

Supporting Statement For OMB Review and Approval of

Agency for Toxic Substances and Disease Registry (ATSDR)

Biomonitoring of Great Lakes Populations Program III

OMB Control No. 0923-171Y (Expiration Date: xx/xx/xxxx)

Type of ICR: New

March 2017

Supporting Statement Part A

Justification

ATSDR Division of Toxicology and Human Health Sciences

Program Official:

Angela Ragin-Wilson, PhD

Title: Program Official/Branch Chief

Phone: 770-488-3807

Email: ARagin@cdc.gov

Fax: 770-488-7187

Table of Contents

List of Attachments.....3

A.1. Circumstances Making the Collection of Information Necessary.....5

A.2. Purpose and Use of the Information Collection.....6

A.3. Use of Improved Information Technology and Burden Reduction.....9

A.4. Efforts to Identify Duplication and Use of Similar Information.....9

A.5. Impact on Small Businesses or Other Small Entities.....10

A.6. Consequences of Collecting the Information Less Frequently.....10

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....10

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency..10

A.9. Explanation of Any Payment or Gift to Respondents.....12

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.....13

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions.....14

A.12. Estimates of Annualized Burden Hours and Costs.....14

A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers.....16

A.14. Annualized Cost to the Federal Government.....16

A.15. Explanation for Program Changes or Adjustments.....17

A.16. Plans for Tabulation and Publication and Project Time Schedule.....17

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate.....18

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

References.....19

List of Attachments

- Attachment 1. Authorizing Legislation
- Attachment 2. 60-day Federal Register Notice
- Attachment 3. Public Comments and Program Response
- Attachment 4a. Program Overview
- Attachment 4b. Map of Milwaukee Estuary AOC
- Attachment 5a. Recruitment Mailings
- Attachment 5b. Eligibility Screening Survey for Licensed Anglers (paper)
- Attachment 5c. Eligibility Screening Survey for Licensed Anglers (screenshots)
- Attachment 5d. Eligibility Screening Survey for Burmese Immigrants and their Descendants
- Attachment 5e. Phone scripts for Licensed Anglers
- Attachment 5f. Appointment Reminder Letters
- Attachment 6a. Consent Form for Licensed Anglers
- Attachment 6b. Consent Form for Burmese Immigrants and their Descendants
- Attachment 7a. Contact Information Form for Burmese Immigrants and their Descendants
- Attachment 7b. Study Questionnaire for Licensed Anglers (paper)
- Attachment 7c. Study Questionnaire for Licensed Anglers (screenshots)
- Attachment 7d. Study Questionnaire for Burmese Immigrants and their Descendants
- Attachment 7e. Network Size Questions for Respondent-Driven Sampling, Burmese Immigrants, and their Descendants
- Attachment 8a. Clinic Visit Checklist and Body Measurements, Licensed Anglers
- Attachment 8b. Clinic Visit Checklist and Body Measurements, Burmese Immigrants and their Descendants
- Attachment 8c. Example Referral Coupons
- Attachment 8d. Example Gift Card Letter
- Attachment 9a. Follow-up Survey, Licensed Anglers
- Attachment 9b. Follow-up Survey, Burmese Immigrants, and their Descendants
- Attachment 10a. Early Results Letter template
- Attachment 10b. Results Package Examples
- Attachment 11. Laboratory Standard Operating Procedures
- Attachment 12a. NCEH/ATSDR Research Determination Form
- Attachment 12b. WIDHS IRB Determinations

A. Justification

Goal of the study: The goal of the study is to evaluate body burden levels of legacy contaminants and chemicals of emerging concern in susceptible Great Lakes populations in the Milwaukee Estuary Area of Concern (AOC) in Wisconsin.

Intended use of the resulting data: Findings from the biomonitoring study will be used to inform participants and other community stakeholders about ways to maximize benefits and minimize risks while consuming locally caught fish in the Great Lakes basin and guide public health action to protect Great Lakes populations from potential exposure to harmful chemicals.

Methods to be used to collect: This study will be conducted by the Wisconsin Department of Health Services following a cross-sectional survey design. Enrolled participants will complete a questionnaire and provide blood, urine, and hair samples. The blood and urine samples will be analyzed for legacy and emerging Great Lakes contaminants, including metals (e.g., mercury and lead), polychlorinated biphenyls, chlorinated pesticides, perfluorinated compounds, and polyaromatic hydrocarbons. The hair samples will be stored for future analyses.

