

Attachment 3b. Program Summary Flow Chart

ATSDR Biomonitoring of Great Lakes Populations Program (N=1,400 respondents) This is a Graphical Summary of Section A.1. Background (Table 1 Study Subpopulations and Areas of Concern)															
	100	100	100	100	100	100	100	100	100	100	100	100	100		
1	MINNESOTA (N=500)					MICHIGAN (N=400)			NEW YORK (N=500)						
2	CARLTON and (SOUTH) SAINT LOUIS COUNTIES					COUNTIES NOT SPECIFIED			MONROE COUNTY		ERIE and NIAGARA COUNTIES				
3	St. Louis River AOC					Saginaw River and Bay AOC		Detroit River AOC		Rochester Embayment AOC		Eighteenmile Creek AOC	Niagara River AOC		Buffalo River AOC
4	American Indians					Shoreline Anglers			Licensed Anglers					Immigrants from Burma	
5	N=500					N=200		N=200		N=150		N=250		N=100	
Outreach, Sampling, and Recruitment For description of state-specific data collection system, see Information Flow Charts and IC forms (Attachment 4-6). See summary of the sampling and recruitment process in Section A.1. Overview of Data Collection System. For detailed justification of sampling methods, see Section B.1.															
6	Sampling from Fond du Lac Human Services Client List Client List will first be restricted (“cleaned”) to persons with known eligible age and recent clinic use (past 3 years). Random sample drawn from Client List (N=793). Subsequent screening will determine if fully eligible (e.g. past year resident in study area, not pregnant, not deceased). Eligibility screening, recruitment, and appointment scheduled by CATI (N=713; Attachment 5b). Refusals will answer questions for nonresponse analysis (N=214; Attachment 5b).					Shoreline Venue-based Sampling (VBS) Interviewers will construct secondary enumeration list with Screening Questionnaire (N=4000; Attachment 4a). Selected locations in close proximity to fishing venues will be used to host clinic screenings. Eligible persons will be identified based on venue screening (N=1,440). Of these, 936 will be willing to participate. A random sample of 500 will be drawn from the sampling frame of 936. Phone interview will be used to scheduled clinic appointment (N=400; Attachment 4b).			Sampling from NY State Licensed Angler Database Mail out recruitment letters soliciting voluntary response (N=14,400) (Attachment 6a). Voluntary responses received by one of two modes (N=1,036; Attachment 6b or N=1,556; Attachment 6c). Active follow-up for non-responders to determine eligibility and to schedule appointment by CATI (N=1,728; Attachment 6d). Among voluntary responders to above two modes, only eligible will be recruited and appointment scheduled by CATI (N=518; Attachment 6e).					Respondent-Driven Sampling (RDS) Sampling , screening , and recruitment will occur at one time (N=184, Attachment 6h).	

Response Rates.

For background on available historical information collections on these subpopulations by state as basis for response rate estimate, see Section A.4. Review of Institutional Reports and Published Literature.

For justification of proposed methods to maximize response rates in relation to payment or gift for each state’s subpopulation, see Sections B.3 and A.9.

For detailed justification for estimated response rates, see Section B.1.

	American Indians (N=500)	Shoreline Anglers (N=400)	Licensed Anglers (N=400)	Immigrants from Burma (N=100)
7	Response Rate: 70% among eligible from sampling frame, based on recent First Nations Biomonitoring Pilot Study. Fish consumption is not an eligibility requirement because the Tribe is interested in assessing the prevalence, along with adherence to traditional practices such as consumption of wild game and plants.	Response Rate: 80% of persons determined to be eligible and willing to participate. Eating two fish meals per month is an eligibility requirement.	Response Rate: 46% based on previous NY studies. Eating at least one fish meal in the previous year is an eligibility requirement.	Response Rate: 81%, based on efficacy of peer-recruitment. Eating 12 fish meals per year is an eligibility requirement.

Enrollment, Interview, Clinical Assessments, and Specimen Collection

For detailed information collection procedures by state, see Section B.2.

For related burdens to the respondent by state, see Section A.12.

Each line in the A.12. Burden Table is indexed to a specific IC form as noted in in Section A.1. Overview of Data Collection System.

