Attachment 5. Determination Letters of Non-research Status

Attachment 5a. ATSDR Determination Letter of Non-research Status

NCEH/ATSDR Human Subjects Research Determination Form

Use this form and the flowcharts for either:

1. CDC projects and activities that do not require CDC IRB review under HHS Human Subjects (45 CFR part 46) or FDA (21 CFR parts 50 and 56) Regulations, which include "non-research", "research not involving identifiable human subjects," or "human subjects research for which CDC is not engaged"; *OR*

2. Human subjects research that will be submitted to the Human Research Protection Office (HRPO) as an Exempt Category of Human Subjects Research.

Project Title: Agency for Toxic Substances and Disease Registry Biomonitoring of Great Lakes Populations Program II

Project Location(s)/Site(s): Syracuse, NY

Project Officer(s): Wendy Wattigney **Telephone:** (770) 488-3802 **Division or Office:** DTHHS

Proposed Project Dates: Start: 03/03/2015 **End:** 03/03/2017 **Time sensitive:** X

Project Funding and Partners (answer both): HHS: CDC Cooperative Agreement **Non-HHS:** External funding

If applicable, name participating external institution(s). New York State Department of Health

Indicate the holder of the key to decipher the identities of coded data or biological specimens. External Institution

Specify CDC role (mark all that apply):

__ CDC is the sole institution conducting activity; OR

If not the sole institution, indicate if:

X CDC is NOT a recipient or provider of private data, specimens, materials or services;

__ CDC is provider of private data/specimens to an institution. __ CDC is recipient of private data/specimens from an institution.

__ CDC is provider of materials/services to an institution. __ CDC is recipient of materials/services from an institution

Questions 1-4 pertain to the HHS Human Subjects Regulations (45 CFR 46):

1. For CDC: Is this activity classified as *research*? **YES __ NO X**

A. Is the activity a systematic investigation including research development, testing, and evaluation? YES __ NO X

B. Is the activity intentionally designed to develop OR contribute to generalizable knowledge? YES __ NO X

CDC activity IS research if both 1A and 1B are "YES."
If 1 is "NO," then STOP; otherwise continue.

2. For CDC: Is this research classified as *human subjects research*? **YES __ NO __**

A. Does the activity only involve the collection or analysis of non-human data or specimens, including entities, organizations, or environmental materials? YES __ NO __

B. Does the activity only involve the collection or analysis of data or specimens from deceased persons? YES __ NO __

CDC activity IS NOT human subjects research if either 2A or 2B are "YES."
If 2 is "NO," then STOP; otherwise continue.

C. Do CDC employees intervene with, interact with, or obtain informed consent from living persons? YES __ NO __

D. Are/Were the data or specimens collected from living persons *specifically* for this proposed activity? YES __ NO __

E. Are/Were extra data or specimens collected from living persons *specifically* for this proposed activity? YES __ NO __

F. Do/Will CDC employees or agents have access to the link between the data or specimens and the identity of these living persons? YES __ NO __

CDC activity IS human subjects research if 2C is "YES."
CDC activity IS NOT human subjects research if 2D, 2E, and 2F are all "NO."
If 2 is "NO," then STOP; otherwise continue.

3. For CDC: Will this activity be submitted to HRPO for approval as *exempt human subjects research*? **YES __ NO __**

A. Does the research pose more than minimal risk? YES __ NO __

B. Will prisoners be involved? YES __ NO __

C. Will interaction with children occur or will identifiable private information about them be obtained? YES __ NO __

D. Based on the *HRPO Worksheet for Exemption from Human Subjects Regulations*, is there an HHS Exempt Research Category for which this activity will be reviewed? If "YES," specify the Category number: Choose an item YES __ NO __

CDC activity IS exempt human subjects research if 3A, 3B, and 3C are all "NO," and an exempt category (3D) applies. Exempt research must go to HRPO; use CDC Form 0.1250X.
If 3 is "YES," then STOP; otherwise continue.

