinic staff.
- Some information and the answers on questionnaires will be sent to the Minnesota Department
 of Health for data analysis linked only to the Participant ID. No identifying information about
 you will be shared.

Who will see the results of my blood tests?

- · Blood specimen data with a Participant ID (not names) will be seen by staff at...
 - o Minnesota Department of Health (MDH) Public Health Laboratory for analysis
 - FISH Project staff at MDH for comparing each participant's blood sample results to her reported fish consumption on the questionnaire
- Blood sample results will be sent to the Sawtooth Mountain Clinic or Grand Portage Health Service. Clinic staff will be link results to participant names and send results to each participant.

What will you do with the data?

- We will test the ability of 3 mercury screening questions to predict a women's exposure to mercury in fish.
- Sawtooth Mountain Clinic and Grand Portage Health Service staff will...
 - o Educate participants how to wisely choose fish to eat
 - Counsel participants with mercury blood levels above the level considered safe about safe-eating of fish and ways of reducing their exposure to mercury
- MDH FISH Project staff...
 - Measure the impact of the Project on individuals (by participant ID) and on participants as a whole
 - Make some generalizations about the fish-eating habits of women in this age range in these communities

Mercury and Contaminants FAQs

What contaminants are found in fish?

- Mercury is the contaminant in fish that causes the most concern. Mercury is found in all fish including all fish from Minnesota's waters.
 - Most mercury in MN waters comes from the air and is a result of emissions from coal combustion, mining, and other human sources. It can also come from improperly stored wastes, abandoned dumps, or storm water run-off.
 - When mercury enters a lake or river, it can be converted to methylmercury by bacteria. Those bacteria are eaten by plankton and other small animals, which are eaten by small fish and then larger fish. Larger, longer living fish feed on other fish throughout their lives, thereby accumulating the highest levels of methylmercury.
 - People are better at excreting mercury than fish. Fish hardly excrete any at all so mercury continues to build up over their entire life. That is one reason why longer lived fish are higher in mercury.
- Fish in Lake Superior and larger rivers (such as the Mississippi) may contain PCBs.
 - Although PCBs can travel in the air, spills, leaks and improper disposal are the main ways they get into the environment.

Are there contaminants in fish from grocery stores and restaurants?

- Yes. Fish from all waters contain some mercury and may contain PCBs as well as other contaminants.
- You should consider all sources of fish in your diet when making choices about eating any fish.

Do lakes and rivers that look clean and are far from industry have less mercury in their fish?

- No. The location or appearance of a lake or river cannot predict the amount of mercury that is found in its fish.
- Much of the mercury deposited from the air into Minnesota waters comes from other states, and countries as far away as China.
- Fish from wilderness lakes in Northeast Minnesota have higher levels of mercury than other
 parts of the state including the metro area. Not because there is more mercury entering the lake
 but because mercury is methylated more easily in lakes in northeastern Minnesota.

Where are mercury and PCBs in fish? How can I get them out?

- Methylmercury:
 - o Most is found in the fish fillet (flesh, meat).
 - o No cooking or cleaning method will lower the amount of mercury in a fish meal.
 - It is important to choose fish low in mercury and spread out the meals you have of higher mercury fish like walleye.
- PCBs:
 - o Accumulate in the fat of fish and in fatty fish like carp and catfish.
 - Cleaning and cooking a fish to remove fat will lower the amount of PCBs.

- Fillet the fish, remove the skin, and trim all fat.
- Cook the fish using a method that allows the fat to drain away, such as broiling and grilling.

Methylmercury and the Human Body

How does methylmercury get into the human body? How long does it stay?

- After eating fish, methylmercury is absorbed from the gastrointestinal tract and into the bloodstream where is becomes distributed to all parts of our bodies.
- About half of the methylmercury from a single meal will be excreted in about 70 days.

Is there any way to get methylmercury out of the body faster?

- No, there is no proven safe method to remove mercury from the body.
- The use of drugs to increase excretion has NOT been shown to speed up elimination and may cause harmful effects.

What are the risks of eating fish? For adults? For children?

- All fish contain at least a small amount of mercury. Fish may also contain other chemicals, such as PCBs. High levels or prolonged exposure to these contaminants may be harmful to your health.
 - o Young children and developing fetuses are most at risk from mercury in fish.
 - o Small amounts of mercury can damage a brain that is just starting to form or grow.
 - Too much mercury can affect a child's behavior and lead to learning problems later in life.
 - o An adult nervous system can be affected at higher levels.
 - Babies exposed to PCBs during pregnancy may have lower birth weight, reduced head size, and delayed physical development.

How is mercury transported from mom to baby?

Mercury in the mom can cross the placenta to the baby.

Should I breast feed?

- Yes.
 - o If you stop nursing, your baby misses out on the proven benefits of nursing.
 - Mercury is present but does not concentrate in breast milk. Breast milk contains omega 3-fatty acids and other nutrients from fish.
 - If you stop eating fish to avoid mercury, your baby may miss out on healthy nutrients from fish for development.
 - Getting enough omega-3 fatty acids in utero and during infancy has a positive effect on a child's vision and cognitive development.

What are the health benefits of eating fish? For adults? For children?

- Fish is a low-fat protein rich in nutrients and an important source of omega-3 fatty acids. These
 are healthy fats that your heart and brain need to function properly.
- Eating fish has been shown to lower the risk of heart disease in adults.

 Eating fish is *especially* important for pregnant women and women who could become pregnant. This will give their infants the nutrients found in fish that are needed for fetus development. The fatty acids in fish promote healthy brain development and function as well as the development of vision and nerves in a growing fetus.

Can fats really be good?

- Omega-3 fatty acids are a type of polyunsaturated fat that is especially beneficial, particularly during pregnancy.
 - Best sources: fatty fish such as salmon, herring, mackerel, anchovies, or sardines. All of these fish are low in mercury.

What about fish oil capsules? Do they do have the same benefits as eating fish?

- Dietary supplements are intended to supplement the diets of some people, not replace the foods important to a healthy diet.
 - We know more about the benefits of eating fish than the benefits of taking supplements.
 - Fish offer more benefits than just Omega-3 fatty acids. Some of them are known and some may not yet be known.
 - Fish meals are high in protein and generally lower in calories and saturated fat than meals with beef or pork. The benefits of eating fish are greater than just the benefits from omega-3s.
- For most people, eating fish every week is the best way to get the health benefits of omega-3 fatty acids and other nutrients found in fish.
- If you don't eat fish, taking fish oil supplements may be a good idea. As with all supplements, it
 is recommended that you consult your healthcare provider before taking them.

Fish Consumption Advice FAQs

Why are there different Safe-Eating Guidelines for women who are or may become pregnant?

 The guidelines are more restrictive because the developing fetus and children are more sensitive to contaminants.

What if I eat more than the recommended amount of fish and shellfish in a week?

- If you eat a lot of fish one week, you can cut back for the several weeks.
- Women who are or may become pregnant and children under age 15 should stick to the more restrictive guidelines as closely as possible.

What is the difference between "white" and "light" canned tuna? What about tuna steaks?

- Studies have shown that canned "white" (or albacore) tuna has more mercury than canned "light" tuna. Briefly explain why?
- On average there is 3 times more mercury in the "white" tuna variety. White canned tuna is
 make from albacore tuna which is a larger, longer lived species than the species in light canned
 tuna. Bigger, longer lived fish have more time to accumulate mercury.
- Mercury levels in tuna steak is similar to canned "white" tuna.

What if I am age 16-50 but won't have any/more children, do I need to follow the guidelines

for women who are or may become pregnant?

No. You can follow the general population guidelines. (Give them the Eat Fish Often Brochure. Or refer to MDH web site. (http://www.health.state.mn.us/divs/eh/fish/eating/safeeating.html)

Results Counseling Questions and Answers (Q & A)



- Having a number above the RfD of 5.8 µg/L means you should think more about your fish choices and eat more fish lower in mercury.
- If your number if below 5.8 μg/L, you can lower your mercury level by choosing to eat fish lower in mercury.

How high is really high? Is there a number at which I am sure to have health problems?

- <u>Really hiah</u> may be very different for different people.
- EPA developed 5.8 μg/L based on probable effects in the developing nervous system at a level of 58 μg/L.

I am pregnant or planning to become pregnant. Is there a mercury level that would mean my baby is in danger?

- Even if you have a high level of mercury in your blood, that doesn't mean that your baby will be affected.
- Because different people respond differently to chemical exposures, it is better to advise
 patients individually.
- My advice to you is based on your fish eating history, as reported by you, on your personal lab values and on other information that you give me.
 - We can work together to come up with an eating plan to lower your mercury exposure or keep it low.
 - Changing fish consumption choices will bring your mercury level down and allow you to continue eating fish for your health and the health of the baby.

Won't my levels go down faster if I stop eating fish altogether?

- Fish low in mercury will not add much to the amount of mercury in your body but they still contain beneficial fatty acids and other nutrients.
 - Fish low in mercury are good for you and for your baby (if you are pregnant or planning pregnancy).
 - Fish are particularly good for the developing fetus if they are high in fatty acids and low in mercury.
- It's a much better idea to not eat fish high in mercury than to not eat any fish at all.

I want my mercury level to be zero.

- Mercury is a natural element of the earth. Everyone is exposed to some mercury.
- We all have a small amount of mercury in our bodies. Our bodies excrete mercury daily.

Is there information about what mercury levels are in the general population?

- Yes. The 2009-2010 National Health and Nutrition Examination Survey (NHANES) collected blood mercury levels in women and children from across the U.S.
 - Most of the children under 5 years did not have detectable amounts of mercury in their blood.
 - o The mean (average) concentration of total blood mercury was 0.845µg/L in women.

- According to the 1999-2000 NHANES Survey, women who had eaten 3 or more servings of fish in the past 30 days had an average level of 1.94 µg/L compared to 0.51 µg/L in women who ate no fish.
 - Women who were Asian, Pacific Islander, Native American, or multiracial had a higher rate of elevated blood mercury than all other participants.

What are the symptoms of mercury poisoning or exposure?

- Symptoms for mercury exposure in adults are nonspecific, such as:
 - o numbness and tingling of hands, feet, or lips
 - o fatigue
 - o trouble walking
 - trouble concentrating
 - o memory loss
 - headaches
 - irritability
 - loss of fine motor skills
 - o change in visual spatial skills
 - o visual field constriction
 - o change in vision
 - Exposure to high levels of mercury can cause a variety of symptoms depending on the person. (List not provided.)
- We expect that most or all women participating in FISH will not have symptoms of mercury exposure.
 - Many symptoms associated with mercury exposure could be caused by a number of other problems.

Should I breast feed?

- Yes.
 - o If you stop nursing, your baby misses out on the proven benefits of nursing.
 - Mercury is present but does not concentrate in breast milk. Breast milk contains omega 3-fatty acids and other nutrients from fish.
 - If you stop eating fish to avoid mercury, your baby may miss out on healthy nutrients from fish for development.
 - Getting enough omega-3 fatty acids in utero and during infancy has a positive effect on a child's vision and cognitive development.



Results Counseling Q&A: Fatty Acids

What are Omega-3 Fatty Acids? Why did you test my blood for them?

- Omega-3 fatty acids are polyunsaturated fatty acids that are essential nutrients for health.
 Our bodies don't make these fatty acids so we need to get them from food.
- There are two fatty acids that come mainly from eating fish: EPA and DHA (eicosapentaenoic acid and docosahexaenoic acid).
 - These are different than omega-3s found in plant foods (ALA-alpha-linolenic acid) such as flax seed, canola oil, and walnuts.
- The main reason we tested your blood for omega-3s is that they indicate whether or not you are eating fish, and to some extent, whether those fish are high in omga-3s.
- For participants who take part in follow-up, we will be able to tell if omega-3s have gone up or down.

What do these fatty-acid levels mean?

We will tell you how the levels in your blood compare to levels in women tested in a national study.

- Fish are a source of fatty acids.
- DHA and EPA are omega-3 fatty acids found in fish.
- Our bodies don't make EPA and DHA so we need to get them from our diet. Eating fish is the primary dietary source of these fatty acids.
- DHA is a building block of the brain and eyes.
- Pregnant women and breastfeeding moms can eat fish to give DHA to their babies.
- Children of women who ate lower mercury fish every week during pregnancy have been found to do better developmentally.

