

# Mini Supporting Statement For OMB Review and Approval of Changes to OMB Control No: 0923-0044

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

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## SECTION A. Justification

24 July 2014

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## A. JUSTIFICATION

### A.1. Circumstances Making the Collection of Information Necessary

This is a change request for the *Agency for Toxic Substances and Disease Registry (ATSDR) Biomonitoring of Great Lakes Populations Program* (OMB protocol #0923-0044, expiration date: October 31, 2015). The original program requested Office of Management and Budget (OMB) approval for two years to complete information collection. The current change request pertains to Year 2 only.

We are requesting approval to re-contact, re-screen, and re-collect blood and urine specimens, and questionnaire responses for 25 previously enrolled study participants (Michigan shoreline anglers) attributed to the Detroit River area. During the analysis of serum samples, the National Center for Environmental Health Division of Laboratory Sciences informed our program that external contamination of 25 samples collected from these participants occurred due to equipment failure. The reason for repeating the questionnaire and urine sample is to chronologically align information collected on exposure parameters per responses to the questionnaire and the body burden measurements of all analytes.

For the 25 re-screened respondents, the approved burden will be an increase from the current inventory. The program's introductory telephone script to recruit participants has been modified to explain that a problem occurred with the laboratory equipment and request participants to return to the clinic to answer the questionnaire and provide an additional blood and urine sample (see Attachment 1). The consent form has also been modified to explain why the 25 participants are being asked to return (see Attachment 2). There is no request to modify the previously approved Biomonitoring Questionnaire (Attachment 3).

#### 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 for the five-year GLRI Action Plan ([http://greatlakesrestoration.us/pdfs/glri\\_actionplan.pdf](http://greatlakesrestoration.us/pdfs/glri_actionplan.pdf)), which 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) implemented the GLRI's billion dollar package of programs to restore the Great Lakes ecosystems.

As part of the Action Plan, the *Department of the Interior, Environment, and Related Agencies Appropriations Act of 2010* (Public Law 111-88), committed federal efforts toward restoration of the Great Lakes. 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 Great Lakes Biomonitoring Program awarded funds to three state health departments under cooperative agreement: 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).

The current change request pertains only to the *Michigan Department of Community Health* (MDCH - #1 U61TS000138).

### **Privacy Impact Assessment**

The following sections provide an overview of the repeat MDCH data collection system.

#### ***Overview of the Data Collection System***

The MDCH data collection will be conducted by a repeated interview, and blood and urine specimens will be collected again for analytical measurements of specific contaminants. The information collection (IC) for 25 respondents will be repeated in three phases: eligibility re-screening and recruitment; re-consent; and repeated personal interviews.

The annualized burden table in Section A.12 is adjusted to include the MDCH's modified data collection forms and to indicate the 25 participants who are requested to respond twice.

There are no changes to the population who are shoreline anglers, defined as urban Michigan residents who fish along shoreline venues on the Detroit River and the Saginaw River and Bay.

There are no changes to the sampling, eligibility screening, or recruitment methodology. All initial data collection is complete. For the 25 participants who will be recontacted, the following procedures will be followed:

- Eligibility re-screening and recruitment: The 25 respondents will be screened for current 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 1). The introductory telephone script has been modified to explain that a problem occurred with the laboratory equipment and request participants to return to the clinic to answer the questionnaire and provide an additional blood and urine sample.
- Re-enrollment: Informed consent, modified to explain why the 25 participants are being asked to return, will be documented on a paper-and-pencil form (Attachment 2). Each enrolled respondent will be asked to verify or update their contact information on the Contact Information Sheet, which remains unchanged.
- Repeat interview: The Biomonitoring Questionnaire will be re-administered by a computer-assisted personal interview (CAPI) to ascertain the respondent's questionnaire responses. Blood and urine collection and clinical measures will also be completed at this time. There have been no modifications to the previously approved Biomonitoring Questionnaire (Attachment 3).

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

No federal or state websites will be developed to collect information for the *ATSDR Biomonitoring of Great Lakes Populations Program*. Likewise, no websites or website information will be directed at children less than 13 years of age. Participants are at least 18 years of age.

### **A.2. Purpose and Use of Information Collection**

The purpose of the ATSDR Great Lakes Biomonitoring Program was previously articulated as 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. There are no changes to the purpose and use of the information collected.

### **Privacy Impact Assessment Information**

There are no changes to the following topics all previously approved by OMB:

- *Why this information is being collected*
- *Collection of information in identifiable form*
- *Impact on privacy*

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

All data collection methodologies and use of improved information technology to reduce respondent burden remains unchanged. We are requesting an increase of 26 hours in approved burden for Year 2 due to technical difficulties in laboratory analysis.

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

The ATSDR efforts to identify duplication and similar information are unchanged from the initial reviews of existing reports and publications, attendance at national meetings, and consultations with state and other agencies and community representatives.

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

No small businesses are 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 (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 MDCH investigators, staff, and their consultants.

