

# Ethical Issues in Research on Environmental Health Interventions

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**Bioethics**

The ideas and opinions expressed in this lecture do not represent the views of the NIEHS, NIH, or federal government.

# Pinch-Hitter

- Richard Sharp was unable to present his lecture, due to a mandatory evacuation of Houston in advance in hurricane Rita.
- This lecture is based on  
Resnik D, Zeldin D, Sharp R. Research on environmental health interventions: ethical problems and solutions. *Accountability in Research* 2005; 12: 69-101.

# Cases

- Kennedy Krieger Institute (Johns Hopkins) lead abatement study
- Research on different types of lead abatement
- 25 families in Baltimore, MD
- 3 groups randomly assigned to receive different degrees of lead abatement
- 2 control groups: 1 living in homes with no lead paint; 1 living in homes with complete abatement.

# Cases

- Collection and measurement of lead levels in dust samples
- Collection and measurement of lead in blood samples from children
- Plans to inform parents of dangerous lead levels
- Agreements reached with landlords. Encouraged them to rent to families with young children and helped them get grants for lead abatement.

# Cases

- Lawsuit: *Grimes v. Kennedy Krieger Institute*, 782 A.2d 807 (Md. 2001).
- Ethical/legal issues: Do researchers in non-therapeutic research (no direct medical benefit) have legal duties to subjects?
- Should investigators have warned subjects about dangerous lead levels 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?

# Cases

Allergen reduction research. NIEHS researchers (Zeldin D, Arbes S).

Looking at the use allergen test kits as an environmental intervention to reduce exacerbations and symptoms among people with asthma. Giving families test kits, showing them how to use them. Giving them education on allergen reduction. Taking dust samples around the house. Allergens: cockroach parts, dust mites, pollen, etc.

**Morgan W et al. Inner-City Asthma Study Group. Results of a home-based environmental intervention among urban children with asthma. N Engl J Med. 2004 Sep 9;351(11):1068-80.**

**BACKGROUND:** Children with asthma who live in the inner city are exposed to multiple indoor allergens and environmental tobacco smoke in their homes. Reductions in these triggers of asthma have been difficult to achieve and have seldom been associated with decreased morbidity from asthma. The objective of this study was to determine whether an environmental intervention tailored to each child's allergic sensitization and environmental risk factors could improve asthma-related outcomes. **METHODS:** We enrolled 937 children with atopic asthma (age, 5 to 11 years) in seven major U.S. cities in a randomized, controlled trial of an environmental intervention that lasted one year (intervention year) and included education and remediation for exposure to both allergens and environmental tobacco smoke. Home environmental exposures were assessed every six months, and asthma-related complications were assessed every two months during the intervention and for one year after the intervention. **RESULTS:** For every 2-week period, the intervention group had fewer days with symptoms than did the control group both during the intervention year (3.39 vs. 4.20 days,  $P<0.001$ ) and the year afterward (2.62 vs. 3.21 days,  $P<0.001$ ), as well as greater declines in the levels of allergens at home, such as *Dermatophagoides farinae* (Der f1) allergen in the bed ( $P<0.001$ ) and on the bedroom floor ( $P=0.004$ ), *D. pteronyssinus* in the bed ( $P=0.007$ ), and cockroach allergen on the bedroom floor ( $P<0.001$ ). Reductions in the levels of cockroach allergen and dust-mite allergen (Der f1) on the bedroom floor were significantly correlated with reduced complications of asthma ( $P<0.001$ ). **CONCLUSIONS:** Among inner-city children with atopic asthma, an individualized, home-based, comprehensive environmental intervention decreases exposure to indoor allergens, including cockroach and dust-mite allergens, resulting in reduced asthma-associated morbidity.

# What is an environmental intervention?

- Environment: broad notion.
- Could include food, air, water, housing, geography, social support, etc.
- Environmental intervention vs. a medical intervention (drugs, surgery, nutrition, psychotherapy, etc.)
- Environmental intervention vs. public health intervention (immunization programs, mosquito control, sanitation, drug testing programs, etc.)

