

Attachment 9. Determination of Non-research Status

ATSDR Determination Letter of Non-research Status





U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Agency for Toxic Substances
and Disease Registry
Atlanta GA 30333

Date: December 15, 2010

From: Vikas Kapil, DO, MPH, FACOEM, Associate Director for Science &
Chief Medical officer 
NCEH/ATSDR

Anne Sowell, PhD, Assistant Director for Science
Division of Health Studies, ATSDR 

Subject: Nonresearch Determination for the ATSDR Great Lakes Biomonitoring Program
(CDC-RFA-TS10-1001)

To: Steve Dearwent, PhD, Chief
Health Investigations Branch, Division of Health Studies, ATSDR

Wendy Wattigney, MS, Project Officer
Health Investigations Branch, Division of Health Studies, ATSDR

In your previous submission regarding the Great Lakes Biomonitoring Program, you provided the following information: the objective of the Program is to provide a baseline assessment of the exposure to persistent toxic substances in the Great Lakes ecosystem among residents, particularly those who are at high risk of exposure. In September 2010, the Centers for Disease Control and Prevention's (CDC) Programs and Grants Office awarded three cooperative agreements to the state health departments in Michigan, Minnesota, and New York to assist in this effort. The data that will be collected by these state partners will be used to make jurisdiction-specific public health decisions.

We determined that the Great Lakes Biomonitoring Program is consistent with CDC's definition of a nonresearch public health activity. As outlined in CDC-SA-2010-02, Policy for *Distinguishing Public Health Research and Public Health Nonresearch*, the purpose of non-research activities is "to prevent or control disease or injury and improve health, or to improve a public health program or service." The purpose of the activity should be "to benefit clients participating in a public health program or a population by controlling a health problem in the population from which the information is gathered."

Per your earlier notification from the Office of Science, CDC Institutional Review Board (IRB) approval is not required for nonresearch data collections. However, each state cooperative agreement partner must determine its own state, tribal, and agency IRB requirements and submit copies of state decision documents of approvals or exempt status to the Great Lakes Biomonitoring Program.

Michigan Department of Community Health IRB Review

Michigan Department of Community Health Institutional Review Board Determination

Capitol View Building, 7th Floor, 201 Townsend Street, Lansing, MI 48913
Phone: 517/241-1928 Fax: 517/335-8297
Authority: Code of Federal Regulations Title 45 part 46

To: Linda D. Dykema "Responsible MDCH Employee"
From: Ian A. Horste MDCH IRB Chair/Administrator
CC: David R. Wade MDCH Bureau/Office Director

MDCH IRB Log #: 990-PHAEPI **Date Received:** 08/17/11

Study Title: **Biomonitoring of Persistent Toxic Substances in Michigan Urban Fish eaters.**


Investigator(s): N/A

Funding Source(s): Agency for Toxic Substances and Disease Registry

Committee Action/Recommendation:

- Tabled
- Not human subjects research*
- Exempt*
- Approved by expedited review without modifications
- Approved by expedited review with modifications*
- Approved by full committee review without modifications
- Approved by full committee review with modifications*
- Disapproved*

***Comments:** This non-research activity is designed to produce information on a specific community of urban fish eaters that is not generalizable. This information will be used to address a specific public health issue for the community and is therefore consistent with public health practice and not research as defined under 46.102(d).

Signature (Chair): 

Date Approved: 08/23/11

Expiration Date:** N/A

***Prior to this expiration date, the project must be re-approved in order for human subject's research to continue.*

The MDCH IRB must approve any change to this study protocol. Approval must precede implementation, unless the change is necessary to eliminate an apparent immediate hazard to the subject. The Responsible MDCH Employee must see that any unexpected problem or adverse event in the research is reported immediately to the MDCH IRB Chair, at (517) 241-0806 or MDCH-IRB@michigan.gov.

