



DUKE UNIVERSITY SCHOOL OF MEDICINE

National Human Subject Protections Conference



U.S. Department of Health and Human Services  
Office for Human Research Protections

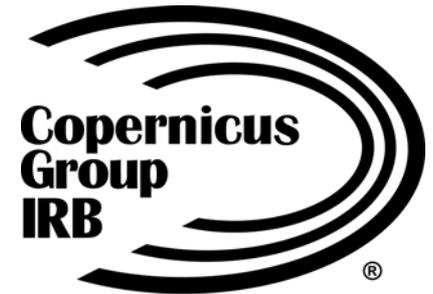
September 25-26, 2006 Sheraton Imperial Hotel and Convention Center, RTP, North Carolina

Crossing the Line: What is Acceptable Risk?

# C1: Ethical Issues in Research on Health Hazards in the Home



U.S. Department of Health and Human Services  
Office for Human Research Protections



NC STATE UNIVERSITY



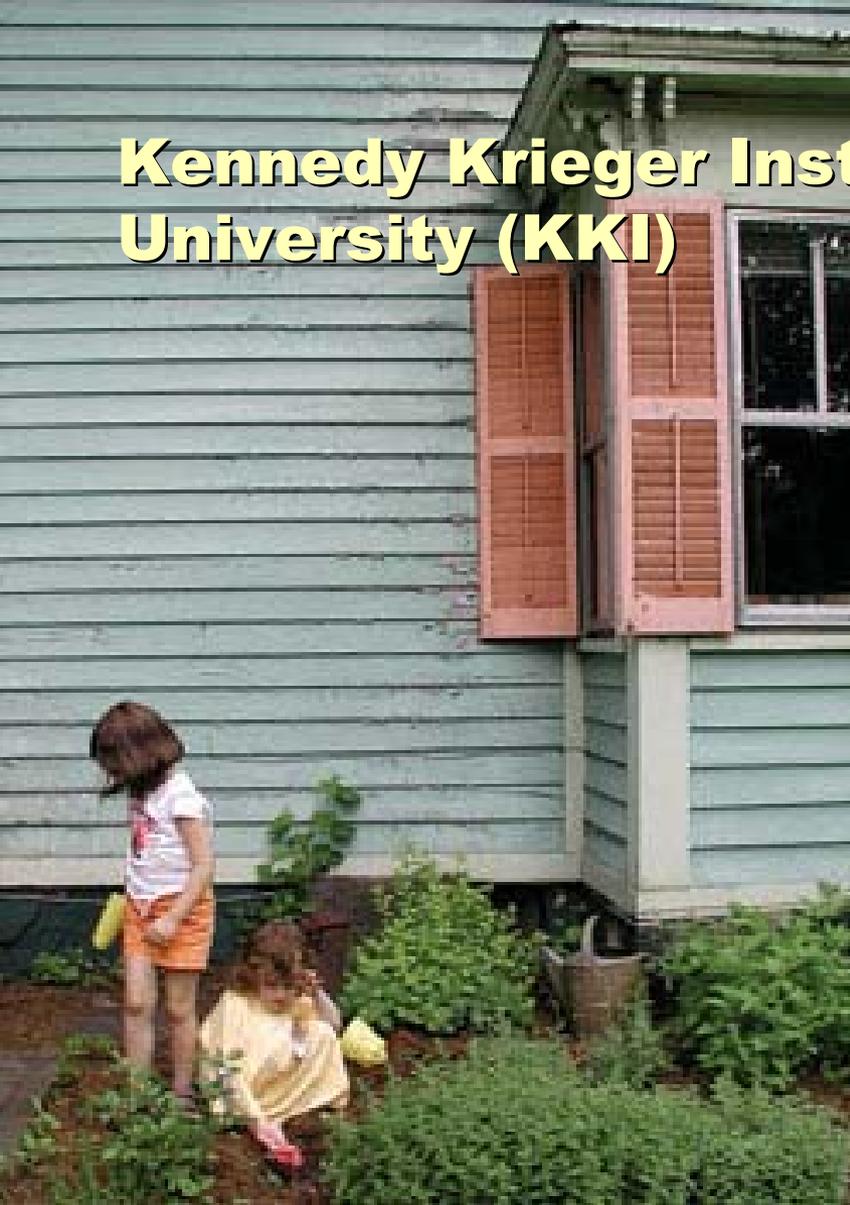
**NIEHS**  
National Institute of  
Environmental Health Sciences