I thought fat was bad for me and made my cholesterol high.

- Omega-3 fatty acids are a type of polyunsaturated fat that is proving to be especially beneficial, particularly during pregnancy.
 - Best sources: fatty fish such as salmon, herring, canned mackerel, anchovies, or sardines. All of these fish are low in mercury.

Should I just take supplements and not eat fish, especially if my levels are high?

- Dietary supplements are intended to supplement the diets of some people, not replace the foods important to a healthy diet.
 - We know more about the benefits of eating fish than the benefits of taking supplements.
 - Fish offer more benefits than just Omega-3 fatty acids. Some of them are known and some may not yet be known.

- Fish meals are high in protein and generally lower in calories and saturated fat than meals with some other sources of protein. The benefits of eating fish are greater than just the benefits from omega-3s.
- For most people, eating fish every week is the best way to get the health benefits of omega-3 fatty acids and other nutrients found in fish.
- If you don't eat fish, taking fish oil supplements may be a good idea. As with all supplements, it
 is recommended that you consult your healthcare provider before taking them. Then find a high
 quality supplement to take.

Appendix 4: CCNSH and GPHS Laboratory and Specimen Procedures

Lab Forms

Blood Collection Procedure

Specimen Processing and Storage

Specimen Packaging and Shipping

Lab Forms

	· · ·	
	Sawtoo	th Mountain Cli
		a 501(c)(3) not-for-profit organization
513 5 th Ave	e. W, Grand Marais, MN 55604	Phone 218-387-2330 Fax: 218-387-1278
•	Sandra L. Stover, M.D.	Paul E. Terrill, M.D.
	Jennifer L. Delfs, M.D.	Lisa Zallar, RN, CNP
	Michael R. Sampson, M.D.	Milan C. Schmidt, M.D.
FISH Pro FISH Coo tests and notified c Primary #	ject protocol: ordinator, RN's are authorized to to notify participants of the nom of abnormal lab results. Provider: Michael R Sampson	order and sign off on the required lab al lab results. Dr Sampson will be
FISH Pro FISH Cod tests and notified c Primary f FISH Proj Diagnosis	ject protocol: ordinator, RN's are authorized to to notify participants of the norm of abnormal lab results. Provider: Michael R Sampson fect Lab Orders s: Health Screening ICD-9 V70.0;	order and sign off on the required lab al lab results. Dr Sampson will be ICD-10 Z13.9
FISH Pro FISH Cod tests and notified c Primary i FISH Proj Diagnosis Tests: Biond Mi	ject protocol: ordinator, RN's are authorized to to notify participants of the norm of abnormal lab results. Provider: Michael R Sampson fect Lab Orders s: Health Screening ICD-9 V70.0;	order and sign off on the required lab al lab results. Dr Sampson will be ICD-10 Z13.9
FISH Pro FISH Coor tests and notified of Primary # FISH Proj Diagnosi: Tests: Blood Me Fatty acid	ject protocol: ordinator, RN's are authorized to to notify participants of the norm of abnormal lab results. Provider: Michael R Sampson fect Lab Orders s: Health Screening ICD-9 V70.0; ercury	order and sign off on the required lab al lab results. Dr Sampson will be ICD-10 Z13.9
FISH Pro FISH Coo tests and notified c Primary i FISH Proj Diagnosis Tests: Blood Me Fatty acid	ject protocol: ordinator, RN's are authorized to to notify participants of the norm of abnormal lab results. Provider: Michael R Sampson Ject Lab Orders s: Health Screening ICD-9 V70.0; ercury d tests	order and sign off on the required lab al lab results. Dr Sampson will be ICD-10 Z13.9
FISH Pro FISH Coo tests and notified c Primary # FISH Proj Diagnosis Tests: Blood Me Fatty acid	ject protocol: ordinator, RN's are authorized to to notify participants of the norm of abnormal lab results. Provider: Michael R Sampson Ject Lab Orders s: Health Screening ICD-9 V70.0; ercury d tests	order and sign off on the required lab al lab results. Dr Sampson will be ICD-10 Z13.9
FISH Pro FISH Coo tests and notified c Primary # FISH Proj Diagnosi: Tests: Blood Me Fatty acid	ject protocol: ordinator, RN's are authorized to to notify participants of the nom of abnormal lab results. Provider: Michael R Sampson fect Lab Orders s: Health Screening ICD-9 V70.0; ercury d tests	order and sign off on the required lab results. Dr Sampson will be ICD-10 Z13.9

Lab Checklist

Laboratory P	rocedures Chec	klist
Fish are Important f	or Superior Health (FISH) Proje	ct
Verify Participant ID and Specimen IDs applied t	<u>:o:</u> (check all)	
□ Lab Order		
Laboratory Checklist	Specimen ID: /-	the debaard
Chain of Custody Form	specimen iD: (a	ittach here)
Lab Verification Form		
Check Lab Pack for broken or missing content	5	
Verify Patient identity and lab order		
Draw Outcome (check one)		
Blood draw complete		
Blood draw must be rescheduled. Rea	son	
Ineligible for blood draw. Reason:		
Participant declined		
Specimen ID Labels		
Fill in: Ppt. ID, collection date and time	ne, and sampler's initials	
Attach labels to proper tube and via	I	Collector Initials:
<u>Complete Lab Verification Form and give to p</u>	atient to return to clinic	Date:///////
Processing		
2 ml purple-top for mercury: Inverted	l eight times	
Volume: 🗆 2 ml 🗆 <2 ml		
2 ml purple-top for fatty acid: Inverte	d eight times, centrifuged; pla	asma aliquoted to 2 ml cryovia
Volume: 🗆 1 ml 🗆 <1 ml 🗆 QN	IS	
Chain of Custody (COC) completed		
 Specimens packed with COC FORM in a bags); then refrigerated at GPHS or fr 	a bio-hazard bag (GPHS use zij rozen at CCNSH	o top, CCNSH use seal top
Staple leftover specimen ID and participant IC) labels to this form	
<u>CCNSH Lab – record specimen in CCNSH Specimen </u>	men Log	

Lab Verification Form

	L Fish are In	ab Verification	Form alth (FISH) Projec	Participant ID: F
Lab Visit Date: _	/	/	Specimen ID:	(attach here)
Phlebotomist:	Date and init	ial only one outcome belov	N.	
Date	Initials	La	ab Visit Outco	ome
		Blood draw complet	te	
		Reschedule. <u>Reason</u> Venipuncture not attem Insufficient sample Other	<u>:</u> pted	
		Ineligible. <u>Reason:</u> Insufficient sample and p Other	patient unwilling to	return
		Participant declines		
Notes:		1		
Form must be	returned	to FISH Coordinat	or	

Chain of Custody Form (COC)

| n Code (2 Lettern) Fr | Affiliation | | 3 | Client / Ag
Project Ma
Report to J | ungo
Email | er Naz | me / 2 | hone | | |

 | | | | Por
If Yes
 | tential H
please a | Stand
lazard
dd info
 | lard Cl
J
maatie | hain of
Tes
an to S | Custo
No
ampler | ty
U
Comu
 | inknou | m |
|-------------------------|--------------|---------------------|--------------------------------------|--|--|---|---|--|---|---
--
--|---|--|--
--
--|---
--|--|---|---|--
---|
| | Affiliation. | | 3 | Project Ma
Report to I | an age | er Naz | me / 2 | konø | | |

 | | | | Por
If Yes
 | tential H
please a | lazard
dd info
 | ۲
matie | 'es
un to S | No
ampler | U
Comu
 | inknow | m |
| to Name | Affiliation. | | 1 | Report to 1 | | 1 | | 2020 | | |

 | | | | If Yes
 | please a | dd info
 | mati | nn to S | ampler | Com
 | monte l | |
| to Namo | Affiliation | | , | Report to I | - | | | | | |

 | | | |
 | |
 | | | | | | | | | | | |
 | | pelor |
| | Affiliation | | | | | | | | | |

 | | | | T/
 | т | Standa
 | rd | Prio | rity | Em
 | ergeno | y |
| | Affiliation | | | | | | | | | |

 | | | | DW = I
 | Drinking 1 | Water
 | Matr | ix Cod
WP = V | es
Vipe |
 | от = | Othe |
| | | | | | Т | # of | Con | taine | ars / I | Prese | rvati

 | res | | | NW=}
 | ion-potal | le Wate
 | ar - | AR = A | ur
interior | l Mate
 | TS = 1 | Tissu |
| | | | | | F | Т | Т | | | | Т

 | Г | 8 | | 30-0
 | T |
 | | | T | | | | | | | | |
 | < | |
| | FRome | | | | - | 18 | | | 륑 | <u></u> |

 | 5 | Filter | ⇒ s |
 | |
 | | | |
 | NN | |
| | | | | | 1 | | piq | 3 | hdm | Inos | 8

 | 1 | N/N | lyse |
 | |
 | | | | | | | | | | | |
 | Y. | |
| tion TD | | Collect | ion | Matri | | | 1 | o Vo | Hun | T I |

 | 1 | ples J
Y | N II |
 | |
 | | | |
 | Intere | |
| identifier) | Sample Foint | Date | (24 Hor | Code | • | H | Sulf | N | Sodi | Sodi | 0 the

 | Tot | Sam | 1 |
 | |
 | | | |
 | 8 | |
| | | | | | Т | Т | Т | | | | Т

 | | | |
 | |
 | | | | Т
 | | Τ |
| | | | | | Т | | Т | | | | Τ

 | | | |
 | |
 | | | |
 | | T |
| | | | | | Т | | ┮ | | | | ╈

 | | | |
 | |
 | | | \square | ╈
 | | T |
| | | | | | T | + | \top | \square | | | ╈

 | | | |
 | | +
 | | | \square | ╈
 | | $^{+}$ |
| | | | | | + | + | + | | | | ╈

 | | | |
 | | +
 | | + | \mathbf{H} | ╈
 | | + |
| | | | | | ╈ | + | + | | | | ╈

 | | | |
 | | +
 | | + | + | ╈
 | | + |
| | | | | | + | + | + | | | | +

 | | | |
 | | +
 | | + | | +
 | | ┢ |
| | | | | | ╈ | + | ╈ | | | | ╈

 | | | |
 | | +
 | | + | + | ╈
 | | + |
| | | | | | ╈ | + | ╈ | | | | ╈

 | | | | -
 | ╉┼┼ | +
 | \vdash | + | ╉┼ | ╈
 | | + |
| | | | | _ | ╋ | + | + | + | | | +

 | + | | | -
 | ╉┼╴ | +
 | \vdash | + | ╉┼ | +
 | | + |
| | | | | | _ | | _ | | | | _

