THE UNIVERSITY OF MICHIGAN DIOXIN EXPOSURE STUDY: PROJECT OVERVIEW

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Introduction and Study Goals

The University of Michigan Dioxin Exposure Study (UMDES) is designed to assess exposures to dioxins, furans and coplanar polychlorinated biphenyls (PCBs), describe the pattern of serum dioxin, furan and PCB (collectively 'dioxins' or 'dioxin-like compounds') levels among adults and to understand factors that explain variation in serum dioxin levels. The study was undertaken in response to concerns among the population of Midland and Saginaw Counties that dioxin-like compounds from the Dow Chemical Company facilities in Midland have contaminated areas of the City of Midland and sediments in the Tittabawassee River flood plain. There is concern that residents' body burdens of dioxins may be elevated because of environmental contamination. To address these concerns the study was designed to measure the serum levels in a random sample of the population in the region and to estimate each individual's past exposure to various factors that are believed to contribute to the body burden of dioxin-like compounds. By measuring factors that reflect potential exposure to dioxins, furans and co-planar PCBs through air, water, soil, food intake, occupations, and various recreational activities, the study can identify factors that correlate with (and explain variation in) serum congener levels. A central goal of the study is to determine which factors explain variation in serum congener levels, and to quantify how much variation each factor explains.

The study includes populations who live in Midland County, Saginaw County, and part of Bay County, both in and out of the Tittabawassee River flood plain; and who live in a region of Michigan (Jackson and Calhoun Counties) that has no known industrial point-sources of dioxins like Dow. By studying these two populations it will be possible to understand whether the serum dioxin, furan and PCB levels among people who live in the Tittabawassee River flood plain are different than those among similar people who live in the same region of Michigan, and whether they are different than those among people who live in other parts of Michigan.

An additional central goal of the study is to communicate the results and the implications of the results in an effective manner to the populations impacted by the study. The study is intended to solicit input from the affected populations, to be responsive to their questions, to provide reliable and valid answers, and to explain those answers in a manner that is desired by the population. The findings of the study will be communicated to the public in a series of open forums, mailing, and a website (www.umdioxin.org). Additionally, public comment has been sought through a Community Advisory Panel (CAP).

The goals of the study are:

1. To communicate with the populations of Midland, Saginaw, Bay, Jackson and Calhoun Counties for the purposes of:
   - Soliciting input on their concerns regarding dioxin, furan and PCB contamination in their environment
   - Designing a scientific study that will help to address these concerns
   - Providing reliable scientific evidence that is responsive to their concerns
   - Explaining what the scientific evidence means and how it addresses the concerns of the affected population

2. To select random samples of five populations:
   - Residents of Midland and Saginaw counties who reside in the flood plain of the Tittabawassee river between the Dow Chemical plant in Midland and the confluence of the Tittabawassee and Shiawassee rivers in Saginaw.
   - Residents of Midland, Saginaw, and Bay counties who reside in census blocks adjacent to the flood plain of the Tittabawassee River between the Dow Chemical plant in Midland and the confluence of the Tittabawassee and Shiawassee Rivers in Saginaw.
   - Residents of Midland, Saginaw and Bay counties who do not reside in the flood plain of the Tittabawassee or Saginaw Rivers or in the confluence flood plain of the Shiawassee River, and also live outside the plume area downwind from the Dow Chemical Company in the city of Midland.
   - Residents who live in the plume area downwind from the Dow Chemical Company in the city of Midland.
   - Residents of Jackson and Calhoun counties in Michigan.

3. To collect the following data from each participant:
   - Responses to a personal interview
   - Measurements of the 29 congeners of dioxins, furans, and co-planar PCBs for which there are consensus toxicity equivalency factors (TEFs)[1], in serum, house dust and soil from around each residence

4. To explain the variability in serum dioxins, furans and PCBs (both specific congeners and toxic equivalents - TEQ) as a function of:
   - Soil and/or house dust congener concentrations
   - Proximity and duration of residence in relation to the Tittabawassee River and the Dow facilities
   - Consumption of fish and game from the Tittabawassee River and flood plain
   - Past occupations and other factors (age, sex, race, diet, etc.)

