

Informed Consent Document
University of Michigan Dioxin Exposure Study
Soil Sampling

1. Title of the research project:

University of Michigan Dioxin Exposure Study – Soil 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 soil sampling will be asked to allow soil samples to be collected from the property surrounding the home where they reside. Soil samples will be analyzed only for selected dioxins, furans and

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PCBs. It is not practical to measure all dioxins, furans and PCBs in soil samples; only the 29 most important ones will be measured, including TCDD.

5. Description of human subject involvement

To be eligible for soil 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 up to 7 triplicate soil samples from the property site of your home. The exact number and location of soil sample collection will be determined by the technicians at the time of sampling. Soil sampling is performed with hand tools (i.e., no heavy equipment). Each soil sample is a ‘core’ approximately 2 inches in diameter and about 6-8 inches deep. The hole created after each sample is removed will be refilled with clean top soil.

If you are a legal owner of the property where you live (i.e., you are an owner of the land on which your home is located), then you are authorized to give consent for soil samples to be collected. However, if you rent your house/apartment, or if you live in a condominium, or if you live with your parents and they are the homeowners (as examples), you are not a legal owner of the property.

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

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

6. Length of human subject participation

A study representative will contact you to schedule soil sampling. It is not necessary for you to be present when soil samples are collected. However, the technicians will first announce themselves at the home before taking any soil samples. The technicians will carry University of Michigan identity badges.

If you wish to be present when soil samples are to be collected, and to help identify the locations from which soil samples may be collected, then soil sampling will be scheduled at a time that is convenient for you to be present. The soil sampling process will take about 1-2 hours and samples will be taken

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on only one occasion. If you wish to be present during sampling then you must be home to meet the sampling team. However, you do not need to be present for the entire sampling process. After greeting the soil sampling team you may leave if you choose.

7. Risks & discomforts of participation

There is no anticipated physical risk to you from soil sampling.

Knowledge of levels of dioxins, furans and PCBs in soil on your property could potentially have negative consequences on the value of the property. At the time of sale of the property you may need to divulge knowledge of these results to potential buyers. Knowledge of the soil analyses could also have negative consequences for landlords or other types of property owners 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 soil analyses. You may elect to not receive the soil analyses, in which case you would not have such information to divulge to buyers or others.

You could also have regulatory issues to address if you have knowledge of the levels of dioxin, furans and PCBs in your soils. The Michigan Department of Environmental Quality (MDEQ) currently has a combined standard (Toxic Equivalents, or TEQ) for dioxins, furans and PCBs in soil of 90 parts per trillion (ppt). MDEQ considers any property at or above this threshold to be a "facility" for the purposes of state regulations. If you have knowledge that your property is a "facility", and you caused the contamination, there are a number of regulatory requirements you must comply with to address the contamination. If you did not cause the contamination, but it migrated onto your property, you have no obligation to notify the MDEQ or clean it up. However, in either case you may not move the contaminated soil in such a manner that it would spread or exacerbate the contamination. Also, in the future, the MDEQ may lower the standard, thus triggering the designation as a "facility" for properties that had previously not been labeled as such. If you do not know results of soil analyses, then you would not know whether your property is a "facility" under state regulations.

Given these considerations, you need to decide whether you want to receive the results of soil analyses from your property.

8. Expected benefits to subjects or to others

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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 soil from your property. However, this study will increase the scientific understanding how dioxins, furans and PCBs get into our blood.

If you are an owner of your property, you can change your decision to receive or not receive your soil 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 soil on your property.

Please indicate whether you want to receive the results of analyses of your soil 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 soil.

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

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.

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 soil around your home could have negative consequences on the value of the home, could trigger actions by other residents on your property, and may also trigger obligations for you under regulations for hazardous substances.

11. Payments to subject for participation in the study

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

12. Confidentiality of records/data

Your identity and your property 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 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

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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

Peter Adriaens, PhD
Professor
University of Michigan College of Engineering
180 Engineering I-A
Ann Arbor, Michigan 48109-2125
(888) 689-0006 (toll free)
email: adriaens@umich.edu

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.

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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