

Informed Consent Document Michigan Dioxin Exposure Study: Questionnaire and Blood Sampling

1. Title of the research project:

University of Michigan Dioxin Exposure Study – Questionnaire and Blood Sampling

2. Sponsor of Study

This study is sponsored by the Dow Chemical Company, Inc.

3. Names of the researchers

All researchers are affiliated with the University of Michigan.

Principal Investigator: David Garabrant, MD, MPH

Co-Investigators: Alfred Franzblau, MD
Brenda Gillespie, PhD
Peter Adriaens, PhD
James Lepkowski, PhD
Xihong Lin, PhD
Avery Demond, PhD

4. Description of the research

Recent studies have shown elevated levels of certain industrial chemicals (i.e., dioxins, furans, and polychlorinated biphenyls or PCBs) in soil samples obtained from the Tittabawassee River flood plain downriver from Midland, Michigan. There are hundreds of different types of dioxins, furans and PCBs. One particular dioxin (abbreviated TCDD) has been identified as a human carcinogen by government and international agencies. The long-term goal of the Michigan Dioxin Exposure Study is to better understand how these chemicals get into blood, i.e., to understand 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; occupation; and many other factors (e.g. age and gender). Further information about this study, including resources for additional information, are provided in the study brochure.

Residents from 3 areas will be the focus of this study: 1) persons who live in the Tittabawassee River flood plain downriver from Midland; 2) persons who live in Saginaw County, Midland County, or parts of Bay County, but who do not live in the Tittabawassee River flood plain, or any other river flood plain; 3)

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persons who live elsewhere in Michigan. A subset of residents from each of these 3 areas will be selected randomly (by chance, like tossing a coin) to be asked to participate in the study.

Subjects invited to participate in this study will be asked to complete a questionnaire and provide a blood sample. Blood samples will be analyzed only for selected dioxins, furans and PCBs, along with serum lipids (i.e., fats in the blood). It is not practical to measure all dioxins, furans and PCBs in blood samples; only the 29 most important ones will be measured, including TCDD. It is also necessary to measure serum lipids in order to properly interpret the chemical test results.

Persons who complete the questionnaire and provide a blood sample will be asked to allow house dust and soil samples to be collected for analyses. These aspects of the study are covered in separate consent documents.

5. Description of human subject involvement

You are being asked to participate in this study because you live in one of the 3 areas to be studied, and you were randomly selected.

To be eligible for this study subjects must be at least 18 years old and must have lived at their current residence continuously for the last 5 years (except for vacations or other absences that total less than 6 months).

Subjects will be asked to complete an interview with a trained interviewer from the University of Michigan. The interview will include questions about residential history, occupational history, recreational activities (e.g., fishing), pregnancy history (for women only), basic demographic information, and diet.

Subjects will be asked to provide a blood sample of 80 milliliters (less than 3 ounces). Blood samples will be analyzed only for selected dioxins, furans, PCBs, and serum lipids. No other analyses will be performed on blood samples, and any left over blood will be discarded; no blood will be stored or 'banked' for future analyses.

Subjects must meet the following blood sample eligibility criteria:

- Weigh at least 110 pounds
- No chemotherapy in the last 6 months
- No history of bleeding or clotting disorders
- Not currently taking blood thinner medications

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Not currently pregnant or nursing
Not currently diagnosed or treated for anemia
No blood donation within the last 8 weeks

Please confirm whether you meet the blood sample eligibility criteria by initialing one of the following statements:

_____ I meet the blood sample eligibility criteria.

_____ I do NOT meet the blood sample eligibility criteria.

If you meet the blood sample eligibility criteria, please confirm whether you want to provide a blood sample for analyses in this study by initialing one of the following statements:

_____ I want to provide a blood sample.

_____ I do NOT want to provide blood sample.

6. Length of human subject participation

The interview will last approximately 60-75 minutes. There will be only one interview. The interview will be conducted at a time and place that is convenient to the subject. Some subjects may be re-contacted (usually by phone) to verify and/or clarify answers on the questionnaire.

Blood sample collection will be scheduled for a time and place that is convenient to the subject. There will be only one blood sample collected, and this should take about 15 minutes.

Members of the research team who come to your home will carry Identity Badges indicating that they are members of the University of Michigan Dioxin Exposure Study team.

