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Report on the Workshop to Discuss State-of-the-Science Approaches for Observational Exposure Measurement Studies

Durham, NC
November 28–29, 2006

Submitted to:

Human Exposure and Atmospheric Sciences Division
National Exposure Research Laboratory
U.S. Environmental Protection Agency
Research Triangle Park, NC 27709

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Notice

This report was prepared by Eastern Research Group, Inc. (ERG), an EPA contractor, as a general record of discussion during the Workshop to Discuss State-of-the-Science Approaches for Observational Exposure Measurement Studies, held November 28–29, 2006, in Durham, North Carolina. This report captures the main points and highlights of the meeting. It is not a complete record of all details discussed, nor does it embellish, interpret, or enlarge upon matters that were incomplete or unclear. Statements represent the individual views of meeting participants.

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1. Introduction

Researchers conduct observational human exposure studies to measure human exposure to chemicals in the environment. The U.S. Environmental Protection Agency's (EPA's) National Exposure Research Laboratory (NERL) has used these studies for several decades in order to gain understanding about exposures and ultimately to support efforts to improve public health. Because they deal with human subjects, however, these studies are complex, with numerous scientific and ethical issues that must be addressed during design and implementation. To ensure that EPA's research continues to be based on the most up-to-date science and the highest ethical standards, the Agency plans to develop a document that will compile "state-of-the-science" approaches for conducting observational exposure studies.

On November 28 and 29, 2006, Eastern Research Group, Inc. (ERG), an EPA contractor, convened an independent panel of eleven experts (Appendix A) in a peer consultation workshop to provide input on the development and content of the Agency's proposed state-of-the-science document. This panel workshop brought together nationally recognized researchers, ethicists, medical practitioners, and community leaders, providing a broad range of expertise on the scientific and ethical dimensions of observational exposure studies.

In its charge to the panelists (Appendix B), EPA asked them to provide recommendations on how to structure the document, what topics to address, and what information sources to consult. EPA also asked the panel to identify elements of observational studies for which the state of the science is most uncertain, and to provide recommendations on approaches for these elements. Prior to the meeting, several panelists submitted potential discussion topics to the panel chair. These preliminary suggestions are provided in Appendix C.

Appendix D contains the agenda for the workshop, and Appendix E provides a list of those who attended the meeting as observers. A phone line was available for any observers who wished to attend remotely. The workshop agenda included two opportunities for observer comment.

This report summarizes the presentations and panel discussions that took place in plenary session. For organizational efficiency, this report groups many of the discussions by topic, rather than strictly chronologically.

2. Opening Session

Jan Connery of ERG opened the workshop by welcoming the panelists and observers. She asked panel members to introduce themselves and then reviewed the meeting agenda.

Connery introduced Kevin Teichman, Acting Deputy Assistant Administrator for Science at EPA's Office of Research and Development, who thanked the panelists and observers for attending the meeting. Teichman explained that observational human exposure studies are critical to EPA's efforts to understand exposure.

Additional remarks were provided by Warren Lux, the Human Subjects Research Review Official in EPA's Office of the Science Advisor. Lux pointed out that EPA not only conducts its own observational exposure studies, but also relies on studies conducted by other parties—some of whom are funded by EPA—as a basis for certain Agency decisions. Noting the importance of applying consistent standards to this research, he outlined his vision for the future of EPA's observational exposure studies program: a human research program driven first and foremost by an ethical framework that can serve as a basis for regulations, with venues for investigators to discuss issues and adapt to changing science. He encouraged the panel to consider these issues, noting that he looked forward to receiving their recommendations and seeing to it that these recommendations are implemented.

Following the opening remarks, Linda Sheldon, the Acting Director of NERL's Human Exposure and Atmospheric Sciences Division (HEASD), presented an overview of human observational studies, which EPA has used for more than 30 years (see Appendix F for her presentation slides). She noted that EPA's mission is to protect public health, which requires understanding of risks to health. Exposure—that is, coming in contact with a chemical—is one half of the risk assessment process; thus it is critical that EPA understand and quantify how exposure actually occurs.

In observational exposure measurement studies, EPA observes people's contact with chemicals under normal day-to-day conditions, collecting samples of environmental media (e.g., air, dust, water) and keeping a record of subjects' activities (e.g., through videotaping or self-reporting diaries). Sheldon presented examples of important observational exposure studies conducted in the past, including EPA's Total Exposure Assessment Methodology (TEAM) studies—which demonstrated the significance of indoor exposures. Other examples include radon studies, which led to increased awareness and development of methods to reduce exposure, and $PM_{2.5}$ studies that demonstrated the association between ambient concentrations and exposure, ultimately leading to a new National Ambient Air Quality Standard (NAAQS). Sheldon also outlined important considerations for future studies, including the need to adhere to the highest and most up-to-date ethical and scientific standards, to avoid encouraging subjects to change their behavior in ways that would increase their exposure, and to work with communities to address their concerns.

Roy Fortmann (NERL/HEASD) explained the purpose of the workshop, as well as EPA's overall goals in developing the state-of-the-science document (see Appendix G for his presentation slides). To ensure that EPA's observational exposure studies continue to meet the highest scientific and ethical standards, it is important to follow the most up-to-date methods, standards, and approaches in study design and implementation. In the document that EPA will develop, the Agency will aim to identify issues that researchers need to consider, compile and evaluate information on state-of-the-science approaches (particularly for ethical considerations), and present this information in a peer-reviewed form for researchers inside and outside EPA.

Observational exposure studies involve complex scientific and ethical considerations, Fortmann explained—particularly those related to the protection of study participants. He listed several key study elements, including researcher responsibilities during design and implementation, communication, balancing risks and benefits, identifying and working with stakeholders, and involving the community throughout the process (design, review, during the study, etc.). He also

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noted that several information sources are available, including existing reports, policies, and guidelines; peer-reviewed literature; and case studies.

Fortmann reviewed the charge to panelists and provided a tentative schedule for producing the document after the workshop. Using the workshop report, EPA intends to prepare the document for external peer review and public comment in May 2007 and for release in July 2007. EPA will give the panelists an opportunity to review a draft of the document during the spring of 2007.

In response to questions from panelists, Fortmann provided the following information about the purpose and scope of the project:

- Although a portion of the document will be geared to a public audience, the main purpose—and the focus of this panel workshop—should be to help researchers.

- Because every study has its own unique set of considerations, EPA envisions this document not as a specific "cookbook" for designing a study, but more as a general resource outlining issues that researchers should address. The document can refer the reader to other sources for more specific information.

- The document should consider science *and* ethics, including issues about community engagement and considerations for special populations. It should remain broad, addressing observational exposure studies in general, not just studies of children or other sensitive groups. It does not need to discuss state-of-the-science for specific measurement techniques.

- This project is motivated in part by some of the perceived concerns surrounding NERL's Children's Environmental Exposure Research Study (CHEERS), which was suspended in 2004 and cancelled in 2005. The "state-of-the-science" document will be a first step in moving EPA's research program forward again. However, this document is not intended as a critical review of CHEERS.

- The panel should provide recommendations about content and how to frame the document so it is most useful to the intended audience. The panel can also recommend a title.

Following EPA's opening remarks, Connery facilitated the first public comment session (see Section 11, "Observer Comments").

Following the public comment, panel chair Tim Buckley presented an overview of the charge and the meeting format (Appendix H provides his presentation slides). He then led the panel in determining topic areas to focus their subsequent discussions. Based on EPA's charge and on

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pre-meeting suggestions from panelists, the panel agreed that EPA's state-of-the-science document should address the following six major topic areas:[1]

- Elements to be considered in study conceptualization
- Ensuring protection of vulnerable groups
- Addressing privacy and other concerns related to personal exposure observational studies
- Creating an appropriate relationship between participant and investigator
- Building and maintaining appropriate community and stakeholder relationships
- Designing and implementing strategies for effective communication

After agreeing on the list of topics, panelists developed a preliminary list of subtopics to guide discussion in each area. Members of the panel also suggested some common themes to consider throughout their discussions. For example, one panelist observed that all of the topic areas require some degree of balance between scientific benefits and risks to the subjects and the community. Panelists also suggested that EPA's document present issues for researchers to consider *before* designing a study. One panelist suggested that when establishing a sound scientific baseline for environmental decisions, deeper philosophical questions arise. What degree of environmental safety is necessary? How much scientific evidence is needed to support the decisions? Before researchers develop a study, they should consider what evidence is needed and what degree of study is justified.

Panelists also noted that EPA has a complicated role in observational exposure studies because the Agency essentially "wears two hats"—it is responsible for both research and regulation. As one panelist observed, there is a tension between pure research (i.e., the best scientific evidence) and constraints upon actually using that evidence to develop regulations (e.g., feasibility). NIOSH and OSHA do not have this problem because their process is transparent; NIOSH publishes a standard based on the scientific evidence and OSHA promulgates a standard that considers feasibility. Ideas for reducing this conflict included having ORD publish a standard based entirely on the scientific evidence and then the EPA administrator promulgating a standard that considers feasibility, or simply recommending that researchers state up front that scientific results do not always translate directly into policy.[2]

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[1] The panel recommended that EPA's document cover each topic area as a separate chapter. Titles for these topic areas evolved over the course of the meeting. For consistency, this report refers to the six topic areas using the final chapter names agreed to by the panel at the end of the meeting.

[2] In post-meeting comments, one panelist (Michael Lebowitz) stated that EPA does have defined pathways for translating research into regulation. For example, observational studies inform the NAAQS through scientific criteria documents, the Science Advisory Board, and then a staff paper that goes to OMB for a review of economics and feasibility. Ultimately, all the information is presented to the Administrator, who legally makes any changes in the NAAQS.

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Panelists then began discussions in the six topic areas. For the first four topics, the panel split into two breakout groups (Exhibit 1), with each group separately covering two of the four topics. Breakout group rapporteurs presented summaries of these discussions to the full panel in plenary session. The last two topic areas were discussed by the full panel on the second day of the workshop.

After lunch on the second day, Connery facilitated a second public comment session. The panel then began their final discussion session, during which they combined the topics and subtopics from their prior discussions into a single master document, provided in Appendix I. The panel also discussed the title, chapter names, and other elements EPA should consider including in the state-of-the-science document.

The remainder of this report provides an overview of all discussions that took place in plenary session, including results from each of the breakout groups as reported back to the full panel. For organizational efficiency, this report groups discussions by topic, rather than strictly chronologically. Sections 3 through 8 correspond to the six key discussion topics listed above, while Section 9 documents the panel's discussions about the title and other elements of the document. Sections 10 and 11 cover suggested information resources and observer comments, respectively.

Exhibit 1. Breakout Groups

Breakout Group A

- Bruce Lanphear, Chair
- David Carpenter, Rapporteur
- Giselle Corbie-Smith
- Natalie Freeman
- Jerry Menikoff

Breakout Group B

- Michael Lebowitz, Chair
- Rebecca Parkin, Rapporteur
- Sophie Balk
- Alan Fleischman
- Loretta Jones

The panel chair (Tim Buckley) rotated between the two breakout groups.

3. Elements to Be Considered in Study Conceptualization

This topic area was discussed initially by the full panel in the opening plenary session, and then discussed in detail by the members of Breakout Group A (see Exhibit 1).

Preliminary Comments

In their opening discussion, panelists developed the following preliminary list of subtopics to discuss within this topic area:

- Ethical principles.
- Need for a clear research plan.
- How is the study problem defined, and by whom? What groups are engaged in defining the problem?

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- Need for a clearly articulated study justification. In communication about the study, it is important for the researcher to explain what questions he/she seeks to answer and justify the investment of time and money. This step should precede study design.

- Funding, particularly conflicts of interest.

- Innovative and alternative study designs. Examples from around the country have shown how an innovative design can lead to greater benefits to the community studied. However, as another panelist pointed out, the study still must be able to test a hypothesis and provide a meaningful scientific outcome.

- Feasibility—Can this study be done within a particular community? What Institutional Review Board (IRB) restrictions are in place?

- Statistical power—i.e., How much scientific evidence does the researcher need?

- What constitutes "acceptable"? When observing subjects' behavior, the researcher must be able to distinguish between conditions that society has determined are acceptable (even if the subjects may be doing things that are not good for them) and conditions that are unacceptable. The researcher must "draw a line" and establish decision points in the study design.

- Transparency of the IRB—Who is on it, and what questions did they ask?

- The "therapeutic misconception." As one panelist explained, subjects believe that scientists have the subjects' best interests at heart, and often expect to benefit from the study, even if explicitly told that they will not. However, as another panelist pointed out, the study usually does not have any large downside either.

- Harm reduction and the potential for backlash. As one panelist noted, people generally assume that consumer products have been tested extensively, and may be upset to learn that their assumptions are incorrect. Another panelist added that the community may blame the researcher for being part of a "flawed" regulatory system, or may expect the researcher to be able to solve a problem that society has thus far failed to solve—e.g., removing a known toxin from household products.

Results from the Breakout Discussion

Following the breakout discussion, Breakout Group A reported back to the full panel. An outline of their presentation appears in Appendix I; detailed points are captured below:

Ethical principles. Fundamentally, many members of the group believe that one should not impose a higher duty on the investigator than society in general imposes to protect children or other vulnerable groups. For example, if society says it is acceptable for a child to grow up in a home with lead paint or where pesticides are used, then it is socially acceptable for the researcher to observe a child in such an environment. However, at least one panelist disagreed with this

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assertion, elaborating on her disagreement in post-meeting comments.[3] The researcher must still grapple with the question of whether it is ethically wrong to let this behavior continue. It is important to consider how the community perceives risks and benefits; for example, whether pesticide spraying is as harmful as the alternative, a home full of cockroaches that could trigger an asthma attack. If the researcher observes an imminent hazard such as child abuse, however, he/she *does* have an ethical responsibility to take action, and may have a legal responsibility to act as well. Thus, it is important to establish a clear line between what is acceptable and what is not.

Overall, panelists agreed that the study should have minimal risk to the participant. One concern is that study design and disclosure could encourage participants to increase their exposure, although several panelists noted that this outcome may be more of a perception than a reality. One way to minimize the possibility of increasing exposure would be to avoid telling the subjects about the study objectives, but this would be contrary to the goal of full disclosure of the study's purpose. After debating the issue, the panel agreed that while "not enunciating clearly" might be in the subjects' best interest, full disclosure is fundamentally more important. As one panelist noted, there are other ways to reduce the risk of encouraging increased exposures. For

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[3] In post-meeting comments, one panelist (Sophie Balk) expressed reservations about not imposing a higher duty on the researcher:

"The 'higher duty' argument depends on your perspective. I disagree with the contention in this slide that 'We should not impose on the investigator a higher duty than our society imposes to protect children.' Society tolerates all sorts of unacceptable circumstances for some people, mostly poor people, including children and most of us would agree that this is not a 'right' thing. I believe that I voiced this opinion at the meeting and I would like the summary to include this viewpoint.

"When pediatricians know what is 'right' and the matter is not minor, we will do our best to find a solution. When I see a child with asthma and I hear that there are housing problems affecting the asthma – holes in the wall letting in cold air, mold growing on walls from water damage – I will refer the parent to a social worker or a lawyer so the family can pressure the landlord to remediate the problems. If pressure doesn't work, the family is advised to sue the landlord. From my perspective, an investigator going into a home where there are known health risks or possible health risks has an obligation to at least educate the family about these risks and to refer the family to their health care provider or community advocacy group for further assistance. In my opinion, if this means that an observational study cannot be done because we can't merely observe an intolerable condition, so be it."

Another panelist (Bruce Lanphear) responded to Sophie Balk's point as follows:

"If we know what is right (i.e., there is evidence about the hazard and how to reduce or control the hazard), then I agree with Sophie. But the point of the research is to figure out whether an agent is a hazard or how to control a child's exposure safely. In other words, there has to be uncertainty about the hazard or the safety and efficacy of an intervention for the study to be ethical. This deserves additional discussion, particularly because it is such an important point and because I am not convinced we are really in disagreement."

A third panelist (Michael Lebowitz) added the following thoughts:

"Almost all observational exposure studies are to determine exposures to known hazards and other chemicals that are monitored for other reasons, and not to determine health hazards *per se*; they are used for risk assessments (to determine the extent of the risk to hazardous exposures and to lead to risk management). Observational studies of potential hazards are epidemiological and not observational studies of exposure *per se*."

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example, if a study covers many classes of chemicals, participants may be less likely to feel that a single risky behavior (e.g., spraying more pesticides) will increase their reward.

Panelists also discussed incentives and compensation. They agreed that unequal compensation is unacceptable—e.g., a scenario in which the researcher gives different incentives to different subjects, such as paying an affluent working mother more for her time than a poor unemployed mother. Rather, incentives should be based on the time it takes to participate—for example, minimum hourly wage—and the degree to which the individual may derive other benefits from participating in the study. Although few studies have been conducted on compensation and retention, the panel generally agreed that adequate compensation is an important factor in retaining participants in long-term studies.

Defining the study problem. The study problem can be defined by a variety of stakeholders, including the researcher, an agency, or the community. Ideally, all three will be involved in defining the study problem, particularly because different groups may have different perceptions of risks and benefits. In general, broad-based studies tend to be more useful than narrow studies. One panelist added that the study problem must be defined in an operational fashion. Another pointed out that investigators may not be able to fully define the problem because they often respond to a problem that has already been defined (e.g., in a request for proposals), and suggested that it might be more useful to define the problem broadly in the solicitation, then let the investigator work with the community to develop a more specific definition that meets their needs.

