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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day-17-17IY]

Agency Forms Undergoing Paperwork Reduction Act Review

The Agency for Toxic Substances and Disease Registry (ATSDR) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

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

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a three-year Paperwork Reduction Act (PRA) clearance for a new information collection request (ICR) titled "Biomonitoring of Great Lakes Populations Program III." ATSDR awarded funds to the Wisconsin Department of Health Services

(WIDHS) to conduct this information collection under cooperative agreement #NU61TS000269-01-00. The purpose of the current program is to evaluate body burden levels of legacy and emerging contaminants in susceptible Great Lakes populations in the Milwaukee Estuary Area of Concern (AOC) in Wisconsin, an area that has not been previously covered by Great Lakes Biomonitoring Programs I and II.

The Great Lakes Basin has suffered decades of pollution and ecosystem damage. Many chemicals persist in Great Lakes waters and sediments, as well as in wildlife. These chemicals can build up in the aquatic food chain, and eating contaminated fish is a known route of human exposure. In 2016, ATSDR initiated the Biomonitoring of Great Lakes Populations Program III to provide additional public health information to supplement the previous cooperative agreement programs CDC-RFA-TS10-1001 "Biomonitoring of Great Lakes Populations" (hereafter referred to as "Program I," OMB Control Number 0923-0044) and CDC-RFA-TS13-1302 "Biomonitoring of Great Lakes Populations-II" (hereafter referred to as "Program II," OMB Control Number 0923-0052) initiated in FY2010 and FY2013, respectively.

WIDHS received funding for the current program. WIDHS will recruit and enroll two subpopulations of adults in the Milwaukee Bay Estuary Area of Concern (AOC) who are known to eat fish from

the Milwaukee River Basin and Lake Michigan. This study will not include pregnant women.

The target populations are: (1) licensed anglers living in proximity to the Milwaukee Estuary AOC and (2) Burmese immigrants and their descendants who are known to eat a substantial amount of fish from this area. WIDHS study staff will work closely with local refugee and citizen support organizations on participant recruitment.

The aims of the information collection in this surveillance project are:

1. Assess levels of contaminants (metals, polychlorinated biphenyls, chlorinated pesticides, perfluorinated compounds, and polyaromatic hydrocarbons) in blood and urine of residents who consume fish from contaminated areas that had not been studied in previous Programs I and II;
2. Use the project findings to inform public health officials and offer guidance on public health actions to reduce exposure to Great Lakes contaminants.

This applied public health program aims to measure contaminants in biological samples (blood and urine) from people who may be at high risk of chemical exposure in the Great Lakes area. These measurements will provide a baseline for current and future restoration activities. The results will be compared to

available national estimates, such as those reported by the National Health and Nutrition Examination Survey (NHANES).

Respondents will be screened for eligibility and consent will be obtained. Participants who consent will respond to a questionnaire and participate in clinic visits for body measurements and biological specimen collection (blood, urine, and hair). Their blood will be tested for polychlorinated biphenyls, metals, perfluorinated compounds, persistent pesticides, and lipids. Urine will be tested for polycyclic aromatic hydrocarbons and creatinine. The hair samples (optional) will be saved for a later analysis.

Respondents will also be interviewed. They will be asked about demographic and lifestyle factors, hobbies, health conditions that may affect fish consumption and fishing habits, and types of jobs which can contribute to chemical exposure. Some dietary questions will be asked with a focus on consumption of Great Lakes fish.

Participation in the study is voluntary. The estimated annualized burden for the program averaged over the three-year study period is a maximum of 225 hours. There is no cost to respondents other than their time spent in the study.

Estimated Annualized Burden Hours

| Type of | Form Name | No. of | No. of | Avg. |
|---------|-----------|--------|--------|------|
|---------|-----------|--------|--------|------|

| Respondents | | Respondents | Responses per Respondent | Burden per Response (in hours) |
|--|--|-------------|--------------------------|--------------------------------|
| Licensed Anglers | Eligibility Screening Survey (paper) | 156 | 1 | 5/60 |
| | Eligibility Screening Survey (screenshots) | 28 | 1 | 5/60 |
| | Study Questionnaire (paper) | 58 | 1 | 30/60 |
| | Study Questionnaire (screenshots) | 87 | 1 | 30/60 |
| | Clinic Visit Checklist and Body Measurements | 134 | 1 | 35/60 |
| | Follow-up Survey | 80 | 1 | 5/60 |
| Burmese Immigrants and their Descendants | Eligibility Screening Survey | 42 | 1 | 5/60 |
| | Contact Information Form | 34 | 1 | 5/60 |
| | Study Questionnaire | 34 | 1 | 40/60 |
| | Clinic Visit Checklist and Body Measurements | 34 | 1 | 35/60 |
| | Network Size Questions | 34 | 1 | 5/60 |
| | Follow-up Survey | 10 | 1 | 5/60 |

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