 | | | |
 | |
 | | _ | | _
 | | _ |
| | | ies ID Sample Zeint | tion ID Sample Point Date MontPeriod | ties ID Sample Zeint Two
MostRey 24 Hz
24 Hz
2010 100 100 100 100 100 100 100 100 100 | tion D Sample Peint Data (24 Herer) Ced
Matrice Ced
Data (24 Herer) Ced
Ced
Ced
Ced
Data (24 Herer) Ced
Ced
Ced
Ced
Ced
Ced
Ced
Ced | tion D Sample Paint Date (24 Hear) from Matrix 1
Matther) Sample Paint Date (24 Hear) for a second | District Time Matrix 0 0 Mattiler) Sample Paint Date Cade 5 2 Image: Date Image: Date | Distriction Matrix 0 | Date Matrix 0 | Sample Print Matrix Note Note | Jame Matrix Nature Nature <td>Jame Theory Matrix B Output D Output Output</td> <td>Sample Zeitar Time (14 Ben) Sample Zeitar Time (14 Ben) Sample Zeitar Sample Z</td> <td>Sample 7 viat Team Matrix: 0</td> <td>Discretion Discretion Date Matrix: 0 <!--</td--><td>Sample Zeint Temp Marria iso of the second seco</td><td>Sample 7-init Statute Sample 7-init Statute Matrix: is <t< td=""><td>Sample 7 vist Concrete Tame Matrix <th< td=""><td>$\begin{array}{c c c c c c c c c c c c c c c c c c c$</td><td>Sample Zeiser Tesse Marine North North<</td><td>Team Matrix 0</td><td>Team Matrix: 0 <th< td=""><td>Sample 7-int Time Matrix: is is</td></th<></td></th<></td></t<></td></td> | Jame Theory Matrix B Output D Output Output | Sample Zeitar Time (14 Ben) Sample Zeitar Time (14 Ben) Sample Zeitar Sample Z | Sample 7 viat Team Matrix: 0 | Discretion Discretion Date Matrix: 0 </td <td>Sample Zeint Temp Marria iso of the second seco</td> <td>Sample 7-init Statute Sample 7-init Statute Matrix: is <t< td=""><td>Sample 7 vist Concrete Tame Matrix <th< td=""><td>$\begin{array}{c c c c c c c c c c c c c c c c c c c$</td><td>Sample Zeiser Tesse Marine North North<</td><td>Team Matrix 0</td><td>Team Matrix: 0 <th< td=""><td>Sample 7-int Time Matrix: is is</td></th<></td></th<></td></t<></td> | Sample Zeint Temp Marria iso of the second seco | Sample 7-init Statute Sample 7-init Statute Matrix: is is <t< td=""><td>Sample 7 vist Concrete Tame Matrix <th< td=""><td>$\begin{array}{c c c c c c c c c c c c c c c c c c c$</td><td>Sample Zeiser Tesse Marine North North<</td><td>Team Matrix 0</td><td>Team Matrix: 0 <th< td=""><td>Sample 7-int Time Matrix: is is</td></th<></td></th<></td></t<> | Sample 7 vist Concrete Tame Matrix Matrix <th< td=""><td>$\begin{array}{c c c c c c c c c c c c c c c c c c c$</td><td>Sample Zeiser Tesse Marine North North<</td><td>Team Matrix 0</td><td>Team Matrix: 0 <th< td=""><td>Sample 7-int Time Matrix: is is</td></th<></td></th<> | $\begin{array}{c c c c c c c c c c c c c c c c c c c $ | Sample Zeiser Tesse Marine North North< | Team Matrix 0 | Team Matrix: 0 <th< td=""><td>Sample 7-int Time Matrix: is is</td></th<> | Sample 7-int Time Matrix: is is |

Blood Sample Shipment Log

Date Shipped://	/ day year	Shipper's Initials:
This shipment contains spec	imens for FIS	H Participants
1. Specimen ID:	Ppt. ID:	Hg Tube Present: FA Vial Present:
2. Specimen ID:	Ppt. ID:	Hg Tube Present: FA Vial Present:
3. Specimen ID:	Ppt. ID:	Hg Tube Present: FA Vial Present:
4. Specimen ID:	Ppt. ID:	Hg Tube Present: FA Vial Present:
5. Specimen ID:	Ppt. ID:	Hg Tube Present: FA Vial Present:
6. Specimen ID:	Ppt. ID:	Hg Tube Present: FA Vial Present:
7. Specimen ID:	Ppt. ID:	Hg Tube Present: FA Vial Present:
8. Specimen ID:	Ppt. ID:	Hg Tube Present: FA Vial Present:
9. Specimen ID:	Ppt. ID:	Hg Tube Present: FA Vial Present:
10. Specimen ID:	Ppt. ID:	Hg Tube Present: FA Vial Present:
11. Specimen ID:	Ppt. ID:	Hg Tube Present: FA Vial Present:
12. Specimen ID:	Ppt. ID:	Hg Tube Present: FA Vial Present:
13. Specimen ID:	Ppt. ID:	Hg Tube Present: FA Vial Present:
14. Specimen ID:	Ppt. ID:	Hg Tube Present: FA Vial Present:
15. Specimen ID:	Ppt. ID:	Hg Tube Present: FA Vial Present:
OTES:		

Blood Collection Procedure

The blood collection steps below are based on CCNSH procedures. Staff will draw 4 mL of blood to measure fatty acids and mercury in participants' blood. SMC participants will be sent to the Cook County North Shore Hospital (CCNSH); Grand Portage Health Service (GPHS) participants will have their blood drawn at GPHS. Participants at special events may either be referred for a later blood draw or may be drawn onsite.

The Laboratory Procedures Checklist (Lab Checklist) will be used by all staff who draw, process, or transfer a participant's blood sample to document completion of all forms and procedures related to lab referral, venipuncture, and specimen processing and storage.

Verifying Patient Identification and Lab Pack Contents

Lab staff will verify the following and note them on the Lab Checklist.

- Participant arrived at the lab with a FISH Project Lab Order and a Lab Pack containing Lab Checklist, Chain of Custody Form, Lab Verification Form, specimen tubes, and Participant ID and Specimen ID labels
- 2. Lab Pack supplies are undamaged.
- 3. Patient is the individual named on the Lab Order.

Assessment for Blood Draw

• The phlebotomist will briefly assess the participant to determine whether there is any reason why they should not give blood at that time (e.g. participant is too ill, or no suitable vein is accessible).

Position

- FISH participants must be drawn in the blood drawing chair with the arm rest in position.
- If it is necessary to draw some participants in unusual places, someone must be in attendance to insure participant safety at these times.

Supplies

- Assemble the following supplies: gloves, collection tubes from FISH Lab Pack, needle, Vacutainer holder, tourniquet, alcohol prep pad, cotton ball, and tape or bandages. Gloves must be worn while drawing the patient and disposed in an appropriate container.
- All items that contact blood samples must be pre-screened to prevent the possibility of interference with analyses. Therefore, only the specimen collection, handling, and storage containers provided by MDH PHL can be used for FISH specimens. MDH will supply the Lab Packs and a supply of extra tubes and vials in case one of the containers in a Lab Packs is missing or broken. Routine blood collection supplies (needles, needle holders, blood transfer devices, pipettes, tourniquets, gloves, alcohol swabs, gauze, and bandages) will be supplied by CCNSH and GPHS.

Each tube in the Lab Pack must be labeled with a Specimen ID label designated for that container. Before applying the label to the tube or vial, the lab technician will add the Participant ID, date and time the sample was collected, and the sampler's initials to the label. Verify that Specimen IDs on all forms and containers are the same. All tubes will be labeled using only ID numbers, not names or other identifiers. An example of the tube labels is below:

SPECIMEN ID LABELS (FOR TUBES)	14E0095 / 1
MDH PHL will provide labels for the two Purple Top tubes, Pink Top cryovial, and fatty acid processing tube. These labels will also include a description of the container (e.g., 2mL Purple Top or blank for processing tube) and space for the lab technician to add: • Participant ID (Ppt. ID) • Collection date and time (Col D/T) • Sampler's initials (Col Init)	Ppt. ID:

NOTE: Visit One and Visit Two Lab Packs will contain the same tubes and forms for the blood draw. However, the MDH PHL will use different Project Codes (FISH1, FISH 2), work order numbers, and Chain of Custody Forms (COC) for Visit One and Visit Two. Lab Packs will be clearly labeled as for either Visit One or Visit Two.

Selection of Vein Site

- The larger and fuller median cubital and cephalic veins are the best, but the wrist and hand veins are also acceptable.
- Factors to consider in site selection:
 - o Extensive scarring (healed burn areas should be avoided, etc.)
 - Mastectomy patients (because of lymphostasis) should be drawn from the opposite side of the surgery
 - Hematomas should be avoided

Procedure for Vein Selection

• Wrap the tourniquet around the arm 3-4 inches above the site. Apply the tourniquet to help locate the vein. Do not leave the tourniquet on for longer than one minute. To do so may result in hemo-concentration and a variation in blood test values. If the tourniquet is left on longer

than one minute in order to locate the vein, it should be released and reapplied after a wait of 2-5 minutes.

- If the participant has a skin problem, put the tourniquet over the sleeve or some other protective material. Ask the participant to close her hand, if necessary, so that the vein will become more prominent. However, vigorous hand pumping should be avoided.
- Palpate and trace the path of the veins several times with the index finger in order to ensure where to place the needle. If veins are not readily apparent, blood can be forced into the vein by:
 - Massaging the arm from the wrist to the elbow
 - o Tapping at the vein site with the pad of a few fingers to cause the vein to dilate
 - o Applying moist heat to the site, which will produce the same result

Preparation of the Selected Site

- Aseptic technique should be maintained throughout the venipuncture.
- Cleanse the vein with an alcohol prep pad using a circular motion from the center to periphery and allow the area to dry. If the venipuncture is difficult and the vein must be touched again to locate it, cleanse the probing finger with alcohol before touching the site. If the tourniquet can be applied without contaminating the prepped area, prepping first would shorten the length of time the tourniquet is on.

Venipuncture Procedure Using Evacuated Tubes

- The mercury sample will be drawn first. Collect the mercury sample first using the Vacutainer tube designated for that tube.
- Thread the appropriate needle into the Vacutainer holder until it is secured, using the needle sheath as a wrench.
- Before use, gently tap all tubes that contain additives (anticoagulants) to ensure that all of the
 additive is dislodged from the stopper and the wall of the tube. Loosely place the blood
 collection tube into the holder. Do not push the tube onto the needle as premature loss of
 vacuum may result
- If possible, make sure that the patient's arm is in a downward position and maintain the tube below the site throughout the procedure. This will ensure that any back flow from the tube will not go into the vein.
- Inspect the needle tip when the cover is removed to be sure it is free of hooks or obstructions in the lumen of the needle.
- Grasp the patient's arm firmly using your thumb and first finger to draw the skin taut. The vein should be fixed or held taut during the puncture. The needle should be in line with the vein and the bevel of the needle in the upward position.
- Push the needle into the vein. A sensation of resistance will be felt, followed by ease of penetration as the vein is entered.
- As soon as you are in the vein, grasp the flange of the needle holder and push the Vacutainer tube forward until the butt end of the needle puncture the stopper, exposing the full lumen of

the needle. Blood will flow immediately into the tube(s). If blood fails to enter the Vacutainer tube, try the following:

- Advance needle a little more the needle may not have been in far enough.
- Slowly withdraw the needle you may have gone completely through the vein. Moving the needle back into the lumen of the vein may allow blood to flow into the tube.
- Draw the tubes:
 - **First:** Purple Top, 2 mL BD Vacutainer (K2 EDTA 3.6 mg) tube for mercury
 - Second: Purple Top, 2 mL BD Vacutainer (K2 EDTA 3.6 mg) tube for fatty acids
- Remove the tourniquet as soon as the flow of blood has been established, if you are sure the pressure is adequate for the flow to continue. Otherwise, release the tourniquet as soon as the specimens have been collected.
- Maintain constant, but slight forward pressure (in the direction of the needle) on the end of the tube. This prevents release of the shutoff valve and stoppage of blood flow. Do not vary pressure or reintroduce pressure after completion of the draw.
- Allow the tube to fill until the vacuum is exhausted and blood flow ceases in order to insure the correct ratio of anticoagulant to blood. The tube will not necessarily be filled completely (this varies for each type of tube).
- When the blood flow ceases, remove the tube from the holder. If a multi-specimen needle is used, the shutoff valve recovers the butt end of the needle, stopping the flow of blood until the next tube is inserted.
- After drawing each tube, gently invert the tubes eight times. To avoid hemolysis, do not vigorously mix any tube.
- To obtain additional specimens, insert the next tube into the holder and repeat the procedure.
- If the total blood draw is < 0.25ml, then send the entire sample uncentrifuged for mercury testing.

Blood Collection Outcomes

After venipuncture is attempted, staff will record one of four outcomes on the Lab Checklist:

1. Outcome: Blood draw complete

Note tube type and volume on the **Lab Checklist**. Proceed with remaining Visit One/Two procedures.

2. Outcome: Blood draw must be rescheduled

Participants whose blood draw must be rescheduled can return to the lab at a later time but will not receive an incentive payment until after the blood draw is complete. **NOTE:** At the discretion of the clinic (and for the convenience of participants who have planned a longer stay at the clinic), **participants whose blood draw must be rescheduled may complete the Detailed Questionnaire (DQ)** at this visit, but **may not** receive the participant education portion of Visit One/Two until after the rescheduled blood draw. In this case, clinic staff will note the completed and incomplete procedures on the **Visit One/Two Checklist** (Appendix 1) and in the **EHR/PM**. The Participant will not receive an incentive until all Visit One/Two procedures are complete.

