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Dr. Garabrant,

As agreed in the telephone conference call on May 6<sup>th</sup>, 2004 the Agency for Toxic Substances and Disease Registry (ATSDR) has prepared comments on the University of Michigan Dioxin Exposure Study protocol received on April 16, 2004.

We look forward to the next conference call at 2:00pm on May 27 to discuss these comments and the "technical comments" submitted by ATSDR in a letter from Tom Sinks sent April 9<sup>th</sup>, 2004.

Sincerely,

## **Study Protocol**

1. We would like a time line of events included in the protocol that describes when the various components of the study will commence and conclude.

## **4.0 Research Plan**

2. Pg. 6 - Three study populations are listed. The second population is described as “residents of the Saginaw County, Midland County, and part of Bay County who do not reside in the floodplains of the Tittabawassee or Shiawassee Rivers or the confluence floodplain of the Shiawassee River.” This population is then described as a referent group with the opportunity for dioxin exposure that is typical for residents of this region of Michigan. Soil dioxin concentrations vary significantly in this area. The residential location of the two populations described as 1) residents of the Tittabawassee Rive Floodplain between the Dow facility in Midland and the Center Street bridge (approx.) in Saginaw and 2) the residents of the Saginaw County, Midland County, and part of Bay County who do not reside in the floodplains of the Tittabawassee or Shiawassee Rivers or the confluence floodplain of the Shiawassee River should be noted, however they should be refereed to as a single population. While the comparison population is the group of residents of Michigan outside of Saginaw and Midland counties.
3. Pg. 6- 7 – UM should consider over-sample known sports fishermen or women within each of the 3 populations, to gain a better estimate of the upper end blood dioxin levels. In addition specific consideration should be made on sampling individuals of all age categories to see how age correlates with dioxin level.

## **4.2 Interviews**

4. Pg. 7 – Bulleted list describes the topics to be addressed in the in-person interviews. It would be helpful if in addition to the questions on weight loss and weight gain that the questionnaire ask about weight and height in order to calculate body mass index or BMI. There is a correlation between BMI and blood dioxin TEQ levels.
5. Pg. 17 – Section 4.7: Power Calculations, 3<sup>rd</sup> paragraph. Fish consumption is referred to as a dichotomous covariate. Fish consumption should be dealt with as continuous variable as blood dioxin levels are known to rise with increased fish consumption. In addition, the effects of the type of fish species and other game grown or caught in the potentially contaminated areas for human consumption should be considered.

### **Appendix 3 Questionnaire**

6. Pg. 13 – Section B: Occupational History. Questions B15 and B18 ask about certain dates related to Vietnam War activities. Please provide a time line to help facilitate participant’s recollection of begin and end year dates. Time line should include date of US deployment to Vietnam, date US troops were withdrawn, and 2-3 well known events that occurred during the war.
7. Pg. 15-17 – Section C: Residential History. The section asks residents to report an address, and move in and out date for every residence they EVER had. Has this section been piloted? This section seems tedious and timely to facilitate. Not only will the process be timely but individuals may not remember ever address they have ever had. How important will this information be? Is there a major loss in data quality if a residential history is collected for only the past 5, 10 or 15 years, or maybe even 20 years?

### **Appendix 5 Household Dust Sampling Protocols – Soft Surface Household Dust Sampling Protocol**

8. Pg. 1 – Soft Surface Household Dust Sampling Protocol. The use of the term “soft surface” is obscure. Use of the term vacuumed surfaces maybe a more accurate description.
9. Pg. 1 – Section 1.0: Scope and Application. The correct reference is the Unites States Environmental Protection Agency Environmental response Team...
10. Pg. 1 – Section 2.0: Method Summary. The technique is the Nilfisk GS-80...
11. Pg. 3 – Section 5.0: Equipment/Apparatus. Please specify the nozzle type.
12. Pg. 4 – Section 7.3: Sample Locations. The living or family room that appears to be the most frequently occupied will be sampled. Documentation must be kept on whether the floor is carpeted or not as this will relate to laboratory results.
13. Pg. 4 – Section 7.4: Field Operations, item 7. Vacuum should be turned off only after the step of wearing surgical gloves, make sure to tap with your hand on the nozzle inlet to dislodge remaining dust in the nozzle or the hose.
14. Pg. 5 – Section 7.5: EWRE Laboratory Operations, item 5. We recommend collecting the course material remaining on the top of the sieve otherwise there may not be enough sample in sieved fraction. Consider combining sieved and non-sieved material. Procedure should be noted and relayed to the laboratory.

## **Appendix 5 Household Dust Sampling Protocols – Hard Surface Household Dust Sampling Protocol**

15. Pg. 1. What is the minimum sample weight necessary for these methods?
16. Pg. 3 – Section 7.3: Sample Location. If the kitchen or bathroom floor is carpeted (not a hard surface) will sample be collected, what will be the method, how will this be documented?

## **Appendix 6 Soil Sampling Protocols**

17. We recommend taking a 1-6” soil sample from each residential home in the Tittabawassee Rive Floodplain between the Dow facility in Midland and the Center Street bridge (approx.) in Saginaw regardless of the dioxin ppt obtained in the 0-1” surface soil sample. The principal exposure on these properties is by way of the floodplain. Therefore subsurface dioxin levels maybe higher than surface levels.
18. If the intent of the 1-6” samples represent historical deposition and potential exposure then both samples should be collected from ALL homes included in the study. Dioxin degradation may occur differently at the surface then subsurface levels.

**In addition to these comments there were other technical comments stated in the April 9<sup>th</sup> letter to Dr. Garabrant and John Phillips by Tom Sinks that have not been addressed.**