



DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Institute of Environmental
Health Sciences
Building 31, Room 5A33
31 Center Drive, MSC 2490
Bethesda, Maryland 20892-2490

September 9, 2004

David H. Garabrant, MD, MPH
Principal Investigator
Professor of Occupational Medicine and Epidemiology
University of Michigan School of Public Health
109 South Observatory Drive
Ann Arbor, Michigan 48109-2029

Dear Dr. Garabrant:

Enclosed is the Confidentiality Certificate protecting the identity of research subjects in your project entitled, "Michigan Dioxin Exposure Study." Please note that the Certificate expires on May 31, 2007.

Please be sure that the consent form given to research participants accurately states the intended uses of personally identifiable information (including matters subject to reporting) and the confidentiality protections, including the protection provided by the Certificate of Confidentiality with its limits and exceptions.

If you determine that the research project will not be completed by the expiration date, May 31, 2007, you must submit a written request for an extension of the Certificate three months prior to the expiration date. If you make any changes to the protocol for this study, you should contact me regarding modification of this Certificate. Any requests for modifications of this Certificate must include the reason for the request, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Please advise me of any situation in which the Certificate is employed to resist disclosure of information in legal proceedings. Should attorneys for the project wish to discuss the use of the certificate, they may contact the Office of the NIH Legal Advisor, National Institutes of Health, at (301) 496-6043.

Correspondence should be sent to my attention at: National Institutes of Health, National Heart, Lung, and Blood Institute, Building 31, Room 5A33, 9000 Rockville Pike, Bethesda, Maryland, 20892-2486, phone number 301-496-5931 and fax number 301-402-0299.

Sincerely,

Sheri A. Hicks
NIEHS Certificate of Confidentiality Coordinator

Enclosure

cc: Ms. Judith A. Nowack
Dr. Kimberly Gray

CONFIDENTIALITY CERTIFICATE

NIEHS 04-13

Issued to

University of Michigan

conducting research known as

Michigan Dioxin Exposure Study

In accordance with the provisions of section 301(d) of the Public Health Service Act 42 U.S.C. 241(d), this Certificate is issued in response to the request of the Principal Investigator, David H. Garabrant, MD, MPH, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Garabrant is primarily responsible for the conduct of this research, which is not supported by the National Institute of Environmental Health Sciences.

Under the authority vested in the Secretary of Health and Human Services by section 301(d), all persons who:

1. are enrolled in, employed by, or associated with the University of Michigan and its contractors or cooperating agencies; and
2. have in the course of their employment or association access to information that would identify individuals who are the subjects of the research pertaining to the project known as "Michigan Dioxin Exposure Study,"

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research.

Recent studies have shown elevated levels of dioxins, furans, and polychlorinated biphenyls (PCBs) in soil samples obtained from the Tittabawassee River flood plain downriver from Midland, Michigan. The long-term goal of the Michigan Dioxin Exposure Study is to better understand whether and how these chemicals get into blood (i.e., to identify sources of human exposure to dioxins, furans and PCBs).

The study will investigate the contribution of many potential sources of exposure to these chemicals, including:

- Soil and house dust
- Residence in the flood plain of the Tittabawassee River, and elsewhere
- Diet (i.e., consumption of game fish)
- Occupation
- Other factors (i.e., age and gender)

This is not a health outcome study. It is a study of exposure pathways.

Residents from 3 areas will be the focus of this study:

1. Persons who live in the Tittabawassee River flood plain downriver from Midland (N=350).
2. Persons who live in Saginaw County, Midland County, and parts of Bay County, but who do not live in the Tittabawassee River flood plain, or any other river flood plain (N=350).
3. Persons who live elsewhere in Michigan (i.e., Jackson and Calhoun counties) (N=350).

A representative subset of residents from each of these 3 areas will be selected randomly and asked to participate in the study. Subjects recruited to participate in this study will be at least 18 years old, and must have resided in their homes for at least 5 years. It is anticipated that a total of 1,050 subjects will be recruited to participate in this study.

Subjects invited to participate in this study will be asked to complete a questionnaire and provide a blood sample. The administered questionnaire will seek information about age, weight, diet, occupation, residential history, and other factors that may impact the body burden of these chemicals. Blood samples will be analyzed only for selected dioxins, furans and PCBs, along with serum lipids. It is not practical to measure all dioxins, furans and PCBs in blood samples, only the 29 congeners that make up the World Health Organization Toxic Equivalency (TEQ) list will be measured, including TCDD. It is necessary to measure serum lipids in order to properly interpret the chemical test results in blood.

Persons who complete the questionnaire and provide a blood sample will be asked to allow house dust and soil samples to be collected. These samples will be analyzed for the same set of 29 congeners of dioxins, furans and PCBs.

Each sample line (address) is assigned a unique numeric identification code. This code follows the sample data through the data collection and analysis process. Data for any sample line is identified only by the numeric code, and not the respondent identifying information. Data that links the sample address to the sample identification code is stored in a physically separate location, whether it is on a computer, server or physical data file. Each completed interviewer is then assigned a numeric case identification number, providing a further layer of security. The case identification number is a sequential number and this number is placed on all sample materials, consent forms and the questionnaire. All data and documents will be stored in secure file cabinets and/or on password-protected, encrypted computers or servers. After data collection, the file linking code numbers to individual subjects will be held in a locked file cabinet by the Principal Investigator and other Key personnel on a 'need to know' basis. Only members of the study team will have access to the data. All members of the research team will sign a confidentiality pledge.

A Certificate of Confidentiality is needed because sensitive information will be collected during the course of the study. The Certificate will help researchers avoid involuntary disclosure that could expose subjects or their families to adverse economic, legal, psychological and social consequences.

This research began on June 1, 2004, and is expected to end on May 31, 2007.

As provided in section 301 (d) of the Public Health Service Act 42 U.S.C. 241(d):

"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

This Certificate does not protect you from being compelled to make disclosures that: (1) have been consented to in writing by the research subject or the subject's legally authorized representative; (2) are required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or regulations issued under that Act; or (3) have been requested from a research project funded by NIH or DHHS by authorized representatives of those agencies for the purpose of audit or program review.

This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services. This Certificate is now in effect and will expire on May 31, 2007. The protection afforded by this Confidentiality Certificate is permanent with respect to any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during any time the Certificate is in effect.

Date:

9/9/04



Kenneth Olden, Ph.D., Sc.D, L.H.D.
Director, NIEHS