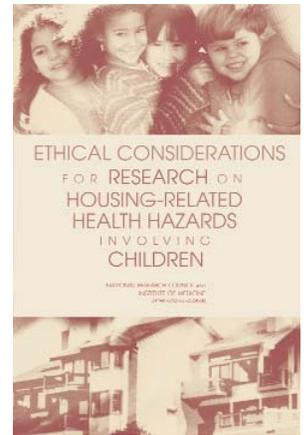


ETHICAL CONSIDERATIONS FOR RESEARCH ON HOUSING-RELATED HEALTH HAZARDS INVOLVING CHILDREN



Homes may contain hazards that can cause physical illness, compromise children's growth and development, and lower school performance. These hazards are particularly serious for young children. Research on such housing-related health hazards has helped to understand how they affect children's health and to develop interventions that can ameliorate or eliminate them. This research is often conducted with children in poor quality housing—disproportionately occupied by low-income families—because they experience the greatest risk and because findings from research involving children in other types of housing may not be relevant. However, targeting research to children from low-income families and conducting research in the home raise numerous ethical concerns.

REPORT BACKGROUND AND CHARGE

A recent legal case, *Grimes v. Kennedy Krieger Institute*, dramatized the ethical issues that surround research into health hazards in the home. Parents of two children enrolled in the study—a comparative study of methods of lead abatement in Baltimore housing—sued the researchers for negligence towards their children. The final court ruling questioned whether the consent process was adequate, whether parents misunderstood the study design, whether the institutional review board (IRB) failed to protect the children, whether vulnerable children were inappropriately targeted for study, and whether children should be enrolled in research that is not intended to directly benefit them.

In response, the U.S. Department of Housing and Urban Development, the Centers for Disease Control and Prevention, and the Environmental Protection Agency requested that the National Academies conduct a study of the ethical issues related to housing health hazards research. The Committee on Ethical Issues in Housing-Related Health Hazards Research Involving Children, Youth, and Families explored the issues and presents new approaches to foster the ethical conduct of this kind of research.

...targeting research to children from low-income families and conducting research in the home raise numerous ethical concerns.

The community is an additional component of the system in the context of housing health hazards research and should be involved early in the process.

NATURE OF THE RESEARCH

Federal regulations on research with human subjects (45 CFR 46) require informed consent, IRB review, and an acceptable level of risk. Research funded by some federal agencies must also comply with Subpart D of these regulations, which provides additional protections for research involving children. However, these protections do not address the full range of ethical issues raised when housing health hazards research is conducted in homes, particularly research conducted in low-income communities:

- Research conducted in homes intrudes on the privacy of all residents.
- Research conducted in low-income communities frequently involves community concerns such as the safety and quality of local housing.
- Parents of potential subjects might mistakenly believe that research designed to test an intervention will actually eliminate the hazard.
- Parents of potential subjects and community residents may be concerned about the housing risks that persist after the research is completed.
- Research that involves the disproportionate enrollment of children in low-income families may raise questions about inequitable selection of subjects.
- Economic and educational disadvantage and limited literacy among low-income parents can make informed consent difficult.
- Financial or other material incentives can influence parental decisions about allowing their children to enroll in a research project.

A SYSTEMS APPROACH

This report endorses a systems approach to ensure that the ethics and science of research involving humans are of high quality. It recommends additional responsibilities for each system component: researchers, in designing and implementing studies; research institutions and IRBs, in approving and overseeing research; and the federal government and sponsors of research, in funding research (see table 1).

The community is an additional component of the system in the context of housing health hazards research and should be involved early in the process. Community involvement in research on housing health hazards with children has been shown to make research more responsive to community needs, identify risks that researchers had not appreciated, improve informed consent, increase study enrollment, enhance data validity and quality, build trust for research, and help translate research into public policy. Community involvement allows researchers to understand the concerns of the community in which research studies are conducted and to respond to them. Community involvement can help researchers ensure that compensation and informed consent processes are appropriate. With community involvement, researchers in turn can present their findings to key local officials to support evidence-based policies aimed at ameliorating housing-related health hazards.

To ensure that consent for children to enroll in research is truly informed, researchers and their oversight bodies must ensure that parents of child subjects understand:

- The risks present in the home pertinent to the topic being studied;
- Ongoing risks in the housing environment that may persist after completion of study interventions;
- The essential elements of the research including whether and when test results will be provided to them and the risks and benefits presented by the research project itself.

