

US EPA ARCHIVE DOCUMENT

Draft Document on *Scientific and Ethical Approaches for Observational Exposure Studies*

**Charge to the Human Studies Review Board
(October 4, 2007)**

Observational human exposure studies are performed to collect information about individuals and the environment around them in order to better understand people's exposures. These studies typically involve measurements of chemicals in the food people eat, the water they drink, the air they breathe and dust on the surfaces they touch. In addition, information about the study participants and their homes, work environments and activities are collected, as well as biomonitoring samples. It is important to understand why and how people are exposed to chemicals in the environment for EPA to fulfill its mission to protect human health.

EPA scientists and their managers take the protection of human subjects who participate in their observational studies very seriously. The steps needed to ensure protection of the human subjects are often complex, and the specific actions will vary depending on the objectives of the study, details about the participants, and the communities in which the studies are performed.

This document is intended as a resource and reference for scientists in EPA's Office of Research and Development (ORD) National Exposure Research Laboratory (NERL) as they develop and implement observational human exposure studies. The authors recognize that this document may also prove to be useful to others involved in exposure science research, but the document is not meant to represent an official Agency "guidance document" and should not be used that way. This document does not provide solutions to the scientific and ethical issues that will undoubtedly arise as such studies are undertaken: no document could provide all of the answers in advance or develop a comprehensive checklist for all such studies. Rather, this document attempts to identify the types of issues that will need to be considered and addressed as NERL researchers plan and implement observational human exposure studies. The researchers will need to work with others – the study team, IRB members, EPA Human Subjects Research Review Official (HSRRO), the participants and their community, and other stakeholders – to identify and address all of the relevant issues for their particular study in order to ensure that the specific elements of the study will safeguard and protect the human research subjects.

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The draft document on *Scientific and Ethical Approaches for Observational Exposure Studies* consists of the following seven sections:

1. Introduction
2. Elements to be Considered in Study Conceptualization and Planning
3. Ensuring Protection of Vulnerable Groups

4. Privacy, Confidentiality, and Other Concerns Related to Observational Human Exposure Measurement Studies
5. Creating an Appropriate Relationship Between Participant and Investigator
6. Building and Maintaining Appropriate Community and Stakeholder Relationships
7. Designing and Implementing Strategies for Effective Communication

The Human Studies Review Board is asked to address the following questions for each section of the draft document:

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?