Michigan Department of Community Health FWA 00007331 IRB00000421

The Michigan Department of Community Health is an equal opportunity employer, services, and programs provider. The Department of Community Health will not discriminate against any individual or group because of race, sex, religion, age, national origin, marital status, political beliefs or disability.

DCH-1280 (01/11)

Attachment 9b. Minnesota Department of Health IRB Review



October 25, 2011

Protecting, maintaining and improving the health of all Minnesotans

Deanna Scher
Minnesota Department of Health
625 N. Robert Street, 3C
St. Paul, MN 55164

Re: IRB #11-268
IRB Original Review Date: October 12, 2011

Dear Deanna:

Thank you for submitting your proposal entitled "Biomonitoring of a Lake Superior Tribal Community for Environmental Contaminants: The 'Gligoonh Ogikendaan' Study" to the Minnesota Department of Health's (MDH) Institutional Review Board (IRB) for review.

The Board reviewed your proposal at its meeting on October 12, 2011 and found that the study is public health surveillance of a specific population group and is not research as defined by the federal regulations. Although the study is not research, the board expressed agreement that the rights of human subjects are adequately protected by the current proposal. Several suggestions were brought up by members of the board for the research team to consider, and these will be forwarded separately.

No further IRB review is needed for this study. However, as Principal Investigator of this project you are required to inform the IRB of any changes in the project that may lead us to classify it as research rather than public health surveillance.

Sincerely,

A handwritten signature in black ink that reads "Peter Rode". The signature is written in a cursive style with a large, sweeping "P" and "R".

Peter Rode
IRB Administrator
PO Box 64882
St. Paul, MN 55164-0882
651-201-5942

cc:
Ann Kowski
Rita Messing

Attachment 9c. New York State Department of Health IRB Review



Nirav R. Shah, M.D., M.P.H.
Commissioner

Sue Kelly
Executive Deputy Commissioner

November 1, 2011

Steve Dearwent, Ph.D., Chief
Health Investigations Branch
Agency for Toxic Substances and Disease Registry
4770 Buford Highway, NE
Atlanta, Georgia 30341

Dear Dr. Dearwent:

I am writing about the New York State (NYS) biomonitoring program titled "*Biomonitoring of Susceptible Populations in New York State's Great Lakes Areas of Concern*." As you know, NYS is one of three states funded by the Agency for Toxic Substances and Disease Registry (ATSDR) to measure contaminant levels in people who eat fish caught in the Great Lakes Areas of Concern.

Our project will measure contaminant levels in blood and urine and collect information about people's fish consumption habits and where people catch the fish they eat. We plan to use information from this project in our sport fish consumption advisory program and other NYS programs associated with Great Lakes' fish and water quality, with an overall goal of reducing exposures to contaminants in fish from NYS waters. This surveillance project is an important part of our on-going efforts to educate people and reduce their exposure to environmental contaminants. It is not a research study.

In its *Policy for Distinguishing Public Health Research and Public Health Non-research* (CDC-SA-2010-02), CDC states that the purpose of a non-research activity is "to prevent or control disease or injury and improve health, or to improve a public health program or service." The policy also states that the purpose of the activity should be "to benefit clients participating in a public health program or a population by controlling a health problem in the population from which the information is gathered." The NYS project was developed with our ATSDR partners to be responsive to the announcement calling for non-research projects and is consistent with the CDC non-research definition above.

If you have questions or need additional information, please contact Syni-An Hwang, Ph.D., Director of the Bureau of Environmental and Occupational Epidemiology, the principal investigator for this project, at 518-402-7950.

Sincerely,

A handwritten signature in black ink, appearing to read "Howard Freed".

Howard Freed, M.D.
Director
Center for Environmental Health

cc: R. Chinery
K. Gleason
S. Hwang, Ph.D.
E. Lewis-Michl, Ph.D.
E. Irvin-Barnwell, Ph.D.
W. Wattigney

HEALTH.NY.GOV
facebook.com/NYSDOH
twitter.com/HealthNYGov