Ethical Considerations for Research on Housing-Related Health Hazards Involving Children

Bernard Lo and Mary Ellen O'Connell, Editors,
Committee on Ethical Issues in Housing-Related Health Hazard Research Involving Children, Youth, and Families

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Board on Children, Youth, and Families
Division of Behavioral and Social Sciences and Education

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the Report Review Committee of the NRC. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by James F. Childress, Institute for Practical Ethics, Department of Religious Studies, University of Virginia, and Judith P. Swazey, Founding President and Senior Associate, The Acadia Institute, Bar Harbor, ME. Appointed by the NRC, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

The committee appreciates the support provided by members of the Board on Children, Youth, and Families under the leadership of Michael I. Cohen. We are grateful for the leadership and support of Michael Feuer, executive director of the NRC's Division of Behavioral and Social Sciences and Education; Jane Ross, director of the Center for Economic, Governance, and International Studies; and Rosemary Chalk, director of the Board on Children, Youth, and Families.

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Bernard Lo, *Chair*
Mary Ellen O'Connell, *Study Director*
Committee on Ethical Issues in Housing-Related Health Hazard
Research Involving Children, Youth, and Families

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Preface

Everyone wants children to grow up healthy. Generally we think of homes as places where children grow, develop, and thrive. However, some homes present serious health risks to children, including risks of lead poisoning, asthma, and fatal accidents. These hazards are particularly common for children with little access to affordable, decent housing, who are disproportionately poor and members of minority groups. This situation is the context of our report.

On one hand, research is needed to better understand housing health hazards and to learn how best to ameliorate them. Children who are most at risk for these hazards may benefit the most from such research. On the other hand, such research presents ethical problems because children who are most at risk may also be vulnerable in multiple ways. The challenge is to carry out research that ultimately will lead to improvements in the health of children, while assuring that vulnerable children participating in research do not face inappropriate risks and that their parents are truly informed about the research.

The highly publicized Kennedy-Krieger case, which dramatized these ethical dilemmas, was the impetus for this study. That case, which has generated considerable controversy, has been viewed as a defeat for the researchers and has called into question the ethics of research with children. Our committee did not attempt to make a judgment about this particular case. Indeed, it would be difficult to do so because the case was resolved after the courts ruled on a motion for summary judgment; no testimony was introduced in court on crucial contested factual issues. Instead, the

committee considered the underlying ethical issues that the case illustrated, which are common in other research on housing health hazards affecting children.

The committee heard testimony from many individuals and read many kinds of evidence. We listened to parents, community leaders, researchers, government officials, and experts in law and ethics. As we listened, read, and discussed, I was struck with how much was to be learned from the disparate perspectives of different stakeholders.

We learned why parents and community representatives were skeptical about the benefits of research. Because most previous research had not led to any improved housing for their communities, they doubted that scientific knowledge by itself would help them reduce their housing health risks. Many community representatives believe that they need economic and policy reforms, rather than more housing research. Hence they want assurance of immediate benefits from research projects. Moreover, they complained that many researchers fail to understand crucial features about their communities. As a result, scientists proposed research methods that would fail to gather reliable information and did not explain research projects in ways that participants could readily understand.

From researchers we learned that when they entered homes to study housing health hazards they faced dilemmas that were markedly different from those facing researchers who work with research participants at medical institutions. In participants' homes, investigators have observed housing hazards and risks to children that were not the focus of their study. Sensitive researchers felt caught between wanting to help children at risk, feeling overwhelmed by the magnitude of hazards in substandard housing, and realizing that intervention could make things worse if residents faced retaliation. Another issue researchers presented is that those who are committed to devoting time and resources to developing partnerships with the community might be at a disadvantage when applying for grants and carrying out projects. From experts in ethics and research oversight we learned how the federal regulations for research with human participants have been developed with biomedical and clinical research in mind and need to be clarified in the context of this research. We were challenged to think about how research carried out in homes and in communities that are disadvantaged in many ways might require fresh interpretations of ethical principles.

As the committee deliberated, we found two guiding themes. First, when researchers discuss a planned study with community representatives, understand their concerns and needs, and respond to them, protocols can be strengthened both scientifically and ethically. Community representatives and parents can identify problems with a project and risks to participants that researchers do not fully appreciate. Moreover, community representatives can suggest better ways to collect data, to explain the project to

participants, and to recruit and retain them. Although there are problems with identifying appropriate community representatives, reasonable efforts to elicit the range of views of the community are preferable to making no attempt to engage the community. Furthermore, working with the community can help the community understand the role and value of research.

Second, the informed consent process needs to be strengthened when research involves children who are vulnerable in many ways. Parents may not understand that the research is not designed to eliminate the hazards being studied and that children will still be at risk for health hazards. In particular, researchers need to take steps to ensure that parents actually understand the essential features of the research study. This requires researchers and institutional review boards to go far beyond their usual focus on describing the risks of research interventions and on refining the consent form.

We believe that these themes have led us to recommendations that will allow important research on housing-related health hazards involving children to proceed in an ethically acceptable manner. Although our focus was on housing-related health hazards involving children, these themes may be pertinent to other research carried out in communities that are economically and socially disadvantaged and whose residents may not share scientists' views about the need for research.

As chair I thank Mary Ellen O'Connell, Liz Townsend, Emily Lamond, and Amy Gawad at the National Academies. Without their hard work and careful organization, this report would not have been possible. I also thank the members of the committee for their willingness to tackle the tough issues, to listen to other viewpoints, and to keep open minds. In the spirit of National Academies' committees, we learned from people from different backgrounds and disciplines. I believe that our deliberations can serve as a model for the discussions that need to take place among the stakeholders in research on housing health hazards involving children. Researchers and sponsors need to listen to the viewpoints of parents and community representatives, learn from each other, and reach common ground. Such conversations take time and are not always easy. Through such discussions, problems that may seem insoluble in the abstract can often be worked out in the context of a specific research project.

Bernard Lo, *Chair*
Committee on Ethical Issues in Housing-Related Health Hazard
Research Involving Children, Youth, and Families

Executive Summary

A home is considered a place where children grow and flourish. However, homes may also 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 because they spend significant amounts of time in their homes, because their normal exploratory behaviors increase the likelihood of exposure to hazards, and because the effect of exposure may be particularly harmful because of their small size and developmental immaturity.

Many health hazards in homes—such as mold, radon, tobacco smoke, and household chemicals—occur in housing at all economic levels. However, some housing health hazards—such as lead poisoning, asthma, and fatal injuries—occur at disproportionately high rates in the poor-quality homes of children in low-income families. Research on housing health hazards involving children is necessary to understand how hazards affect health and to develop interventions that can ameliorate or eliminate them. Such research, typically conducted in children's homes, has contributed significantly to knowledge about the risks of health hazards in homes. Some research is directed toward generalizable knowledge and offers no direct benefit to the children who are enrolled in it, such as studies of how exposure to environmental hazards in homes affects health. This kind of research has resulted in the design of interventions to address hazards, such as window guards that have significantly reduced childhood injuries from falls through windows. Other research has evaluated interventions to ameliorate or eliminate the risks of exposure and harm. This kind of research may offer the prospect of direct benefit to the children who are enrolled in the

studies. Research both identified lead-based paint as a cause of lead poisoning among children and showed that the abatement techniques previously used actually increased lead poisoning because they caused lead contamination of house dust, which children ingest. Research on housing health hazards has led to changes in public policy, such as improved screening for risk factors and regulatory changes to reduce risks.

Housing health hazards research focuses on a risk factor that is not a physical susceptibility to disease, but rather results from environmental conditions that generally exist in poor-quality housing. Many of those conditions could be improved by better quality housing, but there is a lack of decent affordable housing for children in low-income families. Research is often conducted with children in low-income families because they experience the greatest risk and because they have the most to gain from such research.

The 2001 case of *Grimes v. Kennedy Krieger Institute* highlighted uncertainties and conflicts involving several issues integral to research on housing health hazards. Although the case was eventually settled out of court, the ruling of the Maryland Court of Appeals raised important issues involving the adequacy of informed consent, parents' perceptions of risk, duties of researchers to child subjects and their parents, the role of institutional review boards (IRBs), and the authority of parents to provide permission for their children to participate in research that is not intended to provide direct benefit for their children.

The issues posed by that case led the Department of Housing and Urban Development, the Centers for Disease Control and Prevention, and the Environmental Protection Agency to request a study from the National Academies on ethical issues related to housing health hazards research. The Committee on Ethical Issues in Housing Related Health Hazard Research Involving Children, Youth, and Families was formed in response to that request, under the Board on Children, Youth, and Families of the National Academies' National Research Council and Institute of Medicine. Broadly, our charge was to review and synthesize existing approaches to conducting housing health hazards research involving children and the challenges and ethical issues that arise in conducting that research and to identify approaches to ensuring the ethical conduct of that research.

NATURE OF THE RESEARCH

The current regulatory framework that governs research involving human participants (referred to in the regulations as "subjects") that is conducted or funded by certain agencies of the federal government is based on the fundamental ethical principles of respect for person, beneficence, and

justice. Subpart A (of 45 CFR 46) provides various protections related to informed consent, level of allowable risk, and IRB approval. If the research receives funding from the Department of Health and Human Services (DHHS) or certain other federal agencies, Subpart D provides additional protections for research involving children. Oversight is the responsibility of the Office for Human Research Protections (OHRP) in DHHS, with input from the Secretary's Advisory Committee on Human Research Protections (SACHRP).

Because housing health hazards research is conducted in homes, some ethical issues arise that are not as common in biomedical and other types of research.

- Research conducted in homes intrudes on the privacy of all residents and reveals many things about the residents that would not otherwise be apparent or shared.
- The research is almost always based in the community and frequently involves community concerns about the safety and quality of local housing.
- Because some hazards occur disproportionately among children in low-income families who live in poor-quality housing, they are more likely to be candidates for housing health hazards research, and disproportionate enrollment of children in low-income families may raise questions about targeting or inequitable selection of subjects.
- The residents of poor-quality housing in low-income communities often face a range of housing health hazards and may be concerned about hazards other than the one being studied or may mistakenly believe that research designed to test an intervention may actually eliminate the hazard.
- Parents of potential subjects and community residents may be concerned about the housing risks that persist after the research interventions and the study are completed.

Some of these issues may also affect other types of research conducted in homes. Similarly, at least two other features of some housing health hazards research raise general ethical issues, especially as they interact with the ones just noted:

- Economic and educational disadvantage and limited literacy among low-income parents may place them at a disadvantage in the informed consent process.
- Financial or other material incentives may present undue influences for parents in the decision to allow their children to participate in a research project.

A SYSTEMS APPROACH

The report *Responsible Conduct of Research* (Institute of Medicine, 2004) argued that a systems approach is necessary to ensure that the ethics and science of human participants research are of high quality. A systems approach involves responsibilities for researchers, oversight bodies such as IRBs, the OHRP, and research sponsors. This committee concurs with a systems approach and 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.

The committee identifies the community as an additional component of the system in the context of housing health hazards research. 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 views of the community in which research studies are conducted and to respond to those perspectives so that the risks of a research project are minimized and appropriate in light of the anticipated benefits of research, as required by the federal regulations.

Table ES-1 provides an overview of a systems approach, summarizing key characteristics of housing health hazards research, the ethical issues raised by those characteristics, and the committee's recommendations.

RESPONSIBILITIES OF RESEARCHERS

Community involvement is a key element for conducting in an ethical manner housing health hazards research that involves children in their homes. Community involvement can contribute to the ethical conduct of this research, ensuring that parents understand key features of the research and that compensation is 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.

The consent process for research participants in any scientific study should be both informed and freely given without coercion or undue influence. One critical component of the consent process for research involving children is ensuring that parents or other caregivers are aware of and do not misunderstand essential features of the research study. When the parents of child subjects are economically and educationally disadvantaged, particular attention must be paid to potential sources of undue influence as identified

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

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 (Recommendation 8.1) OHRP should issue guidance on key terms used in Subpart D (Recommendation 8.2) Communities should be involved in design and implementation of research projects (Recommendations 5.1 and 5.2)
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 (Recommendations 7.3 and 7.4) Researchers need to recognize obligations to third parties affected by their research (Recommendation 7.2)
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 design and implementation of research projects (Recommendations 5.1 and 5.2) Researchers need to respond to community concerns (Recommendation 5.1)

continued

TABLE ES-1 Continued

Characteristics	Ethical Implications	Recommendations
		Researchers need to recognize obligations to third parties who are affected by their research (Recommendation 7.2)
		Sponsors should require and provide adequate funding to enable community involvement (Recommendation 5.3)
Often conducted with economically and educationally disadvantaged groups	Increased likelihood for therapeutic misconception and other misunderstandings of research procedures and implications	Compensation should be reasonable and avoid potential for undue influence (Recommendation 6.2)
	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 (Recommendations 6.1 and 6.2)

		OHRP should issue guidance with advice from SACHRP on research involving economically and educationally disadvantaged groups (Recommendation 8.3)
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 (Recommendations 6.1 and 6.2) Researchers who design intervention studies should consider innovative designs in which all subjects have the prospect of direct benefit (Recommendation 7.1)
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 (Recommendation 8.4)

in the relevant regulations. To ensure that consent is truly informed, researchers must ensure that parents of child subjects:

- understand the risks present in the home pertinent to the topic being studied;
- understand ongoing risks in the housing environment that may persist after completion of study interventions;
- understand 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.

Researchers should obtain the assent of children to participate in the research as appropriate to their age and developmental status.

The issue of appropriate compensation for children involved in research and their families is an important issue in all research with children, but it is a particular concern with low-income families. Payments should be structured to compensate parents for their time and expenses, and they may include modest incentives or gifts of appreciation. Excessive payments constitute an undue inducement that could lead parents to agree to a greater level of risk than they would otherwise.

Researchers have several other areas of responsibility with regard to ethical housing health hazards research: innovative research designs, anticipatory response plans, and consideration of the effect of their research on third parties.

Innovative research designs are important because of the ethical issues and difficulties of doing randomized control trials for housing health hazards. Community residents often object to randomized trials because of the lack of benefits provided to the comparison group in such research, particularly because virtually all children involved in the research will live in conditions that may pose health risks. Innovative study designs that offer a benefit to both the research and comparison groups, without compromising the integrity of the research, can alleviate some of the ethical concerns. In addition, child subjects should be recruited from potentially affected groups at all income levels whenever feasible.

Because researchers enter families' homes, privacy is compromised: they observe behavior and hear conversations that would otherwise be private. They may observe behaviors or situations that are not related to the research project but that pose a risk or danger to either research subjects or other residents. Researchers should anticipate and define their legal and ethical obligations to both subjects and others. They need to anticipate risks and have plans for dealing with them and inform their staffs of those plans.

When children in a home are at risk of imminent and serious harm, researchers and their staffs are ethically obligated to respond to dangerous

circumstances by discussing these concerns with the family and, if needed, notifying appropriate authorities as required by law or good practice. In cases that pose less serious threats, researchers should respond to observed problems in ways that respect the values and needs of the children's household, respond to community norms, and reflect their own ethical obligations.

Finally, researchers need to consider situations that may require them to obtain permission, provide notification, or act to reduce risks to third parties, such as other residents in the housing, landlords, or neighbors.

Researchers carrying out research on housing health hazards involving children should describe in their protocols and IRB submissions how they have involved and will continue to involve the affected community in the research project, justify the lack of such involvement, and report how they have responded to any community concerns. (Recommendation 5.1)

Researchers who carry out intervention studies or longitudinal cohort studies on housing health hazards with children should implement a process of informed parental decision making by discussing the planned consent process with community representatives, considering their input, and ensuring that parents of child subjects understand the essential elements of the research. (Recommendation 6.1)

Payment for participating in research on housing health hazards involving children should reimburse (1) reasonable expenses directly related to participation; (2) reasonable, age-appropriate compensation to children for time spent in research that does not offer the prospect of direct benefit; and (3) reasonable compensation to parents for time spent in research. Such compensation may be in addition to token gifts to parents and children as gestures of appreciation. Such payments must avoid the potential for undue influence. (Recommendation 6.3)

Researchers designing intervention studies on housing health hazards involving children should consider using innovative designs in which all subjects receive a prospect of direct benefit. (Recommendation 7.1)

Researchers carrying out research on housing health hazards involving children should discuss in their protocols and IRB submissions their legal and ethical obligations to potential third parties affected by their research. (Recommendation 7.2)

Researchers designing research on housing health hazards to children need to anticipate the risks and behaviors that may be observed in the

home, including observations that are not part of the research protocol, develop anticipatory plans that specify how to assess and respond to risks when they are identified, and educate staffs about the plan. (Recommendation 7.3)

RESPONSIBILITIES OF RESEARCH INSTITUTIONS AND IRBS

Research institutions have an obligation to ensure that the research they conduct is done in an ethical manner and in compliance with applicable statutes and regulations. Those institutions and their oversight bodies, such as IRBs, need to have the necessary expertise to provide complete and adequate review and oversight of research on housing health hazards to children.

Subpart D specifies three types of research involving children that can be approved by an IRB: (1) research involving minimal risk (Section 404); (2) research involving a greater than minimal risk with the prospect of direct benefit to subjects (Section 405); and (3) research involving a minor increase over minimal risk with no prospect of direct benefit to the subjects (Section 406). Section 406 research may be approved by an IRB only if the research shows promise of providing information necessary to understand or ameliorate the "disorder or condition" of the children who are subjects in the research.

Disadvantaged children who reside in poor-quality housing stand to gain the most from such research because they are most at risk from many housing health hazards, yet they are also at increased risk for harm from housing health hazards because of their disadvantages.

Institutional review boards should require appropriate community involvement in housing health hazards research involving children and require that investigators' protocols are responsive to any community concerns. (Recommendation 5.2)

Institutional review boards that review intervention studies or longitudinal cohort studies on housing health hazards involving children should require that the informed consent process reflects appropriate community input and includes plans to ensure that parents of child subjects understand the essential elements of the research. (Recommendation 6.2)

Institutional review boards that review housing health hazards research should examine researchers' plans for responding to risks observed in the home and require that they be appropriate in the context of the research and the affected community. (Recommendation 7.4)

Institutional review boards that review housing health hazards research involving children should ensure that those boards have the necessary expertise to conduct a complete and adequate review, including expertise on research involving children and community perspectives. (Recommendation 8.4)

RESPONSIBILITIES OF THE FEDERAL GOVERNMENT AND RESEARCH SPONSORS

Subpart D of the federal regulations governing research that involves children provides specific protections and a solid ethical foundation for the conduct of this research. The primary agencies that sponsor such research include the Department of Housing and Urban Development (HUD), the Environmental Protection Agency (EPA), and the Department of Health and Human Services (DHHS), including the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH). Of them, only DHHS has adopted Subpart D. The committee concludes that these additional protections are critical to establishing consistent conditions for researchers and IRBs when designing and overseeing housing health hazards research.

Subpart D provides a solid foundation for research involving children, but key terms—such as "minimal risk," "minor increase over minimal risk," and "disorder or condition"—which are vital in determining whether research involving children is allowable and the standards that must be applied, are interpreted in widely varying ways. The committee concludes that consistent definitions are critical to providing oversight to IRBs.

In Subpart A of the federal regulations, economically and educationally disadvantaged people are identified as a vulnerable group that warrants particular consideration, specifically in the context of informed consent and justice. However, unlike other designated vulnerable people—children, pregnant women, and prisoners—no specific regulations are provided for applying additional protections for this group. Guidance on how to implement special protections for this vulnerable group are needed to help researchers and IRBs develop appropriate protocols and assure that their rights and welfare are protected.

All federal agencies—including the U.S. Department of Housing and Urban Development and the Environmental Protection Agency—private foundations, and other funders of research on housing health hazards involving children should at a minimum adopt the current regulatory framework in Subpart D of 45 CFR 46. (Recommendation 8.1)

The Office of Human Research Protections should issue guidance to institutional review boards on how to interpret the key regulatory terms—"minimal risk," "minor increase over minimal risk," "disorder or condition," "reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations," and "vital importance"—in the context of housing health hazard research. (Recommendation 8.2)

The Secretary's Advisory Committee on Human Research Protections should develop guidelines for research with economically and educationally disadvantaged participants for use by the Office for Human Research Protections use in issuing guidance for researchers and institutional review boards. (Recommendation 8.3)

Community involvement in research and continued evaluation of the outcomes of this involvement will be advanced if funders require it as part of the research they fund. Meaningful community involvement requires adequate time and resources, including resources to reimburse the expenses of researchers and community residents or to compensate them for the time required; such expenses are not typically included in research grants.

Federal agencies (e.g., HUD, EPA, NIH, CDC), private foundations, and other funders of research on housing health hazards involving children should require researchers to have appropriate community involvement in the research. Funders should provide adequate funding to involve affected communities and should sponsor research to evaluate the outcomes of community involvement. (Recommendation 5.3)

Implementing the committee's recommendations for housing health hazards research involving children can provide needed protection for child subjects and affected communities and researchers, ensure that the rights of child subjects are protected, and allow valuable research to proceed that is intended to benefit children living in poor-quality housing. Critical steps include adoption of Subpart D by all federal agencies and clarification of key terms in Subpart D and efforts by researchers, IRBs, and sponsors to ensure appropriate community involvement and thorough understanding by parents of key elements of the research. To do this successfully will require the commitment of researchers, IRBs, OHRP, sponsors, and representatives of the communities where this research will be carried out. A partnership among all these parties will help develop the scientific basis for public policies that will reduce or eliminate the housing hazards that threaten children's health.

1

Introduction

Everyone wants children to have the opportunity to grow up healthy. And people think of homes as special places where children grow, develop, and thrive—where parents, guardians, and extended family teach children values and nurture their futures. Yet some homes have hazards that present serious health risks to children.

Hazards in housing have long been associated with infectious and chronic diseases, injuries, and even death. By the mid-nineteenth century, with the growth in urban populations and overcrowded tenements, the connection between health and housing was clearly recognized (see Duffy, 1990; Atkins, 1947). Overcrowding, impure drinking water, faulty sanitation, and poor construction allowed the transmission of tuberculosis, diphtheria, cholera, and other communicable diseases in crowded tenements (American Public Health Association, 1938). The sanitarian or public health movement emphasized adequate lighting, ventilation, and sewage and waste disposal. After World War II, however, public health efforts were largely divorced from housing codes and regulations as housing policy shifted toward code enforcement and provision of affordable housing (National Research Council, 2000).

Today, the connection between housing conditions and health has reemerged as an important issue, with the identification of new and often subtler hazards in homes, such as exposure to lead, pesticides, indoor allergens, molds, indoor air pollutants, as well as unintentional injuries in the home (Matte and Jacobs, 2000; Krieger and Higgins, 2002). Young children are uniquely susceptible to these hazards because they spend the majority of their time in the home (Wiley et al., 1991) and because normal

exploratory behaviors increase their likelihood of exposure (Bearer, 1995). In addition, the effects of exposure may be magnified by their smaller size and developmental immaturity (Bearer, 1995).

Among children, those in minority and low-income households are at greatest risk for health hazards in the home because of the generally poorer quality of their housing. Homes occupied by African Americans and low-income residents are 1.7 and 2.2 times more likely, respectively, to have a severe physical problem than other homes (Krieger and Higgins, 2002, citing American Housing Survey data). Children in low-income families are more likely to live in overcrowded households. Fatal residential injuries occur more frequently among African American children (Nagaraja et al., 2005). Evidence suggests that the higher prevalence of asthma and asthma morbidity among children in low-income families is at least partly attributable to housing conditions (Rauh, Chew, and Garfinkel, 2002; Huss et al., 1994). Lead poisoning is concentrated among poor, black children in older, poorly maintained homes in inner cities (Cummins and Jackson, 2001). In agricultural communities, particularly among the children of migrant farm workers, pesticide exposure is common (Bradman et al., 2005).

ISSUES IN RESEARCH WITH CHILDREN

Research with children inevitably raises ethical concerns. First, unlike adults, children cannot directly avoid or mitigate the risks of research because of their lack of experience and lack of control of their environment. Second, young children cannot provide informed consent on their own behalf: their parents or guardians must give permission for them to be enrolled in research. Exposing humans to research risks to which they have not consented always calls for close ethical scrutiny.

The goal of research by definition is the advancement of generalizable knowledge. As such, research interventions primarily benefit society as a whole, or future generations of children, not necessarily the children enrolled in the research and exposed to any risks that may be associated with the research. The federal regulations that govern research with children recognize that children have unique vulnerabilities; the regulations are accordingly designed to provide special protections. Although additional guidance is needed on some aspects of these regulations (discussed in this report), the current regulatory framework provides a solid framework for conducting ethical research with children. However, the particular characteristics of housing health hazards research introduce ethical issues not fully addressed by the current regulations: those additional issues are the focus of this report. Although some of the same characteristics are present in other types of research, and the additional protections proposed could apply in these cases, the focus of this report is specifically on housing health hazards research.

HOUSING HEALTH HAZARDS RESEARCH

Research can identify hazards in homes, characterize the sources and pathways of exposure and mechanisms of adverse health effects, and evaluate interventions to ameliorate or eliminate these risks. Research has led to improved screening for some risk factors, regulatory changes to reduce risks, and more effective interventions to reduce known hazards. For example, early epidemiological research led to requirements for window guards, which led to a significant reduction in childhood injuries from falls through windows. Research identified lead-based paint as a cause of lead poisoning in children; other studies showed that early lead abatement techniques paradoxically increased lead poisoning because they caused lead contamination of house dust, which is then ingested by children. Recent studies have been designed to determine effective strategies for mitigating known environmental risks for asthma and other housing health hazards. Research now under way is aimed at identifying the exposure and adverse effects of pesticides and other chemicals introduced into the home through human activity (e.g., building materials, furnishings, and consumer products).

The promise of improved health from research on housing health hazards involving children has not always been fulfilled. Housing codes may not be upgraded or enforced, regulations may be more significant for public than for private housing, and low-income families often face an inadequate supply of affordable housing that meets code and safety standards. In light of the continued problem of lack of affordable decent housing despite years of research showing the risks to children, community advocates may believe that additional research is unlikely to lead to improved housing for children who live in hazardous housing. In the experience of researchers working with community advisory boards, some community representatives (Krieger et al., 2002a) believe with due cause that the promise of the benefits of research has been deferred too long, and they may be cynical about the value of further research in their communities. Some advocates may believe that, rather than more research about housing health hazards, what is needed is greater political and social commitment to provide the resources or regulatory oversight needed to ensure safe and affordable housing for all children. Other advocates for better housing for children support additional research that may support housing reforms by providing more compelling evidence of how housing hazards impair children's health and how those hazards can be ameliorated.

Housing health hazards research involving children raises particular ethical challenges because it is usually conducted in homes.[1] A home setting

[1]In some cases, research is conducted in vacant housing.

is very different from a clinic setting in that a range of household risks (not covered by the research) may often be present and need to be considered. The researchers' relationship with children and their parents may be more complicated, and there may be conflicts in their roles and ethical obligations that are not always present (or as evident) in clinic-based research. Furthermore, research in homes may uncover personal information which may not be revealed in a clinical setting. In some cases, this information may involve third parties.

In addition, because children in low-income families are more likely to live in poor-quality housing and therefore are at increased risk for many housing health hazards, and to generate the necessary knowledge to understand and ameliorate these risks, such research often involves economically and educationally disadvantaged children. There are a number of ethical concerns about targeting such children for research. They are more likely to experience a range of vulnerabilities, such as poor access to health care and poor-quality schools. Their families are also more likely to be members of minority groups that historically have suffered and may continue to suffer discrimination. These multiple vulnerabilities raise concerns about both the exposure to any risks of research and to barriers to free and informed consent. Moreover, the relative lack of social, economic, and political power by low-income parents in relation to researchers may affect the voluntary nature of informed consent, at the same time that payments for participation may unduly influence parents' decision to allow their children to be enrolled in research. Furthermore, increased risk for housing health hazards of children in low-income families is due, in large part, to social circumstances. Poverty limits their parents' access to affordable, decent-quality housing and ability to pay for improvements that can ameliorate housing hazards. Moving to better quality housing, which would reduce many housing health hazards, is usually not a feasible option.

Researchers conducting housing health hazard research face many challenges. When researchers enter a home, even with the permission of the parents, there is an invasion of privacy. Although researchers were invited in the home to carry out only specific research interventions, they may be in a unique position to identify and help ameliorate hazards beyond those that are the focus of the study. If they do not act, an opportunity to prevent harm may be lost. However, if researchers do not point out any health hazards, parents may infer that there are none in their homes. (In some cases, researchers may have a legal obligation to report observations in the home.) Entering homes to conduct research also raises concerns about the potential effects on third parties, including other residents in the home.

DIFFERENT ASSESSMENTS OF RISKS AND BENEFITS

Assessing the risks and potential benefits of research always depends on value judgments about the salience and significance of the risks and benefits. Researchers may reach different conclusions about the risks and benefits of research than do the parents of potential subjects or other people in the community. Researchers may regard the physical risks of the research they carry out in the home as minimal because it does not involve any invasive medical procedures. However, community leaders and parents of child subjects may take a broader view of risks associated with the research. They may be concerned about baseline risks of the health hazard being studied, as well as any additional risk from any interventions by the researchers as part of the study. They may also be concerned about the risks that persist after the research interventions are carried out and the study is completed.

In an intervention study, parents and others may regard a "usual care" case control as unacceptable (Israel et al., 2003; Minkler and Wallerstein, 2003; Krieger et al., 2002b). These perceptions of risk may be associated with expectations or hopes that the risk will be eliminated, rather than just studied or partially abated. Community representatives may want researchers to reduce the adverse effects of existing housing hazards, even though the researchers' actions have not caused or worsened those hazards. Broadly, some community advocates may see research more as a means to obtain direct benefits of improved housing rather than as a means to gain generalizable knowledge about a health hazard and its remediation. But the views of community representatives are not monolithic or static. Krieger and colleagues (2002b) describe how one community advisory board changed its views over time: at the onset of a project, the community board insisted that the research project provide direct benefits to all children; subsequently, the board decided to support study designs that included a control group, believing that rigorous research was a powerful tool to mobilize support for improvements in housing.

There may also be disagreements over assessment of the potential benefits of the research. Low-income parents may perceive payments for research participation or equipment used in the study (such as equipment to clean homes) as an important benefit of the study. However, focusing on the tangible benefits of participation may constitute an undue inducement and thereby compromise the personal weighing of potential risks and benefits that is part of the informed consent process. As noted above, some community advocates may be more interested in the potential immediate benefit to their community than in the potential benefits to society.

For housing health hazards research, the mechanisms to translate effective interventions into benefits for those affected are more limited than for

biomedical research. In biomedical research, the health insurance and health care systems offer some assurance that effective new tests or therapies will be available to all those who could benefit from them. However, in the context of housing health hazards research, there is a much more limited infrastructure and fewer available public resources to bring the benefits of research to all those who may need them. There are often questions about whether housing interventions shown to be efficacious in research studies will be widely disseminated and implemented. In turn, these questions may affect people's assessment of the benefits of housing health hazards research.

GRIMES V. KENNEDY KRIEGER: AN ILLUSTRATIVE CASE

In 2001 the Maryland Court of Appeals ruling in the case of *Grimes v. Kennedy Krieger* dramatized the ethical dilemmas in research on housing health hazards involving children and became the impetus for this study. Briefly, that study compared three different levels of partial lead abatement in inner-city Baltimore with two control groups. The control groups were living in housing built after 1978, which presumably contained no lead-based paint, or in housing from which the lead had been earlier abated. Blood samples were taken from enrolled children to measure blood lead levels, and dust samples were taken in the homes. Two parents in this study sued the researchers and the research institution after their children developed elevated lead levels while enrolled in the study.

The legal proceedings were complicated, and the case was ultimately settled out of court. However, the court's rulings prior to settlement raised numerous ethical issues that prompted concern in the research community. The court appeared to endorse more stringent criteria for allowable research (applicable in the state of Maryland) than is permitted under the federal regulations: it declared that parents may not consent to their children's enrollment in "nontherapeutic research" that does not offer the prospect of direct benefit. The court suggested that researchers have a legal duty that can be the basis of a negligence action and declared that the informed consent form in this case was not valid because it failed to include essential information related to baseline risks in the home. The court also discussed additional issues, such as the acceptable level of risk for children in research on housing health hazards; discordant perceptions of risk and benefit among families, investigators, and institutional review boards (IRBs); problems with informed consent in vulnerable populations; research oversight; and reporting of results from research tests to families.

Both our charge and our deliberations led us away from the particulars of the case. Because the ruling turned on a motion for summary judgment and the case was settled out of court, there was no court testimony on such

crucial issues as what the researchers told parents about the study and what parents understood. Also, there was no cross-examination of witnesses and no opportunity for the jury to assess the credibility of witnesses. However, the committee considered closely the ethical issues raised by this case. For instance, as we deliberated, we realized that the crucial issue regarding consent was not what information was contained in consent forms, but rather what the parents understood about the study and the hazards present in the home before and after the study.

The court ruling challenged researchers, sponsors, and IRBs to rethink important ethical issues concerning research on housing health hazards involving children. The decision suggests stricter standards for limiting the risk to children enrolled in research, calls attention to the need to better protect vulnerable persons, questions the adequacy of IRB review, and calls for broader informed consent discussions.

THE COMMITTEE'S STUDY

The issues raised by the Maryland Court of Appeals decision provided the impetus for the Department of Housing and Urban Development, the Centers for Disease Control and Prevention, and the Environmental Protection Agency to request that the National Academies, through the National Research Council and the Institute of Medicine (IOM), establish a committee to review research challenges and ethical issues in the design and conduct of housing health hazards research. The Board on Children, Youth, and Families convened the Committee on Ethical Issues in Housing-Related Health Hazard Research Involving Children, Youth, and Families to undertake the following tasks:

- review and synthesize existing approaches to conducting research to identify safe and effective methods for controlling environmental and structural hazards to children's health in housing, and compare and contrast them to approaches for conducting research to identify safe and effective biomedical therapies for children;
- identify the defining characteristics of "therapeutic" vs. "nontherapeutic" studies for controlling housing-related health hazards as compared to biomedical treatments;
- characterize the research challenges that come up during the planning and conduct of housing-related health-hazard research and contrast them with those of biomedical research;
- review and synthesize the ethical issues that are intrinsic to the design and conduct of housing-related health hazard research on children and families and contrast them to those of biomedical research;
- discuss the ethical obligations of researchers to inform child sub-

jects, their parents or guardians, and appropriate others of data collected during a study, including a consideration of how to balance issues such as timely provision of information versus assuring relevance of the data, and making certain that information is provided in a way that is easily understood by recipients of the information; and

- identify approaches to deciding when and how researchers should intervene in a housing-related health hazard study to protect child subjects from harm or treat conditions identified during the course of the study.

The committee was also asked to consider the legal and ethical issues raised in *Grimes v. Kennedy Krieger* and address the full range of issues relevant to the ethical conduct of housing health hazard research with children, including determining whose responsibility it is to determine when a proposed project is considered ethical; whether there is a need for a specific institutional review process for housing research, and how ongoing oversight of such studies should occur, and whether there is a need only for guidance or for the issuance of specific regulations governing this field of research.

The committee met five times over the course of nearly two years. The committee heard from the primary federal agencies who conduct research on the intersection of housing and health, as well as the perspectives of several national groups that work on this subject. The committee commissioned several papers on topics relevant to its charge, including the legal context of *Grimes v. Kennedy Krieger*, ethical underpinnings of children's research, informed consent, and lessons from the behavioral and social sciences. The committee also requested presentations by researchers who conduct housing health hazards research; scholars from bioethics, law, and social sciences who have studied issues pertinent to the committee's charge; representatives of the communities in which research has taken place; and parents of research subjects.

Building on Other National Academies' Reports

This committee undertook its charge in the context of an extensive body of work on research with vulnerable people. Such research is challenging because of an inherent ethical dilemma: research with vulnerable people, targeted to the very conditions that cause them to have disproportionately adverse health (or other) outcomes, may provide benefits to the population from which the participants are drawn, but such research may also inadvertently cause harm or carry risks of harm for people who are already disadvantaged. The ethical and scientific challenge is to carry out research on housing health hazards that ultimately will lead to improvements in the health of children, while assuring that vulnerable children enrolled in that

research do not face inappropriate risks relative to the prospective benefits of the research and that their parents or guardians are truly informed about the research. A number of National Academies committees have considered issues related to the design and conduct of research involving humans. The work of this committee builds on the work of several prior committees, particularly the recent report, *Ethical Conduct of Clinical Research Involving Children* (Institute of Medicine, 2004), which addressed the challenges associated with conducting clinical research with children and reviewed the ethical and legal standards for conducting it. The IOM report thoroughly reviews the history of children's research and the relevant federal regulations governing research involving children, and it makes several recommendations aimed at improving application of the relevant federal regulations. It discusses the regulations in significantly greater detail than this report and can serve as a valuable resource for readers interested in a more detailed description of the regulations.

This committee carefully analyzed the reasoning of the IOM committee and the recommendations it made. We also considered how that reasoning and recommendations would apply in the particular case of research on housing health hazards involving children. We paid special attention to the IOM committee's deliberations about the crucial issues of assessment of the benefits and risks of research and informed permission from parents and assent from children in research. A topic that is particularly important for housing health hazards research is the interpretation of such key regulatory terms as "minor increase over minimal risk" and "disorder or condition." As detailed in Chapter 8, we deliberated at length regarding the IOM committee's recommendations related to research that defines disorder or condition based on social characteristics. Although we agree with the committee's analysis of the issues, we came to a somewhat different conclusion about how to proceed.

The IOM committee also made a number of recommendations about the process of parental permission and children's assent. That committee recommended that these processes "are sensitive to educational, cultural and other differences among families." Our committee carried out further analyses of the consent process and the need to take into account the circumstances of research on housing health hazards involving children that may complicate the consent process. As detailed in Chapter 6, we concluded that the previous committee's basic recommendations about the permission and assent processes are appropriate for housing health hazards research.

Yet another issue that the previous committee considered was payments to children in research. The committee pointed out that payments to adult research participants raise concerns regarding undue inducement and that payments to either children or their parents raise further concerns. The

IOM committee distinguished several types of payment, including reimbursement for expenses, gestures for appreciation, and payment for time involved in research that does not offer the prospect of direct benefit. This committee extended the deliberations of the IOM committee because additional ethical concerns about payment arise when the children enrolled in research are from low-income families and have other vulnerabilities as well, as detailed in Chapter 6.

With respect to IRB review of protocols for clinical research involving children and adolescents, the previous committee recommended that IRBs have adequate expertise in child health care and research. The committee also recommended that, when it is relevant to the study being reviewed, IRBs consult with other child health experts, parents, children, adolescents, and community representatives who can provide relevant family or community perspectives. This committee concluded that the issue of adequate expertise and information is even more pertinent for the review of research on housing health hazards involving children than for other types of research with children. In housing health hazards research, it is even more important for IRBs to understand family and community perspectives because researchers enter children's homes and because of the many vulnerabilities of children enrolled in such research.

