



## Ethical Issues in the Design and Conduct of Community-Engaged Research

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The challenge of balancing scientific rigor, community contexts, and ethical concerns has become increasingly complex.

*Ethics affects scientific, methodologic, & practical concerns of community-based research*

- Ethical issues related to research participants
- Professional relationships
- Relationship between science and society



## Unique Features of Community-Based Research that Impact Ethical Issues?

- More likely that ethical considerations will arise *during* the project
- Requires the ability to deal with unexpected issues as they arise
- No easy answers – think about & consider several 'real world' cases

### Case #1

#### Community Research Assistant Noncompliance



You are conducting an NIH-funded study to evaluate the effects of community education (by lay health educators) to reduce child lead poisoning in a minority community near a former mining site (a Superfund Site).

The study involves collecting behavior and blood lead data in 3-5 year-old children in the community.

You have hired and trained local, community residents to complete these tasks.



The community RA's were trained in phlebotomy and human subjects protection, were certified, and have had strong supervision in their practice sessions.

### Case #1

#### Community Research Assistant Noncompliance



Six months into the study, you hear from one of the RA's that another RA is not drawing blood from study participants, but using their own blood for the study. The reason given is that they feel uncomfortable drawing blood from young children. You sense that there may be some interpersonal conflicts among the RA's which could explain these accusations.



- What is the ethical dilemma you face as a researcher?
- How would you handle this situation?
- What would be your first steps?
- How would you protect the integrity of the research data and the project as a whole?

## Community-Engaged Research



### ➤ Working definition:

"...the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people."

### ➤ General goals of CE

- Involve community members/organizations in research as participants and investigators
- Create and maintain mutually beneficial, trusting relationships between researchers and participants
- Improve overall health outcomes for targeted area

Principles of Community Engagement, second edition, Clinical and Translational Science Awards Consortium, Community Engagement Key Function Committee Task, NIH Publication No. 11-7782, June 2011.

## Roots of CE Research



From: [https://catalyst.harvard.edu/pdf/regulatory/CErR\\_Webpage\\_101\\_Presentation.pdf](https://catalyst.harvard.edu/pdf/regulatory/CErR_Webpage_101_Presentation.pdf)

## Continuum of CE Partnership Models

- Researcher–community partnerships fall along a continuum of possible degrees of involvement and interaction with communities



## Principles of CE

- For community-engaged research to succeed, researchers must...
  - Recognize and respect the diversity of the community
  - Identify and mobilize community assets and strengths
  - Develop the community's capacity and resources to make decisions and take action
  - Be prepared to release control of actions or interventions to the community and be flexible enough to meet its changing needs

*Principles of Community Engagement, Second Edition*



## Challenges regarding researchers' responsibilities to participants, organizations or communities

- Extent of collaboration & shared decision-making
- Whose research agenda?
- Risk of raising false hopes
- Sharing of data and research findings
- Responsibility to establish a long-term relationship with the community
- How does the community define itself and its boundaries?



## Community Advisory Boards (CABs)

- Provide structure for input to investigators:
  - Help frame research question
  - Review data collection procedures
  - Provide input on cultural appropriateness on data collection instruments and intervention materials
  - Provide access to settings for intervention and data collection
  - Aid in interpreting results
  - Assist with dissemination of findings & adopting successful interventions



## Methods of Data Collection

### Unit of observation may be:

- Individuals
- Groups
- Organizations
- Communities
- Geographic
- Political

### Data collection

- Direct – asking questions or conducting observations
- Indirectly – reviewing records or archival sources
- Observation
- Self report surveys and interviews most common



## Basic Ethical Principles

- Respect for Persons
- Beneficence
- Justice



## Respect for Persons

Researchers treat individuals as autonomous human beings who are capable of making their own decisions and choices.