8	Interview Setting: Medical clinic setting with Informed Consent (N=500; Attachment 5c); Interviews (N=500; Attachment 5d, 5e); Specimen collection and clinical assessments (N=500, Attachment 5f).	Interview Setting: Local health department facilities and community medical clinic setting with Informed Consent (N=400; Attachment 4c); Contact information (Attachment 4d). Interviews (N=400; Attachment 4e); Specimen collection and clinical assessments (N=400).	Interview Setting: Collection locations with Informed Consent (N=400; Attachment 6f); Interviews (N=400; Attachment 6g); Specimen collection and clinical assessments (N=400).	Interview Setting: Collection locations with Informed Consent (N=100; Attachment 6i). Interviews (N=100; Attachment 6j); Specimen collection and clinical assessments (N=100). Answer Network Size Questions for RDS (N=100; Attachment 6k).
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Distribution of Tokens of Appreciation

Justification is provided for each state’s proposed schedule and amount in gift cards in Section A.9.

9	Incremental Distribution: Travel and review of Consent Form - \$25; Interview - \$25; Specimen collection and clinical assessments - \$25. Record of participation and distribution of gift cards will be documented (N=500; Attachment 5g).	Incremental Distribution: Consent and Interview - \$25; Specimen collection and clinical assessments - \$50.	Single Distribution for Licensed Anglers and Burmese: Consent and Interview; Specimen collection and clinical assessments - \$100. For RDS, Burmese respondents will be given an additional \$15 for each of up to three eligible recruits (\$45 maximum).
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Program Laboratory Policies and Procedures - Attachment 7

Attachment 7 is dedicated to program laboratory procedures and policies.

This attachment is referenced in the narrative in Section A.1. Items of Information to be Collected.

The Chemical Analyte Overview and Index are provided on the attachment coversheet. It provides the proposed list of required and state-optional analytes, the performing laboratory, the standard operating procedures (SOPs), and the associated biological matrix. For Chemical Analytes by State, see Attachment 7a.

For Biomonitoring of Great Lakes Populations Program Laboratory QA/QC Procedures, see Attachment 7b.

For Clinical Laboratory Improvement Amendments (CLIA) Certificates, see Attachment 7c.

For AMAP External Proficiency Test Reports, see Attachment 7d.

For Laboratory Standard Operating Procedures (SOPs), see Attachment 7e.

	MINNESOTA (N=500)	MICHIGAN (N=400)	NEW YORK (N=500)
10	Performing Laboratories: Minnesota Public Health Laboratory (LAB D) MedTox (LAB E) Michigan Public Health Laboratory (LAB A) New York State Public Health Laboratory (LAB F)	Performing Laboratories: Michigan Public Health Laboratory (LAB A) CDC NCEH Laboratory (LAB B) Sparrow Hospital (LAB C)	Performing Laboratory: New York State Public Health Laboratory (LAB F)

Results Reporting and Communications - Attachment 10

Attachment 10 (Results Reporting and Supporting Information) is dedicated to the reporting procedures by the three states.

This attachment is referenced in A.1. Overview of the Data Collection System,

and the narrative justification is found in Section A.2. Purpose and Use of Information Collection.

	American Indians (N=500)	Shoreline Anglers (N=400)	Licensed Anglers (N=400)	Immigrants from Burma (N=100)
11	Attachment 10b. Templated Results Letters based on need for rapid reporting of alert values to sensitive groups (women of childbearing age) and non-sensitive groups or final reports of normal values. A Metals Rapid Results Reporting Protocol provides detailed justification for the proposed reporting plan. Project factsheets on corresponding metals are provided as supporting information. In addition, the Fish Consumption Advisory Brochure tailored to the American Indian community will provide additional information on mercury exposures. Minnesota does not have a Heavy Metals Surveillance or Registry Program, Therefore, the state and the tribe have developed a detailed plan to disseminate sound information to the respondent.	Attachment 10a. Templated Results Letters based on need for rapid reporting of alert values or final reports of normal values. A project brochure is provided as supporting information. Michigan has an established Heavy Metals Surveillance Program; therefore, the MDCH has an established reporting system and follow-up criteria to take the proper public health actions for the respondent.	Attachment 10c. Templated Results Letters based on need for rapid reporting of alert values or final reports of normal values. New York has an established Heavy Metals Registry Program; therefore, the NYSDOH has an established reporting system and follow-up criteria to take the proper public health actions for the respondent.	