As did the earlier IOM committee that produced *Responsible Research* (Institute of Medicine, 2003), the more recent committee recommended that research organizations and sponsors pay the medical and rehabilitation costs for children injured as a direct result of the research, without regard to fault. Another National Academies report, *Protecting Participants and Facilitating Social and Behavioral Sciences Research* (National Research Council, 2003), examined how the structure and function of IRBs relate to behavioral, social, and economic sciences. That report particularly addressed issues related to informed consent, data confidentiality, and procedures related to minimal risk research. It includes several recommendations that are highly pertinent to the topic of this report, including that the Office for Human Research Protections develop detailed guidance for IRBs and researchers on (1) appropriate consent procedures for different types of populations—including language minorities and vulnerable groups, such as undocumented immigrants—studied in social, behavioral, and economic sciences research; and (2) when it is and is not necessary to obtain consent from third parties about whom participants are asked to provide information.

All of these previous reports contributed significantly to this committee's work, and they are referred to throughout this report.

Report Structure

Chapters 2-4 provide context for housing health hazards research. Chapter 2 describes the connection between housing and health, with emphasis on the particular housing health hazards more commonly experienced among low-income, minority populations. Chapter 3 analyzes the issues raised by *Grimes v. Kennedy Krieger* and how federal regulations have dealt with these issues and details the protections afforded by the current regulations. Chapter 4 analyzes in more detail how housing health hazards research is different than traditional biomedical research and the unique ethical issues raised by these differences.

Chapters 5-8 present and discuss the committee's recommendations to ensure that housing health hazards research is designed and conducted so that it is consistent with the ethical principles of respect for persons, beneficence, and justice. Chapter 5 explores how community involvement contributes to ethical research and lays out the range of possible approaches. Chapter 6 analyzes how the ethical issues raised when research targets primarily economically and educationally disadvantaged populations can be addressed through an informed consent process that embraces community input and emphasizes essential features of the research. Chapter 7 describes the ethical obligations of researchers, including the need to consider innovative research designs, how to handle test results, obligations to potential third parties, and the need to develop anticipatory plans to respond to risks observed in the home. The final chapter presents recommendations for a system of research oversight that acknowledges the roles of research institutions and their IRBs and research sponsors in addition to those of researchers, including the need for guidance on various aspects of the applicable federal regulations.

2

Housing and Health

Housing conditions have been associated with lead poisoning, asthma, injuries, and other negative health outcomes. Children are also exposed to such toxins as environmental tobacco smoke, lead, and pesticides in their homes. Although hazards may be present in the homes of people at all income levels, children in low-income families, who have limited housing options, are at increased risk for many housing health hazards.

Children are more susceptible than adults to hazards in the home in four ways. First, they are at higher risk for exposure to toxins in the environment because, pound for pound, children breathe more air, drink more water, and eat more food than adults (National Research Council, 1993; Bearer, 1995; Landrigan et al., 1998). Second, their exposure to potential toxins is increased because of normal developmental behaviors, such as playing close to the ground and hand-to-mouth activity (Bearer, 1995). Third, because their biological systems are still developing, they sometimes are less able than adults to metabolize, detoxify, and excrete toxins. The developing neurological systems may be especially vulnerable to environmental toxins, such as lead and pesticides (Eskenazi et al., 1999; Faustman et al., 2000), with potential significant effects on the developing brain; neurobehavioral deficits caused by environmental toxins may have life-long consequences for children. Lastly, because children younger than 12 years spend about 75 percent of their time at home, they have more opportunities for exposure than adults (Wiley et al., 1991); see Figure 2-1.

The bulk of this chapter describes the major housing-related hazards for children: asthma triggers, lead, pesticides, environmental tobacco smoke,

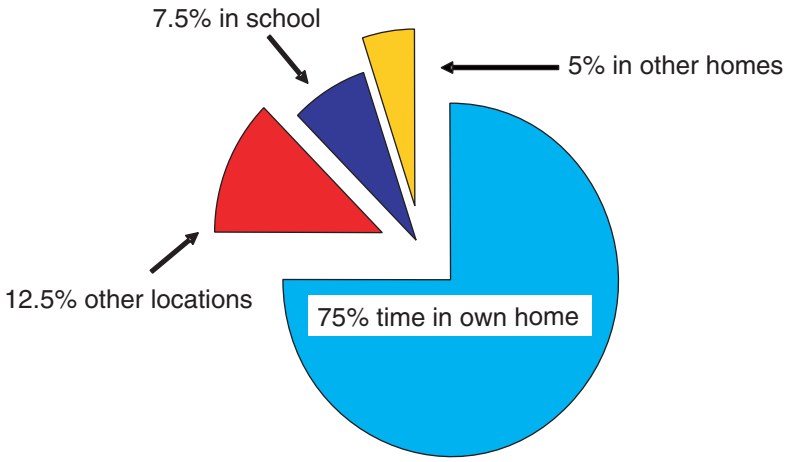

FIGURE 2-1 Time spent in the home by children younger than 12 years.
SOURCE: Data from Wiley et al. (1991).

and injuries, as well as the roles of overcrowding and special problems in rural housing. Although there are numerous possible structural deficits in low-income housing, we do not discuss these in depth except to the extent that they are related to the above health issues, which are the major areas of housing health hazards research. We then discuss the disparities in risk among children, which leads to the final section that presents our conclusion about housing and health.

HOUSING HAZARDS

The state of knowledge about housing health hazards varies widely. For example, there are decades of research on the effects of lead, including the accepted finding that lead in house paint is a leading cause of lead poisoning, while the effects of exposure to pesticides in the home is a relatively new field of study with few definitive findings. Furthermore, even for recognized hazards, strategies to mitigate them effectively continue to evolve.

Asthma Triggers

Asthma is the most prevalent and disabling environmental health problem among children, afflicting more then 4 million children in the United

States. Moreover, it appears to be increasing: between 1980 and 1996 asthma-associated school absences rose by more than 50 percent, to 14 million days per year (Mannino et al., 2002). *Clearing the Air* (Institute of Medicine, 2000) concluded that there is a causal relationship between exposures to allergens produced by cockroaches and dust mites and asthma exacerbations in sensitized individuals as well as between exposure to environmental tobacco smoke and exacerbations of asthma in preschool children. One study reported that exposure to environmental tobacco smoke may account for 150,000 to 300,000 excess cases of asthma in preschool children (Lanphear et al., 2001b). There also is evidence of an association between fungal exposure, which is often associated with visible mold or dampness indicators, and exacerbations of asthma in sensitized persons (Institute of Medicine, 2000). And there is suggestive evidence of an association between nonoccupational formaldehyde exposure and wheezing.

There is an association between some indoor air exposures and the development of asthma, such as exposure to house dust mite allergen and the development of asthma in susceptible children (Institute of Medicine, 2000). One study found that about 40 percent of doctor-diagnosed asthma in children and adolescents is associated with exposures to indoor pollutant and allergens in the home (Lanphear et al., 2001b). There is also an association between nitrogen dioxide and increased airway responses to inhaled allergens and chemical irritants in asthmatic persons (Institute of Medicine, 2000). These effects have been observed at concentrations that may occur in poorly ventilated kitchens with gas appliances in use. Childhood asthma is also associated with use of a gas stove or oven for heating, a practice that is most common in the southeastern United States, especially in poor and rural housing (Lanphear et al., 2001b; Centers for Disease Control and Prevention, 1997b).

The burden of asthma falls disproportionately on certain groups. Asthma is disproportionately high in urban areas characterized by high levels of poverty and minority populations (Institute of Medicine, 2000), particularly among African Americans and Puerto Rican children living on the East Coast. However, very high rates of asthma have also been reported in less urban areas with low levels of poverty.

Specific exposures associated with asthma are also more common in certain population groups. Cockroach sensitization is more common among inner-city poor children (Institute of Medicine, 2000). In contrast, formaldehyde pollution is more common in newly constructed or renovated buildings or in those containing new furniture or carpets with materials that contain formaldehyde resins (Institute of Medicine, 2000). Tightly constructed buildings, such as mobile homes, often contain high formaldehyde concentrations.

The level of asthma triggers can be increased by building defects, such

as inadequate ventilation and moisture accumulation. High moisture levels promote mold growth and attract rodents and cockroaches. Children in low-income families are more likely than other children to be exposed to structural hazards in the home (Cummins and Jackson, 2001). Some experts have concluded that disparities in asthma mortality may be at least partly attributable to disproportionate exposure to "indoor environmental asthma triggers associated with living in substandard housing" (Krieger and Higgins, 2002, p. 760).

Research has shown that some strategies to limit exposures are effective at improving symptoms or lung function in asthmatics. A combination of physical measures has been found to reduce the levels of dust mite allergens and clinical symptoms. There is also suggestive evidence that cockroach extermination plus cleaning of beds, carpets, and clothing can reduce cockroach allergen levels (Institute of Medicine, 2000; Morgan et al., 2004). However, either cleaning or extermination alone appears ineffective. Thus, interventions to remove sources of allergens that are known to cause exacerbations in sensitive individuals may prove, when rigorously studied, to be ineffective. This possibility suggests that, unless measures intended to ameliorate hazards are carefully studied, families may be subjected to expensive but ineffective interventions. Moreover, interventions that reduce the level of exposure may not result in clinical benefits. To date, integrated interventions to reduce cockroach allergen levels have not been able to reduce them below levels that are clinically significant. And there is insufficient evidence on whether reduction in cockroach allergen levels reduces asthma severity. *Clearing the Air* (Institute of Medicine, 2000) called for more research to "address the feasibility and generalizability of intervention programs on target populations " (p. 17) and concluded that "often it is not known what degree of mitigation would be necessary to reduce the risk of attacks in known asthmatic individuals" (p. 406). See Box 2-1 for an example of a recent research project designed to better understand the connection between housing conditions and asthma.

Lead

In the 1950s and 1960s hospitalizations of children for acute lead encephalopathy led government actions to prohibit lead in interior paint, gasoline, and tin cans. Although the average blood lead concentrations of U.S. children fell by more than 80 percent during the ensuing 30 years, levels of childhood lead exposure classified as toxic by Centers for Disease Control and Prevention (currently defined as a blood lead concentration of 10 micrograms per deciliter (μg/dl) or higher) still affect 4.4 percent of children younger than 6 years of age (Pirkle et al., 1998). Infancy is a peak period of vulnerability due to the confluence of mouthing behavior and

BOX 2-1
Interventions Study on Reducing Asthma Triggers in the Home

The Interventions Study on Reducing Asthma Triggers in the Home is an activity of the Healthy Public Housing Initiative (HPHI), a community-centered project designed to engage public housing residents in a collaborative process aimed to improve both the health and quality of life of residents and building conditions. The HPHI is a collaborative including the Harvard School of Public Health, the Boston University School of Public Health, the Tufts University School of Medicine, and a wide variety of actively involved partners that include public housing residents, the Boston Housing Authority, two tenant task forces, the Boston Public Health Commission, the Committee for Boston Public Housing, a pediatric asthma specialist, and specialists in energy efficiency and housing policy and finance.

Three pilot surveys conducted revealed that many environmental health problems reported by residents are associated with the physical conditions of housing, such as water leaks, moisture and mold growth, insufficient ventilation, and pest infestation. With the connection between indoor environmental conditions and resident health established, the HPHI hypothesized that these problems could be addressed through a combination of building improvements, change in maintenance policy, and community health education programs. With input from focus groups with public housing residents, the HPHI designed a study to test the hypothesis that housing-based interventions will reduce asthma triggers.

The study tested the effectiveness of interventions designed to reduce known environmental asthma triggers. The interventions included air filters, new mattresses, deep cleaning, integrated pest management, and resident education; they were conducted in 44 households that had 57 asthmatic children. HPHI measured the change in the health status and quality of life of children with asthma after the completion of the interventions. The study also looked at the health benefits, through pre- and postsurvey results, that might have resulted from the building

increasing mobility (Lanphear et al., 2002). Blood lead levels are higher among African American children than among non-Hispanic white children at all ages; see Figure 2-2: 22 percent of urban, African American children under 6 years were estimated to have blood lead levels above 10 μg/dl (Pirkle et al., 1998). An estimated 1.2 million U.S. children in low-income families younger than 6 years old live in housing that contains one or more lead hazards (Jacobs et al., 2002). Lead poisoning has become concentrated in poor, black children living in substandard housing in inner-city neighborhoods (Cummins and Jackson, 2001).

Subclinical lead toxicity is associated with deleterious and persistent effects of lead exposure on brain function (Bellinger et al., 2003). In one study, there was an estimated 7.4 point drop in IQ scores associated with an initial 10 μg/dl increase in blood lead level (Canfield et al., 2003a). There is some evidence that even blood lead concentrations below 10 μg/dl are associ-

systems upgrades and unit modifications that are part of the housing authority's energy modernization program. The project also evaluated resident response to the interventions, their cost effectiveness, and the ease of implementation. Lastly, the project examined any benefits from the residents' active involvement.

The residents were involved in every stage of the project by working with university partners to assess initial conditions, determining the best mix of interventions to test, evaluating results, and developing action plans. Residents who worked with the project team received training in indoor environmental health, surveying and testing techniques, and identification of appropriate health outreach programs. The housing authority provided support to enhance continued employment opportunities after the completion of the project.

More than 50 percent of asthmatic children in the study are allergic to the cockroach antigen. A large number of samples taken prior to the intervention showed levels of cockroach antigen in bedrooms and kitchens above the threshold for sensitization and exacerbation by this antigen. Determinants of pest-related allergen levels are lack of housing renovation, holes in walls, housekeeping practices, and season. The integrated pest management intervention (deep cleaning, application of gels, sanitation improvements, repair of cracks, crevices and holes) resulted in the reduction of pest allergen levels, which were sustained over 3-4 months and then began to rise, showing the need to implement the intervention on a regular basis to maintain results. In addition, asthma-related quality of life (measured based on symptoms, activity limitations, and emotional function) in enrolled children improved significantly during the health education phase and again over the course of the intervention. Based on these results, the Boston Housing Authority intends to develop a comprehensive integrated pest management program that includes resident educators.

SOURCES: Brugge et al. (2003a); Hynes et al. (2004); Levy et al. (2004); and H. Patricia Hynes (personal communication, 2005).

ated with deficits in cognitive and motor skills (Lanphear et al., 2000; Canfield et al., 2003a; Bellinger et al., 2003; Chiodo et al., 2004). A child's ability to write, draw and construct can be adversely affected by deficits in visual-motor, visual-spatial, and fine-motor coordination (Dietrich et al., 1993a). Poor postural stability can result in clumsiness that can prevent full engagement in sport and recreational activities (Bhattacharya et al., 1988). Deficiencies in impulse control or "executive functions," such as planning, organization, and anticipation of consequences, can occur and may be associated with academic underachievement and behavioral problems (Bellinger et al., 1994; Canfield et al., 2003a; Byers and Lord, 1943; Gittelman and Eskenazi, 1983). Thus, blood lead levels that were previously thought to be safe may be hazardous to children.

Housing built before 1978, when lead was banned in house paint, is the primary source of lead exposure for children today (Lanphear et al., 1998a;

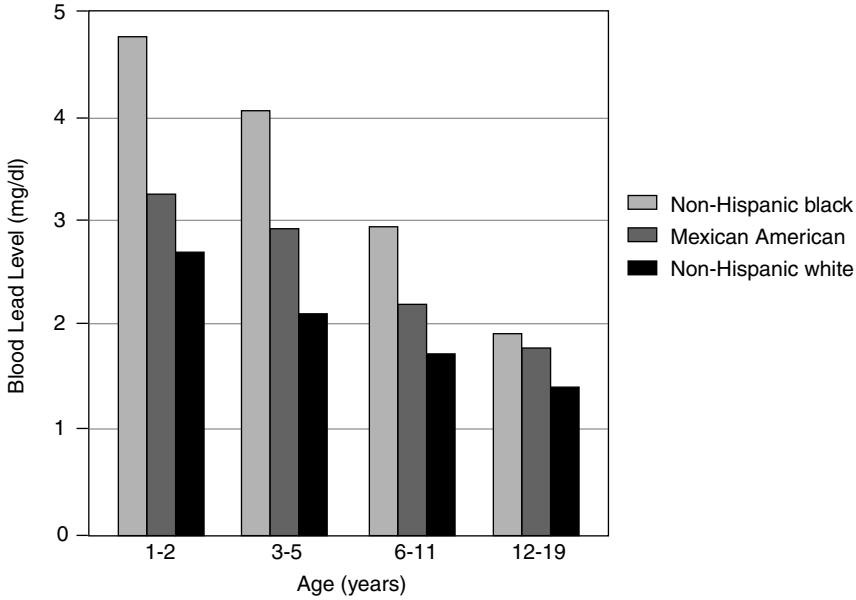

FIGURE 2-2 Racial and ethnic differences in mean blood lead levels among U.S. children, 1988-1994.
SOURCE: Adapted from Pirkle et al. (1998).

Jacobs et al., 2002), and homes built before 1940 have the greatest burdens of lead-based-paint hazards (Jacobs et al., 2002). An extensive body of research links exposure to lead in the home with elevated blood lead levels in children (Charney et al., 1983; Clark et al., 1985; Rhoads et al., 1999; Lanphear et al., 2002). A recent survey estimated that 38 million homes still have lead-based paint, and another 24 million homes have significant lead-based-paint hazards (Jacobs et al., 2002). Moreover, 16 percent of homes had one or more lead dust hazards on floors or windowsills.

Research has clarified the sources and pathways for children's exposure to lead in urban homes. Lead from deteriorating exterior paint or building renovations or demolitions contaminates soil and street dust, which are tracked into the home from foot traffic (Aschengrau et al., 1994; Mielke and Reagan, 1998; Wolz et al., 2003; Farfel et al., 2003). Lead from deteriorating interior paint contaminates house dust (Lanphear and Roghmann, 1997). Household floor dust contaminated with lead gets on the hands of young children, who then put their hands in their mouths (Charney et al., 1980; Lanphear et al., 1998c). This is one way that lead enters the gastrointestinal tract of a child, is absorbed into the blood, and ultimately

affects the child's developing central nervous system (Sayre et al., 1974). Another, more direct pathway is lead in drinking water, most commonly from lead pipes (Levin et al., 1989; Lanphear et al., 2002).

Because the ingestion of flaking and chipping paint is associated with elevations in children's blood lead levels, it was clear that removal of lead paint from homes would be desirable. However, research showed the importance of how lead paint abatement was carried out. Lead paint abatements, if improperly conducted or if not followed with meticulous post-abatement cleanups, actually dispersed lead in dust in homes, resulting in increased blood lead levels in children (Chisholm, 1986; Farfel and Chisholm, 1990; Amitai et al., 1991; Rey-Alvarez and Menke-Hargrave, 1987; Swindell et al., 1994; Aschengaru et al., 1997; Centers for Disease Control and Prevention, 1997a).

This research demonstrated the importance of evaluating interventions that are intended to reduce hazards to discover if there are any unanticipated adverse effects. Without such research, children might have been made worse off with the lead abatement strategies. The research findings about lead abatement interventions led to public policies to protect children. The Department of Housing and Urban Development (HUD) and the Environmental Protection Agency now have policies that require certification of personnel who conduct lead-based abatements; restrict the methods used to conduct abatements; require post-abatement cleanups; preclude families from residing in homes during abatements and until post-abatement cleanups are completed; and require post-abatement reassessment of the levels of lead in children's homes (U.S. Department of Housing and Urban Development, 1995; U.S. Environmental Protection Agency, 2001). Many state and local governments have implemented similar requirements.

Pesticides

Two of the most common classes of insecticides in the United States, organophosphates and carbamates, are considered toxic to the human central nervous system and can cause acute poisoning (Eskenazi et al., 1999). The effects of nontoxic levels of exposure in children, which do not produce overt symptoms, has not been extensively studied on humans, although there is substantial evidence from research with laboratory animals (Eskenazi et al., 1999). The limited research in humans exposed to low levels of certain pesticides, such as organochlorines (Rogan et al., 1986) and organophosphates (Young et al., 2005), raise concerns about possible neurodevelopmental effects on children. Research has been recently undertaken to better understand the pathways and effects of exposure to agricultural pesticides and other widely used pesticides on children; see Box 2-2 for an example of this research.

BOX 2-2
Reducing Pesticide Exposure for Farm Worker Families: CHAMACOS Study

The Center for the Health Assessment of Mothers and Children of Salina Study (CHAMACOS) is designed to try to understand and reduce the environmental health risks of pesticide and other environmental exposures among socioeconomically disadvantaged children living in a rural agricultural community in Salinas Valley in Monterey County, California. The keystone project is a longitudinal birth cohort study that began with 600 pregnant women; the study is currently following their children, who are now 5 years old.

The study has four components: (1) the levels and routes of children's exposure to pesticides and other environmental agents; (2) the potential health effects associated with these exposures; (3) the mechanisms for these potential health effects; and (4) interventions to reduce children's exposure to pesticides. The first component characterizes the magnitude and pathways of pesticide exposure in children by measuring prenatal and postnatal pesticide exposure, characterizing population-level exposure correlates, and identifying exposure-prone behavior. The second component focuses on the relationship of pesticide exposure and allergens and neurodevelopment, somatic growth, and asthma and other respiratory illness. The third component examines mechanisms of neurotoxicity and the relationship of multiple exposures found in agricultural environments, including pesticides and allergens on immunomarkers. The interventions focus on reducing the amount of children's pesticide exposure due to residues brought home by their farm-working parents. There were two different interventions over two growing seasons, in 2003 and 2004. During the first growing season, the technical intervention provided farm workers with coveralls and gloves and installed warm-water facilities for hand washing in the fields. During the second growing season, the intervention was an in-depth pesticide education program with farm worker households specifically aimed at prevention exposure to children.

Results to date include the demonstration of higher levels of urinary pesticide metabolites in the pregnant women in comparison with national reference data, an association of maternal pesticide metabolite levels and shorter gestational duration, and abnormal reflexes in the neonates. Analyses of the mechanism and intervention studies are now under way, with results expected in 2006.

SOURCES: Eskenazi et al. (2004); Young et al. (2005); Bradman et al. (2005); and Brenda Eskenazi (personal communication, 2005).

An estimated 80 to 90 percent of American households use pesticides (Whitemore et al., 1994; Adgate et al., 2001). Exposure can be frequent and at high levels to control cockroach and rodent problems (Whyatt et al., 2002; Gurunathan et al., 1998; Davis and Ahmed, 1998; Bradman et al., 2005). Poor housing conditions are associated with both the presence of

rodents and cockroaches and the use of pesticides (Bradman et al., 2005). A recent report documented widespread residential pesticide exposure in New York City among pregnant women (Whyatt et al., 2002). The study also noted an association between housing disrepair and the proportion of pregnant women who use pesticides. Pesticide exposure in rural agricultural environments may be compounded by spray drift or take-home exposure when farm workers track agricultural pesticides into their homes on their shoes or clothing (Bradman et al., 2005; Fenske, 1997).

Environmental Tobacco Smoke

Tobacco smoke contains more than 4,000 chemicals, including 43 carcinogens. Between 1988 and 1994, an estimated 38 percent of U.S. children younger than 6 years were exposed to environmental tobacco smoke—also referred to as second-hand smoke and passive smoking (Pirkle et al., 1996). Although exposure to environmental tobacco smoke is not unique to homes, it is included here since homes are a significant source of exposure for children, particularly young children, and research on environmental tobacco smoke is often conducted in homes.

Cotinine, a biomarker of exposure to environmental tobacco smoke, is used as an indicator of childhood exposure (Benowitz, 1996). Children have significantly higher serum cotinine than nonsmoking adults (Groner et al., 2004), and younger children have higher levels of cotinine than older children (Centers for Disease Control and Prevention, 2003; Willers et al., 1995). The higher levels of biomarkers in younger children could be due to a number of factors, including greater time inside the home; differences in proximity to a smoker; metabolism; increased respiratory rates; or ingestion of nicotine-contaminated house dust (Matt et al., 2000).

The World Health Organization concluded that environmental tobacco smoke exposure "causes a variety of adverse health effects in children, including lower respiratory tract infections such as pneumonia and bronchitis, coughing and wheezing, worsening of asthma, and middle ear disease" (World Health Organization, 1999, p. 3). Several reviews have concluded that parental smoking has adverse effects on pulmonary function in children (Environmental Protection Agency, 1992; U.S. Department of Health and Human Services, 1986; National Cancer Institute, 1999). For young children, the major source of exposure is smoking by parents and other household members, particularly their mothers. As children grow older, the relative contribution of other exposure sources, including sources outside the home, increases (World Health Organization, 1999).

The association between parental smoking and asthma has remained when studies have controlled for a long list of potential confounders, including gender, age, urbanization, education, crowding, dampness, mold,

cooking fuel, parental respiratory symptoms, parental asthma, and the child's smoking (Weitzman et al., 1990; Martinez et al., 1992; Agabiti et al., 1999). Pneumonia is more common during the first year of life in smoking households, even when controlling for parental symptoms, birth weight, and family size (Strachen and Cook, 1998b). Children in smoking households are at greater risk for hospitalization for respiratory illness (Chen et al., 1986; Anderson et al., 1988). Environmental tobacco smoke has been associated with an approximate doubling of the risk of lower respiratory tract infection in children, with the risk declining after the age of 2 (Li et al., 1999). In four of five studies, the incidence of tonsillectomy is twice as high for children who live in households with smokers in comparison with children living in homes without smokers (Willatt, 1996; Said et al., 1978; Hinton et al., 1993; Stahlberg et al., 1986; Strachen and Cook, 1998a).

Maternal smoking during pregnancy has been identified as a major cause of sudden infant death syndrome (SIDS), the leading cause of death of infants from 1 month to 1 year of age in the United States, as well as reduced birth weight and decreased lung function (Etzel et al., 1997; World Health Organization, 1999; DiFranza et al., 2004). Both the National Cancer Institute and the Surgeon General have concluded that there is sufficient data to infer a causal relationship between maternal smoking in general and SIDS (National Cancer Institute, 1999; U.S. Department of Health and Human Services, 2004; Kharrazi et al., 2004).

Childhood exposure has also been identified with impaired neurobehavioral development and as a possible contributor to cardiovascular disease in adulthood (World Health Organization, 1999; Eskenazi and Castorina, 1999; Fried et al., 1998). Epidemiologic studies suggest that prenatal and early passive exposure to tobacco smoke may contribute to negative behavioral and neurocognitive effects (Eskenzai and Trupin, 1995; Fried et al., 1992, 1998; Yolton et al., 2005), although the evidence to date is considered inconclusive given the confounding of a range of other characteristics common among women who smoke. There is also emerging evidence that environmental tobacco smoke may be associated with increased rates of dental caries (Aligne et al., 2003) and the metabolic syndrome in overweight youth (Weitzman et al., in press).

There is some evidence that suggests that there may be biological differences in susceptibility to housing health hazards. For example, for a given exposure to environmental tobacco smoke, African American children have significantly higher blood lead levels, cotinine levels, and DNA adducts (an altered form of DNA that occurs as the result of exposure to a carcinogen) (Pirkle et al., 1998; Wilson et al., 2005; Richie et al., 1997).

Legislative strategies that restrict where and when people can smoke in public settings are of little use in reducing exposure in homes. Strategies to

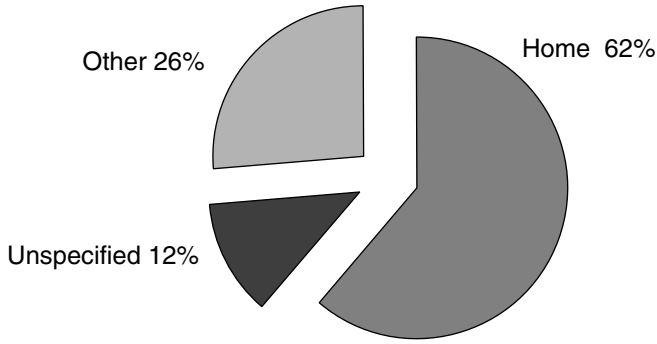

FIGURE 2-3 Fatal injuries by place of occurrence in U.S. children, 1985-1997. SOURCE: Data from Nagaraja et al. (2005).

reduce exposure in homes will have to focus on household decision makers, possibly by educating them about the risks to children from environmental tobacco smoke and ways to eliminate exposures. Smoking during pregnancy has reduced by 33 percent over the past decade (Mathews, 2001); this may be attributable to increased recognition of the harmful effects on the fetus of smoking while pregnant.

Injuries

In the United States in 1998, injuries accounted for 5,189 deaths in children aged 1 to 15 years—40 percent of all childhood mortality (Murphy, 2000). Nonfatal injuries and subsequent disability also account for a major proportion of health service utilization in children (Danseco et al., 2000). Excluding motor vehicle injuries, the majority of fatal injuries in children occur in the home (Scheidt et al., 1995; Powell and Tanz, 2002; Nagaraja et al., 2005; see Figure 2-3). The youngest children are especially vulnerable; 90 percent of fatal injuries among children younger than 5 years occurred in the home (Nagaraja et al., 2005).

Residential injuries can be caused by poor design or disrepair of the home, such as poor lighting, damaged stairs, flooring and railings, or broken windows. Indeed, "housing factors are important determinants (of household injuries) amenable to intervention" (Matte and Jacobs, 2000, p. 10). Injuries can also be caused by poor maintenance of home design elements (National Center for Healthy Housing, 2002). For example, there is some evidence that smoke alarms may be less common in low-income households (Sharp and Carter, 1992). Injuries can also be due to consumer

products in the home such as toys, appliances, electrical equipment, or chemicals (National Center for Healthy Housing, 2002).

There are few data available on any disparities that may exist in injury risks by racial and ethnic status. The rates of nonfatal injuries that occur in the residential environment are lower among minority children (Phelan et al., 2005), although this reported difference may be due to more limited access to health care by minority children and resultant lower rates of reporting. In contrast, the rate of fatal injuries that occur in the home environment is substantially higher for African American children than for white children (Nagaraja et al., 2005). O'Campo and colleagues (2000) reported a relationship between the frequency of housing code violations at the neighborhood level and the risk of injury-producing events among children.

Research on injuries has led to changes in housing laws to better protect children. During the 1970s, health officials in New York City recognized that there were significant numbers of children who were injured or killed by falls from windows and that the incidence was significantly higher during the summer months. Many of these injuries and deaths occurred in low-income areas and lived in housing stock of poor quality or in tenement-type buildings. A pilot project studied the effects of education and provision of free window guards in preventing such falls. Subsequently, it was expanded to all 5 boroughs, leading to a 35 percent reduction in the number of children who died from falls in the city between 1973 and 1975 (Speigel and Lindaman, 1977). The city then passed a law in 1976 that required owners of multiple dwellings to install window guards in housing with residents younger than 10 years old. Follow-up through 1993 showed a consistent decrease in the number of childhood fall-related deaths. In this case, a simple epidemiological observation led to an intervention whose efficacy was demonstrated by research, which in turn led to effective policy changes.

Scald burns from household tap water provide another example of how research can lead to policy changes. Scald burns account for 50-60 percent of all burns in children (Purdue et al., 2002). In 1978, scald burns from tap water were estimated to account for 7-17 percent of all childhood scald burns that required hospitalization (Feldman et al., 1978). Studies of parent education encouraging them to lower the maximum household water temperature were shown to be ineffective. In contrast, studies of passive regulation of household water temperature by limiting the settings on hot water heaters proved effective in reducing scald burns (Webne et al., 1989). These findings led to legislation and changes in building codes to ensure that hot water heaters are set at safe temperatures, leading to a significant decline in childhood scald burns (Feldman et al., 1978).

Safe hot water heater temperatures also protect children from steam radiator burns (Quinlan, 1996). The Consumer Product Safety Commis-

sion and the plumbing industry have published a voluntary standard under which the maximum allowable temperature at the water outlet to the bathing area should be 120°F. There are also national standards by the major plumbing code-making bodies that specify a maximum temperature of 120°F for delivered hot water.

Overcrowding

Overcrowding[1] can contribute to the transmission of infectious diseases such as tuberculosis and respiratory diseases (Krieger and Higgins, 2002) and can cause or exacerbate mental stress (Jones, 2003). Overcrowding is an increasing problem for foreign-born households, especially families with children (Capps, 2001; Center for Housing Policy, 2003). In 2000, 43 percent of foreign-born Hispanic households were crowded, compared with 30 percent in 1980. (The comparable numbers for native-born Hispanics were 15 and 14 percent, respectively; Joint Center for Housing Studies, 2004, Table A-8). Farm workers experience similarly disproportionate high rates of overcrowding. A 2001 study found that almost 52 percent of all housing units for farm workers were crowded, and 74 percent of the units included children (Housing Assistance Council, 2000). In comparison, only 2 percent of all U.S. households and 3 percent of nonmetropolitan households are crowded (U.S. Census Bureau, 1997).

Rural Housing

Approximately 22 million (22 percent) of all occupied housing units in the United States are in nonmetropolitan areas (Housing Assistance Council, 2000). However, housing-based health risks in agricultural and rural households have received relatively little research attention (Bradman et al., in press), although rural housing conditions clearly present many risks to children.

More than 7.7 million rural housing units include children, and 35 percent of these have problems with cost, crowding, or adequacy. Of all rural units with children, 2.8 million were built before 1960, and of these, only 8 percent have been tested for lead (Housing Assistance Council, 2000). Hispanic-headed households in rural areas occupy substandard hous-

[1]Overcrowding is defined by HUD as 1.01 or more persons per room, excluding bathrooms. Therefore, a three-person family living in a home with fewer than three rooms would generally be considered overcrowded. However, a determination of overcrowding may also include consideration of such factors as the number and size of rooms and the number and age of children in the household.

ing at twice the rate for all rural households (Housing Assistance Council, 2000).

A recent study of approximately 650 homes of pregnant Latina women living in poverty in an agricultural community documented many housing hazards (Bradman et al., in press). Pest infestations were common, with 60 percent of the homes containing cockroaches and 31 percent containing rodents. Housing disrepair was widespread: 58 percent had peeling paint, 43 percent had mold, 25 percent had water damage, 16 percent had leaks under sinks, and 11 percent had rotting wood. Of all the homes, 76 percent of the homes were overcrowded. Fewer than 3 percent of them had no adverse conditions (Bradman et al., in press).

RISK DISPARITIES

As discussed above, the scientific literature documents that certain housing health hazards are more common in poor-quality housing, which is more prevalent among the homes of children in low-income families and that outcomes such as asthma, fatal injuries, and lead poisoning are also more prevalent among these children. These disparities may result directly from greater exposures to hazards in older, dilapidated, or poorly maintained housing. In comparison with the general population, low-income and African American people are 2.2 and 1.7 times more likely, respectively, to live in homes with severe physical problems (Krieger and Higgins, 2002, citing American Housing Survey data).

Poor families also lack the resources to move to better quality housing; and there is a severe shortage of affordable low-income housing (see U.S. Department of Housing and Urban Development, 2001). Nowhere in the United States can a minimum wage job generate sufficient income to rent a two-bedroom home at the local HUD fair-market rent (National Low Income Housing Coalition, 2004). In 2004, the average hourly wage needed to pay the national average rent for a two-bedroom unit without spending more than 30 percent of household income for housing was $15.37, which is almost triple the federal minimum wage of $5.15 (National Low Income Housing Coalition, 2004). Consequently, many low-income families have no choice but to live in older dwellings that present health risks such as deteriorating lead paint. For example, of the 29 census tracts in Rhode Island with the highest concentrations of old housing, 25 are in low-income neighborhoods (Rhode Island Kids Count, 2003).[2]

Many children in the United States live in poverty. According to the

[2]Although Rhode Island is not necessarily representative of the United States, it is reasonable to assume that the overall pattern is similar in other metropolitan areas.

U.S. Census Bureau, the poverty rate among children was 17.6 percent in 2003, its highest level in 10 years (U.S. Census Bureau, 2004). The number of children living in extreme poverty, defined as an after-tax income below half the poverty level, was 5 million in 2001 (National Center for Children in Poverty, 2003); this number represents 7 percent of all children in the United States. Children of color are more likely to be poor. In 2001, nearly 1 million black children lived in extreme poverty, which was the highest level in the 23 years for which there are data (Children's Defense Fund, 2003).

Research shows that severely limited purchasing power forces low-income families to choose among the basic necessities of housing, food, health care, and clothing with the result that for many people, unhealthy, poor-quality housing is a necessary reality (Rothenberg, 1971). A recent study showed that, among households in the bottom income quintile, those that devote less than 20 percent of their budgets to housing are able to spend $80 more a month on food and $49 more on health care, on average, than households that spend at least 50 percent of their budgets for housing (Joint Center for Housing Studies, 2004). In 1999, 42 percent of very-low-income families with children in private rental housing lived in severely inadequate housing or spent more than half of their income for housing, what HUD refers to as "worst case housing needs" (U.S. Department of Housing and Urban Development, 2001).

It is difficult to separate the effects of race or ethnicity on health disparities from the effects of socioeconomic disadvantages. Poverty, poor education, and poor access to health care are more prevalent in minority groups and are also associated with adverse health outcomes (Institute of Medicine, 2003). In addition to these effects, there may also be effects due to housing discrimination (see Turner et al., 2002).

Children who are at increased risk for housing health hazards are often the focus of research. Ultimately, the knowledge gained from that is more likely to benefit children at high risk, but as noted through this report, research targeted at high-risk groups also raises ethical concerns because of their many vulnerabilities. In addition, as noted in Chapter 1 and discussed further in Chapter 4, there are few market incentives to translate housing research into improved housing or reduction of hazards. Public resources to ameliorate housing hazards are limited at the same time that operating costs are higher for older properties and low-income housing, the very properties most likely to contain health hazards and to be occupied by low income families; see Box 2-3. Low-income families cannot usually afford to move to better housing.

BOX 2-3
The Economics of Rental Housing

Many factors affect the economics, and ultimately the availability, of low-cost, private-market housing. Empirical studies generally confirm that low-income housing may be relatively more expensive because of greater operating costs, depreciation costs, higher rates of tenant turnover, higher rental collection costs, or delinquencies in payment (Muth, 1969). Recent increases in utility costs, property taxes, and insurance premiums have also put even greater upward pressures on rental operating costs (Goodman, 2004).

Other maintenance costs, such as mold eradication, which threatens to become a pervasive economic as well as health problem, can also cause an increase in operating costs (Goodman, 2004). Older housing, especially in low-income neighborhoods, also tends to have higher operating costs relative to newer housing. For example, one research survey estimated that utility costs are 55 percent less for properties built in the 1990s than for properties of the same quality, size, and location built in the 1970s (Goodman, 2004). In general, properties built since 1980 cost at least 10 percent less to operate than properties built before 1970 (Goodman, 2004).

CONCLUSIONS

Hazards present in the home environment pose numerous and substantial health risks to children in both urban and rural environments, with children in low-income families at greater risk. Housing that is both affordable and hazard free is an increasingly scarce commodity for low-income families. An increase in affordable housing and broader requirements for abatement of hazards would offer prospects of genuinely healthy housing for all children. This has largely been accomplished in some public housing, particularly for lead. However, the private low-income housing market provides limited incentives for landlords to do so. The economics of low-income housing suggests that even if it were technically feasible to eliminate all housing health hazards to children, doing so might exacerbate existing private-market shortages or push up housing costs. Thus, under current housing policies, there is a need for research to identify interventions that are not only effective at ameliorating housing health hazards but also cost effective.