Justifying the study. The study should have a specific goal, address a specific public health need, and be clearly justified. It should address community needs. However, as several panelists observed, public health importance can be considered at different scales (broad, local, etc.).

Funding. In an ideal world, the government might provide all funding for observational exposure studies (e.g., through a fee imposed on chemical use), but in reality, an increasing number of studies are being funded by industry or through public-private partnerships. Researchers should ensure that anyone with a conflict of interest, including industry sponsors, will not have the opportunity to influence the outcome of the study.[4] Many federal agencies and universities have already developed mechanisms to minimize the potential for undue influence—for example, by not allowing industry representatives to participate in certain decisions. Even if no real conflict of interest is present, however, there can still be *perceived* conflicts of interest whenever industry is involved, because people tend to assume that industry-funded research will produce results that are favorable to industry. It is important to discuss these concerns with the community and make sure they have a say in whether to accept industry funding.

Several members of the group noted that they have worked with communities who wanted more than could be funded—for example, repeated visits or a long-term commitment that might outlive the funding source. Researchers should be aware of these expectations.

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[4] In post-meeting comments, one panelist (Alan Fleischman) added that it is also important that the sponsor not unduly influence the *design* of the study.

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Innovative and alternative study designs. The panel expressed interest in studies that test variables with natural histories—for example, comparing homes that have regular application of pesticides versus those that do not—and intervention or lag studies with a control population.[5] In any case, the community should be involved in designing the study.

Later in the discussion, one panelist noted that randomized trials of preventive interventions not only can increase participation, but also can enhance causal inference and test the efficacy of exposure reduction, thus making it easier to translate results into benefits for the participants. Randomized elements could include removing the source or taking steps to prevent exposure. As another panelist pointed out, studies that improve understanding of causal linkages could also be more useful when EPA makes policy determinations. Several panelists questioned whether randomized trials are within the scope of the document EPA plans to write. In response, Warren Lux (EPA) clarified that EPA defines "observational exposure study" to include any exposure study not considered an "intentional exposure study" (a study in which participants are exposed to a substance they would not be exposed to outside of the study). This definition is based on EPA's version of the Common Rule, and specifically refers to the substance under study—not substances that might be introduced as a result of sampling or intervention. The randomized designs described above *would* fall under EPA's definition of an "observational exposure study."

Several panelists agreed to recommend that additional work be done in this area. One panelist suggested that the preamble to EPA's document should define "observational exposure study" and should recommend that researchers at least be aware of alternative designs.

Other issues. Panelists mentioned several additional issues related to study conceptualization:

- Feasibility: The study must be accepted by the community, and must lead to results.[6]
- Statistical power: A study should be conducted only if it has sufficient statistical power to yield appropriate hypothesis testing and, thus, the potential to yield significant results.[7]
- Communication planning: All aspects of the study require communication. The researcher should engage in ongoing dialogue with the community, even after funding ends.

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[5] In post-meeting comments, one panelist (Sophie Balk) expressed reservations about allowing any routine pesticide application in homes with children:

"'Routine' spraying is not something a pediatrician would recommend. We know enough about the bad effects of pesticides on children to worry about this, and tell people to minimize exposure whenever possible. We recognize, however, that this may not always be possible but in many instances, it *is* possible."

[6] In post-meeting comments, one panelist (Michael Lebowitz) suggested a more detailed consideration of what it means to "lead to results." Not all studies will produce significant or meaningful results, as even an appropriately powered study may not reject the null hypothesis or provide results that can be used to change anything. EPA may want to clarify as "…must provide results to those studied," if this is indeed the meaning of the statement.

[7] In post-meeting comments, one panelist (Bruce Lanphear) added, "…unless it is a pilot study."

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- When is it necessary to stop the study? The researcher needs to establish criteria in advance.

- Researchers need to consider whether a study requires a Data and Safety Monitoring Board.

- The researcher should explain how the IRB works and who represents the community's interests on the IRB. The community should advocate for representation that reflects their concerns.[8]

- Harm reduction: The researcher needs to explain the concept of harm reduction to the community, noting that the study will not necessarily eliminate all dangerous exposure.

- As a general rule, communities should be consulted up front, be it for study design, obtaining funding, determining compensation, setting decision criteria, or other considerations.

- It is important to have diversity within the study population, reflecting the range of socioeconomic, ethnic, and other groups who may be impacted by the exposure in question.

Chapter Title

The panel recommended that EPA cover this topic area in a chapter entitled "Elements to Be Considered in Study Conceptualization." Panelists originally considered the term "study design," but agreed with one member's suggestion that "study design" may be too specific, with different implications in different fields. They agreed that "study conceptualization" would be a more inclusive term, encompassing steps that must take place before the study design.

4. Ensuring Protection of Vulnerable Groups

This topic area was discussed initially by the full panel in the opening plenary session, and then discussed in detail by the members of Breakout Group B (see Exhibit 1).

Preliminary Comments

In their opening discussion, panelists developed the following preliminary list of subtopics to discuss within this topic area:

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[8] In post-meeting comments, one panelist (Sophie Balk) elaborated on transparency, suggesting that the following items must be posted on the Internet for public scrutiny: investigators' names, credentials, and affiliations; details of study design; funding sources; information about who is on the IRB and their credentials and affiliations; what questions were asked of the IRB and how they were answered; and consent forms.

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- How to define vulnerable groups. One panelist noted that "vulnerable groups" can be defined in many ways, including life stages (young and old), predisposing diseases, or societal factors such as access to care. Another suggested a slightly different way to look at the term, pointing out that *all* people are technically vulnerable to exposure, and the only difference is the *degree* of vulnerability. Thus, the basic ethical principles should apply to all subjects. A third panelist agreed that the ethical principles apply to all, but noted that laws and regulations specifically talk about the vulnerabilities of children, people with pre-existing conditions, and people who do not have the means to access health care for diagnosis, treatment, or general knowledge about exposure and its effects. As several panelists pointed out, people with low socioeconomic status (SES) are more likely to have elevated exposures—for example, because they may be more likely to live in polluted areas (which they may not have the means to leave), more likely to use appliances that pollute indoor air, and less likely to know that smoking in the home is harmful.

- The culture of the group. Cultural nuances can increase certain people's vulnerability to exposure.

Results from the Breakout Discussion

Following the breakout discussion, Breakout Group B reported back to the full panel. An outline of their presentation appears in Appendix I; detailed points are captured below:

What constitutes a "vulnerable group"? Definitions vary, but in general, vulnerable groups can be defined in terms of *disparities*, which may be demographic, socioeconomic, or educational in nature. Some groups may be more vulnerable to exposure, while others may be more susceptible to harmful effects resulting from exposure—for example, those with preexisting biological conditions. These groups can be defined on either an individual or a societal scale. One important variable is the ability to voluntarily participate. For example, some people may be vulnerable to coercion, or more likely to enroll in a study because of economic need.[9,10]

Protection. Additional protection is justified for vulnerable groups. Protection occurs on two levels—protecting the individual and protecting the community—and is based on the two

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[9] In post-meeting comments, one panelist (Sophie Balk) suggested paying specific attention to children and the "politically powerless," including people with psychiatric conditions and addictions.

[10] In post-meeting comments, one panelist (Alan Fleischman) added, "It is important when discussing 'vulnerable' populations to make the distinction at the outset of the two ways this term is used. Environmental exposure scientists think of vulnerable populations as those who are vulnerable to the exposure (e.g. children, elderly, immune compromised, etc.). In the research ethics world, vulnerability means a group with diminished ability to protect their own interests, manifested generally through a compromised capacity to provide informed or voluntary consent (e.g. children, cognitively impaired, mentally ill, prisoners, educationally and economically disadvantaged)."

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underlying concepts of *beneficence* and *autonomy*.[11] To address beneficence—perhaps the more important of the two concepts with respect to vulnerable populations—the researcher must consider the balance of risks and benefits to the participant. Once the researcher can adequately address the issue of beneficence, then he/she should consider autonomy. The IRB plays a role in considering special protections and concerns.

Minimizing undue burdens. *Justice* is a key principle. During the breakout session, members of the group gave examples of studies in which participants were asked to travel long distances in order to provide samples. The panelists agreed that participation should not require an excessive amount of time and effort. Also, some researchers may feel the need to "collect everything" in one visit, which can put an undue burden on the participant. In addition to minimizing physical burdens, the researcher should also avoid stigmatizing the community or appearing to "blame the victims." The participants should also be the first to realize any benefits from the study. It is not fair to study the poor but then steer the benefits mainly to the rich.

How to study vulnerable groups. Like any participants in a human observational exposure study, vulnerable groups need to be provided with details of the study.[12] It is also important for the researcher to develop an authentic, substantive relationship with the group, based on trust, respect, and empathy. The researcher should be visibly involved, meeting community members (not just sending assistants into the community), learning about the community's needs and concerns, and learning about their culture and how they live their everyday lives. Study design teams and IRBs should include appropriate experts and participant advocates; for example, the IRB for a children's study should include a pediatrician with a working knowledge of the community and the hazard being studied. Members of vulnerable communities can be a valuable addition to research teams because of their understanding of cultural norms, and as one panelist explained, this should not be limited to simply hiring minorities as assistants to interact with the community. Ideally, people from diverse backgrounds would be included at all levels of the research structure, and researchers would endeavor to build that capacity within vulnerable groups.

One panelist pointed out that researchers face many burdens, and may not have the time and funding to develop deep relationships while meeting publishing deadlines and other constraints. However, another suggested that taking the time to develop these relationships will ultimately pay off for the researcher because he/she will be able to ask better questions and get more complete, honest answers in return. To deal with time constraints, one panelist suggested looking at models of paired investigations and apprenticeships, which also could help to build capacity among junior researchers.

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[11] In post-meeting comments, one panelist (Sophie Balk) recommended formally defining "beneficence" for those without an extensive background in ethics.

[12] See footnote 8 for post-meeting suggestions from one panelist (Sophie Balk) on ways to maintain transparency.

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Chapter Title

The panel recommended that EPA cover this topic area in a chapter entitled "Ensuring Protection of Vulnerable Groups." Panelists noted that the chapter titles should be grammatically consistent, and suggested that using active language in all headings may help to convey a sense of actually *applying* these strategies. Panelists also discussed the word "vulnerable," which may be defined differently depending on one's perspective. From a more scientific perspective, one might view the issue in terms of vulnerability to *exposure* (e.g., biological exposure), which led one panelist to suggest clarifying the title as "Study and Protection of Vulnerable Groups." However, others argued that the ethical issues really pertain to a different definition—vulnerability due to special characteristics of the group—and suggested leaving the title as recommended.

5. Addressing Privacy and Other Concerns Related to Personal Exposure Observational Studies

This topic area was discussed initially by the full panel in the opening plenary session, and then discussed in detail by the members of Breakout Group B (see Exhibit 1).

Preliminary Comments

In their opening discussion, panelists developed the following preliminary list of subtopics to discuss within this topic area:

- Emphasizing that despite all the limitations and drawbacks, the home environment is critical to understanding exposures.
- Privacy.
- "Collateral" observations.
- Effects on third parties.
- Breaches of privacy, which are inherent whenever one observes people in their daily routine outside of a controlled laboratory setting—e.g., at home, school, day care, work, or a long-term care center. Privacy is not the same as confidentiality.
- Watching people in their "natural" environments, where one may observe behaviors that are not in the subjects' best interests.
- Observing hazards that are unrelated to the research (e.g., physical hazards such as a child about to fall out of a window). It is important to train researchers and set up a system to deal with these types of observations.
- Working with community organizations and agencies ahead of time to determine how the researcher should deal with issues of reportability. It is important to understand the

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community's standards and consider the ramifications of reporting a "collateral" observation. For example, if the researcher reports a cockroach-infested home to the Department of Youth/Family Services and the family does not have the means to remedy the situation (e.g., because they are renters), the agency could end up removing children from the home.

- Training researchers to be sensitive to cultural differences, including those that may relate to potential hazards.

- Considering sociobehavioral factors.

Results from the Breakout Discussion

Following the breakout discussion, Breakout Group B reported back to the full panel. An outline of their presentation appears in Appendix I; detailed points are captured below:

What is personal exposure? At the outset of the study, the researcher needs to define "personal exposure," working with the community to explain this important concept in language they can understand. The community should understand how samples will be obtained and *why* the study must take place in personal spaces rather than in the laboratory. For example, as one panelist added, personal exposure monitoring has fewer uncertainties than studies based on ambient monitoring. In addition to the scientific fundamentals, researchers and communities should also understand the range of ethical issues that may arise in this line of research (including privacy), and should agree on how these concerns will be addressed.

Invasion of privacy. The issue of privacy invokes strong feelings, and invasion of personal space can seem at odds with the long-standing American ideal of "my home is my castle." Ultimately, to reduce the perception of invading personal space, the researcher's goal should be *to be invited in*. One way to work toward this goal is by addressing privacy issues up front. Cultural sensitivity is also important. All members of the research team—including the principal investigator—should be sensitive to cultural differences and should recognize that people's individual and cultural experiences can affect the way they perceive "invasion of privacy." On a related note, members of the group suggested a need for genuine diversity throughout the research structure, not just the research team.

Confidentiality. Confidentiality differs from personal-space privacy protection, as it relates more to how the researcher treats information that he/she receives from participants. In some cases, a certificate of confidentiality may be required by the IRB or by the circumstances of the study. Certain groups such as adolescents may have unique confidentiality issues.

Risk-benefit balance. It is important to consider risks and benefits in both the scientific and ethical domains. The ideal outcome is for all parties engaged in the process to realize some benefit—i.e., a "win-win" situation. However, the individual may not derive any extra benefit from participating, which should be made clear to the participant at the outset. Some IRBs prescribe language that must be used when explaining risks and benefits to the participant.

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Members of the group noted that some researchers have a tendency to exaggerate benefits or minimize risks to bolster recruitment, but these practices should be avoided.

Researchers should be aware that risk—and the perception of risk—may vary by individual (e.g., by age of the participant), by type of sampling, by the degree of invasiveness, or by cultural norms. For example, certain cultures may consider a hair or fingernail sample to be extremely invasive. The researcher should make participants aware that they have a right to refuse a particular component of sampling if they wish.

Disclosure. Key considerations include when to inform individuals, what information to provide, and how to provide it. Participants often want their individual results reported back in a timely fashion, although as members of the group noted, some individuals may not want to receive results, and they do have a right to refuse. The researcher should work with the IRB, sponsors, and the community to determine what information to provide back and how to do so. In general, participants should be given information about known *and* unknown hazards.

"Collateral" observations. Collateral observations are observations that are unrelated to the purpose of the study. These observations may or may not involve potential harm. The researcher must anticipate that these observations will occur, and must have an action plan to deal accordingly with these observations—including unexpected observations. The action plan should include training research staff in what to do if they observe something of concern. For example, the observer may be required to report to the principal investigator, who is ultimately responsible for any issues of intervention or mandatory reporting. When planning the study, the research team should identify resources to help with decision-making, like individuals who are familiar with the laws about mandatory reporting and appropriate follow-up actions.

Duty to care. Panelists discussed the researcher's responsibility to do things related to the care of the individual. The researcher does not have the same level of obligation as a physician in a clinical setting. Nonetheless, it is important for researchers to be aware of their duties ahead of time, and to understand that they may have biases and perceptions that can influence their sense of "duty to care."[13]

When to stop the study? Circumstances may require that a study be stopped on an individual level *or* across the board. A Data and Safety Monitoring Board (or similar oversight body) can play an important role in this process.

Third parties. An observational exposure study can potentially affect a number of "third parties," including:

- Household members not in the study
- Neighbors and other members of the community
- Insurers

[13] See footnote 3 for post-meeting comments from several panelists regarding the researcher's duty to care.

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- Landlords and rental agents
- School officials and teachers
- Caregivers of children, the elderly, the disabled, or others

The researcher should anticipate that third parties will be present, recognize that they may affect participation in the study, and plan accordingly to minimize impacts on these people and to address their needs and concerns. It is important to respect the presence of third parties—for example, by announcing a home entry in advance in order to avoid catching people off guard. During the planning phase, the community can provide useful input on how to deal with third parties.

In some cases, third parties may be so involved in the study that they essentially become participants themselves, in which case they may need to sign an informed consent form. However, as one panelist noted, in many cases it may be sufficient to receive a waiver for third party consent from the IRB, especially for studies with minimal risk.

Justification for the study. In explaining the study to the participants, the researcher should be clear about *why* the study is important. Justification can include benefits to the individual, benefits to the community, and broader benefits to scientific knowledge.

Chapter Title

The panel recommended that EPA cover this topic area in a chapter entitled "Addressing Privacy and Other Concerns Related to Personal Exposure Observational Studies." Panelists originally suggested the term "home hazards" but as several panelists pointed out, the fundamental issue is privacy, which extends beyond the home. Breaches of privacy are inevitable when observing a subject in a place where the researcher might make collateral observations, etc. However, the panel decided to add "other concerns" to the title after some panelists pointed out that there are still issues beyond privacy. Other panelists suggested adding "personal exposure" to the title in order to encompass all exposures and all locations where the researcher may be intruding. The panel also considered the term "natural environments," but as one member pointed out, these words might imply an outdoor setting.

6. Creating an Appropriate Relationship Between Participant and Investigator

This topic area was discussed initially by the full panel in the opening plenary session, and then discussed in detail by the members of Breakout Group A (see Exhibit 1).

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Preliminary Comments

In their opening discussion, panelists developed the following preliminary list of subtopics to discuss within this topic area:

- Informed consent, including issues around the storage and use of samples (e.g., DNA).

