

Supporting Statement For OMB Review and Approval of

Agency for Toxic Substances and Disease Registry (ATSDR)

Biomonitoring of Great Lakes Populations Program III

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Supporting Statement Part B

Justification

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Part B. Collections of Information Employing Statistical Methods

The Wisconsin Department of Health Services (WIDHS) will look at two adult populations (licensed anglers and Burmese immigrants and their descendants) in the Milwaukee Bay Estuary Area of Concern (AOC) who are known to eat fish from the Milwaukee River Basin and Lake Michigan. 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.

The WIDHS biomonitoring program is not research and the biomonitoring results will not be generalized beyond the Milwaukee Estuary and the defined subpopulations under study. An overview/diagram of the information collection process for the state program can be found in Attachment 4a.

B.1. Respondent Universe and Sampling Methods

Respondent Populations

WIDHS has two respondent populations: (1) licensed anglers living in proximity to the Milwaukee Estuary AOC waterways who eat fish caught in the AOC (“licensed anglers”); (2) Burmese immigrants and their descendants who live in the City of Milwaukee and eat fish caught in the AOC waterways. Table 1 provides a snapshot of the respondent universe and number of respondents by study subpopulation. The catchment area for the licensed anglers will be the ZIP Codes within a 2-mile buffer of the AOC. The catchment area for the fish eaters from Burma is the City of Milwaukee. The target populations will be sampled, recruited, and enrolled independently. The desired number of respondents to complete the study was primarily determined by the level of available program funding (n=400 for licensed anglers and n=100 for Burmese immigrants and their descendants).

Table 1. Respondent universe and number of respondents by study subpopulation over three years

Licensed Anglers	Respondent Universe/Respondents	Estimated Response Rate
Eligibility Screening Survey	9,200	
Number of Eligible	1,840	20%*

Recipients		
Screening response	552	30%
Questionnaire response	434	80%
Study Participants who complete questionnaire and bio-specimens	400**	90%
Follow-up survey response	240	60%
Burmese Immigrants and their Descendants		
Screening response	184	
Number of Eligible Respondents	125	68%
Study Participants	100	80%
Follow-up survey response	30	30%

*Eligibility rate

**Enrolled on a first-come, first-serve basis to meet sex and age strata participation goals.

Licensed Anglers

The respondent population is defined as persons 1) aged 18 years or older, 2) purchased a Wisconsin state resident license which permits fishing for the 2015 season, and 3) with a residential address in the study areas. The type of licenses include resident annual fishing, resident conservation patron (includes Great Lakes trout stamp), and resident sports license.

Sampling method

The sampling frame for the licensed anglers will be drawn from a database of sport fishing and hunting licenses maintained by the Wisconsin Department of Natural Resources (WI DNR). The database contains all licenses sold and includes the following data fields: the type of license, the year it was purchased, the license holder's name, residential address, email address (optional), sex, and year of birth. Wisconsin law requires that any person 16 years of age or older must purchase a license and carry it on his/her person when he/she fishes or hunts in Wisconsin. Because the purchase of a license is required by law and functions similar to a driver's license, the license database is considered a complete and accurate list of sport (i.e., non-commercial) anglers. This database does not, by definition, capture persons who fish illegally.

The sampling frame will be created using the 2015 fishing license database. WIDHS expect that the sampling frame will be comprised of about 45,000 licenses, based on 2014 data provided by WI DNR. WIDHS will extract records (i.e., licenses) as follows: license type, ≥ 18 years of age at the end of 2015, and a residential address within the study area as defined above (as identified by geocoding). Records with non-geocodable address will be excluded. WIDHS will also sort and match records on various fields, such as name and address, to remove duplicate individuals (e.g.

individuals who purchased a sporting license and a Great Lakes Trout stamp). Because the response rate to the screening is expected to be relatively low, at this stage WIDHS will not exclude different individuals with the same address.

License holders in the sampling frame will be selected as a random sex-age stratified sample reflective of the target population of fishing license holders (Table 2). WIDHS will mail a recruitment package that includes a cover letter about the project (Attachment 5a), the screening survey (Attachment 5b), and a business reply envelope. The recipient can complete the mailed paper eligibility screening survey (Attachment 5b) or complete the survey online through REDCap (Attachment 5c). To be eligible, the license holder must: (1) have lived within the study area for at least one year before the screening date; (2) have eaten at least one fish caught in an AOC water body (including near-shore Lake Michigan) in the last 12 months; (3) have been at least 18 years old at the time of eligibility screening; (4) confirm that they are not pregnant (if female) and; (5) responded to the screening survey.

