Date: January 6, 2017

To: Jon Meiman, MD

From: DHS Human Subjects Protection Committee (HSPC)

Participants: Henry A. Anderson, MD
Jeffrey P. Davis, MD
Jon Meiman, MD - abstained
Mark E. Moss, DDS, PhD
James Vergeront, MD
Mark V. Wegner, MD, MPH

Subject: Biomonitoring of Urban Anglers in Milwaukee's Area of Concern

The HSPC constituted under FWA# 00002517 and per its authority under WI ss:154 (Chapter 1) met on January 5, 2017 from 3:00 pm until 3:45 pm to discuss the above plan to conduct biomonitoring of 500 adults (age 18 and older) living within a two mile radius of Milwaukee's Area of Concern who consume fish caught locally. No advance comments or concerns were received. In attendance at the meeting were: Henry A. Anderson, MD, Mark E. Moss, DDS PhD, James Vergeront, MD and Mark V Wegner, MD, MPH. Jon Meiman, MD, presented the study for review.

The proposed project and materials were presented, reviewed, and discussed. This report serves as the minutes of that meeting.

The HSPC determined that the biomonitoring plan meets the standards for public health practice in compliance with existing Wisconsin Statutes. The HSPC concluded that the proposed biomonitoring plan was not research, was public health practice and was therefore exempt from external (formal) IRB review and oversight. The opinion was unanimous.

Committee Comments:

From a public health perspective biomonitoring of potentially toxic substances, surveillance and program evaluation are core activities that provide the information necessary to effectively set priorities, target preventive interventions and determine whether programs are implemented as planned and following best practices. The need for informed consent of participants and maintenance of participant anonymity was appropriately addressed.

Mark E Moss, DDS, PhD
On behalf of DHS Human Subjects Protection Committee

Health Sciences
Institutional Review Boards

UW-Madison QI/Program Evaluation Self-Certification Tool

Purpose:
Projects that do not meet the federal definition of research pursuant to 45 CFR 46 do not require IRB review. This tool was developed by the HS-IRBs to assist the UW-Madison community in determining when a project falls outside of the IRB's purview.

Instructions:
Please complete the requested project information, as this document may be used for documentation that IRB review is not required. Select the appropriate answers to each question in the order they appear below. Additional questions may appear based on your answers. If you do not receive a STOP HERE message, the form may be printed as certification that the project is "not research", and does not require IRB review. Please note that the Health Sciences IRBs Office *does not maintain copies of your responses*.

Name of Project Lead/Investigator:

Jon Meiman

Project Title:

Biomonitoring of Urban Anglers in Milwaukee's Area of Concern

Brief Description of Project/Goals:

This is a cross-sectional biomonitoring study that aims to summarize exposures to legacy and emerging environmental contaminants among residents living near the Milwaukee Estuary area of concern (AOC). Specific objectives include:
• Describe the body burdens of legacy and emerging contaminants in a community living in close proximity to Milwaukee's AOC.
• Identify fish consumption habits and other activities leading to exposures to contaminants in this community.
• Develop comprehensive, culturally and linguistically appropriate outreach and education materials to better inform local residents about risks and benefits of consuming fish, with a focus on impacted waterbodies.
Gathering these data will help to fill gaps in current biomonitoring activities in Wisconsin by targeting a particularly vulnerable population, and using the results to inform remediation efforts, health advisories, and outreach activities.

School/College/Center through which the project will be conducted:

Medicine and Public Health (SMPH)

Q1: Will the project involve testing an experimental drug, device (including medical software or assays), or biologic? [**More Info**]

Yes

No

Q2: Has the project received funding (e.g. federal, industry) to be conducted as a human subjects research study? [**More Info**]

Yes

No

Q3: Is this a multi-site project (e.g. there is a coordinating or lead center, more than one site participating, and/or a study-wide protocol)? [**More Info**]

Yes

No

Q4: Is this a systematic investigation designed with the intent to contribute to generalizable knowledge (e.g. testing a hypothesis; randomization of subjects; comparison of case vs. control; observational research; comparative effectiveness research; or comparable criteria in alternative research paradigms)? [**More Info**]

Yes

No

Q5: Will the results of the project be published, presented or disseminated outside of the institution conducting it? [**More Info**]

Yes

No

Q6: Will the project occur regardless of whether individuals conducting it may benefit professionally from it? [**More Info**]

Yes

No

Q7: Is the project intended to improve or evaluate the practice or process within a particular institution or a specific program? [**More Info**]

Yes

No

The project appears to constitute QI and/or Program Evaluation and IRB review is not required because, in accordance with federal regulations, your project does not constitute research as defined under 45 CFR 46.102(d). If the project results are disseminated, they should be characterized as QI and/or Program Evaluation findings. Finally, if the project changes in any way that might affect the intent or design, please complete this self-

certification again to ensure that IRB review is still not required. Click the button below to view a printable version of this form to save with your files, as it serves as documentation that IRB review is not required for this project.

Current Date: 12/13/2016