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Scientific and Ethical Approaches for Observational Exposure Studies (SEAOES)

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Presentation to EPA Human Studies Review Board
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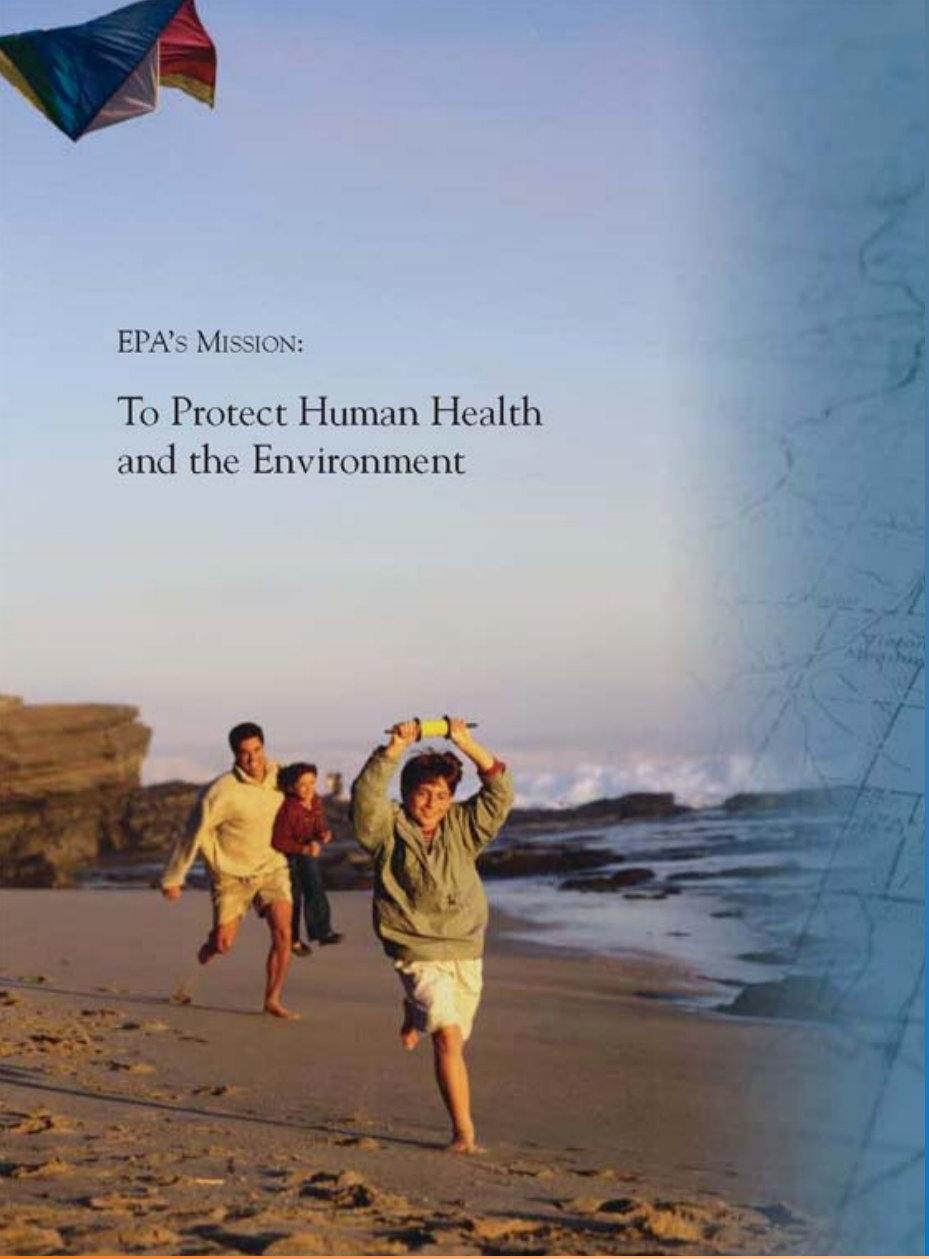
Office of Research and Development
National Exposure Research Lab



