



Practical Strategies for Strengthening IRB Review of Community-Engaged Research

**PRIM&R Workshop
December 7, 2010**



Session Outline

- Who's here & why?
- Background on CCPH & the curriculum
- Community-engaged research: definitions & ethical challenges
- Case study
- Next steps & additional resources



Community-Campus Partnerships for Health

Mission

To promote health (broadly defined) through partnerships between communities and higher educational institutions





CCPH's CBPR & Research Ethics Program

- 2007 Call Series “Ensuring Community-Level Research Protections”*
- CBPR Ethics Listserv
- Oct 2008 JERHRE Theme Issue on CBPR
- National Study, “Understanding Community-Based Processes for Research Ethics Review”
- **IRB-REB Curriculum on Community-Engaged Research***

**co-sponsored with Tuskegee Bioethics Center*



Why an IRB/REB Curriculum?

- Top recommendation from Call Series
- The practice of community-engaged research (CEnR) is growing
- Community-engaged researchers report IRB/REB review as a barrier to CEnR
- Most IRBs don't assess community-level ethical concerns

*Curriculum Workgroup Members**

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**A Canadian committee and a review/advisory committee provide additional input*



Curriculum Purpose

- Bridge knowledge gap between IRB/REB members and researchers in the area of CEnR
- Create a shared understanding of CEnR and the ethical issues that can arise in conducting CEnR
- Ensure that community-level research protections are explicitly and adequately addressed in the research ethics review process



Curriculum Objectives

- Describe the rationale, principles, methods, risks and benefits of CEnR
- Identify ethical considerations that commonly arise in CEnR
- Provide tools and case studies that will help reviewers recognize, analyze and address ethical considerations that arise in CEnR



Curriculum Components

- Introduction/Overview
- Module 1: Definitions and Rationale
- Module 2: Ethical Frameworks and Issues in Community-Engaged Research
- Module 3: Ethical Review of Community-Engaged Research Protocols



Module Components

- Learning objectives
- Key concepts (main text)
- Case studies and training exercises that illustrate key concepts & foster critical thinking
- Citations and recommended resources
- Quiz questions & answers (for CITI course credit)



Curriculum Delivery Options

- Scheduled and/or customized workshops on campuses and at conferences
- Online individually or in groups
- As a resource for discussing/planning how to restructure IRB/REB forms, policies, and practices to apply to CEnR protocols



Intended Outcomes

- Understand what CEnR is and is not
- Articulate ethical issues that arise in CEnR
- Conduct informed ethics reviews of CEnR



Curriculum's working definition of community-engaged research

CEnR as an approach to research in which community members, researchers, agency representatives and academics or institutional representatives form partnerships to accomplish common research goals. These partnerships are characterized by respect, collaboration, equity and fairness.

Defining Community

CCPH board of directors, 2005

- There is no “one” definition of community
- Geography
- Age
- Ethnicity
- Gender
- Sexual orientation
- Disability, illness or health condition
- Common interest or cause
- Shared values or norms



Defining Community

CCPH board of directors, 2005

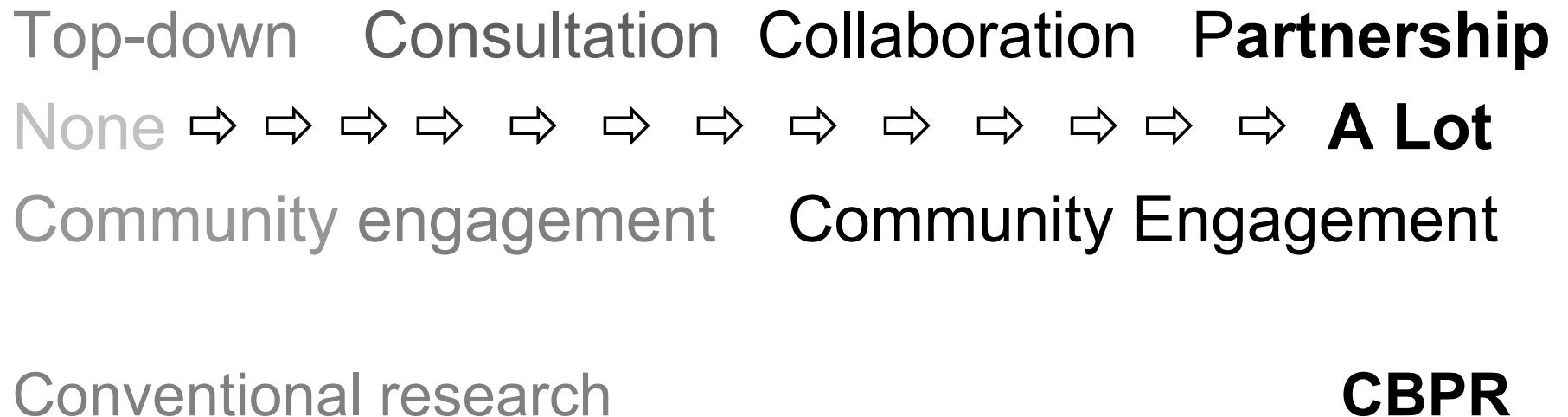


Defining “community” in community-engaged research is more about the process of asking questions than about a strict definition of who “is” community or “represents” community:

- Are those most affected by the problem or issue of study at the table?
- Are those who have a stake in the problem or issue being addressed at the table?
- Do they play decision making roles?