NCEH/ATSDR Version 1.7e Updated Sept 9, 2014

4. Is CDC *engaged* in the non-exempt research involving identifiable human subjects? **YES __ NO __**

A. Did CDC receive funding directly from another HHS agency? YES __ NO __

B. Do CDC employees or agents intervene or interact with living individuals for research purposes? YES __ NO __

C. Do CDC employees or agents obtain individually identifiable private information? YES __ NO __

CDC IS engaged if 4A, 4B, or 4C are "YES."
If 4 is "NO," then STOP. Otherwise, research must go to HRPO; use CDC Form 0.1250.

Question 5 pertains to research involving FDA regulated products (21 CFR parts 50 and 56), not including the use of an FDA approved product in the course of medical practice:

5. Based on the *HRPO Worksheet to Determine FDA Regulatory Coverage*, is the research activity subject to FDA human subjects regulations? **YES __ NO __**

Additional Notes:

Although CDC HRPO review is not required, investigators or project officers must adhere to ethical principles and standards to respect and protect the privacy, confidentiality, and autonomy of participants. All applicable State and Federal privacy laws must be followed. Informed consent may be appropriate. Information disclosed in the consent process should address the basic elements of consent. The consent form and all other required supporting documents must be submitted with this form for review. The list of required documents is found in the *NCEH/ATSDR Guided Checklist for Human Subjects and PRA Determinations*.

Division Approval Signatures and Dates:

Angela Ragan-Wilson 10/23/14
Branch Chief Date Signed

10/23/14
Division ADS/Director Date Signed

For Office of Science Use Only: Final NCEH/ATSDR Center Determination

Request Received Date: 10/23/2014

X **CDC's role does not require HHS human subjects review beyond the center level because:**

- X Activity is not research (Flow chart category NR-1).
- __ Activity is not human subjects research (Flow chart category NR-2 through NR-8).
- __ Activity is non-exempt human subjects research, but CDC is not engaged (Flow chart category HSR-3).

__ **CDC's role does require HHS human subjects review beyond the center level because:**

- __ Activity qualifies as exempt human subjects research (Flow chart category HSR-1).
- __ Activity qualifies as non-exempt, engaged human subjects research (Flow chart category HSR-2).

__ **CDC's role does not require FDA human subjects review beyond the center level because:**

- __ Activity does not require human subjects review under FDA regulations (Flow chart category NFDA-3 through NFDA-4).

__ **CDC's role does require FDA human subjects review beyond the center level because:**

- __ Activity qualifies as human subjects research under FDA regulations (Flow chart category FDA-1 through FDA-2).

NCEH/ATSDR Human Subjects Contact Signature and Date:

Stephanie I. Davis 10/23/2014
Stephanie I. Davis, MSPH Date Signed

Attachment 5b. NYS DOH Determination Letter of Non-research Status

NEW YORK
state department of
HEALTH

Howard A. Zucker, M.D., J.D.
Acting Commissioner of Health

Sue Kelly
Executive Deputy Commissioner

July 28, 2014

Angela Ragin-Wilson, Ph.D., Chief
Environmental Epidemiology Branch
Division of Toxicology and Human Health Studies
Agency for Toxic Substances and Disease Registry
4770 Buford Highway, NE
Atlanta, Georgia 30341

Dear Dr. Ragin-Wilson:

I am writing about the New York State (NYS) biomonitoring program titled "Biomonitoring of populations consuming fish from the Great Lakes Basin's Onondaga Lake and associated water bodies near Syracuse, NY." As you know, NYS is funded by the Agency for Toxic Substances and Disease Registry (ATSDR) to measure contaminant levels in people who eat fish caught from Lake Ontario and its tributaries; including Seneca River, Oswego River and Onondaga Lake.

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,

Nathan Graber, M.D., M.P.H.
Director
Center for Environmental Health

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