Supporting Statement
For OMB Review and Approval of

Agency for Toxic Substances and Disease Registry (ATSDR)
Biomonitoring of Great Lakes Populations Program

SECTION A. Justification

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A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

This is a new Information Collection Request (ICR) for the *Agency for Toxic Substances and Disease Registry (ATSDR) Biomonitoring of Great Lakes Populations Program* (CDC-RFA-TS10-1001). The program requests Office of Management and Budget (OMB) approval for two years to complete information collection.

Background

In 2009, President Obama's Administration announced the Great Lakes Restoration Initiative (GLRI) to protect, restore and maintain the Great Lakes ecosystem. A task force of federal agencies developed milestones and outcome measures to make the five-year GLRI Action Plan (http://greatlakesrestoration.us/pdfs/glri_actionplan.pdf) a national success. The GLRI Action Plan articulates the most significant regional ecosystem problems and the coordinated efforts to address them (GLRI Task Force, 2010). In conjunction with the White House Council on Environmental Quality and 15 other federal agencies, the U.S. Environmental Protection Agency (US EPA) was tasked with implementing the GLRI's billion dollar package of programs that aims to restore the Great Lakes ecosystems.

The Great Lakes - Superior, Michigan, Huron, Erie and Ontario - are an important part of North American environmental, cultural, and economic heritages. The Great Lakes Basin is a complex ecosystem containing over 20 percent of the world's surface freshwater and drinking water supplies for over 40 million people. Outflows from the Great Lakes are less than 1 percent per year, an extremely small part of the total volume of water. Thus, the region is sensitive to the impacts of a wide range of chemical contaminants from many sources: agricultural chemicals, urban waste, industrial discharges, leachate from disposal sites, and direct atmospheric deposition from dust and precipitation.

As part of the GLRI Action Plan, the *Department of the Interior, Environment, and Related Agencies Appropriations Act of 2010* (Public Law 111-88; Attachment 1a), committed federal efforts to make the restoration of the Great Lakes a national priority. The ATSDR-GLRI program development began with external consultations in 2009 with the US EPA Great Lakes National Program Office (GLNPO), with state health departments, and with scientists at various workshops, fora, and conferences (further described in Section A.4). Working directly with the US EPA under an Interagency Agreement, the ATSDR announced a funding opportunity under the *2010 Biomonitoring of Great Lakes Populations Program.* The ATSDR is authorized to conduct this program under the *Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA)*, as amended by the *Superfund Amendments and Reauthorization Act of 1986 (SARA)* (Attachment 1b).

The ATSDR biomonitoring program objectives are linked to the GLRI Action Plan focus area, "Toxic Substances and Areas of Concern (AOCs)." As the sole public health entity among the 16

GLRI Task Force agencies, this program also addresses the "Healthy People 2010" focus area related to Environmental Health Objective 8-25, "Reduce exposure of the population to pesticides, heavy metals, and other toxic chemicals, as measured by blood and urine concentrations of the substances or their metabolites." Measurable program outcomes are aligned with the following ATSDR performance goals: 1) Prevent ongoing and future exposures and resultant health effects from hazardous waste sites and releases; and 2) build and enhance effective partnerships. This program aims to provide a human exposure assessment among targeted subpopulations that will be concurrent with the onset of restoration activities. The program period ends on 29 September 2013.

The *ATSDR Great Lakes Biomonitoring Program* awarded funds to three state health departments to conduct this information collection (IC) under cooperative agreement (Attachment 3a). They are: 1) the *Michigan Department of Community Health* (MDCH - #1 U61TS000138); 2) the *Minnesota Department of Health* (MDH - #1 U61TS000137); and 3) the *New York State Department of Health* (NYSDOH - #1 U61TS000139).

Over time, contaminants that enter the lakes have become more concentrated in biota and sediments. Consequently, top predators such as lake trout and fish-eating birds can have very high exposures to these contaminants. Since humans are at the top of many food chains, the potential for human exposure to these contaminants is greater from consumption of contaminated fish and wildlife than from drinking water. Previously, the ATSDR identified several human subpopulations at risk of the harmful effects of exposure to Great Lakes contaminants (http://www.atsdr.cdc.gov/grtlakes/vulnerable-populations.html#1). These susceptible subpopulations include: pregnant or nursing females; fetuses, nursing infants, and children; racial or ethnic groups with traditional fishing and fish consumption customs; sport anglers; older adults; urban poor; and people with lower immune system function.

Forty-three U.S.-Canadian Great Lakes AOCs were listed in 1987 Great Lakes Water Quality Agreement (GLWQ) as sufficiently environmentally degraded or "impaired" to negatively impact aquatic life in these ecosystems and their beneficial uses. There are currently 30 U.S. AOCs. Their primary remediation goals are to achieve "delisted" status (US EPA, 2011).

Past ATSDR-funded Great Lakes programs have addressed separate and varied subject areas such as toxicology, animal research, and human biomonitoring. This current effort aims to create a framework to address site-specific human exposure assessment. In response to the current ATSDR program requirements to target susceptible subpopulations (http://www.grants.gov/search/search.do?mode=VIEW&oppId=54721), the three state health departments propose to enroll four distinct subpopulations,18 years of age and older, residing in seven AOCs over the two-year information collection period. The selected AOCs are geographically dispersed among four of the five Great Lakes (Attachment 3a – Map and description). The selection of AOCs and subpopulations was driven by the states' own public health practice authorities and needs for their own baseline information. The rationale for the states' selections of AOCs and subpopulations is further discussed in Section A.4.

Table 1. Study Subpopulations and Areas of Concern

State	AOC	Target Subpopulation	N
Michigan	Saginaw River/Bay	Shoreline Anglers [A] in Lake Huron Basin	200
	Detroit River	Shoreline Anglers [A] in Lake Erie Basin	200
Minnesota	Saint Louis River	American Indian Community [B] in Lake Superior Basin	500
New York	Buffalo River	Immigrant Community from Burma [C] in Buffalo, NY	100
	Niagara River Eighteenmile Creek	Licensed Anglers [A] in Erie and Niagara Counties	250
	Rochester Embayment	Licensed Anglers [A] in Monroe County	150

[A] Angling is a principal method of sport fishing by means of an "angle" or a fish hook. [B] Enrollees of the Fond du Lac Band of the Lake Superior Chippewa, their children and grandchildren, and enrollees of other federally recognized tribes.
[C] Immigrant Community from Burma is defined as refugees and immigrants from Burma (or Myanmar) and their descendants. These claim ancestry from majority and minority indigenous ethnic groups like Burman, Shan, Karen, Rohingya, Arakanese (Rakhine), Kachin, Chin, Mon, and other smaller groups (http://www.state.gov/r/pa/ei/bgn/35910.htm#people).

The studies from these three states are not research and the biomonitoring results will not be generalized beyond the selected AOCs and the defined subpopulations under study. The nonresearch determination by the program and by each state is further discussed in Section A.10 (see Privacy Impact Assessment Information Paragraph C).

As a nonresearch program, the ATSDR is not planning to “pool” the data to generalize the biomonitoring results to the overall Great Lakes population. Instead, the states will report deidentified data back to the ATSDR so that trends in human exposures to Great Lakes contaminants can be examined across these distinct subpopulations within distinct AOCs (further described in Section A.2).

The 60-day Federal Register Notice was published on November 4, 2011 (Attachment 2) and is further discussed in Section A.8.

Attachment 3 provides a Program Overview, including maps and general site descriptions (Attachment 3a). A data collection flow chart comparing the three states (Attachment 3b) is provided as an index to locate narrative on the following topics and procedures:

- Subpopulation and AOC Description
- Outreach, Sampling, and Recruitment
- Response Rates
- Enrollment, Interview, Clinical Assessment, and Specimen Collection
- Tokens of Appreciation
- Laboratory Procedures
- Individual Results Reporting and Communications

Privacy Impact Assessment

The following sections provide a program overview of the data collection system, the information to be collected, and a discussion on whether this IC will host a website.

Overview of the Data Collection System

The *ATSDR Biomonitoring of Great Lakes Program* IC will be conducted by interview, and blood and urine specimens will be collected for analytical measurements of specific contaminants. The IC will be implemented in five phases for all state health departments: sampling; eligibility screening; recruitment; enrollment and informed consent; and personal interviews.

During the interviews, structured questionnaires will be administered. The ATSDR worked with the three state health departments, to abstract structured OMB-approved questions from the CDC's National Health and Nutrition Examination Survey (NHANES – OCN 0920-0237, exp. date 11/30/2012), the Behavioral Risk Factors Surveillance System (BRFSS, under the *Monitoring and Reporting System for Chronic Disease Prevention and Control Programs* – OCN 0920-0870, exp. date 11/30/2013), and the National Center for Environmental Health (NCEH)/ATSDR Exposure Investigations (EI) (OCN 0923-0040, exp. date 11/30/2012).

The ATSDR worked extensively with the three states to develop a core set of questionnaire domains. The core questionnaire domains include demographic information, residential history, housing characteristics, job history, lifestyle factors, dietary intake, recreational activities, smoking history, fish consumption patterns with a focus on fish species and locally caught fish, and reproductive history in women.

The biomonitoring questionnaires for each state program were tailored to fit local concerns and designed to assist in the interpretation of analyte levels, and are deemed important to evaluate the body burden levels of the required and optional contaminants in each target population. Because of the differences in target populations, the language used to construct the questions in each specific questionnaire domain are not worded exactly the same across all three state programs. However, the specific language used for each questions will allow us to capture a core set of information. The most notable differences within each questionnaire domain are those questions that address certain cultural aspects of the American Indian population in Minnesota and the Burmese immigrant population in New York. These questions were designed to address cultural sensitivities and differences in lifestyle factors, fish consumption patterns, recreational activities, and so forth.

For example, exposures to perfluorinated compounds (PFCs) are a special concern in the state of Minnesota; therefore, items are asked about carpeting and stain-resistant materials. American Indians may traditionally consume wild animals that are themselves top predators and fish consumers such as bears. These special items are further explained in relation to their intended uses to inform the biomonitoring program, or for those that will be gathered as a benefit to the tribal community. Some questions serve dual purposes, such as the consumption of locally caught fish that may be sources of contaminant or nutrient (selenium) uptake from lakes, rivers, and sediments. Tribal elders also advised that questions on fish consumption be framed in the context of traditional methods of catch and seasons throughout the year (see cover sheet of Attachment 5e - MN Study Participant Questionnaire). Some traditionally foraged wild plants were included at the request of the FDL Natural Resources Department; it is unknown at this time if they may contribute to nutrient uptake (e.g. naturally occurring selenium) from the soil.