Subpopulation to be studied): There will be two target populations, i.e. urban licensed anglers within 2 miles of the Milwaukee Estuary AOC and Burmese immigrants and their descendants that eat fish from the Milwaukee Estuary AOC.

How data will be analyzed: Descriptive statistics will be generated to describe the results. Spearman correlation coefficients, Kruskal-Wallis tests, and multivariate regressions will be used, as appropriate to examine relationships between study variables

A.1. Circumstances Making the Collection of Information Necessary

This is a new Information Collection Request (ICR) under the cooperative agreement (CDC-RFA-TS16-1601) for the *2016 Agency for Toxic Substances and Disease Registry (ATSDR) Biomonitoring of Great Lakes Populations Program III*. ATSDR is authorized to conduct the biomonitoring 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 1). The program requests Paperwork Reduction Act (PRA) clearance approval for three years to complete information collection. The agency published the 60-day Federal Register Notice on January 3, 2017 (Attachment 2), and received and addressed 1 comment. The agencies' response to public comments is found in Attachment 3 and is further discussed in Section A.8.

The Great Lakes Basin has been impacted over time by toxic chemicals, resulting in human exposure to these contaminants via inhalation, dermal contact with water, soil and sediments, ingestion of municipal water drawn from the lakes, and consumption of local fish and game. The U.S. Department of Health and Human Services (DHHS) Agency for Toxic Substances and Disease Registry (ATSDR) initiated the *Biomonitoring of Great Lakes Populations Program* in

2010 aimed to evaluate contaminant exposure in high-risk populations who eat fish caught locally from contaminated Great Lakes waterbodies.

The *Biomonitoring of Great Lakes Populations Program* consists of a series of cross-sectional studies carried out collaboratively with states through ATSDR's cooperative agreements. The first program, CDC-RFA-TS10-1001 "*Biomonitoring of Great Lakes Populations*" (hereafter referred to as "Program I", OMB Control Number 0923-0044) was initiated in 2010 and completed in 2015. The second program, CDC-RFA-TS13-1302 "*Biomonitoring of Great Lakes Populations-II*" (hereafter referred to as "Program II", OMB Control Number 0923-0052) was initiated in FY2013. In the first two Great Lakes Biomonitoring programs, conducted in partnership with health departments in New York, Michigan, and Minnesota. We studied five types of vulnerable populations who lived in seven areas of concerns (AOCs) in these three states. Preliminary data indicate that some target populations had higher body burden of heavy metals and persistent organic pollutants compared to national estimates.

In 2016, ATSDR announced a new funding opportunity CDC-RFA-TS16-1601 "*Biomonitoring Legacy and Emerging Great Lakes Contaminants in Susceptible Great Lakes Populations*" (the current program, hereafter referred to as "*Great Lakes Biomonitoring III*"). ATSDR awarded funds to the Wisconsin Department of Health Services (WIDHS) to conduct this information collection (IC) under cooperative agreement #NU61TS000269-01-00. The purpose of the current program is to evaluate body burden levels of legacy and emerging contaminants in in susceptible Great Lakes populations in the Milwaukee Estuary AOC in Wisconsin, an area that has not been previously covered by the Programs I and II. For the convenience of potential participants, WIDHS refers this project locally as the "Milwaukee Angler Project."

The International Joint Commission Water Quality Board has identified 43 AOCs in the United States that have been severely impacted by contaminants, five of which are located in the state of Wisconsin. Of these, the Milwaukee Estuary AOC is of particular concern because the Milwaukee River Basin is located in the most densely populated area of Wisconsin, encompassing portions of seven counties and home to about 1.3 million people (EPA, 2016). The Milwaukee Estuary was designated an AOC in 1987 because historical modifications and pollutant loads degraded sections of the Milwaukee River and connected waterways, as well as Lake Michigan. Ongoing work conducted by the United States Geological Survey shows the Milwaukee Estuary AOC ranks in the top ten out of the twenty-seven designated AOCs in the Great Lakes Basin for many of the contaminants of concern included in this program.