- <u>SMC</u>: The phlebotomist will note the need to reschedule on the **Lab Checklist**. Participants will be sent back to the clinic with their labeled **Lab Packs** so those supplies can be used when they return for a rescheduled lab. Clinic staff will note the incomplete visit in the **EHR/PM** and reschedule the blood draw.
- <u>GPHS</u>: The nurse/phlebotomist will note the need to reschedule on the Lab Checklist. She will also note the incomplete visit in the EHR/PM and reschedule the blood draw. The now-personalized Lab Pack will be saved for the participant's return visit.

3. Outcome: Ineligible for blood draw

If laboratory staff are unable to or do not attempt a blood draw and determine that a participant is unable to give blood then or later, the woman cannot continue to participate in FISH but will receive a \$25 Visa card. The phlebotomist will note the suspension of the visit on the **Lab Checklist**. Clinic staff will note the closure of participation in the **EHR/PM**.

4. Outcome: Decline

Participants who decline to have their blood drawn will be thanked for their time but will not receive an incentive. Staff will indicate the decline on the **Lab Checklist** and in the **EHR/PM**.

Unused or Incomplete Lab Packs

When the blood draw is incomplete because a participant cannot be drawn, declines to be drawn, or an insufficient sample is obtained, the Lab Verification Form and Lab Checklist will be completed and returned to the Participant Folder. Discard Chain of Custody Forms (COC) and tubes with Participant ID or Specimen ID labels.

When the blood draw is incomplete but is rescheduled, replacement tubes can be taken from extras supplied and be labeled using extra labels in the **Lab Pack** but not from another participant's **Lab Pack**.

Complete Lab Verification Form

Regardless of the outcome, the lab technician will complete the Lab Verification Form. This form must be returned to the FISH Coordinator.

The Lab Verification Form serves two purposes:

- First, it is used to record the outcome of the lab visit. Lab Verification Forms for SMC participants will be returned to the clinic by the participant as proof that labs were done, to trigger a reschedule; or to explain the reason for an incomplete blood draw. Lab Verification Forms at sites other than SMC must also be completed and placed in the Participant Folder after the visit, to provide the same information for staff who are tracking participants' progress.
- 2. Second, the Lab Verification Form triggers payment of one, two, or no incentives.

NOTE: Outcomes recorded on the Lab Verification Form include "Draw Outcomes" from the Lab Checklist. The reason for this duplication is that the Lab Verification Form is placed in the Participant Folder, while the Lab Checklist remains in the lab until samples are shipped.

Chain of Custody Form

A **Chain of Custody Form (COC)** is used to provide an accurate, written record of the possession and handling of a specimen from the time of collection through reporting of results. The **Chain of Custody Form (COC)** will be labeled with the **Specimen ID** by a member of the SMC or GPHS staff prior to the blood draw.

Information will be added to the **Chain of Custody Form (COC)** by the sampler and shipper as indicated in Figure 1 below.

6	9008	MINNES MD DEPARTMENT OF		ain-of-	Custo	ody	y F	01	m	ı		www.ł	Minn Er St	esota nviron 601 F 2 Paul 63 ite.mn.u	Depa ment Rober , MN 51-20 s/divs/	rtment of al Labora t St. Nor 55155-2 1-5300 phl/environ	f Healtl atory th 2531 mental/in	h ndex.html	P	age 1	0	f 1	
ē	les C	Program Code (2 Lett	ters) Project Name		Client / Age	ency	onto	l ho	alth								X St	andard	Chain c	of Custo	dy		
1 5	4	Site ID	FISHI		Project Mar	nager N	Vame /	Phone	aitri							Potentia	al Haza	rd 🗙	Yes	No	Unl	known	
- \		CCNSH (C	ook Co. North Sho	re Hosp.)	Patrici	ia M	cCa	nn							If	TAT		informa	tion to	Sample	r Comme	ents bel	ow
		Report to Name			Report to E	mail									1—	IAI L	<u> </u>	Ma	trix Co	odes	Enter	gency	
		Patricia McC	Cann		patricia	a.mo	ccan	n@	state	e.mr	1.us				DW NW	= Drinki	ng Wate	er Nater	WP =	Wipe	0	OT = Ot	her
	Sampled by (print)	n iii	Affiliation	C		#	of Co	ntain	ers /]	Prese	rvativ	res		1000	SD	- Soil/So	lid		BL =	Biologic	al Materia	d I	
	Dani	Keilly	GPH	5		4	Pi		qe	ate		ers	Itered	\rightarrow		asma						/NA	
		Patto	210-4	75-215	4	7	rie Ac		/droxi	flusoi	l	ntain	eld Fi	yses	cury	In Pi						Y/N	(Q)
z	NIDUA	nemy	~10-1	Collection	1 Matri	cserve	ochlo.	c Acid	um Hy	II II	r hic A	1# Ce	Y /	unal	d Mer	/ Acid:						Intact	Temp
Ê	# (Lab Use Only)	(Usigne Identifier)	Sample Point	Date (24	Time (Hour) Code	Unpr	Hydr	Nitri	Sodi	Sodi	Othe	Tota	Samj	₹ →	Bloo	Fatty						Scal	Lab
έğΠ		Test 6	(F006	5-13-14 (0	030 BL	0	0 0	0	0	0 0			Ν		Х	X							
, å	2																						
0)	3		1																				
	4							\perp			_						\square						
+L	5								1	_		<u> </u>					\square	-	\square				
àc	6							+			_	<u> </u>					\square	_	\square				
;5	7		-					_	$\left \right $		_	_					\vdash		\vdash	_			
t.	8					\square		_		-	-	_						_		-			
ď	9			<u> </u>		+		_			_	_					\square						
	10 Sampler Commente																					199	
	Whole block	od and plasma	samples	-																			
		Relinquished	By / Affiliation		Date	Tin	ne I		1976			Acc	epted E	By / Af	filiatio	a			-	I	Date	Ti	ime
	(Sampler)	Pailler	/Cpuc	É.	13-14	140	20	т.	2	- : (2	P	204	(ct	00	-				5-1	3-14	- 1/-	.00
	Jenn	ifer Back	strom	5-	-15-14	09	00	J	en		eR	10	ack	50	RC	in .			_	51	517		

Figure 1: Completed Chain of Custody Form (COC)

Specimen Processing and Storage

Specimen processing and storage steps used for FISH are based on Cook County North Shore Hospital (CCNSH) and MDH PHL procedures and illustrated in Figure 2 below.



Figure 2: Specimen Processing and Storage

The integrity of each specimen must be preserved from the time of collection to the time of testing. To that end, <u>carefully follow the reminders and procedure described below for specimen processing and storage.</u>

General Reminders

- Keep stoppers on tubes to prevent contamination, evaporation, and aerosolization.
- Check again to be sure that **Specimen IDs** on all tubes and forms are the same.
- <u>Labeled containers and labels cannot be exchanged with labels or containers from another</u> <u>package</u>. If a labeled tube breaks or must be replaced for any reason, use the extra lab supplies and do not mix tubes from different **Lab Packs. Do NOT put patient name or GPHS/CCNSH name labels on any tubes.**
- If needed, add a comment to the Lab Checklist and Chain of Custody Form (COC) to indicate hemolysis, lipemia, or any other observed irregularity, including missing samples or very small samples.
- Complete the Lab Checklist for specimen processing and storage procedures.

Specimen Processing and Storage Procedure Steps

The steps for specimen processing and storage are described below:

- 1. 2 mL Purple Top for mercury analysis
 - o Invert eight times.
 - **GPHS**: Place properly labeled tube with participant's plasma vial and paperwork in refrigerator until transfer on ice to CCNSH in less than 48 hours.
 - **CCNSH**: Place properly labeled tube with participant's plasma vial and paperwork in freezer until shipment to MDH PHL.
- 2. 2 mL Purple Top for fatty acid analysis
 - Holding time:
 - Strongly recommended: Hold at room temperature for no more than one hour before spinning.
 - If it cannot be avoided, samples may be held at room temperature for up to two hours.
 - If it is not possible to centrifuge a sample in less than two hours, the tubes may be refrigerated until they can be spun. However, it will then be necessary to allow them to warm to room temperature before placing in the centrifuge. MDH PHL recommends that this method be used as seldom as possible.
 - Centrifuge time and speed:
 - **CCNSH** centrifuge (Drucker 642VES): With 75mm tube holders, centrifuge 15 minutes at 3070 rpm.
 - **GPHS** centrifuge (Unico C806, fixed angle): With adaptors, centrifuge 15 minutes at 3400 rpm.

- Birch Grove/Special Events Centrifuge (Unico C856): With adaptors, centrifuge 15 minutes at 3400 rpm.
- Note: An even number of samples need to be spun together or a dummy sample should be spun with a single sample, placing them in point symmetry with respect to the axis of rotation. Spin two samples at a time or one sample with a dummy sample (e.g., Vacutainer with 2mL water).
- Remove stopper and then remove plasma with transfer pipette, placing it in the labeled 2 mL Pink Top cryovial.
 - **GPHS**: Place properly labeled plasma vial with participant's mercury tube and paperwork in refrigerator until transfer on ice to CCNSH in less than 48 hours.
 - CCNSH: Place properly labeled plasma vial with participant's mercury tube and paperwork in freezer until shipment to MDH PHL.
- 3. Complete specimen inventory on Lab Checklist.
 - 2 mL Purple Top for mercury analysis
 - volume: □ 2 mL □ <2 mL
 - o 2 mL Pink Top cryovial for (fatty acid) plasma
 - Volume: □ 1 mL □ <1 mL □ QNS
- 4. Check that all required information has been entered on the Chain of Custody Form (COC).
- 5. Wrap each participant's samples in absorbent material and place in a bio-hazard labeled specimen bags with the Chain of Custody Form (COC) (completed with phlebotomist, date and time, and sample information) and <u>any remaining Specimen ID labels</u> in the outside pocket of the bag. Refrigerate specimens at < 4° C until samples are prepared for transfer.</p>

Specimen Packaging and Shipping

Packaging and shipping procedures for blood specimens is illustrated in Figure 3.



Figure 3: Three Layers of Packaging for Shipping Blood Specimens

Supplies for Shipping Blood Specimens

The following supplies will be supplied by MDH for packaging and shipping blood specimens:

GPHS Supplies

- Bio-hazard labeled coolers
- Ice (gel) packs
- Bio-hazard labeled zip top specimen bags with pockets
- Absorbent sheets
- Extra bio-hazard labels

CCNSH Supplies

- Fed-Ex approved, International Air Transport Association (IATA) approved, Category B and UN3373 labeled shipping boxes with Styrofoam cooler inserts, and biohazard labels
 - MDH will purchase, label, and deliver shipping boxes to CCNSH. Periodically, used boxes and ice (gel) packs in suitable condition will be picked up at the MDH PHL and delivered for re-use by CCNSH.
- Pre-printed FedEx labels with MDH expense code addressed to:
 - FISH Project
 - Minnesota Department of Health
 - Environmental Sample Receiving
 - 601 Robert St N
 - St. Paul, MN 55155-2531
- Ice (gel) packs
- Bio-hazard labeled self-sealed specimen bags with pockets
- Absorbent sheets
- Bubble wrap
- Extra bio-hazard labels

Procedure for Packaging and Shipping Blood Specimens

Specimen packaging to prepare for shipment is illustrated in Figure 3 above and described below. **Note:** Specimens collected at GPHS will first be shipped to CCNSH and then combined with CCNSH specimens for shipment to MDH PHL.

Shipment of GPHS Specimens to CCNSH

To package specimens to ship/transfer to CCNSH, GPHS staff will:

- 1. Remove the **Chain of Custody (COC)** forms for each specimen from the outside pocket of the bag and record shipper/relinquisher info, etc. on the **COC**
- 2. Prepare a **Blood Sample Shipment Log** for each shipment of samples sent to CCNSH by entering the following information on the log:
 - Date shipped (transferred in this case)
 - Shipper's initials

- Total number of participants for whom samples are being sent
- For each participant: Ppt. ID, Specimen ID, and the presence of the mercury (Hg) tube and fatty acid (FA) vial.
- 3. Place bio-hazard labeled specimen bags in a bio-hazard labeled cooler with ice or gel packs, adding bubble wrap or other padding as needed.
- 4. Fold and place the **Blood Sample Shipment Log** on top of the samples in the cooler, or hand carry.
- 5. Transfer specimens to CCNSH within 48 hours of collection.

