January 10, 2018

**Change Request for OMB Control No. 0923-0056: Biomonitoring of the Great Lakes Populations Program III**

Justification

This is a nonmaterial/non-substantive change request for OMB Control No. 0923-0056 (expiration date: July 30, 2020). OMB granted approval for data collection for a cooperative agreement program involving the Wisconsin Department of Health Services (WI DHS).

Due to recruitment challenges experienced by the awardee, ATSDR is requesting approval for non-substantive changes to expand the recruitment boundary of the waterbodies on behalf of the WI DHS.

*Licensed Angler Respondents:* WI DHS is currently in the enrollment phase for their licensed angler subpopulation and has experienced severe recruitment challenges in this project. The target enrollment for this subpopulation is 400 licensed anglers. Since their initial recruitment wave in August 2017, WI DHS has mailed out three waves totaling 4,800 recruitment packets and received only 52 eligible responses as of December 28, 2017. The reason for the low rate of eligible responses is now believed to be due largely to the restrictive boundary for the waterbodies included in the study.

WI DHS study staff received feedback from interested screening survey respondents on more common fishing locations that are outside the current waterbody boundaries of this study. After consulting with their project partners and Advisory Committee, the awardee has requested to expand the boundaries for the waterbody of interest from the strict Milwaukee Estuary Area of Concern to a more general area around Milwaukee that contain additional waterbodies with known contamination and fish advisories. This change can increase eligibility and enrollment rates while still fitting the scope and purpose of the Biomonitoring of the Great Lakes Populations Program III as defined in the Funding Opportunity Announcement. Only by increasing eligibility and enrollment rates will the program achieve the target enrollment numbers within the timeline as defined in the cooperative agreement.

*Burmese Respondents:* Recruitment for the Burmese subpopulation will begin in Spring 2018. The awardee is requesting approval for the same boundary expansion to apply to this respondent group’s eligibility criteria and data collection.

Proposed Changes are reflected in the revised Supporting Statements and in the attachments described below:

1. *Expanded geographic area of eligible waterways: T*he description of these waterways is in many of the communication materials and data collection forms; therefore, each of those materials will need to be updated to include the new description of the waterbodies. We have provided a table showing the crosswalk between the original and the revised forms below.
	1. The six revised Information Collection Forms with the updated waterbodies of interests are:
		1. Attachment 5b. Eligibility Screening Survey for Licensed Anglers (paper)
		2. Attachment 5c. Eligibility Screening Survey for Licensed Anglers (screenshots)
		3. Attachment 5d. Eligibility Screening Survey for Burmese Immigrants and their Descendants
		4. Attachment 7b. Study Questionnaire for Licensed Anglers (paper)
		5. Attachment 7c. Study Questionnaire for Licensed Anglers (screenshots)
		6. Attachment 7d. Study Questionnaire for Burmese Immigrants and their Descendants

Below is the change request cross-walk table for all information collection forms. Attached please find the revised documents with both a clean version and track-change version for each document.

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| --- | --- | --- |
| **Information Collection Forms**  | **Requested Change** | **Justification** |
| 5b. Eligibility Screening Survey for Licensed Anglers, paper version | 3. In the past 12 months, I ate at least one fish meal that was caught in ~~the bodies of water listed below~~ any of the lakes, rivers, streams, or ponds pictured in the map printed on the back of this page.*~~Please look at the enclosed maps and read this list of bodies of water. We want to know if you have eaten fish that were caught in any of these rivers, creeks, lakes, or ponds.~~** ~~Cedar Creek~~
* ~~Milwaukee River~~
* ~~Little Menomonee River~~
* ~~Menomonee River~~
* ~~Kinnickinnic River~~
* ~~Lincoln Creek~~
* ~~Near-shore waters of Lake Michigan near downtown Milwaukee~~
 | Update definition and map of waterbodies of interest for this study |
| 5c. Eligibility Screening Survey for Licensed Anglers, electronic version (screenshots) | ~~Please look at the map below and read the list of bodies of water. We want to know if you have eaten fish that were caught in any of these rivers, creeks, lakes, or ponds:-Cedar Creek~~~~-Milwaukee River~~~~-Little Menomonee River~~~~-Kinnickinnic River~~~~-Lincoln Creek~~~~-Near-shore waters of Lake Michigan near downtown Milwaukee~~Please look at the map below of Milwaukee and the surrounding southeastern area of Wisconsin when answering the next question. | Update definition and map of waterbodies of interest for this study |
| 5d. Eligibility Screening Survey for Burmese Immigrants and their Descendants | During the past 12 months, did you eat at least one fish meal caught in any of the water bodies pictured below? Show map ~~of Milwaukee AOC water bodies.~~ | Update definition and map of waterbodies of interest for this study |
| 7b. Study Questionnaire, Licensed Anglers, paper version | See tracked changes version attached, updated questions about local waterbodies and fish consumption | Update definition and map of waterbodies of interest for this study |
| 7c. Study Questionnaire, Licensed Anglers, electronic version (screenshots) | See tracked changes version attached, updated questions about local waterbodies and fish consumption | Update definition and map of waterbodies of interest for this study |
| 7d. Study Questionnaire, Burmese Immigrants and their Descendants | See tracked changes version attached, updated questions about local waterbodies and fish consumption | Update definition and map of waterbodies of interest for this study |

* 1. The seven attachments with revised supplemental information to support the modified forms listed above are found in:
		1. Attachment 4a. Program Overview
		2. Attachment 4b. Map of Waterbody of Interest
		3. Attachment 5a. Recruitment Mailings
		4. Attachment 5e. Phone scripts for Licensed Anglers
		5. Attachment 6a. Consent Form for Licensed Anglers
		6. Attachment 6b. Consent Form for Burmese Immigrants and their Descendants
		7. Attachment 8c. Example Referral Coupons
	2. We estimate that up to 55 participants will have already completed data collection under the original waterbody definitions. WI DHS is requesting approval to re-contact this initial group to ask seven clarifying questions related to eating fish caught in the expanded waterbodies. For the re-contact, phone scripts have been revised in *Attachment 5e* noted above. To collect this additional information, we request to add one new attachment:
		1. Attachment 7f. Updated Questions on Fish Consumption
1. *Small Increase in Annualized Total Burden Hours:* We request the time burden be modified to add 2 additional annual burden hours to accommodate the addition of updated questions on fish caught in the expanded waterbodies (*Attachment 7f).* The annualized estimate is calculated below:
	1. 55 initial respondents ÷ 3 years = 18 respondents (with 1 response each) per year
	2. 18 annualized respondents X 5/60 hours = 1.5 hours per year rounded to 2 hours per year).
2. *Expanded residency boundary for Licensed Angler:* WI DHS plans to expand their sampling pool by increasing the radius of the residency for randomly selected licensed anglers from 2 miles to 5 miles around the Milwaukee Estuary AOC, if the existing pool of licensed anglers within 2 miles is exhausted. This change will not require any revisions to information collection forms.