3

Grimes v. Kennedy Krieger Institute: Revisiting the Ethical Issues

The *Grimes v. Kennedy Krieger Institute* case (366 Md. 29, 782 A.2d 807) in 2001 reinvigorated the debate over core ethical issues raised by conducting research with children, especially children who are economically and educationally vulnerable. Many researchers and scholars criticized the decision as being inconsistent with the federal regulations and forbidding valuable research allowed under these regulations (Ross, 2002; Amici Curiae Association, 2000). Other scholars argued that with some modifications to research protocols, research on abatement of housing hazards could still be carried out under the more protective terms of the ruling (Kopelman, 2002; Nelson, 2005). Regardless of one's position, the ruling illustrated the complexity of the ethical issues involved and the continuing need to debate and refine guidelines for conducting research involving children and families in the context of changing cultural norms and expectations and scientific developments.

This chapter provides a brief summary of *Grimes v. Kennedy Krieger Institute* with a focus on the core ethical issues raised by the court's opinion; presents the reasoning reflected in the current federal regulations in light of issues raised by the court's opinion; and introduces the current federal regulations governing research involving human participants ("subjects").

Although the federal regulations refer to humans involved in research as research "subjects," other recent National Academies reports and the National Bioethics Advisory Committee (NBAC) have adopted the term "participants." NBAC rejected the traditional term in part because it connotes a power imbalance between volunteers and investigators, suggesting that the volunteer is "under the rule of (and being obedient to) the investi-

gator" (National Bioethics Advisory Committee, 2001, p. 33), which is inconsistent with a central tenet of research ethics: that volunteers are autonomous agents, free to choose whether to participate or to withdraw from a study. Adopting the term "participant" addresses this by suggesting that the volunteer is a willing partner in the research enterprise. However, as pointed out by some members of NBAC, many persons who are enrolled in studies are not free and equal participants, and the use of the term "participant" may send a false signal that less vigilance is needed to protect human research participants. Furthermore, the term "participant" does not accurately apply to children, particularly infants and very young children, who are too young even to assent to research. Overall, the term "participant" conveys the aspiration of reducing the power imbalance between researchers and the persons they study. The committee was mindful of these views in its deliberations and in its conclusions and recommendations. The committee has adopted the term participant when referring to general research protection issues, including the federal regulations, but we have retained the term subject when referring specifically to children given the inability of most children to be "free and equal participants."

As noted in Chapter 1, an analysis of the merits of the Grimes case or the court's ruling is beyond the charge to this committee: the committee's consideration of the study and ruling is limited to an analysis of the broad and complex ethical issues raised by the case that are pertinent to research on housing health hazards involving children. This chapter presents the committee's rationale for embracing the balancing of risks and benefits reflected in the federal regulations and rejecting the suggestion that parents not be allowed to enroll children in research that does not offer the prospect of direct benefit ("nontherapeutic" research), core issues raised by the ruling. Other issues raised by the case, including research involving vulnerable populations, the informed consent process, and research oversight, form part of the basis for more detailed discussion in later chapters of the report.

BACKGROUND

Grimes v. Kennedy Krieger Institute has become a key case in the recent history of concern about ethical issues in research. The federal government began overseeing research that involves human participants in 1974, creating a framework for independent review of research protocols and requiring informed consent from participants to assure that research would be conducted in an ethically responsible manner. The regulations that the U.S. Department of Health and Human Services (DHHS) and other federal agencies adopted were based primarily on the recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The commission reviewed the available

literature and the complex debates over the ethical principles for human participants research, especially research with vulnerable populations. On several contentious issues the National Commission tried to strike compromises among conflicting interests and principles.

The Case

The case arose from a lead abatement study (repair and maintenance study) in Baltimore, Maryland, to compare and evaluate the effectiveness of low-cost lead control measures (Johns Hopkins University, 2001) by the Kennedy Krieger Institute of John Hopkins University. Almost all (95 percent) of the private low-income housing in Baltimore at the time had lead-based paint in the home (Johns Hopkins University, 2001). Both the blood lead levels of the enrolled children and environmental samples to measure lead levels inside and outside the homes were monitored during the study; see Box 3-1 for further details about the study.

BOX 3-1
The Kennedy Krieger Study

The goal of the repair and maintenance (lead abatement) study was to determine the efficacy of lead abatement methods in the home at reducing children's exposure to residential paint and dust. The study had five test groups, each with 25 houses. The first three groups were the intervention groups and consisted of homes known to have lead present. The amount of repair and maintenance conducted in these homes increased from Group 1 to Group 2 to Group 3. The fourth group consisted of homes that had had lead present at one point, but had received previous lead abatement. The fifth group consisted of homes built after 1980 and presumably never had lead present (366 Md. at 34). The fourth and fifth groups served as the control groups for the study; there were no families living in homes with unattended lead hazards. After it was determined that a home met the criteria to be in an intervention group, it was randomly assigned to either Group 1, 2, or 3 (366 Md. 29 (2001)).

Group 1 interventions included wet scraping of peeling and flaking paint on all interior surfaces; repainting treated areas; installation of window well caps; repainting exterior window trim and interior window sills; vacuuming of all horizontal surfaces and window components with a high-efficiency particulate vacuum; and wet cleaning all horizontal surfaces. Group 2 interventions included all the elements from Group 1 plus the use of sealants and paints to make floors smoother and more easily cleanable and in-place window and door treatments to reduce abrasion of lead-painted surfaces. Group 3 added window replacement and encapsulation of exterior door trim with aluminum, and the use of coverings on some floors and stars to make them smooth and more easily climbable.

Grimes v. Kennedy Krieger Institute, heard by the Maryland Court of Appeals, the highest court in the state, began as two separate lawsuits brought by the mothers of two children who were study subjects. The plaintiffs in both cases alleged that the researchers and the Kennedy Krieger Institute were negligent in the way they conducted the study and breached their duty of care to the children by failing to notify their parents of the risks of their children's exposure to lead. The plaintiffs' case was based on three basic contentions: (1) that the study design placed child subjects at an unacceptable level of risk; (2) that the institute did not adequately inform the mothers of the risks associated with the study; and (3) that the institute took too long to notify the mothers of elevated levels of lead (366 Md. 29).

Court Rulings

The trial court issued a summary judgment[1] in favor of the defendants, ruling that the plaintiffs' cases could not proceed because, as argued by the defendants, the researchers owed no legal duty of care to the research subjects. The Maryland Court of Appeals consolidated the two cases into one and overruled the trial court, holding that researchers do have a legal duty of care to research subjects and that both plaintiffs presented enough evidence to proceed to trial (366 Md. at 33).

The appeals court ruled that the plaintiffs had presented enough evidence, when interpreted in a light most favorable to them, to support a potential finding of a legal duty and sent it back to the lower court for trial. In doing so, the court was not indicating that the plaintiffs would win at trial, only that there was enough evidence on the specific issue of a duty of care owed by the researchers to subjects for the case to go to trial. The ruling harshly criticized the design of the study and the research oversight process and raised legal and ethical issues related to the exploitation of vulnerable populations, institutional review and oversight of research, and the informed consent process. In addition, the appeals court ruled against allowing research which poses a risk of harm to child subjects in the study but does not offer them a prospect of direct therapeutic benefit. The next section discusses each of these issues.

[1]A summary judgment is requested before a case goes to trial when a party in the case argues that there are no facts in dispute to necessitate a trial. In making the decision whether or not to grant summary judgment, the judge must "view the facts, including all inferences, in the light most favorable to the" party opposing the request for summary judgment (366 Md. at 72).

ISSUES RAISED BY THE APPEALS COURT RULING

Duty of Care

The court ruled that a researcher owes a research subject a legal duty of care, or is legally required to take reasonable actions to protect that person from foreseeable harms. The court described this duty of care as follows:

> This duty requires the protection of the research subjects from unreasonable harm and requires the researcher to completely and promptly inform the subjects of potential hazards existing from time to time *because of the profound trust that participants place in investigators, institutions, and the research enterprise as a whole to protect them from harm* [emphasis added] (366 Md. at 103).

In this case, the court suggested that the researchers would have needed to provide more information about risks in the consent process and would have needed to provide certain environmental and biological sample test results sooner than they did in order to satisfy their duty to the child subjects (Wolf, 2004).[2] However, there were insufficient facts presented in the summary judgment to determine exactly what information the Kennedy Krieger Institute would have needed to provide the plaintiffs to satisfy that duty and whether it had done so (Wolf, 2004).

The court based its ruling in part on the "profound trust that participants place" in researchers. While the reliance on a researcher is a legally significant aspect of the relationship that supports the finding of a duty of care, there are also important ethical considerations based on the trust established between a researcher and a research subject's parents. Parents might reasonably expect that their children will be protected from unreasonable harms and rely on researchers to fully inform them of hazards in their home and risks to their child's health related to the topic of research. In fact, one plaintiff contended that the Kennedy Krieger Institute was negligent because it failed to inform her of the test results that indicated there were potentially dangerous levels of lead in her home, implying that her child's involvement in the study and having her house examined by the investigators "gave her a false sense of security that there were no potential lead-based paint or dust hazards in her house" (366 Md. at 65).

[2]The informed consent document stated that the Kennedy Krieger Institute would provide specific blood lead results and contract families to discuss a summary of the environmental results and possible steps to reduce any risks of exposure.

Exploitation of Vulnerable Populations

Reflecting the apparent outrage of the court, the ruling compared the study to several egregiously unethical research studies. Most notable among these was the Tuskegee syphilis study, in which researchers followed a group of black men infected with syphilis for more than 30 years without informing them of their disease or of the availability of treatment with penicillin when it became available, in order to observe the natural history and long-term effects of the illness (Institute of Medicine, 2004). Although the court explicitly states that the Kennedy Krieger Institute study "differs in large degree from" studies such as Tuskegee (366 Md. at 43), it was clearly concerned that landlords, in its view, were at a minimum encouraged and possibly required to rent to families with children as a condition of receiving abatement resources. The court pointed out that each of the unethical studies involved persons who are members of vulnerable populations: "uneducated African-American men, debilitated patients in a charity hospital, prisoners of war, inmates of concentration camps and others falling within the custody or control of the agencies conducting . . . the experiments. In the present case, children, especially young children living in lower economic circumstances, albeit not as vulnerable as the other examples, are nonetheless, vulnerable as well" (366 Md. at 45). Using this analogy, the court concluded that in-house processes to review research are inappropriate and ineffective to ensure the ethical treatment of humans enrolled in research, especially members of vulnerable populations (366 Md. 29).

Institutional Review Process

The court heavily criticized the John Hopkins University Joint Committee on Clinical Investigation, the institutional review board (IRB) that reviewed and approved the Kennedy Krieger Institute repair and maintenance study, regarding suggestions made to the researchers about amending the protocol so that it would comply with federal regulations and therefore qualify for federal funding. Although the Kennedy Krieger Institute initially presented the study to its IRB as having no prospect of direct benefit, the IRB recommended changing the category of research to providing a prospect of direct benefit, thereby lowering the criteria for review. In its critique of the suggestions made, the court pointed out that "[o]ne of the most important objectives of such [IRB] review is the review of the potential safety and the health hazard impact of a research project on the human subjects of the experiment, especially on vulnerable subjects such as children" and emphasized that an IRB's "function is *not* to help researchers seek funding for research projects" [emphasis in original] (366 Md. at 39).

The court stated that the Johns Hopkins IRB had "abdicated that responsibility" in the interest of securing funding for the study and instead "encouraged the researchers to misrepresent the purpose of the research in order to bring the study under the label of "therapeutic" and thus under a lower safety standards of regulation" (366 Md. at 39).

More generally, the court stated that IRBs "are, primarily, in-house organs. In our view, they are not designed, generally, to be sufficiently objective in the sense that they are as sufficiently concerned with the ethicality of the experiments they review as they are with the success of the experiments" (366 Md. at 45). The decision overall expresses great mistrust of not only the specific research project but also of the system of research oversight.

Informed Consent

The court examined at length the adequacy of the forms provided to parents to provide consent for their children to participate in the research. It seriously questioned whether or not the Kennedy Krieger Institute had provided sufficient information to the mothers about the study design and goals and the risks to their children associated with enrolling in the study so as to obtain truly free and informed consent. Related to the issue of parents' expectations that their children would be protected from foreseeable harms, as discussed above, the court concluded that the "informed consent was not valid because full material information was not furnished to the subjects or their parents," with this line of argument:

> [a] reasonable parent would expect to be clearly informed that it was at least contemplated that her child would ingest lead particles, and that the degree to which lead dust contaminated the child's blood would be used as one of the ways in which the success of the experiment would be measured. . . . Whether assessed by a subjective or an objective standards, the children, or their surrogates, should have been additionally informed that the researchers anticipated that, as a result of the experiment, it was possible that there might be some accumulation of lead in the blood of the children (366 Md. at 90).

This statement points out the critical nature of informed consent and the vital importance of ensuring that parents of potential subjects understand the research study and the risks associated with enrollment. The ruling challenges researchers, sponsors, and IRBs to rethink important ethical issues concerning research on housing health hazards involving children (Glantz, 2002; Nelson, 2005). It suggests stricter limits on risks to vulnerable child subjects, broader informed consent discussions, and stronger IRB review.

Research Risks to Children

The court held that a parent or guardian cannot consent to a child's enrollment in "nontherapeutic" research in which there is any risk of harm to the child that "parents, whether improperly enticed by trinkets, food stamps, money or other items, have no more right to intentionally and unnecessarily place children in potentially hazardous nontherapeutic research surroundings, than do researchers. In such cases, parental consent, no matter how informed, is insufficient" (366 Md. at 41). The ruling suggested that there might be sufficient evidence for a jury to determine that the study design itself placed the children at an unacceptable level of risk.

Johns Hopkins University, together with the Association of American Medical Colleges and the Association of American Universities, asked the Appeals Court to reconsider since the ruling would have prohibited research otherwise allowable under federal regulations (Amici Curiae Association, 2000). The court denied the motion for reconsideration, but issued a clarification of the opinion, stating that by "any risk" it meant, "any articulable risk beyond the minimal kind of risk that is inherent in any endeavor" (366 Md. at 120). It appeared that this clarification would bring the holding in line with the federal regulatory definition of minimal risk research (45 CFR 46.404; see below). However, because the court did not explicitly refer to the federal regulations, it is unclear if that was the intention of the court (Wolf, 2004). The clarification also seems to preclude—at least in Maryland—other types of research that are allowable under the federal regulations, as discussed below.

The legal decision related to "nontherapeutic" research and the court's clarification reflect the perspective that children should not be enrolled in a study with more than minimal risk that does not offer the prospect of direct benefit to the individual child because children are unable to consent for themselves and parents cannot consent on their child's behalf because they are bound to make decisions that are in the best interest of the child. The court concluded that "[I]t is…not in the best interest of any healthy child to be intentionally put in a nontherapeutic situation where his or her health may be impaired, in order to test methods that may ultimately benefit all children" (366 Md. at 105). The National Commission discussed similar issues from an ethical perspective: it recommended a balancing of risks and benefits and rejected the notion that nontherapeutic research with children is ethically unacceptable.

ETHICAL ARGUMENTS IN NATIONAL COMMISSION REPORTS

After the shocking revelations of the unethical treatment of human research participants in the Tuskegee syphilis study, Congress passed the

National Research Act of 1974. The act called for two major actions: (1) the creation of IRBs at all institutions that conducted biomedical or behavioral research with human participants under federal funding to ensure that studies comply with ethical standards; and (2) the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (hereafter, National Commission) to identify the ethical principles for research involving humans, especially principles regarding the protection of vulnerable populations and to recommend ways to ensure that future research is consistent with those ethical principles.

During its tenure, the National Commission produced 17 reports, two of which are directly relevant to this report. The first report and the one best known, the *Belmont Report* (1978), dealt with the ethical principles of research with human participants. It introduced the principles of respect for persons, beneficence, and justice as the pillars of ethical research and formed the basis for the federal regulations (Subpart A of 45 CFR 46) to protect human participants in research (see below). The *Belmont Report* (National Commission, 1978) declares that beneficence is a basic ethical principle for research involving humans. It argues that an absolute prohibition on exposing research participants to risk would preclude "learning what is harmful" or "learning what will in fact benefit" people. The report states: "The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks" (National Commission, 1978, p. 5). The *Belmont Report,* while highlighting the difficult issues involved, did not take a specific position on whether it should be permissible to expose children to greater than minimal risk when there is no prospect of direct benefit.

The second relevant report, *Research Involving Children* (1977), reviewed the debates surrounding the ethical appropriateness of research with child subjects and recommended specific measures to protect children based on the level of risk and prospect for direct benefit. *Research Involving Children* focused on the "Ramsey-McCormick debate," in which two eminent bioethics scholars, Paul Ramsey and Richard McCormick, took fundamentally different views on the ethics of research with children that did not offer any prospect of benefit to the child.

Key elements of the debate, similar to those raised in the Kennedy Krieger case, include the authority of parents to consent to enroll their children in research and the core question of whether or not it is ethically permissible to allow children to be enrolled in research that offers no prospect of individual direct benefit ("nontherapeutic" research). The National Commission concluded that research might be ethically justified on the basis of "direct benefit" when there is a reasonable prospect that the subjects will actually benefit from the procedure or intervention under study

(National Commission, 1977). For research in which the studied procedure or intervention does not present a prospect of direct benefit to the subjects, the National Commission carried out a detailed analysis of complex ethical issues about the protection of children and the authority of parents (National Commission, 1977).

Parental Consent and the Best Interest of the Child

Ramsey argued that research that does not directly benefit children is ethically impermissible, basing his arguments on the distinction between "nontherapeutic" and "therapeutic" or "beneficial" research. First, he argued that nontherapeutic research could be carried out only with the informed consent of the participant. Because children cannot give consent, he contended that enrolling them in such research would violate the principle of respect for persons, by treating the child merely as a means to carry out the ends of the research (National Commission, 1977). Second, Ramsey argued that parents cannot give permission for children to enroll in nontherapeutic research because they have a fiduciary duty to care for and protect the child, by making decisions in the best interests of their individual child.

McCormick, on the other side, argued that parental consent for children to enroll in nontherapeutic research may be morally valid, at least for research that poses only a minimal risk of harm to individual subjects. He contended that children, like all people, have a moral obligation to help fellow human beings when there is little risk to themselves. He argued that it is reasonable to presume that children ought to consent to such research and that parental permission is acceptable. The parent is simply choosing what the child ought to choose for himself or herself, were he or she able to do so. He declared: "There are things we ought to do for others simply because we are members of the human community" (National Commission, 1977, p. 55).

The National Commission disagreed with McCormick's claim that consent may validly be presumed on the basis of an underlying ethical obligation, pointing out that there are many things that adults ought to do, but to which many persons would not consent. Indeed, the idea of respect for persons requires that we respect their right to make their own choices, including "their right not to perform certain actions which other persons believe, with some justification, that they ought to perform" (National Commission, 1977, p. 56). The National Commission expressed more sympathy with a possible modification of McCormick's position, namely that children have a "presumed duty" to participate in minimal risk research (National Commission, 1977, p. 57).

Other National Commission scholars took the somewhat different view

that parents have a moral "obligation to inculcate into their children attitudes of unselfish service" (National Commission, 1977, p. 59). Enrolling children in research that will not benefit them personally but will potentially help other children is one way to foster altruism. These writers believed that children benefit from being enrolled in such research because their moral development is enhanced. Parents should encourage such involvement, but the child should also "be a willing participant" (National Commission, 1977, p. 60).

After a detailed review of different perspectives on these issues, the National Commission concluded: "What seems in need of development is an explanation of the proper balance to be struck between the competing obligations to respect persons and to benefit those in need of help" (National Commission, 1977, p. 63).

Balancing Risks and Benefits

In *Research Involving Children* (1977), the National Commission rejected the distinction between therapeutic and nontherapeutic research and proposed instead an assessment of risks and benefits for three reasons. First, it said that the term "therapeutic research" is logically inconsistent because research "is intended to develop general knowledge," while therapy is "for the benefit of an individual and therefore does not involve any generalizeable component" (National Commission, 1977, p. 54). Second, it expressed concern that "simply because a benefit (therapy) is included in a "therapeutic" research protocol," all sorts of additional interventions not germane to the therapeutic intervention but useful for general knowledge can be regarded as justified" (National Commission, 1977, p. 54) and that these additional interventions might be approved with a lower threshold of allowable risk. Finally, it rejected Ramsey's argument that children should not participate in research that he termed nontherapeutic, pointing out that Ramsey "neglects discussion of the low level of risk involved in most research involving children" (National Commission, 1977, p. 54). Although agreeing that a line must be drawn between permissible and impermissible risk, it characterized his "absolute prohibition" as "too restrictive" (National Commission, 1977, p. 54) since it would block the gaining of important knowledge when only a minimal risk of harm is present. The commission noted that it was "impressed by reported examples of diagnostic, therapeutic and preventive measures that might well have been derived from research involving risk that, while minor, would be considered more than minimal" (National Commission, 1977, p. 67).

In its policy recommendations, the National Commission tried to strike a middle ground, balancing the competing values of respecting children who cannot give consent for themselves and benefiting children through

relevant research. The National Commission determined that under certain conditions it was ethically permissible to enroll children in research that offered them no prospect of direct benefit, provided that the risk was no more than a minor increase over minimal risk and other conditions applied. These recommendations eventually formed the basis of the provisions of Subpart D of the federal regulations governing research with human participants ("subjects"), discussed below.

CURRENT FEDERAL REGULATIONS

In 1978 the U.S. Department of Health, Education, and Welfare (HEW, the predecessor of DHHS) adopted the National Commission's recommendations as agency regulations to govern oversight of research involving humans conducted or funded by HEW. In 1986 the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research[3] recommended that the DHHS regulatory protections for human research participants be extended to apply to all research involving humans conducted by federal agencies or supported with federal funds. Several years later, in 1991, 17 federal agencies and departments adopted the DHHS general human research protection regulations. These regulations, Subpart A of 45 CFR 46, or the "Common Rule," contain the basic requirements that must be met for a research protocol involving humans to qualify for federal funding from most federal agencies or departments.[4]

In 1983, several years after the release of *Research Involving Children,* DHHS became the first agency to adopt the National Commission's recommendations designed to address the unique issues when involving children in research. The Central Intelligence Agency, the Social Security Administration, and the Department of Education have also adopted these additional protections which are specified in Subpart D (of 45 CFR 46).[5] The Department of Housing and Urban Development and the Environmental Protection Agency, two of the main federal sponsors of housing health hazards research, have not formally adopted Subpart D. Therefore, while all of the agencies likely to fund housing health hazard research are subject

[3]This congressionally mandated group was formed in 1978, succeeding the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. It worked independently from January 1980 to March 1983 (for details, see http://www.bioethics.gov/reports/past_commissions/ [November 15, 2004]).

[4]The Common Rule also applies to research conducted by an organization that has proved an assurance to the federal government that all of its research will comply (45 CFR 46.103).

[5]The Food and Drug Administration has regulations largely similar to Subpart D (at 21 CFR 50).

to the Common Rule, some research that involves children may not be governed by the additional protections designed to protect children's unique vulnerabilities.

Elements of the Common Rule: Subpart A

The federal regulations define a human research participant ("subject") as a "living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information" (45 CFR 46.102(f)). Several provisions of the Common Rule are important to understand as context for housing health hazards research involving children.[6]

The Common Rule establishes several general requirements for all research involving human participants to be approved. The first of those requirements is that an institution that conducts a research study that will involve human participants submit an "assurance of compliance" to the Office of Human Research Protection (in DHHS) that demonstrates the steps the institution has taken to ensure compliance with the regulations and ethical principles overall (45 CFR 46.103). As part of this assurance, many institutions agree to ensure that their research adheres to the Common Rule, even it is not funded by a federal agency. Second, an institution is also required to establish an IRB that will review each research protocol involving human participants (45 CFR 46.107-109). Before approving a research protocol, the IRB must determine that it satisfies the regulatory criteria designed to protect human participants (45 CFR 46.111).

In the case of research involving only minimal risk to participants, the IRB can provide expedited review by a less than full committee (45 CFR 46.110). For all other types of research, the protocol must demonstrate the following criteria to the IRB in order to be approved:

- *minimization of risks*: The risks to the participants have been minimized.
- *reasonable risks in relation to the benefits*: The risks posed to participants are reasonable in relation to the anticipated benefits to the participants and the importance of the knowledge that is reasonably expected to be gained from the research. This finding is limited to considering benefits that would accrue to the individual and not to long-term benefits, such as the possible effects of the research findings on public policy.
- *equitable selection of participants*: The selection of the participants

[6]For a more detailed discussion of the regulations, see Institute of Medicine (2004, Chapters 3 and 4). Sections of that report are quoted here.

will be equitable. The IRB is directed to take into account considerations such as the purpose of the research and the setting in which the research will be conducted. The IRB is also specifically directed to be "particularly cognizant of the special problems of research involving vulnerable populations, such as children, . . . or economically or educationally disadvantaged persons" (45 CFR 46.111(a)(3)).

- *informed consent*: Informed consent has been obtained in accordance with 45 CFR 46.116 and is appropriately documented in accordance with 45 CFR 46.117 (see below for more details).
- *measures to protect privacy*: If needed, provisions have been made to protect the privacy of the participants and to maintain the confidentiality of data.
- *additional safeguards for vulnerable populations*: Lastly, if some or all of the participants are susceptible to being vulnerable to coercion or undue influence, such as children . . . or economically or educationally disadvantaged persons, that the research protocol has included additional safeguards to "protect the rights and welfare" of these participants (45 CFR 46.111(b)).

Additional Protections for Research Involving Children: Subpart D

Regulatory provisions that provide specific protections for child subjects in research were formally adopted by DHHS in 1983 as Subpart D.[7] Subpart D specifies three categories of research that can be approved by local IRBs:

- research that does not involve greater than minimal risk (45 CFR 46.404 or "Section 404");
- research that does involve greater than minimal risk, but for which research participation provides a prospect of individual benefit sufficient to offset that risk (45 CFR 46.405 or "Section 405");
- research that involves greater than minimal risk without individual benefit sufficient to offset the risk—but for which the risk is only a minor increase over minimal risk, the excess risk is commensurate with ordinary experiences of the children under study, and the knowledge to be gained from the research is ". . . of vital importance for the understanding or

[7]By 1978, the HEW regulations on research involving humans were located in 45 CFR 46 and contained three subparts: (1) Subpart A, the general regulations on human subject research protections; (2) Subpart B, the regulations specific for pregnant women, fetuses, and in vitro fertilization; and (3) Subpart C, the regulations relating to prisoners (see Institute of Medicine, 2004).

amelioration of the subjects' disorder or condition. . ." (45 CFR 46.406 or "Section 406"). (See Chapter 8 for discussion of this category of research.)

There is a great deal of variability across IRBs in their application of terms in the federal regulations, such as "minimal risk" and "minor increase over minimal risk," and therefore which of the three above categories of research they consider applicable (Shah et al., 2004).

A fourth category of research is set forth in Subpart D (45 CFR 46.407 or "Section 407"): research that presents a greater than minor increase over minimal risk with no prospect of direct benefit, but has the potential to provide knowledge to understand or ameliorate the health condition; see Box 3-2 for the regulatory language for research involving children permitted under Section 406. Such projects may not be approved by a local IRB; they must be reviewed by a national panel and approved by the Secretary of DHHS.

In broad terms, this subpart requires researchers and IRBs to take a more cautious view of allowable risk for research involving children, to seek parental permission under most circumstances,[8] and to seek the assent of the child whenever appropriate. The additional protections required under Subpart D focus to a significant degree on the assessment of risks and benefits. The stricter and more protective criteria established in Subpart D are directly related to the level of risk posed to potential child subjects in research. The relationship between the level of risk presented and the stringency of the procedural requirements is essentially a sliding scale: the greater the level of risk, the more requirements the research protocol must incorporate and satisfy.

SUBSEQUENT ANALYSIS OF ETHICAL ARGUMENTS

The National Commission identified fundamental ethical issues in research with children, which are still salient today. Recent scholars have analyzed issues embedded in the National Commission's debate and come to similar conclusions about the fundamental issues.

Assessing Risks and Benefits

Physician-ethicist Robert Levine pointed out that in any given research study, some aspects may be carried out for therapeutic purposes, while

[8]In some cases, such as research that presents no more than minimal risk of harm and involves no procedures that would normally require consent, the informed consent requirements may be waived by an IRB (45 CFR 46.408(c)).

BOX 3-2
Research Involving Children Permitted Under Subpart D: 45 CFR 46

Section 46.404 Research not involving greater than minimal risk. DHHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 46.408.

Section 46.405 Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual subjects. DHHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

(a) the risk is justified by the anticipated benefit to the subjects;
(b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
(c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 46.408.

Section 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. DHHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) the risk represents a minor increase over minimal risk;

other parts of the protocol are carried out only to answer scientific questions (Weijer, 2000). For example, consider a housing research study that tests the effectiveness of a set of interventions to reduce cockroach allergens in the homes of children who have asthma. The interventions are intended to provide the prospect of direct benefit to child subjects. However, other parts of the study may be carried out solely to answer the research questions, such as administering skin tests for various allergens, taking measurements of the levels of various antigens in the home, and administering questionnaires about the child's activities and limitations to activities. Although these latter activities might provide some benefit to the child (as in alerting parents to other possible allergies), they are included in the protocol solely for scientific reasons.

The philosopher Charles Weijer (2000) extended Levine's attention to

(b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
(c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
(d) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in section 46.408.

Section 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. DHHS will conduct or fund research that the IRB does not believe meets the requirements of 46.404, 46.405, or 46.406 only if:
(a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
(b) the Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:
(1) that the research in fact satisfies the conditions of 46.404, 46.405, or 46.406, as applicable, or
(2) the following:
(i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
(ii) the research will be conducted in accordance with sound ethical principles;
(iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in 46.408.

the different components of a research study. Weijer also pointed out that the use of the term "therapeutic research" may undermine the protection of humans. When the protocol as a whole is classified as therapeutic because some interventions are administered with therapeutic intent, other interventions in the protocol that are administered solely to answer scientific questions may be accepted even though they are inappropriately risky. Weijer proposed a "component analysis" in which the risks and benefits of those components of the study that are carried out with therapeutic intent are analyzed separately from those components that are carried out solely for scientific purposes.

NBAC (2001) agreed that a clinical research study often involves some procedures that offer the prospect of direct benefit to participants and other procedures that serve only research aims and thus offer no prospect of

direct benefit. It therefore also concluded that it makes little sense to classify an entire research project as therapeutic or nontherapeutic when most projects contain elements of each. Thus, the National Commission's reasons for proposing a more nuanced system of balancing risks and benefits has withstood the test of time. More recent analyses have presented reasons for more refined assessment of risks and benefits in part to ensure that projects do not present unacceptable risks to participants.

Best Interests of the Child

One of the ethical issues in research involving children cited in *Grimes v. Kennedy Krieger Institute* is what is in the best interests of the child. As discussed above, Ramsey would have concurred with the court that parents cannot give permission for their children to enroll in nontherapeutic research because they are obligated to act in their children's best interests.

In fact, parents' decisions regarding the welfare of their children have traditionally been granted great deference in the United States. Because parents are presumed to act in the best interest of their children, they are considered the most reliable and effective judges of what is best for them, with the family unit protected from government intrusions in a zone of privacy, which includes parental autonomy over childrearing decisions (Barnes, 2004). However, the doctrine of *parens patriae* (literally, the state is the parent of the nation) grew out of a twentieth-century idea that parental autonomy is not unlimited but is instead contingent on parents' behaving in ways that are socially responsible and not neglectful or abusive. *Parens patriae* justifies a government intrusion in parental autonomy because of the state's interest to protect children (Holder, 1985). When invoking this power, the government is said to be acting in the best interest of the child in place of the parent who has deviated from the accepted norm of care. The philosopher Ruth Macklin (1982, p. 301) commented on the best interests standard: "It is possible to accord a great deal of respect to family autonomy, and to hold a deep commitment to family integrity, and at the same time to recognize that close and loving family units are in no great danger of being destroyed by an occasional outside intervention aimed at serving the interests of a child." In clinical settings, the principle of the best interests of the child has been used to impose standards of responsible action and obligate parents to accept life-saving medical treatments for children (Lo, 2005; Holder and Lo, 2003; Fleischman et al., 1994). Clinicians are obligated to oppose parental refusal of treatments that are known to be effective when such refusal places the child in imminent harm of death or disability (American Academy of Pediatrics Committee on Bioethics, 1997). For example, a state can override a parent's refusal of life-saving blood transfusions or antibiotics for a child even if the parents base their

refusal on religious beliefs (Barnes, 2004). In these clinical situations in which society inserts itself in family decision making, the risk to the child is very serious and likely, and medical interventions are very effective and have only minor side effects (Wadlington, 1994). In situations in which the medical condition is less grave and the treatment is less effective or more burdensome, parents have discretion to make decisions about their children's medical care. The essential dilemma is determining when the danger posed to the child is sufficiently serious and likely to warrant an intrusion into the home, a violation of the zone of privacy, or an abrogation of parental authority (Barnes, 2004).

Parents often make decisions that conflict with one child's best interests because they promote the parent's interests or the interests of another member of the family. For example, society also allows parents to require their children to help other people who are unrelated to them, even when doing so poses some risks to the child (Wendler and Emanuel, 2004). For example, parents may require that their children help neighbors by shoveling snow from their sidewalks or mowing their lawns. Charities, such as the Red Cross and Habit for Humanity, have established volunteer programs for children (Wendler and Emanuel, 2004). Habit for Humanity, for instance, allows children to help build homes for the poor, subject to strict guidelines: starting at age 5, children may help with fund raising; at age 10 they are allowed to help clear debris from construction sites; by age 16 they can help with actual construction (Habitat for Humanity, 2005). None of these activities are risk free.

In deciding what counts as good or bad for a child, judges have looked to outcomes beyond physical well-being. For example, in custody disputes, judges are asked to consider the importance of continuity with a primary caretaker (Barnes, 2004). Mnookin concludes that often the best interests of a child are "indeterminate and speculative" (Mnookin, 1984, p. 679). Parental decisions about participation in research might reasonably be made in the context of family circumstances and values. The federal regulations (see below) are designed to ensure that the level of risk is balanced with the prospect for direct or societal benefit and that children won't be exposed to known life-threatening interventions.

Some observers who have criticized research that observes children in poor-quality housing without intervening have also invoked the principle of "the best interests of the child" to argue that research scientists have obligations to "rescue" children from harm and provide better living conditions for these unfortunate children (Sherav, 2003). Clinicians have an obligation to act in the best interests of their patients, but this obligation refers to the clinical care they provide, not to personally or directly ameliorating the patient's living conditions. Under the Common Rule (see above), the researcher's duty of beneficence requires that the risks of research

interventions be proportionate to the prospective benefits of research and that these risks be minimized. However, researchers have neither the authority nor the resources to provide better housing to all families participating in a research project or to eliminate all housing-related health risks. Although some research may provide the prospect of direct benefit to those involved, a researcher's primary role is to produce new, generalizable knowledge. The intent is that this knowledge will ultimately help alleviate suffering and promote health by leading to changes in public policies and clinical practice. In addition, beneficence directs researchers who observe serious harms to child subjects to take steps to try to prevent harms. However, the researcher's duty is not to personally and directly prevent harm by removing the child from the harmful environment. If the harm is imminent and serious, the researcher must report to child protective services (see discussion in Chapter 7).

It is unrealistic and unfair to hold individual research investigators responsible for ameliorating the social circumstances that they study. Individuals can only be held responsible for actions, decisions, and conditions that are under their control. Researchers are not responsible for the housing of children in research, except in some intervention studies that assign subjects to housing conditions. However, as discussed in Chapter 5, researchers should consider how they can work with the community to ensure that their results are thoroughly disseminated and available to inform policy discussions.

CONCLUSIONS

The federal regulations, particularly the additional protections articulated in Subpart D, provide a solid foundation for research involving children. *Grimes v. Kennedy Krieger Institute* raised many issues that were debated during the development of the regulations and resolved with appropriate protections for child subjects in research. A nuanced balancing of the benefits and risks of research was a significant contribution of the federal regulations and an approach that this committee and recent analyses conclude is sound. Although the court in *Grimes vs. Kennedy Krieger Institute* questioned whether parents should be allowed to enroll their children in research that does not offer a prospect of direct benefit, the committee concludes that it is reasonable to defer such decisions to parents, provided that they are fully informed about the risks and benefits involved, that they understand the essential features of the study, that the level of risk is acceptable, and that payments do not represent an undue inducement. Later chapters of this report outline strategies for ensuring that the risks and benefits of research are truly understood by the parents of potential child subjects in research and that payments are reasonable.

Grimes v. Kennedy Krieger Institute, however, provides a useful context in which to consider the particular issues raised in housing health hazards research and highlights the particular sensitivities that occur when conducting research with socially and economically disadvantaged populations. Subsequent chapters of this report address many of the issues discussed in the court's decision.

4

Characteristics of Housing Health Hazards Research

The primary goal of all research, including housing health hazards research, is to gain generalizable knowledge. The risk or inconvenience to participants that may be present in any type of research needs to be balanced against the potential benefits of the knowledge gained. Although housing health hazard research and other types of research share some general research characteristics, they also differ in several important ways. One difference is that the usual setting for housing health hazards research is in homes and communities rather than in medical institutions. Another difference is that some housing health hazards studies primarily enroll children from economically disadvantaged communities. More broadly, the nature of risks and benefits in housing health hazards research often differ from those typically found in biomedical, social and behavioral, and public health research. In addition, unlike biomedical research, there are few market incentives to translate housing health hazards research into improved housing. Although other types of research, including some biomedical research, are also conducted in homes and communities or target economically disadvantaged populations, the focus of this report is on housing health hazards research. The committee recognizes, however, that its recommendations would apply to other types of research with similar characteristics.

The frequent differences between housing health hazards research and other types of research have important ethical implications for the design and oversight of research and the protection of children in research. Biomedical research has been the prototype of research involving humans, and the relevant federal research regulations were designed with it in mind. However, regulations and ethical guidelines that were crafted for biomedi-

cal research need to be supplemented with additional safeguards to address the ethical issues that commonly arise in research on housing health hazards involving children. This chapter discusses the typical characteristics of housing health hazards research, highlights common differences between this type of research and biomedical research, and presents the ethical issues raised. Subsequent chapters discuss the committee recommendations for addressing these issues.

THE SETTING

In biomedical research, participants generally go to a research institution, such as a hospital, clinic, university, or research office, to be studied. In those settings, researchers have traditionally been viewed as having expertise and power. Role expectations are usually clear: for example, patients come to hospitals and clinics because they need medical care and physicians and other clinicians have expertise. The relationship is inherently unequal because only physicians and other health professionals have the power to order tests and prescribe medicines. In medical institutions, physical arrangements and scheduling generally serve the primary goals of efficiency and convenience for health care providers, with less attention to the difficulties patients experience in obtaining medical care (Cleary, 2003; Nolan, 1998). Patients and their families may experience long waits, indignity, lack of information, and difficulty finding different services in a large medical center (Cleary, 2003); research participants may expect to have similar experiences when participating in research in a medical or other research institution to those encountered when seeking clinical care.