# **Overview of the CHEERS and Kennedy Krieger Institute Studies**

**David B. Resnik, JD, PhD, Bioethicist, Vice Chair,  
NIEHS IRB, National Institute of Environmental Health  
Sciences**

**This research is supported by the Intramural program  
of the NIEHS/NIH. It does not represent the views of  
NIEHS or NIH.**

# Kennedy Krieger Institute at Johns Hopkins University (KKI)



# KKI

- In 1993, the EPA awarded a \$200,000 grant to KKI "Evaluation of Efficacy of Residential Lead Based Paint Repair and Maintenance Interventions." Mark R. Farfel ScD, directed the study.
- The Maryland Department of Housing and Community Development (DHCD) co-sponsored the study and the Baltimore City Health Department and Maryland Department of the Environment collaborated.
- The research was on different types of lead abatement in the homes of 25 families in living Baltimore, MD.
- The goal of the study was to assess the effectiveness of methods of lead abatement that were less than the full level of lead abatement.



- 3 experimental groups were randomly assigned to receive different degrees of less than full lead abatement:
- Group 1 - Repair & Maintenance Level I - Properties receiving a minimal level of repair and maintenance (\$1,650.00).
- Group 2 - Repair & Maintenance Level II - Properties receiving a greater level of repair and maintenance (\$3,500.00).
- Group 3 - Repair & Maintenance Level III - Properties receiving an even greater level of repair and maintenance (\$6,000.00 - \$7,000.00).
- Control group 1: living in homes with no lead paint
- Control group 2: living in homes with complete abatement.

# KKI

- Measurements were taken pre-intervention, post-intervention and at intervals of 12 and 24 months.
- Measurement of lead levels in dust and soil samples and drinking water.
- Measurement of lead in blood samples from children
- There were plans to inform parents of dangerous lead levels.

# KKI

- Agreements were reached with landlords: landlords would rent houses to families with young children in exchange for getting help with applying for and receiving grants for lead abatement.
- Families had to have at least one child under age 4.
- Excluded families with children with severe mental or physical retardation or sickle cell disease.

# KKI

- Grimes v. Kennedy Krieger Institute, 782 A.2d 807 (Md. 2001).
- Plaintiffs alleged that they were not adequately informed of about the risks of the study and dangerous lead levels in their children.
- Ethical/legal issues: Do researchers in non-therapeutic research (no direct medical benefit) have legal duties to subjects?
- Do investigators have a duty to warn subjects about dangerous hazards in the home in a timely fashion?
- What is the level of risk that children may be subjected to in non-therapeutic research?
- How should one resolve conflicts between federal and state laws pertaining to pediatric decision-making?

- Institute of Medicine. 2005. *Ethical Considerations for Research on Housing-Related Health Hazards Involving Children*. *Recommendations:*
- There should be community involvement in research design and informed consent document development.
- There should plans for responding to risks discovered in the home and for informing participants.
- Risks to 3<sup>rd</sup> parties should be addressed.
- All agencies should adopt The Common Rule for studying health hazards in the home.



## **Children's Environmental Exposure Study (CHEERS)**



# CHEERS

- EPA-sponsored, with collaboration from Duval County, Florida Health Dept (Jacksonville) and CDC.
- The DCHD helped to recruit subjects and served as a community liaison.
- Initiated in October 2004.
- Field monitoring study of the effects of pesticides (and other chemicals) on young children in the home environment.
- Would have included 60 young children (under age 3) not attending daycare and living in homes with high pesticide use.
- A control group of 6 children with low pesticide use would also be recruited.

# CHEERS

- The researchers planned to distribute posters and flyers at the Duval County Health Department (DCHD) clinics, pediatrician's offices, schools, churches, stores and three hospitals.
- After the initial screening interview, research staff would schedule a home visit to determine eligibility for the study.
- During this visit, researchers would take surface wipe samples, obtain information about pesticides and cleaning products used in the home, explain the study activities in more detail, and obtain a written consent from the parent.
- If the home was recruited for the high pesticide use group, but evidence did not show high pesticide use, they would be excluded from the study.

# CHEERS

- Following the initial screening visit, the study would have conducted data collection and sampling on six monitoring events over a two-year period.
- Each monitoring event would involve five three-hour visits to the home in which investigators would interview parents, and obtain urine samples, air samples, soil samples, and surface-wipe samples.
- The investigators would also inform parents about following manufacturers' instructions for pesticide use and warn them about unsafe pesticide exposures.