A.2. Purpose and Use of the Information Collection

The ATSDR's *Great Lakes Biomonitoring III* program is an applied public health program that focuses on vulnerable or susceptible subpopulations with the potential for increased risk of exposure to contaminants common to the Great Lakes watersheds and ecosystems, e.g., mercury and polychlorinated biphenyls (PCBs). The aims of the information collection in this surveillance project are:

1. Assess contaminants levels in blood and urine of residents who consume fish from contaminated areas that had not been studied in previous *Programs I and II* and
2. Apply the project findings to inform public health officials and offer guidance on public health actions to reduce exposure to Great Lakes contaminants.

The core program objective is to provide a current ‘snap shot’ of human exposure levels among susceptible subpopulations living around the Milwaukee AOC. This surveillance project will not investigate health outcomes or biological effects from such exposures. The biomonitoring results will not be generalized beyond the selected AOC and the defined subpopulations under study. 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.

Under a cooperative agreement (CDC-RFA-TS16-1601) with ATSDR, the WIDHS will collect this data on a one-time basis. The state will investigate if select subpopulations living in the Milwaukee Estuary AOC area have elevated exposures to Great Lakes contaminants. This information will be used by WIDHS to guide public health practice throughout the restoration process in this area.

An overview of this program is given in Attachment 4a. WIDHS will look at adults living in the Milwaukee area (Attachment 4b) who eat fish from the Milwaukee AOC water bodies. The WIDHS biomonitoring program’s two target subpopulations are:

- licensed anglers (adults over 18 yrs.) who live within 2 miles of the Milwaukee Estuary AOC waterways and
- Burmese immigrants and their descendants (adults over 18 yrs.) who live in the City of Milwaukee.

Pregnant women will not be included in this study. WIDHS study staff will work closely with local refugee and citizen support organizations to get people to take part in the study. Burmese immigrants and their descendants that enroll in the study will also be referred to as Burmese participants in these study materials.

This project will have several information collection activities and methods (further discussion in B.2) and briefly summarized below:

- WIDHS will recruit participants from the two subpopulations described above based on a set of eligibility criteria through screening surveys (Attachments 5a–5d).
- All eligible participants will sign the consent forms (Attachments 6a and 6b); complete contact information form (Burmese participants only, Attachment 7a), study questionnaires (Attachments 7b, 7c and 7d,) and network size questionnaire (Burmese participants only, Attachment 7e), and provide biological specimens during clinic visits (Attachments 8a and 8b).
- Near the end of the program, WIDHS will send out a follow-up survey to study participants (Attachments 9a and 9b).

- The biomonitoring results will be sent to participants using templates (Attachments 10a and 10b). The biological specimens will be analyzed in designated laboratories following established standards operating procedures (Attachment 11).
- At the end of the program, WIDHS will transfer de-identified data to ATSDR.

ATSDR program has required a core set of Great Lakes legacy contaminants for biomonitoring based on environmental occurrence, established analytical methods, reported human burden, and findings from previous programs. The required analytes include well-known toxicants like mercury, PCBs and banned pesticides, and chemicals of emerging concern, such as perfluorinated compounds (PFCs). In addition, WIDHS has selected additional analytes among chemicals of local concern to measure in its target subpopulations, such as polycyclic aromatic hydrocarbons (PAHs).

This ICR represents the first time that the body burdens of a large panel of Milwaukee Estuary AOC contaminants will be determined among susceptible populations such as Burmese immigrants and their descendants and licensed anglers living near the Milwaukee Estuary AOC in Wisconsin (Attachment 4b). Burmese immigrants and their descendants represent a particularly vulnerable subpopulation due to cultural practices and linguistic barriers in accessing and understanding fish consumption advisories. Milwaukee is the primary destination for refugees entering Wisconsin; an estimated 3,600 Burmese refugees have arrived since 2000, and many settle in areas proximate to the AOC (Sallumi, 2015). As a means to promote trust with state health officials, collaborative community partnerships are beneficial when gathering health information from vulnerable communities. The WIDHS will work with their community partners to create culturally relevant educational and advisory messages on the risks and benefits of fish consumption diets in relation to 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.

At the state level, determining which Great Lakes contaminants are entering human populations above background levels will also inform state health officials and their public health actions and advisories throughout the restoration process. The results of this ICR will

- inform prevention of ongoing or future human exposures for the specific subpopulations within the state's jurisdiction.
- improve population-based assessment of exposure to Great Lakes contaminants.
- allow targeted action to reduce exposures and subsequent risk of adverse health outcomes.
- help to inform AOC remediation efforts and clean-up strategies for other local waterways.

