

Ethics and the Protection of Human Subjects

2008



U.S. DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

New Grantee Orientation Conference

Introduction

- The purpose of this presentation to review key terms and issues relative to Human Subject Protection, and how they apply to OHHLHC grantees



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Common Rule

- Federal Policy for the Protection of Human Subjects in Research 45 FR 46
- Adopted by HUD in 24 CFR 60.101
- All programs conducting Research with HUD support are bound by the Common Rule
- Formalized requirements for:
 - Informed consent
 - Institutional Review Board (IRB) review



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What is Research?

- Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to **generalizable** knowledge
- Implies the use of scientific principles and methods, hypothesis testing and/or statistical analysis
- **Most** Healthy Homes demonstration projects include research activities



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IRB Review Required

- Activity involves research
- Research supported by HUD
- Research involves human subjects
 - Investigator intervenes in subjects' environment, interacts with subject, or gathers private information
- Research is *not* exempt from common rule
 - Research involving collection/use of data that are publicly available or have no personal identifiers



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Informed Consent

- A process, not just a form
- Highlighted by subjects' permission to participate in the research, but process is ongoing
- Grantee must ensure that:
 - Participant understands the process
 - Researcher properly trained to obtain it
 - Protections in consent form are followed
- Consent is voluntary and may be withdrawn at any time w/o penalty



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IRB Review

- Are all laws being met?
- Will research assure safety and well-being of participants?
- Will research protect privacy of participants, especially of vulnerable populations?
- Are risks minimized and selection of subjects equitable?

IRB Determines: Full or expedited review



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Cooperative Research

- Involves more than one institution
- Institutions:
 - Are all responsible for safeguarding the rights and welfare of human subjects and for complying with this policy
 - May enter into joint review or review by another IRB
- Single IRB should not be used to defeat intent of Common Rule



Institutional Assurance

- Required of all institutions conducting research supported by U.S. Dept. of Health and Human Services (HHS)
- Required by HUD under the NOFA
- Requires institutions to pledge conformance with HHS regulations (common rule and all subparts), mandate ethical research from its investigators, and use IRBs registered with OHRP



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HIPAA Privacy Rule

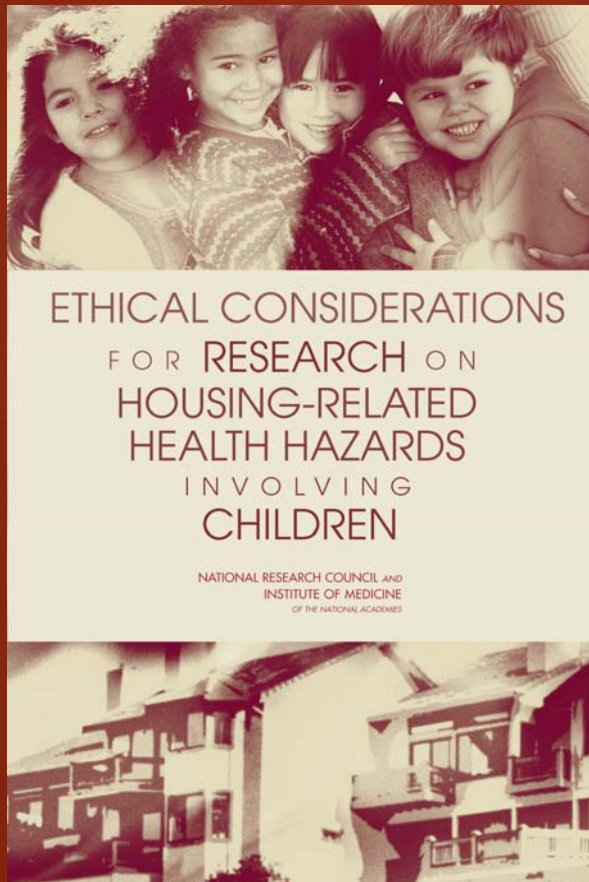
- Standard of privacy protections that limits use of patients' personal medical information by “covered entities”
- Covered entities include most health care providers (e.g., doctors and hospitals) and all health plans
- Health care providers should check with your organization if you are covered
 - Public health activities may be exempted



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



NATIONAL RESEARCH COUNCIL AND
INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Bernard Lo and Mary Ellen
O'Connell, *Editors*, NAP,
Washington, DC, 2005.



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Ethical Implications of Research w/Children in Low-income Families

- Vulnerable
 - Children cannot provide informed consent and have limited ability to protect themselves
 - Economic and educational disadvantages
 - Often members of ethnic minorities
- Challenges to informed, voluntary consent
 - Misunderstandings, therapeutic misconception
 - Payment amount may be undue inducement



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Ethical Implications of Research Conducted in Home

- Intrudes on privacy
- Observes risks not related to research questions
- Often intervenes on limited set of hazards
- Affects others in the home



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Ethical Implications of Research in the Community

- Possible distrust of researchers
- Community members and researchers may have different priorities and evaluate risks differently
- Findings may have community-wide implications



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Core Researcher Responsibilities

- Involve communities and respond to community concerns
- Ensure parents understand essential elements of research and that incentives are not an undue influence



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General Reporting Responsibility of Researcher

IOM Report (2005) makes three
recommendations on reporting:

- Participants should have a choice regarding receipt of results
- Participants need to understand significance of results and where they can go for help
- Participants should understand what they will receive as part of informed consent process



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Issues for Consideration

- Option not to notify
- Property owner notification; third party disclosure
- Lead disclosure rules
- Unknown/uncertain reference levels
- Medical results
- Language
 - Native language
 - Reading level



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