Response rate

WIDHS will randomly select a sample of 9,200 anglers in the sampling frame in order to provide a sufficient number of licensed anglers to recruit 400 participants. WIDHS plans to send initial recruitment packets and screening surveys to 9,200 anglers. Of those, WIDHS estimates that 1,840 anglers (20%) will meet all eligibility criteria (limited by consumption of fish, which is the only unknown factor). Based on response rates to previous surveys, WIDHS estimates a 30% response rate (i.e. 552 anglers will fill out the screening survey, Table 3).

Of those who respond to the screening survey, WIDHS estimates a 72% completion rate to reach 400 participants who complete the study questionnaire, attend clinic visit, and provide biological specimens. Study staff will call eligible respondents, confirm the eligibility and willingness to participate, and schedule an appointment. At this stage, study staff will also confirm that there are no other enrolled participants at the same address, using REDCap to cross-reference. For this step, WIDHS estimates that 442 anglers (80% of those who responded to the screening survey) will be successfully contacted by study staff via telephone. Of those, we estimate 434 (98%) will agree to participate and will be sent the survey and scheduled for an appointment. Of those, WIDHS estimates that 400 (90%) will fully complete the study survey and clinic visit. Nonresponse bias for response to the screening survey will be assessed between people who respond to the screening questionnaire and those who do not using data extracted from the fishing license database. Nonresponse bias among eligible respondents will be evaluated by using data collected as part of the screening survey.

At the end of the project after result reporting, participants will receive a follow-up survey (Attachment 9a), which may be approximately 1 to 1.5 years after initial study activities. The follow-up survey will ask for feedback on this project and will not ask for sensitive information. WIDHS estimates a 60% response rate for the follow-up survey among the licensed angler participants.

Table 2. Recruitment goals for licensed anglers, by sex and age

Sex	Age Group	TOTAL
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	N (%)		
	18 to 45	46 and older	
Female	60 (15%)	40 (10%)	100 (25%)
Male	180 (45%)	120 (30%)	300 (75%)
TOTAL	240 (60%)	160 (40%)	400 (100%)

Table 3. Recruitment steps and number of anglers to reach participation goals, assuming 30%, 50% and 70% response rates

Recruitment step	30% Response Rate	50% Response Rate	70% Response Rate
Fishing licenses (# anglers)	45,000	45,000	45,000
Randomly select	20.4%	12.3%	8.8%
Eligibility screening survey (# anglers)	9,200	5,520	3,945
Eligibility rate	20%	20%	20%
Number of eligible recipients	1,840	1104	789
Response rate	30%	50%	70%
Screening response	552	552	552
Completion rate	72%	72%	72%
Participants (#anglers)	400	400	400

Burmese Immigrants and their Descendants

Sampling method

Because there is no known sampling frame for the Burmese immigrants and their descendants who eat fish from the AOC, respondent-driven sampling (RDS) will be used. RDS is suitable for reaching “hidden” populations for which there is no known sampling frame. RDS has been shown to increase efficiency and decrease cost compared to other sampling designs and has been shown to be suitable for refugee populations. For several reasons, RDS will be an effective approach for recruiting Burmese participants. By virtue of being refugees, the Burmese are connected socially, culturally, geographically, and, to some extent, politically. Second, information about the Burmese population living in Milwaukee indicates that individuals will have knowledge of each other’s fishing and fish consumption habits. Third, high participation rates can be achieved because RDS uses peer-recruitment. The initial recruits, referred to as seeds, will be individuals who are well-connected and respected in the community and interested in participating in the project. These assumptions will be verified during formative research. RDS has been shown to be effective in earlier Biomonitoring of Great Lakes Programs I and II (TS10-1001 and TS13-1302).

The RDS process will start with a formative research phase during which WIDHS staff work with a local community group and individuals in the community to identify the “seeds.” A seed

is an initial recruiter who meets the eligibility criteria and is a member in good standing of the community. WIDHS staff will select 3 to 6 seeds that have large social networks. If the study staff learns that women and men have limited social interactions (are less likely to recruit peers of the opposite sex), male and female seeds will be selected, or if social interactions are closer among certain ethnic or political subgroups, the seeds will be identified based on these characteristics.

An overview of data collection process is described in details in section A.2. Eligibility for the study will be determined using a screening survey, administered via telephone or in-person by trained study staff. The survey, as well as the interview questionnaire, will be translated into Burmese and Karen and administered by a Burmese or Karen interpreter. By definition, seeds are eligible to participate. In addition to the eligibility criteria listed above, to be eligible, recruited individuals must know the recruiter, not be a member of the recruiter's household, and not have already participated in the project (as a licensed angler or Burmese participant who eats their catch).