At the federal level, the ATSDR biomonitoring results will

- provide human chemical exposure information to complement other environmental monitoring of legacy and emerging contaminants in biota, sediments, and water quality.
- inform multi-level government policies and programs responsible for controlling and reducing environmental pollution in the selected areas and Great Lakes Basins.

The project's outreach activities, the collaboration with Advisory Committee members, and the dissemination of findings will

- enhance efforts to educate current and potential fish consumers about ways to maximize benefits and minimize risks while consuming locally caught fish.
- increase awareness of the value of biomonitoring as a tool for exposure assessment.
- increase understanding of potential adverse health effects associated with exposure to Great Lakes contaminants.
- guide public health action.
- strengthen existing partnerships and foster new ones.
- allow for sharing of results and outreach materials generated by this work.

Specific public health uses of the exposure information include

- determining which chemicals get into the target populations and at what concentrations
- estimating the prevalence of people with levels of chemicals in blood or urine above a known reference value (e.g., blood lead greater than or equal to 5 micrograms per deciliter)
- tracking trends in levels of exposure over time in the target populations

ATSDR will provide technical oversight to ensure scientifically valid sampling strategies, collection of a core set of precise analyte quantification, and the collection of relevant questionnaire information on exposure pathways, demographics, and lifestyles. ATSDR will not pool data for analysis across subpopulations or previous programs. ATSDR serves as the steward and coordinator of the program to ensure adherence to the goals and objectives of the project and to ensure scientific integrity. WIDHS will conduct all data collection activities.

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

Electronic data collection will be used to reduce the burden on participants where possible. For licensed anglers, much of the information collected in this study will be via electronic reporting in the form of computer-assisted personal interviewing (CAPI) or web-based surveys (Attachments 5c and 7c). There will also be an option to complete the eligibility survey and study questionnaire on a hard copy form (Attachments 5b and 7b), if the participant prefers, with responses entered into the CAPI instrument by trained study personnel. The questions on the paper form will be identical to that in the CAPI/web-based survey. Study staff will briefly review electronically submitted surveys for completeness prior to each patient's visit; paper surveys will be briefly reviewed for completeness at the time of the clinic visit. A secure web-based application (REDCap) will be used to enter and manage all collected data, with the exception of laboratory results which will be managed and created as described in laboratory protocols. For the Burmese participants, the survey instrument and study questionnaire (Attachments 5d and 7d) will be translated into Burmese and Karen and administered by a Burmese or Karen interpreter.

For the REDCap survey instrument (Attachments 5c and 7c), 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. These data collection methods will also eliminate errors in the sequence of questions and accelerate the interview process. They 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.

WIDHS estimates that 15% of licensed angler participants will complete the web version of the screening survey, while the remaining 85% will return the included paper screening survey (Horevoorts, et al. 2015). Based on the available demographics of this population (e.g., age and sex), WIDHS estimates that 60% of the licensed angler participants will complete the web-based detailed study survey while 40% will request and complete the paper version of the survey.

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

ATSDR has determined that no similar data currently exists. Our efforts to identify duplication of the proposed ICR included reviews of existing reports and publications, attendance at national meetings, and consultations with state and other agencies and community representatives. Data collection from the previous Great Lakes programs occurred in other AOCs located in three other states. ATSDR worked with the WIDHS to identify whether the proposed ICR is duplicated for the proposed subpopulations, the specific area, and the proposed chemical contaminants.

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

This data collection will not involve small businesses.

A.6. Consequences of Collecting the Information Less Frequently

The *Great Lakes Biomonitoring III* 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 January 3, 2017, Vol. 82, No. 1 FR, pp. 124-126 (Attachment 2, and available at <https://federalregister.gov/a/2014-20100>).

CDC’s Information Collection and Review Office (ICRO) received 1 request for the 60-day package including information collection plan and instruments from Carolyn Malestic of Idem Translations. ICRO provided Carolyn Malestic the materials that s/he requested. No other comments or inquiries were received during the public comment period.

B. Under the cooperative agreement, ATSDR has worked directly with the following WIDHS investigators, staff, and their consultants on all facets of the proposed program activities. The WIDHS sought the input of fisheries and wildlife management, community representatives, university researchers, and other public health surveillance programs.

