

Informed Consent Document
University of Michigan Dioxin Exposure Study
House Dust Sampling

1. Title of the research project:

University of Michigan Dioxin Exposure Study – House Dust 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 University of 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.

Subjects invited to participate in house dust sampling will be asked to allow samples of house dust to be collected in their home. House dust samples will be analyzed only for selected dioxins, furans and PCBs. It is not practical to measure all dioxins, furans and PCBs in dust samples; only the 29 most important ones will be measured, including TCDD.

Informed Consent Document
University of Michigan Dioxin Exposure Study
House Dust Sampling

5. Description of human subject involvement

To be eligible for house dust sampling you must have completed the questionnaire and provided a blood sample in the study entitled “University of Michigan Dioxin Exposure Study – Questionnaire and Blood Sampling”.

If you are eligible, you will be asked to allow collection of house dust samples in your home. House dust is collected by using a vacuum cleaner equipped with a special filter to trap the dust. Vacuuming will be performed in normally trafficked areas in the home on both hard and soft (carpeted) surfaces. It is not necessary to perform any special cleaning prior to house dust sampling.

If you are a legal owner of your home, then you are authorized to give consent for house dust samples to be collected. If, for example, you rent your house/apartment, or if you live with your parents and they are the homeowners, you are not a legal owner of the home.

Please confirm that you are a legal owner of the home in which you live by initialing the following statement:

_____ I am a legal owner of the home I live in.

6. Length of human subject participation

Collection of the house dust samples will be scheduled for a time that is convenient for you, and will require entry to your home. The sampling process will take about 60 minutes. The technicians who come to your home will carry University of Michigan Identity Badges.

7. Risks & discomforts of participation

There is no anticipated physical risk associated with house dust sampling in your home.

Knowledge of levels of dioxins, furans and PCBs in house dust could have negative consequences on the value of your home. At the time of sale of the home you may be obligated to divulge your knowledge of these results to potential buyers.

Knowledge of levels of dioxins, furans and PCBs in house dust could also have negative consequences for landlords or other types of property owners

Informed Consent Document
University of Michigan Dioxin Exposure Study
House Dust Sampling

if, for example, tenants or other residents on the property want you to take remedial actions.

It is your choice whether to receive results of the house dust analyses. You may elect to not receive the house dust analyses, in which case you would not have such information to divulge to buyers or others.

8. Expected benefits to subjects or to others

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

You can change your decision to receive or not receive your house dust results by notifying the Principal Investigator in writing.

If you choose to receive your results, we encourage you to share them with other people who may have exposure to the house dust on your property.

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

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

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

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.

Informed Consent Document
University of Michigan Dioxin Exposure Study
House Dust Sampling

10. Costs to subject resulting from participation in the study

There are no direct costs associated with participation in this study. However, as explained above, knowledge of levels of dioxins, furans and PCBs in house dust could have negative consequences on the value of your home, and could trigger actions by tenants and others.

11. Payments to subject for participation in the study

If you agree to participate in this study you will be paid \$20 for the time and inconvenience of allowing house dust sampling in your home. Payment will be made after the dust samples have been collected.

12. Confidentiality of records/data

Your identity and your home location will not be identified in any reports on this study. 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 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

Informed Consent Document
University of Michigan Dioxin Exposure Study
House Dust Sampling

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

Ms Kate Keever
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540 East Liberty Street, Suite 202
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