After completing the interview in person and providing blood, hair (optional), and urine samples, each seed is trained on how to recruit other people from the Burmese community into the study. Each seed will receive three referral coupons to distribute to individuals in his/her network. The coupons are uniquely numbered, so that the recruiter can be linked to his/her recruits, and include instructions on how the recruited peer can participate in the project. A recruit brings the coupon to a site, is screened for eligibility, and is invited to complete the procedures. The participant is then offered the chance to be a recruiter and, if he/she accepts, is trained and given three coupons. Seeds and recruiters will receive a gift card as a token of appreciation for each person who is eligible and completes the procedures. To successfully use RDS, WIDHS will set remuneration appropriately, ration the coupons (3 per recruiter), track the coupons associated with each recruiter (including the seeds), record the network size of each recruiter, and document the relationship of the recruit to the recruiter. As WIDHS approaches the target enrollment, they will add an expiration date to the coupons and reduce the number of coupons per participant (for example, two coupons when we reach 80% of the enrollment goal, one coupon when we reach 95%).

Each set of recruits from a single recruiter is a recruitment "wave." The recruitment process continues until either enrollment goals have been met or equilibrium is reached. Equilibrium is the expected sample composition had the initial participants been selected at random. As part of RDS we will track the traits of the participants, including sex, age, the neighborhood where they reside (current address), and how many years they have lived in the U.S. We expect that we can reach our goal of 100 Burmese participants quickly using RDS, provided that each participant can make three referrals and that participation is high. For example, one seed (wave 0) recruits three people, all three show up at the project site, and two are eligible and participate (screening and participation occur at the same place and time). This wave (wave 1) produces two new participants. If this scenario continues through four waves, one seed will generate 31 participants and six seeds will generate 186 participants. Some seeds may "dry out." It is therefore preferable, when possible, to balance the number of seeds against the number of recruitment waves expected to reach the enrollment goal.

Response rate

Using a networking driven sampling strategy appropriate for ‘hidden populations’ such as refugees and immigrants from Burma, it is estimated that 68% of respondents to RDS recruitment will be eligible. Based on previous programs, WIDHS estimates that 80% of those eligible will enroll and complete the study. A high participation rate can be achieved because the respondent-driven sampling (RDS) strategy uses peer-recruitment. The initial recruits, referred to as seeds, will be individuals who are well-connected and respected in the community and interested in participating in the project. The respondent driven sampling strategy affords a dual incentive system that helps maximize response. In addition to the typical material incentive that programs provide as a token of appreciation, RDS uses peer-recruitment and thus has a social incentive for people to participate. The enrollment goal for the Burmese target population is 100 persons who eat fish caught from the AOC waterways.

At the end of the project after result reporting, participants in this study will receive a follow-up survey (Attachment 9b), which may be approximately 1 to 1.5 years after initial study activities. The follow-up survey will ask for feedback on this project and will not ask for sensitive information. Given that literacy is likely to be a problem in this community, WIDHS estimates a response rate of 30% for the follow-up survey among the Burmese participants.

B.2. Procedures for the Collection of Information

Licensed Anglers

Recruitment will continue until achieving the target enrollment of 400 licensed anglers. Recruitment will occur on a first-come first-serve basis until the recruitment goal has been met for each sex and age strata. Recruitment packets (Attachment 5a) will be mailed out in batches to 1,314 individuals at a time to facilitate scheduling. After two weeks, non-respondents will receive a follow-up postcard as a reminder to complete the screening survey. Three weeks after the reminder mailing, the initial recruitment packet will be mailed again to non-respondents. Eligibility will be determined from information in the license database and responses to the screening survey completed via mail or online (through REDCap) (Attachments 5b and 5c).