For New York, the questionnaire for the Burmese was tailored in very different ways compared to the licensed anglers. For instance, NYSDOH anticipates, based on advice from their resettlement agencies, a very different pattern of fish consumption or family structure. Also, understanding ways to estimate income for the Burmese was couched in terms of government food stamps or WIC programs (see Attachment 6j – Cover Sheet Burmese Questionnaire).

Each state health department will use a combination of IC modes. Each line in the annualized burden table in Section A.12 reflects each of the states' data collection forms, which are outlined below.

Michigan:

- Population: Shoreline anglers, defined as urban Michigan residents who fish along shoreline venues on the Detroit River and the Saginaw River and Bay. An index of the IC forms and a diagram of the data collection process are found on the cover page of Attachment 4.

- Sampling frame: Formative research for the primary enumeration of urban anglers at each fishing venue was completed in Spring and Summer of 2011. Primary enumeration provided visual estimates of the density of shoreline anglers on certain days of the week and at specific times of the day at identified fishing venues. No respondent burden was imposed at this stage.

- Eligibility screening: When data collection commences, the sampling frame will be constructed in a secondary enumeration of eligible and willing shoreline anglers at selected venues. The enumeration list will be constructed from paper-and-pencil personal interviews using the Screening Questionnaire (Attachment 4a).
- Recruitment: From the secondary enumeration list, a random sample will be selected screened for exclusions, and be scheduled for enrollment in the study. Trained study staff will collect this information using the scripted Telephone Questions for Scheduling Appointments in the form of a computer-assisted telephone interview (CATI) (Attachment 4b).
- Enrollment: Informed consent will be documented on a paper-and-pencil form (Attachment 4c). Each enrolled respondent will be asked to verify or update their contact information on the Contact Information Sheet (Attachment 4d).
- Interview: The Biomonitoring Questionnaire will be administered by a computer-assisted personal interview (CAPI) to ascertain the respondent's questionnaire responses (Attachment 4e). Blood and urine collection and clinical measures will also be completed at this time.

Minnesota:

- Population: American Indians, including enrolled members of the Fond du Lac (FDL) Band and their descendants, and enrolled members of other federally-recognized tribes, who live in the vicinity of the St. Louis River AOC and Lake Superior. These American Indians are all English speakers; translation services will not be required for study

materials and questionnaires. An index of the IC forms and a diagram of the data collection process are found on the cover page of Attachment 5.

- Sampling frame: The MDH and the Fond du Lac (FDL) Band of Lake Superior Chippewa (also known as Ojibwe) have established a formal relationship via Tribal Resolution (No. 1008/11) to jointly conduct this study. In agreement with the tribe, a list of American Indian recipients of medical and social services will be provided by the FDL Human Services Division (HSD) as a sampling frame (called the Client List). No respondent burden will be imposed at this stage.
- Eligibility screening and recruitment: For efficiency, eligibility screening, recruitment, and appointment scheduling will be administered simultaneously by CATI using the Recruitment Calling Script. Each sampled person will be asked questions to determine his or her eligibility. Next, recruitment and scheduling will take place and the responses recorded (Attachment 5a). For eligible persons who decline to participate, the Refusal Questions Form will be administered as an aid for nonresponse analysis (Attachment 5b).
- Enrollment: An Informed Consent Brochure will be provided to explain the study to the respondent. Written informed consent will be documented on the Individual Consent Form. Both the brochure and the form are provided in Attachment 5c.
- Interview: The Contact Information Form will be administered by paper-and-pencil personal interview (Attachment 5d). The Study Participant Questionnaire will be administered by CAPI (Attachment 5e). Completion of blood and urine collection and clinical body measures will be recorded on the paper-and-pencil Clinic Visit Form. This form will also be used to record responses to two questions on past year weight loss or gain (Attachment 5f). The paper-and-pencil Participation Record will be used to show receipt of a token of thanks in the form of a gift card for participating in the study (Attachment 5g).

New York: NYSDOH will study two different subpopulations. Licensed anglers will be provided materials, instructions, and interviews in English and Spanish. Spanish language translation services will be obtained after OMB approval of the English language documents and forms. Respondent immigrants and refugees from Burma and their descendants are largely unable to read written materials in their native dialects; therefore, study materials will be formatted in English. Interpreters and verbal translation services from English to ethnic dialect will be used to assure that the intent of the questions are properly conveyed and the translation of the responses from native dialect to English are accurately recorded on the IC forms. An index of the IC forms and diagrams of the two separate data collections are found on the cover page of Attachment 6.

- Licensed Anglers:
    - Population: Licensed anglers who reside in the western New York Counties of Erie, Niagara, and Monroe.
    - Sampling frame: A list of licensed anglers will be abstracted from the New York State Fishing License Database which will be provided by the New York State Department of Environmental Conservation. No respondent burden will be imposed at this stage.

- Eligibility screening: Upon receiving study recruitment materials and instructions in the mail (Eligibility Screening Packet) (Attachment 6a), licensed anglers will be asked to notify NYSDOH of their eligibility by one of two options:
    - Return mail paper-and-pencil Eligibility Screening Survey (Attachment 6b).
    - Online Eligibility Screening Survey (Attachment 6c).
- Recruitment:
    - If a timely response is not received by the above two modes, the following will be done to increase response rates. For sampled persons with working telephone numbers from the license database, trained study staff will follow-up with a CATI, the Telephone Script for Non-responders to Screening, to complete determination of eligibility, to determine interest in participation, and to schedule an appointment for interview (Attachment 6d).
    - If a timely voluntary response is received by either of the above two modes, trained study staff will follow-up only with eligible licensed anglers using another CATI, the Telephone Script for Eligible Responders to Screening, to determine interest in participation and to schedule an appointment for interview (Attachment 6e).
- Enrollment: Informed consent will be documented on a paper-and-pencil form (Attachment 6f).
- Interview: Responses to the Interview Questionnaire for the licensed anglers will be collected by CAPI (Attachment 6g). During this interview, blood and urine specimens and body measures will be collected.

- Immigrant Community from Burma:
    - Population: Immigrants and refugees from Burma and their descendants who live in the City of Buffalo and who eat fish caught in the targeted New York AOCs.
    - Sampling frame, eligibility screening, and recruitment: Respondent driven sampling (RDS) will be used. An alternative sampling strategy such as RDS is suitable for reaching hidden populations for which there is no known sampling frame (Salganik & Heckathorn, 2004; Johnston & Sabin, 2010; Sabin, 2011). Therefore, sampling, screening, and recruitment will occur simultaneously. Organizations with ties to this community, such as the Jericho Road Ministries (http://www.jrm-buffalo.org/) and the Buffalo Niagara Riverkeepers (http://bnriverkeeper.org/), will help identify two to five initial recruits (referred to as “seeds”) who are socially well-connected, respected in the community, and interested in participating. All RDS-identified community members will respond to the Eligibility Screening Survey by paper-and-pencil personal interview (Attachment 6h).
    - Enrollment: Informed consent will be documented on a paper-and-pencil form (Attachment 6i).
    - Interview: Responses to the Interview Questionnaire for the Burmese will be collected by CAPI (Attachment 6j). During this interview blood and urine specimens and body measures will be collected.

- After the interview, up to three additional respondents will be referred by current respondents who volunteer to identify and recruit from within their community network. Enrolled respondents will answer Network Size Questions for RDS by paper-and-pencil personal interview (Attachment 6k).

Items of Information to be Collected

The IC will acquire information in identifiable form (IIF) permitting sampling, screening, recruitment, and results reporting to respondents. The categories of directly identifiable information to be collected include: names, date of birth, street address, mailing address, phone numbers, email addresses, and biological specimens. At this point, the IIF will be stored and managed in Michigan's and New York's already established record systems by their authorized and trained staff and contractors. In Minnesota, all IIF will be stored and managed in the FDL-HSD's already established record system as part of its contract with the MDH. MDH will not receive any IIF under this IC.

- MDCH has contracted with the Wayne State University (WSU) Department of Medical Anthropology to conduct venue-based sampling in the target study locations. WSU will collect that information so that MDCH can re-contact participants after random selection so that they can confirm their participation and schedule them into a clinic. WSU will collect the information on hard copy secondary enumeration forms and deliver such forms to MDCH for entry into an electronic database. MDCH will contract with Michigan State University (MSU) Department of Epidemiology to provide support for project activities such as study design, sample collection, data analysis, and interpretation.

- MDH will contract with the FDL-HSD to recruit and enroll participants from their Client List, schedule appointments, administer questionnaires, handle specimens, and manage study records and documentation. Trained FDL-HSD clinic staff and interviewers will also collect blood and urine specimens, blood pressure, body dimension measures. The FDL public health nursing staff will be listed as the study contacts who will provide clinical advice on the biomonitoring results and on ways to reduce exposures. If required, appropriate environmental or clinical interventions will be recommended on a case-by-case basis. A physician will be consulted for advice on medical follow-up when necessary. The FDL-HSD will deliver deidentified records to the MDH, which will in turn, deliver these records to the ATSDR at the end of the study.

- NYSDOH will contract with resettlement agencies and community organizations to hire trained interpreters for the interview process, and to help find "seeds" in the Immigrant Community from Burma. They will also hire and train temporary staff to call non-responding licensed anglers and as follow-up to respondents, as needed. Other than these circumstances, the majority of the data collection will be done in-house with plans to hire a full time interviewer and data analyst.

- All three states will include a core set of chemicals be analyzed in blood and urine specimens. Optional state-specific chemical analytes of local concern will also be measured. The laboratory analyses for the three state programs will be provided by a combination of in-house and contracted state laboratories, the Centers for Disease Control and Prevention (CDC) Environmental Health Laboratory, and commercial laboratories (Attachment 7 – Program Laboratory Policies and Procedures). Blood and urine specimens will be labeled by study ID number only. Laboratory personnel will not see or have access to any records with IIF.
    - Some of the core analytes will be analyzed by contracted arrangements as indicated in Attachment 7a (Table 1-4).
    - QA/QC and interlaboratory proficiency testing will be implemented in accordance with the program's laboratory procedures policy (Attachment 7b).
    - All state laboratories are approved by the Clinical Laboratories Improvement Amendments of 1988 (CLIA). The state laboratories' current CLIA certificates are appended to Attachment 7c.
    - All state laboratories participate in the Arctic Monitoring and Assessment Program (AMAP). AMAP designed and implemented a coordinated external proficiency testing and monitoring program to monitor levels of pollutants and assess the effects of pollution in all compartments of the Arctic environment (atmospheric, terrestrial, freshwater and marine environments, and human populations). Interested parties may contact the states to obtain information on current AMAP external proficiency test reports and pertinent laboratory standard operating procedures (SOPs) (Attachment 7d).