- Incentives and compensation.

- Advertisements.

- Grievance procedures. If participants have a problem with the study, do they know where to raise their concerns and obtain support? The IRB plays a role in designing a thorough informed consent form, but as one panelist noted, subjects may not remember what was in the informed consent form. A broader solution would be to go beyond simply writing down conditions and try to create a truly "supportive" environment for research and interaction.

- Ensuring that recruitment/retention methods will not change subjects' behavior. In particular, the study should not *encourage* risky behavior. The opposite issue—*discouraging* exposure—poses a greater ethical challenge because reducing exposure may be a desirable outcome, yet intervention to reduce risky behavior could skew the results of a study. As one panelist pointed out, if the researcher does not tell the whole truth to the community, it can breed distrust. However, another cautioned that providing too much information can be overwhelming, in addition to potentially jeopardizing the study. Panelists generally agreed that all subjects should be informed of the basic risks up front (e.g., in the informed consent), and should be reassured that if the researcher identifies an imminent hazard, he/she *will* bring it to their attention. To ensure that intervention will not jeopardize the integrity of the study, the researcher should anticipate potential behavior changes and the need for intervention in advance, and should design the study accordingly. Another solution might be to avoid an observational study altogether if another type of randomized study design might be more appropriate.

- Maintaining communication with subjects to keep them involved. For example, the researcher must inform participants and the community of the results. If the samples will take a long time to process, the researcher must inform the participant that there will be a time lag before he/she can learn the results.

- Strategies for recruiting from the target population.

- Deciding when to stop the study, perhaps by adapting strategies from clinical trials. For example, one panelist suggested that if exposures exceed established guidelines, the study should be stopped or switched to an "intervention" phase, similar to what happens when bad results are observed in a clinical drug trial.

- Involving community leaders to make sure recruitment, retention, and study methods are culturally acceptable.

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- Defining and balancing risks and benefits to the researcher, the subject, and the community.

Results from the Breakout Discussion

Following the breakout discussion, Breakout Group A reported back to the full panel. An outline of their presentation appears in Appendix I; detailed points are captured below:

Informed consent. All members of the breakout group agreed that informed consent is important, although they expressed differing views on exactly how extensive the informed consent must be. In addition to explaining risks related to the substance(s) being studied, the group generally agreed that if the researcher observes a preexisting risk such as a mother smoking in the home, he/she should err on the side of providing adequate warning.[14] However, they also agreed that it is impossible to convey the entire universe of conceivable risks to the participant. Panelists also raised concerns about risks that may not be fully understood, such as a chemical that is believed to be harmful but has not been studied thoroughly.

One panelist suggested that in theory, the researcher's level of duty may fall into four categories:

- No duty[15]
- Duty regarding risk imposed by research on subject
- Duty regarding risks known to be caused by preexisting behavior of subject
- Duty regarding other risks unrelated to the study

Several aspects of the informed consent require careful attention. The researcher should not promise anything he/she cannot deliver—e.g., a long-term commitment in cases with short-term funding. It is also helpful to talk with both parents in two-parent homes and to involve child subjects in the consent process if they are of sufficient age, although as one panelist clarified, laws and regulations generally require only the mother's consent—and the child's assent when appropriate—in order to study a child. The consent form should explain procedures for storage and use of samples (particularly DNA). Some panelists also felt that the informed consent form should clearly state that the family *can* change their behavior without losing compensation, although others expressed concern about how this might affect retention and sample size.

In general, the consent form should use language appropriate to the population, and the researcher should test participants to make sure they truly understand. There is an extensive body of literature on the effective use of informed consent. As one panelist noted, however, in many

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[14] In post-meeting comments, one panelist (Bruce Lanphear) cautioned that "a researcher has to be sensitive about lecturing a participant about a 'socially accepted' behavior."

[15] Panelists agreed that in practice, "no duty" is not a viable option for a researcher in this field.

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academic settings the IRB dictates the language of the informed consent document. This language may be difficult for the community to comprehend, making it hard for the researcher to communicate effectively.

Incentives and compensation. Compensation is critical for recruitment and retention, but can also be an area of controversy because of the concern that it might unduly influence participants' behavior. If compensation is too high, it might affect recruitment in such a way as to influence the representativeness of the sample and the generalizability of the results. Compensation can also affect the validity of results if, for example, the incentives are so high as to influence participants' answers.

Panelists disagreed on the extent to which "undue influence" can actually cause participants to increase risky behavior, and they disagreed on the extent to which one needs to worry about this outcome in studies with minimal risk. However, as one panelist pointed out, compensation could increase risk above minimal risk. Another noted that even the *perception* that compensation could increase people's risk might weaken a study's credibility.

As far as an appropriate level of compensation, the panel agreed that all participants in a study should be compensated at an equal rate, but disagreed on whether minimum wage is appropriate or whether it may be so high as to unduly influence behavior among some groups. A large body of literature is available regarding the influence of compensation and the relational ethics of the process. For example, some studies have compared the way different incentives affect retention; one method used was a raffle, although that approach may raise questions about legality.

To reduce the possibility that compensation could unduly influence participants (or the possibility that it could be *perceived* as such), the researcher should design the study to minimize the potential to alter behavior in a way that might lead to greater risk-taking by study participants. The researcher should also emphasize up front that participants are being reimbursed for the burden of participation, *not* for assuming a risk. Panelists agreed that researchers should avoid overemphasizing compensation in advertisements; one noted that community engagement tends to be a more effective recruitment strategy anyway. The researcher should also talk with the community about details such as whether participants would prefer to be paid in a lump sum or by the hour.

Grievance procedures. Participants should have an avenue to express their concerns to a third party (i.e., not the investigator or the IRB co-chair). It may be useful to appoint an ombudsman or use a community advisory board—although some panelists noted that community advisory boards may represent a small group of activists rather than a true cross-section of the community.

Creating a supportive environment for research and interaction. To create a supportive environment, the researcher must develop community relationships prior to initiating the study. Planning grants can help the researcher work with the community to develop a communication plan, thereby building trust.

Ensuring that recruitment/retention methods will not change subjects' behavior. Although the informed consent process may change behavior, it is ethically imperative that this process be followed. Although decreasing exposure may affect the results of the study, it may still be a net

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benefit. Communication is helpful in this area; for example, providing participants with a "risk/risk" statement that acknowledges the hazards of exposure *and* the hazards of the alternative.[16] One example would be a statement that explains the risks of pesticides as well as the dangers of having pests in the home.

Ongoing communication and reporting results. Ongoing communication is critical for retention, especially in long-term cohort studies. Reporting results can also be an incentive. If the study involves collecting biological data that may reflect immediate hazards to participants, results should generally be provided with a fast turnaround time. Less critical information may take longer to process; for example, many studies have a three-year time lag. In any case, it is critical to let the community know ahead of time what type of turnaround they can expect.

Some panelists suggested that the researcher should only report data from which meaningful conclusions can be drawn, while others would prefer to provide all results, regardless of clinical significance. In either case, it is important to establish clear procedures up front, working with the community to determine what data *they* would like to be given.

Recruitment strategies. Churches and other community associations, agencies, etc., can promote the recruitment strategy to which the community agreed, but are not themselves a source of representative participants.

Deciding when to stop the study. The researcher should work with the community ahead of time to establish standards for when the study will be stopped because of risk. This issue is discussed further under "study conceptualization."

Procedures for collateral observations. The group agreed that the investigator must identify and take action on imminent hazards he/she observes even if independent of the subject of the study, but thresholds should be set relatively high because the community may evaluate dangers differently. It is important to discuss this issue with the community in advance.[17]

Chapter Title

The panel recommended that EPA cover this topic area in a chapter entitled "Creating an Appropriate Relationship Between Participant and Investigator." This topic was originally identified as "Recruitment," but panelists also noted the importance of *retention*—or, in a broader sense, *participation*. The panel agreed to start the title with an active word ("creating"), and they agreed that this section also should cover the basic factors to consider with respect to the *relationship* between the researcher and the participant.

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[16] In post-meeting comments, one panelist (Sophie Balk) added that participants should also be given information about how to abate these hazards.

[17] In post-meeting comments, one panelist (Sophie Balk) cautioned that this does not necessarily mean that researchers have a *higher* standard than the community does for defining danger—just that they may have *different* standards.

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7. Building and Maintaining Appropriate Community and Stakeholder Relationships

Panelists discussed this topic area during the opening plenary session and then again in greater depth during a plenary session, chaired by Loretta Jones, on the second day of the workshop.

Preliminary Comments

In their opening discussion, the panel developed the following preliminary list of subtopics to discuss within this topic area:

- How to define "community."
- Determining who represents the community.
- Engaging the community throughout the process. The researcher should work with the community to gather information and share results, then help address their concerns. As another panelist pointed out, there have been many cases in which a researcher lost the community's trust because he/she failed to engage the community at a particular step of the process.
- Building relationships and building trust before beginning the study. One panelist explained that three major factors contribute to building trust: (1) respect for the individual and the culture; (2) equity of grant resources; and (3) a commitment to empower the community.
- Building a lasting infrastructure. The community may expect a long-term, rewarding relationship. As several panelists noted, a project should invest in the community so that even after grant funding ends or the last paper is published, the community will have the resources to address their concerns without relying on the researcher for assistance. Building a lasting infrastructure may be an obligation of the sponsor.
- Developing a community contract that outlines the roles and expectations of the researcher and the community, including expectations of control.
- Honesty, partnerships, and power relationships.
- Issues around revealing findings.
- Importance of language. One panelist provided an example of a study in the U.S./Mexico border region, in which materials had to be translated into the local dialect ("border Spanish"). The researcher can involve community members as interviewers and translators.

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- The role of the community on the IRB. As one panelist noted, the Office of Human Subjects Protection requires that every IRB include at least one community representative, but institutions differ in how they define "community representative" and the extent to which community representatives truly have a voice on the IRB. Some IRBs include more than one community member.

- Researchers should make an effort to look at communities' resiliencies and report *positive* observations along with the negatives. Communities tire of hearing about only the things they are doing wrong. They also want to be told what they are doing *right*.

- How to define "stakeholders" and determine what role they should play. Stakeholders include business, industry, and various levels of government. Relations with stakeholders may be confrontational, and people with conflicts of interest should not be making key decisions.

Subsequent Discussion

Why be concerned about community engagement? Panelists began the discussion by confirming the importance of engaging the community in the research process. One panelist noted that by its very nature, observational exposure research must take place in community settings. As the recent NAS report pointed out, ethical principles from the "ivory tower" of academia may take on new meanings and reveal unique nuances when applied in the field ("Ethical Considerations for Research on Housing-Related Health Hazards Involving Children"—see Section 10, "Information Resources," for a full citation). Another panelist explained that many of the communities targeted by observational exposure research may not feel fully "accepted" by society, thus making it even more critical to partner with those communities to identify acceptable research models.

Panelists agreed that fundamentally, the purpose of engaging the community is to ensure that the following four aspects are in place:

- Respect for the individual

- Respect for the culture

- Equity of resources

- Empowering the community to endure

There are many ways to involve the community during the research process. On an advisory level, community members can help the researcher make sure he/she is "doing the right thing." They may also be able to help conduct research. Some aspects of community engagement may be unique to observational exposure studies; for example, as one panelist noted, emergency research studies may have a very different notion of how the community should be involved.

Defining "community." Communities can be defined in many ways—e.g., by geography, shared cultural and social characteristics, or common values and interests. For example, a

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“community” of Native Americans may consist of a tribe whose members are scattered throughout the country. How the researcher defines “community” will depend on the nature of the study.

Panelists noted that “community” can be defined broadly or narrowly. In the broadest sense, “community” might include anyone who is not part of the research team, or anyone who does not have responsibility or authority for the study. This broad definition could include local agencies, stakeholders, and the press, for example. For EPA’s document, however, the panel suggested defining “community” more narrowly as “the population from which study participants are selected.” This definition captures participants and their social/cultural community, including community “experts,” but excludes government agencies, industry, and others who do not necessarily represent the interests of the participants.

It is important to distinguish between community (in the narrower sense of the word) and stakeholders, and the panel recommended that EPA define both terms clearly. As one panelist explained, a critical difference is that the community has a right to speak for its own interests, while stakeholders cannot speak directly for the community. Nonetheless, stakeholders have useful information and expertise, and should be engaged accordingly. For example, stakeholders can play an important role on advisory boards because they understand impacts and can help implement change. One panelist cautioned the group not to be overly restrictive when defining terms, recognizing that some people’s definitions of “community” and “stakeholder” may overlap.

Who represents the community? In defining “community,” several panelists raised the issue of “voice”—namely, the community’s right to speak for its own interests, and the importance of identifying voices within the community who can articulate those interests on the community’s behalf. Identifying the appropriate voices may be harder than it appears because as one panelist noted, the *loudest* voices (i.e., the activists) may not always be the most representative, and in many cases, it may take several voices to adequately represent the diversity of viewpoints within the community (e.g., through a community advisory committee).

One of the researcher’s first steps in engaging the community should be to ask them who *they* see as a legitimate voice who can speak for them. For example, one panelist recounted an example in which she interviewed several community members and asked each to suggest five people who could speak for their interests, then compared notes to identify names that were suggested repeatedly. Community “leaders” can also help identify appropriate voices. For example, the researcher may find it helpful to consult with elected officials, religious leaders, community associations, or a community elder or matriarch (e.g., the “great mother”).

For assistance, researchers also can consult a growing body of literature on community representation. One panelist suggested reviewing sociological and ethnographic research on identifying community leaders, while another pointed to a large body of literature on community-based intervention research, including discussions on community advisory boards and guiding principles in CDC’s online journal, *Preventing Chronic Disease* (see Section 10, “Information Resources”). Community-campus partnerships may provide useful case studies.

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Panelists also discussed the value of tuning in to the recent debate on emergency research studies. Unlike observational exposure studies, emergency research studies involve participants who cannot consent to participate because they are in a state of extreme physical trauma at the time (e.g., suffering a massive loss of blood). However, two panelists noted that there are also many parallels between observational exposure studies and emergency research, particularly the need for community input ahead of time. In the case of emergency research, it is particularly important to identify appropriate voices within the community because these voices will essentially be providing advance consent on behalf of those who will become participants. There are also some lessons to be learned from missteps that have occurred in this line of research.

Importance of language and culture. Language and culture are sometimes thought of as a barrier to community engagement, but if the researcher understands and appreciates the unique linguistic and cultural characteristics of the community, this can facilitate engagement. Panelists noted the importance of avoiding misconceptions and overgeneralization; instead, the researcher should recognize and appreciate heterogeneity within communities or groups. Differences extend beyond nationality or ethnic background; for example, different tribal groups from the same region may have very different cultural traditions.

Spoken language is one variable but not the only one. Groups may have different cultural norms too; for example, one panelist noted that some Native American groups do not like pictures taken of them, while some voodoo practitioners may be reluctant to provide hair or fingernail samples. Groups can also differ in the way they make decisions. One panelist described an Amish community that traditionally deliberates for a long time (compared to typical U.S. norms) before answering a question; another recalled working with Native American groups who place a strong emphasis on reaching decisions by consensus. In both cases, the research partnership was more effective once the researcher learned to work within the community's decision-making culture.

Building trust. Throughout the discussion, panelists echoed a common theme: that trust must be *built*, not assumed. It is incumbent upon the researcher to demonstrate trustworthiness throughout his/her relationship with the community.

A key first step in developing trust is to establish a relationship with the community before the study. This relationship—and the ensuing research partnership—should be built on honesty and equity of resources (i.e., sharing equally). Panelists also emphasized the importance of honoring voices from both sides. Beyond just listening to the other side or respecting what they have to say, *honoring* voices means actually taking those voices into consideration, which the community has a right to expect.

Another way to build trust is by establishing a contract with the community. As one panelist pointed out, a community contract can clarify the expectations, roles, and responsibilities of both sides of the partnership. A contract can also establish limits. Many communities see value in formalizing this contract as a memorandum of understanding (MOU) because, as another panelist noted, having these expectations and limits in writing will reduce the likelihood of misunderstanding. A formal MOU can serve as a platform for resolving disputes, and can also build expectations for a lasting infrastructure, which panelists highlighted as an important ingredient in a successful relationship.

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For more information on building trust, one panelist noted that a great deal of literature has been written on developing relationships, setting expectations, and other aspects of trust building. Another pointed to a formal protocol signed by members of an interagency/tribal group in Arizona as part of the "Turning Point" program (see Section 10, "Information Resources"). Several panelists recommended that EPA provide researchers with sample MOUs, noting that many examples are available.

Honesty, power relationships, and partnerships. Because every study is different and every community is unique, is hard to define exactly what an effective research partnership will look like. However, a few general principles should be considered. As described in the previous section, panelists noted that honesty is an important part of any partnership. Several panelists suggested that the researcher also consider power dynamics—specifically the *balance* of power.

As one panelist observed, researchers often spend a great deal of time searching for funding or working to meet the demands of an IRB, which can leave them feeling like they have very little power. However, in the context of community relations, the researcher must recognize that he/she actually has a great deal of power. This power can take many forms.

One of the more tangible forms of power is monetary power. A related consideration is *access to resources*. As one panelist noted, if the community cannot access the resources they need in order to understand or participate in the study, or they *feel* they cannot access these resources, it can result in an imbalance of power.