In recent years, the traditional structure of medical institutions and health care has been modified. A historical emphasis on the biomedical aspects of disease has led to complaints that the social and psychological context of illness has been ignored, and many patients have become more active and sought shared decision making with physicians (Peele et al., 2005; Elwyn et al., 2004; Naik et al., 2005; Makoul and Clayman, 2005; Siminoff and Step, 2005). Similarly, in clinical research, some participants and advocacy groups have become more active in setting research priorities and designing and implementing studies (Dresser, 2001). Yet, in most research studies the nature of the data collected and interventions carried out, as well as the scheduling of visits and procedures, are determined primarily by the researchers.

In contrast to most biomedical research, housing health hazards researchers generally enter childrens' homes to collect data and, in some cases, conduct interventions. Research carried out in the home rather than in a research institution raises distinct ethical issues that researchers must address.

The Sanctity of the Home

When researchers enter childrens' homes to carry out research, expectations and constraints may be strikingly different than when research is carried out in a medical setting.[1] Researchers are guests. A home provides not only shelter, but also "a refuge from danger, humiliation, worldly stress, and the struggle for recognition" (Noddings, 2002, p. 151). No one may enter a home without permission or an invitation. In his or her home, a person can control things. The home is therefore different from the workplace or public places, where an employer or society can set rules, procedures, and restrictions on behavior and appearance (Rybczynski, 1986).

In fact, the adage that a "man's house is his castle" is one of the oldest and most deeply rooted principles in Anglo-American legal history and is "part of the fabric of the Fourth Amendment," which protects individuals' homes and property from unreasonable searches and seizures by the government (Hafetz, 2001, p. 175). Although the courts have lessened the protection of privacy in other places, such as cars, airports, or schools, the home has retained its zone of privacy in search and seizure law (Hafetz, 2001). Indeed, the jurisprudence of protecting an individual's privacy has grown beyond that of Fourth Amendment search and seizure law, which protects private property, to include protections from government intrusions into the exercise of certain individual liberties, such as marriage, reproductive decisions, and childrearing practices (Hafetz, 2001). Recently, for example, the Supreme Court struck down a Texas anti-sodomy law on the ground that the law violated an individual's right to privacy guaranteed by the liberty interests protected by the Fourteenth Amendment. The court held that under the Constitution, liberty "protects the person from unwarranted government intrusions into a dwelling or other private places" (Whitman, 2004, p. 1214, quoting 123 S. Ct 2472, 2475 (2003)).

The home represents more than just a negative right to keep people away and to be free of control by others. It also offers a place where people can express their own values, which may include religious beliefs, cultural norms, and family expectations. People can arrange their homes in ways that a "room conveys the character of its owner" (Rybczynski, 1986, p. 43). A home also is where special, intimate relationships flourish, including marital relationships and relationships with children. In these relationships, people function both as individuals and as members of a family or household unit.

[1]Although there may be boundary issues in the relationship between other professionals and their clients, the focus here is on the relationship between researchers and those enrolled in research.

Raising children is an activity in which the home is particularly important. Within the home, parents "shape the character and personality of the child" (Noddings, 2002, p. 63). Parents or guardians have control over the children's basic needs, discipline, education, and religious upbringing. In the United States, there is a presumption that parental values and decisions should be given great deference. Parents have a right to raise their children in the way that they view as most appropriate, without interference from other people or the government, as long as their actions fall within a broad range of socially permissible options (Mnookin and Weisberg, 2000).

Ethical Issues in Entering a Home

When people invite someone into their home, they reveal many things about themselves that would not otherwise be apparent and that they might not reveal in other contexts. Researchers who enter homes to conduct their research may observe things that they would not see in medical settings, that may not be included in the data collection protocol, and that may have little to do with the topic of the research. Observations might include the physical environment, activities within the home, and interactions among persons in or around the home. Such observations will be particularly far ranging if the researchers physically inspect the home as part of the research project. As we discuss in more detail in Chapter 7, researchers may observe conditions or actions that may pose some risk to children. For example, researchers may note serious physical hazards to a child, such as a lack of window guards or access to chemical products, which may or may not be part of the research. In addition, the appearance of the child may raise concerns about physical injuries or neglect.

When people visit a home, there are social expectations about what is acceptable behavior. People who are invited into a home are expected to be sensitive to and respectful of the host's customs and values. For example, visitors are expected to comply with the rules of the home, such as taking off shoes or not smoking (Rybczynski, 1986, p. 74-75). At the same time, within a home "social conventions could be set aside or at least loosened" (Rybczynski, 1986, p. 110). Generally it would be considered an affront for others to criticize or give advice about someone's home, unless they are asked to do so. Even relatives may be expected to refrain from disputing choices that parents have made about their home and children. Social roles for strangers in a home are usually clear. Salespeople, repair persons, or workers installing an appliance are there for certain purposes only. They do not have an open-ended invitation to give advice on other topics.

When researchers enter a home, their relationship with participant families may be complicated, and there may be conflicts in their roles and ethical obligations. If the researcher makes only one visit to administer a

questionnaire, the expectations and role are similar to that of a plumber or repairman carrying out a single task. However, if a research project follows children over time, the relationship may become ambiguous. First, the research staff may give the parents small gifts of appreciation, such as T-shirts and coffee mugs. These gifts can be seen as similar to gifts that a friend or acquaintance may bring when invited to one's home. In return, the host may offer coffee or other refreshment. These social rituals may transform a working relationship between strangers into a more personal one.

Second, research staff may reside in the same community as the families participating in the research and may even know some of them prior to the study. Such prior relationships will complicate the research relationship. Staff must be trained on privacy and confidentiality, and consideration must be given to staff's prior relationship with families in determining which staff to send to homes to minimize possible breaches of privacy or confidentiality. Third, the research staff may observe behaviors or other information about other residents in the household other than the children who are the subjects of the study or their parents.

Finally, researchers differ from other visitors to the home because they have special expertise about housing health hazards and have opportunities while in the home to identify hazards. These features of the relationship may create role-specific obligations for researchers and their staff. Researchers may be in a unique position to identify and help ameliorate hazards. If they do not act, a unique opportunity to prevent harm may be lost. In addition, if researchers studying housing hazards fail to point them out, parents may infer that there are none in their home.

If the researcher's role is ambiguous or unclear, there may be both advantages and disadvantages. A more personal relationship between researchers and parents may make participation more enjoyable and may also enhance the quality of research through more complete data collection, but there may also be misunderstandings and dilemmas. Parents may not fully understand what researchers will and will not do, particularly with regard to housing hazards that are not the focus of the study. Furthermore, they may not appreciate that researchers will observe information about them and their home that is not part of the research protocol and, in some circumstances, may act on that information.

It is important that researchers anticipate possible misunderstandings about their role and take steps to correct them. Researchers need to think through these issues when they design their projects and discuss them with parents during the informed consent process. In addition, investigators need to ensure that their front-line staff, who enter childrens' homes, understand their role as members of the research team, how that role differs from the role of neighbor or friend, and how they should respond when they make observations about risks that are not part of the protocol. These issues are discussed in more detail in Chapter 7.

VULNERABLE POPULATIONS

As discussed in Chapter 2, children often are at greater risk than adults for housing health hazards because they are unable to protect themselves in hazardous environments. Small children may have greater exposures because they tend to play on the floor, where they may be exposed to dust or dirt, and because of normal exploratory behavior, which includes putting objects in their mouths. Research to identify, characterize, and ameliorate these hazards is needed to address this disproportionate prevalence. Because children are not merely "little adults," studies conducted with adults often have little application to them. Their smaller size and immature systems may lead to greater effects from exposures (Bearer, 1995).

Children in housing health hazards research are especially vulnerable for multiple reasons. First, as recognized in the federal regulations, they are vulnerable because they are children. Younger children cannot consent for themselves; their parents or guardians must give permission for their enrollment in research (see Chapter 6 for a discussion of informed consent). Whenever research participants cannot give informed consent, ethical concerns arise because they have not consented to any risks involved in the research, particularly if the project does not offer the prospect of direct benefit.

The target population for some housing health hazards research raises the additional vulnerabilities of poverty and minority status. As discussed in previous chapters, children in low-income families often live in poor-quality housing that is associated with higher than average rates of some negative health outcomes. These children are also more likely to attend low-quality schools, belong to ethnic groups that historically have suffered discrimination and stigma, and have limited housing alternatives. Furthermore, children in low-income families may lack health insurance and access to health care. Their parents may be poorly educated and may not understand the health hazards present in their home or be able to easily access information about such hazards. Moreover, the power differential between low-income parents and investigators may affect the voluntary nature of informed consent, and incentives for participation may unduly influence parents' decision to allow their children to be enrolled in research.

Ethical Issues

Given these concerns, what might be persuasive ethical arguments for focusing housing health hazards research on children in low-income families who are at increased risk for the hazards? Efficiency in carrying out the research would not be an acceptable justification. The majority of housing health hazards research reviewed by the committee primarily enrolled children in low-income families. If research could be practicably carried out

with children from all socioeconomic backgrounds who experience a given hazard, it would be ethically preferable to do so. For example, a cross-sectional lead prevalence study used a representative sample of all housing units and a project in the Cincinnati metropolitan area designed to test the safety and efficacy of lead hazard controls and injury controls recruited families from various socioeconomic backgrounds and from various racial and ethnic groups (Jacobs et al., 2002; Eskenazi et al., 2005).

Historically, the approach to vulnerable populations has been to exclude them from research. While this protects them from harm, it also may result in useful research not being conducted and therefore deprive the vulnerable population from the knowledge gained and potential benefits from research. As research has been increasingly viewed as an activity that not only generates new knowledge but also provides potential benefits as well as possible risks, there has been a trend to try to include vulnerable populations in research when appropriate, while requiring extra scrutiny and additional safeguards to ensure that they are adequately protected (National Bioethics Advisory Committee, 2001); this committee shares that view.

Housing health hazards research sometimes targets children in low-income families because it is necessary to include these children in order to adequately understand the hazard or how to ameliorate it. Research may be designed to document the relationship between housing conditions and health, to better understand the mechanisms by which housing affects health, or to develop interventions to address housing hazards. Such studies are justified when they are designed to improve the very circumstances that have led to higher risks in children's daily lives (Wendler and Emanuel, 2004). Furthermore, it is necessary to study these children in order to gain scientific knowledge that might lead to improvements in housing. In biomedical research, subjecting sick children to a level of risk slightly greater than well children is justified on the basis of learning about their illness and ultimately affecting it. In the case of housing health hazards, which are exacerbated by poverty or housing conditions, it is necessary to study children in that situation to identify specific ways of affecting it.

The generalizability to children in low-income families of studies of children living in hazard-free housing, or even substantially different housing, would be questionable. For example, interventions to ameliorate risk that are effective in higher income households may not be effective in low-income households. The household triggers for asthma differ in low-income and higher income households, and interventions designed for one group might not translate to the other. Similarly, the results of an intervention designed to identify effective ways of addressing housing hazards may be muted when subjects live in widely different housing with varying hazards. Researchers are trying to ameliorate the circumstances of living in poor-

quality housing, not use this circumstance to justify exposing children to risks for other purposes. The research therefore expresses the view that these conditions are unacceptable; not doing the research would limit the potential to change the condition.

In *Grimes v. Kennedy Krieger Institute*, the court and subsequent commentators raised the issue of whether the investigators simply studied children who happened to live in houses known to contain lead paint, or whether the research methods amounted to the investigators' placing these children in houses or encouraging them to remain in houses known to contain lead paint. If the latter is the case, then there are ethical concerns about complicity or "dirty hands," even if the research is designed to find ways to ameliorate the children's unfortunate circumstances (Wendler and Emanuel, 2004).

Even when the selection of primarily children in low-income families is justified, disproportionate enrollment of these children leads to concerns about or the perception of inequitable selection of subjects and informed consent. The *Belmont Report* (National Commission, 1978) cautions that an injustice occurs when research participants are unduly burdened or exploited for the benefit of others. Historically, the burdens of serving as research participants have fallen largely on poor patients, while the benefits of improved medical care have flowed primarily to those who are can afford health insurance and health care. For African Americans, the notorious Tuskegee project symbolizes the possibility that research may exploit rather than benefit them (Freimuth et al., 2001; Corbie-Smith et al., 1999; Fairchild and Bayer, 1999). In the context of research involving children, the ethical concern is that vulnerable children may be being used as a means to benefit other children.

Addressing the Ethical Issues

One useful approach to these complex dilemmas is for researchers to discuss a proposed study with representatives of the community in which the study will be carried out (Krieger et al., 2002b; Israel et al., 1998). If the researchers cannot persuade community representatives that the study is of vital importance, has acceptable risk, and is likely to provide benefit in the long run, they need to seriously reconsider the study's goals and design (see Chapter 5). This may include the adoption of innovative research designs (see Chapter 7). Community involvement can also increase the likelihood that research will be used to benefit the intended community.

Approval from the community, while beneficial, is not sufficient. As we suggest later in the report, studies with vulnerable populations also should meet additional criteria to safeguard children in housing health hazards research. When subjects have multiple vulnerabilities, investigators and

institutional review boards must provide safeguards to ensure that the balance of risks to benefits in the research are acceptable and that parents are able to make informed and voluntary decisions about their children's enrollment in research (National Bioethics Advisory Commission, 2001; Institute of Medicine, 2004; see Chapter 6). Ethical concerns about targeting low-income populations are perhaps most pronounced when research involves more than minimal risk and no prospect of direct benefit. In such cases, researchers and IRBs should ensure that there is a body of evidence that establishes a connection to the health hazard under study and should engage in meaningful and ongoing dialogue with the community.

RISKS AND BENEFITS

Housing health hazards research often differs from biomedical and other types of research in regard to the type and perception of risk and the mechanisms to implement the results of the research. We illustrate these differences with a comparison of housing health hazards and biomedical research.

The Nature of Risk

Biomedical research often involves invasive medical procedures or testing of new drugs. The risks of such research include physically adverse events, which may be serious or even life-threatening. The risks of the research intervention must be distinguished from the risks of the participant's disease or condition. For example, suppose a patient with cancer participates in a research project that studies the out-of-pocket costs of care: the study intervention is gathering information about expenses. This intervention presents minimal risk. The participant may suffer serious health problems or even die if the cancer spreads, but the researcher is not held responsible for the adverse health outcome because it was not caused by the research intervention.

In contrast, research interventions on housing health hazards usually do not pose more than minimal physical risks to children. Generally such research involves questionnaires, observations of children's activities and the physical characteristics of their homes, measurements of air and dust samples from homes, and measurements involving the urine, hair, or blood specimens from children. If the research involves an intervention, it is typically education or changes to the home environment. Interventions in housing health hazards research do not typically pose physical risks to children, such as might be the case with an intervention testing a new drug. However, children in the study may still be at risk for adverse health outcomes be-

cause they live in housing with health hazards; these risks would be present whether or not the children were involved in a research study.

Therapeutic Misconception

Biomedical research has produced advances in therapies that have benefited many people. Over the past 20 years, new treatments for cancer, heart attacks, AIDS, and organ transplantation have resulted in dramatic clinical improvements. Perhaps as a result, Americans tend to support biomedical research, and funding for the National Institutes of Health has doubled in the past decade. Moreover, public and disease advocacy groups view clinical research as access to new therapies. Participation in biomedical research is generally no longer viewed as "being a guinea pig," but instead is often viewed by both physicians and patients as an opportunity to receive new treatments (National Bioethics Advisory Commission, 2001; Dresser, 2001). Thus, there is widespread support for developing new tests or therapies through clinical research.

Parents may overestimate the benefits of clinical research. Participants often believe that clinical research will benefit them personally, although the goal of Phase 1 clinical trials is to establish safety and dosing, not to test effectiveness. This widespread mistaken belief that clinical research is intended to provide direct benefits to participants has been termed the therapeutic misconception (Appelbaum, 1987; Lidz and Appelbaum, 2002). A similar misconception can exist in housing health hazards research. In the case of housing health hazards, parents may also mistakenly believe that participation in the research will eliminate or reduce health hazards in their homes.

Long-Term Benefits of Research

For biomedical research, the U.S. health care system has mechanisms by which research discoveries may be translated into clinical benefits for the patients who need them. For example, discoverers of a new test or drug have financial incentives to translate their research into marketable products. After drug manufacturers gain government approval for new drugs, the health insurance system provides a process by which patients who need a drug can generally get it. Even though many Americans lack private health insurance, they can often receive new drugs through Medicaid programs, at public hospitals and clinics, and through free-access programs established by pharmaceutical companies.

In contrast, there are few market incentives to translate housing research into improved housing or reduction of health hazards. There are no

institutional equivalents of drug manufacturers and insurance companies, who would profit from interventions to reduce housing health hazards. Public resources to ameliorate housing hazards are limited. Many serious housing hazards, such as lead poisoning and asthma, occur disproportionately in poor-quality housing: the adverse health effects of these housing hazards could usually be eliminated by moving those at risk to better quality housing. However, low-income families often cannot afford to move to better private housing and the availability of public housing (usually lead free) is very limited.

Research on housing health hazards involving children has in some cases led to tangible benefits to affected communities and individuals. Examples are laws that require smoke alarms, window bars to protect children from falls, and prohibitions on lead in paint. However, research on other housing health hazards has not typically led to tangible benefits for those exposed to the hazards. As a result, affected communities may question the need for or the value of additional research.

Housing health hazards researchers commonly report that community advisory boards and partners note that previous research has not provided any benefits to the community (Israel et al., 2003; Minkler and Wallerstein, 2003). At the first meeting of this committee, community representatives similarly testified about the lack of benefit from much research that had been carried out in their community. Indeed, a common demand from the affected community is that the research must provide some immediate benefit to families participating in the research and the community (Israel, 2003; Minkler and Wallerstein, 2003; Krieger et al., 2002b); they may not trust that they will benefit from research findings in the future. The *Grimes v. Kennedy Krieger Institute* ruling stated that research involving more than minimal risk needed to offer direct benefits to the children participating in the study. It is worth noting that the goal of the repair and maintenance study (see Chapter 3) was to identify less expensive methods of lead abatement. If such methods had been found to be as effective as the known expensive methods, there might have been wider adoption of the lower cost method and an increased supply of lead-safe housing. These issues have implications for the design of research protocols, as discussed in Chapter 7.

Different Assessments

Although laypeople may weigh the risks and benefits of any research study differently than investigators, such differences may be particularly pronounced if the research focuses on hazards occurring in low-quality housing where residents are likely to be poor and members of minority groups. Although there is limited empirical evidence supporting this point,

the experience of housing researchers on the committee and researchers who discussed their work with the committee supports this conclusion.

Researchers may regard the physical risks of the research interventions they carry out in the home as minimal, because no invasive procedures or new drugs with physical risks will be administered. Community leaders and parents, however, may take a broader view of the risks. First, they may be concerned about baseline risks concerning the health hazard under study, as well as the risk from what is done by the researchers as part of the study. They may also be concerned about the risks of living in the homes that persist after the research interventions are carried out and the study is completed. In an intervention study, they may regard a "usual care" control group as unacceptable (Israel et al., 2003; Minkler and Wallerstein, 2003; Krieger et al., 2002b). These perceptions of risk may be associated with expectations or hopes that the risk will be eliminated, rather than just studied or partially abated. Community representatives may expect or want researchers to reduce the adverse effects of housing hazards, even though the researchers' actions have not caused the hazards.

Second, parents and community representatives may perceive risks that researchers do not appreciate, such as the risk of attempted eviction from housing if landlords disapprove of the study or the risk of recrimination from others living in the home. Similarly, community representatives may be concerned that improvements to the property will increase its value, raising rent beyond the reach of current tenants. Third, parents who enroll their children in research may not appreciate some of the risks of the study, such as invasion of privacy. Possible discrepancies in perceptions of risk ought to be identified in the early planning stages of a project, when the protocol might be modified or clarified.

In other fields of research, scientists and laypeople also may have very different perceptions of risk. In environmental health, experts and nonexperts often come to different conclusions about the magnitude and significance of specific risks (National Research Council, 1989). The result is two distinctly different estimates of risk: one by experts and another by nonexperts. The risk estimates of experts ostensibly rely on what are objective criteria, such as magnitude of the hazard and the probability of its occurrence.

In research on housing health hazards, the evaluation of the risks of interventions and the balance between benefits and risks is often based on expert opinion. In some circumstances, the community's estimates of risks may incorporate other aspects of risk outside of the scientific data that experts use and may reach different conclusions. Empirical research has shown that the risks that people view as unfamiliar, beyond their control, and imposed from the outside are perceived to be a greater problem than

risks that are voluntarily assumed (Slovic, 2000). Ignoring these "non-quantitative" aspects of risk may lead to anger or outrage in a community about a particular risk; the risks that lead to outrage are often not the same ones that harm or kill people (Sandman, 1993). Outrage is often related to perceived fairness. The factors that lead to discrepancies in risk assessment are also at play in the assessment of the benefits and risks of housing health hazards research. The perceived unfairness of the lack of affordable decent housing may lead community members to demand that researchers improve housing health hazards, not merely study them.

Researchers and residents of the community where the research would be carried out may also disagree over the likely benefits of research (Minkler and Wallerstein, 2003; Israel et al., 2003; Krieger et al., 2002b). Researchers may believe that the scientific knowledge gained from the study will ultimately benefit the children who are exposed to home health hazards. However, as discussed above, community members may doubt that the community will receive any benefits from the knowledge gained.

Differences in expectation regarding risks and benefits raises ethical considerations that must be considered during the design of housing health hazards research. Researchers should discuss their protocol with community representatives to ensure that they understand the community's views about the risks and benefits of the research and that the community and individual parents who give permission for their children's enrollment in research understand the risks and benefits of the research. This issue is discussed in more detail in Chapters 5 and 6.

CONCLUSIONS

Scientific, public health, and medical research is generally viewed as an important societal good, performed to create new knowledge and ultimately to develop strategies for preventing illness and to understand, ameliorate, and even cure disease. However, all research involving human participants requires a careful balancing of the rights and welfare of the individual participants in the research with the need to make scientific and medical progress.

As described in the previous chapter, the present regulatory framework in Subpart D places specific limits on the level of risk that children are permitted to experience in a research study, dependent on the potential of the research to directly benefit them as individuals. The *Belmont Report*, the relevant federal regulations, and *Ethical Conduct of Clinical Research Involving Children* (Institute of Medicine, 2004) all call for the selection of research subjects to be equitable. The broad ethical principles of respect for persons, beneficence, and justice articulated in the *Belmont Report* are applicable to all research with human participants, including children.

In subsequent chapters the committee presents specific recommendations in response to these characteristics to provide protections for children involved in research on housing health hazards. These additional protections can provide needed clarification about a research project for both the parents of these children and investigators, ensure that the rights and welfare of vulnerable subjects are protected, and allow valuable research to proceed that is intended to ultimately improve the well-being of vulnerable children. Certain characteristics that occur frequently in housing health hazards research are much less frequent in other types of research. These characteristics need to be carefully considered and their ethical implications taken into account in the design and implementation of the research.

5

Community Involvement

The context of housing health hazards involving children requires a fresh look at the ethical framework for research involving humans. The ethical principles of respect for persons, beneficence, and justice may have particular meaning within the context of research that takes place in the home and community.

ETHICAL FRAMEWORK

The ethical principle of respect for persons incorporates both the notion that individuals should be treated as autonomous agents and that persons with diminished autonomy are entitled to protections. In the context of housing health hazards research, one can question whether the community environment compromises voluntariness of consent. The environment can be viewed as potentially coercive when persons are living in hazardous conditions and when moving out of the situation (e.g., to better housing) is not a feasible option.

The principle of beneficence requires that persons are treated in an ethical manner, not only by respecting their decisions and protecting them from harm, but also by facilitating their well-being. It assumes that researchers are operating in a manner that will both maximize the potential benefits and minimize the possible harms of the research. Concern about the application of this principle can be raised because parents and community representatives may have markedly different assessments of the benefits and risks of such research than researchers and institutional review boards (IRBs).

Finally, justice addresses the questions of who should receive the benefits of research and who should bear its burden. An injustice occurs if someone is denied a benefit to which he or she is entitled or when a burden is unduly imposed. The principle of justice is typically discussed in the context of equitable selection of participants, so that no group receives a disproportionate share of the benefits or burdens of research; it has generally received less attention than the other two ethical principles. However, it is particularly salient in the context of housing health hazards research.

The distributive paradigm of justice may be challenged when considered in the context of communities that lack economic, social, and political power. Residents of these communities may have experienced a history of racism, classism, segregation, unequal access to quality health care, discrimination, and past research abuses. The resultant pervasiveness of distrust toward researchers and research institutions among many individuals and communities in which this research will take place is one aspect of the difficulty in applying the principle of justice. Community residents may believe that changes in housing and economic policies to improve low-income housing are needed, rather than more research. In addition, as discussed in Chapter 4, community residents may have a different view than researchers regarding what constitutes a risk and whether a particular research project is worthwhile.

Some ethicists have suggested using a relationship paradigm that acknowledges the notion that an individual is situated in his or her social context, environment, or community to support thinking about complex ethical issues in underserved or vulnerable communities (King et al., 1999; Fisher, 1997). A relational approach to ethical decision making draws attention to complex social, cultural, and political contextual factors. This paradigm acknowledges that researchers and participants may differ in their assessment of research risks and benefits and values each perspective. Researchers are encouraged to engage participants and community residents—and community residents are encouraged to proactively engage researchers—as partners in designing research that meets the needs and addresses the values of all stakeholders. In this paradigm, justice evolves into a principle that goes beyond the issues of participant selection to a principle that is related to past, present, and future distributions of power (King et al., 1999; Institute of Medicine, 1999). This shift reflects the view that research is part of a broader societal context and that the conduct of research often mirrors a system in which power is unequally and perhaps unfairly distributed.

Through discussion with potential and actual research participants, the respective views of researchers and community residents can be examined and a research plan can be constructed that accommodates the views and values of prospective participants, their families, and their communities

(Fisher, 1997; National Bioethics Advisory Commission, 2001). A relational approach can help address concerns regarding respect for persons, beneficence, and justice in housing health hazards research. Community involvement, through enhancing respect for persons and shaping research that addresses the needs and priorities of the communities, is one way to address fundamental ethical principles.

VALUE OF COMMUNITY INVOLVEMENT

Involving a community in housing health hazards research, especially when the involvement is in the nature of partnerships, offers many advantages. Community representatives bring different perspectives, values, and competencies, which can contribute to the research project; see Box 5-1. While investigators bring technical knowledge about the subject of study and about research methodology, representatives of the community bring knowledge of community concerns, needs, values, and priorities. They also can bring a history of activism, leadership, and coalition building and a network of community contacts. Their expertise can shape research in constructive ways by posing significant questions for study, pointing out ethical concerns, suggesting how to modify a study to reduce risks and increase acceptance of the research in the community, assuring that data collection instruments are culturally appropriate, and promoting enrollment and retention. Community input also can help researchers determine what and when compensation for participation in research is appropriate and design informed consent processes that ensure that parents understand the essential features of the research protocol. (See Chapter 6 for additional discussion of these issues.) Furthermore, community groups can help researchers anticipate and respond to risks observed in the home when the observations are not part of the research protocol. (See Chapter 7 for discussion of this issue.)

Moreover, although there is little empirical evidence on this point, community groups can use research results to advocate for changes in public policy that will allow research interventions to be sustained and disseminated. Research findings often validate long-held community concerns. Thus, community involvement may increase the likelihood that research results are translated into actions and changes that benefit the communities in which it is conducted. Communication between researchers and community members can help identify ways in which research results can be effectively communicated to and applied by the affected community, including identification of public officials whom researchers should include in their dissemination plans.

BOX 5-1
An Early Experience with Community Involvement

The Boston Lead in Soil Study, funded by the Environmental Protection Agency in the 1980s, was one of the first large-scale intervention studies that examined the housing-based health hazards posed to children. The study was designed to examine whether certain low-cost methods for the removal of lead-contaminated soil surrounding a home would reduce the blood lead levels of young children living in homes in disadvantaged neighborhoods.

Community representatives participated in and contributed to the project in multiple ways. An individual who was both an employee of the health department that conducted the study and an active neighborhood resident insisted that a community advisory group be formed, that it be active in all phases of the study, and that it be a part of the decision-making process. The sense of ownership that the community held towards the project was based on the successful education and dissemination of information about both the specific potential link between the soil in the neighborhood and the high incidence of lead poisoning of the neighborhood children and the general connection between environmental hazards in and around homes and child health. The community advisory board made several significant contributions to the project:

- The comprehensiveness of the consent forms was largely attributable to feedback and oversight by residents who ensured that the risks and benefits of the study were described in an understandable manner.
- A community resident insisted that students from a local community college be trained as lead abatement workers, to ensure that the skills gained from participating in the study would stay in the community and create employment opportunities.
- A community member helped solve practical design issues by raising the common sense question of how cemeteries bury people in the middle of winter in the northeast which resolved the problem of removing frozen soil.

SOURCE: Michael Weitzman, principal investigator (personal communication, December 2004).

PRINCIPLES OF COMMUNITY INVOLVEMENT

Community involvement can take many forms. The Centers for Disease Control and Prevention recommends that researchers apply and adapt with "understanding, skill, and sensitivity" concepts from literature on community participation, community mobilization, community empowerment, cultural influences, and others. Representative strategies to engage communities in research include capacity building, coalition building, and community organizing (Centers for Disease Control and Prevention, 1997c).

In the context of health interventions, it is recognized that efforts to

involve the community should address multiple levels of the social environment. For example, health behaviors are influenced by culture. Efforts to engage residents will be advanced when they feel a sense of community, see the process as worthwhile and inclusive, and believe the benefits outweigh the costs. A sense of empowerment is crucial to successful engagement efforts. Active community involvement will take time: community mobilization and self-determination frequently need nurturing. In the end, however, coalitions can be used for mobilizing, developing, and using community assets for health decision making and action (Centers for Disease Control and Prevention, 1997c).

Several authors have enumerated key principles in community engagement as it relates to community based participatory research, one form of community involvement (see below) (Centers for Disease Control and Prevention, 1997c; Israel et al., 1998; Minkler and Wallerstein, 2003). These principles might also be useful with other types of community involvement. First, researchers need to recognize the community as a unit of identity and attempt to work with existing communities. Investigators can use tools of community assessment and diagnosis to learn about the community and its economic conditions, history, norms, demographic trends, and political structure. Successful research collaboration requires researchers to understand how residents structure and maintain communities (Kone et al., 2000).

Second, community engagement and research collaboration should build on strengths and resources within the community by explicitly recognizing and supporting social structures and processes that contribute to the ability of residents to work together to improve health. Resources may include skills and assets of individuals, networks of trusting relationships, or existing organizations and institutions, such as places of worship. Because of the intensive nature of community-based participatory research, investigators who advocate for this type of community involvement move beyond these concepts to stress the importance of equal partnerships (Green and Mercer, 2001; Israel et al., 1998).

Researchers may benefit from including on the research team or consulting with individuals who are knowledgeable about or representative of the community. Such persons might be scholars in relevant social science disciplines, leaders of community-based organizations, or front-line social service or medical practitioners. Consultants familiar with a community might help identify diversity within a geographic community; a given community might have multiple groups with different demographics, social structures, and neighborhood and cultural histories.

Researchers might ask a series of questions related to the community during an initial assessment phase to help address important issues in planning a project:

- Have I conducted preliminary research to ascertain the concerns of the community from which I will enroll children?
- Has a community needs assessment been done to inform the research agenda?
- Is the proposed research relevant to the communities of concern?
- What role should community residents play in order to improve the research, facilitate informed decision making by parents, and translate and disseminate findings to the community, the broader public, and policy makers?
- What capacity building is necessary to achieving meaningful involvement in the community?
- How will I evaluate the effectiveness of the approach taken to community involvement?
- Is there an interdisciplinary research team and advisors to guide the study and help evaluate process and outcomes?
- Do I have plans to ensure that the research staff are culturally competent and sensitive to the issues in the community?

Researchers should also anticipate the questions likely to be raised by community residents (adapted from Center for Minority Health, 2004):

- What is/are the exact question(s) you are attempting to answer?
- How will this research benefit the targeted population?
- How does this research address the stated problem?
- What jobs will be available as a result of this research study and how will the community be informed about them?
- What will be your method of recruiting children?
- What is your proposed outcome(s)?
- How will you disseminate your research findings?
- How will you ensure that families can understand your questions?
- How will you ensure your study is implemented in a culturally competent manner?
- What written materials will be given to the parents of child subjects or potential child subjects?
- What does the informed consent form say?
- Are health literacy issues taken into consideration?
- Is the recruitment material culturally appropriate for the targeted population?
- What has the research team done to recruit the targeted population?
- How culturally diverse is the research team?

BOX 5-2
Preventing Agricultural Chemical Exposure Project

The Preventing Agricultural Chemical Exposure (PACE) project was a 4-year project to reduce pesticide exposure of farmworkers in North Carolina using a community-participation framework. PACE involved a partnership among Wake Forest University School of Medicine, the University of North Carolina at Chapel Hill, and the North Carolina Farmworkers' Project (NCFP). Many of the Latino farmworkers in this project came directly from Mexico, they were not unionized, and advocacy organizations for this population were relatively new. These characteristics suggested that pesticide safety interventions developed elsewhere in the United States might be inadequate for this population.

The project used a two-part planning framework, known as "precede-proceed": "precede" focused on problem identification and intervention planning, and "proceed" focused on implementation and evaluation.

The precede phase included review of existing data sources and training manuals, solicitation of information, quarterly advisory meetings, and data collection from four constituencies: (1) farmworkers, (2) farmers, (3) staff of the Cooperative Extension of the U.S. Department of Agriculture, and (4) health care personnel. The four groups varied in their perceptions of farmworker pesticide exposure, risks of exposure, and effectiveness of regulations in protecting farmworkers. For example, while health care personnel believed that pesticide exposure was underreported and undertreated, farmers and Cooperative Extension staff perceived no problem with exposure. Farmworkers were concerned about pesticide exposure, but evidence indicated they were not fully aware of the risks. From these data, specific behavioral changes to be implemented in future phases were identified related to hand washing, wearing clothes that cover most exposed skin, wearing work clothes only one day before washing, and washing work clothes separately from household clothes. Specific environmental changes were also identified, including increasing farmworkers' control of their work environment and reducing pesticides in housing. Constituent input also helped identify factors that could predispose or

APPROACHES TO COMMUNITY INVOLVEMENT

Community involvement can occur along a broad spectrum. Residents can be involved as parents of child subjects or as staff who conduct interviews, moderate focus groups, or contribute to the analysis and interpretation of findings. Alternatively, they may have a decision-making role as members of IRBs or as research partners. Greater involvement of community residents is associated with maximizing the potential for capacity building, salience of research questions and proposed solutions, and the relevance and sustainability of interventions (Hatch et al., 1993); see Box 5-2 for an example.

position farmworkers to make changes (e.g., farmworkers' lack of knowledge of pesticide residues and existing regulations regarding pesticide exposure and perceived susceptibility to pesticide-related health problems), reinforce beneficial changes that farmworkers made (e.g., use of field safety promoters to provide education and support and use of *El Terror Invisible* symbol in educational materials to represent pesticide residues), and enable workers to make appropriate changes.

The design of the intervention was guided by three ideas: (1) that the intervention *focus* on key concepts; (2) that it be *relevant* to the local farming system; and (3) that it assist workers in maximizing their *control* over pesticide exposure. Both product and process evaluations were conducted.

The collaborative nature of the PACE project led to the development of a pesticide safety program that has been sustained and disseminated in several ways:

- The NCFP has adapted the pesticide safety education framework developed by PACE and has continued using it to provide pesticide safety training to farmworkers. PACE investigators served as consultants to the NCFP work.
- The PACE pesticide safety education framework was also used by Student Action with Farmworkers (in Durham, NC) for the Into the Fields Pesticide Safety Program in 2004 and 2005, with plans to continue in 2006. PACE and NCFP investigators provided training to the project interns.
- Details of the PACE training program were developed into *Preventing Agricultural Chemical Exposure: A Safety Program Manual–Participatory Education with Farmworkers in Pesticide Safety*. Several hundred copies of this manual have been distributed nationally and internationally.
- Some of the key concepts of the PACE pesticide training program were incorporated into the Spanish-language training video, *El Terror Invisible: Pesticide Safety for North Carolina*.

SOURCES: Information from Arcury et al. (1999, 2001); Quandt et al. (2001).

The mechanisms used for community involvement may be additive. And, as researchers and community members develop trust and working relationships, the level of community involvement may evolve. Investigators may use multiple strategies to maximize the communities' capacity for current and future research partnerships and advocacy (Quandt et al., 2001; May et al., 2003). Community residents can be involved in the research process as research staff, through community consultation and review, membership on community advisory boards, and involvement in a community-based participatory research process. As discussed in Chapter 8, IRBs may also seek out input from community residents as part of their review of housing health hazards research protocols.

Research Staff

Community representatives may ask whether the research team has appropriate cultural diversity and whether community residents will have the opportunity to gain employment and learn job skills. Community advisory boards may ask specifically how people will be informed of possible jobs with the research project (Center for Minority Health, 2004).

As paid research staff, community members can directly benefit from the research process through the development of new skills and expertise. A variety of potential staff roles include (1) consultation on protocol development and research design; (2) consultation and development of data collection instruments; (3) recruitment and retention, including outreach to families in their homes; (4) data collection; (5) data analysis and interpretation; and (6) dissemination of findings within the community. Researchers must ensure that community members who are hired have the requisite skills for the tasks identified and are not merely those most vocal or visible in the community. The extent to which community residents who serve as research staff can influence the research process will depend on the context of the study and the willingness of those in supervisory roles to elicit and incorporate their views. A challenge is to avoid letting such staff become marginalized on the research team. In addition, researchers must guard against the possibility of corruption of local staff's views while remaining open to views different than their own.

Community Consultation or Review

Community consultation or review enhances respect for families involved in research and communities. By deliberately bringing together researchers and community residents in dialogue, community consultation allows everyone to be informed about the potential risks, burdens, and potential benefits of research to the group and may provide more meaningful input than merely hiring community residents as staff. Foster and colleagues (1999) describe a range of activities that might be a part of community consultation: informal discussions with community members; community involvement in research planning; community participation in the evaluation of human subject protections; and negotiations of formal community agreements. Dula recommends that such consultation be "culturally sensitive, jargon free, and strictly honest about the benefits and burdens of experimentation" and be offered in a spirit of "professional humility" (Dula, 1994). Community consultation can be a key part of the "the process of engagement, dialogue, and feedback" that is engaged in before, during, and after research (Dula, 1994). While in no way replacing individual informed consent, community consultation might lead to better

communication about research-associated risks and potential benefits and might improve the informed consent process. Levine and colleagues (1991), in the context of clinical trials of new antiretroviral medications for AIDS, recommend that "prior and ongoing community consultation should be an integral part of the planning and design of clinical trials of nonvalidated therapies" (p. 10). They identify determining whether the trials are considered acceptable by the majority of prospective participants as a specific objective of community consultation.

