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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
NATIONAL EXPOSURE RESEARCH LABORATORY  
RESEARCH TRIANGLE PARK, NC 27711

October 3, 2007

OFFICE OF  
RESEARCH AND DEVELOPMENT

**MEMORANDUM**

**SUBJECT:** Transmission of Materials for Review by the Human Studies Review Board for its October 24 – 26, 2007 Meeting

**TO:** Paul Lewis, Ph.D.  
Designated Federal Official  
Human Studies Review Board  
Office of Science Advisor (8105R)

**FROM:** Roy Fortmann, Acting Director  
Human Exposure and Atmospheric Sciences Division (E-205-01)

This memorandum describes the materials being provided for review by the Agency's Human Studies Review Board (HSRB or Board) at the meeting scheduled for October 24 - 26, 2007. The materials provided with this memorandum specifically address review of the draft document titled *Scientific and Ethical Approaches for Observational Exposure Studies*.

Scientists at the U.S. Environmental Protection Agency's (EPA's) National Exposure Research Laboratory (NERL) have conducted observational exposure measurement research for several decades to understand how and why people come into contact with chemicals and other stressors in their everyday lives. These studies are performed to determine what chemicals people are exposed to, the concentrations of the chemicals, the most important sources contributing to people's exposures, the routes and pathways of exposure, and the factors that have the biggest impact on exposure.

EPA strives to follow the most up-to-date approaches in designing and performing observational exposure studies to ensure that these studies are based on sound science and meet the highest ethical standards. To meet that goal researchers in NERL have prepared a draft document that identifies key scientific and ethical issues and provides information and resources to assist researchers as they plan and implement observational exposure studies. The document is not meant to represent an official Agency "guidance document." Moreover, it recognizes that

researchers will work with others – EPA’s Human Subjects Research Review Official, Institutional Review Board (IRB) members, the participants and their community, and other stakeholders – to identify and address all of the relevant issues for any specific study to ensure that all participants are respected and protected.

The external review draft document, *Scientific and Ethical Approaches for Observational Exposure Studies*, is being submitted to the HSRB for their recommendations and advice.

EPA is providing the following materials to the HSRB relevant to the review of the draft document:

1. External review draft document titled *Scientific and Ethical Approaches for Observational Exposure Studies*,
2. Charge Questions
3. Report on the *Workshop to Discuss State-of-the-Science Approaches for Observational Exposure Measurement Studies*, dated January 25, 2007. The report provides background on the framework for the document and topic areas recommended by an expert panel.

The charge questions are as follows:

1. One of the goals of the document is identify the major scientific and ethical areas and issues that researchers should address in the design and implementation of observational human exposure measurement studies, with the emphasis on the areas requiring ethical considerations. Does each section identify the major areas and issues where ethical considerations should be addressed?
2. The document is intended to serve as a reference and resource of information that researchers can use in the design and implementation of observational exposure studies. For each section, are there additional sources of information that should be considered for inclusion?
3. Is the information presented accurately and clearly in each section?

Attachments (3)