A secondary purpose of this IC is to obtain demographic factors and lifestyle information that potentially contribute to a higher likelihood of exposures including: ethnicity and race or tribal affiliation, age, sex, education and income level, dietary patterns, hobbies, occupations and employment status, residential history, and household exposures (Attachments 4e, 5e, & 6g, & 6j). Some items purely of local interest are collected as a benefit to the community and for the individual respondent. These response items will not be delivered to ATSDR. State-specific examples include laboratory measures of hemoglobin A1C, a diabetes indicator, for the Minnesota American Indians. Two questionnaire items that are of interest to Minnesota include wild food items (see Attachment 5e: Question I2. Wild fruits or berries, and Question I3. Other edible plants or wild foods such as maple syrup, hazelnuts, wild asparagus, wild mushrooms, fiddle heads). For the New York immigrant community from Burma, NYDOH will ask in-depth household information to evaluate potential public health impact of sharing locally caught fish and associated outreach.

The ATSDR will not receive identifying information including name, address, residential history, and household demographics. The ATSDR will also not receive information that in 'raw' form may indirectly identify an individual. For example, occupation will be classified into one of 23 major groups according to the 2010 Standard Occupational Classification (SOC) system. Furthermore, data will be collapsed into groups for any cross-tabulation of data that results in a 'cell size' of 5 or less.

As soon as laboratory results become available to the state principal investigators (PIs), individual results reporting will begin. The analytical results will be examined and properly routed based on established threshold and alert values. Each state has developed individual results reporting form templates (Attachments 10a-c), so that the respondent's own biomonitoring results are disseminated as rapidly as possible. The established procedures for results reporting and communication are further described in Section A.2.

At the end of the data collection, the state health departments will deliver deidentified data to ATSDR, through a secure and encrypted file transfer protocol further described in Section A.10. Information Flow Charts are provided on the cover sheets of Attachments 4-6 to indicate the steps and modes by which IIF are collected and the point at which deidentified records are delivered to ATSDR. Results reporting by each state and ATSDR's uses of the data are further discussed in Section A.2.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

No federal websites will be developed to collect information for the *ATSDR Biomonitoring of Great Lakes Populations Program*. Likewise, the MDCH and the MDH will not collect any study information by website.

Based on prior experience, the NYSDOH will provide prospective respondents the option to submit responses for screening eligibility by one of two modes: 1) a paper-based screening questionnaire with a return mail envelope (Attachment 6b); or 2) a web-based survey with access by an assigned unique identifier per respondent using Zoomerang™ Online Survey Software (Attachment 6c). The NYSDOH has a premium subscription to Zoomerang™ that offers SSL encryption, storage of IIF in secure password protected databases as well as database and network firewalls to prevent the loss, misuse or alteration of personal or survey information. In addition to collecting actively submitted survey data, the software uses tracking cookies to passively collect information in connection with future visits from that web site, to recognize previous visitors, and to track user activity at their site. The Zoomerang™ privacy policy and terms of use may be viewed at http://www.markettools.com/company/privacy-policy and http://www.zoomerang.com/Terms-of-Use/, respectively. Access to the Zoomerang™ account and the data are password protected and limited to trained study staff in the NYSDOH Bureau of Environmental and Occupational Epidemiology.

No websites or website information will be directed at children under 13 years of age. Participants from all three states will be at least 18 years of age.

A.2. Purpose and Use of Information Collection

The ATSDR Great Lakes Biomonitoring Program is an applied public health program that focuses on vulnerable or susceptible subpopulations with the potential for increased risk of exposure to persistent contaminants common to the Great Lakes watersheds and ecosystems. This surveillance project is designed to learn about levels of contaminants that can be detected in

blood and urine of residents who consume fish, wildlife or locally grown food from contaminated areas. This surveillance project is not investigating health outcomes or biological effects from such exposures. Project findings will be used to inform policy regarding reducing Great Lakes contaminants and exposures to contaminants.

The ATSDR and its state cooperative agreement partners will collect this data only on a one-time basis. Under state codes, these health departments and associated environmental programs are responsible for addressing the public health concerns in their respective states and for issuing fish consumption advisories for their own waterbodies. Each state will use its own information to determine if select subpopulations living in specific AOCs have elevated exposures to Great Lakes contaminants. Without this baseline information, responsible state and tribal health officials will not have the necessary tools and information to protect the people in their jurisdictions. Specifically, they will not be able to determine if and which Great Lakes contaminants are bioaccumulating above background levels in these select susceptible subpopulations. This information is necessary to guide public health practice throughout the restoration process and into the future.

This IC also represents the first time that the body burdens of a large panel of Great Lakes contaminants will be determined among lower income, urban, racial, ethnic, and tribal subpopulations with subsistence or traditional fishing customs and cultural fish diets. The state health departments will be able to work with their community partners to create culturally relevant educational and advisory messages on the risks and benefits of fish consumption diets and chemical exposures. Therefore, this program will have direct utility in targeted outreach, education, and protection of potentially susceptible subpopulations that would otherwise be missed in general population biomonitoring studies.

The results of this IC are aimed to inform the restoration process for specific subpopulations; therefore, the results from this nonresearch program are not intended to be generalizable beyond the target subpopulations living in the seven AOCs.

Privacy Impact Assessment Information

Why this information is being collected. As a 2010 federal appropriation under Public Law 111-88, this effort is a national priority. This information is being collected to provide a baseline assessment of the chemical exposures of susceptible Great Lakes Basin subpopulations as part of the FY10-FY14 GLRI Action Plan (http://greatlakesrestoration.us/pdfs/glri_actionplan.pdf) and for future restoration activities.

The GLRI Action Plan continues the legacy of the historic U.S.-Canadian International Joint Commission (IJC), established by the 1909 Boundary Waters Treaty to develop lakewide management plans. As such, the IJC committed to active ecosystem management under the 1978 Great Lakes Water Quality Agreement (GLWQA), and as amended in 1987. Under the GLWQA, a working list of criteria pollutants was established (http://www.ijc.org/rel/agree/quality.html). From this IJC list and for this GLRI activity, the ATSDR selected persistent toxic substances that were most feasible for biomonitoring (costs, established analytical methods, and human burden).

Thus, the ATSDR program has required a core set of Great Lakes legacy contaminants for biomonitoring [polychlorinated biphenyls (PCB congeners 28, 52, 101, 105, 118, 138, 153, 180); mercury; lead; mirex; hexachlorobenzene; dichlorodiphenyltrichloroethane (DDT); dichlorodiphenyldichloroethylene (DDE)] (http://www.grants.gov/search/announce.do;jsessionid=5rz9PZyQnjVT3bTthcl1xwRn6Q2NcvNnFplSSVKspT1ltfMM2lpR!687519751) (Attachment 7 – Program Laboratory Policies and Procedures).

In addition to the well-known toxicants like mercury, PCBs, and banned pesticides, there are chemicals of emerging concern that have been detected in the Great Lakes over the past several years, which may pose threats to the ecosystem. Therefore, each state has selected optional analytes, from among chemicals of local concern to test for among its target subpopulation (Attachment 7a – Tables 1-4 and the Chemical Analytes Justification). The states currently lack this information necessary to inform jurisdiction-specific public health actions and environmental protections.

Communicating individual biomonitoring results. Each state developed materials and methods to provide the respondent with his or her own biomonitoring results (MDCH - Attachment 10a; MDH – Attachment 10b; NYSDOH – Attachment 10c). They were advised to follow state guidelines for reporting requirements and action levels, where applicable. An overview of the state-required and provisional action levels are provided in Attachment 10 (Table 1 - Respondent Results Reporting Overview).

For each state, Attachment 10 Table 1 provides:

1. Indicators for analytes of clinical relevancy (i.e. of known health consequence with associated action levels or interpretation), such as for toxic or heavy metals, nutrients, and blood pressure;
2. Laboratory analytes measured in biological matrices;
3. Individual biomonitoring results to be reported or not reported to the respondent;
    a. In Minnesota, the MDH and the FDL will report all biomonitoring results back to their respondents, whether of known health consequence or not.
        i. For the American Indian community, transparency in all study methods and procedures was deemed important to establish effective state-to-tribal community and government-to-government relationships. Therefore, all results will be reported to the respondent.
        ii. In addition, the FDL Human Services Division views this study as an important opportunity to obtain clinically useful and representative community prevalence estimates for chronic health conditions that disproportionately affect American Indians. These will include cardiovascular disease risk measures and diabetes. Therefore, as a benefit to the community and for the individual respondent, the MDH-FDL will provide reports on clinical assessments such as obesity measures, blood pressure, and hemoglobin A1C results (Attachment 10b1 – Clinical Reults Letter). These additional benefits for the data collection are described in the Informed Consent Brochure and the Informed Consent Form

(Attachment 5c). Obesity measures, such as body mass index (BMI) will serve a dual role as important predictors of body burdens of lipophilic Great Lakes contaminants such as PCBs and pesticides.

b. In Michigan and in New York, the individual analyte results to be reported are those generated from CLIA-approved laboratory methods (Table 1). For example, NYSDOH is not CLIA-approved for PBDEs, PFCs, and toxaphene; these results will not be included in Attachment 10c1. The methods used to analyze the required analytes are all CLIA-approved methods; the required analyte results will be reported back to individual respondents (Table 1).

4. Where available, national reference values, such as those from the *Fourth National Report on Human Exposure to Environmental Chemicals 2009*, the corresponding *Updated Tables, February 2011* (See http://www.cdc.gov/exposurereport/), or the *Second National Report on Biochemical Indicators of Diet and Nutrition in the U.S. Population 2012* (See http://www.cdc.gov/nutritionreport/pdf/Nutrition_Book_complete508_final.pdf#zoom=100) will be used to make comparisons to the U.S. general population.
    a. Table 1 delineates those analytes with NHANES reference values, and the year of collection.
    b. Where those data are lacking, or where established clinical guidelines are available, Table 1 provides alternative published sources of reference values.
    c. For some chemicals, no NHANES reference range values are available. Nevertheless, for MDH, objective measures of some of these analytes (e.g. fatty acids, selenium, toxaphene) will serve as additional biomarkers of fish consumption. These measures will be compared to self-reported dietary fish intake assessed by questionnaire. Other chemicals, such as cotinine from smoking, are expected to act as effect modifiers of body burdens of many of the Great Lakes contaminants. Obtaining these additional analytes will help MDH determine whether body burdens of Great Lakes contaminants may be attributed to diet, smoking, or other lifestyle choices, in addition to the environment.
5. Rapid toxic metals reporting (See Attachment 10. Table 1 for action levels).
    a. The Michigan Public Health Code (PA 368 of 1978) requires clinical laboratory reporting of all test results for arsenic, cadmium, and mercury in blood and urine, and all blood lead test results. The MDCH PI will utilize these established reporting mechanisms and action levels to identify, interview, and establish proper clinical and exposure interventions. Attachment 10a lists established MDCH action levels for its Heavy Metals Surveillance Program (http://www.michigan.gov/mdch/0,1607,7-132-2945_5105-127047--,00.html). Attachment 10a2. provides rapid respondent feedback in the event of action level exceedences for heavy metals.
    b. The State of Minnesota has no statewide heavy metals surveillance program. For this biomonitoring study, the MDH has developed a detailed two-tiered threshold system of rapid results reporting for mercury, lead, and cadmium in blood (Attachment 10b2a). These levels are both above the 95th percentile concentrations for adults in NHANES, so they are not expected to occur frequently.