The theory and practice of community consultation has its limitations. Most community consultation guidelines on protecting communities from research harms have focused on indigenous communities, which are generally geographically bounded, socially distinct, and have traditions of self-identification and political autonomy. To the extent that other communities do not have these characteristics, community consultation may be problematic (Weijer and Emanuel, 2000). Indeed, it may be difficult to define the community in question or to identify appropriate representatives. Community consultation may produce locally variable findings in geographically dispersed populations and highlight difficult-to-reconcile perspectives caused by nested social identities (Foster et al., 1999). More formalized processes, though more involved, may address some of these concerns

Community Advisory Boards

Community advisory boards have been proposed as one mechanism for meaningful community input into the design of research projects (Quinn, 2004; Morin et al., 2003). Advisory boards offer an opportunity to adopt a relationships paradigm that enables researchers to anticipate and address the context in which communities understand risks and benefits and individuals give consent (King et al., 1999; Fisher, 1997). Community advisory boards can be created to advise a specific study or have oversight of multiple studies by an investigator or institution; see Box 5-3 for an example. They often advise researchers by assisting in the development of materials, representing participant concerns, disseminating information about the study and its risks and benefits to the community, providing a set of recommendations to help potential participants decide whether or not to participate in a study, and acting as advocates for rights of human subjects. Advocacy might include creating documents and resources that support participants' rights and promote community perspectives, refocusing the research question on the needs of vulnerable groups, and modifying or stopping trials that are considered or become unethical (Cox et al., 1998; Morin et al., 2003; Quinn, 2004).

BOX 5-3
Seattle Partners for Healthy Communities

The goal of Seattle Partners for Healthy Communities (SPHC) is to "support and evaluate community-based health promotion programs that are sensitive to the cultural needs of minority communities in Central and Southeast Seattle." SPHC uses a participatory action research approach that stresses "participation, equal power, and joint planning." SPHC developed a community-researcher model that included a community board of residents, activists, community-based organization staff, health professionals, and researchers. This board developed collaborative principles that (1) ensure community participation; (2) respect community values, contributions, and perspectives; and (3) ensure community benefit from the research. Responsibilities of the board include selecting and monitoring projects, as well as approving grant applications, budgets, and hiring decisions. Each project has its own steering committee, which designs the project and evaluation, oversees the project budget and implementation, reviews findings, and helps disseminate results. The board provides feedback and offers suggestions to steering committees on a quarterly basis.

One SPHC project is the Seattle-King County Healthy Homes Project (SKCHH), designed to "improve asthma-related health status by addressing poor housing and indoor environmental quality." The first phase of SKCHH was a randomized controlled trial of an outreach and education intervention to reduce exposure to allergens, irritants, and toxins in homes. The intervention included home environmental assessment by a community health worker, who developed an action plan with participants to reduce exposures. Over the next year, outreach workers made seven additional visits to provide education, social support, and resources to reduce exposure, and advocacy for improved housing conditions.

The project steering committee included representatives from national and

Community-Based Participatory Research

Community-based participatory research is an intensive approach that allows communities affected by research to participate in all phases of the research process. Under the principles of community-based participatory research, research must address the concerns, needs, and priorities of the communities where it is conducted and lead to actions and changes that benefit the community. Community stakeholders are active partners in all aspects of the study, from the formulation of research questions to the application of findings. They use their knowledge and experience in the community to specify issues to be studied, develop research questions in culturally sensitive ways, and use study results to help support relevant program and policy development (Israel et al., 2003). Community-based participatory research has been used in research on a range of topics, in-

community organizations—including the American Lung Association, Center for Multicultural Health, Community Coalition for Environmental Justice, Seattle Housing Authority, Community Health Centers—the health department, and university faculty. The steering committee promotes power sharing between the community and researchers, oversees project implementation, and reviews evaluation findings. In addition, a parent advisory group was convened to obtain input directly from affected community residents. Members were recruited through contacts in public housing, health, and environmental justice communities. Each member is reimbursed for meeting time ($10/2-hour meeting) and is provided with dinner, child care, and transportation. The group meets once or twice a year to provide advice on project implementation and evaluation, as well as their perceptions of the collaborative process.

Issues raised by community partners have included: tensions between working to improve housing quality while minimizing risk of eviction for tenants; sensitivity of entering homes and evaluating levels of asthma triggers (e.g., presence of cockroaches, level of household cleanliness); recruitment difficulties related to mistrust of government by people of color, especially immigrants; the length, cultural appropriateness, and validity of surveys; use of control groups that receive no benefit and randomization of study participants; and the high complexity and unacceptability of some intervention protocols. These concerns were addressed openly at steering committee meetings. Resolutions included protocols developed to instruct tenants on their rights, show them how to approach their landlords, and make referrals to the tenants union; simplification or elimination of other protocols; removal or revision potentially offensive or overly intrusive questions on the survey and the provision of a lower-intensity version of the intervention to the control group.

SOURCES: Information from Kone et al. (2000); Krieger et al. (2002a, 2002b); Metzler et al. (2003); and Krieger et al. (2005).

cluding cancer screening, international public health, nutrition, genetics, tobacco control, as well as research on housing health hazards (Viswanathan et al., 2004; Ammerman et al., 2003; Corbie-Smith et al., 2003; Israel et al., 2003; Lam et al., 2003; Lewis et al., 2004; Metzler et al., 2003; Minkler and Wallerstein, 2003; Naylor et al., 2002; Parker et al., 2003a; Riley et al., 2001; Sloane et al., 2003; Weijer and Emanuel, 2000; Mercer et al., 2004).

Community-based participatory research views community members as equal partners with researchers (Viswanathan et al., 2004; Minkler and Wallerstein, 2003). Such a partnership requires a long-term process of mutual learning, capacity building, and sharing of resources. This approach builds on the strengths and resources within communities. It involves learning on the part of both researchers and community representatives, recognizing the expertise of each individual; see Box 5-4. Scientists need to learn the values and perspectives of the community and the organizations and

BOX 5-4
Community Action Against Asthma

Community Action Against Asthma (CAAA) is a project of the Michigan Center for Environment and Children's Health, which was funded by the National Institute of Environmental Health Sciences and the Environmental Protection Agency. The housing-based intervention of the project stemmed from research on the effect of indoor and outdoor air quality on childhood asthma and was adapted from the Seattle-King County Healthy Homes Project (see Box 5-3). The intervention consisted of at least 12 home visits over 2 years by a "community environmental specialist" who provided families with education and materials related to the reduction of exposure to asthma triggers. In addition to the housing-based intervention, there was a complementary neighborhood intervention in which community organizers worked with community residents to reduce physical and psychosocial environmental asthma stressors on a neighborhood level. Recruitment occurred in public schools, where screening questionnaires were sent to parents of children aged 6-10 to identify those with symptoms of asthma; 328 families agreed to participate. It was a randomized study design with delay, so that half the families received the household intervention immediately after baseline data collection and the other half received the intervention during the second year.

Of the families that began the intervention, 81 percent of the children were African American, 10 percent were Latino; 46 percent of the families reported incomes of less than $10,000 a year; 47 percent of the children fell into the moderate to severe asthma category; and 82 percent of the children had been previously diagnosed with asthma.

The adoption, implementation, and evaluation of CAAA was conducted in accordance with the principles of community-based participatory research. One focal point of the project was the establishment of a steering committee that was actively involved in all major phases of research. The steering committee was made up of representatives from community-based organizations, the local health department, an academic institution, the integrated health care system, and one non-institution-affiliated member. Sample accomplishments included:

- building a diverse steering committee with good working relationships;
- identifying previously undiagnosed children with asthma;
- obtaining a better tailored research endeavor because of the community member input in the formation stage;

resources within the community. Community representatives need to learn about the problems to be studied, research methodologies, and organizational skills. Partners need to learn from each other and be willing to teach each other. This process requires patience, openness to new knowledge, interpersonal skills, and respect for people from different backgrounds. Community representatives can be empowered through data, the communication of study findings, and health literacy materials or workshops to take

- providing opportunities for interdisciplinary learning; and
- disseminating of data and information into the community.

There were also several challenges encountered in the implementation of community-based participatory research principles, including:

- identifying and recruiting new steering committee members from local health care systems, parents of children with asthma, specific ethnic groups and residents in geographic locations, and other academic institutions;
- managing the constraints and costs of doing community-based participatory research across different organizational cultures;
- ensuring community participation in day-to-day research and governance decisions;
- tension between the time, energy, and resources spent in conducting basic research time for the intervention component;
- feeding back research data to the community in a timely and understandable fashion;
- sharing information and learning ways to communicate; and
- maintaining trust.

The research and community partners of CAAA derived several lessons from each effort to adhere to the principles of community-based participatory research. For example, they found that:

- time and support are needed in the early stages of the project in order to establish trust and jointly define priorities;
- trust and positive working relationships need to be monitored and maintained, and decisions around governance and the decision-making structure need to be revisited throughout the project;
- continuous process evaluation, including feedback, reflection, and action, is necessary;
- the costs of participation must be considered and incorporated into the project budget; and
- strategies to minimize those costs also have to be pursued.

SOURCES: Information from Lewis et al. (2004); Parker et al. (2003a, 2004).

action on their own behalf. The process is cyclical and iterative, requiring time and commitment. Communities may change over time, and therefore the relationship between researchers and communities will also evolve. Partnerships ideally are developed for the long term, not just to obtain a single grant or project.

Community-based participatory research advocates sharing of decision-making power and resources between researchers and community part-

ners. Most often this takes the form of community advisory committees, although there are also examples of steering committees in which community partners had equal power. For example, at the Columbia Center for Children's Environmental Health, the community partner serves as a co-principal investigator and is codirector for the community outreach and translational research component of the project.

Even with this approach there can be considerable variability in the extent of community influence on the research process. An evidence-based review conducted for the Agency for Healthcare Research and Quality found that community partners were involved in intervention design and implementation in 93 percent of intervention studies and involved in participant recruitment and retention in 83 percent of intervention and nonintervention studies (Viswanathan et al., 2004). Community partners were involved with helping to set research priorities in 47 percent of all studies. There was little mention of community involvement in data interpretation or manuscript preparation. In some cases, limiting the community's involvement in data interpretation may be appropriate to avoid actual or perceived lack of objectivity. At the same time, community partners might be able to help the researchers understand why certain results have occurred.

Community participation varied greatly across projects carried out through the Centers for Children's Environmental Health and Disease Prevention Research, all of which were required to incorporate a community-based participatory research component (Israel et al., 2005). At most centers, community partners made valuable contributions in research design, development of data collection instruments, and recruitment and retention activities. For example, in one study community partners who insisted that all child subjects receive some direct benefit from the research convinced investigators to change a control group to a delayed treatment group. Community partners could also suggest new topics for data collection and ensure that instruments were culturally appropriate. Community partners were active in developing appropriate and effective strategies for recruitment and retention of child subjects. In some cases, community partners were involved with data collection through the hiring and training of local residents. Moreover, community partners played important roles in disseminating the findings of the research to the community in various ways, as well as providing general information to the community about the topic of study. However, community partners played little role in defining the research topic and questions and in data analysis and interpretation.

Community involvement in housing research has the potential to produce tangible research benefits in terms of better recruitment, better data, better analysis, and more relevant and sustainable interventions. However, there is also the potential for manipulation of individuals and communities, especially when involvement is limited and decision-making power of com-

munity members is absent (Hatch et al., 1993). When considering involvement of the community, it is important for researchers to clearly define the relevant community and carefully consider the extent of community involvement that enhances the research.

EVIDENCE ABOUT COMMUNITY INVOLVEMENT

While some consider achieving meaningful community involvement "a prerequisite for effective and efficient studies of children's environmental exposure" (Needham and Sexton, 2000, p. 615), most evidence regarding the benefit of community involvement relates to process measures rather than outcomes. These findings document both the degree of involvement community members had in the research process, as well as the intermediate results of that involvement (e.g., better recruitment and retention of study participants, greater participant satisfaction, more willingness to engage in further research studies, increased trust in researchers). The details are most commonly found in qualitative reports that are usually published separately from the main intervention results. This information is critical to determining whether the principles of community-based research are being followed (Israel et al., 1998) and may be helpful in improving the validity and reliability of data (Kagawa-Singer, 2000).

Greater participation may help investigators to determine how best to understand, approach, and address housing health hazards in a particular community. A systematic review of community-based participatory research interventions (Viswanathan et al., 2004) found the most common outcomes were enhanced program quality (11 of 12 studies) and recruitment efforts (8 of 12 studies). Other outcomes included improved research methods, dissemination, and descriptive measures.

One example of these enhanced research processes comes from The East Side Village Health Worker Partnership in Detroit (Schulz et al., 2002). The partnership addressed social determinants of health problems, such as childhood asthma, using interventions and community change strategies at the individual, organizational, and community level. As a consequence of collaboration with the community, the research team produced a context-specific conceptual framework that guided development of a community survey. The researchers also concluded that the regular partnership meetings enhanced their understanding and interpretation of research findings.

Similarly, the Cameron Park Project of Cameron Park, Texas, used participatory action research in order to obtain valid and reliable information from community residents for an environmental health education program assessment (May et al., 2003). The communities were *colonias,* isolated, unincorporated rural settlements near the U.S.-Mexico border with marginalized Hispanic populations. The program used *promotoras,* or in-

digenous outreach workers, to address concerns that resident wariness would affect participation rates and data quality. The *promotoras* were involved in different areas of research design (e.g., designing the interview protocol), implementation (e.g., sampling and data collection), and evaluation (e.g., analyzing and interpreting data). These community members provided specialized expertise that improved data quality, accuracy, and interpretation.

Community involvement may also increase residents' trust of researchers (Corbie-Smith et al., 2004; Schulz et al., 1997). High levels of distrust of researchers are well documented, especially among minority populations (Corbie-Smith et al., 2002). In the Cameron Park Project, for example, using community residents in both decision-making and implementation roles helped to bridge researcher and community cultures in order to overcome resident guardedness towards outsiders (May et al., 2003). Increasing community participation in the research process may help establish and maintain "reciprocal relations," a two-way flow of resources that benefits the investigator, individual study participants, and larger community (Corbie-Smith et al., 2004). For example, increased trust was one of the intermediate outcomes identified in urban research centers, funded by the Centers for Disease Control and Prevention (Metzler et al., 2003), which required community collaboration. All members of the collaboration invested significant energy and resources into building trust. This increased trust was assisted by the creation of collaboratively developed principles and procedures, as well as the successful pursuit of research funds.

Less information is available on whether community involvement strategies lead to improvements in health outcomes or other project-level outcomes. One systematic review of community-based participatory research studies was unable to conduct a comparison of the relative health effects of the interventions, because methods and outcomes differed across projects (Viswanathan et al., 2004). Another review of health-focused collaborations found evidence of community-wide behavior change (e.g., decreased substance abuse, increased physical activity, more safer sex) as a result of the partnerships (Roussos and Fawcett, 2000); however, the authors concluded that there was insufficient evidence to determine the impact of collaborative activities on population-level morbidity and mortality.

There are limits to what is known or can be known about the outcomes of community involvement. First, the published literature about community involvement in environmental health research is most commonly about community-based participatory research strategies. Second, most research on community collaboration has been descriptive rather than comparative (Thompson et al., 2003; Zakus and Lysack, 1998), and few studies have investigated whether greater community involvement in research is related to better project outcomes (Roussos and Fawcett, 2000; Viswanathan et al.,

2004). Additional outcomes research is needed to better understand the effects of various levels of community involvement in research on the subsequent health and well-being of communities and families who participated in research.

ISSUES IN COMMUNITY INVOLVEMENT

Involving communities and community residents in research poses challenges that must be considered in the design of the research project.

Definition of Community

Communities may be characterized in a variety of ways (Weijer and Emanuel, 2000). The term *community* is used to refer to a variety of populations comprised by persons who have, or are perceived to have, commonalities that can be identified. Weijer and Emanuel (2000) propose a typology of morally relevant characteristics of communities involved in research. These include a common culture and history, legitimate political authority, geographical localization, a common economy and resources, and self-identification as a community. At one end of the spectrum are communities with a defined political and cultural identity, such as Native American tribes; other communities, such as those defined by a disease, may be much less cohesive.

Because the word is used in a variety of contexts and with different meanings, it needs to be defined carefully. Some groups are cohesive in the sense that they self-identify as a community. Some groups may be defined by geographical boundaries, while other groups may be physically dispersed. Some groups may be characterized by a common culture or ethnicity, while other groups may be culturally or ethnically diverse. Still others may be defined by a particular physical condition. Before they undertake a project, researchers need to identify the community that is relevant for that project.

Researchers on housing health hazards involving children must recognize that a community that appears homogeneous may actually be quite heterogeneous. For instance, residents of a low-income neighborhood may appear to be homogeneous—for example, African American and Latino. However, the perceived African Americans may be of African or Caribbean heritage, and the Latinos may have emigrated from a variety of Spanish-speaking countries with differing cultures, history, and traditions.

The continuing legacy of institutionalized racism, housing segregation, or "residential apartheid," as sociologist and environmental justice advocate Robert Bullard writes, tends to cluster residents of color—whose backgrounds are of specific ethnic, racial, or national origin (regardless of in-

come and class)—in contiguous, overlapping, or densely populated geographic areas (Bullard, 1994). For example, a multifamily building may be located in a low-income area but may have residents of differing class, income levels, and educational attainment. To the extent that persons of higher educational and economic levels live in housing containing health hazards, it would be advisable for researchers to try to include such children as study subjects.

The projects of the Centers for Children's Environmental Health and Disease Prevention Research took a variety of approaches to defining community. Most used "geographic boundaries and common characteristics," which included "lack of resources and disproportionate burden of health problems they face" (Israel et al., 2005). Some centers involved "communities of identity," defined by ethnic background. In two cases, centers decided that diverse stakeholders in a large geographical area needed to be involved, for example "both farm workers and representatives from agricultural industry organizations." One center defined the community in terms of having a child with a specific condition.

Identification of Community Representatives

Once "community" is defined, it may still be unclear which residents are representative of the identified community. There may be diverse views regarding the research. Some communities may have a formal governmental structure and a recognized political authority, as Native American tribes. Other communities may lack political authority but have clearly defined leaders, as in religious communities. However, leadership may be contested: even when there is legitimate political authority, critics may charge that the leaders are not acting in the best interests of the community with regard to the proposed research project.

In communities with a diversity of leaders and views, there is a risk that researchers will selectively work with those who are favorable to the research project. Moreover, there are ethical concerns that the community representatives with whom the researchers are working may not legitimately represent the interests and views of those who have not been consulted about the research (Juengst, 2000). At the extreme, researchers may engage in "forum shopping," which has been characterized as "the 'morally problematic' practice of seeking out population spokespeople and research participants whose positive response to a research plan can be predicted in advance" (Juengst, 2000). In many communities, there are multiple sources of leadership and authority. Careful consideration must be given to what aspect of the community a particular person or organization will represent and how researchers can hear the range of views in a community. Researchers need to be imaginative in trying to identify different voices in a commu-

nity and ensure that residents are represented. While the specific community representatives to be consulted depend on the protocol and the communities where the studies will be carried out, researchers should consider reaching out to multiple nongovernment organizations such as places of worship, social service agencies, tenant advocacy groups, and other advocacy groups.

Goals of Community Involvement

Weijer and Emanuel (2000) specify various ways in which communities might be protected in research, including consultation in protocol development, disclosure of information about the research to the community, informed consent by the community before individuals are approached about participating in the research, involvement in the conduct of the research, and involvement in dissemination and publication of results. They argue that there are "particular characteristics of communities . . . necessary for the implementation of specific protections" (Weijer and Emanuel, 2000, p. 1143). In their view, only cohesive communities with legitimate political authority can make binding decisions to approve or reject a study on behalf of the community. No one set of protections or procedures for community involvement will be appropriate in all situations and types of research. Similarly, others argue that community approval "seems workable only with small groups that have a well-defined leadership structure" (Reilly, 1998, p. 684). However, Foster et al. (1999, p. 1719) argue that "community concerns can be incorporated into existing review mechanisms without necessarily giving communities the power to veto research proposals." Foster provides two examples in which broadly based consultation in communities that lacked political organization and established moral leaders identified risks in the research that were perceived as important in the communities. Moreover, the researchers were able to address those concerns by revising the protocols. Foster suggests that the aim of community discussions should be "to identify possible risks and concerns, not to formally approve or disapprove individual research protocols" (Foster et al., 1999, p. 1723).

Although the above analyses of the challenges in community involvement in research were based on genetics research, much of the analysis is pertinent to research on housing health hazards involving children. Testimony of community representatives before the committee, as well as the experiences of Committee members who carry out such research, confirm that community discussions can identify concerns and risks that researchers (and IRBs) would not have identified or weighed as much. Although community representatives need not be given decision-making power over protocols, and community consensus is not a precondition to conduct research, it

is possible for community concerns to be addressed by researchers in ways that do not compromise, and may enhance, the scientific value of a study. Indeed, responding to community concerns may reduce the risks of the study and enhance its benefits. These kinds of discussions can be carried out in many ways, depending on the project, the community, and the relationship between the researchers and the community. However, the level of risk and the potential for direct benefit to the child subjects should be considered when determining how to involve the community, with projects that present more than minimal risk and no prospect of direct benefit expected to engage the community in a meaningful way, consistent with the principles of community-based participatory research (see Chapter 8 for a discussion of research that presents more than minimal risk and no prospect of direct benefit). In all cases, however, the committee believes that the most important issue is to ensure that the community is informed, their concerns about the research are articulated and heard by the researchers, and that researchers respond to those concerns.

Practical Challenges

Community involvement requires infrastructure and the investment of researchers' and residents' time, which are not typically supported by research grants. Because grants usually do not cover the true effort required in community involvement, researchers and community partners often have to "donate" considerable time, as well as resources, for travel and related expenses. At a minimum, community residents or organizations involved with a research project should be reimbursed for expenses; ideally, they would also be compensated for their time. However, researchers have to balance the need to provide appropriate compensation with the possibility that the level of compensation will affect, or be perceived as affecting, individuals' or organizations' views about the research. The appropriate level and method of payment will depend on the specific project. Several authors have advocated for funders to take a more active role in supporting and encouraging community involvement in research (Green and Mercer, 2001; Minkler et al., 2003; Israel et al., 2005).

Policies at research institutions may make it difficult for researchers to provide tangible support to community partners. Overhead charges imposed by research institutions on subcontracts to community groups may be substantial and may discourage full partnerships. Plans to hire research staff from the community may conflict with institutional human resource policies, which may require traditional job descriptions and educational degrees. However, many community-based organizations and social services groups employ staff from the community with diverse skills and professional backgrounds in public health, urban planning, social work, and

health education. The Columbia Center for Children's Environmental Health contracts with a community-based environmental justice organization to provide specific outreach and organizing efforts in order to translate center findings into policy and educational interventions (Peggy Shepard, personal communication, November 2004).

Different communication styles may make partnerships difficult, even when stakeholders can overcome a history of mistrust. In some communities, English may not be the predominant language, and few researchers may speak the prevalent language in the community. Even if translators are available and documents are translated, residents who do not speak English fluently may not be able to participate actively in meetings. Other aspects of communication style may also present unintentional barriers to full participation by community partners. Researchers commonly use e-mail to communicate, but community partners may prefer face-to-face communication or may lack access to the Internet.

The characteristics of the community, the kinds of resources available, and the history of community organizing will have implications for the type of involvement in research that is feasible and appropriate. There will be times when researchers have to make decisions to retain the scientific rigor of their project over feedback from the community. A single set of guidelines for community participation will not be appropriate for the disparate types of communities that may be involved in different types of research projects (Israel et al., 2003; Weijer and Emanuel, 2000). In several research projects on housing health hazards involving children, community participation has been incorporated in the planning, design, and implementation of the research project. However, no single model of community involvement will work in all situations and in all types of research (Israel et al., 2005; Minkler and Wallerstein, 2003; Weijer and Emanuel, 2000; Israel et al., 1998). A number of commentators argue that the characteristics of community-based participatory research are an ideal but may not be attainable in every case (Israel et al., 1998; Reilly and Page, 1998).

CONCLUSIONS AND RECOMMENDATIONS

Community involvement in research on housing health hazards with children has the potential to lead to greater understanding of community perspectives of the risk and benefits of research, improve informed consent, increase study enrollment, enhance data validity and quality, and build trust for research. When involving communities in the design or conduct of research, researchers must resolve questions about who represents communities and their subgroups, how conflicting viewpoints in the community are voiced, and whether the process for selecting community partners is appropriate.

Community involvement, though time and resource intensive, is a necessary and useful component of housing health hazard research with the potential to enhance trust and increase the relevance of research to affected communities. Thus, attention to the issues raised by the community and consideration of the most appropriate method of community involvement for a given research project is warranted. As funders and researchers devote more attention to community involvement, the mechanisms and effective approaches to community involvement will become further refined.

Recommendation 5.1: Researchers carrying out research on housing health hazards involving children should describe in their protocols and IRB submissions how they have involved and will continue to involve the affected community in the research project, justify the lack of such involvement, and report how they have responded to any community concerns.

Recommendation 5.2: Institutional review boards should require appropriate community involvement in housing health hazards research involving children and require that investigators' protocols are responsive to any community concerns.

Recommendation 5.3: Federal agencies (e.g., U.S. Department of Housing and Urban Development, the Environmental Protection Agency, National Institutes of Health, Centers for Disease Control and Prevention), private foundations, and other funders of research on housing health hazards involving children should require researchers to have appropriate community involvement in the research. Funders should provide adequate funding to involve affected communities and should sponsor research to evaluate the outcomes of community involvement.

6

Parental Permission, Consent, and Payment

Ensuring that decisions to enroll in research are truly informed and voluntary can be a challenge in any type of research involving human participants. Research indicates that adult research participants frequently do not understand important aspects of the research. Furthermore, when research projects provide payments to participants, it raises complicated ethical issues regarding undue influence. Similar ethical issues occur when parents give permission for their children to be enrolled in research. Potential problems may be even more pronounced for research with economically and educationally disadvantaged populations, particularly those who have low literacy levels or are non-English speaking and therefore may have particular difficulty understanding important aspects of a research protocol. In addition, when research participants have limited incomes, there is particular concern that payment levels may have undue influence over their decision to enroll in the research project. This chapter analyzes the current regulatory requirements related to consent and the ethical issues regarding consent and payment in the context of housing health hazards research and offers recommendations to achieve the goals of informed, and voluntary consent.

INFORMED CONSENT

Free and informed consent is considered a fundamental requirement of research. It respects participants by ensuring that they do not participate in research without their knowledge and consent. Informed consent requires that the decision to participate is intentional and voluntary and that the

decision maker understand the nature of the research and its prospective benefits and risks.

When young children are the subjects of research, they cannot give informed consent because they lack the maturity to make informed decisions; instead, their parent(s) or guardian(s) must give informed permission. In addition to parental permission, a child generally must assent to participate in the research when this is developmentally appropriate. Parental permission and the child's assent when developmentally feasible are ethically appropriate because they show respect for children as persons. Although young children cannot be autonomous, their preferences can still be respected. In this report, "consent" is used to refer to the combination of parental permission and child assent.

Parental Permission

Informed permission from parents may be particularly problematic with regard to research on housing health hazards involving children. Often parents in such studies are poor, poorly educated, and members of ethnic groups that have suffered discrimination. They may have difficulties making informed decisions about their children's enrollment in such research, particularly in light of problems that are known to occur in the research consent process. We discuss these issues in greater detail later in the chapter.

The *Belmont Report* (National Commission, 1978; see Chapter 3) identified the three elements of informed consent as information, comprehension, and voluntariness. However, as stressed in the report of the National Bioethics Advisory Commission (2001b, p. 98), "the actual procedures emphasize disclosure requirements, and in so doing may distort the understanding of the ethical principle of respect for persons."

The federal regulations governing federally funded or conducted research involving humans outline a number of requirements for both the process of obtaining informed consent to participate in research and the substantive information that must be provided to a prospective participant.[1] Researchers must allow sufficient opportunity for a prospective participant to consider the decision to participate and minimize the possibility of coercion or undue influence (45 CFR 46.116). The information must also be communicated to the potential participant in a language that is understandable to the participant; see Box 6-1 for the information that the regulations require be included in the consent process.

[1]Informed consent is not required for research that is exempt from review and can be waived under certain limited conditions (see 45 CFR 46.117 (c)).

BOX 6-1
Required Informed Consent Information

During the informed consent process, parents of potential child subjects must be provided detailed specific information about the research, including (45 CFR 46.116(a)(1)-(8)):

- an explanation of the purposes of the research,
- the expected duration of the child's involvement,
- a description of procedures to be followed and identification of any experimental procedures,
- a description of any reasonably foreseeable risks or discomforts to the child subject,
- a description of any reasonably expected benefits to the child subject or others,
- a disclosure of appropriate alternative procedures that may be advantageous to the child subject,
- a description of the extent to which the confidentiality of records will be maintained,
- an explanation as to whether any compensation is provided or what treatments are available if injury occurs if the research involves more than minimal risk,
- an explanation of whom to contact for questions about the research, and
- a statement that enrollment is voluntary and that refusal to continue to participate will not result in a loss of benefits the child is otherwise entitled.

Additional information may be required under appropriate circumstances (45 CFR 46.116(b)).

Specific additional information that may be relevant to include in the consent process for housing health hazards research would include information about the risks of the hazards being studied. As discussed in Chapter 1, this information may be very relevant to a parent's decision whether or not to enroll her or his child in the study. Furthermore, a parent may need information before the study commences on what hazards pertinent to the topic of the study are present in the housing, what hazards will continue to be present in the home after the research is completed, and how those hazards may adversely affect a child's health. This information will help to prevent common misconceptions about housing research and reduce the likelihood that parents have a "therapeutic misconception" about the research. An additional topic that needs to be discussed during the informed consent process is whether the results of any tests conducted as part of the research protocol will be provided to parents and if so, how and when they will be provided (see Chapter 7).

Whether the permission of one parent is sufficient or the permission of both parents is required depends on the type of research.

> If the IRB [institutional review board] determines that the research involves more than minimal risk but is not expected to benefit the child subject, the regulations require that investigators secure permission from both parents. If the IRB determines that research involves no more than minimal risk or that it holds out the prospect of direct benefit to the child, the IRB may decide that the permission of one parent is sufficient. Permission from one parent is also sufficient if that parent is legally responsible for the care and custody of the child or when the other parent has died or is unknown, incompetent, or not reasonably available (Institute of Medicine, 2004, p. 104).

Assent

With certain exceptions, the federal regulations provide for children's agreement or assent to be involved in research. Researchers must seek a child's assent unless the institutional review board (IRB) determines that (1) the children to be involved (as a group or individually) are not capable of providing assent, given their age, maturity, or mental state; (2) the research has a prospect of an important direct benefit for the child that is possible only in the research context; or (3) the research involves circumstances that would allow waiver of consent for adults. Assent is obtained after the protocol has been approved and usually after the parents have decided that it is appropriate for their child to be involved. IRBs are given discretion in evaluating assent provisions in any given protocol; the federal regulations do not describe the information that must be provided to children.

The report *Ethical Conduct of Clinical Research Involving Children* (Institute of Medicine, 2004) points out that, although the literature is limited and somewhat inconsistent, it supports a gradual expansion in children's involvement in discussions regarding enrollment in research participation as they mature and provides some guidance. It recommends that the views of children be considered and respected both individually and as part of a family unit and that the process of assent should

> be developmentally appropriate given the ages and other characteristics of the children to be approached; provide opportunities for children to express and discuss their willingness or unwillingness to participate; clarify for parents and children (as appropriate) the degree of control that each will have over the participation decision; and when appropriate, describe to children and parents the kinds of information about the child that will or will not be shared with the parents (Institute of Medicine, 2004, p. 205).

Comprehension of Potential Participants

Considerable research indicates that adult participants in research studies commonly fail to understand important aspects of research protocols (Institute of Medicine, 2004; National Bioethics Advisory Commission, 2001; Advisory Committee on Human Radiation Experiments, 1998; Wendler, 2004). Most of the empirical studies involve adults consenting to be research subjects themselves. However, evidence from more limited pediatric studies suggests that there are also misunderstandings when adults are giving permission for their children to enroll in research. The informed consent process and research on adult's comprehension of the content of informed consent point to several areas of concern.

First, IRBs place their attention on consent forms rather than on the process of providing and discussing information. Federal regulations specify what kinds of information must be provided to research participants or their representatives (see Box 6-1). IRBs typically spend considerable time revising consent forms. However, an analysis of model consent forms posted on IRB websites found that the average readability score was higher than the tenth-grade level, above the level recommended by IRBs themselves (Paasche-Orlow et al., 2003). Studies of actual research project consent forms show that many are written at the level of a college graduate (Advisory Committee on Human Radiation Experiments, 1998). There is some evidence that revisions of consent forms by IRBs lowers their readability scores (Burman et al., 2003). Simplified consent forms can improve comprehension by research participants (Coyne et al., 2003), and several studies report that parents found discussions with research staff more useful than consent forms (Flory and Emanuel, 2004).

Second, adult participants in research commonly have misunderstandings about the purpose of research. Joffe and colleagues found that participants in early clinical trials usually expect that they will personally benefit from the trial, even when the primary purpose of the research study is to test safety not efficacy (Joffe et al., 2001). This tendency to view clinical research as providing a personal benefit has been termed the "therapeutic misconception" (Lidz and Applebaum, 2002).

Third, adult participants may misunderstand essential features of the design of the research study (Wendler, 2004). Randomization is a frequently misunderstood concept (Kodish et al., 2004). In one study of parents who had discussed with researchers their child's participation in leukemia clinical trials, researchers found that 50 percent of parents did not understand randomization although physicians had discussed randomization with parents in 83 percent of the discussions (Kodish et al., 2004).

Although there are relatively few studies of consent in the pediatric setting, problems have been documented. For example, Tait and colleagues

adapted the Deaconess Informed Consent Comprehension Test to test parents' and children's understanding of parental permission and child assent in multiple studies, focusing mainly on research during anesthesia for surgical procedures. They found that "parents . . . had inadequate understanding of the elements of informed consent" and "children . . . have limited understanding of the elements of disclosure, particularly if they are younger and did not read the disclosure information" (Nelson and Reynolds, 2004, pp. 19-20 [citing Tait et al., 2003a, p. 606; Tait et al., 2003b, p. 609]). Individual perceptions of risk appear to affect informed consent. In research involving diabetic adolescents, several adolescents and their parents did not consider hypoglycemia that might result from study procedures to be a risk because of their confidence that they would be able to handle the situation should it occur (Nelson and Reynolds, 2004). That is, perceptions of risk may be influenced by parents' previous experience with the disorder or condition being studied.

An additional issue that may contribute to parents' comprehension of research projects is low literacy in the United States, particularly among low-income populations, *Health Literacy: A Prescription to End Confusion* found that about 40 million Americans cannot read complex texts, like those typically found in research consent forms (Institute of Medicine, 2004). It reported that "the levels of informed consent documents . . . exceed the documented average reading levels of the majority of adults in the United States" (p. 191) and that literacy levels are lower among those who are poor, minority populations, and groups with limited English proficiency, such as recent immigrants (Institute of Medicine, 2004). These findings suggest that comprehension of written consent forms is even more challenging for the groups often targeted for housing health hazards research.

Moreover, adults with limited literacy often have limited knowledge of disease management and of health-promoting behaviors. One study of the consent process for a clinical trial for childhood leukemia compared non-English-speaking Latino parents with English-speaking non-Caucasian parents from several ethnic backgrounds and English-speaking Caucasian parents. Researchers found that the physicians tended to omit key information from discussions with non-English-speaking parents, such as information about randomization and the right to withdraw from a clinical trial. Physician explanations of the clinical trial were less clear with the non-English-speaking parents. Moreover, non-English-speaking parents asked fewer questions than parents in the other groups. Despite the need for translation, total time spent did not differ among the three groups. Most important, the study found that fewer non-English-speaking parents understood key concepts, such as randomization, the difference between clinical trials and standard care, and the voluntary nature of research (Simon et al.,

2003). In this study, differences might have resulted from many factors, including different amounts of information provided and social status, as well as English proficiency.

There are no systematic studies of the consent process in research on housing health hazards involving children. Some findings from studies carried out in other situations, particularly studies with children recently diagnosed with leukemia (Kodish et al., 2004; Simon et al., 2003), may not be generalizable to research on housing health hazards involving healthy children. However, the Grimes case (see Chapter 3) highlighted issues specific to housing health hazards research. Among other allegations, the plaintiffs claimed that they were not fully informed of the risks, raising concerns about the consent process. As mentioned in Chapter 3, the court ruled that the consent form was not valid because "full material information was not furnished" and determined that, even though some of the housing units had been abated and the others contained lead prior to the research, the researchers needed to disclose that "some of the children might ingest dust lead particles" and "there might be some accumulation of lead in the blood of the children." This case raised the specific issue of whether consent discussions should be broadened to include discussion of risks to children that might occur as a result of their normal living environment rather than as a result of the research interventions: for example, the risks of living in housing that contains lead paint or other health hazards.

In light of these data, researchers and IRBs cannot assume that parents understand information about the research project that has been disclosed to them. To ensure that parents understand the project, researchers would need to test their comprehension. *Responsible Research: A Systems Approach to Protecting Research Participants* (Institute of Medicine, 2002) emphasized that informed consent should be an ongoing discussion of relevant information between investigator and participant, not a signature on a long and complex consent document. That report recommended that the informed consent process should include an "assessment of the individual's understanding of the discussion" (p. 120). While there are several tools available to assess comprehension that have been used in research on informed consent (e.g., Deaconness Informed Consent Comprehension Test and the MacArthur Competence Assessment Tool for Clinical Research), there are no standard mechanisms for assessing comprehension in the practical context of research (Nelson and Reynolds, 2004).

Interventions to Improve Comprehension

Informed consent requires that researchers provide to participants (or to the parents of child subjects) information that they can comprehend. In light of the evidence that research participants frequently do not under-

stand important features of research, investigators need to consider what they can do to help potential child subjects and their parents better understand the research project. A recent critical review of research on interventions to improve research participants' understanding of information concluded:

> Efforts to improve understanding through the use of multimedia and enhanced consent forms have had only limited success. Having a study team member or a neutral educator spend more time talking one-on-one to study participants appears to be the most effective available way of improving research participants' understanding (Flory and Emanuel, 2004, p. 1593).

Of 12 trials of multimedia interventions, only one showed a significant improvement in understanding using a computerized presentation of information. Interventions to improve consent forms also had limited success. The only rigorously designed study that showed improvements in a real consent process shortened the consent form from four to two pages, removing standard but irrelevant information on risk. Evidence for improved understanding was stronger for interventions that increased discussion between research staff and study participants. There was also evidence that a test-feedback approach increased participants' understanding: in these studies participants were tested on their understanding and given additional information on questions they answered incorrectly. However, these studies were flawed methodologically because they may have tested memorization rather than understanding. Although this research on improving consent has been carried out with adults participating in clinical research, similar findings may hold in the setting of parents giving permission for their children to enter research studies as well.

A more detailed description of some studies that showed improvement in comprehension shows the flavor of interventions that might be carried out. One study was a randomized clinical trial of an intervention to improve the consent process in a hypothetical HIV vaccine trial (Coletti et al., 2003). The study intervention involved setting the reading level at the eighth-grade level, enhancing the visual display of consent documents, making an audiotape of the consent form for low-literacy participants, having educators who are independent of the research team discuss the research with participants, and providing time and opportunity for participants to ask questions and discuss the trial. This consent intervention improved participants' understanding of key concepts about the trial, and the effect was found for people at all educational levels and for all ethnic groups.