Table 1. *Michigan Department of Community Health\**

Name	Title	Phone	Email
<i>MDCH Toxicology and Response Section</i>			
Linda Dykema, PhD	Principal Investigator	(517) 335-8566	<a href="mailto:dykema@michigan.gov">dykema@michigan.gov</a>
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<i>MDCH Analytical Chemistry Section</i>			
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<i>Michigan State University</i>			
Julie Wirth, PhD, MS	Epidemiologist Consultant	(517) 432-8383 x199	<a href="mailto:wirthj@msu.edu">wirthj@msu.edu</a>
Joseph Gardiner, PhD	Biostatistician/Epidemiologist	(517) 353.8623 x110	<a href="mailto:gardine3@msu.edu">gardine3@msu.edu</a>

\* Community Partners.

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

Respondents will be re-administered informed consent. In total, a maximum of \$75 in gift cards will be distributed to each respondent for successful completion of the repeated 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.

### A.10. Assurance of Confidentiality Provided to Respondents

There are no changes to the ATSDR and MDCH privacy protections previously approved by OMB. The Privacy Impact Assessment information remains the same.

### A.11. Justification for Sensitive Questions

There are no changes to the ATSDR and MDCH justification for sensitive questions.

### A.12. Estimates of Annualized Burden Hours and Costs

A. The original IC request presented estimated annualized burden hours averaged over a two year IC for each study population in the three state-specific programs and in total. The current IC change request to repeat data collection for 25 Michigan shoreline anglers due to laboratory specimen contamination pertains only to Year 2 burden estimates for Michigan. Burden estimates for the other state populations remain unchanged. The requested increase in burden hours is 26 hours for Michigan shoreline anglers in Year 2, or a total of 1,026 hours requested for Year 2.

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
	Telephone Questions for Scheduling Repeat Appointments	25	1	7/60	3
	Informed Consent	200	1	1/60	3
	Informed Consent for Repeat Appointments	25	1	1/60	1
	Contact Information	200	1	2/60	7

	Sheet				
	Biomonitoring Questionnaire	175	1	52/60	152
		25	2	52/60	43
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	184	1	5/60	16
	Informed Consent	100	1	1/60	2
	Interview Questionnaire	100	1	1	100
	Network Size Questions for Respondent Driven Sampling	100	1	5/60	8
Program Grand Total					1026



B. Estimated Year 2 burden costs have been adjusted to account for a burden increase of 26 hours for the repeat data collection on 25 Michigan shoreline anglers in the Detroit River area due to laboratory specimen contamination. Cost estimates for the other subpopulations remain unchanged. 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 areas in the three states. The 2010 median hourly wage for the MSA that corresponded with each area was applied.

Type of Respondents	Total Burden (in hours)	Hourly Wage Rate	Total Burden Costs
Shoreline Anglers from Detroit River AOC <sup>A</sup>	358	\$17.67	\$6,326
Shoreline Anglers from Saginaw Bay and River AOC <sup>B</sup>	47	\$14.76	\$694
American Indians from Minnesota in St. Louis River AOC <sup>C</sup>	190	\$15.38	\$2,922
Licensed Anglers from Buffalo River, Niagara River, Eighteenmile Creek AOC <sup>D</sup>	191	\$16.00	\$3,056
Licensed Anglers from Rochester Embayment AOC <sup>E</sup>	115	\$16.45	\$1,892
Immigrants from Burma or Descendents in City of Buffalo, NY <sup>D</sup>	126	\$16.00	\$2,016
Program Grand Total			\$16,906

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/oesrcma.htm>. <sup>A</sup> Detroit-Warren-Livonia MI MSA; <sup>B</sup> Saginaw-Saginaw Township North MI MSA; <sup>C</sup> Duluth MN MSA; <sup>D</sup> Buffalo-Niagara NY MSA; <sup>E</sup> 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.
- The repeat data collection on 25 Michigan shoreline anglers in the Detroit River area due to laboratory specimen contamination is estimated to cost an additional \$21,000.

#### **A.15. Explanation for Program Changes or Adjustments**

We are requesting approval to re-contact, re-screen, and re-collect blood and urine specimens, and questionnaire responses for 25 previously enrolled study participants (shoreline anglers) attributed to the Detroit River area. During the analysis of serum samples, the National Center for Environmental Health Division of Laboratory Sciences informed our program that external contamination of 25 samples collected from these participants occurred due to equipment failure. The reason for repeating the questionnaire and urine sample is to chronologically align information collected on exposure parameters per responses to the questionnaire and the body burden measurements of all analytes. We are requesting an increase of 26 burden hours for Year 2 only.

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

The repeat data collection on 25 previously enrolled study participants will not change the project time schedule. Program close out activities remain as previously reported.

#### **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.

## **ATTACHMENTS to the Modified Supporting Statement**

Attachment 1. Telephone Questionnaire for Scheduling Repeated Appointments

Attachment 2. Informed Consent for Repeated Appointments

Attachment 3. Biomonitoring Questionnaire