If a respondent's result is above the lower Tier 1 level, he or she will be notified rapidly by mail, within 3 weeks after results are received from the laboratory (Attachment 10b2b1-5). The goal is to help the respondent identify potential sources and ways to reduce exposures. The public health nurse consultant's name and contact information will be provided along with a mercury, lead, or cadmium factsheet (Attachment 10b2c-e). An additional MDH-FDL fish consumption advice brochure will accompany the mercury letter (Attachment 10b2f).

If a respondent's result is above the higher Tier 2 level, he or she will be notified rapidly by mail, in the same manner as the Tier 1 notification. In Tier 2 cases, the respondent will receive a follow-up call from the public health nurse consultant. The appropriate interventions to recommend during the phone call will be determined on a case-by-case basis. A medical consultant will be contacted for advice when necessary.

c. The New York State Department of Health (NYSDOH) Heavy Metals Registry (HMR) is a tool for the surveillance of adult exposures to lead, mercury, cadmium and arsenic. The HMR was established in 1980 under the State Sanitary Code (10 NYCRR) and authorized by Public Health Law. Reporting to the HMR began in 1982. The NYSDOH receives reports of all blood lead tests performed on New York State residents, along with reportable levels of mercury, arsenic and cadmium. Once reports are received, registry staff conduct interviews to determine the source of exposure, for those heavy metal levels exceeding certain thresholds, which vary by metal and gender. When the threshold is exceeded, information is provided to exposed individuals and employers on reducing hazards and eliminating exposure. Where it appears that family members may be exposed, recommendations are made for reducing exposure and the local health department is contacted, if applicable (http://www.health.ny.gov/environmental/workplace/heavy_metals_registry/). Attachment 10c2. provides a metals report template that can be used in the event an action level is exceeded for heavy metals.

Intended use of the information. At the federal level, the ATSDR biomonitoring results will have direct utility in providing parallel human chemical exposure information to complement GLRI environmental monitoring of legacy and emerging contaminants in biota, sediments, and water quality. The Action Plan will target and remediate contaminated sediments and address other major pollution sources in order to restore and "delist" the most polluted sites in the Great Lakes Basin (GLRI, 2010). Under its relevant focus area, "Toxic Substances and Areas of Concern," findings about human exposures from the *ATSDR Biomonitoring of Great Lakes Populations Program* will likewise inform federal, state, and tribal policies and programs responsible for controlling and reducing environmental pollution in the selected AOCs and Great Lakes Basins.

Some GLRI priorities cut across focus areas. Under the "Nearshore Health and Nonpoint Source Pollution" focus area, the GLRI Task Force will geographically target activities, such that federal, state and other stakeholders can leverage efforts to restore areas that are highly degraded and of high ecological importance. Geographic targeting across the focus areas will take place at the Genesee River (Rochester, NY), St. Louis River (Duluth, MN), and Saginaw River (Saginaw,

MI) watersheds where environmental problems and their solutions have been clearly identified (GLRI, 2010). Biomonitoring among target subpopulations living in AOCs in these watershed areas are included in the ATSDR program.

At the local level, determining which Great Lakes contaminants are entering human populations above background levels will also inform state and tribal health officials and their public health actions and advisories throughout the restoration process. The results of this IC will help determine if prevention of ongoing or future human exposures is necessary for the specific subpopulations within each state's jurisdiction.

These efforts aim to ensure statistically valid sampling strategies and encourage harmonization of data collection and analyte quantification among the three state programs to the greatest extent possible The core program objective is to provide a current 'snap shot' of human exposure levels among susceptible subpopulations living in specific Great Lakes AOCs. Sampling strategies differ among the state programs in accordance with cost-effective, established methods to enumerate the state-specific targeted subpopulation(s). Some eligibility criteria (e.g., number of fish meals consumed and pregnancy) differ among programs based on regional, cultural, and behavioral differences in the specific subpopulations; and, in part due to the influence of pregnancy status in measuring dioxins and furans in the Michigan shoreline anglers. These differences mean that ATSDR will not be able to make direct statistical comparisons across the three state subpopulations and their subgroups. Within each AOC, to the extent that there are resources available in the future, it may be possible to design follow up studies that can help us understand whether body burdens of the contaminants of interest are changing in the subpopulations of interest. These data will provide a baseline assessment for tracking restoration progress in future decades.

It is not the ATSDR's intent to pool the data for analysis. The states will evaluate current body burdens to guide public health actions for each sub-population in their study. The ATSDR serves as the steward and coordinator of the program to ensure adherence to the goals and objectives of the GLRI and to ensure scientific integrity. The ATSDR has provided technical oversight to ensure scientifically valid sampling strategies, collection of a core set of precise analyte quantification (including laboratory SOPs and QA/QC protocols), and the collection of relevant questionnaire information on exposure pathways, demographics, and lifestyles.

At the completion of the state data collections, ATSDR requires that the programs provide data deliverables. ATSDR will serve as the central data repository. Federal programs are encouraged to make data collected with federal funds available to investigators to maximize the public health benefit. ATSDR understands the importance of maintaining individual confidentiality in sharing data. Prior to the transfer of data, ATSDR will establish a Data User Agreement with each state program in consultation with the National Center for Health Statistics (as an independent subject matter expert) to utilize rigorous de-identification/privacy standards.

Data deliverables. The states will collect and deliver information in the form of analyte measurements and questionnaire items in support of the overall program biomonitoring goals.

Therefore, as part of the Data User Agreement with each state, the ATSDR will require delivery of deidentified information related to the program biomonitoring goal.

Some health-related items will be collected to better understand exposure levels. Since lipophilic compounds such as required analytes like PCBs and pesticides are stored and released from fat tissue, measures of obesity serve as important information to evaluate chemical body burden levels. For example, height and weight will be used to calculate body mass index (BMI) by all three states. Minnesota will collect additional girth measures (e.g. waist circumference). Programs are also collecting information on reproductive history. Knowing the duration of breastfeeding based on parity is also important to help evaluate chemical body burden levels because lipophilic analytes are mobilized from fat and bone during breastfeeding. Cholesterol and triglycerides are part of the laboratory process to perform lipid adjustment of lipophilic compounds. The three health department programs will provide respondent feedback on BMI, blood pressure, and cholesterol as a public health service. Additionally, NYSDOH will report triglycerides and MDH will report waist circumference as a public health service. The ATSDR will not receive data on cholesterol, triglycerides and blood pressure.

As mentioned in Sction A.1, some items will be of purely local interest and are collected as a benefit to the community and for the individual respondent. These response items will not be delivered to ATSDR. State-specific examples include laboratory measures of hemoglobin A1C, a diabetes indicator, for the Minnesota American Indians. Two questionnaire items that are of interest to Minnesota include wild food items (see Attachment 5e: Question I2. Wild fruits or berries, and Question I3. Other edible plants or wild foods such as maple syrup, hazelnuts, wild asparagus, wild mushrooms, fiddle heads).

Collection of information in identifiable form. Of utmost importance, information in identifiable form (IIF) will not be part of the deliverables to ATSDR. Each state will gather the respondent's IIF in different ways due to the differences in sampling plans for each subpopulation. For example, the Minnesota American Indians and the New York licensed anglers will be sampled from existing lists that will be up to three years and one year old, respectively. For the immigrants from Burma, the nature of RDS will result in recruitment and informed consent taking place on-the-fly; therefore, reliance on a pre-existing database will not be required. The Michigan shoreline anglers will have no existing sampling frame. For Michigan, contact information will be gathered during the secondary enumeration in order to construct a sampling frame; therefore, this information will be obtained prior to informed consent out of necessity. For these four subpopulations, up-to-date contact information will be verified after informed consent is obtained so that results reports can be mailed to the respondents.

As previously described in Section A.1, IIF will be collected, managed, and stored by the MDCH and the NYSDOH in their already established record systems. The FDL-HSD will collect, manage, and store IIF on behalf of the MDH. The three states will use IIF for the purposes of sampling, screening, recruitment, and results reporting to respondents. There are no plans for the states or the tribe to share IIF with ATSDR.

Impact on privacy. Because the MDCH, NYSDOH, and the FDL-HSD on behalf of the MDH, will store, manage, and maintain IIF on their already established record systems, there would be

a likely effect on the respondent's privacy if a breach of data security occurred. Therefore, these established state and tribal record systems have stringent safeguards in place as described in Section A.10.

For ATSDR, deidentified information that might be considered sensitive, such as pregnancy status in the past year among female respondents, will not have associated information that might directly identify these respondents; therefore, after data delivery the proposed data collection will have little or no effect on the respondent's privacy.

A.3. Use of Improved Information Technology and Burden Reduction

For the program, an estimated 85 percent of the total burden hours for this IC will be collected by electronic reporting in the form of CATIs, CAPIs, or web-based surveys.

For both CATI and CAPI, trained interviewers will ask each question and will record responses using portable or desktop personal computers. Developers will program skip logic and editing functionality such as field restrictions and automatic validity checks to help ensure data quality and minimize missing data. The CATI and CAPI data collection method will also eliminate errors in the sequence of questions and accelerate the interview process. It will improve respondent reporting and reduce the number of data errors especially since responses to a large number of potential questions regarding food consumption will not apply to every respondent. Using the CATI and CAPI, the interview will be automatically tailored to each specific individual. Data security on laptops will include administrative, physical, and technical controls as described in Section A.10.

~~Electronic reporting will be used to collect all questionnaire data for this program.~~ Structured interviews will be conducted using CAPIs. During the interview, respondents will be asked questions about where they have lived, jobs that they have had, their smoking habits, outdoor activities, hobbies, the fish and other foods they eat, education, income, and the number of children that women have breastfed (Attachments 4e, 5e, 6g & 6j). The MDCH, ~~and~~ the NYSDOH, and ~~will use the Rapid Data Collector (RDC) CAPI development tool which is provided through the CDC Secure Data Network (SDN). The RDC provides the ability to rapidly collect data while in the field. A Form Design tool will allow states to design a data collection form which can be used via Windows application to collect questionnaire data. The data entry screens are dynamically generated via Visual Basic.Net (VB.Net) in a Windows application that can be disconnected from the Internet and taken into the field. When operating in a disconnected manner, data is stored locally using Extensible Markup Language (XML). Once the user returns to the office or has access to the CDC Local Area Network (LAN), all data collected is uploaded into a centralized data store in Structured Query Language (SQL) Server 2005 via Web Services. Data collected can be aggregated, reported and exported using a variety of formats including XML and Microsoft Excel. T~~the MDH will develop a Microsoft Access™ based CAPI survey instrument. The CAPI will be deployed on laptop computers to collect data in designated ~~the FDL-HSD~~ clinics.