If the respondent meets eligibility criteria and provided necessary contact information, he/she will be contacted by project staff to confirm interest and schedule an in-person clinic appointment within two weeks from when screening survey is received, until sex and age recruitment goals are met. Three phone calls will be attempted to reach each person. If no contact is made after three calls, then an email will be sent to the participant. If still no contact is made, then two more phone calls will be made before the person is dropped from the contact list. To be enrolled in the study an angler must (1) be interested in participating, (2) be physically able to participate (i.e., travel and donate blood, hair, and urine; complete an online or paper version of the survey), and (3) schedule an appointment to complete specimen collection. During the phone call (Attachment 5e) with the eligible participant project staff will inform the participant that

they will be sent the survey one week prior to their in-person appointment. The participant will be asked how they would prefer to receive the survey; options include receiving a URL to access the survey online via REDCap or to be sent the paper survey. Their preference will be noted in the tracking database. Paper surveys will be mailed to participants who indicate that they do not have internet access to complete the survey online. A reminder call will be made a few days before the appointment confirming the date and location of the appointment and other pertinent information (such as directions to the sampling location, persons to contact for questions, an additional reminder to complete the survey). This step is estimated to take up to four weeks.

One week prior to the in-person appointment, project staff will mail and email an appointment reminder (Attachment 5f) letter to each participant that will include the following: date, time, and location of appointment. This letter will also provide the URL to access their survey electronically in REDCap. The letter will inform the participant that by completing the survey ahead of their appointment that they are implying their consent to complete it. The email will also include a copy of the consent form (Attachment 6a) so that the participant can review it prior to their appointment. Project staff will review all completed surveys for completeness and accuracy prior to the appointment.

The study will be conducted in an appropriate community location (e.g., local health department, church, University space) which will allow privacy for specimen collection. The identity of the participant will be verified. The participant will have a quiet place to read the consent document (Attachment 6a), which will be available in English and Spanish. Project staff will not verify eligibility at the appointment because we have verified eligibility in the screening and enrollment phases. We expect that some participants will be found ineligible based on the data collected during the interview, but we will let the participant complete the visit rather than turn him/her away after making the effort to come to the clinic. In addition, some participants will be unable to donate a specimen or the specimen may become unusable (e.g., clotted or contaminated). The former will be considered post-participation ineligible and the latter post-participation incomplete. For the ineligible participants and those without a usable specimen, any data that are collected will be omitted from the final datasets.

After the consent process, study staff will administer the questionnaire (Attachment 7b) and enter the participant's responses into REDCap, if the participant did not complete the questionnaire online before the visit. If the participant completed a paper copy of the questionnaire before the visit, the paper questionnaire will be collected and the responses will be entered into REDCap by study staff. Project staff will take body measurements (weight, height, and blood pressure), and the participant will provide a blood sample, a urine specimen and a hair sample (Attachment 8a).

At the end of the appointment, the participant will receive a copy of the consent document and gift cards for up to \$60 as a token of appreciation for participating in the project. Participants will receive a \$20 gift card for completing the questionnaire; a \$20 gift card for urine collection and attempted blood collection; and an additional \$20 gift card if they complete both. No gift cards for any incidental expenses (such as travel) will be provided.

After participants receive their biomonitoring results (Attachment 10a and 10b) and the study staff have generated some preliminary results, the study team will contact participants to obtain

feedback about the project (Attachment 9a). Questions in the follow-up survey will cover the participants' experience and understanding of the materials they received throughout the study, and will provide information on how to improve future studies.

Burmese Immigrants and their Descendants

For recruitment, enrollment and screening of non-English speakers, the local organizations assisting with the program will help identify and train interpreters to serve as interviewers. The recruitment script, eligibility survey, consent form and questionnaire interview will be translated into Burmese and Karen and administered by trained interpreters for corresponding non-English speakers.

All contact, consent and data collection documents for the Burmese subpopulation can be found in Attachments 5d, 6b, 7a, 7d, and 7e. After confirming the prospective participant's eligibility, he/she will be given a quiet place to read the consent document, which will be available in English and the participant's primary Burmese language. If a participant expresses difficulty with reading, the consent document will be read to them by an interviewer or trained interpreter. Before beginning any procedures, a trained interviewer or trained interpreter will ask the participant if he/she has any questions. When the participant's questions have been answered to his/her satisfaction, the participant and the interviewer will sign the consent form. After obtaining signed informed consent (Attachment 6b), participants will be administered a contact information form (Attachment 7a), a questionnaire interview (Attachment 7d), and a network size questionnaire for RDS (Attachment 7e). Then the participants will have their body measurements taken and provide a blood, urine and hair (optional) sample (Attachment 8b).