Another study, published after the review article cited above, was a randomized trial that compared a videotape providing an overview of the informed consent process and the decision to enroll in a clinical trial with a

control educational videotape about the historical and regulatory aspects of human subjects protection (Wirshing et al., 2005). The videotapes were 16-18 minutes long and written at a fifth-grade educational level. The informed consent videotape resulted in a small enhancement in knowledge about informed consent, in comparison with the control videotape.

The National Cancer Institute (NCI) has developed a template for simplifying informed consent documents that uses a question-and-answer format.[2] The form is written at an eighth-grade level, and flow charts, diagrams, calendars, and other graphics are encouraged. A cross-sectional study provides some evidence that this template is effective (Joffe et al., 2001): it found that participants in cancer clinical trials who received information following the NCI template, had a nurse present at the consent discussions, and had more time to consider participation in the clinical trials had greater understanding and fewer misconceptions about research than those who did not.

Assessing the Adequacy of Informed Consent

Assessing whether research participants understand the information discussed in the informed consent process has been carried out in several international clinical trials (National Bioethics Advisory Commission, 2001; Fitzgerald et al., 2002; Coletti et al., 2003; Mariner, 2003; Woodsong and Karim, 2005). Participants in developing countries are vulnerable in numerous ways, including poor education, poverty, and poor access to medical care. Thus, international clinical trials face many of the same ethical concerns that arise in research on housing health hazards with children. When research is carried out in developing nations, concerns have been raised that participants do not understand the nature of the research, the difference between research and clinical care, the voluntary nature of research, and key features of the research design, such as randomization (National Bioethics Advisory Commission, 2001; Mariner, 2003; Woodsong and Karim, 2005). Researchers in these settings have developed simple questions to test whether participants understand key elements of the research. For example, participants in an HIV vaccine trial may not comprehend that they are still at risk for HIV even if they receive the experimental vaccine.

In some studies, researchers require potential participants to demonstrate that they understand crucial aspects of the trial before they are permitted to enroll in the study. Crucial items for demonstration might include

[2]The template can be found at http://www.nci.nih.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs/page2 [June 2005].

the following: (1) the research is different from clinical care; (2) interventions are determined by chance and not by what is thought best for the individual participant; (3) the effectiveness of the research intervention is unknown; (4) the research intervention has risks; and (5) the participant remains at risk for the outcome of the study (HIV infection) (National Bioethics Advisory Commission, 2001). Such assessments often are combined with enhanced discussions with participants about the research and provision of additional information to correct misunderstandings. HIV researchers in developing countries have found community advisory groups to be very helpful in identifying issues that are difficult to understand, pointing out concerns and problems that were not apparent to the researchers, and helping to develop more effective consent processes and materials (Woodsong and Karim, 2005). In the context of research on housing-related health hazards involving children, researchers could provide enhanced information on how the purpose of research is to obtain generalizable knowledge, not to benefit the child subjects directly.

This approach of testing to ensure that participants understand the essential features of the research study might also be used in other research (Wendler, 2004), particularly with research on housing health hazards involving children. For example, in a lead abatement study in which lead may exist in the home, a parent needs to know that the child is at risk for elevated blood levels despite the abatement procedures, as well as basic information about the project, such as the frequency and types of tests carried out. The specific information about a housing study that a parent needs to understand will vary depending on the study. Two important questions are who decides what is essential and what criteria should be used to make that determination.

The IRB is the arbiter of what information needs to be communicated to participants in a particular study. To make this judgment, the IRB should take into account the views of the community, and researchers should be required to solicit the views of the community. As discussed in Chapter 5, community representatives and advocates for child subjects and their parents may have different perceptions than researchers of what constitutes a risk or benefit and how much weight to give specific risks or potential benefits.

An argument can be made for weighing several elements of consent more heavily than others. The *Belmont Report* suggests that the essential information should be determined using the standard of the reasonable volunteer:

> It may be that a standard of "the reasonable volunteer" should be proposed: the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care *nor perhaps fully understood*, can decide whether they wish to participate in the fur-

> thering of knowledge. Even when some direct benefit to them is anticipated, the participants should understand clearly the *range of risk* and the *voluntary nature* of participation [emphasis added] (National Commission, 1978, p. 5).

This statement suggests that the two elements of "risk" and "voluntary choice" should have priority over the other elements of consent.

Voluntariness and Undue Influence

Voluntariness is an essential requirement for informed consent. According to a recent review by Nelson and Merz (2002), a voluntary act is an act of free will or personal choice that must be "done volitionally or with intent and deliberateness" and be "free from coercion and undue influence" (p. 69). Being a child, having low socioeconomic status or poor education, and having few options because of disease or social situation are characteristics that may constrain a person's ability to make voluntary choices. Although having limited options does not necessarily make choices nonvoluntary, it might make people more vulnerable to various influences.

Some actions by researchers may compromise the voluntariness of participants' decisions to enter research projects. The probability that a researcher's actions may be so strong as to control or determine the decision to participate depends on both the nature of the action and the vulnerability of the potential subjects. Some actions that could be readily resisted by most people might have a powerful influence on vulnerable persons. For instance, a payment level for participation that would have little influence on wealthy individuals might be difficult for a poor person to turn down: the threat to informed consent is that a person may make a decision to participate based on the payment level, without considering the risks of the research.

One way to determine whether a decision is voluntary is to consider whether parents would enroll their children if the potential influence were not present. Another approach is to ask people whether the decision to enroll their children in the study was a personal choice as opposed to feeling pressure from other people to join the study (Pace and Emanuel, 2005). While both approaches seem plausible, neither has been rigorously validated. Also both have conceptual shortcomings. The criterion of whether parents would agree to enroll their children without an incentive is difficult to test empirically. It may be useful to discuss the question with community representatives, who may have a different view than researchers of whether parents would participate without an incentive. Asking parents directly whether they made the decision themselves is another option. Their response may provide useful information if they say that others influenced them. However, a negative response may not be definitive because people

may not be conscious of strong influences on their behavior or may hesitate to disclose them to others.

The ethical concern is that some payments may be an undue inducement, which the *Belmont Report* defined as "an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance" (National Commission, 1978, p. 8). Undue influence needs to be distinguished from coercion, which can also subvert informed consent. Coercion is the use of a threat of harm or punishment to influence behavior (Institute of Medicine, 2004); payments cannot constitute coercion per se.

A recent review covered the topic of undue inducements (Emanuel, 2004). Federal regulations require investigators to minimize the possibility of coercion or undue inducement. The regulations do not define "undue inducement," but the IRB guidebook states that "offers that are too attractive may blind prospective subjects to the risks or impair their ability to exercise proper judgment" (U.S. Department of Health and Human Services, 1993, pp. 3-44). Thus, an undue influence is ethically problematical because it makes participants discount the risks of a research project and impairs their judgment. Emanuel (2004) argues that an undue inducement must lead a person in ways that "entail a substantial risk of serious harm that contravene a person's interest" (p. 101). In other words, the issue is not simply one of distorted judgment but "potentially serious adverse consequences of the bad judgment" (p. 101). He further argues that the key ethical issue is not the amount of money being paid to research participants but the level of risk the research poses. If the risk is acceptable (and judged to be so by an IRB), then a high payment level to participants is not an undue inducement but rather a boon to the participants. If the risk is unacceptable, that is the primary ethical problem with the study, not the amount of payment to participants. From a logical point of view, concerns about undue inducements are really concerns about excessive risk, inadequate IRB deliberations, exploitation, and problems with informed consent. Emanuel argues that such problems should be addressed directly; reducing payments to participants in a study will not address them. However, as discussed throughout this report, there is particular sensitivity regarding the acceptable level of risk in housing health hazards research.

Thus, this committee takes a somewhat different view of undue inducements. When concerns about undue inducement are raised, the underlying ethical problem may be unacceptable risk in the study, as suggested by Emanuel. Concerns may also be raised when there is a difference of opinion regarding risk between families involved with the research and researchers. In addition, large payments may compromise the research if parents' primary motivation is related to the incentive rather than the research itself. In such cases, child subjects and their parents may be less likely to provide

accurate and timely information. Because of concerns about the adequacy of the IRB review process, and the ongoing controversy regarding acceptable payment levels, the committee believes that identifying payments to participants that seem inappropriately large is useful.

First, IRBs may not identify risks that families regard as important. As noted in Chapter 4, parents may be concerned about not only the risks posed by interventions carried out by researchers, but also with risks of living in their housing environment, which their children will face regardless of any interventions by the researchers. Emanuel is certainly correct that problems with IRB review need to be addressed directly, and the committee recommends that IRBs require investigators to take adequate steps to consult with community representatives about their perceptions of a study and to respond to any questions raised (see below; see also Chapter 5). However, integrating community involvement into the research infrastructure may take time. In the interim, IRB attention to undue inducements can be useful in identifying problems with studies.

Second, seemingly high payments may serve to alert an IRB that it needs to look more closely at the risks of the study. In other words, apparently high payments may be a warning that there are other problems with a protocol.

Third, the issue of whether a person's judgment is compromised by financial incentives is an appropriate concern in the research setting even if the risks of the study are acceptable. Free and informed consent is an ethical requirement in human participants research even when the risks and benefits are acceptable. Thus, features of the study that impair free and informed decisions are objectionable because they violate the principle of respect for persons, independent of any problems with unacceptable risk that they may also cause.

The issue of whether payments will lead a potential participant to fail to adequately consider the risks of a study may be difficult for IRBs at research institutions to determine without greater input from people from similar socioeconomic backgrounds as the participants. In Chapter 8, the committee recommends that IRBs take steps to get input from community representatives; this input should include compensation levels. Finally, the committee was continually reminded that research projects on housing health hazards in children often enroll families who are vulnerable due to economic and educational disadvantage, in addition to bearing the burden of adverse health outcomes. In the communities in which research on housing health hazards in children is often carried out, there is frequently a mistrust of researchers. The perception of undue influence may be as important as the question of whether the concerns are really displaced concerns about other ethical issues. Rather than saying the undue inducements are not a problem in research on housing health hazards in children, it

would be better to say that the issue requires continued attention, if only to draw attention to other ethical concerns about such research, including unacceptable risk to child subjects.

PAYMENTS

Payments are often given to acknowledge the time and inconvenience of participating in research or to reimburse participants for any costs they incur. The term compensation is often used in the context of compensation for research-related injuries (see below). To avoid confusion with compensation in this context, we have adopted the term payment when referring to all payments that are given to all participants, whether or not an injury occurs.

Amounts and Characteristics

Payment amounts and type should be specified on the informed consent form and should be reasonable in relation to the demands of the study. There are several ethical and practical issues that must be considered in determining whether the payment(s) offered by a given research project is reasonable. Wendler and colleagues (2002) propose a useful typology of four types of payment for participation in research:

- reimbursements for expenses, such as parking or bus fares;
- tokens of appreciation (e.g., $25 in cash, toys, gift certificates, movie coupons); and
- recognition of the time and inconvenience involved in participating in research (e.g., payments at minimum wage levels for hours spent in research);
- incentive payments beyond those listed above: such payments may raise ethical concerns about undue inducements that undermine the voluntariness of the consent process.

Payments to children involved in research and their families remains a controversial issue (Wendler et al., 2002; American Academy of Pediatrics, 1995). The burdens of some research projects may be considerable and might include time and out-of-pocket expenses, inconvenience, and lost income. It would be unfair to expect families to make considerable sacrifices to participate in a time-consuming activity that is designed to advance scientific knowledge rather than benefit themselves directly. Reimbursement for expenses and some modest payment for time spent in research activities is thus justified on the grounds of fairness. Furthermore, a small

token gift to a child as a thank you for involvement in research shows respect for them and presents no serious ethical concerns. Moreover, if families did not receive some payment for participating in research projects that require considerable time, the burden on economically disadvantaged families might be prohibitive because they cannot afford the costs of transportation, child care, and other out-of-pocket expenses.

Yet if payments are too high, they may distort parents' decisions about enrolling their children in a research project. Criticisms are strongest if the project puts children at an inappropriately high level of risk and the magnitude of payments leads parents to enroll them in the study. Hence, the concern is that too high a payment may undermine free and informed consent by leading parents to expose their children to unacceptable risks: too attractive an incentive may be an undue influence. Furthermore, *how* the payment is made may also result in undue inducements. For example, if payment for a long-term follow-up study is made in a lump sum and only if the subjects complete the entire study, it could constitute an undue influence to stay in the study. If, on the other hand, the money is paid weekly, the effect would not constitute an undue influence. Some commentators believe that children should never receive payment for research involvement because this may be an undue inducement and affect the voluntariness of enrollment. Similarly, they argue that parents ought not be paid to enroll their children in research.

The issue of payment for participation in a research project is further complicated because of countervailing ethical guidelines. In addition to avoiding undue influence, another ethical consideration is treating different participants fairly. Payment that is trivial for some families may be substantial for economically disadvantaged families (Wendler et al., 2002). Yet to pay economically disadvantaged families less than more affluent families for participating in research is unfair because it requires similar sacrifices of time and inconvenience from both. For example, a study may involve several geographic sites. The remuneration needed to gain sufficient enrollment in a high-cost city may be significantly higher than that needed to enroll people in a rural, low-cost area. It might be unfair if the researcher offers lower payment in the area where the cost of living is lower. But if the same payment level is used for each area, the amount for those in the lower cost area might be high enough to be considered coercive and unduly encourage low-income people to enroll just for the "high" payment. A similar situation might arise in a study that enrolls participants from diverse socioeconomic backgrounds in the same area.

The ongoing controversy regarding payment in research involving children is illustrated by the recent Children's Environmental Exposure Research Study (CHEERS), which generated substantial public controversy

over the amount of money participant families were to receive (among other things).[3] Families participating in the study were to receive a total of close to $1,000 over 2 years and a video camera. Critics charged that this was too much and would inappropriately induce low-income families to enroll their children solely for monetary purposes, without regard to the risks of the research, which they also perceived as inappropriately high. Others noted that participation in this study required the parents to collect many types of information and samples over a 2-year period. To collect urine samples, parents needed to label and save diapers and have the child subject wear a one-piece union suit with socks. To document what children ate, parents had to collect a duplicate of all the food and beverages that the child subject eats and drinks during a 24 hour period. To record the child's activities, parents were asked to keep a diary of the child subject's activities during a 5-day period and videotape the child's behavior. Calculated on a per-day basis over the duration of the study, the amount to be received was $20 to $40 a day. This amount was defended as appropriate and consistent with hourly amounts research volunteers typically receive in other research projects. This example illustrates that when the level of payment is based on the length of time required by the research, a modest incentive for each activity in the study may be perceived as an undue inducement if the cumulative amount of the incentives is viewed as excessive and able to influence parents' decisions to enroll their children in research.

Practices and Policies

Empirical studies show that IRB policies and practices on payments to parents and children varies considerably (Wolf et al., 2005; Weise et al., 2002). Many IRBs do not have written policies on these topics. Many allow reimbursement to parents for time and expenses related to their children's involvement in research (e.g., child care, travel, parking, and meals). A few permit payment of "incentives" or "inducements" to parents who enroll their children in research. With respect to payments to child subjects, policies range from prohibiting to encouraging such payments. A few IRBs

[3]The CHEERS study was designed to fill important data gaps in understanding how children may be exposed to pesticides (such as bug spray) and chemicals being used in households and generated substantial public controversy because of the compensation level, perception that children were being intentionally exposed to pesticides, and industry involvement. Some of this controversy seemed to be created by misinformation or incomplete information about the project. The project was initially halted pending review by an external national review panel and stopped by the Environmental Protection Agency before the review was completed (Johnson, 2005).

advise against monetary payments to children and offer specific alternatives (e.g., toys, gift certificates, books). Although several IRBs recommend that young children should receive smaller gifts or payments than adolescents or adults, none provides specific justification or a formula for determining an appropriate amount (Wolf et al., 2005). If local IRBs permit payments or token gifts to children, researchers who provide such payments should explain to the children the reason for the payment or gift. The payment levels allowed by IRBs vary considerably. The maximum cash amount approved by IRBs in pediatric studies ranges from $10 to $1000, with a median level of $100 (Weise et al., 2002). These data provide little guidance for researchers, however, since payment levels should vary based on the demands of the research. If the time commitment and burden is significant, one would expect a higher payment level.

Payments are sometimes made in cash rather than checks on the basis of the recommendation of community groups, who point out that low-income families may not have easy access to a low-cost method for cashing a check (Jordan et al., 2000) or because they may not have a Social Security number. To reduce the perception of undue influence, many housing health hazards research studies have provided incentives in the form of goods or services rather than cash: examples include food coupons, fire extinguishers, smoke detectors, home cleaning, allergen impermeable covers, vacuum cleaners, air purifiers, and professional pest control (Eskenazi et al., 2005; Morgan et al., 2004; Rhoads et al., 1999). However, providing goods and services may not eliminate the problem of undue inducement. If the only way a low-income parent can get professional pest control in an apartment overrun by vermin is through participation in a study, that would be a very big inducement.

The Office for Human Research Protections has issued some guidance to IRBs on payments, stating that "Offers that are too attractive may blind prospective subjects to the risks or impair their ability to exercise proper judgment" (U.S. Department of Health and Human Services, 1993, pp. 3-44). The guidance does not explicitly discuss payment to children or parents despite empirical evidence that IRBs have widely divergent policies regarding payment in research involving children and so address the ethical issue of undue influence in inconsistent ways.

Two recent reports from The National Academies agree that payment to research participants is allowable, with certain caveats. *Ethical Conduct of Clinical Research Involving Children* states that agreement to enroll children in research should not be coerced or unduly influenced by psychological, financial, or other pressure (Institute of Medicine, 2004). Similarly, *Intentional Human Dosing Studies for EPA Regulatory Purposes: Scientific and Ethical Issues* (National Research Council, 2004) recommended that IRBs ensure that "payments to participants in . . . are neither so high as to

constitute undue inducement nor so low as to be attractive only to individuals who are socioeconomically disadvantaged. Proposed levels of and purposes for remuneration (e.g., time, inconvenience, and risk) should be scrutinized in light of the principles of justice and respect for persons" (p. 120).

This conclusion highlights the potential for the same payment to have a differential influence on parents from varying socioeconomic status. As discussed above, the families of children who are the subjects in housing health hazard research are often poor, have limited education, and may not understand the purpose or description of a research study. They are more likely to be nonnative English speakers, to live in rental units, and to be at risk for deportation. Most importantly, these families often lack resources to eliminate housing hazards and usually are unable to afford safer housing. For all these reasons, incentives offered by researchers that may be acceptable under some circumstances may be an undue inducement in this context. *Ethical Conduct of Clinical Research Involving Children* warned that "an amount that neutralizes the burden of research participation for one family may exceed it for another and, thereby, act as an inducement" (Institute of Medicine, 2004, p. 214). To avoid unintentionally creating an undue influence for low-income participants, it has been suggested that compensation for time be set at the minimum wage level (Dickert and Grady, 1999). However, for unemployed families, this amount may be equivalent to paying the parents for enrolling their children in research (Institute of Medicine, 2004): "If such payments are proposed for studies that focus on low-income populations, IRBs should assess the potential for undue influence" (p. 214).

Ethical Conduct of Clinical Research Involving Children recommended that IRBs and sponsors "adopt explicit written policies on acceptable and unacceptable types and amounts of payments related to research participation" (Institute of Medicine, 2004, p. 225). It also recommended that

> in addition to small gifts or payments to parents and children as gestures of appreciation, investigators may also—if they minimize the potential for undue influence—act ethically to reduce certain barriers to research participation when they (a) reimburse reasonable expenses directly related to a child's participation in research; (b) provide reasonable, age-appropriate compensation for children based on the time involved in research that does not offer the prospect of direct benefit . . . (p. 226).

However, it further determined that "Certain types of payments to parents . . . are usually if not always acceptable, for example, reimbursement for reasonable expenses that are necessary for research participation. Other payments are never appropriate in pediatric research, for example, paying parents for the use of their child in research" (p. 226) and rejected "financial encouragement for children's participation in research based on the level of risk involved" (p. 227). While it may be morally acceptable to

pay adults more for high-risk work, the committee that wrote the quoted report believed that this was not acceptable for children, who cannot make decisions for themselves. The committee concluded that age-appropriate recognition could be given to children in clinical studies, but that larger payments for assumption of greater risk should not be permitted (Institute of Medicine, 2004).

This committee agrees that investigators are acting ethically to reduce barriers to research enrollment if they reimburse reasonable expenses directly related to the research, provide reasonable and age-appropriate compensation for time, and offer reasonable accommodations for parent convenience, such as home visit times that address parental work schedules and family commitments. For children, the use of age-appropriate nonmonetary gestures of appreciation, such as toys and educational materials, are allowable and indeed often encouraged by IRBs and community groups. The IOM committee noted:

> Unfortunately, no bright line distinguishes proper and reasonable payments to parents and children from payments that are inappropriate. A mix of group or individual circumstances may determine when a particular type or level of payment crosses the line. What is excessive in one situation may not be in another, and reasonable people may sometimes differ in their judgments (Institute of Medicine, 2004, p. 214).

In the context of research with families who are poor or members of minority groups, researchers need to be aware that ethical problems may arise if payments or gifts are too small as well as too large. Although small payments and token gifts avoid the potential for undue influence, they may be regarded as so low as to be exploitative. Payment for time, effort, and inconvenience is a way of paying respect to the parents and children. Tokens of appreciation are often warmly accepted, but they might be resented as a symbol of their small worth to the researcher. Many low-income, minority persons are already suspicious of research and researchers (Corbie-Smith et al., 1999; Israel et al., 2003; Minkler and Wallerstein, 2003). They may think that a token of appreciation is a way for researchers to get away with not giving anything of value back to the community.

Because people have different perspectives on the line between acceptable payment and undue influence, community representatives can provide important input in determining appropriate levels of payment. They can help researchers understand how payments might influence parental decisions in the context of the particular study and study population, thereby helping to avoid payments that may constitute undue influence as well as payments that are a barrier to enrollment or are regarded as exploitative.

There are no clear guidelines for establishing whether a given payment level is considered an undue influence. The payment level that would be considered an undue influence may vary from one community to another

given varying income levels and costs of living across geographic areas. Additional research to better understand the affect of varying payment levels on consent decisions is needed. In addition, guidance from local IRBs and community representatives on appropriate payment levels considering local circumstances would aid researchers' efforts to design compensation plans. However, community input regarding payment can also be problematic: a community representative might try to maximize the payment. Thus, the community representatives' desires could lead to undue inducements. There are a number of questions that IRBs may want to consider when reviewing the materials submitted by a housing health hazards researcher to determine the adequacy of the informed consent process and payment levels:

- Was the community involved in the informed consent process and were the community's views considered? Were the planned payment levels discussed?
- What are the essential elements of the research, and were they understandably presented during the consent process? Was the difference between research and clinical care explained? Were baseline and continuing risks explained? Should moving away from the hazard be mentioned as an alternative? Are there essential aspects of the research that if not fully understood by parents should preclude enrolling their children in the study?
- How will the comprehension of the subjects' parents be assessed? Is it appropriate and adequate?
- What are the planned payments for involvement in the research? Do they create an undue influence on parents' decisions to enroll their children? Are the payment levels appropriate given local incomes and living expense levels?

THIRD-PARTY CONSENT AND INCENTIVES

Some studies of housing health hazards may require informed consent from third parties, such as other household members or landlords. The federal regulations define a research participant ("subject") as "a living individual about whom an investigator . . . obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information" (45 CFR 46.102(f)). If a third party meets the regulatory definition, all the provisions of the Common Rule come into play unless the Common Rule does not apply or there are grounds for an exemption from the Common Rule. In particular, the research must obtain informed consent unless there are grounds for a waiver of informed consent. The challenge in determining when a third party becomes a research participant is that both "private" and "individually identifiable" are not easily defined

(National Institutes of Health, 2001).[4] The Common Rule (see Chapter 3) provides some guidance by stating that information is considered private if the individual "can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record)" (§ 46.102(f)). Information that also falls outside the definition of private is information about family relationships, marital status, social networks, and occupation (National Institutes of Health, 2001). Information about a third party that is obtained from the research participant as background information about the participant is generally not considered private; rather, it is seen as contextual because it is usually unverified and is used as background information relevant to the condition or circumstances of the participants. If verification of the information about the third party is necessary, the National Institutes of Health report recommended that the third party should then be considered a research participant and informed consent should be obtained (National Institutes of Health, 2001).

In housing health hazards research, there are cases when consent or permission might be necessary even if informed consent is not. For example, a landlord's permission may be necessary to conduct pest control in a multi-unit building or to implement structural modifications to a housing unit (e.g., window replacements) as part of a study intervention. While other household residents may be present when a researcher enters the home, their permission would typically not be required if the child subject's parent has provided permission. However, notifying them in advance or suggesting that the parent notify them when researchers will be present is warranted. Such notification shows respect for these residents by making it possible for them to minimize invasions of privacy or inconvenience. In all cases, researchers should consider their legal and ethical obligations to potential third parties; this is discussed in more detail in the next chapter.

When the cooperation of third parties is necessary for the successful implementation of a research study, investigators may want to consider offering incentives to third parties. If structural modifications to a housing unit are being done, the value of the repair and potential increased property value may be sufficient incentive for landlords. If the intervention offers minimal direct benefit and the landlord's cooperation is needed for proper access or implementation (e.g., pest control in a multi-unit building) minimal payment for time and effort is warranted.

Community groups are also important third parties in many housing health hazards studies. Appropriate incentives for community groups and

[4]The National Institutes of Health (NIH) document cited made recommendations to the Office of Human Research Protections (OHRP) but does not constitute NIH or OHRP policy.

community residents who help with recruiting or other tasks are an important feature of many study designs, but they have the potential for an ethical conflict of interest if community groups receive direct payments for recruiting subjects. In-kind arrangements, such as a commitment to hire community members to be research staff or conducting community briefings, is preferable and avoids this potential conflict of interest.

COMPENSATION FOR RESEARCH-RELATED INJURIES

Research-related injuries may put families at risk because they may lead to missed work time or job loss. Because many low-income families lack health insurance, such injuries are potentially catastrophic. *Ethical Conduct of Clinical Research Involving Children* (Institute of Medicine, 2004) urged compensation for child subjects who are injured in the course of research because children who have permanent injuries must live with them for a long period. The financial burden may be particularly severe for low-income families who participate in housing health hazard research. That report recommended that research organizations and sponsors should pay the medical and rehabilitation costs for children injured as a direct result of the research, without regard to fault. Consent and permission documents should disclose to parents (and adolescents, if appropriate) the child's right to compensation and the mechanism for seeking such compensation. Previous national commissions have also recommended no-fault compensation for research related injures. The National Bioethics Advisory Commission (2001) pointed out that such compensation would require a national program.

This committee supports that basic approach. However, the phrase "direct result of research participation" may be difficult to interpret, particularly in the context of housing health hazards involving children. A research injury usually refers to an adverse event caused by research interventions, not by the course of a disease or a pre-existing condition. For example, failure of an experimental cancer intervention is an unfortunate outcome for the child, but the growth of a cancer would not be considered a research injury. In the context of housing health hazard research, distinguishing between injuries resulting from the research and injuries resulting from the baseline risks present in the child subject's home may prove difficult. It would be reasonable to assume that researchers should not be held accountable for injuries that result from conditions that existed in the home before the research and were not affected by the research. However, in situations in which research is designed only to partly eliminate a particular risk (e.g., partial lead abatement) and an injury results, it may be difficult to determine whether the harm resulted from the research or from the baseline risk. This complex issue warrants additional exploration and guidance.

CONCLUSIONS AND RECOMMENDATIONS

Ethical Conduct of Clinical Research Involving Children (Institute of Medicine, 2004) made a number of recommendations to strengthen the process of obtaining parental permission and children's assent in clinical research. Several recommendations have particular salience for research on housing health hazards in children. That report suggested "educating—not merely presenting information to—parents about issues critical to informed decision making and, as appropriate, assessing the degree to which these critical issues are understood" (p. 199). The report also suggested that for groups with low levels of literacy, investigators might use information tools that do not depend on written documents, such as simple graphics, oral explanations, and videos.

This committee agrees with these recommendations on strengthening the permission process. Even more importantly, this committee emphasizes the report's recommendation, also made by the National Bioethics Advisory Committee (2001), for protections tailored to the specific vulnerabilities of the participants in a particular research study. This targeted approach is an alternative to traditional approaches to vulnerable participants, which excluded them from research. Broad exclusion of vulnerable populations from research on housing health hazards in children may cut off research that is needed to understand and ameliorate the hazards and deleterious outcomes that such populations disproportionately encounter. Nonetheless, the characteristics of many parents of child subjects in housing health hazards research—including poor education, poverty, and lack of power relative to researchers—may result in poor comprehension or undue influence. There are several ways to improve the process. First, researchers need to talk with appropriate community representatives about the consent process, including planned payments for participation. Such consultation allows researchers to ascertain what information parents are likely to need when deciding whether to enroll their children in research. Community representatives can also suggest how to present information in a clear and understandable manner and what misunderstandings or questions parents are likely to have. In addition, community representatives can suggest what level of payment might lead to undue influence or be considered exploitative by the community.

Second, after understanding the community perspectives, researchers need to consider how to respond to the concerns and suggestions raised. In many instances, researchers and community representatives can agree on how to do so. When agreement cannot be reached, community representatives should not have a formal veto over the protocol. However, researchers need to consider their perspective seriously, provide a thoughtful response, and explain to the IRB both the community's perspective and their re-

sponse. Moreover, researchers should appreciate that a research project may not be feasible to carry out in the face of widespread community opposition.

Third, researchers who carry out research on housing health hazards involving children need to expand their perspective on what information should be disclosed to parents of prospective child subjects. In order for parents to make informed choices, they need to understand the risks and benefits of enrolling their children in research, as well as the risks and benefits of the alternative of not doing so. Parents need to understand the key features of the protocol. In addition, parents need to understand the risks that their housing environment presents with respect to the condition and end of the study: those risks were present before the research commenced and might also be present after the conclusion of the study.

Finally, what the parents understand about the research study is ethically more important than what researchers disclose. Thus, researchers who are studying housing health hazards involving children should have an appropriate means for checking that parents have understood the crucial features of the research project. Any misunderstandings or gaps in knowledge need to be corrected through additional discussions before a parent's permission to enroll a child in the study can be accepted as ethically valid.

Recommendation 6.1: Researchers who carry out intervention studies or longitudinal cohort studies on housing health hazards with children should implement a process of informed parental decision making by discussing the planned consent process with community representatives, considering their input, and ensuring that parents of child subjects understand the essential elements of the research.

Informed consent should be regarded by researchers as a process that begins with a community-based discussion and concludes with an assurance that individual parents of child subjects understand the essential elements of the research. Researchers should discuss the project and aspects of the project that will be addressed in the consent form with appropriated community representatives, including the planned payment levels and the risks and benefits of the research. Their IRB submission should describe the community's reaction and how they have responded to the community. Consent forms should be written as clearly and simply as possible while fully addressing necessary aspects of the research. Researchers and IRBs should consider approaches to improving consent that have been tried in other types of human participants' research and test those that seem suitable for housing health hazards research. It is essential that researchers ensure that parents of child subjects understand the essential elements of the research, including baseline risks pertinent to the topic being studied and ongoing risks in the housing environment that may still be present after

study interventions. Researchers should have appropriate plans for ensuring that the essential elements are understood and should consider alternative ways (such as neutral educators) to educate parents about the research. The informed consent process should also include discussion with the community about any experimental tests that may be part of the research and the informed consent form should clearly state whether such test results will be available to parents. This issue is discussed in detail in the next chapter. IRBs should require that these criteria are met.

Recommendation 6.2: Institutional review boards that review intervention or longitudinal cohort studies on housing health hazards involving children should require that the informed consent process reflects appropriate community input and includes plans to ensure that parents of child subjects understand the essential elements of the research.

Recommendation 6.3: Payment for participating in research on housing health hazards involving children should reimburse: (1) reasonable expenses directly related to participation; (2) reasonable, age-appropriate compensation to children for time spent in research that does not offer the prospect of direct benefit; and (3) reasonable compensation to parents for time spent in research. Such compensation may be in addition to token gifts to parents and children as gestures of appreciation. Such payments must avoid the potential for undue influence.

7

Researchers' Responsibilities

Investigators who conduct research in homes face complex ethical concerns. Making observations in a home can intrude on personal privacy, including the privacy of all persons in the household. Researchers need to consider, first, whether their research is likely to present inconvenience or harm to potential third parties who are not otherwise involved with the research. Moreover, researchers cannot avoid making observations that are unrelated to the research question at hand but may be relevant to the health and well-being of the children who are the subjects of the research or other household members (Gordis, 1991). For example, researchers described to the committee sometimes observing housing code violations, illegal drug use, firearms, and even suspected child abuse or neglect. Researchers face the ethical dilemma of what if any action to take in the face of conflicting ethical and legal obligations to protect children from harm and to respect privacy and confidentiality.

All investigators carrying out research with human participants have legal and ethical responsibilities under the Common Rule (see Chapter 3) and the standards of institutional review boards (IRBs), such as obtaining informed consent, ensuring the risks of research are proportional to the expected benefits, and minimizing risks. Specific features of housing health hazard research place several additional ethical responsibilities on researchers. Previous chapters recommended involving community representatives and ensuring fully informed and voluntary parental permission for children to enroll in research. In this chapter we discuss other ethical issues and obligations: innovative research designs; reporting test results that have not been validated; potential third parties who may be affected but are not

research participants; and researchers' role-specific obligations to develop plans for responding to risks that are incidentally observed when they enter children's homes. On these issues we point out how the perspectives of community representatives may differ from those of researchers. Hence, the process of understanding and responding to the views of community representatives as described in Chapter 5 is also important for helping researchers clarify their ethical responsibilities.

RESEARCH DESIGN

A variety of study designs are used in housing health hazards research to obtain information on hazards and to test methods to reduce health risks. The study design chosen by researchers depends on the aims of the study, existing knowledge on the topic, and the perceived magnitude of the hazard. Regardless of the specific approach, all study designs should be scientifically and ethically sound. Well-designed and well-executed research is necessary to improve the health of children living in poor-quality housing. For some large-scale intervention studies, the approach might include conducting a small pilot study to minimize the potential for unanticipated negative consequences prior to implementation of the full research project.

At the most basic level, there are observational studies that describe or enumerate specific hazards associated with housing, such as case reports, surveillance by public health agencies, or descriptive studies by researchers. Some observational studies conduct home walk-throughs, others use existing records, reports, and data or conduct telephone or in-person interviews. Some studies include measurements of physical (e.g., radon), chemical (e.g., lead), biological (e.g., cockroach antigens), or psychosocial (e.g., accidents, violence) hazards in homes or neighborhoods. Although causality can generally not be inferred from observational studies, in some instances in which the hazard and remedy are clear, observational studies may be sufficient for devising preventive strategies, as in the case of window guards to prevent falls from windows (see Chapter 2). For many housing-related problems, however, the causal chain between a specific hazard or set of housing conditions and a health outcome is not clear. Observational studies may still be useful in determining if persons with certain baseline characteristics are more likely to experience the outcome of interest.

Even if the causal links between a housing condition and an adverse health outcome are established, however, it may be uncertain how to prevent or remedy the condition. If there are multiple contributing factors, it may not be clear which ones should be targeted for interventions. Studies on asthma in children, for example, indicate that it is associated with multiple indoor pollutants, including settled allergens (cockroach, dust mite, cat and dog), environmental tobacco smoke, and mold or fungi (Institute of

Medicine, 2000). It may not be known whether plausible interventions are in fact effective, or whether the benefits of preventing or ameliorating the hazard outweigh the adverse effects of the intervention. Moreover, with housing hazards, some effective interventions—such as moving a child to housing without the hazard—may not be feasible because of resource constraints.

To evaluate interventions, researchers conduct experimental studies that compare outcomes in a group that receives an intervention with outcomes in a control group. In order to conclude that outcome differences between the groups are the result of the intervention rather than some other factor, the only difference between the control and intervention groups should be the intervention. That is, the intervention and control groups need to be similar at the baseline and with respect to other changes over the course of the study. Quasi-experimental designs, such as those using comparison or control groups from a previous period ("historical controls"), are less able ensure that the intervention and control groups are comparable. The "gold standard" for evaluating interventions is randomized controlled trials with strict study entry criteria, detailed protocols, and well-defined treatment and control groups to which participants are assigned randomly. Randomization is important because it helps to ensure that the intervention and control groups are similar at the baseline in all pertinent characteristics. Rigorous clinical trials on housing health hazards can provide the evidence base for promulgating intervention "best practices," regulatory standards, and health-based benchmarks for interpreting environmental or human biomonitoring measurements.

In a clinical trial, an important question is whether it is ethically acceptable to randomly assign participants to intervention and control groups. The term "research equipoise" has been coined to describe the genuine uncertainty that should exist about whether the intervention or control arm is better (Freedman, 1987, as cited in National Bioethics Advisory Committee, 2001). As described by the National Bioethics Advisory Committee (2001, p. 78), "research equipoise does not require numeric equality of intervention risks or potential benefits. Rather, research equipoise requires approximate equality in the relation between the risks and potential benefits of the study and control interventions." The committee believed that in clinical trials expert practitioners should make judgments about research equipoise. In housing health hazards research, however, the assessments of risks and benefits by researchers may differ from those of community representatives or the parents of potential child subjects, as discussed in Chapter 5. Thus, for research on housing health hazards in children, the assessment of research equipoise should balance scientific expertise and the views of community representatives.

Study interventions may attempt to affect a clinical or behavioral outcome in child subjects, a change in their housing environment, or some

combination of these factors. Because public health practice is not strictly codified, there is uncertainty because of the ambiguity of what constitutes "accepted practice." This uncertainty makes it more difficult to determine if "approximate equality" exists between risks and potential benefits of interventions in the experimental and control groups. Often the control group receives the best current practice; however, ethical dilemmas arise in housing health hazard research if the best current practice is considered impracticable. The situation is similar in some clinical trials, in which a shorter, less toxic, or less expensive treatment is compared with standard therapy. Other dilemmas arise when an experimental intervention is widely believed to be effective, despite the lack of rigorous empirical evidence. The ethical concern is whether the study is harming members of the control group by withholding or delaying an intervention believed to offer them the prospect of direct benefit.

Determining whether a particular clinical trial is ethically acceptable requires value judgments about the weight of the evidence, the level of uncertainty, and the potential effects of the research study on changing housing standards or policies. A weight-of-evidence approach is often used by expert panels or regulatory bodies to analyze data from experimental or quasi-experimental studies to assess the strength of association between a specific exposure and health outcome or to test the efficacy of an intervention designed to reduce mortality, morbidity, or exposure. Community residents may have different judgments than researchers or IRBs.

Community representatives often ask that research provide some direct benefit to those in both the intervention and control groups, as well as to the community. They may expect that direct benefits beyond the best available practice be provided. In the Seattle project, Partners for Healthy Communities, the community board challenged a design in which the control group would not receive a benefit. The study design was altered to address these concerns:

> The group receiving the full intervention was compared with a group receiving a lower intensive intervention, rather than a control group that received only usual care. Although the researchers were concerned that this would diminish the ability of the study to demonstrate the impact of the full intervention, community members felt that providing benefit to all participants was more important (Krieger et al., 2002a, p. 366).