Electronic reporting will also be used as part of the NYSDOH screening process to determine eligibility. A random sample of licensed anglers in the sampling frame will be mailed a screening survey. The respondent will have the ability to complete the screening survey using an online (electronic) screening questionnaire (Attachment 6c). The online form will be developed using Zoomerang© 2011 MarketTools, Inc. and will have the same format as the paper survey. It is anticipated that 60% of the respondents will choose to use the online screening questionnaire. Non-responders will be contacted via telephone and/or email as a way to maximize response rates. They will be offered the opportunity to complete the screening survey over the telephone, by mail, or online (Attachment 6c). For non-responders with an email address only, emails with the link to the online survey will be sent. It is anticipated that 60% of the non-responders to the initial mailing who subsequently agree will choose to complete the online screening questionnaire option. This method will be used to increase participation as a convenience for the respondent with internet access. Eligibility screenings for the Immigrant Community from Burma in New York and for the MDCH shoreline anglers will be paper instruments. The MDH will conduct its screenings by CATI in Microsoft Access™ (Attachments 5a & 5b) These screenings are estimated to pose no more than 5 minutes of response time for each participant.

Consent forms that collect the signature of participants will be paper instruments and a copy will be given to each respondent. Height, weight, and other applicable body measures will be recorded on a paper form since this station will be separate from the electronic interview. The nature and brevity of this information does not support investment in additional electronic equipment and programming costs for data collection.

A.4. Efforts to Identify Duplication and Use of Similar Information

The ATSDR efforts to identify duplication of the proposed IC included reviews of existing reports and publications, attendance at national meetings, and consultations with state and other agencies and community representatives. Specifically, ATSDR worked with the state health departments to identify whether the proposed IC is duplicated for 1) the proposed subpopulations; 2) the specific AOCs; and 3) for the proposed chemical contaminants. ATSDR has determined that no similar data currently exists.

Review of Institutional Reports and Published Literature

Michigan. The Great Lakes Fish Eater and the Great Lakes Charter Boat Captain Studies are the two largest chemical exposure studies of Michigan local-caught fish consumers. Today, nearly all participants from these studies are over 70 years old. These studies indicate that local-caught fish consumption over several years can result in two-to-fivefold elevations of PCB, p,p'-DDE, or dioxin-like compounds in body burdens of local caught fish eaters compared to the referent population. Participants in the previous studies were largely white and middle-income with a fish consumption pattern of eating the more common local-caught fish such as lake trout, salmon, walleye, and perch. Other than for lake trout, most species consumed by these participants tend to be less contaminated than other species (Anderson HA et al., 1996; Anderson HA et al., 1998; Anderson HA et al., 2008; Falk C et al., 1999; Fiore BJ et al., 1989; Hanrahan L et al., 1999; He et al., 2001; Knobeloch L et al., 2009; Persky V et al., 2001; Turyk M et al., 2006; Courval et al.,

1999; He JP et al., 2001; Tee PG et al., 2003; Hovinga ME et al., 1993; Humphrey HEB, 1988; Humphrey HEB & Budd ML, 1996; Humphrey HEB et al., 2000; Schantz SL et al., 1999; Schantz SL et al., 2001).

These previous study populations are not likely to represent the most vulnerable and highly exposed local-caught fish eating subpopulations. Lower-income or minority fish consumers eat more contaminated fish, such as catfish or bass, out of necessity, cultural preference, or a lack of awareness of fish advisories in the Saginaw River and Bay AOC and the Detroit River AOC (West et al. 1993; MDCH 2007; Kalkirtz et al. 2008). Therefore, the MDCH proposes to evaluate body burdens of persistent bioacumulative toxic substances in subpopulations of Michigan residents most at risk of exposure to contaminants in local-caught fish, that is, among shoreline anglers living in the Detroit River and Saginaw River and Bay AOCs who regularly consume local-caught fish. This IC represents the first time that the body burdens of these classes of Great Lakes contaminants will be determined among the Detroit and Saginaw shoreline anglers of Michigan. These anglers are from racial, ethnic, and lower income subpopulations that are not expressly represented in national surveys; therefore, baseline body burden estimates are not currently available.

Minnesota. In 1991, the ATSDR and the Indian Health Service (IHS) Bemidji Service Area Office conducted a methylmercury exposure study among the FDL Band of the Chippewa Tribe in northern Minnesota in relation to fish consumption patterns restricted to the summer months. Investigators found a positive association between blood mercury levels greater than or equal to 10 µg/l and consumption of bass, fish from one section of the St. Louis River, and more than one-half meal of fish per week. Consumption of commercial frozen fish relative to no consumption was protective (ATSDR, 1994). Because the methods of recruitment by sampling frame are similar to the current proposed IC among the FDL Band, the 1991 study suggests this proposed IC to be a feasible plan. Although the AOC and subpopulations are duplicated in this IC request, the greatly expanded list of proposed Great Lakes legacy and state-optional contaminants have not been previously assessed in this particular subpopulation of American Indians in northern Minnesota, blood mercury excepted. In addition, MDH will provide a more complete assessment of fish consumption patterns for all four seasons and by traditional methods of catch, thus addressing a limitation of the 1991 study. In an ecology study of 1982-2006 mercury concentrations in fish sampled from Minnesota lakes, mercury concentrations were on a downward trend before the mid-1990s but on an upward trend thereafter (Monson, 2009). The potential for a more recent increase in mercury concentrations in fish from Minnesota lakes is of particular relevance for the FDL Community who are traditional fish consumers.

The MDH and the FDL Band have partnered together in this effort through formal Tribal Resolution (No. 1008/11). Specifically, the intent of their study and its results are to evaluate "whether toxins and pollutants are present in the waters and fish of the St. Louis River Area of Concern," and "to inform and guide public health actions to reduce exposure to environmental contamination as the Great Lakes Restoration process develops." The results of this study will inform the tribe's public health mission to educate and encourage community members to select "healthy and traditionally important food choices, such as fish, to promote health and prevent chronic diseases."

New York. This proposed IC has two target subpopulations, both aged 18-69 years and who eat their catch: 1) licensed anglers who live in proximity to four AOCs in western New York; and 2) refugees and immigrants from Burma and their descendants who live in the City of Buffalo.

The 1992-1995 New York Angler Cohort Study characterized exposure to PCB congeners, DDE, hexachlorobenzene (HCB), and mirex in approximately 18,000 western New York state anglers from 18 counties, aged 18 to 40 years, who consumed Lake Ontario sport fish and waterfowl. Lipid-adjusted serum values for PCB congeners and mirex were significantly correlated with an index of fish consumption (Vena 1996, Bloom 2008). Although some of the legacy Great Lakes contaminants from the 1992-1995 study are being replicated, this proposed IC has included an expanded list of legacy (adding lead, mercury, DDT) and state-specific chemical analytes, which will contribute to new biomonitoring information in these subpopulations.

Three of the original 18 counties will be included in the current IC. The Buffalo River, Niagara River, and Eighteenmile Creek AOCs are in Erie and Niagara Counties and the Rochester Embayment AOC is in Monroe County. The catchment area for the licensed anglers will be the ZIP Codes within a 10-mile buffer of the AOCs. Although the proposed target subpopulations currently aged 35-60 years may have been previously studied in 1992-1995 as 18-40 year olds, this proposed IC will include younger anglers currently aged 18-34 years, for whom biomonitoring information does not exist. Although previously studied in 1992-1995, New York licensed anglers from Erie, Niagara, and Monroe Counties do not have up-to-date estimates of these chemical body burdens that coincide with the GLRI program period.

This will be the first time that the Immigrant Community from Burma will be included in biomonitoring efforts in the Great Lakes. Many local resettlement agencies in Buffalo, NY receive funding to work with these immigrants from the Office of Refugee Resettlement (http://www.acf.hhs.gov/programs/orr/) including Catholic Charities (http://www.ccwny.org/), International Institute of Buffalo (http://www.iibuff.org/), Journey's End of the Episcopal Church (http://www.jersbuffalo.org/), Jewish Family Services (http://www.jfsbuffalo.org/), and Jericho Road Ministries (also United Way funded) (http://www.jrm-buffalo.org/). These agencies provide many services to the refugees including employment, health, interpretation, family support groups, transportation, educational and legal consult. NYSDOH will work with such agencies to support outreach and study recruitment, and to maximize response rates.

Consultations

Since 2009 and in preparation for the program announcement, award, and administration of the cooperative agreements, ATSDR has had ongoing consultations with US EPA's GLNPO, state environmental public health officials, environmental health laboratory scientists, and other stakeholders to identify program needs and specifications for the *ATSDR Biomonitoring of Great Lakes Populations Program.*

Specific ATSDR efforts included attendance at a workshop on program needs and objectives for GLNPO senior staff and ATSDR program leads at US EPA headquarters in Chicago, IL

(September 2009); a stakeholder meeting at the 2009 National Forum on Contaminants in Fish, Portland, OR, with the GLNPO and state health departments (November 2009); and presentation of program plans and solicitation of feedback from leading Great Lakes research scientists at the International Association for Great Lakes Research Conference, Toronto, Canada (May 2010). Specifically for the Minnesota program, ATSDR consulted with the Indian Health Service Bemidji Service Area Office, Bemidji, MN, to discuss this proposed IC (September 2011).

Table 2. *ATSDR External Consultations*

Name	Title	Phone	Email
Great Lakes National Program Office (GLNPO)			
Jacqueline Fisher	Biologist	(312) 353-1481	fisher.jacqueline@epa.gov
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Edwin (Ted) Smith	Environmental Engineer	(312) 353-6571	smith.edwin@epa.gov
State Health Department Representatives			
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Kory Groetsch, MS	Michigan Department of Community Health	(517) 335-9935	groetschk@michigan.gov
Patricia McCann, MS	Minnesota Department of Health	(651) 201-4915	patricia.mccann@state.mn.us
Toni Forti	New York State Department of Health	(518) 402-7800	ajf01@health.state.ny.us
Thomas Barron	Pennsylvania Department of Environmental Protection	(717) 787-9614	tbarron@state.pa.us
Henry Anderson, MD	Wisconsin Division of Public Health	(608) 266-1253	anderha@dhfs.state.wi.us
Indian Health Service, Bemidji Service Area, Bemidji, MN			
Dawn Wyllie, MD, MPH, FAAFP CAPT USPHS	Deputy Area Director Chief Medical Officer	(218) 444-0491	dawn.wyllie@ihs.gov

Since 2009, ATSDR has had ongoing consultations with CDC laboratory scientists to determine appropriate required and state-optional analytes for this program. The CDC National Center for Environmental Health (NCEH) Division of Laboratory Sciences (DLS) produces periodic biomonitoring reports and national reference values on the U.S. general population exposure to environmental chemicals, such as the *Fourth National Report on Human Exposure to Environmental Chemicals 2009* and the *Updated Tables, February 2011* (see http://www.cdc.gov/exposurereport).