Researchers do not use people as a means to an end

Researchers provide extra protections to those who are vulnerable

## Respect for Persons

**Full Autonomy means... participants can understand the information & choose freely to participate or withdraw, w/o coercion or undue influence**

Respect for Autonomy = Right of individuals and groups to make decisions for themselves

- Informed consent
- Voluntary data provision and participation
- Avoidance of excessive inducements to participate/incentives

## Respect for Persons

### Disclosure

- Statement of purpose
- Explanation of procedures
- Description of discomforts and risks

### Informed Consent

- Provision of complete information may lead to:
  - refusal to participate
  - behavior change
  - biased responses

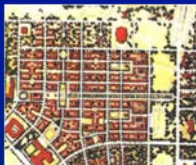
Group, organization or community consent?

**Informed consent is not a document but a process**



## Case #2

### Community Consent – is it needed?



You are conducting a descriptive study of the built environment in several neighborhoods, which vary by SES and racial composition. You want to learn about health disparities and social determinants of health.

The neighborhoods are defined as census block groups for which you were able to get race and SES data from the Census.

The study includes looking at the condition of the sidewalks, streetscapes, and exteriors of buildings. It also involves conducting observations of the types of foods that are for sale in stores, and their prices.



- Do you need permission from the 'neighborhoods' or 'communities' to collect these data? Why or why not?
- Do you need to tell the 'neighborhoods' or the food store owners what you are trying to study? Who should you tell? How specific do you need to be? Why or why not?

## Case #2

### Community Colleagues' Permission?

You are beginning your study; you selected the neighborhoods based on certain Census-based criteria.

It turns out that you have colleagues at a different university who are conducting CE research in one of the neighborhoods.

You tell them that you are working in NorthEast Park (the neighborhood), and offer to share your data with them so they may use it for an intervention study in the future, if they want to.

Rather than being pleased, they are furious that you are 'in their neighborhood' without their permission.

- Do you need the other university colleagues' permission to conduct the research in that neighborhood?
- If so, why? If not, why not?
- Depending on your answer, what would you do next?



## Informed Consent and Literacy

- Vocabulary used to communicate required elements of informed consent to potential study participants
  - Low income persons
  - Minorities
- Readability level
- Non-English speakers



## High Risk and Vulnerable Communities

- Increased CE intervention research directed to minority and low-income communities
- Health equity concerns and funding priorities both drive this trend
- Distrust of health researchers (Tuskegee Syphilis Study; HeLa cells)
  - Formal safeguards and reforms may be insufficient
  - Researchers and funding institutions may either
    - object that community partnerships introduce biases and compromise rigor, OR
    - Hold strong opinions about who should represent the community's consent



## Autonomy Concerns

### Use of incentives

- Small gifts
- Payments
- Reimbursements
- Usually does not compromise ethics if they do not involve unreasonable enticements or appear as coercion



## Privacy Issues

- Privacy
  - Sensitivity of information
  - Setting being observed
  - Linkage of information to subject names
  - Confidentiality vs anonymity
  - Confidentiality essential in:
    - Home/community
    - Work settings
    - Where services provided
    - Educational settings



## Privacy Issues

### Respect for Privacy in CER

- More likely to use face-to-face interviews, less anonymity
- Small communities, identifiability
- Familiarity with data collectors
- Reporting illegal behaviors (e.g., domestic abuse, drug use)?
- Research reports, naming communities?



## Beneficence

*Doing good, having the interests of the participants in mind*

**Community expectations →**

**Disillusionment if benefits not realized**



## Beneficence



- **Minimize risk, maximize potential benefits to study or society**
- Potential risks include:
  - Psychological distress resulting from participation
  - Physical danger
  - Respondent burden
  - Loss of self-esteem and anxiety
  - Legal, economic, social/psychological risks
- **Obligation to provide referral and follow up for screening or health exam participants at-risk**

## Case #3 Informed Consent & Disclosure of Adverse Events (non-clinical)



- ➔ Parent asks for survey
- ➔ **Angry about suspected sponsor**
- ➔ **Disclosure to IRB**

*Waiting period/  
halt study...  
What to do???*



You are conducting a large, NIH-funded tobacco prevention study in 24 middle schools (n = 3,600). The consent process involves obtaining **written parental consent and student assent**. Your research team has carefully prepared materials to inform parents about the purpose of the research, the procedures, and the funding source.