On receipt of the shipment, CCNSH staff will:

- Remove the Chain of Custody Form (COC) from the pocket of each participant's specimen sample bag, check the Blood Sample Shipment Log against the contents of the cooler, and fill in the "receiver/accepted by information" for each specimen.
- 2. Check the **Blood Sample Shipment Log** against the contents of the cooler and file the GPHS shipment log. **GPHS** sample information will be added to a new log for shipment to MDH PHL.
- 3. Enter specimens in CCNSH specimen log.
- 4. Place in freezer until transfer to MDH PHL.

Shipment of CCNSH and GPHS Specimens to MDH PHL

CCNSH will ship specimens by FedEx to MDH PHL. Specimens can be shipped any day of the week, except Fridays. However, the goal is to ship specimens on Tuesday or Wednesday each week. Shipments picked up at noon are expected to arrive at MDH PHL before close of business the next day.

Shipments will be packaged according to regulations for shipments defined as "Category B" and require triple packaging as described:

- <u>A primary receptacle</u>: In this case, leak-proof plastic specimen tubes wrapped in absorbent sheets (whole blood mercury tubes are not being opened and are considered leak-proof; plasma will be shipped in plastic, screw-cap vials and is also considered sealed/leak-proof).
- <u>Secondary packaging</u>: Fed-Ex and IATA-approved biohazard specimen bag with an outside pocket for the **Chain of Custody Form (COC)**.
- <u>Outer packaging</u>: FedEx and IATA-approved cardboard box with a cooler insert; absorbent material around the ice packs, and cushioning for all of the secondary packages within. In addition to a "FISH Project" sticker, the exterior of the box must be labeled with a bio-hazard label, the text "Biological Substance Category B", and a label with the mark UN3373.

To package specimens to ship to MDH PHL, CCNSH staff will:

- 1. Verify the number of specimens to be shipped against CCNSH specimen log
 - Remove the **Chain of Custody Form (COC)** from the pocket on the outside of each participant's specimen sample bag and enter the following information: shipper name and agency; date and time shipped.
 - Make a copy of each COC form to be filed/retained by CCNSH

- 2. Put the **COC** form back in the outside pocket of Self-Seal Biohazard Bag (Category B approved).
- 3. Prepare a **Blood Sample Shipment Log** for each shipment by entering the following information on the log:
 - Date shipped (transferred in this case)
 - o Shipper's initials
 - o Total number of participants for whom samples are being sent
 - For each participant: Ppt. ID, Specimen ID, and the presence of the mercury (Hg) tube and fatty acid (FA) vial.
- 4. Make a copy of the **Blood Sample Shipment Log** to be filed/retained by CCNSH. SMC will collect and transfer copies to MDH as needed.
- 5. Place Self-Seal bio-hazard labeled specimen bags into the labeled shipping box with Styrofoam insert.
- 6. Wrap icepacks in absorbent material and add to cooler.
- 7. Use bubble wrap or other padding as needed around specimen bags.
- 8. Place the completed **Blood Sample Shipment Log** in an envelope between the Styrofoam inner cooler and cardboard outer container of the shipping container.
- 9. Ship overnight by FedEx (Tuesday or Wednesday).
- 10. Notify MDH on the day specimens are shipped. Send an email to <u>patricia.mccann@state.mn.us</u> stating the number of specimens shipped and date.

On receipt of the shipment, MDH PHL staff will:

- 1. Remove the **Chain of Custody Form (COC)** from the pocket of each participant's specimen sample bag.
- 2. Check the **Blood Sample Shipment Log** against the contents of the cooler.
- 3. Fill in the "receiver/accepted by information" for each specimen.
- 4. Proceed with MDH PHL sample receiving procedures.

MDH PHL will notify MDH of any discrepancy between samples received and the **Blood Sample Shipment Log**. MDH will contact CCNSH to clarify and resolve discrepancies.

Appendix 5: Sawtooth Mountain Clinic Policies

Employee Use of Technology

Protected Health Information, Confidentiality, and Information Access Agreement

Employee Health and Safety

Employee Use of Technology

Page 1 of 3 Page 1 of 3 Approved by: Date 04/05/2013 CEO Date 05/20/2013 Board of Directors Date 05/20/2013 D	SUBJECT: Employee Use of Information Technology Approved by: CEO Date 04/05/2013 Board of Directors Date 05/20/2013 Policy Review/Revision Signature Date 05/20/2013 Policy Review/Revision Signature Date 05/20/2013 Policy Review/Revision Policy Review/Revision Signature Date 0 Revised Date 0 CC Review Date 0 Policy: Policy: The Sawtooth Mountain Clinic's (SMC) information technology, including but not limited to computer systems, e-mail, voice-mail and internet capabilities are to be used for Clinic related purposes. All communications utilizing the Clinic's information technology is subject to other SMC policies, including the policy regarding harassment and confidentiality. Abuse of the Clinic's information technology may result in disciplinary action up to and including termination.	SUBJECT: Employee Use of Information Technology Approved by: CD Date 05/20/2013 Board of Directors Date 05/20/2013 Policy Review/Revision Signature Image: Comparison of Compar	Sav	vtooth Mount:	ain Clinic	Policy Nur Dept: Info Coordinat Effective I	mber: 700-2 ormation To or: Rita Plo Date: 05/20	echnology urde /2013			
Approved by: Date 04/05/2013 Board of Directors Date 05/20/2013 Policy Review/Revision Date Signature Signature Image: Colspan="2">Image: Colspan="2">Image: Colspan="2">Colspan="2" Colspan="2" Colspan= 2" <td colspa<="" th=""><th>Approved by: CEO Date 04/05/2013 Board of Directors Date 05/20/2013 Policy Review/Revision Date Signature Bignature Image: Signature Revised Image: Signature CC Review Image: Signature Policy: The Sawtooth Mountain Clinic's (SMC) information technology, including but not limited to computer systems, e-mail, voice-mail and internet capabilities are to be used for Clinic related purposes. All communications utilizing the Clinic's information technology is subject to other SMC policies, including the policy regarding harassment and confidentiality. Abuse of the Clinic's information technology may result in disciplinary action up to and including termination.</th><th>Approved by: CEO Date 04/05/2013 Board of Directors Date 05/20/2013 Policy Review/Revision Date <u>Signature</u> Signature <u>Internet Content of Content of</u></th><th>SUBJECT</th><th>: Employee</th><th>Use of Inf</th><th>ormation T</th><th>echnology</th><th></th><th>Page 1</th><th>of 3</th></td>	<th>Approved by: CEO Date 04/05/2013 Board of Directors Date 05/20/2013 Policy Review/Revision Date Signature Bignature Image: Signature Revised Image: Signature CC Review Image: Signature Policy: The Sawtooth Mountain Clinic's (SMC) information technology, including but not limited to computer systems, e-mail, voice-mail and internet capabilities are to be used for Clinic related purposes. All communications utilizing the Clinic's information technology is subject to other SMC policies, including the policy regarding harassment and confidentiality. Abuse of the Clinic's information technology may result in disciplinary action up to and including termination.</th> <th>Approved by: CEO Date 04/05/2013 Board of Directors Date 05/20/2013 Policy Review/Revision Date <u>Signature</u> Signature <u>Internet Content of Content of</u></th> <th>SUBJECT</th> <th>: Employee</th> <th>Use of Inf</th> <th>ormation T</th> <th>echnology</th> <th></th> <th>Page 1</th> <th>of 3</th>	Approved by: CEO Date 04/05/2013 Board of Directors Date 05/20/2013 Policy Review/Revision Date Signature Bignature Image: Signature Revised Image: Signature CC Review Image: Signature Policy: The Sawtooth Mountain Clinic's (SMC) information technology, including but not limited to computer systems, e-mail, voice-mail and internet capabilities are to be used for Clinic related purposes. All communications utilizing the Clinic's information technology is subject to other SMC policies, including the policy regarding harassment and confidentiality. Abuse of the Clinic's information technology may result in disciplinary action up to and including termination.	Approved by: CEO Date 04/05/2013 Board of Directors Date 05/20/2013 Policy Review/Revision Date <u>Signature</u> Signature <u>Internet Content of Content of</u>	SUBJECT	: Employee	Use of Inf	ormation T	echnology		Page 1	of 3
Board of Directors Date 05/20/2013 Policy Review/Revision Date	Board of Directors Date 05/20/2013 Policy Review/Revision Date	Board of Directors Date 05/20/2013 Policy Review/Revision Date Image: Comparison of the service of	Approved by: CEO			I	Date 04/05/20	013			
Policy Review/Revision Date	Date Date Signature Image: Comparison of the system of the sy	Policy Review/Revision Date Image: Comparison of the service	Board of Direc	ctors		Date	e 05/20/2013				
Revised Image: CC Review CC Review Image: CC Review Policy: Image: CC Review The Sawtooth Mountain Clinic's (SMC) information technology, including but not limited to computer systems, e-mail, voice-mail and internet capabilities are to be used for Clinic related purposes. All communications utilizing the Clinic's information technology is subject to other SMC policies, including the policy regarding harassment and confidentiality. Abuse of the Clinic's information technology may result in discipling regarding the policy regarding harassment and confidentiality.	Revised Image: CC Review Image: CC Review Image: CC Review Policy: The Sawtooth Mountain Clinic's (SMC) information technology, including but not limited to computer systems, e-mail, voice-mail and internet capabilities are to be used for Clinic related purposes. All communications utilizing the Clinic's information technology is subject to other SMC policies, including the policy regarding harassment and confidentiality. Abuse of the Clinic's information technology may result in disciplinary action up to and including termination.	Bevised Image: CC Review CC Review Image: CC Review Policy: Policy: The Sawtooth Mountain Clinic's (SMC) information technology, including but not limited to computer systems, e-mail, voice-mail and internet capabilities are to be used for Clinic related purposes. All communications utilizing the Clinic's information technology is subject to other SMC policies, including t policy regarding harassment and confidentiality. Abuse of the Clinic's information technology may result disciplinary action up to and including termination.	Date Signature		1	oncy Re	view/Kevisio				
Signature Image: Constraint of the second secon	Signature Image: CC Revised Image: CC Revised Image: CC Review CC Review Image: CC Review Image: CC Review Image: CC Review Policy: Image: CC Review Image: CC Review Image: CC Review The Sawtooth Mountain Clinic's (SMC) information technology, including but not limited to computer systems, e-mail, voice-mail and internet capabilities are to be used for Clinic related purposes. All communications utilizing the Clinic's information technology is subject to other SMC policies, including the policy regarding harassment and confidentiality. Abuse of the Clinic's information technology may result in disciplinary action up to and including termination.	Signature Image: Constraint of the second seco	Date								
Revised Image: CC Review Image: CC Review Policy: Policy: Image: Communication Clinic's (SMC) information technology, including but not limited to computer systems, e-mail, voice-mail and internet capabilities are to be used for Clinic related purposes. All communications utilizing the Clinic's information technology is subject to other SMC policies, including the policy regarding harassment and confidentiality. Abuse of the Clinic's information technology may result in disciplinary action up to and including termination.	Revised Image: CC Review CC Review Image: CC Review Policy: Image: Computer systems, e-mail, voice-mail and internet capabilities are to be used for Clinic related purposes. All communications utilizing the Clinic's information technology is subject to other SMC policies, including the policy regarding harassment and confidentiality. Abuse of the Clinic's information technology may result in disciplinary action up to and including termination.	CC Review Construction Policy: Policy: The Sawtooth Mountain Clinic's (SMC) information technology, including but not limited to computer systems, e-mail, voice-mail and internet capabilities are to be used for Clinic related purposes. All communications utilizing the Clinic's information technology is subject to other SMC policies, including to policy regarding harassment and confidentiality. Abuse of the Clinic's information technology may result disciplinary action up to and including termination.	Signature								
Policy: The Sawtooth Mountain Clinic's (SMC) information technology, including but not limited to computer systems, e-mail, voice-mail and internet capabilities are to be used for Clinic related purposes. All communications utilizing the Clinic's information technology is subject to other SMC policies, including the policy regarding harassment and confidentiality. Abuse of the Clinic's information technology may result in fiscial insurance of the clinic's information technology.	Policy: The Sawtooth Mountain Clinic's (SMC) information technology, including but not limited to computer systems, e-mail, voice-mail and internet capabilities are to be used for Clinic related purposes. All communications utilizing the Clinic's information technology is subject to other SMC policies, including the policy regarding harassment and confidentiality. Abuse of the Clinic's information technology may result in disciplinary action up to and including termination.	Policy: The Sawtooth Mountain Clinic's (SMC) information technology, including but not limited to computer systems, e-mail, voice-mail and internet capabilities are to be used for Clinic related purposes. All communications utilizing the Clinic's information technology is subject to other SMC policies, including t policy regarding harassment and confidentiality. Abuse of the Clinic's information technology may result disciplinary action up to and including termination.	CC Review								
isophilary action up to and including termination.			The Sawtooth	Mountain Clin il, voice-mail a	nic's (SMC) ir nd internet cap	nformation tec pabilities are t	chnology, incl to be used for	uding but not li Clinic related p	imited to comp purposes. All	puter	
			communicatio policy regardin disciplinary ac	ns utilizing the ng harassment tion up to and	Clinic's infor and confidenti including term	mation techn ality. Abuse nination.	ology is subjection of the Clinic's	ct to other SMC	C policies, inc echnology ma	luding the y result in	
			communicatio policy regardin disciplinary ac	ns utilizing the ng harassment tion up to and	Clinic's infor and confidenti including term	mation techn ality. Abuse nination.	ology is subjea	ct to other SMC	C policies, inc echnology ma	luding the y result in	
			communicatio policy regardin disciplinary ac	ns utilizing the ng harassment tion up to and	Clinic's infor and confidenti including term	mation techn ality. Abuse nination.	ology is subjea	ct to other SMC	C policies, inc echnology ma	luding th	
Sawtooth Mountain Clinic Policy Number: 700-2 Dept: Information Technology Coordinator: Rita Plourde Effective Date: 05/20/2013 SUBJECT: Employee Use of Information Technology Page 2 of 3 Procedure Version 700-2 Procedure Review/Revision Date Signature Revised CC Review **PROCEDURE:**