7. Risks & discomforts of participation

The only physical risk associated with participation in this study is related to obtaining the blood sample. The blood sample will be obtained by a trained, professional phlebotomist using sterile, disposable equipment. The risks of bleeding, bruising, or infection are small, and similar to having blood drawn at your doctor's office. Some subjects report a feeling of faintness or brief dizziness upon blood donation. However, the volume of blood (80 milliliters)

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is small, and will be replaced quickly by your body. For comparison, donation of blood normally involves about 500 milliliters, and it is permissible for a healthy person to donate this much blood as often as every 8 weeks.

The interview will include questions about residential history, occupational history, recreational activities (e.g., fishing), and diet. The interview does not include questions that might be considered potentially embarrassing (e.g., use of illegal drugs or other criminal behavior).

8. Expected benefits to subjects or to others

You are unlikely to benefit directly from participation in this study, except that you can choose to learn the results of tests for dioxins, furans, PCBs and lipids in your blood. However, this study will increase the scientific understanding of how dioxins, furans and PCBs get into our blood.

You should be aware that almost everyone has measurable levels of dioxins, furans and/or PCBs in their blood. And, there is no medical treatment for removing these chemicals from our bodies.

Please indicate whether you want to receive the results of analyses of your blood for dioxins, furans, PCBs and lipids by initialing one of the following choices:

_____ I want to receive results of analyses for dioxins, furans, PCBs and lipids in my blood.

_____ I do NOT want to receive results of analyses for dioxins, furans, PCBs and lipids in my blood.

You can change your decision about receiving results by notifying the Principal Investigator in writing.

9. Management of Physical Injury

Should you get physically injured as a result of research-related procedures, the University of Michigan will provide first-aid medical treatment. Additional medical treatment will be provided, if the University determines that it is responsible to provide such treatment. However, the University does not provide compensation to a person injured while taking part as a subject in research.

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10. Costs to subject resulting from participation in the study

There are no costs associated with participation in the questionnaire and blood sampling phase of this study.

11. Payments to subject for participation in the study

Subjects who agree to participate in this study will be paid \$60 for completing the questionnaire and providing a blood sample. If you complete the interview, but then withdraw from the study before you have provided a blood sample or are unable to provide a blood sample, you still will be paid \$60. If you choose to complete the questionnaire but refuse to provide a blood sample, you still will be paid \$60.

If you complete the questionnaire and provide a blood sample, you may be invited to allow house dust and soil samples to be taken. If these samples are obtained, you will be paid \$20 for each of these samples, for a total of an additional \$40. Hence, participation in all phases of this study (i.e., the questionnaire and blood sampling, house dust sampling, and soil sampling) can result in payments totaling \$100.

12. Confidentiality of records/data

Individual subjects will not be identified in any reports on this study. Research records will be kept confidential to the extent provided by federal, state, and local law. However, University and government officials responsible for monitoring this study may inspect these records.

The sponsor of this study will not have access to any records or identifiable results. Your decision to participate or to not participate will not be revealed to your employer by the University.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or

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evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The researchers will not make any disclosure of information that would identify you as a participant in this research unless you provide written authorization to the Principal Investigator to do so.

13. Availability of further information

If significant new knowledge is obtained during the course of this research which may relate to your willingness to continue participation, you will be informed of this knowledge.

14. Contact Information

If you have questions about this research, you may contact:

Dr. David Garabrant
Professor
University of Michigan School of Public Health
109 South Observatory
Ann Arbor, Michigan 48109-2029
(888) 689-0006 (toll free)
email: dhg@umich.edu

Ms Barbara Lohr Ward
Survey Research Center
University of Michigan Institute for Social Research
P.O. Box 1248
426 Thompson Street
Ann Arbor, Michigan 48109-1248
(888) 689-0006 (toll free)
email: barbward@umich.edu

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Should you have questions regarding your rights as a research participant, please contact:

Ms Kate Keever
Institutional Review Board
540 East Liberty Street, Suite 202
Ann Arbor, MI 48104-2210
(734) 936-0933
email: irbhsbs@umich.edu.

15. Voluntary nature of participation

Your participation in this project is voluntary. Even after you sign this informed consent document, you may decide to stop further participation in the study at any time without penalty or loss of benefits to which you may otherwise be entitled. Data and specimens that have already been collected will remain in the study. You may skip or refuse to answer any survey question without affecting your study compensation.

16. Documentation of the consent

One copy of this document will be kept together with the research records of this study. Also, you will be given a copy to keep.

17. Consent of the subject:

I have read [or been informed] of the information given above. Dr. Garabrant or his representative has offered to answer any questions I may have concerning the study. I hereby consent to participate in the study.

ADULT SUBJECT OF RESEARCH

Consenting signature

Printed Name

Witness signature

Printed Name

Date