Other forms of power may be more subtle, but are still important for the researcher to consider. As one panelist noted, peer pressure can influence decisions about participation in a study, as can the power of expectation—the feeling that one is *expected* to participate, and the fear of repercussions if one does not participate. The power of expectation and fear of repercussions can be compounded by confusion over the role of government agencies in the study; for example, if the participant believes that the people running the study may be connected with those who provide benefits such as food stamps. Housing relationships are particularly ripe for misunderstanding and imbalance of power. For example, as one panelist noted, people in public housing could feel compelled to participate out of fear that not doing so could jeopardize their relationship with the Housing Authority.

In addition to the researcher's real or perceived power to affect the physical well-being of participants, the researcher also possesses the power to stigmatize the community through his/her actions. One panelist noted that the researcher may stigmatize the community by reporting findings in a particular way; another added that simply conducting research in a particular community might be perceived as *labeling* that community in a negative light.

Not all forms of power are necessarily tipped in favor of the researcher. One particularly important characteristic of the researcher-community relationship is the imbalance of knowledge, which works in both directions. The researcher has some knowledge that the community does not have, but as several panelists pointed out, the community also possesses some knowledge that the researcher lacks. One benefit of partnership, therefore, is that it allows both sides to pool their knowledge and resources—i.e., to engage in knowledge transfer.

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Studies involving children can raise additional issues related to power dynamics. As one panelist noted, because children have less power than adults, it is up to the parent to understand as much as they can about the study. In some cases, it may be helpful to consult outside experts (e.g., pediatricians) to improve understanding.

Leaving a lasting infrastructure. Panelists agreed that building a lasting infrastructure is an important part of the relationship between the researcher and the community. Rather than simply "take" from the community, the researcher should give back by helping to build a sustainable infrastructure that empowers the community.

Empowerment and capacity-building begin with the planning stage of the project. Several panelists echoed the feeling that infrastructure-building must occur throughout the project—not just at the end—and therefore the researcher must include this consideration in the overall plan. Panelists also emphasized the importance of involving the community in the planning process, including negotiations about capacity-building. One panelist specifically emphasized the need to be forthright with the community regarding funding limitations. The community may not like the ephemeral nature of funding and they may be apprehensive about taking on more responsibilities in the future, but as the panelist pointed out, a well-designed program will cultivate their confidence and expertise over time.

Panelists discussed several ways to build capacity during the study, such as involving members of the community in certain roles—e.g., performing interventions. Ultimately, the goal is to train community members so that in the future, they can perform some of the functions that are initially performed by the research team. Panelists noted that certain research grants specifically support training. Panelists also noted that training "works both ways." As two panelists pointed out, allowing the community to train the researchers not only is a sign of respect, but also can lead to important new understanding. For example, one panelist recalled working with a Native American tribe who insisted upon training the entire research team on cultural sensitivity; the result was greater awareness and a stronger partnership.

Once funding for the study ends, the researcher can still continue his/her relationship with the community. One panelist described an example in which the research team remained accessible to the community if they needed technical support after funding ended. Researchers can "build bridges" by helping community members identify new funding opportunities and write grant applications. In general, panelists agreed that the end of funding *should not* mean the end of the relationship.

While the researcher plays an important role in building a lasting relationship, the panel emphasized that the sponsor bears some responsibility as well. As one panelist pointed out, many sponsoring institutions (for example, the Kellogg and Robert Wood Johnson Foundations) already recognize the importance of enduring commitment, and have used a variety of approaches to ensure that these relationships are able to continue. For example, some grants may tail off over a five-year period, allowing time for a more gradual transition to self-sufficiency. This panelist recommended that universities and federal agencies consider similar "umbrella" funding mechanisms.

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Another important step is to formalize the relationship between the community and the *institution* conducting or sponsoring the research, not just between the community and the individual researcher. As several panelists noted, institutional relationships can survive even if individuals leave—for example, if the researcher moves to a different university. Thus, panelists also emphasized the need for researchers to build support within their own institutions. One panelist cautioned that institutions—particularly universities—may be reluctant to build enduring relationships with communities if they do not see long-term financial value in this investment. Another agreed that getting long-term commitments from universities can be particularly difficult, but suggested a growing awareness among many high-level university officials that relationships with the community really do produce long-term gains. Researchers may be able to get more support from university officials if they can document their successes.

Panelists recommended that EPA's document highlight some examples of sustainable partnerships. For example, one panelist mentioned the "Turning Point" program (see Section 10, "Information Resources").

Chapter Title

The panel recommended that EPA cover this topic area in a chapter entitled "Building and Maintaining Appropriate Community and Stakeholder Relationships." This topic area was originally labeled "Community Participation," but panelists agreed that "engagement" is a more appropriate term than "participation." As one panelist noted, "participation" happens on many levels, sometimes simple or superficial, while "engagement" reflects a more long-term, lasting relationship. Panelists agreed that it is important to distinguish between stakeholders and the community (in the narrower sense of the word), noting that all of these parties must be engaged at some point in the course of the study. Two panelists noted that because researchers are themselves a part of the engagement process, the title should also reflect the importance of a two-way *relationship*.

8. Designing and Implementing Strategies for Effective Communication

Panelists discussed this topic area during the opening plenary session and then again in greater depth during a plenary session, co-chaired by Michael Lebowitz and Giselle Corbie-Smith, on the second day of the workshop.

Preliminary Comments

In their opening discussion, panelists developed the following preliminary list of subtopics to discuss within this topic area:

- What are the roles and responsibilities of the researcher? The researcher should know whom he/she is obligated to communicate with (participants, community, sponsors, the

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press, etc.), and should know what, when, and how to communicate with these parties. Can the researcher acknowledge participants at the end of the study without breaching privacy?

- Developing lay language or—more broadly—communicating at different levels. The researcher must be able to communicate effectively with scientists, journalists, politicians, and the community. Each group has its own degree of scientific literacy.

- Communicating *with* others—i.e., recognizing that communication is a two-way interaction.

- Posting plans so they are accessible to the community, not just on a web site.

- What is exposure? What pathways need to be considered? Several panelists suggested defining key terms in any communications with the community.

- Educating the community about the principles of research (e.g., "do no harm") and discussing these principles at an accessible level.

- Explaining what constitutes "acceptable" conditions. The researcher should let the community know in advance where he/she intends to "draw the line"—i.e., at what point the researcher will inform participants of dangerous conditions.

- How to reveal findings to individuals and reveal aggregate findings to the community.

- Issues around public use datasets. Participants may be concerned about sample storage and the use of data in subsequent studies, including studies of environmental-genetic interactions. DNA is emerging as a hot-button issue, as people grow concerned about who may have access to their genetic data, and for how long. Protocols must be communicated clearly.

- Legal ownership of data. As one panelist noted, communities are increasingly aware that if studies are publicly funded, *the people* own the data; thus, they expect to be able to mine the de-identified dataset.

- Communication extends beyond the principal investigator; it should also include the IRB, for example.

Subsequent Discussion

Roles and responsibilities. Panelists discussed the researcher's responsibilities related to communication—namely what, when, and how to communicate. Members of the group agreed that communication is an important aspect of engagement with participants and the community, and it is critical to maintaining transparency throughout the study. They also noted the importance of effective communication with stakeholders (including relevant agencies whose jurisdiction includes the community), sponsors, the media, and others.

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Members of the panel outlined some general steps for researchers to consider. Several panelists suggested that even before securing funding, the researcher should open a dialogue with the community, letting them know what he/she would like to study and soliciting their input on how the study could be designed. As one panelist noted, engaging the community at this stage can be valuable even if some aspects of the study may be "set in stone" in the request for proposals (RFP). Next, the researcher can approach the sponsor with a preliminary plan in place, including ideas about how the community will be involved. After securing funding, the researcher can go back to the community for help refining the study design. At this stage, a community advisory group also can help the researcher recruit or select participants.

Panelists also discussed interaction with the media. Before the study begins, the researcher may want to alert the media through press releases, although as two panelists noted, the study should not be publicized widely until funding is securely in place (i.e., the study will definitely happen).[18] The amount of detail to publicize depends on the study design. For example, a truly random sample design requires a lot of advance publicity—perhaps including public service announcements—in order to let members of the community know that they may be contacted by the research team. In other cases, too much publicity may be detrimental to the study. One panelist suggested media training for all study partners, noting that the entire team needs to convey a clear, consistent message to the press and to the public throughout the course of the study.

Once participants have been selected, panelists agreed, it is important to provide them with information about the study methodology, including how the researcher plans to provide results. This information is most often conveyed through the informed consent. As one panelist noted, it is important not only to define the study methodology, but also to *justify* it. Another panelist discussed the value of describing the study to a broader audience, noting that criticism from activists and politicians may be a symptom of insufficient communication (see discussion on "anticipating and responding to criticism," below).

To maintain transparency, the researcher should continue communicating with participants and the community on a regular basis throughout the course of the study. One way to maintain communication is through written reports; for example, one panelist noted that sponsors may require regular progress reports. The research team can also hold community meetings. These reports and meetings can keep the community informed about project status (e.g., recruitment success, trajectories); meetings can also be a valuable way to solicit feedback from participants, the community, and stakeholders. In addition, panelists noted the value of *educating* participants and the community both before and during the study. Educational information can be general in nature—for example, one panelist suggested enhancing participants' scientific literacy by educating them about the scientific method and the basics of epidemiology. The researcher also can provide general information about risks and indoor hazards, as well as more specific information about how an observational exposure study works, what types of data will be

[18] In post-meeting comments, one panelist (Michael Lebowitz) noted that advance publicity can also occur through community associations and agencies, and probably through other willing stakeholders as well.

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obtained, and what the results will look like.[19] One panelist discussed the value of educating participants about issues of confidentiality and data ownership, noting that communities occasionally ask to know *everyone's* results without realizing that this would be improper.

Once results are available, the researcher faces a number of decisions about how to report them. Panelists emphasized the need to report both individual and aggregate results in an understandable and timely fashion. They highlighted several factors for the researcher to consider:

- Order of communication. As one panelist observed, participants may be unhappy if they first learn the results of the study at a meeting or through the media. Participants should be the first to learn the results, not the last.

- Providing timely results. Panelists agreed that timely reporting is an important goal, but they also recognized the importance of balancing timeliness with the need for quality control. In some cases, results cannot be processed and returned to the participant until several years after the data are collected. In other cases, preliminary results can be provided quickly, but further analysis could lead to a different interpretation. To address these concerns, one panelist suggested working with communities to find out exactly what information they feel is most important to have in a timely fashion. For example, the community may be happy to receive some preliminary results in the form of general trends. Another panelist suggested that the researcher focus on timely reporting of any results of "alarm." As this panelist noted, some people believe the researcher also has an obligation to ensure that *intervention* occurs in any situation with alarming results, but this belief is controversial.

- Reporting in a useful fashion. Panelists discussed ways to provide participants with results that are useful and understandable. One panelist pointed out the distinction between *data* and *findings*, noting that the latter involves explaining what the numbers actually mean. Another explained the utility of presenting individual results in the context of aggregate results, so participants know how their results compare to the overall distribution. In general, the researcher should consult with the community in advance to find out what type of reporting would be most useful to them.

- Whether to report *all* results or just the "meaningful" results. One dilemma faced by researchers is whether to give participants *all* results or only the "scientifically relevant" results—i.e., results associated with known risks to one's health or well-being. Panelists recognized advantages and disadvantages to each approach:

    - The "meaningful" results are probably the most useful to the participant, while reporting every result may seem like a "data dump" with little meaning. Further, some IRBs involved with child research have restricted reporting out of concern that too much information can overwhelm participants and lead to undue stress.

[19] In post-meeting comments, one panelist (Michael Lebowitz) recommended that community/participant education also cover the utility of observational exposure studies.

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For example, if participants learn that several hundred compounds were detected in their environment, and they do not know what all the levels mean, they may worry unnecessarily about their health and feel powerless to do anything about it.

- Providing only "meaningful" results means that someone (e.g., the investigator) must make a judgment about what may or may not be dangerous. Even if objective criteria are available (e.g., government guidelines), there are often several different guidelines from which the investigator must choose. Regarding concerns about added stress resulting from a "data dump," one panelist suggested that the public may be more capable of dealing with uncertainty than is sometimes assumed.

To resolve this dilemma, one panelist suggested giving participants a choice. For example, the informed consent could include check boxes asking how each participant wants to receive results (or if he/she wants to receive results at all). The researcher also can ask for each participant's preference once the results are ready, and can provide participants with the option to contact the researcher if they initially opt out but later decide they do want to learn the results. Another panelist suggested reporting all results by default, but making sure to explain clearly whether each result constitutes a risk. Panelists emphasized the importance of outlining all reporting procedures up front in the informed consent, and recommended that the study design clearly identify which guidelines will be used to determine risk.

- Role of stakeholders. The researcher should provide some aggregate data to stakeholders. Certain stakeholders may have reservations about reporting data to communities, due to concerns about the potential economic or political impacts of releasing this information. One panelist recommended that the researcher listen to stakeholder concerns, but not let these concerns override the researcher's obligation to report back to participants. Another pointed out that with public funding, the aggregate results are public information anyway, so they will inevitably find their way to the Internet or another public forum. Results are likely to end up in peer-reviewed literature as well.

Along with reporting results to participants and the community, the researcher will probably be expected to report the findings in peer-reviewed literature—which, as two panelists noted, is frequently required by the sponsor.[20] The researcher can continue to engage the community at this stage. For example, one panelist reported that he often includes a community member as a coauthor in his publications.

Develop lay language. Reflecting on earlier discussions, panelists reiterated the importance of defining key terms and communicating in a way that is linguistically appropriate.[21]

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[20] In post-meeting comments, one panelist (Michael Lebowitz) added that researchers are often expected to place the data on web sites and to provide the data to local agencies and the media.

[21] In post-meeting comments, one panelist (Sophie Balk) suggested changing the title of this section to "Develop understandable language," noting that medical and environmental health professionals may not be familiar with all

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What constitutes "acceptable" conditions? During the course of a study, the research team may identify exposures of concern, both related to the study and unrelated. Panelists discussed numerous complexities regarding when and how to report these concerns to participants.

Several panelists emphasized the importance of defining limits up front, including thresholds for imminent danger. For many substances, federal or state laws define "acceptable" exposure levels. In other cases, however, the researcher might have to consider whether a surrogate standard is appropriate—for example, should indoor $PM_{2.5}$ concentrations be compared to the outdoor NAAQS? The researcher should also consider guidance from agencies and organizations like the American Academy of Pediatrics, which has policies on pesticide use, mold, environmental tobacco smoke, and other hazards in homes and schools.

Panelists agreed that the researcher has a duty to inform participants about risks related to the study. However, they disagreed on the extent to which it is necessary to inform participants about risks unrelated to the study.[22] Some panelists favored providing all participants with a general fact sheet on common household hazards (e.g., injury risks, chemical hazards), rather than assessing and reporting these hazards on an individual basis. A general fact sheet would prevent the researcher from getting bogged down in assessing every possible hazard (of which there are many), and would prevent participants from being confronted with a "laundry list" of criticism from the researcher, which might leave them feeling overwhelmed or insulted. However, another panelist argued that relying on general education rather than individual reporting of hazards has led to criticism in the past—including some of the criticism that led EPA to convene this panel. To improve observational exposure studies in the future, this panelist recommended that EPA be scrupulous about informing participants about risks in their homes.

To address the issue of risk communication, panelists suggested some precedents for EPA to consider, including NAS and World Health Organization (WHO) documents that describe thresholds for reporting—for example, informing participants about indoor exposures that exceed occupational standards (see Section 10, "Information Resources"). One panelist suggested giving participants a choice by asking in the informed consent whether they would like to be told about hazards unrelated to the study. Panelists also discussed the importance of *how* the researcher reports these hazards to participants. In one study, the research team offered to remedy certain physical hazards rather than simply telling the participant to do it. The research team also can provide recommendations and resources that empower participants to remedy hazards. For this approach to work, it helps to have a friendly, trusting relationship with the participant and to know what resources are at his/her disposal. For example, as one panelist noted, a renter may not have control over mold in his/her apartment. In this case, rather than just tell the tenants that they have a mold problem they can do nothing about, the researcher can provide recommendations and resources to empower the *community* to tackle larger problems (e.g., landlord issues) through legal or political action.

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the relevant terminology either, even though they probably do not consider themselves "lay people." This panelist also emphasized the importance of defining all acronyms.

[22] In post-meeting comments, one panelist (Sophie Balk) discussed the need to reconcile this idea of "duty" with the way the panel defined the researcher's duties in the "Study Conceptualization" and "Addressing Privacy" chapters.

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Ownership of data. Panelists identified several issues related to ownership, including access to data, retention and future use of samples, and specific concerns related to DNA and genetic-environmental interaction. They also noted that issues of ownership generally fall into two domains: the legal and the ethical.

Legal aspects of data ownership are prescribed by law or by court precedent. For example, one panelist noted that new laws require certain datasets to revert to the public domain after a specified amount of time. Agencies also have their own regulations. Another panelist cited the court case of *Catalona v. Washington University*, which deals with ownership of tissue samples provided to a researcher. The researcher cannot change the rules, but can educate participants and the community so they are aware of legal rights and restrictions.

For ethical issues regarding data ownership, the researcher has more room to negotiate with the community in order to meet their needs and address their concerns. As several panelists noted, communities often feel that they should own the data—particularly if their tax dollars are funding the study. By engaging the community throughout the study, the researcher can help the community feel a sense of ownership. One panelist suggested that the researcher also has an ethical responsibility to give the community access to any data that will help them reduce exposure in the future. Another panelist reiterated the distinction between data and findings, noting that the community typically wants the researcher to provide the latter, but may still want access to the former as well.