1. No Expectation of Privacy

All information transmitted over any of the Sawtooth Mountain Clinic's (SMC) information technology systems, including voice-mail, e-mail and the internet, as well as all information stored in the SMC computer systems, is the property of the Clinic. Employees, contractors, and anyone else with access to the Clinic's information technology do not have an expectation of privacy regarding their use of the system. While it is not the Clinic's intention to invade the privacy of its employees, the Clinic may access voice-mail, e-mail, documents, and internet usage patterns, at any time, with or without notice.

2. Harassment

Using the SMC information technology and communication systems in a manner that may be considered to be obscene, harassing, racist, sexist, defamatory, libelous or otherwise offensive is a violation of the Clinic's policy and is strictly prohibited.

3 Voice-mail

Voice-mail is provided for employees' convenience to allow individuals outside the SMC to contact employees when the Clinic is closed. Voice- mail is not a substitute for accepting phone calls. Employees are expected to answer their phones during normal business hours and to frequently check their voice-mail messages when they are unavailable to answer their phone calls.

4. E-mail

The Sawtooth Mountain Clinic's e-mail system is intended to be used for business purposes only.

Medical Information. a.

Employees are prohibited from sending medical information over the e-mail system (internally or externally).

Solicitation and Distribution. Employees are prohibited from using the e-mail system to b. solicit money or information or distribute information not directly related to the employee's scope of employment.



Protected Health Information, Confidentiality, and Information Access Agreement

-	Sawtooth Mountain Clinic	
	PROTECTED HEALTH INFORMATION, CON	FIDENTIALITY AND INFORMATION ACCESS
	AGREI	EMENT
C -	Sum	mary
of inc pat wit cor	uncertaint characteristics (SMC) is dedicated to safeguardin our patient, employee, and organizational information (coll dudes protected health information that is any personal, en tient's treatment, payment, or health care operations of org th a patient or other medical staff, and/or information which nfidentiality, integrity, and availability of protected health in	ectively "Confidential Information"). Patient information nployment-related, or medical information relating to a ganization as determined through observation, conversation is created and/or stored in any information system. The formation must be maintained at all times.
Thi all infe me as	is Confidentiality and Information Access Agreement ("Agr users that access any of SMC's information systems as a ormation system user signing this Agreement may only ac adium as needed to perform his/her job responsibilities as a agreed upon between said user and Sawtooth Mountain C	eement") is required to be read, signed, and complied with b condition of access to any information system. The cess, use, and disclose Confidential Information in any allowed by law, organization policies and procedures, and/or Clinic.
1.	I understand and agree that I must safeguard and	8. I understand that access to all SMC's Information
	maintain the confidentiality, integrity, and availability of all Confidential Information I use, disclose, and/or access at all times, whether or not I am at work and regardless of how it was accessed.	Systems including Email and Internet are intended for business usage.
2.	I will only access, use, and/or disclose the minimum necessary Confidential Information needed to perform my assigned duties and disclose it to other individuals/organizations who need it to perform their assigned duties or as allowed by law. Protected health information is specifically protected, by law, from further disclosures without prior authorization.	 I will practice secure electronic communications by transmitting Confidential Information only to authorized entities, in accordance with approved privacy and security standards.
3.	I will not access my own, or my family's, record in any	10. I will only access or use the systems or devices that I
	information system without prior Authorization at SMC (unless required to perform your job responsibilities).	am being authorized to access and agree not to demonstrate the operation or function of any of SMC's information systems or devices to unauthorized individuals.
4.	I will not disclose any Confidential Information with	11. I will never use tools or techniques to break/exploit
5.	others who do not have a need to know it. I will not in any way <u>divulge</u> , copy, release, sell, loan, alter, or destroy any Confidential Information except as properly authorized	security measures. 12. I will never connect to unauthorized networks through SMC's systems or devices.
6.	I will not download any Confidential Information off SMC's information systems to store or use it on any other system or computer diskettes, compact discs, digital video discs, zip discs, other portable media, etc. or removable storage devices such as removable USB flash discs, except in situations whereby explicit approval to do so has been granted by SMC's Information technology (IT)Department. If I received this approval to download data I will assume sole and absolute responsibility to manage and protect it based upon standards listed in this Agreement and according to the law.	13. I understand that I have neither ownership interest nor expectation of privacy in any information accessed or created by me during my relationship with <u>SMC_SMC</u> may audit, log, access, review, and otherwise utilize information stored on or passing through its systems for many reasons, including to maintain the confidentiality, security, and availability of Confidential Information.
7.	I will not download any software program onto SMC equipment without prior approval from the SMC IT Department.	 I will not use SMC's information systems to transmit, retrieve, nor store any communications consisting of discriminatory, harassing, obscene, solicitation, or criminal information

Sawtooth Mountain Clinic	
15. I understand that my User Login ID(s), password(s) are used to control access to SMC's information systems and an electronic signature(s) is the equivalent to my legal signature. I will not disclose them to anyone nor allow anyone to access any information system using my User Login ID(s) and password(s) for any reason.	19. I will immediately report to SMC EHR_support any activity that violates this agreement, Confidential Information laws, or any other incident that could have any adverse impact on Confidential Information.
 I understand that I will be held accountable for all inquiries, entries, and changes made to any SMC information system using my User Login ID(s) and password(s). 	 Upon completion and/or termination of access to SMC's information systems, the EHR support team wi delete Users access to information systems/applications
 I will only use my officially assigned, personal User Login ID(s) and password(s). 	21. I affirm that I will maintain the confidentiality, integrity, and availability of all Confidential Information even afte termination, completion, cancellation, expiration, or other conclusion of access to SMC's information systems.
 I will immediately notify <u>SMC's_EHR</u> support if my password has been seen, disclosed, or otherwise compromised. 	22. I understand that violation of this Agreement may resul in disciplinary action, up to and including termination of employment or business relationship, suspension and loss of privileges, termination of authorization to work within SMC, as well as legal actions.
By signing this Agreement, I agree to comply with its terms a excuse for violating it. ①De①/EHR_support Department may is not returned signed and dated.	nd conditions. Failure to read this Agreement is not an deny access to SMC's information systems if this Agreemer
Signature	Date

OSHA Blood and Body Fluid Exposure Control Plan

SUBJECT: OSHA Blood and Body Fluid Exposure Control Plan Approved by: Clinical Director Date CEO Date Board of Directors Date Very New New Section Date Signature Date Very New New Section Date Signature Date Very New New Section Date Signature Date Very New New Section Date Out C Review Date POlicy Review Revision Tota dot of Directors Date Policy Review Revision Date Signature exclusion in a construction of Date (Section a construction of the endeavor, the following exposure to bloodborne pathogens, or a construction of this endeavor, the following exposure to bloodborne pathogens, or a construction of the endeavor, the following exposure to bloodborne pathogens, or a construction of the endeavor, the following exposure to bloodborne pathogens, or a construction of the endeavor, the following exposure to bloodborne pathogens, or a construction of the endeavor, the following exposure to bloodborne pathogens, or a construction of the endeavor, the following exposure to bloodborne pathogens, or a construction of the endeavor, the following exposure to bloodborne pathogens, or a construction of the endeavor (Section a key document to a satist our clinic in implementation endeavore endeavere endeavere endeavere endeavere endeavere endeavere ende		vtooth Mount	ain Clinic	Policy Dept: (Coordin Effectiv	Number: 200 Clinical nator: Teres ve Date: Draf	-18.0 a Borak, RN t		
Approved by: Clinical Director Date CEO Date Board of Directors Date Board of Directors Date Policy Review/Revision Policy Review/Revision Onte Signature Revised CC Review POLICY The Sawtooth Mountain Clinic is committed to providing a safe and healthful work environment for our entrice saff. In pursuit of this endeavor, the following exposure control plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with OSHA standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens." The ECP is a key document to assist our clinic in implementing and ensuring compliance with the standard, thereby protecting our employees. This ECP includes: * Determination of employee exposure * Implementation of various methods of exposure control, including: Universal precautions Engineering and work practice controls Personal protective equipment Housekeeping * Post-exposure evaluation and follow-up * Recordkeeping * Procedures for evaluating circumstances surrounding an exposure incident The subsequent pages of this ECP.<	SUBJECT	: OSHA BI	ood and B	ody Fluid	Exposure C	Control Plar	n Page	e 1 of 9
Clinical Director Date CEO Date Board of Directors Date Policy Review/Revision The signature Date Signature Date Revised Date CC Review Date POLICY The Sawtooth Mountain Clinic is committed to providing a safe and healthful work environment for our entire staff. In pursuit of this endeavor, the following exposure control plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens." The ECP is a key document to assist our clinic in implementing and ensuring compliance with the standard, thereby protecting our employees. This ECP includes: * Determination of employee exposure * Implementation of various methods of exposure control, including: Universal precautions Engineering and work practice controls Personal protective equipment Housekeeping * Hepatitis B vaccination * Post-exposure evaluation and follow-up * Recordkeeping * Procedures for evaluating circumstances surrounding an exposure incident The methods of implementation of these elements of the standard are discussed in the subsequent pages of this ECP.	Approved by:							
CEO Date Board of Directors Date Policy Review/Revision <u>bate</u> <u>bate</u> Signature Revised Image: Ima	Clinical Direc	tor			Date			
Board of Directors Date Policy Review/Revision Date Signature Image: Construction of the second se	CEO				Date			
Board of Directors Date Policy Review/Revision Signature	D 1 (D)				D (
Policy Review/Revision Signature Image: Constraint of the second secon	Board of Dire	otors			Date			
Date Image: Construct the second			Р	olicy b	eview/Revisio	n		
Signature Revised Revised Image: Control of the second	Date							
Revised Image: CC Review CC Review Image: CC Review POLICY The Sawtooth Mountain Clinic is committed to providing a safe and healthful work environment for our entire staff. In pursuit of this endeavor, the following exposure control plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with OSHA standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens." The ECP is a key document to assist our clinic in implementing and ensuring compliance with the standard, thereby protecting our employees. This ECP includes: * Determination of employee exposure * Implementation of various methods of exposure control, including: Universal precautions Engineering and work practice controls Personal protective equipment Housekeeping * Hepatitis B vaccination * Post-exposure evaluation and follow-up * Communication of hazards to employees and training * Recordkeeping * Procedures for evaluating circumstances surrounding an exposure incident The methods of implementation of these elements of the standard are discussed in the subsequent pages of this ECP.	Signature							
POLICY The Sawtooth Mountain Clinic is committed to providing a safe and healthful work environment for our entire staff. In pursuit of this endeavor, the following exposure control plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with OSHA standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens." The ECP is a key document to assist our clinic in implementing and ensuring compliance with the standard, thereby protecting our employees. This ECP includes: * Determination of employee exposure * Implementation of various methods of exposure control, including: Universal precautions Engineering and work practice controls Personal protective equipment Housekeeping * Post-exposure evaluation and follow-up * Communication of hazards to employees and training * Recordkeeping * Procedures for evaluating circumstances surrounding an exposure incident The methods of implementation of these elements of the standard are discussed in the subsequent pages of this ECP.	CC Roview							
	The ECP is a l standard, there * Determinati * Implementa Universal prece Engineering a Personal prote Housekeeping * Hepatitis B * Post-exposu * Communica * Recordkeep * Procedures for The methods of pages of this E	eey document eby protecting on of employe tion of various autions nd work practi- ctive equipme vaccination re evaluation a tion of hazards ing for evaluating of implementa GCP.	to assist our our employe e exposure methods of e ice controls ent and follow-up s to employee circumstance tion of these	clinic in imp es. This ECI exposure con es and traini es surroundin elements of	olementing and p includes: ntrol, including ng ng an exposure the standard are	ensuring comj : incident e discussed in	pliance with t	he