Table 3. *Consultations with CDC NCEH Laboratories*

Name	Title	Phone	Email
Kathleen Caldwell, PhD	Inorganic and Radiation Toxicology Branch	(770) 488-7990	kcaldwell@cdc.gov
Antonia Calafat, PhD	Organic Analytical Toxicology Branch	(770) 488-7891	acalafat@cdc.gov
Andreas Sjodin, PhD		(770) 488-4711	asjodin@cdc.gov
Wayman Turner, PhD		(770) 488-7974	wturner@cdc.gov

Ongoing Consultations with Cooperative Agreement Partners. Since November 2010, the ATSDR has continuously worked with the state health department investigators and their consultants to develop questionnaire items and data collection forms; and to select state-specific chemical analytes and laboratory standard operating procedures, among other protocol requirements for this proposed IC. These consultations are further detailed in Section A.8.

A.5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

A.6. Consequences of Collecting the Information Less Frequently

The *ATSDR Biomonitoring of Great Lakes Populations Program* is a one-time data collection. There are no legal obstacles to reduce the burden.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. 60-day Federal Register Notice was published in the *Federal Register* on November 4, 2011, Vol. 76, No. 214, pp. 68462-4 (provided in Attachment 2, and available at http://www.gpo.gov/fdsys/pkg/FR-2011-11-04/pdf/2011-28564.pdf). No comments or inquiries were received during the public comment period.

B. Under cooperative agreement and continuously since the November 2010 program kickoff meeting in Chicago, IL, the ATSDR has worked directly with the following state health department investigators, staff, and their consultants to obtain their views on the availability of data, the clarity of instructions and record keeping, disclosure, or reporting format, and on the data elements to be collected. The three state health departments sought the input of fisheries and wildlife management, pollution prevention agencies, community representatives, university researchers, and other public health surveillance programs. Additional representatives from these entities are listed in Attachment 8.

Table 4. *Michigan Department of Community Health**

Name	Title	Phone	Email
MDCH Toxicology and Response Section			
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Michigan State University			
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* Community Partners. See Attachment 8.

Table 5. *Minnesota Department of Health**

Name	Title	Phone	Email
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MDH Chronic Disease and Environmental Epidemiology Unit			
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Fond du Lac (Band of the Lake Superior Chippewa) Human Services Division, Public Health Nursing			
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Bonnie LaFromboise, RN, PHN	Lead Public Health Nurse Consultant	(218) 878-2132	bonnielafromboise@fdlrez.com

* Advice Council members. See Attachment 8.

Table 6. *New York State Department of Health**

Name	Title	Phone	Email
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* Advisory Board members. See Attachment 8. An early consultant, Ms. Gomez is currently working at a new assignment within the NYSDOH.

A.9. Explanation of Any Payment or Gift to Respondents

Based on past experience, investigators from the three state health departments have advised the ATSDR that tokens of appreciation for participation in the form of gift cards will increase the ability of this program to recruit hard-to-reach eligible respondents and to collect more reliable information on the proposed susceptible subpopulations. This observation has been borne out by other studies on survey methods to maximize response rates and to improve data quality among special, often under-represented, populations (Singer, 2002).

For the three programs, respondents will be administered informed consent, and indicate their willingness to take part in the study. In total, a maximum of $75 in gift cards will be distributed to each respondent for successful completion of the IC. A participant will receive gift cards totaling less than $75 if they finish parts of each IC phase.

- Phase 1: $25 as a token of thanks for giving or attempting to give blood and urine specimens.
- Phase 2: $25 as a token of thanks for taking part in the interview and clinical assessments.
- In a priority effort to maximize information collected, another $25 will be given as a token of thanks for those respondents who complete both IC phases.
- A one-time distribution of gift cards will be made to the respondents when they exit the study.

Michigan. During the screening process for eligibility, the Michigan shoreline anglers will also receive a small flashlight as a token of appreciation during the secondary enumeration (Attachment 4a). Previously, such tokens of appreciation have been shown to be effective in recruiting and retaining minority and low-income respondents (Singer, 2002), and the MDCH investigators recommend that this be offered to Michigan shoreline anglers (Attachment 4c).

Minnesota. To show receipt of gift cards, each respondent will be asked to sign a Participation Record (Attachment 5g). The MDH recommends, based on advice from their tribal advisors, that monetary tokens of appreciation will aid in maximizing response rates (Attachment 5c). Potential respondents may be resistant to participation out of mistrust of and apathy toward the federal government and for concerns about public disclosures of their identities. These reasons offered by the FDL Biomonitoring Advice Council have been previously observed among other populations (Lujan, 1990).

New York. NYSDOH is also planning to provide monetary gift cards as tokens of appreciation for the sports anglers (Attachment 6f). In the past, two members of its Advisory Committee (Matthew Bonner and Michael Bloom; listed in Attachment 8) observed a 30 percent response rate to an initial mailed screening survey in 1991 and 2008. From among those who return the

screening survey, only 20 percent are estimated to be eligible (based on age, residential history, and consumption of locally caught fish) due to the success of the state's fish advisory campaigns (Fitzgerald, 2004). NYSDOH estimates a response rate of 46 percent among eligible licensed anglers. Therefore, these tokens of appreciation are crucial to help maximize the recruitment of the portion of the subpopulation that still chooses to consume Great Lakes fish despite state advisories against this practice. Individuals who complete the screening interview but are ineligible or refuse to participate will be given a small gift for their effort (i.e., a T-shirt and fishing license case with the fish advisory website link).

The second NYSDOH subpopulation are respondents from the Immigrant Community from Burma who live in Buffalo, NY (n = 100). Because there is no reliable census or sampling frame for this community, RDS will be used as the most appropriate method to identify and recruit eligible respondents (Attachment 6i). Along with a maximum of $75 in gift cards, each respondent will be invited to refer others using a coupon ration system. Those who agree can recruit up to three other eligible respondents. The NYSDOH will give a $15 gift card per successful recruit as thanks for the referring respondent's willingness to assist. Referred individuals who complete the screening interview but are ineligible or refuse to participate will be given a small gift for their effort (i.e., a T-shirt and fishing license case with the fish advisory website link).

A.10. Assurance of Confidentiality Provided to Respondents

All IIF will be stored and managed in MDCH's and NYSDOH's already established record systems. All IIF for the MDH study will be stored in the established record system of the FDL-HSD. The state and tribal health departments will use the IIF, described in Section A.1, for the purposes of sampling, screening, recruitment, and results reporting to respondents. There are no plans for the states to share IIF with ATSDR. During the informed consent process, all respondents will be told about the measures that will be taken to keep their identity safe from disclosure.

- The MDCH does not have provisions for future contact beyond this IC; therefore, IIF will be permanently delinked from survey responses and laboratory analyte results at the end of the study. During informed consent, respondents will be told that their biological specimens will be destroyed at the end of the study (Attachment 4c).

- MDH will not receive nor store IIF in its established record system. MDH has no plans to recontact respondents. The FDL-HSD, however, will retain IIF for those respondents who consent to allow the tribe's public health nurses to recontact them for future study. During informed consent, the MDH and the FDL-HSD will tell respondents that their biological specimens will be destroyed at the end of the study (Attachment 5c).

- Per respondent consent, the NYSDOH will store biological specimens (blood and urine) after completion of the study period. These biological specimens will be used to measure analytes whose laboratory test methods are still under development. Additionally, these store specimens may be used to test for other environmental contaminants that may be

found in the Great Lakes in the future. IIF will be retained for consenting respondents who wish to be notified about future analytical tests (Attachments 6f & 6i). All directly identifiable information for respondents who consent to future contact will remain in the already established NYSDOH record system with a mechanism to relink their IIF for future analytic testing by NYSDOH.

Privacy Impact Assessment Information

A. This supporting statement is taking the place of a full privacy impact assessment (PIA). The NCEH/ATSDR Confidentiality and Privacy Officer and the CDC/ATSDR's Branch of the Office of General Counsel have performed a review of this project and have determined that the data collection described in this ICR does not implicate the Privacy Act. The data collected within this program will not be collected, maintained, or disseminated by an ATSDR information system. Deidentified ATSDR records will be retrievable by study ID number only; therefore, no ATSDR system of records applies to this IC.

B. Each state health department will deidentify all records to be delivered to the ATSDR, according to CDC/ATSDR deidentification standards. Examples of such standards include the CDC Public Health Information Network (PHIN) or Biosense models. Deliverables will be in the form of Statistical Analysis Software (SAS; Cary, NC) flat files. Files will be delivered to the ATSDR in an approved manner for secure and reliable transmission.

At CDC/ATSDR, data security is maintained by policies on physical, technical, and administrative controls that comply with the *CDC/ATSDR Protection of Information Resources Policy* and the *CDC/ATSDR IT Security Program Implementation Standards.* These policies apply to all authorized ATSDR employees and contractors.

Physical controls – The CDC/ATSDR issues identity credentials based on the Federal Information Processing Standards (FIPS) Publication 201 for Personal Identity Verification (PIV) authentication of government employee and contractor identities. This credential is referred to as a PIV Card; it employs microprocessor-based smart card technology, and is designed to be counterfeit-resistant, tamper-resistant. Security measures for physical access to secured facilities include the use of PIV Cards, security guards, and closed circuit TV monitoring.

Technical Controls – CDC/ATSDR policy requires employees to gain authorized logical access to its information systems through an electronic identity (commonly called a "User ID") unique to her/him. The computer-controlled limits on what can be done by the "User ID" are assigned based on program roles and privilege requirements.

Administrative Controls –Authorized CDC/ATSDR employees and contractors are required to:

- Complete required privacy and information security refresher training.
- Read, acknowledge, sign (if online completion is not available), and comply with the HHS Rules of Behavior, as well as other applicable CDC/ATSDR- and system-specific rules of behavior before gaining access to the CDC/ATSDR's systems and networks.

- Adhere to the requirements set forth in the *CDC/ATSDR IT Security Program Implementation Standards*, and other security policies and procedures that minimize the risk to CDC systems, networks, and data from malicious software and intrusions.
- Abide by all applicable acceptable use policies and procedures regarding use or abuse of CDC/ATSDR IT resources.

Prior to delivery of deidentified records to the ATSDR, the provision of data security by each state health department is described below.