Biosphere

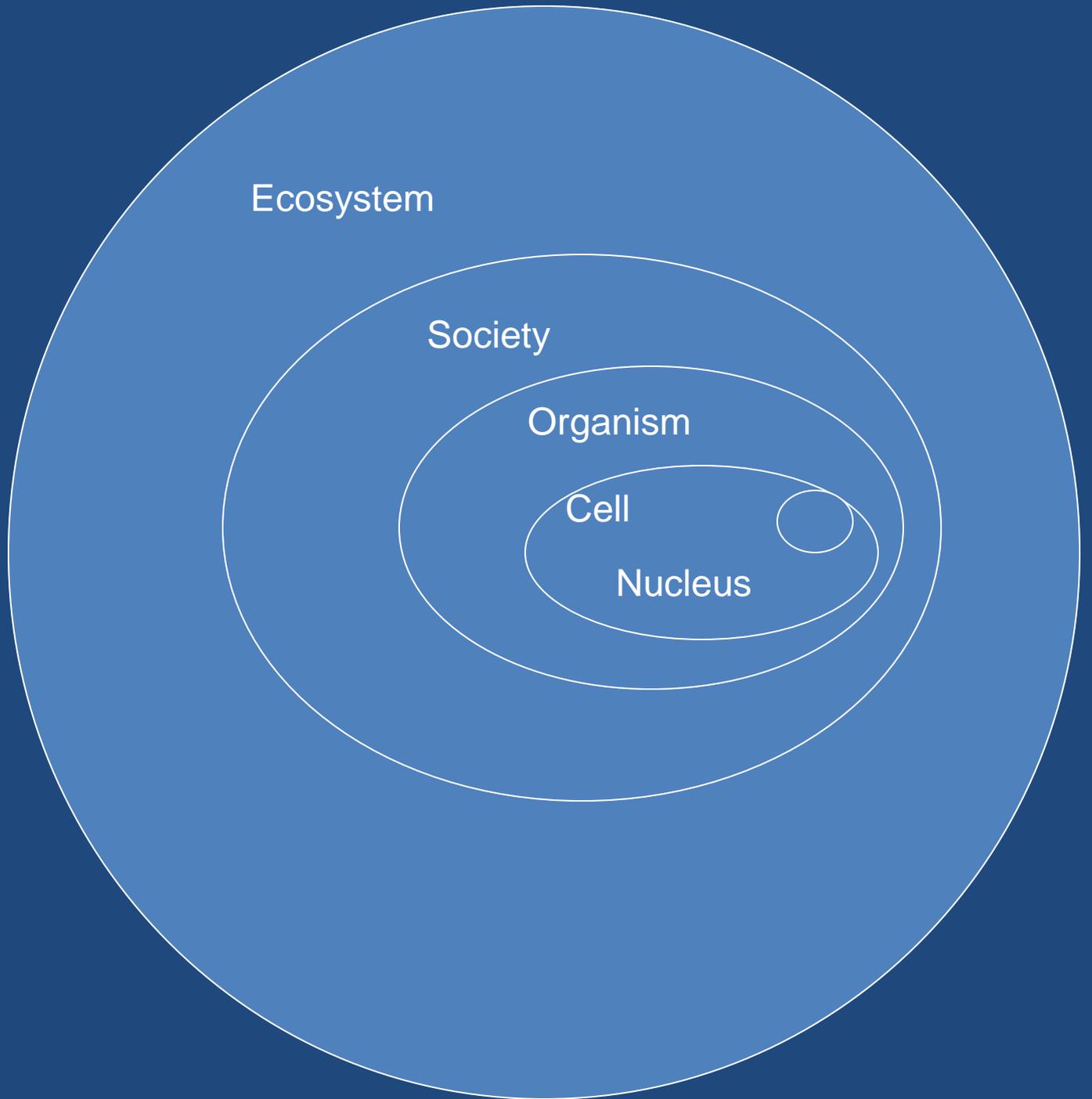
Ecosystem

Society

Organism

Cell

Nucleus



# What is an environmental intervention?

- Both cases focus on interventions in the home environment (could also be: the work environment, hospital, etc.)
- Measurement of health-related outcomes

# Research methods

## Controlled studies

- Active controls (KKI study) vs. Inactive controls (placebo)
- Randomization vs. No-randomization
- Blinded vs. Un-blinded

## Uncontrolled studies

- Field observations (CHEERS)
- Epidemiological (prospective vs. retrospective)
- Case reports
- Surveys/interviews/focus groups

The randomized controlled trial (RCT) is recognized as the gold standard for proving causation in biomedicine, but other methods can provide useful information and may be appropriate in circumstances where it is not ethical or practical to conduct an RCT.