Policy Number: 200-18.0 Dept: Clinical Coordinator: Teresa Borak, RN Effective Date: Draft

SUBJECT: OSHA Blood and Body Fluid Exposure Control Plan

Page 2 of 9

Procedure Review/Revision

Date				
Signature				
Revised				
CC Review				

PROCEDURE:

- Sawtooth Mountain Clinic's Exposure Control Coordinator (ECC) is responsible for the implementation of the ECP. The ECC will maintain, review, and update the ECP at least annually, and whenever necessary to include new or modified tasks and procedures.
- Those employees who are determined to have occupational exposure to blood or other potentially infectious materials (OPIM) must comply with the procedures and work practices outlined in this ECP.
- ECC will maintain and provide all necessary personal protective equipment (PPE), engineering controls (e.g., sharps containers), labels, and red bags as required by the standard.
- ECC will ensure that adequate supplies of the aforementioned equipment are available in the appropriate sizes.
- ECC will be responsible for ensuring that all medical actions required are performed and that appropriate employee health and OSHA records are maintained.
- ECC will be responsible for training, documentation of training, and making the written ECP available to employees, OSHA, and NIOSH representatives.

EMPLOYEE EXPOSURE DETERMINATION

The following is a list of all job classifications at our establishment in which all employees have <u>occupational</u> exposure:

JOB TITLE DEPARTMENT/LOCATION

Physicians/CNP	Clinic Exam Rooms/Nurse's Station
RN <u>,LPN,CMA</u>	Clinic Exam Rooms/Nurse's Station
Front Desk staff	Clinic waiting area
Billing/Finance	Clinic Business offices

The following is a list of job classifications in which some employees at our establishment have occupational exposure. Included is a list of tasks and procedures, or groups of closely related tasks and procedures, in which occupational exposure may occur for these individuals: JOB TITLE DEPARTMENT/LOCATION TASK/PROCEDURE

Physicians/CNP/Nurses	Handling Sharps and Regulated Waste
Front Desk staff	Possible handling of regulated waste

Sawto	oth Mountain Clinic		
Santo		Policy Number: 200-18	3.0
		Dept: Clinical	
		Coordinator: Teresa B	orak, RN
		Effective Date: Draft	
SUBJECT:	OSHA Blood and Bo	dy Fluid Exposure Con	ntrol Plan
			Page 3 of
Billing/Finance		Possible handling of regula	ated waste
Housekeeping/Er	nvironmental Services	Handling Regulated Waste	
METHODS OF	IMPLEMENTATION A	AND CONTROL	
Use of universal	Precautions		
Exposure Contro. Employees cover	I Plan ed by the bloodborne path	ogens standard receive an ex	planation of this
ECP during their	initial training session. It	will also be reviewed in their	annual refresher
training. All emp	loyees have an opportunit	y to review this plan at any ti	me during their
work shifts by co	ntacting the ECC. If reque	ested, we will provide an emp	ployee with a copy of the ECP
of charge and wit	hin 15 days of the request	t.	
ECC is responsib	le for reviewing and upda	ting the ECP annually or mor	re frequently if necessary to re
Lee la responsio		this the Ler annually of mor	re nequently if necessary to re
any new or modi	fied tasks and procedures	which affect occupational exp	posure and to reflect new or re
any new or modifiemployee positio	fied tasks and procedures ns with occupational expo	which affect occupational exposure.	posure and to reflect new or re
any new or modi: employee positio Engineering Cont	fied tasks and procedures ns with occupational expo trols and Work Practices	which affect occupational exposure.	posure and to reflect new or re
any new or modi: employee positio Engineering Com	fied tasks and procedures ns with occupational expo trols and Work Practices rols and work practice cor	which affect occupational exposure.	or minimize
any new or modi employee positio Engineering Cont Engineering cont exposure to blood	fied tasks and procedures ns with occupational expo trols and Work Practices rols and work practice cor dborne pathogens. The spe	which affect occupational exposure. atrols will be used to prevent ecific engineering controls an	or minimize d work practice
any new or modi employee positio Engineering Cont Engineering cont exposure to blood controls used are	fied tasks and procedures ns with occupational expo trols and Work Practices rols and work practice cor <u>aborne</u> pathogens. The spe listed below:	which affect occupational exp osure. htrols will be used to prevent ecific engineering controls an	or minimize d work practice
any new or modi employee positio Engineering Cont Engineering cont exposure to blood controls used are Personal p	fied tasks and procedures ns with occupational expo trols and Work Practices rols and work practice cor dborne pathogens. The spe listed below: protective equipment.	which affect occupational exp osure. ntrols will be used to prevent ecific engineering controls an	or minimize d work practice
any new or modi employee positio Engineering Cont Engineering cont exposure to blood controls used are Personal p Self Sheat	fied tasks and procedures ns with occupational expo trols and Work Practices rols and work practice cor dborne pathogens. The spe listed below: protective equipment. thing needles	which affect occupational exposure. ntrols will be used to prevent	or minimize d work practice
any new or modi employee positio Engineering Cont Engineering cont exposure to blood controls used are Personal p Self Sheat Sharps co	fied tasks and procedures ns with occupational expo trols and Work Practices rols and work practice cor dborne pathogens. The spe listed below: protective equipment. thing needles ntainers	which affect occupational exposure.	or minimize d work practice
any new or modi employee positio Engineering Cont Engineering cont exposure to blood controls used are Personal p Self Sheat Sharps co Hand/Eye Sharps disposal c	fied tasks and procedures ns with occupational expo trols and Work Practices rols and work practice cor dborne pathogens. The spe listed below: protective equipment. thing needles ntainers wash facilities ontainers are inspected an	which affect occupational exposure. https://which.affect.occupational.exposure. https://which.affect.occupati	or minimize d work practice
any new or modi employee positio Engineering Cont Engineering cont exposure to blood controls used are Personal p Self Sheat Sharps co Hand/Eye Sharps disposal c whenever necessi	fied tasks and procedures ns with occupational expo trols and Work Practices rols and work practice cor dborne pathogens. The spe listed below: protective equipment. thing needles ntainers wash facilities ontainers are inspected an ary to prevent overfilling.	which affect occupational exposure. ntrols will be used to prevent ecific engineering controls an d maintained or replaced by 1	or minimize d work practice
any new or modi employee positio Engineering Cont Engineering cont exposure to blood controls used are Personal p Self Sheat Sharps co Hand/Eye Sharps disposal c whenever necess This facility iden	fied tasks and procedures ns with occupational expo trols and Work Practices rols and work practice cor dborne pathogens. The spe listed below: protective equipment. thing needles ntainers wash facilities ontainers are inspected an ary to prevent overfilling. tifies the need for changes	which affect occupational exposure. atrols will be used to prevent ecific engineering controls an ad maintained or replaced by 1 is in engineering control and w	or minimize d work practice housekeeping or nursing staff
any new or modi employee positio Engineering Com Engineering cont exposure to blood controls used are Personal p Self Sheat Sharps co Hand/Eye Sharps disposal c whenever necess This facility iden through review o	fied tasks and procedures ns with occupational expo trols and Work Practices rols and work practice cor dborne pathogens. The spe listed below: protective equipment. thing needles ntainers wash facilities ontainers are inspected an ary to prevent overfilling. tifies the need for changes f OSHA records and upda	which affect occupational exposure. atrols will be used to prevent ecific engineering controls an ad maintained or replaced by 1 is in engineering control and w tes.	or minimize d work practice housekeeping or nursing staff
any new or modi employee positio Engineering Con Engineering cont exposure to blood controls used are Personal p Self Shear Sharps co Hand/Eye Sharps disposal c whenever necess This facility iden through review o We evaluate new	fied tasks and procedures ns with occupational expo trols and Work Practices rols and work practice cor dborne pathogens. The spe listed below: protective equipment. thing needles ntainers e wash facilities ontainers are inspected an ary to prevent overfilling. tifies the need for changes f OSHA records and upda procedures or new product	which affect occupational exposure. atrols will be used to prevent ecific engineering controls an ad maintained or replaced by 1 is in engineering control and w tes. cts regularly by examining th	or minimize d work practice housekeeping or nursing staff vork practices e current literature, supplier
any new or modi employee positio Engineering Com Engineering cont exposure to blood controls used are • Personal p • Self Sheat • Sharps co • Hand/Eye Sharps disposal c whenever necess This facility iden through review o We evaluate new information and p	fied tasks and procedures ns with occupational expo trols and Work Practices rols and work practice cor dborne pathogens. The spe listed below: protective equipment. thing needles ntainers wash facilities ontainers are inspected an ary to prevent overfilling. tifies the need for changes f OSHA records and upda procedures or new productor	which affect occupational exposure. atrols will be used to prevent ecific engineering controls an ad maintained or replaced by 1 is in engineering control and w tes. cts regularly by examining th	or minimize d work practice housekeeping or nursing staff vork practices e current literature, supplier
any new or modi employee positio Engineering Con Engineering cont exposure to blood controls used are Personal p Self Shear Sharps co Hand/Eye Sharps disposal c whenever necess This facility iden through review o We evaluate new information and p	fied tasks and procedures ns with occupational expo trols and Work Practices rols and work practice cor dborne pathogens. The spe listed below: protective equipment. thing needles ntainers e wash facilities ontainers are inspected an ary to prevent overfilling. tifies the need for changes f OSHA records and upda procedures or new produc- products.	which affect occupational exposure. atrols will be used to prevent ecific engineering controls an ad maintained or replaced by 1 is in engineering control and w tes. cts regularly by examining th fficials are involved in this pr	or minimize d work practice housekeeping or nursing staff vork practices a current literature, supplier
any new or modi employee positio Engineering Con Engineering cont exposure to blood controls used are Personal p Self Sheat Sharps co Hand/Eye Sharps disposal c whenever necess This facility iden through review o We evaluate new information and p Both front line w Nursing staff & E	fied tasks and procedures ns with occupational expo- trols and Work Practices rols and work practice cor dborne pathogens. The spe listed below: protective equipment. thing needles ntainers wash facilities ontainers are inspected an ary to prevent overfilling. tifies the need for changes f OSHA records and upda procedures or new produ- products.	which affect occupational exposure. Introls will be used to prevent ecific engineering controls an ad maintained or replaced by 1 is in engineering control and w tes. cts regularly by examining th fficials are involved in this pr implementation of these reco	or minimize d work practice housekeeping or nursing staff vork practices a current literature, supplier rocess: mmendations.
any new or modi employee positio Engineering Con Engineering cont exposure to blood controls used are Personal p Self Sheat Sharps co Hand/Eye Sharps disposal c whenever necess This facility iden through review o We evaluate new information and p Both front line w Nursing staff & E	fied tasks and procedures ns with occupational expo- trols and Work Practices rols and work practice cor dborne pathogens. The spe listed below: protective equipment. thing needles ntainers e wash facilities ontainers are inspected an ary to prevent overfilling. tifies the need for changes f OSHA records and upda procedures or new produc- products. orkers and management of ECC will ensure effective ve Equipment (PPE)	which affect occupational exposure. atrols will be used to prevent ecific engineering controls an ad maintained or replaced by 1 is in engineering control and w tes. cts regularly by examining th fficials are involved in this pr implementation of these reco	or minimize d work practice housekeeping or nursing staff vork practices e current literature, supplier rocess: mmendations.
any new or modi employee positio Engineering Con Engineering cont exposure to blood controls used are Personal p Self Sheat Sharps co Hand/Eye Sharps disposal c whenever necess This facility iden through review o We evaluate new information and p Both front line w Nursing staff & E Personal Protecti PPE is provided t	fied tasks and procedures ns with occupational expo- trols and Work Practices rols and work practice con dborne pathogens. The spe listed below: protective equipment. thing needles ntainers wash facilities ontainers are inspected an ary to prevent overfilling. tifies the need for changes f OSHA records and upda procedures or new produc- products. orkers and management of ECC will ensure effective to our employees at no cos	which affect occupational exposure. atrols will be used to prevent ecific engineering controls an ad maintained or replaced by 1 is in engineering control and w tes. cts regularly by examining th fficials are involved in this pr implementation of these reco	or minimize d work practice housekeeping or nursing staff vork practices e current literature, supplier rocess: mmendations.
any new or modi employee positio Engineering Con Engineering cont exposure to blood controls used are Personal p Self Shear Sharps co Hand/Eye Sharps disposal c whenever necess This facility iden through review o We evaluate new information and p Both front line w Nursing staff & E Personal Protecti PPE is provided t appropriate PPE f	fied tasks and procedures ns with occupational expo trols and Work Practices rols and work practice cor dborne pathogens. The spe listed below: protective equipment. thing needles ntainers wash facilities ontainers are inspected an ary to prevent overfilling. tifies the need for changes f OSHA records and upda procedures or new products. orkers and management of ECC will ensure effective to our employees at no cos for the tasks or procedures	which affect occupational exposure. htrols will be used to prevent ecific engineering controls an ad maintained or replaced by 1 is in engineering control and w tes. cts regularly by examining th fficials are involved in this pr implementation of these reco st to them. Training is provide s employees will perform.	or minimize d work practice housekeeping or nursing staff vork practices te current literature, supplier rocess: mmendations. ed by <u>ECC in</u> the use of the
any new or modi employee positio Engineering Con Engineering cont exposure to blood controls used are Personal p Self Sheat Sharps co Hand/Eye Sharps disposal c whenever necess This facility iden through review o We evaluate new information and p Both front line w Nursing staff & E Personal Protecti PPE is provided t appropriate PPE f	fied tasks and procedures ns with occupational expo- trols and Work Practices rols and work practice cor dborne pathogens. The spe- listed below: protective equipment. thing needles ntainers wash facilities ontainers are inspected an ary to prevent overfilling. tifies the need for changes f OSHA records and upda procedures or new produ- products. orkers and management o ECC will ensure effective ve Equipment (PPE) to our employees at no cos for the tasks or procedures and available to employees at	which affect occupational exposure. https://which affect occupational exposure. https://which.affect occupational exposure. https://which.affect occupational exposure. https://which.affect.affec	or minimize d work practice housekeeping or nursing staff vork practices te current literature, supplier rocess: mmendations. ed by <u>ECC in</u> the use of the
any new or modi employee positio Engineering Con Engineering cont exposure to blood controls used are Personal p Self Sheat Sharps co Hand/Eye Sharps disposal c whenever necess This facility iden through review o We evaluate new information and p Both front line w Nursing staff & E Personal Protecti PPE is provided t appropriate PPE f The types of PPE Gloves:	fied tasks and procedures ns with occupational expo- trols and Work Practices rols and work practice cor dborne pathogens. The spe- listed below: protective equipment. thing needles ntainers wash facilities ontainers are inspected an ary to prevent overfilling. tifies the need for changes f OSHA records and upda procedures or new produ- boroducts. orkers and management of ECC will ensure effective ve Equipment (PPE) to our employees at no cos for the tasks or procedures available to employees at Protective Clothing:	which affect occupational exposure. throls will be used to prevent ecific engineering controls an ad maintained or replaced by 1 is in engineering control and w tes. cts regularly by examining th fficials are involved in this pr implementation of these reco st to them. Training is provide s employees will perform. re as follows: Respiratory Protection:	or minimize d work practice housekeeping or nursing staff vork practices te current literature, supplier rocess: mmendations. ed by <u>ECC in the use of the</u> Eye & Face <u>Protec</u>