However, attitudes towards control group interventions changed over time, as the trade-offs between providing immediate benefit to children in the study and gaining data that would provide compelling evidence that an intervention should be widely adopted became apparent. Ultimately, the Seattle partnership reached consensus that the evaluation of the intervention was "less convincing because it did not have a usual-care control

BOX 7-1
Two Innovative Study Designs

The Children's Lead Exposure Reduction Study (CLEARS)

CLEARS was a randomized clinical trial carried out between 1992 and 1995. It studied whether regular household cleaning to reduce house dust lead levels would reduce lead exposure in moderately poisoned young children (blood lead levels between 10 and 25 mg/dl). The households in the cleaning intervention group received education about lead and biweekly assistance in household cleaning. The control group received education about lead and accident prevention. Thus, the control group received some direct benefits that were not available to the intervention group.

The Health Outcomes and Measures of the Environment Study (HOME Study)

The HOME Study is an ongoing randomized study that tests interventions for two different hazards, lead poisoning and injuries. In one group, research staff will make repairs to reduce residential lead hazards (e.g., window replacement, paint repair, dust control, and water filters). In the other group, research staff will repair residential injury hazards (e.g., smoke alarms, window guards, stair gates, safety latches). The experimental group for one intervention serves as the control group for the other intervention. This is the first randomized trial to test the efficacy and safety of multifactorial passive environmental alterations to prevent childhood lead poisoning and residential injuries.

group. The consequence was less benefit to the community because it made it harder to find funding to sustain project activities" (Krieger et al., 2002b, p. 367). In the renewal grant for the project, the study had a usual-care control group that will receive the intervention after a delay of one year.

Innovative study designs can offer a benefit to both the intervention and control groups and thereby resolve some of the ethical concerns about housing health hazards research. First, as done in the Seattle project, the control group might receive the study intervention in a delayed manner, although there still may be objections to delaying an intervention that is believed to be effective (Krieger et al., 2002b). Second, child subjects in the control group might receive an intervention on a different housing health hazard. For example, in a clinical trial of the effect of periodic house cleaning on children's blood lead levels, the control group received household injury reduction education visits (Rhoads et al., 1999). A variation on this is a 2×2 intervention trial that tests interventions for two different conditions, with the control group for one condition receiving the active intervention for the other condition (Bruce Lanphear, personal communication); see Box 7-1. Third, crossover designs provide one or more interven-

tions to all child subjects on a staggered basis, offering the prospect of direct benefit to all child subjects in a study (Israel et al., 1998). These various designs that provide the prospect of direct benefit to all child subjects can eliminate or reduce ethical concerns about placing vulnerable children at inappropriate risk.

REPORTING OF TEST RESULTS

Researchers commonly carry out experimental tests on samples collected from child subjects or their environments. Unlike tests used in routine clinical practice, the significance of experimental test results may be unknown. Indeed, a goal of the research might be to establish the validity of such tests or to determine the health implications of the results. Ethical dilemmas may arise if parents of child subjects or community representatives believe individual parents should have the results of those tests. On one hand, information whose significance is unknown or uncertain may not provide objective benefit to parents; on the other hand, respect for persons may imply that parents should be the ones to judge whether they want information that researchers have obtained about themselves or their homes. The particular salience of the issue of reporting test results in housing health hazards research was highlighted by the Grimes case (see Chapter 3), in which plaintiffs charged that the researchers failed to provide them information about the level of lead in dust in the homes in a timely manner; the significance of the measurements was not known.

Studies of housing health hazards often collect human tissue samples, such as blood or urine, to establish the child subject's exposure, health effects, or susceptibility to a specific health outcome. These tissue samples are used to measure a variety of parameters, such as immune response to specific allergens or levels of specific compounds in body fluids, such as blood lead levels (Centers for Disease Control and Prevention, 2003; Needham and Sexton, 2000), or levels of urinary metabolites of tobacco smoke, pesticides, or persistent compounds (Quandt et al., 2004; Adgate et al., 2001; Hecht et al., 2001). In addition, such studies may collect environmental samples to establish the magnitude of exposure to a variety of potential hazards, such as chemical or biological agents. Levels can be measured from samples collected in or on household carpets, furniture, or other surfaces (Lanphear et al., 1996; Platts-Mills et al., 2000; Rich et al., 2002), as well as in air (Institute of Medicine, 2000), water and house dust (Colt et al., 2004; Rudel et al., 2003), or soil (Aschengrau et al., 1994; Mielke and Reagan, 1998). Several issues arise with regard to the reporting of test results to parents: the validity of the tests, the time frame for reporting results, and the parents' expectations. Similar issues of reporting test

results occur in biomedical research, when the validity and clinical significance of certain tests may not be known.

Validity of Tests

In housing health hazards research, both routine clinical tests and experimental tests may be done, depending on the study design and the problem under investigation. For clinical tests, there are standardized testing methods, age-specific normal ranges, predictive value for various diagnoses or conditions, and levels at which clinical interventions should be instituted. Blood lead measurements are an example of a clinical test often used in housing health hazards research: test results can be obtained from certified laboratories within days or weeks of sample collection and have established health benchmarks (Centers for Disease Control and Prevention, 1991). If researchers carry out tests that are also used in clinical practice, they typically provide patients or their physicians with the results, a description of the normal range of values, and the implications of results outside the normal range. Providing results of clinical tests in the range of concern to parents of child subjects in a timely manner is ethically required because it allows appropriate medical follow-up to be obtained.

In contrast, experimental tests may have uncertain validity. Indeed, one goal of the research may be to determine the validity of a new method of measuring a variable or the strength of an association between a new measurement and a clinically meaningful outcome. Two types of validity are pertinent (Secretary's Advisory Committee on Genetic Testing, 2000): analytic validity and clinical validity. Analytical validity indicates how well the test measures the property or characteristic it was intended to measure: it encompasses reliability—the probability of obtaining the same result with repeated measurements. Clinical validity refers to the probability that a test result correctly diagnoses a condition or predicts a disease or clinical condition.

In research on housing health hazards, some experimental tests may be carried out to help characterize the extent of potential exposure. For most such results, a description of the normal range of values and an assessment of the implications of the results is uncertain or unknown. Many types of tissue and environmental sample measurements do not have established analytical protocols, well-established laboratory quality control and assurance processes, or normative reference ranges or health benchmarks that permit ready interpretation of the test results (Centers for Disease Control and Prevention, 1991, 2003). The significance of results from such experimental tests for an individual subject may be unknown or uncertain until long after the samples have been collected, often not until all study data have been analyzed, and sometimes not even then.

Ethical Issues in Reporting

The threshold criteria in determining whether to share test results are typically whether the results are valid in the two senses discussed above. There is no clinical benefit to reporting the results to individual parents if they cannot be meaningfully interpreted. In biomedical research, when the validity of experimental tests on biological specimens is not established, individual results generally are not reported to participants. For example, a model consent form for genetics studies states that "the study is not meant to test your personal medical status" and that participants will not receive the results of research on their sample (Beskow et al., 2001). In some cases, some validity of the test can be established at the completion of the study; if so, the researchers may agree to then offer the tests results.

In some studies, community representatives or parents of prospective child subjects may believe that parents have a "right to know" information that researchers have obtained about their children regardless of whether the validity of the tests have been established. They may not trust or may disagree with researchers' judgments that the significance of the results is not known. Or they may simply want to have information about themselves even if there are no actions they could take that are known to reduce their risk of health hazards. That is, they may value the information about themselves for its own sake, even though its significance is unclear. Researchers report that in some cases community groups would like the results of experimental tests (such as urinary pesticide metabolite levels) without clear clinical implications to be nonetheless made available to the tested individuals if requested (Eskenazi et al., 2005).

When such disagreements arise, researchers have several ethical obligations that are not spelled out in the federal regulations. As a first step, they should discuss with parents of potential child subjects and community representatives what tests they will be conducting, explaining the limitations of the experimental tests and the potential misinterpretation of results. They also need to discuss whether test results should be made available. In some cases, researchers may persuade community representatives that there is little benefit and much risk to making results of unvalidated experimental tests available. In other cases, the community may persuade researchers that the results of individual tests should be made available to all the parents whose children are in the study.

If researchers decide to make results of experimental tests available, they need to consider how to do so in ways that minimize the harms and maximize the benefits of providing results. First, the researchers should offer parents a choice of whether or not to receive results of experimental tests. Some parents will want to know such information, while others will not. Respect for persons requires that individual parents be given a choice. Second, parents need to understand the potential significance and limita-

tions of the results of experimental tests (Needham and Sexton, 2000). Parents also need to know where, if anywhere, they might go for help (e.g., personal physician, community clinic, or public health office). Third, the researchers need to make clear during the informed consent process whether, when, and how the results of experimental tests will be offered to parents. Some tests are run shortly after samples are taken, while others may be run in batches, sometimes at the end of the study after all samples have been obtained. In some cases, the health significance of particular test results will become known over time, for example, as research on a particular biomarker advances. Parents should be told in the informed consent process what the researcher will do in such situations. Similarly, some test results (e.g., measurement of a particular hazard in the home) may suggest a hazard to other residents in the household; researchers should consider how to provide them information about the findings, taking into account the wishes of the subjects' parents.

To address these ethical dilemmas, researchers should discuss experimental tests that are part of the research protocol with the community (see Chapter 5) and should ensure that the informed consent process includes thorough disclosure of whether, when, and how the results of such tests will be shared with parents (see Chapter 6).

ETHICAL OBLIGATIONS TO THIRD PARTIES

All research can have unintended consequences. Research on housing health hazards in homes can have unintended consequences for individuals who are not study participants ("subjects," as defined in the federal regulations)—individuals with whom researchers interact or about whom they collect identifiable information. If third parties meet either of these criteria, researchers must obtain their informed consent (see Chapter 6). However, even if the federal regulations do not consider them research participants, people living in the same household, the same multiunit dwelling, or the same neighborhood as a study subject may be affected by research. Researchers may have ethical obligations to such third parties.

Other household residents may experience psychosocial harms, such as embarrassment or shame, if they or other residents are observed to be living in substandard housing or engaging in certain behaviors, such as alcohol abuse. Residents may also face legal liability if they are identified as carrying out illegal activities in their homes. In addition, residents may encounter physical risks, such as exposure to noise or dust, resulting from procedures carried out as part of the study: if these other residents are not notified, they cannot make plans to be out of the home.

Researchers need to anticipate and make plans for the effect of their research on other household residents. Often the researchers can simply ask

a parent of the child subject to notify other residents about the study and the interventions. Such notification gives other residents an opportunity to be absent from the home when the research interventions are carried out so that they are not inconvenienced by interviews, inspections, or repairs and so that their privacy is not compromised.

Research carried out in rental properties can have consequences for landlords. Researchers need to examine the specific terms of a lease for any restraints on the normal right of the occupant to invite any law-abiding person into the dwelling and to make minor improvements, such as installing battery-powered smoke alarms. If researchers propose to make significant structural changes to the home, such as installing new windows, the permission of the owner needs to be obtained. However, minor modifications that a tenant would have authority to make do not ordinarily require additional permission. Researchers should also take reasonable steps to provide information to landlords about possible public resources for helping to correct housing hazards and code violations, particularly if such hazards might be reported to authorities.

Neighbors may also experience adverse consequences of research. For example, pest management carried out in one unit of an apartment building may cause pests to flee to other units. Researchers need to anticipate such unintended results and take steps to minimize them. In the case of pest control, for example, researchers might reframe the study intervention to carry out pest management throughout a building rather than in a single unit to avoid causing harms to residents of other units. In other research studies, such as when repairs are made to a single unit, researchers should provide neighbors whatever notice would be expected if the landlord or tenant were carrying out similar activities outside the research context. If potentially disruptive activities are planned, informing neighbors of the plans gives them the opportunity to act as they wish in response to the activities (such as by leaving their units).

It is important to note that third parties may benefit from research as well as suffer inconvenience or risks. Educational activities may benefit neighbors as well as the family participating in the study. For example, in a study of a pesticide intervention involving rural farm workers, some participating parents brought friends or family to meetings to discuss strategies for reducing pesticide exposure (Salvatore et al., 2004). The diffusion of information from families participating in a research study to neighbors may result in the neighbors' altering their health behaviors and reducing their exposure to hazards. Landlords benefit if the research involves such improvements as pest control, the installation of smoke detectors, or other interventions that increase the quality and value of their properties.

Community groups may also be third parties in many housing-related research studies. Community representatives sometimes ask for benefits to

the community beyond whatever benefits individual subjects might receive, as well as the general benefit of increased knowledge (see Chapter 5). Often, community groups seek to have local residents hired as research staff and receive training that will enhance their employability in the future. Furthermore, the community may want researchers to specify how they will present the project's findings when it is completed so that the community can use the new knowledge, for example, to advocate for funding of effective interventions. Researchers should also present relevant findings—either on their own or in conjunction with community representatives—to local, state, or federal officials and testify at pubic hearings to support evidence-based public policies that would ameliorate housing health hazards. Researchers cannot be expected to ensure that research findings are fully implemented, but these steps can help the community benefit from the findings. Researchers should develop a plan to disseminate results to the families participating in the study, as well as the affected community.

The appropriate actions regarding third parties will vary according to the particular study and need to be determined on a case-by-case basis, following the general ethical guidelines of respect for persons, beneficence, and justice. Consulting with community representatives and parents of potential child subjects will help researchers understand the full range of a project's potential effects, as well as what those people believe researchers need to do to fulfill their ethical obligations (see Chapter 5).

In considering risks to third parties, researchers need to focus on risks that are foreseeable and significant rather than those that are conceivable but extremely unlikely or of minor importance. It is important not to place requirements on researchers that are overly broad, vague, or open-ended, lest they deter important, soundly designed research that is intended to alleviate housing health hazards that are disproportionately severe in vulnerable populations.

Although research staff are not technically "third parties," the committee notes the responsibilities of a project's leaders regarding the physical safety of staff working in the communities and entering child subjects' homes. These risks to staff may be greater than when research is carried out in a medical institution. As with all research, housing health hazards researchers have an obligation to consider the safety of their staff and to develop plans appropriate to their particular research project: such plans might include having staff conduct home visits in pairs or only during daylight hours or providing staff with cell phones.

RISKS OBSERVED IN HOMES

When researchers enter homes for their work, they cannot avoid making observations beyond the information collected as part of the research.

They may observe risks that are not related to the topic of the study. If a researcher learns about environmental hazards or behaviors by others that place a child in imminent risk of serious harm, there may be a legal requirement to report such information to specific authorities. However, interventions to reduce risks could violate confidentiality and could be ineffective or even counterproductive. In addition, the child at risk or the person(s) engaging in behavior that puts a child at risk may not be a participant in the research study (as defined in the federal regulations). The researcher may have no prior relationship with those being observed and may be viewed as invading their privacy.

Confidentiality

Confidentiality must be distinguished from the related concept of privacy. A loss of privacy occurs if others intervene in "zones of secrecy, anonymity, seclusion, or solitude" or in intimate relationships, causing a person "to be observed, touched, or intruded upon" against his or her wishes (Beauchamp and Childress, 2001, pp. 295-296). Privacy is also violated if others obtain information about a person that he or she wants to keep inaccessible. Confidentiality refers to limits on the dissemination of information disclosed by a person within a special professional relationship, such as the doctor-patient relationship or participant-researcher relationship (Beauchamp and Childress, 2001). Within these special relationships, the disclosed information is protected against disclosure to third parties by professional codes of conduct and by law. Furthermore, researchers often promise confidentiality of research data, with certain limitations, during the informed consent process. Thus, for example, when physicians have permission to gather medical information about a child patient, they may learn that the child is at risk for child abuse or domestic violence or places others at risk because of a contagious disease. To take steps to protect the patient or third parties, the physician would have to breach confidentiality; the ethical issue is whether it is appropriate to do so. In housing health hazards research, a researcher who has permission to enter a home to collect research data might incidentally observe evidence of child abuse or domestic violence, even though these are not the topic of the research. Here the ethical issue is whether it is appropriate to use information obtained under permission to collect research data for purposes that go beyond the scope of this permission.

Overriding confidentiality in such situations poses dilemmas for researchers because several strong ethical guidelines may be in conflict. First, researchers have an ethical or professional obligation to try to prevent harm to children who cannot protect themselves. In some situations, they may also have legal responsibilities through statutory reporting duties, which

depend on who is making the observation and in what state the research is being conducted. Second, well-intended actions may be ineffective or counterproductive and actually cause greater harm. Actions intended to alleviate risks may have unintended adverse effects (see the discussion below), such as the attempted eviction of the household after a unit has been reported for housing code violations. Third, researchers have an ethical obligation to respect the privacy and confidentiality of the residents of the homes in which their research is being carried out. Privacy and confidentiality show respect for persons affected by the research. Far-ranging interventions by researchers, even if intended to benefit residents of the household, may be considered meddlesome intrusions by them. In addition, privacy and confidentiality have instrumental research value by making it more likely that people will agree to participate in research.

In clinical medicine and public health, confidentiality may be overridden in certain situations to protect a person or third party from harm without legal repercussions; in some situations confidentiality must or may be overridden. For instance, confidentiality must be overridden in some circumstances to protect someone from child abuse, domestic violence, or elder abuse. In addition, confidentiality must be overridden to protect third parties, as when specified infectious diseases are required to be reported to public health officials. Widely accepted ethical guidelines (Beauchamp and Childress, 2001; Gostin, 2000; Lo, 2000) identify such situations in which confidentiality may or must be overridden to protect a person or third party from harm:

- The potential harm to identifiable persons is of serious magnitude and high likelihood.
- Breaching confidentiality will allow steps to be taken to prevent harm.
- There is no less invasive alternative to overriding confidentiality for warning or protecting those at risk.
- Harms resulting from the breach of confidentiality are minimized and acceptable. Disclosure should be limited to information essential for the intended purpose, and only those persons with a need to know should receive the information.

The more of these criteria that apply, the stronger are the ethical reasons for an obligation or a license to disclose confidential information. These guidelines form the ethical underpinnings of laws and regulations regarding the confidentiality of personal health information. This approach of balancing the likelihood of preventing serious harm against the harms caused by a breach of confidentiality can help researchers respond to risks they observe. The informed consent process (see Chapter 6) should clearly specify the situations in which confidentiality will be overridden.

Role-Specific Researcher Obligations

When physicians provide medical services to patients, they have a clear ethical duty to place the interests of the patient above their own self-interest or the interests of third parties, such as insurers. The doctor-patient relationship, based in trust, obligates physicians to behave in a competent and professional manner and assures patients that only interventions thought to be in their best interests will be recommended. As discussed in Chapter 4, research participants often conflate research and clinical care ("therapeutic misconception"). This is particularly understandable when the researchers are physicians or other health care professionals. In addition, research participants are familiar with relating to health professionals in the clinical setting and expect such professionals have their interests at heart.

Unlike clinical care, the primary objective of research is not to benefit participants directly, but rather to produce generalizable knowledge. While investigators are not obligated to act solely in the interests of individual participants, they have legal duties to protect them by obtaining informed consent, ensuring that the risks of research are proportional to the expected benefits, and minimizing risks. In particular, investigators need to inform participants about the interventions that will be carried out during the research and their risks and benefits. In addition, researchers must guard against the possibility of conflating research and clinical goals.

As discussed above and in previous chapters, two role-specific obligations are (1) to provide information beyond that required in the federal regulations, if appropriate, for parents to decide whether to enroll their children in the research project (see Chapter 6) and (2) to have a plan to deal with risks observed in homes that are unrelated to the research.

In addition, researchers may be in a special position to prevent harms from housing health hazards because they have expertise about housing hazards and a unique opportunity to intervene because they are in subjects' homes. If researchers do not act, an opportunity to prevent serious harm may be lost because no one else with similar expertise observes the conditions. Moreover, parents of research subjects are likely to expect that investigators will inform them if environmental hazards detrimental to their health are discovered in the course of the research, even if those hazards are not the focus of study. These characteristics—their expertise, the unique opportunities to prevent harm, and the reliance and expectations that parents place on them—distinguish researchers from a plumber or electrician who enters someone's home and is expected to carry out only a specific task.

Although some research critics argue that researchers who observe children in poor housing environments should "rescue" these children from harm and provider better living conditions (see Sherav, 2003), this seems an unreasonable expectation in most situations. Nor do researchers have an obligation to eliminate all housing health hazards in the households they

study: indeed, this task is beyond their power and resources. However, they do have an obligation to do what is reasonable under the circumstances. Above all, they should not make the situation worse for those already at risk. The appropriate course of action will depend on the specific situation: the type of risk identified, who experiences the risk, the nature of the research project, and the availability of community resources.

Researchers have an ethical obligation to anticipate what kinds of risk they are likely to observe, to develop reasonable plans to address anticipated risks which include procedures for how staff will be expected to respond to specific risks, and to train staff on these plans. Researchers also have an obligation to discuss how they will respond to such risks as part of the informed consent process. The first step for researchers is to consult with community representatives to identify likely risks and community resources.

Community Consultation

Community representatives can help researchers identify and understand risks that they are likely to observe. They can also help researchers understand what responses to these risks might be considered acceptable and effective by families likely to participate in the research. They can inform researchers about community service organizations, and perhaps particular contacts within these organizations, that can provide information, support, and advocacy services to child subjects and their families. For example, researchers may want to be aware of the alternative housing resources in the community. The next step is to develop a plan based on the level of risk.

Risks That Are Imminent and Serious

In cases of suspected child abuse and neglect, where there is evidence of "imminent risk of serious harm," such as clearly excessive force in disciplining children, the situation should be reported to child protective services for appropriate action. Each state has a child abuse and neglect reporting law and an agency designated to receive such reports; see Box 7-2. If a research staff member belongs to a profession that makes her or him a mandated reporter under the state's law, the staff person is legally required to report such cases of neglect or abuse.[1]

There is considerable variation in each state's child welfare system and

[1]The National Clearinghouse on Child Abuse and Neglect Information reported that as of June 2003, 18 states (Delaware, Florida, Idaho, Indiana, Kentucky, Maryland, Mississippi, Nebraska, New Hampshire, New Jersey, New Mexico, North Carolina, Oklahoma, Puerto Rico, Tennessee, Texas, Utah, and Wyoming) have universal reporting requirements; see http://nccanch.acf.hhs.gov/general/legal/statutes/manda.pdt [May 2005].

BOX 7-2
Reporting Laws on Child Abuse and Neglect

The 1974 Child Abuse Prevention and Treatment Act (CAPTA) (42 USC 5101, et seq.) as amended and reauthorized by the Keeping Children and Families Safe Act of 2003 (P.L. 108-36), imposes certain requirements on states to be eligible for federal funds, including a child protective service and a mandatory child abuse and neglect reporting law. Although each state has its own definition of child abuse, federal law (42 USC 5106g(2)) sets the minimum definition for child abuse or neglect as "any recent act or failure to act on the part of a parent or caretaker, which results in death, serious physical or emotional harm, sexual abuse or exploitation, or an act or failure to act which presents an imminent risk of serious harm."

All 50 states have a mandatory reporting statute, but there is considerable variation in the laws, most notably in the types of situations that must be reported and the kinds of persons who must report. In some states only helping professionals, such as health care workers, school personnel, child care providers, law enforcement workers, and mental health professionals, must report; in other states, any person who suspects abuse or neglect has a mandatory duty to report (Sieber, 2004). Almost every state imposes penalties, in the form of a fine or imprisonment, on those who "knowingly" or "willfully" fail to report.

CAPTA also requires states to provide legal immunity for good faith reporting of suspected abuse or neglect (42 USC 5106a(b)(2)(A)(vii)). The combination of potential penalties for failing to make a report and the immunity protection creates legal incentives to report: as long as there is a good faith reason to suspect abuse or neglect, it is in a potential reporter's best legal interest to make the report rather than remaining silent.

governing status, and specific state requirements may change frequently. State laws differ, for example, in their definitions of mandatory reporters, definitions of abuse and neglect, the obligations and protections for discretionary reporters, and the time frames for submitting a report. In developing their anticipatory plans, researchers should consult with the local child protective services office to ensure that they understand applicable laws. The state or local protective services office may also be a resource in developing plans for responding to particular situations that are likely to arise in a research project. However, even when legal obligations don't exist, there is an ethical obligation to act in cases when the risk is imminent and serious. Researchers who conduct housing health hazards research will likely also encounter situations when they need to determine on an individual basis if the presence of physical hazards in the home present an imminent risk of serious harm and therefore warrant reporting the situation to child protective services.

For example, if a researcher enters a home to conduct a vigorous clean-up of household allergens and discovers a large hole in the middle of the floor with a drop-off to the floor below, does this obvious safety risk to any child in the home fall within the definition of child abuse or neglect? In developing plans for how to respond to this physical hazard, investigators should first consider the relevance of the state child abuse and neglect law. If this situation falls within the scope of state law and the researcher is a mandated reporter, it must be reported to child protective services. In addition, all researchers should consider whether the parents can take steps to eliminate the hazard. For example, the parents might be able to report the situation to the local housing authority so that they can initiate repairs, get the landlord to make repairs, or obtain help from community organizations to set up barriers around the hazard. In contrast, if the child has already fallen into the hole and suffered injuries and the parents refuse to acknowledge the presence of risk, the investigators may be obligated to report the cause of the child's injuries to child protective services.

Researchers have countervailing concerns when faced with evidence indicating potential child abuse or neglect. There are strong reasons to report, such as the desire to help and protect a child or the threat of civil and criminal liability. Yet, many professionals may believe that reporting would have a negative effect on the trust and the alliance they have built with the research participants. In addition, some researchers believe that child protective service agencies lack the necessary resources and discretion to effectively handle a reported case (Goldstein, 1999, Ch. 9). Physicians have given several reasons for not reporting suspected child abuse and neglect: lack of sufficient evidence that abuse had occurred; belief that the abuse was not serious enough; belief that the case had already been reported; belief that the report would disrupt current treatment; belief that the situation had already resolved itself; belief that they could help the child better themselves; and belief that child protective services agencies were of poor quality or that the agencies overreacts to reports (Kerns et al., 1994). Researchers may be concerned that reporting suspicions to child protective services agencies will undermine parents' willingness to continue participation in the study. Although the committee acknowledges these concerns, the ethical and in some cases legal obligation to act in cases of imminent and serious risk is binding.

Risks That Are not Imminent and Serious

Researchers need to consider options for preventing harms that are not imminent and serious, and for each option, to analyze its effectiveness,

adverse consequences, steps to mitigate those adverse consequences, and acceptability to the parents. Researchers need to balance the harm that is likely to be averted against the harms resulting from breaches of confidentiality. Community organizations may have useful programs or services to help families address such risks, and they may be able to reduce the potential adverse consequences of responding to harms. For instance, legal services organizations may help families enforce their rights as tenants or protect them from attempts at retaliatory evictions, which are illegal.

Responses to these risks need not be as urgent as in the case of suspected abuse and neglect, and in some situations no response may be necessary. Discussing the observed risk with parents and providing information about community resources may be sufficient, particularly in observational studies. In some cases, a parent may not be aware that a particular situation presents a risk (e.g., improper application of pesticides, cleaning products in easy reach of children), and a sensitive, diplomatic discussion with the parent could resolve the situation. It is clearly not the researchers' responsibility to eliminate all risks in homes.

In these situations, input from parents should be part of the plan. Specific responses will have to take into account parental values because the parents will have different views about childrearing and will have to live with the consequences of researchers' actions. Although staff may intend to reduce risks, their actions may have unintended adverse consequences, such as disruption of the household, retaliation, or identification of a family that includes illegal immigrants or is living in overcrowded conditions in violation of a lease. Staff also need to understand why parents may be reluctant to accept a recommended action for reducing risk. Parents will often have legitimate concern that the intervention will not be as effective as expected or that the risk of unintended adverse consequences is greater than the researcher appreciates. Generally, the staff and parents can agree on an approach that both reduces risk and respects the parents' values.

For example, a researcher might observe mold in the home. Mold presents a health risk to children and is a code violation in some jurisdictions. However, if more than one family is living in the unit, the parent may not want to report (or have the researcher report) the situation to the landlord for fear of eviction. An alternative might be to share information regarding how to control growth of mold, such as using particular cleaning products or using exhaust or other fans. In another situation, the family might not be aware that the landlord is responsible for the condition. This family might be advised to follow up with the landlord and be given information about possible community resources (e.g., legal services, code enforcement) that are available.

Informed Consent

The informed consent process should discuss reasonably foreseeable situations in which researchers may have to breach confidentiality to protect study subjects from imminent and serious harm (e.g., reporting of suspected child abuse or neglect). The discussion should be tailored to the situations that are likely to arise in the project; researchers cannot give an exhaustive list of all situations in which confidentiality might have to be overridden.

If researchers observe risks that they believe require them to override confidentiality, they need to discuss confidentiality again with the parents. The discussion at the time of enrollment in the study was hypothetical; after a serious risk has been identified, the researcher needs to discuss the specific situation that poses the risk, the various alternatives for preventing the risk, and the parents' preferences on how to proceed. Ideally, researchers and parents can agree on a course of action that resolves the risk without requiring a breach in confidentiality. However, this may not be possible in the case of suspected child abuse and neglect, particularly if the staff person is a neighbor and does not feel responsible for correcting the situation. In some cases, it may be possible to make an anonymous report to child protective services, which would be the appropriate response to ensure the safety of both the child and the staff. If the case needs to be reported to a responsible official (e.g., if a child in the study is being abused by someone else in the household), it is ethically desirable to obtain parents' concurrence with reporting, as well as to help the parents and child find supportive services to protect them against retaliation. Such interactions show respect for parents.

Staff Training

Researchers should train their research field staffs about what they might encounter and how to respond to risks they observe in homes, develop policies and procedures to address them, and provide necessary oversight and back-up. Research staff who visit homes will be the ones facing the dilemma of how to respond to observed risks. Training should include information on privacy and confidentiality, any applicable legal obligations related to suspected child abuse and neglect (below), and the appropriate procedures for reporting such cases. When unanticipated situations arise, staff should be able to contact the principal investigator or a senior investigator for guidance on how to respond.

The research team should be aware of relevant available community resources to help enable them to respond in a timely, helpful manner. They should also identify specific contact people in those organizations for urgent assistance so staff can provide such information to parents.

Senior staff should be able to help resolve situations in which the immediate, intuitive response may be misguided. For example, field staff who notice firearms in the home within access of children may consider calling the police to prevent violence. However, doing so may cause many unintended problems, including embarrassment, recriminations by other family members, reprisals from a gun owner, or attempted eviction from housing. Harm can be averted in other ways, as by having the gun locked and unloaded. Unless situations present an imminent and serious harm, staff responses need to respect parents' preferences.

IRBs are charged with protecting participants in research; hence, they need to review and approve researchers' plan for responding to risks they observe in the home, including any anticipated situations that warrant overriding confidentiality.

CONCLUSIONS AND RECOMMENDATIONS

The committee reached several conclusions about researchers' responsibilities. The particular context of housing health hazards research raises ethical obligations for researchers beyond those addressed in the applicable federal regulations. Community concerns related to the provision of benefit to all children enrolled in research can be addressed though the use of innovative designs. Research conducted in the home might affect third parties who are not participating in the research. In addition, researchers may observe a range of behaviors and conditions not related to the research. Researchers have an ethical obligation to thoroughly consider these issues and to inform the parents of potential child subjects of any circumstances under which the researchers anticipate they will need to breach confidentiality.

Recommendation 7.1: Researchers designing intervention studies on housing health hazards involving children should consider using innovative designs in which all child subjects receive a prospect of direct benefit.

Recommendation 7.2: Researchers carrying out research on housing health hazards involving children should discuss in their protocols and IRB submissions their legal and ethical obligations to potential third parties affected by their research.

Recommendation 7.3: Researchers designing research on housing health hazards to children need to anticipate the risks and behaviors that may be observed in the home, including observations that are not part of the research protocol, develop anticipatory plans that specify how to assess

and respond to risks when they are identified, and educate their staffs about the plan.

Recommendation 7.4: Institutional review boards that review housing health hazards research should examine the researchers' plans for responding to risks observed in the home and require that they be appropriate in the context of the research and the affected community.

8

Research Oversight

A well-designed systems approach to research oversight that involves researchers, institutional review boards (IRBs), and funders best ensures that the ethics and science of human participants research are of high quality (Institute of Medicine, 2002). Many of the recommendations presented in previous chapters envision parallel roles for researchers and IRBs. In response to specific ethical issues raised by the context of housing health hazards research, the committee recommends that researchers consult with the affected communities (Chapter 5), ensure that parents' decisions to enroll children in research is truly informed and voluntary (Chapter 6), and specify plans for addressing risks observed in the home, including risks that are not part of the research project (Chapter 7). In those chapters, we articulate complementary recommendations for IRBs, recognizing the IRBs' role in reviewing, approving, and overseeing research; see Box 8-1.

Funders of research also play a significant role in establishing the requirements of the research they fund. Chapter 5 includes a recommendation that funders of housing health hazards research require and provide adequate funding for community involvement in such research. In addition, federal agencies that develop regulatory guidance play a significant role in developing guidance for IRBs and researchers on how regulatory requirements should be interpreted.

The general purpose of an IRB is to ensure that a research protocol that proposes to involve human participants protects the rights and welfare of human participants and complies with ethical standards and federal regulations. The effectiveness of IRB review and of the implementation by the

BOX 8-1
Recommendations for IRBs from Other Chapters

Recommendation 5.2: Institutional review boards should require appropriate community involvement in housing health hazards research involving children and require that investigators' protocols are responsive to any community concerns.

Recommendation 6.3: Institutional review boards that review intervention studies or longitudinal cohort studies on housing health hazards involving children should require that the informed consent process reflects appropriate community input and includes plans that ensure that parents of child participants understand the essential elements of the research.

Recommendation 7.4: Institutional review boards that review housing health hazards research should examine the researchers' plans for responding to risks observed in the home and require that they be appropriate in the context of the research and the affected community.

U.S. Department of Health and Human Services (DHHS) of its regulations has been the subject of critical reports in recent years (Institute of Medicine, 2004). In response to those criticisms, DHHS in 2000 reorganized its oversight structure to emphasize the importance of protections for human research subjects: the entity charged with principal responsibility for human research subject protections was moved from an office in the National Institutes of Health (NIH) to the Office of Public Health and Science, which is in the office of the DHHS secretary (Institute of Medicine, 2004). This principal entity, now named the Office for Human Research Protections (OHRP, formerly the Office for Protection from Research Risks), is charged with overseeing compliance with DHHS regulations for the protection of human subjects. OHRP establishes criteria for and approves assurances of compliance with institutions engaged in DHHS-conducted or DHHS-funded human subject research, provides guidance on involving humans in research, develops and implements educational programs and resource materials, and promotes the development of approaches to enhance human subject protections.

OHRP is guided by the 11-member Secretary's Advisory Committee on Human Research Protections (SACHRP). The advisory committee members are selected on the basis of their expertise in any of the several disciplines and fields pertinent to human subjects protection or clinical research. Membership of SACHRP also includes non voting ex-officio members who

represent the Agency for Healthcare Research and Quality; the Centers for Disease Control and Prevention (CDC); the Food and Drug Administration; NIH; the Department of Housing and Urban Development (HUD); the Environmental Protection Agency (EPA); and any other ex-officio member the Secretary deems necessary. (Before 2002 the entity was known as the National Human Research Protection Advisory Committee).

SACHRP meets at least twice a year to discuss recommendations and advice to be provided to the secretary regarding ways to improve protections for human research participants. There are currently two active subcommittees, one focused on prisoners involved in research and one focused on children involved in research. The Subcommittee on Research Involving Children is currently evaluating the definitions and application of certain key regulatory terms under Subpart D, such as "minimal risk," "minor increase over minimal risk," "condition," and "reasonably commensurate." A key unresolved issue is "whether or not there is a . . . magnitude of harm above which normal children are routinely exposed to which we believe that they, like their disordered counterparts, should be exposed for the benefit of scientific [knowledge] on health problems affecting children" (Hawkins, 2004).

The rest of this chapter discusses issues specific to IRBs and funders that would further enhance the system of research oversight. In addition, it discusses in detail issues related to research that involves a minor increase over minimal risk and no prospect of direct benefit given the particular concerns regarding this type of research in the context of housing health hazards research.

RESEARCH PROTECTIONS

As discussed in Chapter 3, Subpart A of the federal regulations (45 CFR 46, the "Common Rule") establishes the basic rules for the conduct of research; it also specifies the findings that an IRB must make in order to approve a research proposal (45 CFR 46.111). Subpart D of 45 CFR 46 provides a more substantive guide for research involving children, with protections balanced with the risk and benefits of a given design.

The primary funders of housing health hazards research involving children are HUD, CDC, NIH, and EPA. DHHS, which includes CDC and NIH, has adopted all the regulations in 45 CFR 46, including subpart D. HUD and EPA have adopted Subpart A, but they have not adopted Subpart D. As a result, there may be circumstances in which housing research involving children would not be required to comply with Subpart D, and the possibility of research placing children at risk without the oversight provisions is left open. While additional protections beyond those specified in the regulations are warranted, as discussed in this report, the federal

regulations in Subpart D provide a useful framework for the conduct of all housing health hazards research involving children.

Guidance Regarding Interpretation of Subpart D

Subpart D specifies the types of research involving children that can be approved by an IRB. Provided other applicable criteria are met, projects may be approved if the research involves (1) no more than minimal risk, (2) greater than minimal risk but a prospect of direct benefit, or (3) a minor increase over minimal risk and no prospect of direct benefit but the potential to yield generalizable results about the participants' disorder or condition. Projects that are not approvable under one of these categories may only be approved by the DHHS secretary, after review by a special national panel. Interpretation of the level of risk presented by specific interventions is inconsistent across IRBs (Shah et al., 2004; Institute of Medicine, 2004). For example, Shah et al. (2004) found that 23 percent of IRB chairs consider allergy skin testing minimal risk, 43 percent a minor increase over minimal risk, and 27 percent more than a minor increase over minimal risk. This variation is troublesome, because some IRBs may be allowing children to be subjected to inappropriate risks in research, while other IRBs may be rejecting valuable research whose risks are acceptable.

The categories of risk specified in Subpart D are crucial in determining the criteria under which a research project may be approved, but they are conceptually difficult to define. Shah et al. (2004) concluded that "IRB chairpersons need guidance on applying the federal risk and benefit categories" (p. 476). The difficulties are further complicated in the context of research on housing health hazards that is conducted in the participants' homes because potential participants and community representatives may have a different view on what is minor or acceptable risk than do researchers or IRBs.

SACHRP is currently considering these terms and is expected to propose an updated list of interventions that may appropriately be considered minimal risk and minor increase over minimal risk, together with an explanation of the reasons for the decisions. The committee supports this ongoing work and believes it will provide the necessary foundation for OHRP to issue guidance that will help IRBs and researchers carefully consider what would justify labeling an intervention minimal risk or minor increase over minimal risk. In addition, a clearer understanding and agreement on minor increase over minimal risk, and greater consistency across IRBs, would help ensure that children in research are protected against risks that are unacceptable.