EPA's mission is public health protection

- Responsible for regulations that protect public health
- Uses risk assessments to identify and characterize environmentally related health problems
- Exposure is one-half of the risk assessment process
- Understanding and quantifying exposure is critical

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Purpose of the SEAOES document

- Serve as useful resource for researchers in the National Exposure Research Laboratory (NERL)
- Identify important scientific and ethical issues for consideration during the design and implementation of studies
  - Provide resources / references for NERL researchers
- Ensure that science is of the highest quality and ethical standards are understood and upheld at the highest possible level

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Motivation

- NERL scientists and managers take protection of research participants seriously – we want to meet the regulatory requirements *and* the spirit of the ethical standards that motivates the regulatory requirements
- Exposure studies can make a difference in people's lives – see examples in table

Issue	Impact / Action from Observational Studies
$PM_{2.5}$	Addressed NAS issues about relationship of ambient PM and exposure: PM NAAQS based on good exposure science
VOCs	Indoor concentrations observed to be high – voluntary reductions in toxic chemicals in consumer products & materials (EPA, CPSC, states, manufacturers)
Radon	Problem identified, solutions available, less exposure means less lung cancer
Formal-dehyde	Less formaldehyde in consumer products & building materials (EPA, HUD, CPSC)

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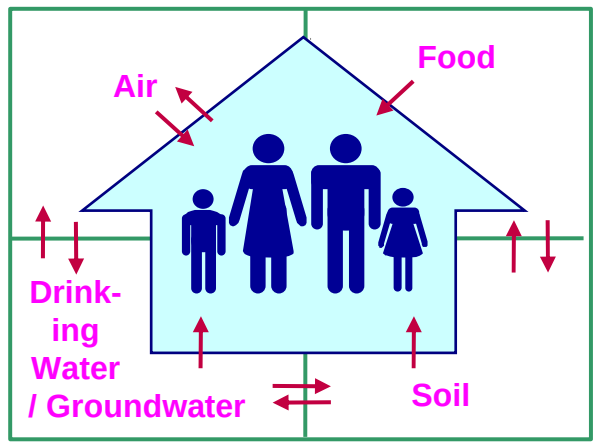
Fundamental concepts

- Exposure is the contact of an individual with a chemical – through the air we breathe, the food we eat, the water we drink, the surfaces we touch
- Understanding and characterizing people's exposure requires understanding two things:
  - Environmental concentrations in people's environments
  - Human activities that bring people into contact with the chemicals
- Data are collected through human exposure studies that are observational



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Observational human exposure studies

- Studies in which we observe and measure people's contact with the chemicals that are already present in their environment:
  - under real-world conditions (in their homes, offices, cars or vehicles, and outdoors)
  - during normal day-to-day activities

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Types of samples collected

- Air *(outdoor, indoor, personal)*
- Food, water, and beverages
- Hand wipes, residue transfer
- Surface residues
- Dust
- Soil
- Biological – urine and blood

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Other Data Collected

- Time/Activity information
- Personal activities/product use/diet/occupation
- Housing characteristics

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Approach to drafting the document

- Stakeholder conversations
- Expert panel workshop – Nov. 28-29, 2006
- Internal review – program offices, scientists
- HSRB review
- Public comment period – Oct. 4 – Nov. 19, 2007
- Final document – revise and publish early 2008

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Charge questions for HSRB

- Does each section identify the major areas and issues where ethical considerations need to be addressed?
- Are there additional sources of information that should be considered for inclusion in the sections?
- Is the information presented accurately and clearly in each section?

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Organization of the document - 1

- Introduction, purpose, and scope
  - Observational human exposure studies
  - Ethical issues in observational human exposure studies
  - Purpose of this document
  - Process for developing this document
  - Organization of the document

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Organization of the document - 2

- Elements to be considered in study conceptualization and planning
  - Problem conceptualization
    - Defining the study problem, justifying the study
  - Planning and scoping
    - Innovative and alternative study designs, assessing benefits and risks for participants, …
    - Developing the study design & human studies protocol
  - Independent scientific and ethical review
  - Establishing criteria for data and safety monitoring of scientific and ethical issues