One parent requests a copy of the survey for his review to decide whether or not to consent for his child to participate in the study. *It includes questions about whether students recognize brand-specific tobacco ads (which have been found to be associated with starting to smoke).*

After receiving it, he writes an angry letter to you, the PI, as well as to the principal and teacher, charging that he thinks the study is funded by the tobacco industry. You talk to the principal and teacher, who state that they have calmed the parent down, and think they know the origins of his concerns (which have nothing to do with the research).

You understand that you are supposed to report this incident to the university IRB, and do so. They ask you to revise the study information materials to clearly state that the study is not industry-sponsored. They state that you **must stop all data collection until the IRB approves the revised materials, which may take two to three months.**



Waiting 2-3 months puts your study – which must be conducted during the school year – at risk, since it would be impossible to complete the study without this time, and the time line including the intervention and data collection might not be able to be completed. You appeal to the IRB chair and are told you simply must wait for the IRB's approval.

- What is the ethical dilemma?
- What would you do? How would you handle the situation?
- Would you handle a similar situation differently in the future?



## Justice

**Fair distribution of benefits and burdens of research among potential subjects**

- Public benefit should be maximized

**Selection and randomization of research subjects and communities**

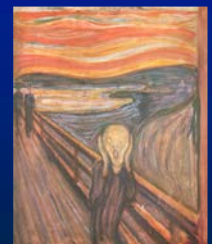
**Additional protection for vulnerable populations**



## Ethical Issues Related to Professional Relations and Interactions

**Research relationships may present ethical dilemmas**

- Funding sources
- Professional colleagues
- Collaboration, dependability
- Distribution of resources
- Credit for research products





## Case #4 Publication Credit

- Joint community-researcher publication plans
- Journal ethical guidelines
- Community participant non-responsive

**What to do?**  
**How to handle?**



You are working with a community and a CAB through your Prevention Research Center (PRC). The PRC has created Collaboration Guidelines, which set up a process for co-authoring publications that come out of your research.



You recently completed a community-based research project; the CAB helped to interpret the findings; and you are now writing a paper for a scientific journal. Two community members are on the writing team. However, one does not respond to calls for participation; she does not even comment on several drafts of the paper.

**Authorship and contributorship**  
*Clear policies (that allow for transparency around who contributed to the work and in what capacity) should be in place for requirements for authorship and contributorship as well as processes for managing potential disputes*



The journal guidelines require signed statements that specify each co-author's role on the paper, and participating in planning or data collection alone does not qualify. You are stumped about how to deal with this designated co-author who has not contributed.



- What is the ethical dilemma?
- What would you do? How would you handle the situation?
- How would you prevent similar situations in the future?

## Emerging Ethical Issues: Global Research & Protection of Subjects

Growth of international health research

- Research in less developed countries
  - Burden of infectious and communicable diseases (HIV/AIDS, malaria, tobacco use)
- Research ethics systems may not be in place, gatekeepers may demand payments etc. (despite WHO rules)
- Potential mismatch between US rules and infrastructure, culture, context



## Emerging Ethical Issues: Internet/Mobile Research

- Internet/mobile devices offer unique access to research participants
  - Assurance of confidentiality
  - Ability to protect participants from harm
  - Viability of truly informed consent
  - Designing online consent methods the disclose information without creating a barrier
  - Continually changing technology landscape



- Ethical issues in community-based research are dynamic and ongoing



- There are no easy answers and often formal IRB's are not prepared to deal with some issues {so you need to work with them}

## Acknowledgments

Thanks to all my community-based research colleagues, partners, and participants. We're still learning.

Kegler MC, Coughlin S, Glanz K

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