The UMDES is an exposure pathway study. This study is not intended to address potential adverse health effects of exposures to dioxin-like chemicals. The focus of this study is on potential dioxin exposures of people; it is not intended to provide information on the geographic distribution of soil contamination with dioxins, furans and PCBs in Midland and Saginaw Counties or elsewhere. The study does not address potential economic consequences of dioxin contamination or exposures. Full details on the study design, field and laboratory methods, and study findings are posted on the study website (www.umdioxin.org) and reported elsewhere.[2,3,4,5,6,7,8]

The Scientific Advisory Board

The investigators report to an independent Scientific Advisory Board (SAB) which oversees all aspects of the study conduct. The University of Michigan investigators do not report study data or results to the Dow Chemical Company. No study data or results have been or will be provided to the Dow Chemical Company in any form unless they are made publicly available in the same form. The SAB has or will perform a number of functions, including the following: 1) review and comment on the draft study design; 2) convene in person in Michigan (either

Ann Arbor or in the Midland/Saginaw area) twice yearly for 1-2 days each time to meet with the investigators, representatives of the Michigan Department of Community Health and other health officials, representatives of the community advisory panel and other stakeholders; 3) monitor the conduct of the UMDES and provide feedback to the investigators regarding the conduct of the UMDES; and 4) review and comment on draft reports from the investigators before they are released to the public and scientific community, and release final reports on the UMDES to the public.

The University of Michigan appointed the SAB members, with membership based on independence, qualifications in research relevant to the dioxin issues, and scientific stature. The investigators solicited nominations to the SAB from interested stakeholders, recognized scientific organizations, and from colleagues who are knowledgeable in areas relevant to dioxin exposure studies. The SAB members are posted on the study website (www.umdioxin.org).

As is customary with academic research, the University of Michigan investigators retain the right to conduct this research and report the results in the open scientific literature. The SAB functions in an advisory capacity to the investigators. The SAB has the right to comment on and issue reports regarding the UMDES, including dissenting opinions and criticisms. In instances where the SAB recommends that modifications to the conduct, analyses, or reporting of the UMDES is needed, the investigators will either adopt the recommendations of the SAB or will respond in writing to the SAB, indicating their reasons for disagreement. The goal is to encourage open dialogue between the SAB and the UMDES investigators.

Communications Plan and Community Advisory Panels

Potential exposures to environmental toxins such as dioxins are a public health concern. Residents and public health professionals in the Tittabawassee River area have a great interest in the design and execution of this study. The research team is committed to proactive community engagement in the design and implementation of the study. Communications with the population of Midland, Saginaw, Bay, Jackson and Calhoun counties for the purposes of soliciting input on their concerns regarding dioxin, furan and PCB contamination in their environment, designing a scientific study that will help to address these concerns, providing reliable and valid scientific evidence that is responsive to their concerns, and explaining what the scientific evidence means and how it addresses the concerns of the affected population have been central to the conduct of this research. There are six key areas of the research team's community outreach efforts:

- Research has been conducted to clarify the concerns of the community and to identify key community resources and leaders. Data collection has included focus groups and key-person interviews. This research has solicited information on concerns within the community and the prevalence of those concerns. These investigations have allowed identification of areas that can be addressed by the study team and have helped to guide interactions with the community.
- The investigators formed a CAP with membership based on independence, representation of community groups, and stature and respect in the community. Nominees were solicited during focus groups and key-person interviews (see above). The CAP provides feedback to the investigators regarding the concerns of the community and helps to inform the community about the conduct and progress of the study. The members of the CAP are posted on the study website (www.umdioxin.org).
- The research team has developed a broad outreach/educational campaign to describe the efforts of the research team and provide critical information to the public. The campaign has involved media resources (e.g., television, radio and print media) and web site development.
- The research team has performed outreach to targeted groups. Targeted audiences include area physicians, elected officials, public health officials and key community leaders.
- The investigators have disseminated messages to a variety of audiences. These messages have included descriptions of the research study, periodic updates on study progress, findings from the study as they have

become available for release, and interpretations of the findings (see study web site for examples: www.umdioxin.org). The investigators have met with community members to discuss results and answer questions.
- Research has been conducted to determine how best to communicate results to the community that is relevant to their needs and concerns. Data collection has included focus groups.

Results of the UMDES study will be reported to participants. Individual participants have been given the results of their tests (measurements of serum, house dust and soil, if they wish to receive them) by mail. Aggregate data will be presented in scientific reports which will be peer-reviewed by the SAB. Scientific reports that have been reviewed by the SAB will be posted to a website which will be publicly available.

Protection of Human Subjects in Research
This study has been performed in compliance with University of Michigan and federal policies and procedures governing the use of human subjects in research. Copies of all informed consent forms and written communications with potential subjects are available on the study website (www.umdioxin.org). The study was granted a Certificate of Confidentiality from the National Institutes of Health (NIH), which provides added protection to prevent forced disclosure of confidential data through subpoenas, Freedom of Information Act (FOIA) requests, and other legal mechanisms. A copy of the Certificate of Confidentiality is also available on the study website.

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