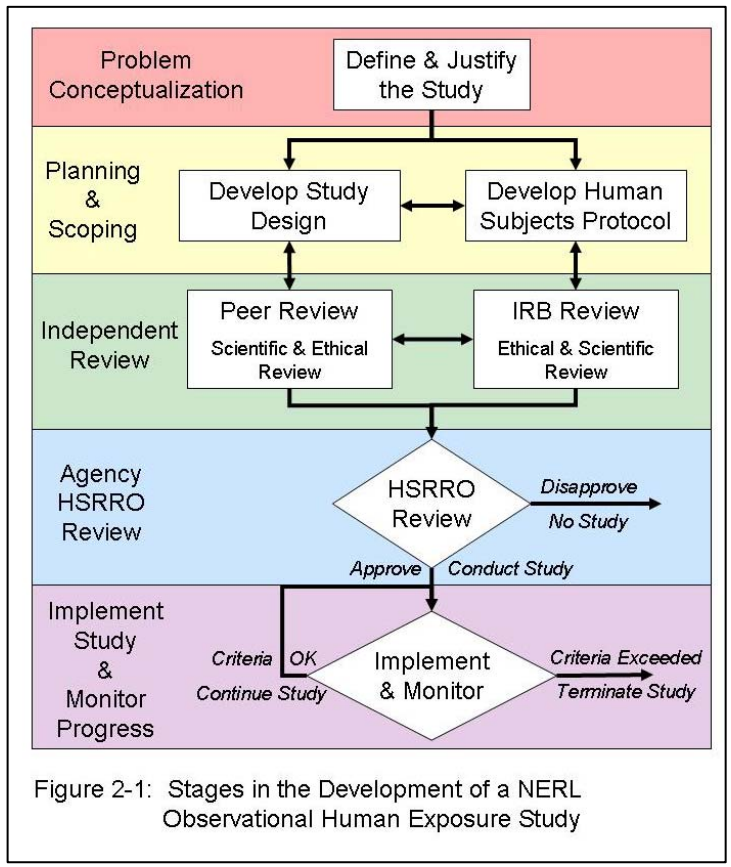

Figure 2-1: Stages in the Development of a NERL Observational Human Exposure Study

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Organization of the document - 3

- Ensuring protection of vulnerable groups
  - Identification of vulnerable groups
  - Justification for involving vulnerable groups
  - Minimal risk and vulnerable groups
  - Research involving children
  - Women as research subjects
  - Other potentially vulnerable groups

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Organization of the document - 4

- Privacy, confidentiality, and other concerns related to observational human exposure studies
  - Privacy issues
  - Confidentiality of information and participation
  - Collateral observations
    - Non-study hazards, reporting requirements, hazard communication, planning and staff training
  - Third-party issues
  - Data and safety monitoring and oversight

Organization of the document - 5

- Creating an appropriate relationship between the participant and the researcher
  - Informed consent
    - Information, comprehension, voluntary participation
  - Payments to research participants
  - Research rights and grievance procedures
  - Creating a supportive environment
  - Recruitment strategies
  - Retention strategies

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Organization of the document - 6

- Building and maintaining appropriate community and stakeholder relationships
  - Defining the “community”
  - Identifying who represents the community
  - Building relationships and trust
  - Community advisory boards
  - Engaging the community throughout the study
  - Identifying and interacting with other stakeholders

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Organization of the document - 7

- Designing and implementing strategies for effective communication
  - Developing a communication strategy and implementation plan
  - Individuals and groups involved in the communications
  - Communication materials, timing, level
  - Educating the participant and the community
  - Reporting results to the participant and the community
  - Reporting unanticipated results or observations
  - Anticipating and responding to criticisms
  - Responding to media, public inquiries, and stakeholders

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Summary

- Observational human exposure studies are important because they collect real-world information that determines:
  - What chemicals people are coming into contact with,
  - Concentration of the chemicals,
  - Most important sources, pathways, and routes of exposure, and
  - When, where, how often, and why people come in contract with chemicals.
- Understanding exposure is critical to EPA's efforts to reduce risks and to protect human health
- Protection of research participants is taken seriously by scientists and managers in the National Exposure Research Laboratory
- Not only do we want to meet regulatory requirements but we also want to live up to the spirit of the ethical standards that motivates those requirements