Table A.8.1. Wisconsin Department of Health Services Study Staff

| Name | Title | Email | Phone |
|-------------------------|---|--|--------------|
| Johnathan Meiman, MD | Principal Investigator | jonathan.meiman@dhs.wisconsin.gov | 608-261-6375 |
| Brooke Thompson, MPH | Project Coordinator | Brooke.Thompson@dhs.wisconsin.gov | 608-261-9325 |
| Emilia Wollenburg, MPH | Outreach Specialist | Emelia.wollenburg@wi.gov | 608-267-3242 |
| Curtis Hedman, PhD | Laboratory Manager* | curtis.hedman@slh.wisc.edu | 608-224-6271 |
| Krista Christensen, PhD | Programmer; Data manager; Epidemiologist; Data analyst; Statistical Advisor | Krista.Christensen@dhs.wisconsin.gov | 608-266-6762 |
| Michelle Raymond, MS | Programmer; Data manager; Epidemiologist; Data analyst | michelle.raymond@dhs.wisconsin.gov | 608-261-9433 |
| Meghan Williams, MS | Toxicologist | Meghan.Williams@wisconsin.gov | 608-267-9665 |
| Chris Gjestson | Fiscal administrative support | christopher.gjestson@dhs.wisconsin.gov | 608-266-0472 |
| Jeff Phillips | Bureau Director | jeffrey.phillips@dhs.wisconsin.gov | 608-264-9880 |
| | | | |

*Wisconsin State Laboratory of Hygiene, University of Wisconsin-Madison

Consultations

ATSDR has consulted with federal and state environmental public health officials, environmental health laboratory scientists, and other stakeholders to identify program needs and specifications. In addition, ATSDR has had ongoing consultations with CDC environmental health laboratory scientists to determine appropriate required and optional analytes for this program. The CDC National Center for Environmental Health (NCEH) Division of Laboratory

Sciences (DLS) produces biomonitoring reports and national reference values on the U.S. general population, such as the *National Report on Human Exposure to Environmental Chemicals 2009* and the *Updated Tables, February 2015* (see <http://www.cdc.gov/exposurereport>).

Table A.8.2. Consultations with CDC/NCEH/DLS Laboratories

| Name | Title | Phone | Email |
|------------------------|---|----------------|--|
| Kathleen Caldwell, PhD | Inorganic and Radiation Toxicology Branch | (770) 488-7990 | kcaldwell@cdc.gov |
| Antonia Calafat, PhD | | (770) 488-7891 | acalafat@cdc.gov |
| Andreas Sjodin, PhD | Organic Analytical Toxicology Branch | (770) 488-4711 | asjodin@cdc.gov |
| Xiaoyun Ye, MS | | (770) 488-7502 | xye@cdc.gov |

Furthermore, ATSDR has ongoing consultations with cooperative agreement partners. For the currently proposed ICR, ATSDR will continue to work with WIDHS investigators and their consultants to adopt questionnaire items and data collection forms; select specific chemical analytes and laboratory standard operating procedures, among other protocol

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

WIDHS has advised 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. The use of tokens of appreciation has been shown to benefit other studies among special, often under-represented, populations. In addition, Programs I and II used tokens of appreciation and they proved to be beneficial in previous programs.

The licensed anglers will receive a token of appreciation for each part of the study in which they complete participation. Participants will receive a \$20 gift card for completing the questionnaire; a \$20 gift card for urine collection and attempted blood collection at the initial clinic visit; and an additional \$20 gift card if they complete both. No gift cards for any incidental expenses (such as travel) will be provided. Participants will receive their gift cards for up to \$60 as a token of appreciation at the clinic appointment for blood and urine collection, after signing the consent form.

Respondent-driven sampling (RDS) uses a chain referral sampling strategy. Referred individuals can present to scheduled clinics anytime during the date/hours on their referral coupon.

Eligibility screening, recruitment, and all biomonitoring study information collection occur at a single visit. Eligible respondents who provide informed consent and take part in the study will receive a gift card valued up to \$60 as a token of thanks, based on each part of the study in which they have participated. Along with the \$60 gift card, each respondent will be invited to refer others using referral coupons (Attachment 8c). Those who agree can recruit up to three other eligible respondents. WIDHS will give a \$15 gift card per successful recruit as thanks for the referring respondent's willingness to assist (Attachment 8d).