Michigan. The State of Michigan Information Privacy Council was established via Executive Order 2009-18 (http://michigan.gov/documents/dmb/EexecutiveOrder_2009-18_327565_7.pdf). The Council was formed under the leadership of a Chief Privacy Officer (CPO) appointed by the Governor. The Council is comprised of Information Privacy Protection Officers (IPPO) from each Executive Agency, including the MDCH. The MDCH IPPO will assist the state in its efforts to comply with state and federal privacy laws and to educate the residents of the state on their rights related to these laws. Specifically, the Executive Order cited, in Paragraph 5, the required federal privacy law [Privacy Act of 1974, the Right to Financial Privacy Act of 1978, and the Health Insurance Portability and Accountability Act of 1996 (HIPAA)].

The associated authorities and responsibilities of the MDCH are denoted under the State of Michigan Public Health Code, Act 368 of 1978 Part 26 (Data, Information, and Research) (http://www.legislature.mi.gov/(S(wq3euuv4uo0xuq55byxpf155))/documents/mcl/pdf/mcl-act-368-of-1978.pdf). Specifically, Section 333.2637 describes the MDCH authority to establish internal policies and procedures to ensure that all protected health information is appropriately and securely collected, stored and transmitted. All MDCH staff are required to complete HIPAA and data security training on an annual basis. Data that are electronically stored or transmitted via the internet are required to be encrypted using a method that is Advanced Encryption Standard (AES) compliant, as specified in the FIPS Publication 197 (http://csrc.nist.gov/publications/fips/fips197/fips-197.pdf).

MDCH personal computers and network applications are password protected and default to locked screen saver mode after five minutes of no activity. Paper files of protected health information are kept in a locked filing cabinet in a locked room on a locked floor at MDCH. All MDCH data files with personal identifiers will be password protected and will be accessible only to study personnel.

Minnesota. All study staff will receive training on data practice requirements, procedures, applicable rules, and policies to comply with the Minnesota Statutes Chapter 13 (Minnesota Government Data Practices Act) (https://www.revisor.mn.gov/statutes/?id=13). This act classifies individual biomonitoring data as private health data (Section 144.96 Subdivision 3 at https://www.revisor.mn.gov/statutes/?id=144.996 and Section 13.3805 Public Health Data at https://www.revisor.mn.gov/statutes/?id=13.3805). As such, biomonitoring results with personal identifiers may be released only to the participant. Section 144.658 of the act specifies that “health data on an individual collected by public health officials conducting an epidemiologic investigation to reduce morbidity or mortality is not subject to discovery in a legal

action." The Minnesota House of Representatives has made available an information brief and overview of the salient procedures for state agencies to follow in collecting and keeping records, in addition to special protections for individuals who are being asked to supply information about themselves (see http://www.house.leg.state.mn.us/hrd/pubs/dataprac.pdf). This overview presents specific data classifications with statutory references, the legal requirements to prevent unauthorized disclosures, and the remedies and penalties for violations of the Act. The MDH also makes available upon request the *MDH Data Practices Catalog* that lists the kinds of data kept about individuals, how each kind of data is classified, and what law classifies that kind of data.

Pursuant to the Minnesota Government Data Practices Act, secure management of the study data will be a joint MDH-FDL tribal endeavor. The Min No Aya Win Clinic and the MDH Data Center in St. Paul are restricted-access secure facilities. After-hour physical security is provided in the form of a motion-sensor alarm system at the clinic and around the clock security guards and patrols at MDH. Employees at both facilities are required to display ID badges at all times. Recruiters contacting potential participants after clinic hours will use FDL HSD computers at the FDL Assisted Living Facility, which has 24-hour staff access.

Paper documents at both facilities will be kept in secure (locked) rooms in locked file cabinets. Study staff will physically transport paper and electronic records and biospecimens from the Min No Aya Win Clinic to the MDH Data Center and MDH Public Health Laboratory. Electronic study files will be maintained behind MDH and FDL firewalls with antivirus and password protection. Data on FDL and MDH servers are backed up every 24 hours. At MDH, offsite backups occur weekly. Both MDH and FDL computers meet Federal Government data encryption standards. All MDH computers are currently migrating from PointSec to Microsoft's Bitlocker Full Disk encryption, using the highest level of security.

All IIF will be kept only at the Min No Aya Win Clinic in a separate, secure database, which will provide the study ID link between participant identities and their responses, body and clinical measurements, and lab results. All biospecimens sent to the four laboratories for analysis will be labeled only with these ID numbers. All study results will be kept separate from the participant's medical record; participants may independently choose to provide them to a health care provider. Neither MDH nor ATSDR will receive IIF from the FDL-HSD.

New York. The State of New York Committee on Open Government has enacted its *Personal Privacy Protection Law* (http://www.dos.ny.gov/coog/pppl.html) under the *Public Officers Law, Article 6A.* As defined under Section 92 Paragraph 11, the term "system of records" means any group of records under the actual or constructive control of any state agency pertaining to one or more data subjects from which personal information is retrievable by use of the name or other identifier of a data subject. The remainder of the law discribes the agency obligations, and the permitted circumstances for granting or denying access to or disclosure of records.

Pursuant to the *Personal Privacy Protection Law*, any electronic data generated for the project will be stored on a password-protected network in project-specific password-protected folders. If it is necessary for data collected in the field to be stored electronically, the computers will be password protected, hard drives encrypted, and data deleted within a specified timeframe. All

data collected electronically in the field will be encrypted, backed up daily on an external hard drive, and comply with NYS DOH security guidelines, with oversight by NYSDOH IT specialists. Alternatively, using an AirCard®, data can be transmitted back to the NYSDOH Center for Environmental Health using the HCS Secure File Transfer Utility. Personal identifiers will be stored locally in a separate database and will not be transmitted with sample results or interview data.

C. The ATSDR Office of Science has determined that the *ATSDR Biomonitoring of Great Lakes Populations Program* is a non-research public health program (Attachment 9); therefore, CDC/ATSDR IRB approval is not required. Each state health department has reviewed and obtained its own local non-research determination (Attachment 9). Although not human subjects as defined under 45 CFR 46 (for research only), the states interpret their responsibilities to their respondents in a broader context. The states will provide each respondent rights and protections, such as for privacy, confidentiality, and informed consent (Attachments 4d, 5c, 6f, & 6i).

- *Michigan.* MDCH will work with its Advisory Committees to select appropriate locations for collection clinics to administer informed consent, questionnaire interviews, and biospecimen collection. Examples of appropriate locations include local community centers, local health department facilities, and community medical clinics.

- *Minnesota.* Informed consent and study responses will be obtained in the FDL-HSD Min No Aya Win Clinic. Trained study staff will meet with the respondent to review the consent documents, answer any questions, and obtain signed informed voluntary consent before study activities occur.

- *New York.* Eligible licensed anglers and immigrants from Burma and their descendants will meet with trained study staff in a clinic or similar private setting. After the respondents have had sufficient time to read the consent form and ask questions, written informed consent will be obtained. Any respondent indicating difficulty with reading will have the consent document read to him or her by the interviewer or an interpreter trained in Spanish language or Burmese dialects.

D. All respondents will be informed about the voluntary nature of their responses in program materials and during informed consent. The Privacy Act does not apply to this IC; information supplied by respondents will be delivered to ATSDR as deidentified files. Data received by ATSDR will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

A.11. Justification for Sensitive Questions

Pregnant Women. A history of pregnancy or breastfeeding in the past 12 months will be asked of all women during the interview, MDCH and MDH will exclude women if they are currently pregnant during eligibility screening.

- MDCH chooses to exclude women who are currently pregnant or who have breastfed in the past six months, along with men and women who have lost more than 15 pounds in the past year. These conditions can affect steady-state body burdens of lipophilic target analytes. MDCH is also restricting eligibility to those who can safely donate 83-mL of blood (e.g. large volume needed for dioxins and furans).

- MDH will exclude pregnant women because the FDL Biomonitoring Advice Council has deemed it culturally inappropriate to take blood from an expectant woman when it is not necessary. MDH's exclusion is a matter of cultural sensitivity at the request of the tribe.

- Pregnancy and breastfeeding can mobilize and, consequently, alter levels of some contaminants. NYSDOH will include women in its data collection regardless of current pregnancy or breastfeeding status. The NYSDOH will account for potential effect modification from pregnancy and breastfeeding among women during statistical analysis. The state does not report any cultural concerns in asking these questions among their Burmese subpopulation.

- In support of their biomonitoring efforts among female respondents, MDCH and NYSDOH are asking additional questions about reproductive history prior to the past 12 months. Women will be asked to list the years in which children were born and the number of months each one was breastfed. As previously described, the number of pregnancies and duration of lactation is needed to help understand the effect of these physiological processes which mobilize some of the analytes from body stores in fat and bone among the female respondents.

In preparing summary program reports and examination of trends, the ATSDR will be able to align the data such that statistical analysis is performed and reported on consistently defined sub-groups across the three states, for instance, restricting analysis to all nonpregnant and nonbreastfeeding women.

Race and Ethnicity. The MDH is requesting an exemption for collecting OMB standard ethnicity and race categories on behalf of the FDL Band of the Minnesota Lake Superior Chippewa Tribe. Such an exemption is allowable under the 2011 Department of Health and Human Services *Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status*. See http://aspe.hhs.gov/datacncl/standards/ACA/4302/index.shtml. The policy states that if a data collection activity of an HHS Agency, component, or HHS-funded program is directed to one or a limited number of categories of a specific demographic variable, only that specific demographic variable would be excluded. Other standards would still be required. An example provided in the guidance are cirumstances such as an Indian Health Service survey.

The MDH has provided the following rationale for this request for exemption:

American Indians do not view themselves as simply one of many racial categories within the general population. The implication that American Indians are a racial minority is insensitive to their heritage.

- To query about race and ethnicity as is commonly done in national surveys is an affront to how American Indians identify themselves as part of distinct Nations within a Nation.
- For the purposes of this IC, MDH will collect information on tribal affiliation from its respondents.

The ATSDR has provided additional supporting information for this request to the OMB and the HHS Assistant Secretary of Planning and Evaluation (ASPE). On 05/23/2012, this request was approved by the HHS Office of General Counsel.

A.12. Estimates of Annualized Burden Hours and Costs

The burden estimates published in the 60-day FRN were based on informal testing among state health department program staff. IRB nonresearch determinations and reviews were completed during the 60-day comment period. During this period, each state health department revised its protocol and tested its state-specific forms among fewer than 10 respondents. Each state tested its full-length questionnaire among a maximum of three respondents. We anticipate that patterns of fish consumption and eligibility criteria will be the chief contributor to variability in questionnaire time burdens among the selected subpopulations.

With respect to time burdens for the states' questionnaires, both the MDH questionnaire for American Indians and the NYSDOH questionnaire for licensed anglers are estimated to take 30 minutes. The questionnaires for the NYSDOH immigrants from Burma and the MDCH shoreline anglers are estimated to take approximately one hour and 52 minutes, respectively.