In the context of research that presents a minor increase over minimal risk and no prospect of direct benefit (Section 406), the federal regulations

also specify that research must present experiences to child subjects that are reasonably commensurate with those "inherent" in their medical, psychological, or social situation. However, the regulations do not define "reasonably commensurate," and there is no empirical information on what interventions are typically regarded as such by IRBs. Although the committee believes that skin testing is reasonably commensurate with having immunizations, a part of every child's experience, IRBs differ in their views on what level of risk this poses (Shah et al., 2004). Similarly, the intervention must be "likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition." Again, the regulations do not define "vital importance," and there are no empirical data on how IRBs interpret the term. Finally, the regulations are not specific about whether healthy children with certain characteristics, including social or environmental characteristics (e.g., living in poor-quality housing) that place them at risk for adverse health outcomes, are intended to be included in this category of research (see below for discussion of this issue). Although decisions about whether a specific research protocol meets these criteria will still involve some value judgments on the part of IRBs, clarification on the intended meaning of these terms will help minimize differences across IRBs.

Additional guidance can be provided to clarify unusual circumstances. Guidance from federal oversight agencies or professional societies, such as public health and pediatric societies, can help clarify how to apply the regulations to atypical contexts. For example, an ethical argument can be developed for a specific decision with respect to seeking consent from individuals who are not the primary subjects of the research (see Chapter 7 for discussion of third parties). Without specific guidance, an IRB may find it difficult to decide which arguments to accept.

Guidance Regarding Economically and Educationally Disadvantaged Populations

Subpart A of the federal regulations reminds IRBs to "be particularly cognizant of the special problems of research involving vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, and economically and educationally disadvantaged populations" (45 CFR 46.111(a)(3)) and asks them to consider whether vulnerability calls for additional protections (45 CFR 46.111(b)). In the case of children, Subpart D articulates specific additional protections. Subparts B and C specify additional protections for pregnant women and prisoners, respectively. No similar regulatory guidelines, nor any guidance on how to interpret these provisions, have been issued in the case of economically and educationally disadvantaged populations, although some researchers have

called for them (Stone, 2003). The broad directives in Subpart A regarding such disadvantaged populations provide little specific guidance and few specific requirements.

As stressed throughout this report, housing health hazards research raises unique issues related to targeting residents of poor-quality housing who are typically economically and educationally disadvantaged. While community involvement and enhanced efforts to facilitate informed consent as we recommend will address some of the issues raised in this research, specific guidance on how to design and conduct research with economically and educationally disadvantaged populations would benefit IRBs and researchers.

Special Considerations Regarding Section 406 Research

IRBs that review research that presents a minor increase over minimal risk and no prospect of direct benefit (Section 406) under Subpart D must assess whether the research is likely to generate generalizable knowledge about the targeted children's "disorder or condition." The intention of such research is to gain knowledge "of vital importance" about their disorder or condition with the goal of ultimately preventing or ameliorating it. In the biomedical fields, such studies might explore the pathophysiology of a childhood disease in order to develop better tests and therapies. For example, a research project might place an intravenous catheter into a child with diabetes to measure levels of blood sugar and hormones that regulate blood sugar levels, in order to understand how those levels are affected by such daily activities as exercise. Such studies might lead to recommended regimens for administering insulin that better control blood sugar. Although this would benefit future generations of children with diabetes, there is no direct benefit to the child subjects. Such research is permitted under Section 406 in order to advance treatment protocols and potentially improve the functional health of children with diabetes. Section 406 attempts to strike a balance between allowing research that could lead to improved health among children and not putting vulnerable children at greater than minimal risk without the prospect of direct, personal benefit.

Ethical Conduct of Clinical Research Involving Children (Institute of Medicine, 2004) grappled with definitional issues related to Section 406 research in the context of clinical research and offered the following recommendation:

> In determining whether proposed research involving a minor increase over minimal risk and no direct benefit can be approved, the term condition should be interpreted as referring to a specific (or a set of specific) physical, psychological, neurodevelopmental, or *social characteristic(s)* that an

> established body of scientific evidence or clinical knowledge has shown to negatively affect children's health and well-being or to increase their risk of developing a health problem in the future [emphasis added] (p. 130).

The report noted that a narrow definition of "disorder or condition" to refer only to an "illness, disease, injury, or defect" would discourage research with "children who are currently healthy but at risk of serious illnesses that could potentially be prevented or mitigated through early interventions" (p. 129). At the other extreme, a very broad interpretation of disorder or condition would include "almost any social, developmental, or other characteristic" and therefore "justify exposing a child to a higher level of research risk" (p. 129). The report also noted that it is important to "identify specific circumstances or conditions" that "contribute to children's poor or good health" but cautioned that "children's social, economic, racial, ethnic, and environmental characteristics or circumstances do not, in themselves, necessarily justify exposing a child to a higher level of risk in research that is not expected to benefit them directly" (pp. 129-130). It further required:

> Investigators who define a research population on the basis of social characteristics or "conditions"—such as ethnicity, family circumstances, or economic status—must present a case that the condition has a negative impact on children's health and well-being that is relevant to the research question (p. 130).

This committee agrees with the issues outlined in *Ethical Conduct of Clinical Research Involving Children* and its concerns about justice. We appreciate that "disorder or condition" must be interpreted to include healthy children at risk for a serious condition in order to carry out studies of the pathophysiology of diseases and to create the foundation of knowledge that allows therapeutic and preventive interventions or diagnostic tests to be developed.

However, for research on housing health hazards involving children, the ethical dilemmas are particularly pronounced given the context of the research—research that is often conducted with economically and educationally disadvantaged populations with multiple vulnerabilities. The primary factor that places them at risk is environmental: poor-quality housing because of the lack of decent affordable housing for children in low-income families. Thus, the health risk results not from a physical susceptibility to disease, but from environmental conditions that could be improved by better quality housing. At the same time, such populations potentially have the most to gain from such research because they bear an undue burden of poor health resulting from poor-quality housing.

Supporters of this research argue that it is needed to understand and ameliorate the health hazards in poor-quality housing that put children at

risk. Such research might lead to better tests to identify children at risk for adverse health outcomes and to affordable interventions that effectively and safely mitigate the risks of poor-quality housing. Identification of such interventions is particularly important because it is unlikely that the stock and availability of good-quality, affordable housing will increase in the foreseeable future. To forgo such research might also forgo the opportunity to develop better approaches to ameliorating health disparities and improve the health outcomes of children in poor-quality housing: in trying to be sensitive to the potential for exploitation of poor and minority children, the opportunity to reduce the causes of their disadvantages may be lost. Advocates of research further argue that such research can be designed and implemented in a way that is sensitive to and does not exacerbate existing inequalities because, by definition, the physical risks of such procedures are no greater than a minor increase over minimal risk and are transient.

On the other side, there are also strong ethical concerns about allowing research to be carried out that presents more than minimal risk but does not offer the prospect of direct benefit. The committee is reluctant to allow children who are already vulnerable because of poor housing, poverty, and poor educational opportunities to be subjected as a group to greater risks in research than children from more privileged backgrounds. Moreover, it could be stigmatizing for children who already have multiple vulnerabilities if they are selected for such studies on the basis of poverty and living in poor housing, rather than on a more individualized determination of increased risk for disease and disability. Children from these environments are disproportionately from racial and ethnic groups that have suffered discrimination, and research may reinforce negative stereotypes. Finally, the committee is concerned that the long-term benefits of research might not accrue to the low-income populations who bear the burdens of research. For example, children with asthma from housing exposure to allergens who are from higher socioeconomic classes might be more likely to benefit from any clinical advances because they have better access to health care or the resources to implement environmental interventions.

The justification for a short-term risk to research participants is long-term improvements in health. However, the connection between well-intentioned research and improved health for disadvantaged populations may be tenuous. People who are poor and members of ethnic minorities in the United States have suffered discrimination in health care and experience ongoing health disparities (Institute of Medicine, 2003). They might question whether policy makers will actually implement the health and housing policies that research suggests would effectively ameliorate health disparities.

The committee struggled with these ethical dilemmas. Although the committee could not identify any specific housing health hazards research project that is or was conducted under Section 406, we did not want to

close off potentially valuable research to ameliorate housing health hazards. At the same time, the committee is also deeply troubled by ethical concerns in putting vulnerable children at more risk than children from more privileged backgrounds. The committee considered strong arguments for allowing such research to proceed carefully and also strong arguments for protecting children who were already vulnerable in many ways.

The committee noted that the original recommendation by the National Commission that established this category of research did not address the definition of disorder or condition (including whether characteristics that place healthy children at risk for a negative health outcome or increase the risk of developing a health problem should be included), and that no specific guidance or regulations related to disorder or condition have been issued. However, the National Commission's report also states that "It is necessary to learn more about normal development as well as disease states in order to develop methods of diagnosis, treatment and prevention of conditions that jeopardize the health of children, interfere with optimal development, or adversely affect well-being in later years" (National Commission, 1977, p. 11). This could be interpreted to suggest that the National Commission envisioned a wide latitude for the term "condition" and believed it encompassed all circumstances that jeopardize the health of children or adversely affect well-being in later years—including poverty and poor-quality housing. Others believe that that the overall language in the report suggests that this was not the National Commission's intent.

Because of this ambiguity and the substantial potential controversy when this type of research involves economically and educationally disadvantaged populations, this committee concludes that the OHRP should clarify what constitutes a disorder or condition before research that defines disorder or condition based on social characteristics should be allowed to proceed. In developing such clarification, OHRP should articulate implementation considerations and ensure that there is the opportunity for significant public comment in addition to the public input received during the development of SACHRP's recommendations (see above). A determination of whether guidance is sufficient or, alternatively, if additional regulations are warranted should be made part of this public process.

The several additional protections outlined in this report should be considered as part of the guidance. Specifically, the committee concluded that such research should require that the community is meaningfully consulted (Chapter 5) and that procedures are in place to ensure fully informed and voluntary consent (Chapter 6). Although Chapter 5 outlines a range of approaches to community involvement, the committee concludes that research involving more than minimal risk and no prospect of direct benefit

that targets economically and educationally disadvantaged children heightens sensitivity to historical issues of injustice and distrust of research and warrants an intensive, ongoing approach to community involvement. Investigators should be required to engage in meaningful and ongoing dialogue in partnership with the community regarding the design of the project, including discussion of the research question, the risks of the research and the hazard being studied, the knowledge to be gained by the research, and the relevance and importance to the community. This approach will ensure that potentially controversial research with children with multiple vulnerabilities is vetted with the affected communities, carefully justified, and fully understood by the parents of child subjects.

The committee believes that if the definition of disorder or condition is determined to include a social characteristic or condition that is associated with poor health outcomes or an increased risk of developing a health problem, the review of these protocols would be strengthened if IRBs were more explicit and transparent about their reviews. Given the considerable public controversies surrounding some research protocols under Section 406, IRBs should be encouraged to state their reasoning explicitly and document it. An IRB should explain how it determined that *all* the criteria in Section 406 were met: that the research presents a minor increase over minimal risk, that the intervention presents experiences that are reasonably commensurate with the medical and psychosocial situations of the child subjects, that the knowledge gained from the research is of vital importance to understanding or ameliorating the participants' disorder or condition, and that provisions for parental permission and children's assent are adequate. Moreover, as the Institute of Medicine committee suggested: "Investigators who define a research population on the basis of social characteristics or 'conditions'—such as ethnicity, family circumstances, or economic status—must present a case that the condition has a negative impact on children's health and well-being that is relevant to the research question" (Institute of Medicine, 2004, p. 130). The process of community consultation will be helpful in this regard; the protocol and consent documents should be circulated to community representatives for their comments and suggestions. If researchers decide not to adopt major suggestions from the community consultation process and the IRB agrees, the IRB should communicate the reasons for its decision to the community representatives. This communication will allow the IRB to explain its reasoning to the community and also to hear the community's response. The committee believes that significant disagreements are best resolved before a study begins and children are enrolled, rather than after it has begun. In addition, heightened monitoring by IRBs and, where appropriate, by data and safety monitoring boards of progress reports of research projects approved under Section 406 may be warranted. Careful monitoring would help ensure that children do not experience unwarranted risks.

The guidance recommended above on research involving economically and educationally disadvantaged populations would assist IRBs in reviewing such protocols. Similarly, guidance on how to interpret minimal risk, and minor increase over minimal risk are essential since the decision about whether a given protocol represents minimal risk, a minor increase over minimal risk, or more than a minor increase over minimal risk emanates from the IRB.

If an IRB determines that a project is not approvable under Section 406 but is likely to generate knowledge of national significance, the protocol can also be considered for review under Section 407, which provides for the review of protocols by a special national panel, an opportunity for public comments on the protocol, and approval by the DHHS secretary. In the past, the 407 process was often prolonged, and few protocols have been reviewed and approved under this mechanism (Kopelman and Murphy, 2004). OHRP has improved the review process, eliminated the backlog of cases, and reduced the amount of time required for a decision. The greatest advantage of these special panels is the opportunity for public discussion of the merits of proposals and about "the level of research risk that should be permitted with minor subjects" and "how the values of scientific progress and the protection of the rights and welfare of subjects should be ranked when they conflict" (Kopelman and Murphy, 2004, p. 1788). Particularly for projects likely to generate substantial controversy, transparency in the review process will result in greater accountability and ultimately in greater public trust that the review has been impartial and fair. Furthermore, IRBs that review sensitive protocols, particularly protocols likely to generate substantial controversy, can request a review by OHRP of whether a project they are considering approving should instead undergo a special panel review under Section 407. OHRP can provide guidance on whether the proposed protocol is approvable under Section 404, 405, or 406, or if it requires review under 407.

INSTITUTIONAL REVIEW BOARDS

The Common Rule specifies requirements related to IRB functions and operations, including both the initial review of projects and their continuing review, as well as requirements for IRB membership (45 CFR 46.107; 21 CFR 56.107). IRBs are responsible for reviewing research protocols to ensure that they meet all of the regulatory requirements to protect human participants. In conducting their review, IRBs must make a series of determinations related to whether specific aspects of the protocol meet the requirements of the federal regulations (see Chapter 3). In the case of research involving minimal risk to participants, an IRB can provide an expedited review by less than the full committee (45 CFR 46.110).

In their continuing review of ongoing research (see, e.g., 45 CFR 46.109), IRBs must pay particular attention to any unanticipated risks that emerge during the course of the research and meet several requirements. Continuing review must occur at least annually, with more frequent review required if the research protocol changes significantly or if the level of risk presented by the protocol warrants it. If, as a result of continuing review, the IRB determines that the research as conducted does not meet the requirements of the federal regulations and is not consistent with the IRB's initial approval, or if it finds unexpected serious harm to participants in the research, the IRB may suspend or terminate its approval of the research. In such cases, the IRB must give the reasons for such action and promptly notify the investigator, "appropriate institutional officials, and the Department or Agency head" (45 CFR 46.113).

An IRB must have at least five members. At least one member must be concerned primarily with scientific topics, and at least one member must be concerned primarily with nonscientific topics. At least one must not be affiliated with the institution (that houses the IRB) directly or through a family member. These nonaffiliated and nonscientific members are expected to represent the concerns of research participants and the communities from which participants are drawn. Taken together, the members must have sufficient expertise, experience, and diversity of backgrounds to promote competent review of the usual kinds of research conducted by the institution and to promote "respect for its advice and counsel. Diversity of backgrounds includes not only areas of scientific or professional expertise but also culture, race, and gender" (Institute of Medicine, 2004, p. 97). IRBs also have ways to supplement their expertise. IRBs that regularly review proposals that include children are not required to have a member or members who have expertise and experience with children, but they are advised to consider the inclusion of such individuals. The regulations provide that IRBs may seek assistance from "individuals with competence in special areas . . . which require expertise beyond or in addition to that available on the IRB (45 CFR 46.109 (f)). OHRP guidance also strongly recommends that institutions provide appropriate education and training for investigators, IRB members, and others involved in research oversight.

The goals of research oversight are to safeguard research participants and to ensure that research is conducted in an ethical manner. Neither goal is well served if a review is either too permissive or too stringent because of unusual features of a specific research project. Several issues affect the ability of IRBs to provide effective oversight of housing health hazards research.

IRB Expertise

The criteria for the approval of research and the elements of informed consent as set forth in Subpart A of the federal regulations are broadly applicable to a wide variety of research types. However, a specific type of research under review may differ from that usually conducted at a given institution and seen by its IRB. Moreover, the language of the regulations suggests that the authors had clinical trials in mind. For example, the consent requirement that research participants be told what alternatives they may be forgoing is worded in terms of "alternative procedures *or courses of treatment*" (45 CFR 46.116(a)(4) [emphasis added]). If a researcher proposing a hypothesis-generating ethnographic study comes before an IRB that is most familiar with drug trials and other hypothesis-testing research, the IRB members may have little basis for evaluating the risks and benefits. The social, behavioral, and economic sciences research community reports such concerns, with IRBs perceived as overestimating the risks presented by research in those fields and thereby obstructing worthwhile research (National Research Council, 2003). Thus, the research community has concerns that IRBs are not able to accurately assess the risks presented by protocols unfamiliar to them.

To determine whether risks have been minimized to the extent possible, consistent with sound research design, an IRB must understand the types of research it is reviewing. The IRB must include members (or consultants) who know what constitutes sound research design and who can judge whether less risky approaches than those proposed can be used without compromising the science at hand. Typically, an institution will recruit as its IRB(s) members who are themselves researchers and who have a basic familiarity with the sorts of research that frequently come under scrutiny. In the case of housing health hazards research, IRBs should consider the possibility of including local community residents who are representative of the community: for example, if the community is primarily a low-income minority community, the IRB representative should be as well. If the IRB reviews a significant amount of housing health hazards research, it should consider constituting a community advisory board.

Although there is no empirical evidence that IRBs do not have the necessary expertise to review housing health hazards research, several recent IOM reports have pointed to the need for IRBs to have expertise relevant to the type of projects being reviewed. *Ethical Conduct of Clinical Research Involving Children* (Institute of Medicine, 2004) emphasizes that IRBs that review research involving children need expertise in the "biological, medical, behavioral, and emotional dimensions" of research involving children and points out that IRBs have a variety of mechanisms available to ensure the necessary expertise, including using consultants or referring pro-

tocols to other IRBs with the requisite expertise. *Responsible Research* (Institute of Medicine, 2003) suggests that "the goal of research organizations should be to assemble a board with at least 25 percent of its membership not affiliated with the institution, not trained as scientists, and able to represent the local community and/or the participant perspective" (p. 96). This suggestion mirrors a similar recommendation made by the National Bioethics Advisory Committee (2001). As discussed earlier in this report, issues of community representation are particularly salient in the context of housing health hazards research.

Although research on housing health hazards appears to be increasing, there are still relatively few institutions that conduct such research in comparison with other types of research, such as biomedical research. IRBs that do review such research should ensure that they have the necessary expertise to provide a thorough review. IRBs can increase their familiarity with any unique aspects of housing health hazards research when such studies begin to be presented for review and can expand their expertise as necessary.

The regulations recommend that when IRBs deal frequently with vulnerable participants, "consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with" such persons and issues (45 CFR 46.107(a)). An IRB should have or develop the competence necessary to carry out the tasks set forth in the regulations. IRBs need to develop familiarity with housing health hazards research if they are to perform a good risk-benefit assessment, know what questions to pose to help (or challenge) an investigator, and be consistent in interpreting the regulations in this context. Federal regulations require that the IRB membership include people with the necessary expertise to "promote complete and adequate review of research activities commonly conducted by the institution" (45 CFR 46.107(a)). Although the regulations do not specifically require that the IRB membership include the expertise to review research not commonly conducted by the institution, there are other strategies an IRB can pursue to facilitate "complete and adequate review."

Several models for improving IRB expertise are possible, with the appropriate choice being based on the volume of such research seen by a given IRB. If a center does a large amount of nonclinical research, it may be appropriate to have dedicated IRBs that specifically review projects involving housing health hazards research and develop the needed expertise. It will often be appropriate to include IRB members who have a good working knowledge of housing health hazards research.

If an institution becomes involved only occasionally in housing health hazards research or in nonclinical research more generally, it is unlikely that an IRB with sufficient expertise can be empaneled locally. In such cases, federal regulations specifically allow an IRB to engage a nonvoting consultant to assist in the review (45 CFR 46.107(f)). The regulations also

provide opportunities for IRBs to conduct cooperative or collaborative reviews for projects that involve more than one institution (45 CFR 46.114). In the case of cooperative projects, IRBs may "enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort."

There are also other options available to obtain expertise in a consultative capacity. For example, central review boards can serve as consultants to local IRBs that lack the needed expertise. These could be central review boards not affiliated with an institution, or they could be the IRB of an institution at which such research is more common and where the needed expertise resides. In addition, central review boards can serve as the IRB of record in such circumstances: that is, a local IRB can delegate review of the protocol to a central review board with the requisite expertise.

If a specific competence or expertise is needed to thoroughly review a particular protocol, there may be both internal and external ways to meet this need, and the two may often be used well together. For example, if an institution and its IRB often review housing health hazards research, members of the target community or communities can be invited to serve as institutionally unaffiliated IRB members. If this unique role is taken seriously by the sponsoring institution and the IRB, it can enhance community representatives' ability to influence the manner in which research is conducted.

Research on nonaffiliated and nonscientific members demonstrates that they believe their role is to represent the community of human participants, especially those considered vulnerable by race, age, or social class, in addition to giving feedback on the accessibility and appropriateness of consent documents (Sengupta and Lo, 2003). However, many feel intimidated in interactions with scientific members of the review boards and believe that more training and education would allow them to perform their roles more effectively. In addition, IRBs often have one token community member or a community resident affiliated with the institution. One resident cannot represent the diversity of an entire community and should not be viewed as doing so. In addition, community representation on an IRB should not in and of itself be considered adequate community involvement. As discussed in Chapter 5, researchers should be required to involve the affected community in the design and implementation of their studies.

If inviting a community member(s) to serve on the IRB is not feasible or is too limited (e.g., if the communities served are several and diverse), persons from the community of interest can be called on to serve as nonvoting consultants in the review process. Finally, if the structure exists or can be developed within the community under study, a community advisory board can be established to consult with the institution and its IRB on research oversight issues. To ensure that the IRB provides independent

BOX 8-2
Possible Approaches to Ensuring Adequate IRB Review

- Include institutionally affiliated IRB members with a good working knowledge of housing health hazards research
- Involve community representatives as institutionally unaffiliated IRB members
- Use a nonvoting IRB consultant with necessary expertise
- Use community residents as IRB consultants
- Establish a community advisory board to consult with the IRB
- Delegate review to a central review board with requisite expertise
- Conduct a collaborative review with another IRB (when more than one institution is involved)
- Establish a dedicated IRB to review housing health hazards research

review, such a board should be distinct from any community advisory board(s) established by researchers (see Chapter 5).

The particular expertise needed will vary depending on the specific research protocol, and the appropriate IRB response will vary based on the frequency with which it is asked to review housing health hazards research and the nature of the research; see Box 8-2 for a summary list of possible approaches. Community perspectives might include expertise on cultural and language issues specific to the community. Another perspective that may be needed is environmental health.

IRB Submissions

IRBs should convey a clear expectation that ethical issues will be addressed in research protocols. Requiring structured information can help ensure that an IRB has adequate information to determine whether a given study is allowable under the federal regulations and has met the additional requirements articulated in this report. IRBs can also increase the likelihood that applications will include the detail and background necessary to understand how and why the research may meet the requirements for approval (Council for International Organizations of Medical Sciences, 2002). Institutions should strive to develop an oversight process that leads researchers to present their protocols to the IRB in a way that focuses on the pertinent regulatory and ethical issues.

One option would be development of targeted application forms for nonclinical research that asks for specific information and allows it to be

provided in a format appropriate to the type of research. Currently, researchers are often expected to fit their study description into a form designed for a quite different type of research, such as a clinical trial. For example, for a study that will involve a minor increase over minimal risk without the prospect of direct benefit (see above), the application process and form could specifically solicit a description of the "condition" that might make the study eligible for approval under Section 406. In addition, the application could ask for information specific to the recommendations in this report; for example, it could include clear requirements for researchers to provide information on how they have consulted with the affected community and responded to the community's needs, expectations, and concerns; how they have ensured that parents of child subjects understand the essential features of the research and relevant risks; and what plans they have developed for responding to risks observed in the home.

CONCLUSIONS AND RECOMMENDATIONS

The existing federal regulations under Subpart D provide a useful beginning framework for research involving children. However, the committee recommends additional safeguards to help ensure that housing health hazards research will meet careful ethical scrutiny. We believe that they will offer meaningful protections and ensure that vulnerable children are not subjected to unacceptable research risks, while allowing appropriate research aimed at ultimately ameliorating housing health hazards. At the same time, these recommendations will allow research of vital importance ultimately ameliorating housing health hazards to proceed without undue delay. The committee further concludes that the composition of an IRB is an important determinant in whether it has the necessary expertise to provide complete and adequate oversight of housing health hazards research.

Recommendation 8.1: All federal agencies—including the U.S. Department of Housing and Urban Development and the Environmental Protection Agency—private foundations, and other funders of research on housing health hazards involving children should at a minimum adopt the current regulatory framework in Subpart D of 45 CFR 46.

Recommendation 8.2: The Office of Human Research Protections should issue guidance to institutional review boards on how to interpret the key regulatory terms—"minimal risk," "minor increase over minimal risk," "disorder or condition," "reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations," and "vital importance"—in the context of housing health hazard research.

Recommendation 8.3: The Secretary's Advisory Committee on Human Research Protections should develop guidelines for research with economically and educationally disadvantaged participants for use by the Office for Human Research Protections in issuing guidance for researchers and institutional review boards.

Recommendation 8.4: Institutional review boards that review housing health hazards research involving children should ensure that those boards have the necessary expertise to conduct a complete and adequate review, including expertise on research involving children and community perspectives.

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Appendix

Biographical Sketches of Committee Members and Staff

Bernard Lo (*Chair*) is a professor of medicine and director of the Program in Medical Ethics at University of California in San Francisco and a practicing general internist. He directs the Greenwall Faculty Scholars in Bioethics Program and is a member of the Recombinant DNA Advisory Committee at the National Institutes of Health (NIH) and the Data Safety Monitoring Board for NIH-sponsored clinical trials in diabetes. He formerly was a member of the National Bioethics Advisory Commission and the Data Safety Monitoring Board for the AIDS Clinical Trials Group at NIH. He also directed the national coordinating office for the Robert Wood Johnson Foundation Initiative to Strengthen the Patient-Provider Relationship in a Changing Health Care Environment, and he chaired the End-of-Life Committee convened by the American College of Physicians. He is a former member of the Board of Directors of the American Society of Law, Medicine, and Ethics and the American Society for Bioethics and Humanities. He has written extensively on such issues as decisions about life-sustaining interventions, decision making for incompetent patients, physician-assisted suicide, ethical issues regarding HIV infection, and the doctor-patient relationship in managed care. He is a member of the Institute of Medicine (IOM) and serves on the IOM Council and on the Report Review Committee of the National Academies.

John Adgate is an associate professor in the Division of Environmental Health Sciences at the University of Minnesota School of Public Health. His research focuses on improving exposure assessment in epidemiologic studies by documenting the magnitude and variability of human exposure to air

pollutants, pesticides, metals, and allergens. He has written more than 40 research articles and book chapters on exposure assessment, risk analysis, and children's environmental health. He has served on many science advisory panels of the U.S. Environmental Protection Agency, exploring technical and policy issues related to residential exposure to pesticides, metals, and implementation of the Food Quality Protection Act of 1996. He has also served as an elected councilor of the International Society of Exposure Analysis, and he is the recipient of its Joan M. Daisey Outstanding Young Scientist Award. Dr. Adgate received a BA degree in biology from Calvin College, an MS degree in environmental science from the School of Public Health of the University of North Carolina at Chapel Hill, and a PhD degree in environmental health granted jointly by the University of Medicine and Dentistry of New Jersey and Rutgers University.

Gordon Cavanaugh is a former partner in the Washington, DC, law firm of Reno & Cavanaugh, PLLC, where he served, among other things, as general counsel to the Council of Large Public Housing Authorities from 1981 to 2002. He is the former chairman of CHF, International (formerly known as the Cooperative Housing Foundation), the founding executive director of the Housing Assistance Council, and a former board member of the Housing Research Foundation. He served as administrator of the Farmers Home Administration in the U.S. Department of Agriculture between 1977 and 1981. Previously, he chaired the Philadelphia Housing Authority and the Philadelphia Housing Development Corporation, served as the City of Philadelphia's Commissioner of Licenses and Inspections, and had a private and public law practice. He is a member of the District of Columbia Bar Association (D.C. Affairs Committee) and a former member of the University of Pennsylvania Law Review. He graduated cum laude from Fordham University and received his law degree from the University of Pennsylvania.

Giselle Corbie-Smith is an associate professor in the Department of Social Medicine and Internal Medicine at the University of North Carolina (UNC) at Chapel Hill and director of UNC's Program on Health Disparities at the Sheps Center for Health Services Research. Before coming to UNC, she was a faculty member in the Department of Medicine at Emory University/ Grady Memorial Hospital. She is currently the principal investigator on a National Institutes of Health Research Career Development Award and a Robert Wood Johnson Minority Medical Faculty Development Award to examine the patient-specific and investigator-specific factors that influence participation in research. Dr. Corbie-Smith has dedicated her academic career to understanding the health of minority and underserved communities, especially with regard to access to care and the influence of culture, race, ethnicity, and social class on health. Her research focuses on efforts to

address African American participation in research. She received an MD degree from Albert Einstein College of Medicine.

Brenda Eskenazi (*Board Liaison*) is a professor of maternal and child health and epidemiology at the University of California at Berkeley. She is a neuropsychologist and epidemiologist whose long-standing research interest has been on the effects of toxicants—including lead, solvents, environmental tobacco smoke, dioxin, and pesticides—on human reproduction (both male and female) and child development. She is the principal investigator and director of a National Institutes of Health and U.S. Environmental Protection Agency of the Center for Excellence in Children's Environmental Health Research (the "CHAMACOS" Project), which investigates the pathways and health effects of pesticide exposure in farmworkers and their children and develops interventions to prevent future exposure. She is also the principal investigator on two projects on endocrine disruption, one investigating the reproductive health of a cohort of women exposed to high levels of dioxin and another examining persistent and nonpersistent endocrine disrupting pesticides. Dr. Eskenazi is a fellow of the American College of Epidemiology and is on the editorial boards of several journals. She has contributed widely to the field of children's environmental health, including the Surgeon General's Report on Smoking and Women's Health, the World Health Organization's Tobacco-Free Initiative's report on environmental tobacco smoke, and the United States-Vietnam Committee on the Human Health and Environmental Exposures of Agent Orange and Dioxin in Viet Nam.

Alan R. Fleischman is a senior advisor at the New York Academy of Medicine, and a clinical professor of pediatrics and of epidemiology and population health at the Albert Einstein College of Medicine. He also currently serves as chair of the Federal Advisory Committee and ethics advisor to the National Children's Study at the National Institute of Child and Health Development of National Institutes of Health. Dr. Fleischman was a founding member of the American Academy of Pediatrics National Committee on AIDS and a member of the National Human Research Protections Advisory Committee for the Office of Human Research Protections in the U.S. Department of Health and Human Services (DHHS). He is currently a member of many advisory groups, including the New York State Governor's Task Force on Life and the Law (Bioethics Commission) and he is a consultant to the March of Dimes where he is cochair of the National Bioethics Committee.

Fernando A. Guerra is the director of Public Center for Environmental Health of the San Antonio Metropolitan Health District, clinical professor

of pediatrics at the University of Texas Health Science Center in San Antonio, and adjunct professor of public health at Brooks Air Force Base School of Aerospace Medicine. He has been active with local, national, and international forums on a variety of health issues, which include improving access to health care for migrant children; the development and implementation of a centralized immunization registry/tracking system; the integration of public health into managed care systems; and community-based programs for prevention of child abuse and adolescent pregnancies. Dr. Guerra is a member of the Children's Environmental Health Institute, the Board of Trustees of the Urban Institute, the New York Academy of Medicine, the Federal Advisory Committee for the National Children's Study, the Bioethics Committee for March of Dimes, and the Institute of Medicine.

Dale Hammerschmidt is an associate professor of medicine in hemotology and oncology at the University of Minnesota. His clinical practice centers around hematologic malignancies, refractory autoimmunity, and blood clotting disorders. He has been involved in regulatory affairs and research ethics at Minnesota for many years, and he served for several years as director of education in human subjects protection. His interest in research ethics developed "in the trenches," dealing with the problems of consent in the face of devastating new diagnoses and dealing with the "therapeutic misconception" in early trials involving desperate patients. In addition to his work in research ethics, Dr. Hammerschmidt's scholarship has centered on the tension among privacy statutes, patient expectations, ethical norms, and researchers' interests. He serves as editor in chief of the *Journal of Laboratory and Clinical Medicine*. He has received the Watson Award and the Medal of the Portuguese Society for Intensive Care Medicine and has been named to fellowship in the American College of Physicians.

Patricia King is the Carmack Waterhouse professor of law, medicine, ethics, and public policy at the Georgetown University Law Center and an adjunct professor in the Department of Health Policy and Management at the Bloomberg School of Public Health at Johns Hopkins University. She is a member of the American Law Institute and the Institute of Medicine and a fellow of the Hastings Center. Her work in the field of bioethics has included service on the Advisory Recombinant DNA Advisory Committee of the former U.S. Department of Health, Education, and Welfare, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and the Ethics, Legal and Social Issues Working Group of the Human Genome Project. She is a board member of the National Partnership of Women and Families, chair of the Board of Trustees of Wheaton College, and vice chair

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David H. Krantz is a professor of psychology and statistics at Columbia University. He previously chaired the Department of Statistics and was active in the leadership and administration of the Earth Institute at Columbia, which led to a number of ongoing research collaborations on climate-related and hazard-related decisions. Prior to joining Columbia, Dr. Krantz served as the head of the Human Information Processing Research Department at Bell Laboratories and taught at the University of Michigan. Dr. Krantz's current research focuses on decision theory and the foundations of probability and statistics, including how people use technical information (especially probabilistic information) in decision making and in decision making with multiple goals. His publications include a three-volume work on the foundations of measurement (co-authored with Duncan Luce, Patrick Suppes, and Amos Tversky) and publications on approaches to measurement, theory of evidence, and related issues in decision making.

Bruce P. Lanphear is the Sloan professor of children's environmental health and the director of the Cincinnati Children's Environmental Health Center at Cincinnati Children's Hospital Medical Center and the University of Cincinnati. He has conducted numerous epidemiologic studies and randomized controlled trials of environmental hazards, including dust control and soil abatement to prevent childhood lead exposure and HEPA-CPZ air cleaners to reduce children's exposure to environmental tobacco smoke. He is the principal investigator for a 5-year study at the—funded by the National Institute of Environmental Health Sciences and the U.S. Environmental Protection Agency—Children's Environmental Health Center on fetal and early childhood exposures to prevalent environmental neurotoxins, including lead, alcohol, pesticides, mercury, PCBs, and environmental tobacco smoke. He is currently conducting a randomized controlled trial to test the safety and efficacy of housing repairs to reduce childhood lead exposure and residential injuries in 400 children who are being followed from birth.

Mary Ellen O'Connell (*Study Director*) is a senior program officer in the Division of Behavioral and Social Sciences and Education (DBASSE) of the National Research Council, where she also serves as study director for the Committee on Standards of Evidence and the Quality of Behavioral and

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Jacqueline Patterson is peer consultation and review program manager and also vice president of Toxicology Excellence for Risk Assessment (TERA), a nonprofit organization dedicated to the best use of toxicity information for risk assessment. Ms. Patterson has developed and managed databases for the U.S. Environmental Protection Agency (EPA) and TERA, has written and reviewed numerous reports on risk assessment and related topics, and developed training courses and materials for various audiences. Recent projects include developing peer consultation procedures for risk assessment; an evaluation of the ethical conduct of 15 human pesticide studies for private companies; development of a framework and approach to characterize the effectiveness and risk from use of nonlethal weapons for the Department of Defense Joint Nonlethal Weapons Directorate and development of TERA's international toxicity estimates for risk database, which was added to the National Library of Medicine's TOXNET system in 2004. Previously, Ms. Patterson worked for the EPA as the integrated risk information system (IRIS) coordinator in Cincinnati, managing IRIS development and support activities. Ms. Patterson is a member of the Society for Risk Analysis and served as president of the Ohio chapter. She serves on the editorial board for the *Journal of Children's Health*. She holds an MS degree in environmental science from Miami University.

Peggy Shepard is executive director and cofounder of West Harlem Environmental Action, Inc. (WE ACT), New York's first environmental justice organization created to build community power to improve environmental health, protection and policy in communities of color which operates in partnership with the Mailman School of Public Health at Columbia University. Ms. Shepard received the 2005 Children's Environmental Health Excellence Award from the U.S. Environmental Protection Agency (EPA) and the 2003 Heinz Award for the Environment from the Heinz Foundation. Ms. Shepard was the first female elected chair of the National Environmental Justice Advisory Council to the EPA, and she is cochair of the Northeast

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Michael A. Stegman is the Duncan MacRae '09 and Rebecca Kyle MacRae professor of public policy, planning, and business at the University of North Carolina at Chapel Hill, chair of the Department of Public Policy, and director of the Kenan Center for Community Capitalism in the Kenan-Flagler Business School. Previously he served as the Assistant Secretary for Policy Development and Research at the U.S. Department of Housing and Urban Development (HUD). He is a fellow of the Urban Land Institute and a member of the board of directors of the Initiative for a Competitive Inner City and of the One Economy Corporation. He is a past member of the Affordable Housing Advisory Council of the Federal Home Loan Mortgage Corporation ("Freddie Mac"), the advisory board of the Brooking Institution's Center on Urban and Metropolitan Policy, and is past vice president of the Association for Public Policy Analysis and Management (APPAM) and a member of APPAM's Policy Council and Executive Committee. He has written extensively on housing and urban policy, and while at HUD, was founding editor of *Cityscape*. His most recent books are: *Savings and the Poor: The Hidden Benefits of Electronic Banking* (Brookings Institution Press, 1999) and *State and Local Affordable Housing Programs: A Rich Tapestry* (The Urban Land Institute, 1999).

Michael Weitzman is executive director of the Center for Child Health Research of the American Academy of Pediatrics and professor and associate chair of pediatrics at the School of Medicine and Dentistry of the University of Rochester. Previously, he was pediatrician-in-chief at Rochester General Hospital and the director of the Division of General Pediatrics at the University of Rochester; director of maternal and child health for the city of Boston; and director of general pediatrics at Boston City Hospital and Boston University School of Medicine. He has conducted research and written extensively on a wide range of issues, including epidemiology, childhood lead poisoning, chronic illness, passive and prenatal exposure to ciga-

rette smoke, breast feeding, excessive school absences, the academic benefits of the School Breakfast Program, health risk behaviors, school failure, and childhood asthma. He has published more than 200 articles, chapters, books, and abstracts of scholarly work, and he is coeditor of two pediatric textbooks. Dr. Weitzman also currently serves on the National Advisory Committee of the Robert Wood Johnson Generalist Physician Faculty Scholars Program and is a former member of the Childhood Lead Poisoning Prevention Advisory Committee of the Centers for Disease Control and Prevention. He was the 1997 recipient of the research award of the Ambulatory Pediatric Association's Research Award and the 1998 recipient of the association's teaching award.