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The NCEH/ATSDR Information System Security Officer has reviewed this submission and determined that the Privacy Act does not apply.

Information in identifiable form (IIF) will not be part of the deliverables to ATSDR. WIDHS intends to collect the minimum amount of sensitive information necessary to meet the study objectives, contact and track participants in the program. WIDHS will acquire IIF permitting eligibility screening 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 WIDHS's established record system by their authorized and trained staff. All respondents will be consented and informed that their participation is voluntary, that they will not be named in any publications, and that they can choose to not answer any question. ATSDR will not receive identifying information including: name, address, residential history, and household demographics.

Blood and urine samples will be coded and sent to designated laboratories for chemical measurements. Hair samples will not be analyzed as part of this project and will be coded and stored for future analysis at WIDHS. Specimens will not have any identifying information on the labels. At the end of the study, samples will be stored by WIDHS. The storage of samples will be described in the consent form.

At the end of the study and as part of the program requirements, WIDHS will transfer de-identified data to ATSDR through a secure and encrypted file transfer protocol. Data received by ATSDR will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. Records will be retrievable by study ID number only. ATSDR will not receive any identifying information, including name, address, residential history, and household demographics. ATSDR will also not receive information that in 'raw' form may indirectly identify an individual. For example, occupation will be classified into one of the 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. 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.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

The *Great Lakes Biomonitoring III* is a non-research public health program (Attachments 12a and 12b). The biomonitoring results will not be generalized beyond the Milwaukee Estuary AOC and the defined subpopulations under study. Therefore, CDC/ATSDR IRB approval is not required (Attachment 12a). The WIDHS has reviewed and obtained its own local non-research determination (Attachment 12b). Although not human subjects as defined under 45 CFR 46 (for research only), the state interprets its own responsibilities to its respondents in a broader context.

Pregnant women will not be included in this study. Therefore, in addition to questions about chronic conditions, female participants will be asked to self-report their pregnancy status to determine their inclusion in the study. No information will be collected that are of personal or sensitive nature.

A.12. Estimates of Annualized Burden Hours and Costs

The burden estimates were based on estimates from WIDHS program staff. WIDHS plans to test its subpopulation-specific forms among fewer than 10 respondents. We anticipate that patterns of fish consumption will be the chief contributor to variability in questionnaire time burdens among the selected subpopulations. With respect to time burdens for the study questionnaires, the WIDHS questionnaire (Attachment 7b and 7c) for licensed urban anglers is estimated to take 30 minutes. The questionnaire (Attachments 7d) for the Burmese participants is estimated to take approximately 40 minutes. The Burmese and Karen questionnaires will take longer to administer than the angler questionnaire for two primary reasons: 1) the process of administering questionnaires to the Burmese participants involves translations, which are expected to add to the required time; and 2) there is additional content in the questionnaire for Burmese participants to include more culturally relevant questions about home remedies and fish preparation methods.

- A. Estimated annualized burden hours, averaged over the requested three-year approval period, are presented for each study population and in total. A detailed description of response rates for each information collection is given in Section B.1. The total estimated annualized time burden for all information collection activities is 225 hours.

Table A.12.1 Estimated Annualized Burden to Respondents

| Type of Respondents | Form Name | No. of Respondents | No. of Responses per | Avg. Burden per | Total Burden (in |
|---------------------|-----------|--------------------|----------------------|-----------------|------------------|
|---------------------|-----------|--------------------|----------------------|-----------------|------------------|

| | | | Respondent | Response (in hrs.) | hrs.) |
|--|--|------------------------------|------------|-----------------------|-------|
| Licensed Anglers | Eligibility Screening Survey (paper) | 156 | 1 | 5/60 | 13 |
| | Eligibility Screening Survey (screenshots) | 28 | 1 | 5/60 | 2 |
| | Study Questionnaire (paper) | 58 | 1 | 30/60 | 29 |
| | Study Questionnaire (screenshots) | 87 | 1 | 30/60 | 44 |
| | Clinic Visit Checklist and Body Measurements | 134 | 1 | 35/60 | 78 |
| | Follow-up Survey | 80 | 1 | 5/60 | 7 |
| | Burmese Immigrants and Descendants | Eligibility Screening Survey | 42 | 1 | 5/60 |
| Contact Information Form | | 34 | 1 | 5/60 | 3 |
| Study Questionnaire | | 34 | 1 | 40/60 | 22 |
| Clinic Visit Checklist and Body Measurements | | 34 | 1 | 35/60 | 19 |
| Network Size Questions | | 34 | 1 | 5/60 | 3 |
| Follow-up Survey | | 10 | 1 | 5/60 | 1 |
| Total | | | | | |

B. Estimated annualized burden costs are presented for each study population and in total. To estimate the cost to the respondent, the median hourly wage was selected for all occupations for the Milwaukee-Waukesha-West Allis, WI area.