# CHEERS

- Parents would assist in the data collection by recording their pesticide and anti-microbial purchases during the two-years of the study, observing their child's activities during the monitoring periods, keeping a food diary during the monitoring period, and collecting samples of food, hand wipes, and urine.
- They would also videotape the daily activities of their children. Each child would wear an electronic activity monitor around the ankle and be videotaped during the monitoring period.

# CHEERS

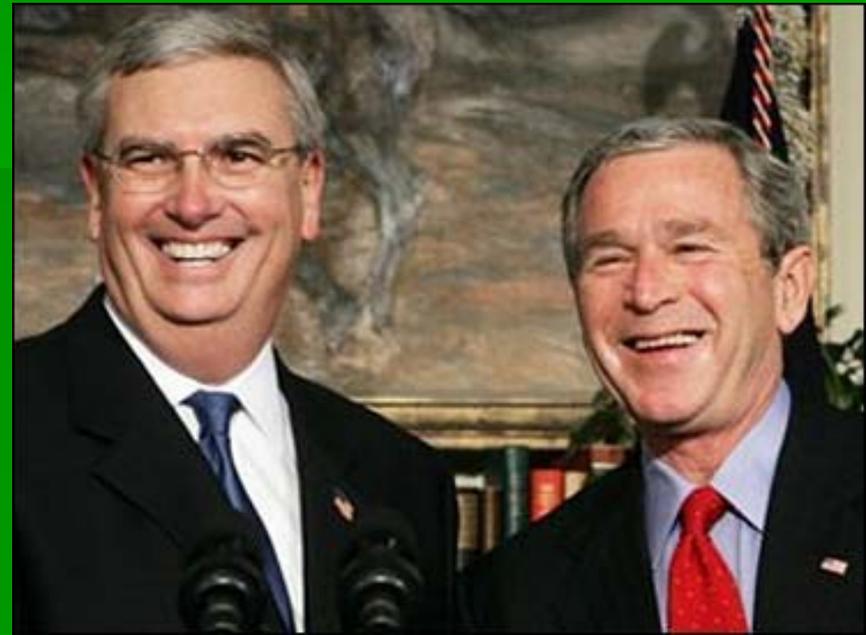
- Parents would not be required to begin using pesticides or continue using pesticides.
- They were free to withdraw from study or change their pesticide use.
- CHEERS would pay participants up \$970 to complete the study and give them some promotional items, such as bibs and t-shirts. Parents would also be allowed to keep the video camera that they would use to record data for the study.

# CHEERS

- The study was approved by Institutional Review Boards at Battelle Memorial Institute, the University of Florida, and the Florida Department of Health.
- The American Chemistry Council (ACC) gave the EPA a \$2.1 million grant to expand CHEERS to collect data on exposures to chemicals present in consumer products, such as phthalates and flame retardants.
- The ACC would have no control over the design of the study, data analysis, or publication.

# CHEERS

- CHEERS became embroiled in controversy.
- Environmental advocacy groups objected to the study on the grounds that it would intentionally expose children to pesticides and exploit minority groups.
- Barbara Boxer (Dem-Cal) threatened to derail Stephen Johnson's nomination EPA administrator if he did not stop the study.
- Johnson cancelled CHEERS on April 8, 2005.



# CHEERS

- Boxer sponsored an amendment to legislation (P.L. 109-54) which passed in 2005.
- The amendment places a one-year moratorium on the EPA accepting any third party data relating to human pesticide studies and EPA funding of studies that intentionally expose human subjects to pesticides.
- It also bans intentional exposure studies on children, infants, or pregnant women, and requires the EPA to establish an independent review board to review intentional exposure studies.
- On February 6, 2006, the EPA adopted new regulations pertaining to research on human subjects, which became effective on April 7, 2006.
- The regulations are consistent with Boxer's amendment.

# **Ethical Issues in Research on Health Hazards in the Home: Lessons from the Kennedy Krieger Study**

Michael A. Stegman,  
Duncan MacRae '09 and Rebecca Kyle MacRae Professor Emeritus  
of Public Policy  
University of North Carolina at Chapel Hill  
Director of Housing & Policy  
The John D. and Catherine T. MacArthur Foundation

## The larger context I

- In 2001, there were only 42 units affordable and available to every 100 poor renter households, a national shortage of 4.9 million units.