Panelists agreed that legal and ethical issues are important to discuss with communities in advance and should be included in the study design. If some aspects of ownership are negotiated through dialogue with the community, this agreement can be formalized through a memorandum of understanding.

Members of the panel discussed some key ownership issues, including confidentiality. One panelist noted that communities often request identifiable data, but confidentiality rules prevent these data from being shared. Thus, it is important to educate the community about confidentiality. Another panelist pointed out that communities, schools, and other organizations and institutions have a right not to be identified in public datasets and literature. The researcher should be sure to inform the community about its right not to be identified, which can prevent stigmatization.

Emerging concerns include the issues of retention, use, and ownership of genetic information, particularly given recent efforts to patent genes (e.g., a recent court case regarding ownership of the gene that causes Canavan disease) and a growing number of studies on genetic-environmental interaction. One panelist noted that IRBs may have special rules regarding sample retention, although others suggested that certain aspects of retention and use are open to negotiation with participants. The scientific community is currently engaged in debate about whether genetic data can ever be de-identified. One panelist noted a growing consensus that genetic data *cannot* be de-identified, suggesting that in the future, public use datasets will have to be modified accordingly.

Building a relationship with the IRB. One panelist emphasized that the researcher should build a relationship with the IRB, rather than simply view it as an obstacle to progress. However,

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another panelist cautioned that the members of the IRB may prefer to keep some distance between themselves and researchers.

Anticipating and responding to criticism. As one panelist pointed out, observational exposure studies can attract criticism from activists, politicians, and others who may have a different worldview from the research community. In some cases, this criticism may be based on misconceptions. To dispel misconceptions and reduce criticism, one panelist recommended that researchers anticipate criticism in advance, decide how to address it, and then create a strategy to get the word out and explain the study before others have a chance to mischaracterize it. Another emphasized the value of a timely response to criticism, suggesting that researchers partner with agency administrators and public relations staff to respond quickly with a clear explanation and justification for the study. Researchers may find it helpful to consider approaches used by EPA and CDC (see Section 10, "Information Resources").

General thoughts on the communication strategy. One panelist urged EPA to treat the communication strategy as more than an exercise in public relations. As the panelist noted, it is important to anticipate and respond to criticism, but the overall strategy should be much broader. Other facets of the communication strategy include two-way communication with participants and the community—for example, soliciting feedback throughout the study.

Chapter Title

The panel recommended that EPA cover this topic area in a chapter entitled "Designing and Implementing Strategies for Effective Communication." One panelist noted (and others agreed) that the title should include the word "strategies," reflecting the idea that communication should be planned in advance and should be based on shared expectations with the community.

9. Document Title and Other Elements

Toward the end of the workshop, panelists discussed ideas for the title of EPA's document, the preamble, and other recommended sections.

Title

The panel recommended that EPA's document be titled "Scientific and Ethical Approaches for Observational Exposure Studies." As several panelists pointed out, ethical issues were a major part of the panel's discussion, and should be referenced in the document title. Panelists agreed to keep "observational exposure studies" in the title per EPA's charge, which Larry Reiter (Director of NERL) confirmed. One panelist expressed concern that limiting the document to "observational exposure studies" could "tie EPA's hands" and make it hard for the Agency to conduct other types of studies in the future, noting that the two major studies that prompted this review—CHEERS and Kennedy Krieger—were technically intervention studies. However, another panelist pointed out that the major controversies in these intervention studies involved the observational aspects, which would be covered by the guidance in EPA's proposed

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document. Panelists agreed that their findings are applicable to many types of studies (including intervention studies), and suggested highlighting this connection in EPA's document, perhaps in a preamble.

The panel recommended using the word "approaches" rather than "practices" because the latter might imply that the report covers specific methods or case studies. They also decided to remove the word "measurement," which may be redundant or may be perceived as limiting the scope.

Preamble

The panel recommended that EPA include a preamble, which will "set the stage" and provide context for the rest of the document. Panelists suggested that this preamble cover the following items:

- The scope of the document, which covers scientific *and* ethical concerns. This document focuses on observational exposure studies, but the preamble should explain that many of the concepts in the document can apply to other types of studies as well, including intervention studies. One panelist suggested encouraging researchers to consider alternative and innovative designs as well.

- The intended audience. The document should clearly identify that it is intended for NERL scientists.

- The complexity of the issues. One panelist suggested listing the key scientific and ethical issues that must be considered; another suggested that this list could take the form of some type of schematic. Several panelists pointed out that scientific and ethical approaches can be study-specific, depending on study intensity and duration, risks, and societal norms. For example, a study with greater risks to participants may require more scrutiny, and a longer or more intense study might require more engagement with the community. It may be useful to provide illustrative examples of a few key concerns—e.g., observing behaviors that may or may not be socially acceptable.

- Key terms. Most terms can be defined in a glossary, but words related to the title and scope—e.g., "exposure"—need to be defined up front for the reader.

- Context for why this effort came about. Panelists disagreed on the degree of detail to provide, with one noting the importance of the CHEERS controversy as a precipitating event but another advising a more general discussion of potential controversies related to this type of study. The panel ultimately agreed that while case studies can be useful, this document should not emphasize CHEERS as a case study. They noted that CHEERS was a complex political problem that would require a great deal of careful analysis to reach conclusions. The panel did not talk extensively about CHEERS, and they did not have all the information they would need for a constructive analysis. Panelists also noted EPA's emphasis on "moving forward." Instead of discussing CHEERS, one panelist recommended that EPA choose other illustrative case studies—for example, some of the studies mentioned in Linda Sheldon's presentation (see Appendix F).

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- The importance of observational exposure studies. One panelist noted that the first two paragraphs of EPA's charge to the panel provide some good language.

Other Items to Include in the Document

In addition to the preamble and the six main topic chapters, members of the panel recommended that EPA include the following elements in its document:

- Information about how the document was developed, including the names of the authors, panelists, and peer reviewers who contributed to the process.[23]

- An introductory chapter on the science of observational exposure studies. This will allow EPA to keep the preamble succinct.

- An introductory chapter on some of the major ethical issues associated with observational exposure studies. Some of the ethical principles that are currently listed under "Elements to be Considered in Study Conceptualization" could be addressed more generally in this introductory chapter, leaving the more specialized chapter to focus specifically on issues related to observational exposure studies.

- At the end, the document could include a section with general conclusions and recommendations—for example, recommending that similar documents be created for other types of studies.

- A glossary. The preamble should define terms that are vital to understanding the title and scope of the document; however, it would be cumbersome to define too many terms in the preamble. Other key terms (e.g., "community") should be defined in a glossary.

Panelists also suggested that every chapter include a section on information sources.

10. Information Resources

In the charge to panelists, EPA asked the group to identify sources of additional information to assist with the development of the document. During the meeting, members of the panel provided a number of references, to which they added several post-meeting suggestions. These potential sources are listed below by general topic area:

[23] In post-meeting comments, one panelist (Sophie Balk) suggested that this information also include the academic affiliations and titles of the panelists.

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Elements to Be Considered in Study Conceptualization

- Researchers can review the literature to obtain more information about how to conduct a study and when to stop the study.

Ensuring Protection of Vulnerable Groups

- The World Health Organization (WHO) and the European Union (EU) have conducted extensive research on the elderly and populations with preexisting conditions. WHO documents are available from http://www.who.int/publications/en/; information on EU research can be found at http://ec.europa.eu/research/index.cfm.

- Researchers may want to consult geriatric and cultural health journals and National Academy of Sciences (NAS) and Institute of Medicine (IOM) reports. NAS documents are available from http://www.nap.edu/; IOM reports are available from http://www.iom.edu/CMS/2955.aspx.

- One panelist emphasized that when studies involve children, the researcher should consult pediatricians with expertise in dealing with particular environmental hazards.

Addressing Privacy and Other Concerns Related to Personal Exposure Observational Studies

- Researchers can review the literature to obtain more information about how to conduct a study and when to stop the study. Ethics journals are an important and often overlooked source of information, particularly for scientists who are used to consulting the chemical/toxicological literature but less familiar with ethical research. Panelists suggested that researchers be given rapid access to ethical reviews.

Creating an Appropriate Relationship Between Participant and Investigator

- There is a large body of literature on effective strategies for informed consent and what constitutes appropriate compensation.

- The *Grimes v. Kennedy Krieger Institute* court ruling provides information about the court's views on compensation, influence, and the researcher's duty of care.

- The 2005 NAS report "Ethical Considerations for Research on Housing-Related Health Hazards Involving Children" discusses issues related to the Kennedy Krieger ruling. See http://www.nap.edu/catalog/11450.html#toc.

- Hoffmann, Diane E., and Karen H. Rothenberg. 2002. "Whose Duty Is It Anyway? The Kennedy-Krieger Opinion and Its Implications for Public Health Research." *J. Health Care Law & Policy* 109.

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- Coleman, Carl H., et al. 2005. *The Ethics and Regulation of Research with Human Subjects*. Possible categories of duty to the participant are discussed on pp. 580–583. This discussion responds to Hoffmann and Rothenberg (2002).

- EPA and researchers can consult relational ethics literature regarding issues of power, hierarchy, and social context.

Building and Maintaining Appropriate Community and Stakeholder Relationships

- The 2005 NAS report, "Ethical Considerations for Research on Housing-Related Health Hazards Involving Children," has a chapter on engaging communities. See http://www.nap.edu/catalog/11450.html#toc.

- An initiative called "Turning Point: Collaborating for a New Century in Public Health," a national program supported by the W.K. Kellogg and Robert Wood Johnson Foundations, has published "Fourteen Policy Principles for Advancing Collaborative Activity Among and Between Tribal Communities and Surrounding Jurisdictions." Several tribes have signed onto these protocols. See http://www.naccho.org/topics/infrastructure/TurningPoint.cfm and http://archive.naccho.org/documents/TP-policy-principles.pdf.

- Panelists recommended that EPA provide researchers with good examples of a memorandum of understanding with the community. One panelist specifically suggested working with experts like Barbara Israel at the University of Michigan.

- Several articles on trust, community, etc., appear in *Preventing Chronic Disease*, a CDC web-based journal available at http://www.cdc.gov/pcd/. Several other journals discuss these issues too, including *Ethnic Health*.

- Blumenthal, Daniel S. 2006. "A Community Coalition Board Creates a Set of Values for Community-based Research." *Preventing Chronic Disease* 3(1):1-7. http://www.cdc.gov/pcd/issues/2006/jan/pdf/05_0068.pdf.

- Veazie, M.A., Teufel-Shone, N.I., Silverman, G., Connolly, A., Warne, S., King, B., Lebowitz, M.D., and Meister, J.S. 2001. "Building community capacity in public health: The role of action-oriented partnerships." *J PH Mgt & Prac* 7:21-32.

- The University of Kansas has an online tool box with many resources on community-level public health, including community-campus partnerships (http://ctb.ku.edu/tools/en/tools_toc.htm).

- Community-campus partnerships could be supported by the Community-Campus Partners for Health web site at the University of Washington (http://depts.washington.edu/ccph/index.html).

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- Emergency research rules may provide some insight on ways to communicate with communities. The FDA version of these rules appears at 21 CFR Section 50.24.

- Coleman, Carl H., et al. 2005. *The Ethics and Regulation of Research with Human Subjects*. A general discussion on emergency research rules appears on pages 321–327, along with citations for other writings on this topic.

- Corburn, Jason. 2006. "Community knowledge in environmental health science: co-producing policy expertise." *Environ. Sci. Policy* (in press).

- One panelist suggested the Superfund Program's "Community Involvement Handbook" (particularly chapters 1 through 3), although some of the material is limited in scope and/or not fully updated. Therefore, the reader should use this resource in conjunction with more current sources. It is not specific to observational exposure studies. See http://www.epa.gov/superfund/tools/cag/ci_handbook.pdf.

- Several resources are available through EPA's Office of Environmental Justice. These resources are not specific to observational exposure studies, but may still provide helpful information on community engagement:

    - EPA's "Environmental Justice Strategy" provides a framework and underlying principles. It provides a few examples of pilot projects with community involvement. See http://ww.epa.gov/compliance/resources/policies/ej/ej_strategy_1995.pdf.

    - "Environmental Justice: Guidance under NEPA." Pages 7 through 17 are focused on public participation issues throughout NEPA processes. This resource has lists of innovative involvement methods. One important point is that "the public" is different at different phases of a project, and staff are cautioned to actively attend to these changes during the process. See http://www.epa.gov/compliance/resources/policies/ej/ej_guidance_nepa_ceq1297.pdf.

    - The "Enforcement Assessment Tool" has sections on identifying populations with respect to minority, vulnerability, and /or economic factors. See http://www.epa.gov/complicance/resources/policies/ej/ej-seat.html.

    - Section 3.3 of the "Toolkit for Assessing Potential Allegations of Environmental Injustice" expands on the "Enforcement Assessment Tool"'s concepts of indicators of subpopulations. See http://www.epa.gov/complicance/resources/policies/ej/ej-toolkit.pdf.

    - The "Environmental Justice Collaborative Problem-Solving Cooperative Agreement Factsheet" includes a brief list of the program's key elements for community and stakeholder involvement. See http://www.ep.gov/compliance/resources/publications/ej/factsheets/fact-shet-ej-cps-grants-6-13-03.pdf.

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- The National Environmental Justice Advisory Council's (NEJAC's) "Model for Public Participation" lists desired participants, as well as core values and guiding principles. See http://www.epa.gov/compliance/resources/publications/ej/nejac/model-public-part-plan.pdf.

- Chapter 4 of the "Guide on Consultation and Collaboration with Indian Tribal Governments" discusses public participation. This document cross-references NEJAC's Model for Public Participation. See http://www.epa.gov/compliance/resources/publications/ej/nehac/ips-consultation-guide.pdf.

- NEJAC's May 2000 Meeting Report, "Environmental Justice and Community-Based Health Model Discussion," includes a summary of data gathering efforts (Section 1.A), along with source citations. It also mentions the need for exposure data. See http://www.epagov/compliance/resources/publications/ej/nejac/community-based-health-recom-report.pdf.

- "Environmental Justice and Federal Facilities" includes recommendations to improve agency-community relationships and agencies' cultural sensitivity. See http://www.epa.gov/compliance/resources/publications/ej/nejac/ffwg-final-rpt-102504.pdf.

- "Meaningful Involvement and Fair Treatment by Tribal Environmental Regulatory Programs" defines "meaningful involvement" and "fair treatment," and describes tribal views of appropriate public participation and due process. See http://www.epa.gov/compliance/resources/publications/ej/nejac/ips-final-report.pdf.

- "Future Mechanisms to Improve Stakeholder Involvement" provides recommendations to improve stakeholder involvement in environmental justice-related processes. See http://www.epa.gov/compliance/resources/publications/ej/nejac/stakeholder-involv-9-27-06.pdf.

- Although ATSDR has written risk communication primers, one panelist pointed out that these documents were written between the late 1980s and mid-1990s, and are not well-suited to this workshop. ATSDR health assessments or specific sites might offer some valuable lessons, however. Interviews with staff may be the most expeditious way to capture relevant lessons learned.

Designing and Implementing Strategies for Effective Communication

- For ideas on anticipating and responding to criticism, researchers may find it helpful to consider approaches formerly used by EPA's Office of Risk Communication. One

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panelist suggested that although this office may have been disbanded, it did produce some useful documents in the past.

- At CDC, the Office of Communication has been developing emergency risk communication strategies since the anthrax events that occurred a few years ago. These approaches may be helpful to researchers. See http://www.bt.cdc.gov/erc/.

- To address the issue of risk communication, panelists mentioned that certain NAS and WHO documents describe thresholds for reporting. NAS documents are available from http://www.nap.edu/; WHO documents are available from http://www.who.int/publications/en/.

- Guidelines and standards for indoor air have been published by the following agencies:

    - ATSDR publishes guidelines in its "Toxicological Profiles."

    - WHO has published air quality guidelines for Europe (indoor and outdoor).

    - NIOSH publishes occupational guidelines.

    - EPA has its own air and water guidelines and standards.

General Pediatric Resources

- EPA can consult the NAS report entitled "The Ethical Conduct of Clinical Research Involving Children." See http://www.nap.edu/catalog/10958.html.

- The American Academy of Pediatrics (AAP) Pediatric Environmental Health Handbook, 2nd Edition. Elk Grove Village, IL: American Academy of Pediatrics, November 2003. This resource is available through the AAP web site (www.aap.org/publications).

- The AAP Committee on Environmental Health Policy has published and continues to update and publish new statements and technical reports on many subjects (http://www.aap.org/visit/cmte16.htm). A new statement on mold appears in the December issue of *Pediatrics* (http://pediatrics.aappublications.org/cgi/reprint/118/6/e1909).

- Pediatricians who staff the Pediatric Environmental Health Specialty Units can be helpful. See http://www.atsdr.cdc.gov/HEC/natorg/pehsu.html.

- EPA's Office of Children's Health Protection maintains the searchable Toxicity and Exposure Assessment for Children's Health (TEACH) database, which contains overviews of scientific literature on children's environmental health. See http://www.epa.gov/teach.

- Public Health Partners Children's Environmental Health World Wide Web Sampler. This resource is a directory of pediatric environmental health web sites, including government,

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academic, and non-governmental sites such as the AAP's Committee on Environmental Health and Physicians for Social Responsibility. See http://www.phpartners.org/cehir/sampler.html.

- Many other pediatric resources are available, including several EPA web sites.

11. Observer Comments

Six observers provided oral comments during the two public comment sessions on the first and second days of the workshop. This section summarizes their remarks.