# Risk/benefit issues

- Benefits of the interventions to the subject (health benefits, education) and society (advancement of knowledge, development of new health interventions)
- Risks of the research procedures, such as the environmental intervention and the data collection (privacy risk)
- Risk of not receiving an intervention (if in an inactive control group)
- Legal risks, e.g. duty to report neglect/abuse

# Risk/benefit

- Is the research minimal risk?
- Restrictions on the participation of vulnerable subjects in non-beneficial, more than minimal risk research.
- *Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. 45 CFR 46.102(i)*
- Risk of using an allergen test kit; risk of loss confidentiality (should be minimal if procedures are in place to protect confidentiality); legal risks.
- Are risks reasonable in relation to benefits?

# Risk minimization

- Warning participants about dangerous conditions, such as dangerous allergen or lead levels.
- How far should researchers go with this? What if they discover defective air vents, insulation, leaking water, gas lines, etc.? Should they make referrals to experts to deal with this?
- Excluding some subjects or families who would be at risk, such as children with very bad health problems.
- Protecting confidentiality: security measures + certificate of confidentiality.
- Data and Safety Monitoring Board

# Using control groups

- In clinical research, it is unethical to use an inactive control if an effective treatment is available for a significant medical problem. Not offering the treatment would be withholding medical care.
- Is an environmental intervention like medical treatment? (Both could be beneficial.)
- Is relationship between researcher and subject like the relationship between physician and patient? (Both relationships involve the potential for vulnerability or dependence.)
- What duties do researchers have to participants in non-medical research, duties of beneficence, non-exploitation?

# Using control groups

- If there is a proven environmental intervention, such as lead abatement, then withholding could be considered unethical exploitation.
- Consider lead abatement: suppose that the KKI study had used inactive controls of families living in houses with lead paint and no lead abatement.
- Would it be unethical to monitor families living in homes with lead paint and not offer them some form of lead abatement?
- What constitutes “proof” of effectiveness? The weight of scientific evidence, community acceptance, commercial success?

# Informed consent

- Studies enroll households/families
- Who are the research subjects?
- Who gives consent?
- Who are you collecting data or obtaining identifiable private information about?
- ***Human subject*** means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or 2) Identifiable private information.

45 CFR 46.102(f)

# Informed consent

- **Common situation: parent enrolls household in study.**
- **Parent or perhaps a child is the research subject.**
- **Parent could consent for child.**
- **Child's assent may be appropriate.**
- **Should other people in the household be informed about the research?**
- **Should they consent? What if they say no?**
- **What about other third parties, landlords, etc.?**
- **Investigators may have to exclude some households if they run into problems like these.**

# Informed consent

- Subjects/participants should be informed about the risks of research participation.
- What about other risks, such as the risks of living in a home with hazardous conditions, such as lead paint, allergens, etc.?
- Duty to inform participants about these risks as well so they can understand why investigators are conducting the research and decide whether they can to be in the study or consider changing their home environment.

# Community consultation

- Community involvement is important for research that can have a significant impact on the community.
- Community consultation can help with research design, development of consent forms, recruitment, and public support.
- Lead and allergens in homes are community issues.

# Other issues

- Payments/incentives.
- Collaboration with private industry; financial conflicts of interest.
- Statistical issues: sample size.
- Advertising.
- Communicating results to the public.

# Conclusion

- Some commentators have expressed the concern that the KKI lawsuit would have a chilling effect on research on environmental interventions.
- Hopefully, this is not the case: research on environmental interventions can improve human health and enhance our understanding of the relationship between health and the environment.
- Since environmental interventions are a relatively new area of research ethics, it is important to continue exploring and clarifying the ethical, legal, and social issues that arise in such studies.