For the MDH study of American Indians, the questionnaire was timed and administered to both male and female personnel who had varying consumption habits of locally caught fish (number of species, method of catch, and seasons consumed), bought fish, wild game, and wild plants. These staff were nonsmokers and the female did not give birth in the past year. Their responses to the questionnaire averaged 25 minutes in time burden. Therefore, a 30-minute time burden is a reasonable estimate for the tribal subpopulation. Fish consumption is not a requirement to participate, because the FDL tribe is interested in assessing the prevalence of persons who adhere to traditional practices such as methods of catch and consumption of locally caught fish, wild game, wild rice, and other foraged edible plants. These dietary habits will also be used to assess their contributions to chemical body burdens.

In general, the NYSDOH questionnaire for licensed anglers is relatively succinct and limited to the core question domains agreed upon by all three programs. For the licensed anglers, eating at least one fish meal in the previous year is an eligibility requirement. The NYSDOH, due to the success of its fish advisory programs, believes that consumption of fish will be low in this study subpopulation; therefore, a 30-minute time burden is reasonable to complete the fish consumption questions. For the NYSDOH study, the Burmese questionnaire will take longer to administer than the angler questionnaire for three primary reasons: 1) NYSDOH has been informed that the Burmese do not like to be rushed through an activity; 2) the process of administering questionnaires to the Burmese involves translations, which are expected to add to the required time; and 3) there is additional content in the Burmese questionnaire due to

anticipated higher fish consumption, more varied fish preparation, and more complex fish-eating histories. For this subpopulation, eating 12 fish meals per year is an eligibility requirement.

The MDCH biomonitoring questionnaire is estimated to take 52 minutes to complete, which is considerably longer than the 30-minute completion time for Minnesota Indians and New York anglers. The difference in the estimated response time is that the eligibility requirement for shoreline anglers (eating two fish meals per month) is, by design, likely to recruit a subpopulation that proportionately eats more fish species from more waterways compared to the Minnesota Indians and the New York anglers. Therefore, it will take longer to gather these responses.

A. Estimated annualized burden hours, averaged over the requested two year IC, are presented for each state study population and in total.

Type of Respondents	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Michigan Shoreline Anglers	Screening Questionnaire	2000	1	5/60	167
	Telephone Questions for Scheduling Appointments	250	1	7/60	29
	Informed Consent	200	1	1/60	3
	Contact Information Sheet	200	1	2/60	7
	Biomonitoring Questionnaire	200	1	52/60	173
American Indians from Minnesota	Recruitment Calling Script	396	1	5/60	33
	Refusal Questions Form	107	1	2/60	4
	Individual Consent Form	250	1	3/60	12
	Contact Information Form	250	1	2/60	8
	Study Participant Questionnaire	250	1	30/60	125
	Clinic Visit Form	250	1	1/60	4
	Participation Record	250	1	1/60	4
New York State Licensed Anglers	Mail-in Eligibility Screening Survey	518	1	5/60	43

	Online Eligibility Screening Survey	778	1	5/60	65
	Telephone Script for Non-responders to Screening	864	1	5/60	72
	Telephone Script for Eligible Responders to Screening	259	1	5/60	22
	Informed Consent	200	1	1/60	3
	Interview Questionnaire	200	1	30/60	100
Immigrants from Burma and Descendents	Eligibility Screening Survey	92	1	5/60	8
	Informed Consent	50	1	1/60	1
	Interview Questionnaire	50	1	1	50
	Network Size Questions for Respondent Driven Sampling	50	1	5/60	4
				Program Grand Total	937

B. Estimated annualized burden costs are presented for each state health department and in total. To estimate the cost to the respondent, the median hourly wage was selected for all occupations for the metropolitan statistical areas (MSAs) corresponding to the selected AOCs in the three states.

On an annualized basis, MDCH will recruit 100 urban anglers from each AOC (total n = 200 Michigan anglers per year); therefore, 50 percent of the total burden hours (n = 379 hours) are attributed to each Michigan AOC (or 190 hours each, with rounding).

Likewise, NYSDOH will recruit a total of 200 licensed anglers each year of the two-year data collection: 125 will be from the Buffalo River, Niagara River, and Eighteenmile Creek AOCs located in Erie and Niagara Counties; and 75 will be from the Rochester Embayment AOC located in Monroe County. Therefore, 62.5 and 37.5 percent of the total burden hours (n = 305 hours) have been assigned to the two sampling groups (191 and 115 burden hours, respectively).

After apportioning the expected burden hours for each geographic area, the 2010 median hourly wage for the MSA that corresponded with each AOC was applied.

Type of Respondents	Total Burden	Hourly Wage Rate	Total Burden Costs

	(in hours)		
Shoreline Anglers from Detroit River AOC [A]	190	$17.67	$3,357
Shoreline Anglers from Saginaw Bay and River AOC [B]	190	$14.76	$2,804
American Indians from Minnesota in St. Louis River AOC [C]	190	$15.38	$2,922
Licensed Anglers from Buffalo River, Niagara River, Eighteenmile Creek AOC [D]	191	$16.00	$3,056
Licensed Anglers from Rochester Embayment AOC [E]	115	$16.45	$1,892
Immigrants from Burma or Descendents in City of Buffalo, NY [D]	63	$16.00	$1,008
		Program Grand Total	$15,039

Source: BLS, 2010. *May 2010 Metropolitan and Nonmetropolitan Area Occupational Employment and Wage Estimates: Median Hourly Wage for All Occupations.* http://www.bls.gov/oes/current/oessrcma.htm. [A] *Detroit-Warren-Livonia MI MSA;* [B] *Saginaw-Saginaw Township North MI MSA;* [C] *Duluth MN MSA;* [D] *Buffalo-Niagara NY MSA;* [E] *Rochester NY MSA.*

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no additional capital and maintenance costs for the *ATSDR Biomonitoring of Great Lakes Populations Program* for respondents or recordkeepers.

A.14. Annualized Cost to the Government

The Environmental Protection Agency has transferred funding and responsibility for executing this program to ATSDR under an interagency agreement (IAA) for the *ATSDR Biomonitoring of Great Lakes Populations Program*.

The total estimated cost to the government is $11.4 million, based on the current actual costs for the first year spent in protocol and ICR development and the estimated costs for this program's request to collect information over the next 2 years.

The estimated average annualized cost of the program is $3.8 million ($11.4 million divided by the three years of the total program period).

- Personnel: $262,000 per year. This is based on percentages of time spent on the project by ATSDR staff.
- Travel: $21,000 per year. This amount is based on the number of site visits conducted following the General Services Administration Schedule for travel and per diem.
- Cooperative Agreements: $3,500,000 per year. This amount is based on the approved applications of the current grantees.

A.15. Explanation for Program Changes or Adjustments

This is a new information collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Upon completion of data collection and laboratory analysis, each state health department will tabulate and report individual results of laboratory analysis back to the respondent. In the event that clinically significant laboratory results are detected, such as for toxic metals like mercury and lead, the principal investigators will provide advance notification to the respondents. Summary reports for each state health department will be tabulated and released to the public.

In consultation with the three state health departments, the first year of the program period was dedicated to planning and protocol development. Upon receiving their first year awards, the three health state departments have been working on outreach, health education, planning activities, formative research, and protocol development and IRB review for their respective data collections. The states also assisted the ATSDR in developing this ICR.

IC procedures will begin upon the date of OMB approval. Therefore, the two years of information collection will require a timely approval of this ICR to complete this federal acquisition.

The schedule for project completion is as follows:

Activity	Time Schedule*
Recruitment letters sent to respondents	1-4 month after OMB approval
Respondents enrolled, interviewed, and blood and urine specimens collected	2-18 months after OMB approval
Field work, laboratory analysis complete	19-21 months after OMB approval
Data validation, data entry, data analysis complete	22 months after OMB approval
Respondent results reporting complete	23 months after OMB approval
Summary study reports complete	24 months after OMB approval

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The *ATSDR Biomonitoring of Great Lakes Population Program* will display the OMB Control Number and expiration date on all data collection forms as required.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

LIST OF ATTACHMENTS

Attachment 7. Program Laboratory Policies and Procedures

Attachment 7a. Chemical Analytes

Table 1. Great Lakes Biomonitoring Chemical Analyte Overview and Index
Table 2. Michigan Department of Community Health Chemical Analytes
Table 3. Minnesota Department of Health Chemical Analytes
Table 4. New York State Department of Health Chemical Analytes
Chemical Analytes Justification

Attachment 7b. Biomonitoring of Great Lakes Populations Laboratory QA/QC Procedures

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

Attachment 7d. Contact Information for Proficiency Test Reports and Laboratory Standard Operating Procedures

Attachment 8. Additional Consultations Outside the Agency

Attachment 9. ATSDR and State Determination Letters of Non-research Status

Attachment 10. Results Reporting and Communications

Attachment 10a. Michigan Results Communications

Attachment 10a1. Letter 1: Full Results for results not exceeding action levels
Attachment 10a2. Letter 2: Action Level Exceedences for Heavy Metals
Attachment 10a3. Letter 3: Action Level Exceedences for Elevated Cholesterol
Attachment 10a4. Letter 4: Full Results for Those Receiving Letter 2 or 3
Attachment 10a5. Letter 5: Full Results for Those with Exceedences of Other Chemicals
Attachment 10a6. Blood Pressure Factsheet

Attachment 10b. Minnesota Results Communications

Attachment 10b1. Clinical Results Letter
Attachment 10b2. Metals Rapid Results Materials
10b2a. Metals Rapid Results Protocol
10b2b. Rapid Results Letters (Tier 1)
Letter 1: Mercury > 5.8 µg/L (women of childbearing age)
Letter 2: Mercury > 17.4 µg/L (women of childbearing age)
Letter 3: Mercury > 17.4 µg/L (non-sensitive population)
Letter 4: Lead > 5 µg/dL
Letter 5: Cadmium > 1.7 µg/L
10b2c. Mercury Information Sheet
10b2d. Lead Information Sheet
10b2e. Cadmium Information Sheet
10b2f. FDL-MDH Fish Consumption Advisory Brochure
Attachment 10b3. Final Results Letters
10b3a. Letter 1: No rapid results letter sent/Hg below 5.8 ug/L
10b3b. Letter 2: Mercury rapid results letter sent
10b3c. Letter 3: Cadmium or lead rapid results letter sent
10b3d. Letter 4: No rapid results letter sent/Hg above 5.8 ug/L and below 17.4 ug/L

Attachment 10c. New York Results Communications

Attachment 10c1. Sample letter reporting chemical results (English and Burmese Translation)
Attachment 10c2. Sample letter reporting metal, cholesterol, and triglyceride results (English and Burmese Translation)