Tuesday, November 28, 2006

Heather O'Maonaigh, Oak Ridge Center for Advanced Studies

Noting that the "state of the science" is constantly evolving, Heather O'Maonaigh encouraged the panel to consider ways to structure the document so it can be adapted in response to changes in the science and comments from researchers or the public. She suggested that some type of structured review process—e.g., an annual review—might be a good way to make sure EPA's document remains a "living" resource in the future.

Wednesday, November 29, 2006

David Marker, Westat

David Marker suggested several additional items for the panel and EPA to keep in mind. He highlighted the following five considerations:

- Although community engagement is important, some EPA studies are so large in scope that it can be difficult to reach out to every participant's community. For example, many EPA studies are national or even international in scope; others are longitudinal studies that follow a group of participants over a long period of time, during which they may move to different communities. In studies like these, it may be unrealistic to require a high level of engagement in every community from which data are collected. Marker suggested that the panel may want to caveat their comments and perhaps consider other approaches for large-scale studies, like talking to a certain subset of communities to gain the necessary insight.

- Language and socioeconomic status (SES) can affect many aspects of a study. For example, when working with a community with limited English proficiency or basic literacy, the basic design of the informed consent and subsequent protocols will be crucial in determining whether information is shared effectively—particularly if a member of the

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research team is not present to guide the participant through the document. Researchers should consider these factors throughout the study plan.

- Marker urged the panel to consider the overlap between issues of statistical power and representativeness of the sample, which can be affected by recruitment and retention methods.

- Relationships with third parties can be quite complex—particularly relationships with landlords. Landlords may serve as *gatekeepers*, requiring their permission to access their property. Landlords also may prefer *not* to be given certain results because this disclosure can lead to new legal requirements. For example, if a landlord is made aware of lead-based paint on the premises, he/she becomes responsible for disclosing this information to future buyers, possibly resulting in a lower property value.

- Marker wondered whether some of the panel's recommendations might differ depending on the funding source. For example, should extra requirements be placed upon privately funded studies in order to ensure objectivity?

Robert Clickner, Westat

Exploring some of the tradeoffs related to data quality, Robert Clickner noted that increasing the incentive for participation can boost the sample size yet at the same time reduce the quality of the data by attracting disinterested participants who are "in it for the money." He explained that data from observational exposure studies fall into three categories, with the potential for data quality problems depending on the category. The categories are as follows:

- Data that the field staff collects on its own (e.g., samples). These data are the least likely to be influenced by participant motivations because the research team is in full control of data collection.

- Data that the field staff collects by interacting with participants—for example, through a questionnaire. There is some potential for error here because disinterested participants can answer questions untruthfully. However, a well-trained interviewer can elicit more honest responses, and a well-designed questionnaire can minimize the opportunity to be dishonest.

- Data that the participant collects on his/her own—e.g., by keeping duplicate diet records or filling out a diary. This category holds the greatest potential for what statisticians call non-sampling error or item non-response measurement error, in which the disinterested participant can affect data quality. If the researcher is aware of these issues up front, however, he/she can take measures to reduce the potential for error.

Noting the concerns raised by the panel about potentially motivating participants to increase exposure, Clickner observed that in many cases, a more realistic concern is that the study might motivate participants *not to decrease exposure*. Both possibilities can lead to criticism of a study.

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Marcia Nishioka, Battelle Memorial Institute

Speaking on the topic of study design, Marcia Nishioka noted that the extent to which participants can control exposure varies, and this is an important factor when selecting an appropriate study design. Control over exposure falls along a broad spectrum, ranging from $PM_{2.5}$—an exposure over which people have very little control—to household pesticides and chemicals like PFOS and PFOA, which people control directly through their use of consumer products. Certain study designs may be more appropriate for certain types of exposures, both scientifically and ethically; for example, a longitudinal study may be less ethically defensible if the exposure can be controlled easily (i.e., it may be harder to justify "sitting back and watching" for a long period of time while a participant is exposed to a substance over which he/she *does* have control). Nishioka suggested that the panel (and EPA) consider whether certain study designs are more appropriate for particular exposure situations.

Cynthia Yu-Robinson, NERL

Cynthia Yu-Robinson suggested some additional information sources that might reduce the need for EPA to "reinvent the wheel" in preparing this state-of-the-science document. Drawing upon her experience working on community involvement with EPA's Superfund program, she noted that the following agencies and programs have already developed materials that could be useful in the context of observational exposure studies:[24]

- EPA's Superfund program publishes a Community Involvement Handbook, which the program's Community Relations Officers update every year to reflect new lessons learned. This handbook is publicly available through EPA's web site.

- EPA's Environmental Justice Program may have useful guidance on working with minority and low-SES communities.

- EPA's Office of Enforcement and Compliance Assurance (OECA) has developed protocols for audits and other visits to manufacturing facilities. These protocols cover disclosure of sampling results, community right-to-know rules, imminent hazards, and other issues that may have parallels in the context of human observational exposure studies. OECA may have useful guidance manuals on these topics.

- The Agency for Toxic Substances and Disease Registry (ATSDR) has extensive experience with risk communication. Among other things, ATSDR works with communities to understand what is known about exposures, what gaps remain, and what additional measures could help fill those gaps.

[24] Following the meeting, one panelist (Rebecca Parkin) researched several of these resources and added specific citations to Section 10, "Information Resources."

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Lisa Melnyk, NERL

As one of the researchers who will ultimately use the document EPA plans to produce, Lisa Melnyk noted that even when the researcher follows all the appropriate steps to develop a study that is scientifically and ethically sound, his/her efforts can still be stymied by misperceptions and by the personal or political agendas of others. She urged the panel to give researchers some recommendations on how they may be able to dispel misconceptions and get their point across effectively to the politicians and activists who may be preventing a study from going forward.

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Appendix A

Panelists

Expert Panel Workshop on the State-of-the-Science Approaches for Observational Exposure Measurement Studies

Hilton Durham near Duke University
Durham, NC
November 28-29, 2006

Invited Experts

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Appendix B

Charge to Panelists

United States
Environmental Protection Agency
National Exposure Research Laboratory

Expert Panel Workshop on the State-of-the-Science Approaches for Observational Exposure Measurement Studies

November 28-29, 2006
Durham, NC

Charge to the Expert Panel

Purpose of the Workshop

Observational human exposure measurement studies are performed by researchers both within and outside of EPA to measure human exposure to chemicals in the environment. These studies involve measurements of chemicals in environmental media (e.g., air, water, food, soil, and dust); biomonitoring (e.g., collection of urine, saliva, or blood samples), and collection of information about the voluntary study participants, their homes, their work environments, and their activities. EPA and other federal agencies have been performing observational human exposure measurement studies for over two decades. These are critical to improving our understanding of human exposure to chemicals and meeting our goal of improving public health.

Observational exposure measurement studies are complex in their design and implementation. Many scientific and ethical issues need to be addressed in the planning, scoping and study design; the community interactions; study implementation; and communications with the study participants and their communities. EPA wants to ensure that the observational studies conducted by the Agency for measuring human exposure to environmental chemicals continue to be based on the most up-to-date sound science and the highest ethical standards. To meet that objective, researchers in EPA's National Exposure Research Laboratory (NERL) are examining the latest approaches, methods, techniques, and ethical standards for performing such studies and intend to compile a set of state-of-the-science approaches for performing observational human exposure measurement studies. Examples of study elements include survey design, identification of community groups and interactions with communities during the scoping and planning of studies, participant recruitment methods, informed consent procedures, identification and reporting unanticipated results, communication of study results, etc. EPA wants to ensure that their observational studies not only represent excellence in science, but also the highest standards of ethical conduct.

Accordingly, the purpose of this workshop is to obtain expert advice and public comment on the development and content for a "state of the science" document. The workshop panel consists of experts from different disciplines with relevant expertise on scientific and ethical issues to be addressed in the design and implementation of observational human exposure measurement studies.

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Charge to the Panel

The panel is asked to consider these issues prior to the workshop in preparation for discussion during this workshop meeting:

1. Provide recommendations on the content and organization of the document.
    a. Identify the major scientific and ethical areas/issues in the design and implementation of observational human exposure measurement studies that should be considered for inclusion in the document.
    b. Identify specific elements in each of these major areas that should be considered for inclusion in the document.
    c. Provide recommendations on the type and level of information that should be considered for inclusion in the document when describing state-of-the-science approaches, methods, techniques, or standards.
    d. Provide recommendations on the criteria that should be considered when evaluating and identifying the state-of-the-science for the approaches, methods, techniques, or standards.

2. Provide recommendations and listings of sources of information for developing the document including case studies where available.

3. Identify at least ten specific elements of the design and implementation of these studies that the panel considers to have the most uncertainty with regard to the "state-of-the-science," discuss these elements, and provide recommendations on state-of-the-science approaches for them.

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Appendix C

Panelists' Pre-Meeting Input

Panelists' Pre-Meeting Input: Suggested Topics for Discussion

Sophie Balk

Ideas for components or sections for a framework for conducting observational human exposure studies:

- Studies must have an explicit focus on children. Studies should consider children as a separate category. Children have different and generally higher exposures compared to adults. The health and developmental consequences of their exposures may be more serious and lifelong. Pediatricians and other child health experts should be a part of the study design and approval process.

- Studies must be designed to conform to best pediatric practices. Study planners should design observational studies to protect children and be consistent with current pediatric advice. For example, pediatricians usually discourage pesticide spraying in homes where children reside, preferring other methods of pest control whenever possible. If routine spraying is allowed as part of an observational study, this contradicts best pediatric practices.

- The process for approving studies must be transparent and accessible to the public. Study design and information about Human Subjects Review must be posted for public review. Information about study design must incorporate detailed information about the study. Information about Human Subjects Review includes the membership and affiliations of the Human Subjects Review Panel, questions they asked and answered while reviewing the study, and any modifications made. Scientific information must be presented in ways that are understandable to the general public.

- Community participation must be ensured. Community representatives, (including parents if children are involved) must be included at all points of study design and approval.

David Carpenter

My suggestions for issues to be discussed at the workshop are as follows:

- When should results of human testing be reported back to the individual, and when is it ethically justified not to report results?

- How must an investigator deal with explaining results when reporting back to a study subject if the result is somewhat abnormal, but the health consequence of the abnormal

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result is not clear? Which is worse - scaring the subject or giving the subject a false sense of security?

- What sort of compensation is appropriate under the circumstances where a biomonitoring program is being done in order to determine background levels of a contaminant in the general population and where there little or no immediate benefit to the individual who participates?

- How far can an investigator ethically go in utilizing invasive procedures when doing human testing that is being done for the purpose of obtaining background data in a population? Is something like a fat biopsy appropriate? What about X-rays or other procedures that carry a small risk?

Gisele Corbie-Smith

The following are what I see as key issues:

- Ethical principles in community based research with underserved populations

- Community engagement in observational exposure research

- Community input in review and IRB approval of community based research

Natalie Freeman

The specific elements of a study need to be based on the objectives of the study and the hypotheses being considered. Observational studies, while not "experiments," can if properly designed be used to test hypotheses. Observational studies may be simply descriptive or by comparing well defined groups, can be used to evaluate and infer differences based on characteristics of the groups.

Study design issues include: location in terms of region(s) of the country, urban and/or rural, residential and/or institutional, monitoring period in terms of days, weeks, months, years, study population(s) and its/their representativeness of the population(s) of concern, monitoring protocol including sampling times and durations, media of interest, analytes of interest, survey and questionnaire information.

Ethical issues focus on outreach and consenting activities, providing potential participants with an adequate understanding of the study, its goals, and both participant and researchers' expectations.

There has been a great deal of discussion as to the reasonableness of incentives and remuneration to participants and whether these are in fact bribes. There is an extensive literature on the impact

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of incentives on participation and research outcomes. It is this commenter's opinion that it is unethical not to remunerate participants for their time and activities. I also believe that incentives are permissible as long as they are not so great as to modify people's behavior.

A second part of linked study design/ethical issues is related to communicating results to participants. Sharing exposure results with study participants is a multifaceted process. The communication begins before the study starts during the outreach and informed consent process and addresses the objectives of the study, and anticipated results for the participant.

Solicitation of participants is driven by the study design. Presenting to study objectives to potential participants is only one part of solicitation and outreach. To be successful, the researcher needs to understand something of the range of motivations and concerns that prompt individuals to participate in exposure science projects.

Loretta Jones

EPA NERL speaking points:

- Community Engagement
- What's the win-win for community?
- Observational Studies—when to inform Community of a danger that exists?
- Follow-up to Children's Studies
- How to connect to other Research and Advocacy

Bruce Lanphear

I had a few ideas:

- Reporting individual test results
- Definition of community input, involvement and representation
- Funding observational studies; should industry have any involvement?
- Definition of appropriate remuneration

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Michael Lebowitz

I think the five key issues relate to:

- The type of sampling used in the study design (random vs. stratified cluster) with emphasis on over sampling presumed high exposure & low SES clusters (to maximize the info on the upper 25th percentiles of exposure and reduce cost)

- Use of lessons learned from NHEXAS & other major exposure studies, especially regarding recruitment of participants (see below)

- The engagement of the communities involved (including communications strategy - a NHEXAS draft will be sent if/when I can find it)

- The development of staged sampling with improved screening methods

- Concentration on the cells in the chemical-media that are likely to yield knowledge, ignoring those known to be close to null, especially those deemed important re: regulations/laws/etc.

There's more, also very important in my mind: design and modeling to provide input for risk assessment and for epidemiological studies.

We shouldn't forget the words to the wise either:

Lioy P, Leaderer B, Graham J, Lebret E, Sheldon L, Needham L, Pellizzari E, Lebowitz MD. "The application of exposure assessment to environmental health science and public policy." *J Expos Analysis & Environ Epidemiol.* 2005.

EPA - NHEXAS - LESSONS LEARNED - Supplemental Notes by Mike Lebowitz

(pre- & post- Workshop of 8/14/01) (in partial fulfillment of P.O.)

<u>I. Project Leadership</u>

What was good:

- NHEXAS leadership showed that it was possible to mount and conduct large-scale, multi-media studies in the field

- Leadership, and the cooperative agreements, worked well in general; collaborations were very evident

- Communications with all worked well in general

- Working with communities and other partners (AZ & Region 5) went well

What were the problems:

- Delays, delays, delays
- Over-committed and under-funded
- Insufficient time and money to perform analyses and disseminate results

Primary lessons for the future include:

- Leadership should prepare and agree upon a study design and the logistics plan early
- Prepare the rest of the framework so that each new endeavor doesn't start from scratch, and be flexible
- There should be a limited set of objectives and focus
- Leadership should utilize what's already known, use standard instruments & pre-test new instruments quickly, and get all-around approval early
- Get the QSIPs & SOPs done early, partly by modifying existing ones
- Get the IRB and other reviews started right away
- Set milestones and try to adhere to them (but be flexible)
- Budget & forward fund appropriately, and be cognizant of relative costs

<u>II. Design</u>

What went well:

- There was a study design and a research plan (logistics) for each consortium
- The primary objectives (population distributions of exposure and 90th percentiles) were met
- There were some hypotheses

What were the problems:

- Too many objectives

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- Strenuous sample size calculations
- Too much and too many SOPs, and too difficult to follow changes
- Logistical problems getting participants (and not knowing compliance)
- Too many non-detects - especially for some compounds in some media

Primary Lessons for the Future:

Study Design:

- Very much need to focus more and determine what the goal is, then design & calculate sample size
- If what is wanted is Total-Cumulative-Aggregate exposure, especially longitudinally, then design the studies for that purpose (which is different than designing it for pop distributions of exposure)
- Balance SOWs, burdens , costs, compatibilities, response rates
- Determine what can be effectively used for screening, in advance

Logistics:

- Secure a dedicated and trained staff to best work in the region for what is planned
- Pre-plan, pre-test, and set
- Improve response rates and identify the characteristics of the non-respondents
- Measure compliance, and identify the characteristics of the non-compliant
- Make, track and document modifications easier
- Script important SOPs
- Maximize the quantification and completeness of the data base
- Streamline everything
- Minimize burden of investigators and participants
- Use reference “labs” throughout

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VI. Data Base(s) (post-workshop summary)

Issues & Recommendations:

- Timeliness
- Input tied to forms, data shells, built-in QA/QC
- Consider CAPI and/or CATI systems
- Use standard programs, formats, codes (including for non-detects), & SOPs where possible, or create ahead of time
- QA/QC
- Data Tracking and pre-determination of division of labor (and responsibilities)
- Flag and document problems
- Completeness
- Presence of resources and funding
- Tie data base formation to: reporting, analysis, products, marketing
- Archive originals (SOPs, modifications, data forms, codes, etc.)

VII. QA (post-workshop summary)

(refer also to above)

- Create framework & streamlined procedures
- Needs to be collaborative
- Prepare early, use past experience and SOPs
- Need pre-planning and testing; decrease delays
- Need reference materials and labs
- Need consistency/uniformity and comparability studies
- Need good documentation & audits

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Jerry Menikoff

Here are some ideas for discussion points, as was requested:

- Payment Issues: Payments to subjects should be designed in such a way that they do not encourage parents to change their behaviors in a way that increases the exposure of children to chemicals. This goal can require more than merely verifying that payments are similar to the hourly amounts that the parents would receive in similar jobs; it may also require verifying that the parents could as readily obtain such similar payments without major alterations in their daily lives (e.g., if in a study the parents are paid for time they spend at home, could they receive similar payments for time spent at home if there was no such study).