On an annualized basis, WIDHS will recruit approximately 33 Burmese immigrants and descendants and 133 urban subsistence anglers located in the Milwaukee Estuary AOC each year of the three-year data collection. The 2015 median hourly wage that corresponded to Milwaukee-Waukesha-West Allis, WI was applied.

Table A.12-2. Estimated Annualized Cost to Respondents

| Type of Respondents | Total Burden* (in hours) | Hourly Wage Rate | Total Burden Costs |
|------------------------------------|-----------------------------|------------------|--------------------|
| Licensed Urban Anglers | 173 | \$17.88 | \$3,093 |
| Burmese Immigrants and Descendants | 52 | \$17.88 | \$930 |
| Program Grand Total | | | \$4,023 |

*Total burden hours are taken from the burden hour table in section A.12.1.

Source: BLS, 2015. *May 2015 Metropolitan and Nonmetropolitan Area Occupational Employment and Wage Estimates: Median Hourly Wage for All Occupations*. [http://www.bls.gov/oes/current/oesrcma.htm](http://www.bls.gov/oes/current/oessrcma.htm).

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

There will be no additional capital and maintenance costs for the *ATSDR Great Lakes Biomonitoring III* program for respondents or record keepers.

A.14. Annualized Cost to the Federal Government

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

The total estimated cost to the government is \$1.9 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 3 years.

The estimated average annualized cost of the program is \$ 633,000.

- Personnel: \$60,000 per year. This is based on percentages of time spent on the project by ATSDR staff.
- Travel: \$5,000 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 to fund this program: \$ 538,000 per year. This amount is based on the approved applications of the current grantee.
- Indirect Cost: \$30,000.

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, WIDHS 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 metal like lead, the principal investigator will provide advance notification to the respondents. Summary reports will be tabulated and released to the public.

Six months of the program period was dedicated to planning and protocol development. Upon receiving their first year awards, WIDHS has been working on outreach, health education, planning activities, piloting instruments for clarity and burden estimation (9 or fewer people), and protocol development and IRB review for data collection. The state also assisted the ATSDR in developing this ICR.

IC procedures will begin upon the date of OMB approval. Therefore, the three 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 | Estimated Time Schedule |
|---|---------------------------------|
| Formative work to learn about characteristics of the social networks in each target community for RDS and identification of 'seeds' | 1-2 months after OMB approval |
| Recruit and enroll, interview, and biological specimens collection for each subpopulation | 2-36 months after OMB approval |
| Laboratory analysis | 6-36 months after OMB approval |
| Data validation, data entry, data analysis complete | 6-36 months after OMB approval |
| Respondent results reporting complete | 18-36 months after OMB approval |
| Follow-up survey complete | 30-36 months after OMB approval |
| Summary study reports complete | 36 months after OMB approval |
| Data transfer to ATSDR | 36 months after OMB approval |

| | |
|--------------------------|----------------------------------|
| Publications and reports | Up to 5 years after OMB approval |
|--------------------------|----------------------------------|

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

The display of the OMB expiration date is appropriate.

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

There are no exceptions to the certification.

References

EPA. *Milwaukee Watershed Wiki Page*.

https://wiki.epa.gov/watershed2/index.php/Milwaukee_Watershed Accessed 13 January 2016.

Horevoorts, N. J., P. A. Vissers, F. Mols, M. S. Thong and L. V. van de Poll-Franse (2015). Response rates for patient-reported outcomes using web-based versus paper questionnaires: comparison of two invitational methods in older colorectal cancer patients. *J Med Internet Res* **17**(5): e111.

Sallumi, A., *Arrival of Burmese Refugees in Milwaukee*, M. Metcalf, Editor. 2015.