# The larger context II

“Childhood lead poisoning is directly related to a shortage of safe, affordable housing. Deteriorating lead-based paint is the main cause of childhood lead poisoning...The lack of affordable housing in many communities results in low-income families living in older dwellings with deteriorating lead paint, placing children at increased risk for lead poisoning.” (Issue Brief, Childhood Lead Poisoning, Rhode Island Kids Count, February 2003, p. 1.)

## **Triage: the political economy of housing in Baltimore**

“We have three types of neighborhoods in our city: neighborhoods that are stable; neighborhoods that are under stress; and neighborhoods that are under siege. As we work with better policing, better youth opportunities and better addiction treatment to lift the siege, we must, at the same time, strategically invest our housing dollars in ways that will reduce stress, spread stability and build from strength.”

(Mayor O'Malley, November 13, 2000).

## Housing health hazards research affecting children raises important issues

- Intrudes on the privacy of all residents.
- Involves community concerns about the safety & quality of housing—special problems in multifamily housing.
- Because some hazards occur disproportionately among low-income children & minority children are disproportionately poor, raises questions of targeting subjects, or inequitable selection of vulnerable populations;
- Economic & educational disadvantage & limited literacy may complicate or compromise the informed consent process.

# CAPTA duty to report

Child Abuse Prevention & Treatment Act of 1974

- Federal government & all 50 states have a mandatory reporting law on child abuse & who is required to report & all provide legal immunity for good faith reporting;
- But what about reporting housing-based health hazards to children such as large holes in floors, frayed wiring, broken stairs, etc.?

# The Kennedy Krieger repair & maintenance study I

- Determine efficacy of lead abatement methods in the home at reducing children's exposure to residential paint & dust.
- Participating families randomly assigned to 1 of 3 treatment groups, or either of 2 control groups.
- Treatment groups were homes known to have lead present.
- Control group homes either had had lead present at one time but were previously treated, or were built after 1980 & presumably never had lead present.

# The Kennedy Krieger repair & maintenance study II

- The amount of repair & maintenance conducted in treatment homes increased from Group 1 to Group 2 to Group 3.
- Landlords who volunteered to place their housing in study (some lead present required) received free lead abatement.
- They were also obligated to rent their units to families with young children.

# The Kennedy Krieger repair & maintenance study III

- Litigation brought by mothers of two children who were study subjects who were found to have elevated blood levels during course of study.
- Suit alleged that researchers & KKI were negligent in way they conducted study & breached their duty of care to the children by failing to notify parents of risks of children's exposure to lead.
- Virtually all (95%) of the private low-income housing in Baltimore at the time of the study had lead-based paint in the home.

# The Kennedy Krieger repair & maintenance study IV

- Plaintiffs' Case based on three contentions:
  1. Study design placed child subjects at an unacceptable level of risk;
  2. That KKI did not adequately inform mothers of the risks associated with the study; and
  3. That KKI Institute took too long to notify mothers of elevated levels of lead.

# The Kennedy Krieger repair & maintenance study V

- Informed consent document stated KKI would provide specific blood lead results & contact families to discuss a summary of environmental results & possible steps to reduce any risks of exposure.
- One plaintiff contended negligence because KKI failed to inform her of test results indicating potentially dangerous levels of lead in her home...
- Her argument implied that her child's involvement in study & having her house examined by investigators gave her a false sense of security that there were no potential lead-based paint or dust hazards in her home."

# Why litigation is important to researchers

- Prior to settlement, Court appeared to endorse more stringent criteria for allowable research (applicable in MD) than is permitted under federal regulations:
  - declared that parents may not consent to their children's enrollment in "nontherapeutic research" that does not offer the prospect of direct benefit

## Recommendations for IRBs that review housing health hazard research involving children

- Research designs should provide for appropriate community involvement & protocols should be responsive to community concerns;
- Informed consent process should reflect appropriate community input & include plans that ensure parents understand essential elements of research;
- Examine researchers plans for responding to risks observed in home & require that they be appropriate in the context of the research & the affected community.

## Recommendations for IRBs that review housing health hazard research involving children

- Include institutionally affiliated IRB members with a good working knowledge of housing health hazards research;
- Involve community representatives as institutionally unaffiliated IRB members;
- Use community residents as IRB consultants;
- Establish a community advisory board to consult with the IRB.

**Thank You**