  A related issue is that payments should be designed so as to not only discourage changes in behavior leading to increased exposure to chemicals for the purpose of being admitted to the study, but also to prevent participation in the study from altering decisions made after enrollment in the study.

- Issues relating to initial identification of prospective subjects: If there is a concern regarding the possibility that prospective subjects might have an incentive to alter their behaviors in order to participate in the study, how can we identify prospective subjects in a way that provides objective evidence of pre-existing behaviors by the subjects, so that we know they will not have to alter their behavior to qualify for the study? Are there objective indicia of pre-study behaviors that can be verified as part of recruiting subjects?

  A related issue might be to what extent the specific criteria for enrollment in the study might be kept somewhat confidential. To the extent subjects are not aware of those criteria, it would make it difficult for them to be attempting to demonstrate that their prior behaviors are consistent with those eligibility criteria.

- The Ethics of Watching Harmful Behaviors: To what extent is it appropriate for researchers to sit by and watch subjects participate in potentially harmful behaviors (such as exposing their children to pesticides)? It would be desirable to address which such behaviors are considered “acceptable” (and thus it is appropriate for researchers to allow such behaviors to continue, while watching and collecting information), and which such behaviors would not be acceptable and under what circumstances the researchers would therefore intervene and stop the behavior. (E.g., allowing pesticides to be used according to their labeling instructions, but not permitting subjects to apply pesticides in a way that violates those labeling instructions).

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Rebecca Parkin

Here are some ideas for key elements for the document. I have not ordered them in any particular way:

- What is the problem being addressed?
- How is the problem defined and by whom?
- How are affected persons and the community engaged? (e.g., design, feedback, and decisions)
- What level of exposure assessment precision is needed for addressing the problem?
- What are the sources of uncertainty and types of variability that need to be considered when interpreting the measurements?
- What is exposure? Is it a single factor, cumulative, aggregate, etc? What is the right exposure to be measured?
- What is the right set of exposure metrics? Are the metrics reliable?
- What are the key cofounders? Can they be measured?
- What role to do behaviors play? Can they be adequately characterized for addressing the problem?
- How will “state of the science” disputes be resolved?
- Is there a complete exposure pathway—conceptually and in reality? Can the entire pathway be measured?
- Are the modes of action, mechanisms understood?
- Is information (e.g. toxicokenetics) available to reliably transfer biological metrics from animals to humans?

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Appendix D

Meeting Agenda

United States
Environmental Protection Agency
National Exposure Research Laboratory

Expert Panel Workshop on State-of-the-Science Approaches for Observational Exposure Measurement Studies

Hilton Durham
Durham, NC
November 28-29, 2006

Agenda

DAY 1 – Tuesday, November 28, 2006

7:45 AM	Registration/Check-in
8:30 AM	Introductory Remarks ..... Jan Connery, ERG
8:40 AM	Welcome Remarks ..... Kevin Teichman, EPA/ORD
8:45 AM	Opening Remarks ..... Warren Lux, EPA/OSA
9:00 AM	Panel Introduction ..... Jan Connery, ERG
9:15 AM	Overview of Observational Exposure Measurement Studies..... Linda Sheldon, EPA/NERL
9:30 AM	Background on State-of-the-Science Approaches for Observational Exposure Measurement Studies..... Roy Fortmann, EPA/NERL
9:45 AM	BREAK
10:00 AM	Observer Comment Period ..... Jan Connery, ERG
11:00 AM	Overview of the Charge and Workshop Format..... Tim Buckley, Panel Chair, Ohio State University
11:30 AM	Panel Discussions: General Comments
12:30 PM	LUNCH (on own)
1:45 PM	Breakout Groups: Discuss Topics I & II (to be determined)
3:15 PM	BREAK

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DAY 1 – Tuesday, November 28, 2006 – continued

3:30 PM	Plenary: Group Reports & Discussion on Topics I & II
4:15 PM	Breakout Groups: Discuss Topics III & IV (TBD)
5:00 PM	ADJOURN

DAY 2 – Wednesday, November 29, 2006

8:00 AM	Breakout Groups: Discuss Topics III & IV (continued)
8:45 AM	Plenary: Group Reports & Discussion on Topics III & IV
9:30 AM	BREAK
9:45 AM	Plenary: Discuss Topics V & VI (TBD)
Noon	LUNCH (60 minutes)
1:00 PM	Observer Comment Period
1:30 PM	Plenary Discussions: Development of Recommended Framework • Discussion and formulation of responses to charge questions • Framework for document
2:30 PM	BREAK
2:45 PM	Plenary Discussions (continued)
4:20 PM	Concluding Remarks
4:30PM	ADJOURN

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Appendix E

Meeting Attendees

United States
Environmental Protection Agency
National Exposure Research Laboratory

Expert Panel Workshop on the State-of-the-Science Approaches for Observational Exposure Measurement Studies

Hilton Durham near Duke University
Durham, North Carolina
November 28-29, 2006

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Appendix F

Presentation by Linda Sheldon, EPA

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Observational Exposure Measurement Studies

Linda Sheldon
U.S EPA
Office of Research and Development
National Exposure Research Laboratory

November 28, 2006

Outline

- Describe the framework for EPA's research
- Describe observational measurement studies
  - what they are,
  - how they are conducted,
  - why they are important.
- Describe important considerations for future studies

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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

Fundamental Concepts

- Exposure is the contact of an individual with a chemical
- Contact can be in the air we breathe, the food we eat, the water we drink, on the surfaces we touch

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Fundamental Concepts

- Understanding and characterizing exposure requires understanding
  - Environmental concentrations
  - Human activities that bring people into contact with contaminated media
- Data are collected through Observational Exposure Measurement Studies

Observational Exposure Measurement Studies

- Studies in which we observe people's contact with chemicals:
  - under real-world conditions (in their homes, offices, and outdoors)
  - during normal day-to-day activities

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Observational Exposure Measurement Studies

- During these studies we follow people to:
  - collect the air they breathe, food they eat, water they drink, and dust on surfaces they touch
  - learn about the things they do that bring them into contact with chemicals every day
- Studies are often complex and difficult to implement

Samples Collected

- Air
- Surface Residues
- Hand wipes
- Cotton garment for dermal loading estimate
- Floor dust
- Upholstered furniture dust
- Soil
- Diet
- Biological samples – urine and blood

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Air Monitoring

Exposure Measurements

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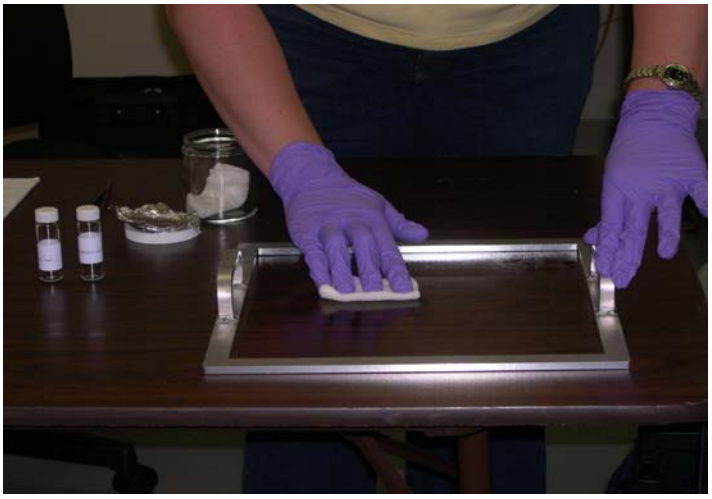
Surface Residue Wipes



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Hand wipes, Residue Transfer

Dust Samples

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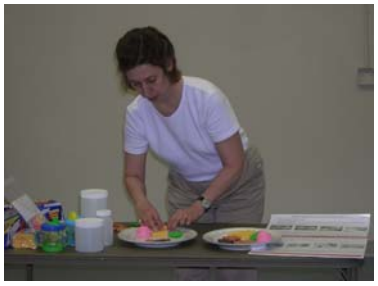
Dietary Samples

- Solid food
- Beverages
- Breast milk
- Water



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Activity Data

- Diaries
- Videotaping
- Metabolic activity
- Location

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Observational Studies Are Essential to Improved Public Health

- The American public benefits from observational measurement studies because they determine:
  - What chemicals people are coming into contact with
  - Concentration of the chemicals
  - Most important sources and pathways
  - When, where, how often, and why people come in contract with chemicals

Examples of Observational Studies - TEAM

- Description – Early EPA observational (Total Exposure Assessment Methodology) studies showed that people came into contact with many more chemicals, at higher levels, indoors than outdoors
- Results -The manufacturers and general public recognized the importance of chemicals in consumer products, furnishings, and building materials.
- Impact – People became more educated on ways to reduce their contact with chemicals indoors and manufacturers voluntarily replaced or reduced toxic chemicals in their products. Indoor environments became more healthy

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Examples of Observational Studies - Radon

- Description – EPA observational studies showed that this naturally-occurring, cancer-causing chemical was entering homes and other buildings.
- Results –The magnitude of the problem was determined, the factors affecting movement into buildings were identified, and solutions were developed to prevent entry into buildings.
- Impact – The second leading cause of lung cancer in the U.S. was significantly reduced, improving public health.

Examples of Observational Studies – $PM_{2.5}$

- Description – The relationship between ambient measurements of PM and exposure was a key scientific uncertainty associated with the 1997 PM NAAQS
- Results – Numerous observational exposure studies showed a strong association between the two measures, verifying that ambient concentrations could be used as a surrogate for exposure in epidemiology studies
- Impact – The scientific basis for the NAAQS was demonstrated; the lower standard was accepted.

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Future Studies

This project will ensure that:

- We are conducting all observational studies using the most up-to-date ethical and scientific standards,
- We are not inadvertently causing people to change their daily activities or increase their contact with chemicals, and
- We are working with the communities and participants to understand and address their environmental and public health concerns.

Summary

- Observational exposure measurement studies have been conducted for over 30 years by EPA and others
- There are many examples of how these studies have be used to reduce exposures
- These studies are important because they collect real world information that can be used to understand risk and to reduce exposures
- This project will ensure that EPA used the most current and highest ethical standards and high quality science

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Appendix G

Presentation by Roy Fortmann, EPA

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State-of-the-Science Approaches for Observational Exposure Measurement Studies

Roy Fortmann
U.S. Environmental Protection Agency
National Exposure Research Laboratory
Office of Research and Development
Research Triangle Park, NC

November 28, 2006

Background (1)

- EPA has been conducting observational exposure measurement studies for over three decades
- These studies are critical to the goal of improving public health
- The studies are based on sound science, support Agency needs, and are of the highest ethical standards

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Background (2)

- EPA strives to follow the most up-to-date methods, standards, and approaches for the design and implementation of observational studies to ensure that they meet the highest ethical and scientific standards
- The approaches evolve over time to meet changing study requirements and standards
- There have been concerns about participant involvement, particularly for children, in observational studies

3

Goals of this Project

- Identify the issues that researchers need to consider in the design and implementation of observational exposure measurement studies to ensure that the highest ethical standards are met
- Evaluate the state-of-the science for ethical considerations in the these studies

4

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Goals of this Project

- Compile information on the current methods, standards, and approaches for conducting observational studies
- Prepare a peer-reviewed document that will serve as an information resource for researchers both within and outside of EPA

5

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The Process and Timeline

Sep 2006	Plan workshop, form Expert Panel, and conduct outreach
Nov	Issue FR Notice, post website, conduct outreach
Nov 28&29	Conduct Expert Panel Workshop
Dec	Receive report from the Workshop
Dec - Mar	Prepare the draft document
Mar	Complete internal review and plan external peer review
Apr	Issue FR Notice and release external review document
May	Hold external peer review panel meeting
Jun	Revise document
Jul 2007	Finalize EPA document

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Purpose of this Workshop

- To convene an independent panel of experts that can provide EPA with recommendations on:
  - The framework for the document
  - Major areas to be considered
  - Specific elements to be addressed
  - Sources of information
  - The state of the science for specific study elements

7

State-of-the-Science Approaches

- Observational exposure measurement studies are complex in their design and implementation, involving both scientific and ethical considerations
- There are many study elements that need to be addressed to ensure protection of the participants in these studies

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Scoping, Planning, and Design – Examples of Study Elements

- Goals and objectives
- Scope (varies from small pilot studies to large cross-sectional studies)
- Assessment of individual and group risks and benefits of the research
- Technical and ethical peer reviews (in addition to Institutional Review Board)
- Community involvement in scoping, planning, and designing

9

Community Interactions – Examples of Study Elements

- Identifying key stakeholders
- Community involvement in the design and implementation of the study
- Benefits to the community
- Community advisory boards
- Community engagement during the study
- Innovative study designs

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Study Implementation – Examples of Study Elements

- Researcher responsibilities
- Recruitment and enrollment procedures
- Equitable selection of participants
- Informed consent forms and processes
- Participant compensation
- Communication of benefits and risk
- Third party issues
- Hazard identification and notification issues

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Collaborators and Stakeholders – Examples of Study Elements

- Identification of the multiple stakeholders
- The community as stakeholder and collaborator
- Study participants as collaborators
- Working with external stakeholders

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Communications – Examples of Study Elements

- Communications with the community, the participants, and stakeholders
- Communication of risks of the chemicals being studied
- Communication of unanticipated results
- Communication of non-study hazards
- Participant education and training
- Communication of study results to the participant and the community

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Example Sources of Information

- Report from the Committee on Ethical Considerations for Research on Housing-Related Health Hazards Involving Children, Youth, and Family (2005)
- Existing policies and guidelines
- Published peer-reviewed literature, including "lessons learned" manuscripts and reports
- Community-based participatory research case studies

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Charge to the Panel

- Framework and content of the document – what areas and elements should be addressed? How should the information be presented?
- Sources of information – what sources are available to ensure that the state of the science is captured?
- State of the science - for specific elements identified by the panel, what is the state of the science? How do researchers determine what is the state of the science?

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Questions

- Questions from the panel?

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Appendix H

Presentation by Tim Buckley, Panel Chair

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Overview of the Charge and Meeting Format

Charge to the Panel

1. Provide recommendations on the content and organization of the document.
   - Identify the major scientific and ethical areas/issues in the design and implementation of observational human exposure measurement studies that should be considered for inclusion in the document.
   - Identify specific elements in each of these major areas that should be considered for inclusion
   - Provide recommendations on the type and level of information that should be considered for inclusion in the document when describing state-of-the-science approaches, methods, techniques, or standards.
   - Provide recommendations on the criteria that should be considered when evaluating and identifying the state-of-the-science for the approaches, methods, techniques, or standards.

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Charge (cont)

2. Provide recommendation and listing of sources of information for developing the document including case studies where available.
3. Identify at least ten specific elements of the design and implementation of these studies that the panel considers to have the most uncertainty with regard to the "state-of-the-science," discuss these elements, and provide recommendations on state-of-the-science approaches for them.

Workshop Format

- Breakout session topics: identify and balance the scientific benefits of human observational studies with risks to the community and participating subjects in:
  - Study Design (Group A)
  - Studies Involving Vulnerable Groups (Group B)
  - Recruitment (Group A)
  - Studies of Home Hazards (Group B)
  - Community Participation (Group A)
  - Communication (Group B)

Breakout Groups

- Group A
  - Carpenter
  - Corbie-Smith
  - Freeman
  - Lanphear
  - Menikoff
- Group B
  - Balk
  - Parkin
  - Fleischman
  - Jones
  - Lebowitz

Groups self-select a discussion facilitator and rappateur.

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Appendix I

Topics and Subtopics Discussed by the Panel

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Workshop to Discuss State-of-the-Science Approaches for Observational Exposure Measurement Studies

November 28-29, 2006
Durham, NC

Notes from the Plenary Discussion

1

Title

- Do we recommend a new/different title?
  - Original title: "State of the Science Approaches for Observational Exposure Measurement Studies"
  - **Recommendation: "Scientific and Ethical Approaches for Observational Exposure Studies"**

2

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Preamble

- Do we recommend a "Preamble"? **YES**. Content?
  - Define scope of document (scientific + ethical)
  - Define the intended audience
  - Complexity of issues
    - Range of study risks
    - Societal norms related to ethical concerns (e.g., observing behavior that is socially accepted or allowed)
    - Variability, depending on type/intensity/duration of study
    - Examples
  - Define key terms (e.g., "exposure")
    - Define other terms in glossary
  - Context for understanding and using the rest of the document
  - Importance of observational exposure studies

3

Include CHEERS as a case study? **NO**.

- Pros:
  - Value of case studies in general
- Cons:
  - Political issues: too complex to analyze in this document
  - This document is about moving *forward*
  - This panel would need more information about CHEERS

4

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Other items to include in the document

- How the document came to be
  - Names of panelists
  - Authorship
  - Peer review process

5

Elements to be Considered in Study Conceptualization

6

Ethical Principles

- Concern that the design of the study will result in an increase in exposure.
  - But is this a real likelihood?
  - Is it OK to watch kids in a lead-tainted environment?
  - Is the study a minimal risk study?
- Are incentives appropriate?
  - Do you need a third party?
  - Should pay minimal wage for time.
  - Should consider whether the study will benefit the individual or the population as a whole.
  - Should a poor woman who is spending time at home be paid less than another person?
  - There have been few studies re: compensation and retention.
  - Compensation should be equitable regardless of income of subject.
- Consider doing a study involving multiple SES, ethnic populations.
- What level of deception, if any, is appropriate?
- We should not impose on the investigator a higher duty than our society imposes to protect children.
  - There are two questions – does our society allow kids to play in lead-exposed dust in an old house, and is this wrong?
  - When do we have sufficient information to take some action? Our policies are not intended to protect human health – rather to protect industry and the economy. But there are imminent hazards that need to be immediately addressed (child abuse, a hole in the floor, etc.). Must always consider risk vs. benefit. Investigators should always consider how the community views risk vs. benefit, and where the line is drawn.