TABLE 1. Housing Health Hazards Research: Characteristics, Ethical Implications, and Recommendations

Key Characteristics	Ethical Implications	Recommendations
Conducted with children	Children are vulnerable and unable to provide informed consent	All funders should at a minimum adopt the protections of Subpart D of 45 CFR 46 The Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services should issue guidance on key terms used in Subpart D Communities should be involved in the design and implementation of research projects
Conducted in the home	There is a breach of privacy Researchers are likely to observe risks not related to research questions	Researchers need to develop anticipatory plans to assess and respond to observed risks and behaviors and educate their staffs on these plans Researchers need to recognize obligations to third parties affected by their research
Conducted in the community	Research procedures and findings affect the entire community Differences in priorities between researchers and community members	Communities should be involved in the design and implementation of research projects Researchers need to respond to community concerns about the project Researchers need to recognize obligations to third parties who are affected by their research Sponsors should require and provide adequate funding to enable community involvement
Often conducted with economically and educationally disadvantaged groups	Increased likelihood for therapeutic misconception and other misunderstandings of research procedures and implications Amount of payment may constitute undue inducement	The informed consent process for intervention or longitudinal studies should include community input and should ensure that parents of child subjects understand essential features of the research Compensation should be reasonable and avoid potential for undue influence OHRP should issue guidance with advice from the Secretary's Advisory Committee on Human Research Protections on research involving economically and educationally disadvantaged groups
Presence of multiple health hazards in homes of child subjects	Research may address only one aspect of problems in the home	The informed consent process for intervention or longitudinal studies should include community input and should ensure that parents understand essential features of the research Researchers who design intervention studies should consider innovative designs in which all subjects have the prospect of direct benefit
Lack of IRB expertise and experience in housing health hazards research	Potential for inadequate review and oversight of research	IRBs need to ensure that they have the necessary expertise to review such research

The informed consent process for intervention or longitudinal studies should include community input and should ensure that parents of child subjects understand essential features of the research

COMMITTEE ON ETHICAL ISSUES IN HOUSING-RELATED HEALTH HAZARD RESEARCH INVOLVING CHILDREN, YOUTH, AND FAMILIES

BERNARD LO (*Chair*), Program in Medical Ethics, University of California, San Francisco; **JOHN L. ADGATE**, Division of Environmental Health Sciences, School of Public Health, University of Minnesota; **GORDON CAVANAUGH**, Former General Counsel to the Council of Large Public Housing Authorities; **GISELLE CORBIE-SMITH**, Department of Social Medicine and Medicine, University of North Carolina, Chapel Hill; **ALAN FLEISCHMAN**, The New York Academy of Medicine; **FERNANDO A. GUERRA**, San Antonio Metropolitan Health District; **DALE HAMMERSCHMIDT**, Department of Medicine, University of Minnesota; **PATRICIA KING**, Georgetown University Law Center; **DAVID KRANTZ**, Department of Psychology, Columbia University (until February, 2005); **BRUCE LANPHEAR**, Cincinnati Children's Hospital Medical Center and University of Cincinnati; **JACQUELINE PATTERSON**, Toxicology Excellence for Risk Assessment, Cincinnati; **PEGGY SHEPARD**, West Harlem Environmental Action, Inc., New York City; **MICHAEL STEGMAN**, Department of Public Policy, University of North Carolina, Chapel Hill; **MICHAEL WEITZMAN**, Department of Pediatrics, University of Rochester; **BRENDA ESKENAZI**, *Liaison*, Board on Children, Youth, and Families; School of Public Health, University of California, Berkeley

STUDY STAFF

MARY ELLEN O'CONNELL, *Study Director*; **AMY GAWAD**, *Research Associate*; **ELIZABETH TOWNSEND**, *Senior Program Assistant*; **EMILY LAMOND**, *Christine Mirzayan Science & Technology Policy Graduate Fellow*; **ROSEMARY CHALK**, *Director, Board on Children, Youth and Families*

FOR MORE INFORMATION:

Copies of *Ethical Considerations for Research on Housing-Related Health Hazards Involving Children* are available for sale from the National Academies Press at (800) 624-6242 or (202) 334-3133 (in the Washington, DC metropolitan area) or via the NAP homepage at www.nap.edu. Full text of the report, a free pdf copy of the Executive Summary, and this report brief, are also available at www.nap.edu.

This study was funded by the U.S. Department of Housing and Urban Development, the Environmental Protection Agency and the Centers for Disease Control and Prevention. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the views of the agencies that provided support for the project.

Copyright ©2005 by the National Academy of Sciences. All rights reserved. Permission is granted to reproduce this document in its entirety, with no additions or alterations.

This study is a project of the Board on Children, Youth, and Families within the Division of Behavioral and Social Sciences and Education of the National Research Council, and the Institute of Medicine.

www.bocyf.org

202-334-1935

THE NATIONAL ACADEMIES

Advisers to the Nation on Science, Engineering, and Medicine

The nation turns to the National Academies—National Academy of Sciences, National Academy of Engineering, Institute of Medicine, and National Research Council—for independent, objective advice on issues that affect people's lives worldwide.
www.national-academies.org