

Biomonitoring of the Great Lakes Populations Program:

**Circumstances of Change Request for OMB #0923-0044**

This is a change request for OMB protocol #0923-0044 (expiration date: October 31, 2015). OMB approval was granted for data collection for a cooperative agreement program involving three state health departments (Michigan Department of Community Health, New York State Department of Health and Minnesota Department of Health).

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.

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. 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 are no requested modifications to the previously approved Biomonitoring Questionnaire.

Previously enrolled study participants who consent to repeat the study will be given \$25 gift cards as a thank you for answering the questions, another \$25 gift card as a thank you for providing blood and urine samples, and another \$25 gift card for completing both parts of the study, for a total of up to \$75 in gift cards.

A modified Supporting Statement A is provided that addresses the proposed changes to the data collection.

We would appreciate your expedited consideration of this request.