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How is study problem defined, and by whom?

- Can be defined by an agency, individual, or community.
- All should be involved.
- Should address a public health question.

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Clearly articulated study justification

- Should have a targeted and specific goal.
- Encourage studies more broadly on subjects like children's health.
- Should consider things like maternal depression, etc.
- Broad focus of environmental influences on children's health is important.
- Address broad community needs.

9

Funding:

- Should industry funding be allowed?
  - Acceptance makes an investigator vulnerable to community and peer concern.
  - Maybe all research should be government funded.
  - Should there be a fee on all chemicals that goes into a general fund?
  - Should not allow someone from ACC to sit on a group that determines funding for research studies.
- Distinguish between a true conflict of interest and an apparent conflict.
  - May be more important to discuss how to accept funds and find ways to create a process for assuring that there will not be undue influence tied to the funding.
- The community should have a voice in determining whether or not to accept industry funding.
- Knowledge of the concerns that industry-funded research tends to give results favorable to the industry.
- Problems when community demands things that cost a lot of money – like letters, regular reports, travel etc. Problems in that the community may consider a long-term contract when funding may expire before study completed.

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Innovative and alternative design strategies:

- Should test something with natural histories – i.e., compare homes that have regular (i.e., routine, not family) application of pesticides vs. those who do not. Or lag exposed (or intervention) vs. control population – one for one year then switch. Involve the community in design of study.

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Other issues

- Feasibility
  - Need to have study that will be accepted by community and will lead to results.
- Statistical power - designed to meet study objectives?
- Include communication planning: Needs to be done
- Balance: When do you stop the study? Criteria?
- When should a study involve a data safety and monitoring board?
- Need good communication with the communities re: importance of maintenance of funding.
- Therapeutic misconception
- What constitutes “acceptable” conditions?
- Transparency of IRB:
  - Need to make sure that there is real community participation. Need to communicate how the IRBs work to the communities being studied. Need to advocate appropriate representation on IRBs.

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Harm Reduction

- What if the chemical of interest has not yet been tested for safety?
- Need to communicate what harm reduction is – not to lead to the idea that all dangerous exposure will be ended.

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Ensuring Protection of Vulnerable Groups

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Who are They?

- Clarify and define
  - Disparities
  - Individual and societal scales
  - Characteristics
    - Ability to voluntarily participate
    - Susceptible to coercion
    - Economically or educationally disadvantaged

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Protection

- Two scales for protecting rights
  - Individual
  - Community
- Underlying concepts
  - Beneficence (key, first consideration)
    - Risk-benefit balance
  - Autonomy
    - IRB role in considering special protections, concerns

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Minimize Undue Burdens

- Where the study occurs
- What data are collected

- Underlying principle = justice
  - Do not stigmatize the community
  - Do not blame the victims
  - Provide benefits to affected first

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How to Study Them?

- Make the study details transparent
- Be visibly involved, in the community
- Build knowledge of the community/group needs, concerns
- Build cultural awareness
- Create authentic relationships
- Ensure respect, trust, empathy
- Include appropriate experts, participant advocates
  - IRB
  - Study design team

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Information Sources

- Ethics journals
  - Review ethics literature, just as would do for a specific chemical
    - Ensure rapid access to reviews
  - Look for:
    - How to do studies
    - When to stop a study
- WHO and the European Union
  - Elderly, pre-existing conditions

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Addressing privacy and other concerns related to personal exposure observation studies

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What IS **Personal** Exposure?

- Define it clearly
  - Involve the community
  - In terms the community understands
- Teach the community and researchers
  - Scientific issues and importance
  - Ethics and means of monitoring
    - Why it must be done in your space? (not lab, clinic)
    - Privacy issues
- Goal = Increase understanding

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Ethical Issues (1 of 5)

- Invasion of privacy
  - Be upfront about it
  - Respect how powerful invasion of privacy can be
  - Team needs to be culturally sensitive
  - Seek diversity in entire research structure
- Confidentiality
  - Not the same as personal-space privacy protection
  - May need certificates of confidentiality
  - Special issues: e.g., adolescents

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Ethical Issues (2 of 5)

- Risk-Benefit balance
  - Ethics and science
  - What is the win-win?
  - May not be benefits to the individual participant
    - State upfront
    - Don't exaggerate benefits or minimize risks, burdens
  - Be aware of differences in risk-benefit perception of investigator, individual participant, and community
  - Risks vary by age, invasiveness of sampling, cultural norms
    - Participants may refuse participation in parts of study, sampling

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Ethical Issues (3 of 5)

- Disclosure
  - Timely feedback, results to individuals
  - When to inform individuals?
    - Individual may refuse to receive results
  - What information?
    - Known and unknown hazards
    - Tailored using input from IRB, sponsor, individuals, community
  - How to inform?
    - Work out with IRB and community

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Ethical Issues (4 of 5)

- "Collateral" observations (unrelated to the study)
  - MUST anticipate
  - MUST have an action plan (even for unexpected)
    - Train research staff
    - PI must be responsible for interventions, mandatory reporting, etc
    - Identify resources to help with decision-making

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Ethical Issues (5 of 5)

- Duty to care
  - Not the same as for clinical care
    - Doctor-patient duty
    - Researcher-participant duty
  - Researchers need to address their biases, perceptions
- When to stop?
  - Levels
    - Participant
    - Entire study
  - Role of data safety monitoring boards

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Third Parties

- Who are they?
  - Household members not in the study
  - Neighbors
  - Community
  - Insurers
  - Landlords, rental agents
  - School officials, teachers
  - Caregivers of:
    - Children
    - Elderly
    - Disabled
  - Etc
- Minimize potential impacts on them
  - Respect their presence
  - Announce home entry in advance
  - Recognize they may affect participation
  - Have a plan to address them
- When does a third party become a participant?

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Justification for the Study

- Agency
- Researcher
- Community
- Individual
- Application of results to policy
- Part of policy change
- Altruism
- Potential for personal gains

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Creating an Appropriate Relationship Between Participant and Investigator

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Informed consent

- Storage and use of samples (particularly DNA)
- Other issues

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Information to disclose

- Question of whether one should discuss with subjects possible hazards of at least the substance you are studying.
  - Like pregnant women who smoke.
  - Should err on the side of adequately warning the subjects. But there are too many possible hazards to cover everything, and many or the risks are uncertain.
- Duty of researcher
  - no duty,
  - duty regarding risk imposed by research on subject,
  - duty regarding risks known to be caused by preexisting behavioral of subject and duty regarding other risks unrelated to the study.
  - Refer back to NAS study.
- Researcher must be careful regarding what they can promise for long-term activity.
- Refer to literature on what kind of informed consent really works.
- Do tests to be sure the subjects understand.
- Use language appropriate for the population.
- Child assent is important - needs attention.
- Question of how many adults one should deal with.
- Information re: storage and use of samples.
- Consent form should state that the family can change behavior without losing compensation. But this has implications for retention and sample size.

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Incentives, compensation:

- Transparency of incentive: clearly describe what it is for, i.e. participant burden, NOT risk
- Relational ethics (Giselle to provide references): issues of power, hierarchy, social context
  - There also is a large literature on what level of compensation is undue influence.
- Can affect the science in representativeness of sample
- Provides significant scientific / practical benefit in recruitment
- Study design can be used as a means to guard against altering behavior
- Less concerned about undue influence when there is minimal risk. Here issues of equity and importance of incentives for retention more important in this case.
- We do relatively little to protect children from usual risks, but there remains the question of whether the study will increase exposure. Some have used a raffle to improve retention.
- Question of overemphasizing compensation. Hourly rate vs. lump sum? Involve the community on how to do it.
- Advertisements

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Creating a supportive environment for research and interaction

- Importance of developing community relationships prior to initiation of the study.
- Planning grants help.
- Communication plan helps.
- At same time investigator must identify and take action on imminent hazards he/she observes even if independent of the subject of the study. But the community may not see this in the same way – so there needs to be communication in advance. Investigator needs to be careful on what level of danger fits level for action. Researcher does have a duty that is different from that of a plumber, but the level/threshold should be set high. This is a complex issue.

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Ensure that recruitment/retention methods won't change behavior in ways that would increase exposure

- Real dilemma here - by having informed consent we may change behavior. Recognize this is a risk but recognize also this is the ethical way to go.
- May be a benefit to reduce exposure even though may cause problems in the research.
- Need to have a risk/risk statement – this is what we know about hazards of pesticides and this is what we know about dangers of pests.

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Timely Reporting of Results to Participants

- This is particularly important when we collect biological data that may reflect hazards to children/adults
- Need a fast turn-around time. At least need to be upfront about timing.
- Question of reporting all results is more complex.
- Needs to be clear information on whether or not clinically less significant results will be reported back.
- Community representation is important re: giving information that represents the will of the participants.

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Other issues

- Strategies about the population to be recruited
- Question of justification of one population vs. another. Who do you reach out to? Churches?
- Grievance procedures
- Ombudsman; Use community advisory board; Find persons other than the IRB chairperson or PI.
- Communication throughout the study
  - Is critical for retention in longer term cohort studies. Question of reporting all results back to subjects – it can be an incentive for participation.
- Set standards for when you stop the study because of risk: One should consider this issue upfront. See above.

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Building and Maintaining Appropriate Community and Stakeholder Relationships

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Why be concerned about community engagement?

- The nature of the research—it takes place within communities
- Ethical issues can take on different meanings
- Four critical aspects of engagement
  - Respect for the individual
  - Respect for the culture
  - Equity of resources
  - Empowerment
- Many ways to involve community
  - Advisors—utilize community to make sure you're doing the right thing
  - Help conduct research

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How do we define “community”?

(1 of 3)

- Varies, depending on the study
  - Geographic
  - Other shared characteristics (cultural, social)
  - Breadth of the definition
- Broad sense:
  - Anyone not part of research team
    - Press
    - Local agencies
    - Stakeholders
    - Etc.
  - Anyone without a supervisory role

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How do we define “community”?

(2 of 3)

- For this effort: population from which study participants are selected
  - Participants and their social/cultural community
  - Community experts
  - Excluding government, industry, etc.

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How do we define “community”?

(3 of 3)

- Distinction between “community” and stakeholders
  - Community has a right to speak for its interests
  - Stakeholders have information or expertise, but can’t speak for community
  - Stakeholders are still important on advisory boards
  - There are overlaps
- The chapter should carefully define “stakeholder” and “community”

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Who represents the community? (1 of 2)

- Different people can help you identify the appropriate voices:
  - Elected officials
  - Community associations
  - Community elder, matriarch, etc.
- Considerations for the researcher:
  - Important to ask the community who they see as a legitimate voice
  - Loudest voice is not necessarily the most representative
  - Usually not just one person (need multiple viewpoints)

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Who represents the community? (2 of 2)

- Information sources:
  - Sociological/ethnographic research about identifying community leaders
  - Large body of literature on community-based intervention, partnerships
  - Emergency research literature
    - Some similar issues
    - Lessons learned

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Importance of language and culture

- Can facilitate or be a barrier to community engagement
- Spoken language
- Different norms
  - Taking pictures
  - Sensitivities about certain types of samples (e.g., hair, fingernails)
- Different decision-making culture
  - Length of deliberation
  - Consensus building
- Keys for researchers
  - Avoid over-generalization
    - Part of process is to appreciate heterogeneities

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Building trust (1 of 2)

- Honesty
- Equity
- Building contracts
  - Each side has expectations
  - Setting limits
  - Some communities like a formal memorandum of understanding
  - Expectations re: a lasting infrastructure

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Building trust (2 of 2)

- *Honoring* voices from both sides
  - Beyond simply *respecting* those voices
  - People have a right to expect that their voices will be taken into consideration
- Trust must be built, not assumed
  - Build relationships before project begins
  - Must demonstrate trustworthiness
- Sources:
  - Interagency study *[M. Lebowitz suggestion]*

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Honesty, power relationships, and partnerships (1 of 2)

- Partnerships
  - Specific definitions may vary
  - Some general characteristics
    - Must consider power dynamics
- Acknowledge that researchers may feel like they have little power, but in the context of community relations, they do

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Honesty, power relationships, and partnerships (2 of 2)

- Forms of power
  - Monetary
  - Peer pressure
  - Expectations
  - Housing relationships
  - Imbalance of knowledge
    - Community has knowledge the researcher doesn't have
    - Researcher has knowledge the community doesn't have
    - Potential for knowledge transfer
  - "Power to stigmatize"
    - How researchers report their findings
    - Simply by doing the research (labeling communities)
    - Etc.
  - Age considerations
    - Children have less power
  - Access to resources

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Leaving a lasting infrastructure

(1 of 3)

- Important part of the relationship (don't just *take* from the community and then leave)
- Goals:
  - Empowerment
  - Sustainability
  - Capacity-building
- Researcher should discuss in advance with the community
- Build capacity throughout the project

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Leaving a lasting infrastructure

(2 of 3)

- Include training in the project
  - For researchers
  - For the community (capacity-building)
- Responsibilities of the sponsor
  - Many sponsors do make lasting commitments
  - Federal agencies should think of similar mechanisms
    - Tail-off of funding
    - Other approaches
- Relationship shouldn't end when funding ends
  - Help people learn to write grant applications
  - Help ID additional funding sources
  - Be available to provide technical support

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Leaving a lasting infrastructure

(3 of 3)

- Researchers need to solicit support within their own institutions
  - Ensure that relationship continues even if individual researcher leaves
  - Formal agreements to sustain relationships between organizations
  - Recognize realities of how some universities prioritize funding
  - Important to emphasize benefits of these relationships

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Designing and Implementing Strategies for Effective Communication

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Roles and responsibilities (1 of 4)

- When to communicate:
  - Start with the community
  - Then obtain funding
  - Involve community in next steps
    - Refining the study design
    - Finding participants
  - During the study
    - Communicate on a regular basis
      - Community meetings
      - Written communications
      - Etc.
  - Communicating results
    - In a timely fashion
    - But also recognize need for quality assurance

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Roles and responsibilities (2 of 4)

- What to communicate
  - Education
    - Risks; general info about indoor hazards
    - Scientific literacy
    - Confidentiality and data ownership
  - Methodology
    - Study methodology
    - How you plan to provide results (explain this in the informed consent)
  - Results [see next slide]

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Roles and responsibilities (3 of 4)

- Communicating results
  - Aggregate and individual
  - Report in an understandable fashion
  - At minimum, follow consent form and give participant the opportunity to receive results
  - Pros of full reporting of individual results:
    - Researcher won't have to make judgment about what's "dangerous" enough to merit reporting
  - Cons of full reporting of individual results:
    - IRB restrictions
    - "Data dump" can overwhelm, cause added stress to participants
  - Consider other useful, timely ways to report back (e.g., trend indicators)
  - Recognize difference between *data* and *findings*

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Roles and responsibilities (4 of 4)

- Other considerations for researchers
  - Recognize need for transparency
  - Importance of media training for study partners
  - Involve community in drafting of manuscripts
  - Importance of the *order* of communications
    - People don't want to hear results from the media first
  - Ultimately, results are public information
    - Tensions
      - Stakeholders' feelings about releasing aggregate findings
    - Likely to end up in peer-reviewed literature
  - Building relationships with IRBs

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Develop lay language

- Researcher should define key terms up front

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What constitutes “acceptable” conditions? (1 of 2)

- With respect to exposure…
- Define limits up front
  - Investigator must identify appropriate guidelines/limits
  - Learn about relevant policies– e.g., Academy of Pediatrics policies

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What constitutes “acceptable” conditions? (2 of 2)

- To what extent should the investigator warn people about risks?
  - Researchers have duty to inform participants about risks related to the study
  - Risks unrelated to the study:
    - Difficult to cover *all* possible risks
    - Could provide general (not personalized) fact sheet about risks ahead of time
    - Have a threshold for imminent danger
  - Precedents:
    - NAS and WHO documents: inform people about indoor exposures exceeding occupational standards
  - Importance of how you say it
    - Provide resources
    - Empower individuals to remedy situations if possible
    - Empower communities to advocate for broader remedies

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Ownership of data (1 of 3)

- Legal aspects
  - Laws about data reverting to public after some amount of time
  - Agencies’ rules
  - Investigators don’t have power to change rules
- Ethical aspects
  - Many communities feel they must own data
  - Investigators *do* have power to give communities a sense of shared ownership
  - Communities point out that they are taxpayers too

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Ownership of data (2 of 3)

- Must determine ahead of time
  - Include in study design
  - Dialogue with community
- Distinction between data and findings (interpretation)
  - Community wants *findings*
- Importance of education
  - Inform people about legal aspects
  - People, schools, etc. have a right not to be identified in publications
  - Explain confidentiality issues

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Ownership of data (3 of 3)

- Genetic-environmental interaction
  - Growing interest in this area
  - Debate: can you ever de-identify genetic data?
    - General opinion: NO (at least not in future)
    - Must modify public-use datasets accordingly

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Communication strategy

- Beyond PR: communication throughout the process
  - Get feedback from participants, etc.
- Anticipating and dealing with criticism
  - Researchers must work with agencies' administration and public relations staff
  - Should be able to respond to criticism in a timely fashion
    - Justify the research
    - Explain how the community has been involved throughout
- Sources:
  - EPA's risk communication strategies
  - CDC approaches

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