Upon completing the project activities, each participant will be invited to be a recruiter. If the participant is interested, he/she is trained to recruit other persons like him/herself. Each recruiter is then given three referral coupons and three payment coupons (Attachment 8c). The coupons have the name, address, and a photograph of the project site, the dates during which the coupons are valid, and the same unique coupon number. The coupon number allows the program to link the recruiter to his/her recruits. In addition, the referral coupon does not list any information about the project so that the recruiter must actively recruit new participants. The recruitment steps are as follows:

1. The recruiter gives the referral coupons to up to three people in his/her network (i.e., recruits) and keeps the payment coupons.
2. The recruit takes the referral coupon to the project site, where he/she will be screened for eligibility, will be invited to participate (if eligible), and will complete the procedures.
3. The recruiter returns the payment coupons to the project site and will receive a gift card if the corresponding recruits were eligible and participated in the project.

At the end of the appointment, the participant will be given a copy of the consent document along with their gift card as a thank you for participating. Participants will receive a \$20 gift card for completing the questionnaire, a \$20 gift card for the blood and urine collection, and an

additional \$20 gift card if they complete both. Hair sample collection participation is optional. If the participant chooses to be trained to recruit new participants, he/she will be given a \$15 gift card for each referral who is screened, eligible, and agrees to participate. In addition to the clinic incentives, participants will be given at most \$45 for recruiting three peers.

After participants receive the results of their biomonitoring and the study staff have generated some preliminary results, the study team will contact participants to obtain feedback about the project (Attachment 9b). Questions in the follow-up survey will cover the participants' experiences and understanding of the materials they received throughout the study, and will provide information on how to improve future studies.

B.3. Methods to Maximize Response Rates and Deal with No Response

Licensed Anglers

An initial sampling frame of licensed anglers is estimated to include approximately 45,000 individuals in the study area. We will contact a randomly selected sample of 20.4% of the anglers in the study area. This should provide a sufficient number of licensed anglers to reach our participation goals. We anticipate a 20% eligibility rate, a 30% response rate among those eligible, and a 72% of completion rate among those who responded to the screen survey.

WIDHS has taken several steps to maximize the response rate, described in earlier sections: providing the option for participants to fill out the screening questionnaires and study surveys online, following up with potential participants to remind them to complete the screening process, and by providing a token of appreciation of up to \$60 for participating in the project.

Burmese Immigrants and their Descendants

As a means to promote trust with the state program and maximize response rates, the WIDHS will work with community partners to conduct outreach, recruitment and enrollment, and screening activities. WIDHS will collaborate with local organizations such as International Institute of Wisconsin (<http://www.iiwisconsin.org>) to support outreach and study recruitment, and to maximize response rates for the Burmese subpopulation.

A high participation rate can be achieved because the RDS strategy uses peer-recruitment. RDS has been shown to be an effective approach for recruiting target populations within social networks. The initial recruits, referred to as seeds, will be individuals who are well-connected and respected in the community and interested in participating in the project. The respondent driven sampling strategy affords a dual incentive system that helps maximize response. In addition to the typical material incentive that programs provide as a token of appreciation, RDS uses peer-recruitment and thus has a social incentive for people to participate.

Consistent with previous ATSDR grantees, efforts to maximize participation also include providing tokens of appreciation. Burmese participants will be given gift cards for up to \$60 as a

token of appreciation for participating in the project. In addition, as part of the RDS, if the participant chooses to be trained to recruit new participants, he/she will be given a \$15 gift card for each referral who is screened, eligible, and agrees to participate. In addition to the clinic incentives, participants will be given at most \$45 for recruiting three peers.

B.4. Test of Procedures or Methods to be Undertaken

WIDHS will pilot the questionnaire interview and screening surveys on up to four people representative of each of their target audiences, with the total number of pilot subjects being less than ten. Pilot testing serves to identify questionnaire items that were not clear and to evaluate the burden that each item as well as total items posed. Questionnaire items will be refined and items that pose a significant time burden for the information gained will be revised or eliminated.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

B.5.1 Study design and sampling plan:

The study design and sampling plan were adapted from prior experience in the FY 2010 and FY2013 Biomonitoring of Great Lakes Populations I and II (OMB Control No: 0923-0044 and 0923-0052). Modifications were developed as a collaborative process between ATSDR subject matter experts, WIDHS staff, and program-specific consultants and contractors.

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WIDHS has a contract with the University of Wisconsin-Madison (UW-Madison) to provide staffing and technical support for project activities such as study design, data analysis, and reporting. Additionally, WIDHS will contract with the Survey of the Health of Wisconsin (SHOW), which is operated through the School of Medicine and Public Health at UW-Madison, to conduct screening and recruitment activities.

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B.5.2 Questionnaire design

The questionnaire surveys were designed as a collaborative process between ATSDR program staff, WIDHS staff, and program-specific consultants and contractors.

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B.5.3 Data collection

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B.5.5 Data Analysis

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References

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