Sawtooth Mountain Clini	c Policy Number: 200-18.0 Dept: Clinical Coordinator: Teresa Borak, RN Effective Date: Draft
SUBJECT: OSHA Blood and	d Body Fluid Exposure Control Plan Page 4 of 9
Vinyl <u>Bouffants</u> Sterile Surgical Booties Utility glove	Face Shield
PPE is located in each providers offic obtained through the Exposure Contro Fit testing for N95 masks will be prov	e & at the nurse's station and exam rooms or may be ol Coordinator. rided annually.
* Remove PPE after it becomes conta	minated, and before leaving the work area.
* Used PPE may be disposed of in cor * Wear appropriate gloves when it can hand contact with blood or OPIM, and gloves if torn, punctured, contaminate * Utility gloves may be decontaminate compromised; discard utility gloves if tearing, puncturing, or deterioration. * Never wash or decontaminate dispo * Wear appropriate face and eye protect droplets of blood or OPIM pose a haz * Remove immediately or as soon as if OPIM, in such a way as to avoid contt The procedure for handling used PPE Sawtooth Mountain Clinic will utilized equipment for face shields, eye protect	ntainers for laundering, decontamination, or disposal. n be reasonably anticipated that there may be d when handling or touching contaminated items or surfaces; replace ed, or if their ability to function as a barrier is compromised. red for reuse if their integrity is not f they show signs of cracking, peeling, sable gloves for reuse. ection when splashes, sprays, spatters, or ard to the eye, nose, or mouth. feasible any garment contaminated by blood or act with the outer surface. is as follows: the North Shore Hospital's used PPE policy and decontamination otion and resuscitation equipment as necessary.









Sawtooth Mo	ountain Clinic	Policy Number: 200-18.0 Dept: Clinical Coordinator: Teresa Borak, RN Effective Date: Draft	
SUBJECT: OSHA	Blood and B	ody Fluid Exposure Control Plan	
			Page 9 of 9
Sharps Injury Log			
Sharps Injury Log Establishment/Facilit	y Name:		
Sharps Injury Log Establishment/Facilit Dated filled out:	y Name: By:	Time of Injury:	
Sharps Injury Log Establishment/Facilit Dated filled out: Job title:	y Name: By: Work Area	Time of Injury: a where injury occurred:	
Sharps Injury Log Establishment/Facilit Dated filled out: Job title: Brief description of h [i.e., procedure being done, action body part injured	y Name: By: Work Area now the incider being performed (disp	Time of Injury: a where injury occurred: nt occurred: posal, injection, etc.),	
Sharps Injury Log Establishment/Facility Dated filled out: Job title: Brief description of h [i.e., procedure being done, action body, part injured Type of Device: (e.g., syringe, suture needle	y Name: By: Work Area now the incider n being performed (disp	Time of Injury: a where injury occurred: nt occurred: posal, injection, etc.),	
Sharps Injury Log Establishment/Facility Dated filled out: Job title: Brief description of h [i.e., procedure being done, action body, part injured Type of Device: (e.g., syringe, suture needle Brand Name of Device	y Name: By: Work Area now the incider n being performed (disp) e:	Time of Injury: a where injury occurred: nt occurred: posal, injection, etc.),	
Sharps Injury Log Establishment/Facility Dated filled out: Job title: Brief description of h [i.e., procedure being done, action body, part injured Type of Device: (e.g., syringe, suture needle Brand Name of Device [i.e., procedure being done, action body, part injured]	y Name: By: Work Area now the incider h being performed (disp) re: h being performed (disp	Time of Injury: a where injury occurred: nt occurred: posal, injection, etc.),	
Sharps Injury Log Establishment/Facility Dated filled out: Job title: Brief description of h [i.e. procedure being done, action body part injured Type of Device: (e.g., syringe, suture needle Brand Name of Device [i.e., procedure being done, action body part injured] 29 CFR 1910.1030, OSHA's Bloo Log for recording all percutaneous devices being used in healthcare must be kept in addition to the inju a calendar.year. The log must be preserves the confidentiality	y Name: By: Work Area work Area ow the incider being performed (disp being performed (disp being performed (disp being performed (disp call of the second being performed (disp call of the second call of	Time of Injury: a where injury occurred: nt occurred: posal, injection, etc.), posal, injection, etc.), ndard, in paragraph (h)(5), requires an employer to establis curring from <i>contaminated</i> sharps. The purpose of the Log to identify problem devices or procedures requiring additio ired by 29 CFR 1904. The Sharps Injury Log should includ following the end of the year to which it relates. The Log m	sh and maintain a Sharps Injury is to aid in the evaluation of inal attention or review. This Io e all sharps injuries occurring in ust be kept in a manner that
Sharps Injury Log Establishment/Facility Dated filled out: Job title: Brief description of h [i.e., procedure being done, action body, part injured Type of Device: (e.g., syringe, suture needle Brand Name of Device [i.e., procedure being done, action body part injured] 29 CFR 1910.1030, OSHA's Bloo Log for recording all percutaneous devices being used in healthcare must be kept in addition to the inju a calendar, year. The log must be preserves the confidentiality	y Name: By: Work Area tow the incider to being performed (disp be: the being performed (disp be: the being performed (disp dome Pathogens Stars injuries in a facility oc and other facilities and and other facilities and and and facilities and and and facilities and and and facilities and and and and facilities and and and and facilities and and facilities and facilities and and faciliti	Time of Injury: a where injury occurred: nt occurred: posal, injection, etc.), posal, injection, etc.), ndard, in paragraph (h)(5), requires an employer to establis curring from <i>contaminated</i> sharps. The purpose of the Log it o identify problem devices or procedures requiring additio ired by 29 CFR 1904. The Sharps Injury Log should includ following the end of the year to which it relates. The Log m	sh and maintain a Sharps Injury is to aid in the evaluation of nal attention or review. This lo e all sharps injuries occurring in ust be kept in a manner that
Sharps Injury Log Establishment/Facilit Dated filled out: Job title: Brief description of h [i.e., procedure being done, action body, part injured Type of Device: (e.g., syringe, suture needle Brand Name of Device Brand Name of Device [i.e., procedure being done, action body part injured] 29 CFR 1910.1030, OSHA's Blog Log for recording all percutaneous devices being used in healthcare must be kept in addition to the inju a calendar, year. The log must be preserves the confidentiality	y Name: By: Work Area now the incider heing performed (disp heing performed (disp heing performed (disp comparing performed (disp heing performed (disp comparing performed (d	Time of Injury: a where injury occurred: a where injury occurred: bosal, injection, etc.), posal, injection, etc.), ndard, in paragraph (h)(5), requires an employer to establis courring from <i>contaminated</i> sharps. The purpose of the Log Ito identify problem devices or procedures requiring additio ired by 29 CFR 1904. The Sharps Injury Log should include following the end of the year to which it relates. The Log m	sh and maintain a Sharps Injury is to aid in the evaluation of ınal attention or review. This Io a all sharps injuries occurring in lust be kept in a manner that