The Community-Engaged Research Continuum



References: Winer and Ray, Anucha



Four Levels of Community Participation

1. Persons consulted by the researchers are at the periphery of the community, often working for human service agencies and living outside the community. Community residents are unaware of the research.

Hatch J et. al, 1993 as presented by Blumenthal D 2010



Four Levels of Community Participation

2. The project's advisors are leaders drawn from organizations and churches within the community, but the researchers retain total control of the project. There is community involvement, but it is passive.

Hatch J et. al, 1993 as presented by Blumenthal D 2010

Four Levels of Community Participation



3. Community leaders are asked not only for endorsement of the project, but for guidance in hiring community residents to serve as interviewers, outreach workers, etc. This model is community-based but not community-involved, since community members do not contribute to the design of the research. Offers potential for community manipulation by hiring influential community members.

Hatch J et. al, 1993 as presented by Blumenthal D 2010



Four Levels of Community Participation



4. Community members are first among equals in defining the research agenda, identifying the problem to be studied, analyzing its contributory factors, and proposing possible solutions.

Hatch J et. al, 1993 as presented by Blumenthal D 2010




CEnR Continuum

- Community Oriented Research
- Community Placed Research
- Community-Based Research
- Community-Based Participatory Research

Why CEnR?


- Conventional research has failed to solve complex health problems
- Significant community involvement increases scientific rigor: community are the experts
- Research findings can be applied to interventions
- Approach builds greater trust & respect between researchers and communities
- Builds community capacity; Sustainability of projects



“(Public) distrust of medical research is firmly entrenched and is a significant obstacle to clinical trials participation....”

“Involving the community... in assessing the need for specific studies, and in planning and conducting the research itself have proven effective in overcoming distrust and expanding the reach of prevention and treatment advances into communities. Specifically, communities must be involved early in research protocol development, and researchers must ensure that the community benefits from participation and receives research results.”

**Translating Research into Cancer Care: Delivering on the Promise
National Cancer Institute, President’s Cancer Panel, 2005**



Examples of challenges between CEnR and IRBs

- Lack of understanding of CEnR
- Differences in key considerations
 - How is the community engaged?
 - What are the direct benefits to the community involved? Does the research question answer a community priority? How will the findings be translated into action to address the identified priority area?
 - How have possible individual and community harms been minimized?
- Accessibility to IRBs
- Other challenges you have experienced?



Recommendations



- Mutual understanding & relationship building
 - IRB reviewers to understand basics of CEnR
 - Research teams to understand basics of IRB process
 - Communication and understanding between institution-based IRBs and community-based review processes

Recommendations

- Developing questions to guide the IRB process...
 - Is there community involvement?
 - How was the partnership formed?
 - Who are the different partners?
 - How are the partners involved?
 - What are the potential impacts of this project?
 - Who benefits, and what are the short and long term benefits (accounting for both individual and community level)? Who determines what constitutes a “benefit”?
 - What are the short and long term risks (accounting for both individual and community level)? What steps have been taken to minimize these risks? Who determines what constitutes a “risk”?
 - How will the findings be used? Will they be used to effect social change?



Recommendations

- Committee composition
 - Reviewers with expertise in community engagement and community-engaged research
 - Reviewers who understand the context and cultures of communities in which research is conducted

Self-Assessment Questions

- What steps has your IRB taken in the past to *recruit non-affiliated members*?
 - What has worked well, and why?
 - What have been some of the challenges, and why?
 - What additional steps could your committee take to identify non-affiliated members who are in the position to provide critical insight into both community benefit as well as harm?
 - How many community members or non affiliated members should be included on your board?
- In your experience, once you have successfully recruited for the non-affiliated position(s), what steps are important to assure that all members feel supported and encouraged to become active (versus more token) members of the committee?



Self-Assessment questions

- Could your IRB approve a project without clearly knowing if the community listed in the proposal has agreed to the research design/partnership?
- Is it possible that “partnership” research is being done at your institution without actual community involvement and support?
- Do your applications ask the “right” questions or request the “right” information from the “right” people to further facilitate the review of a CEnR proposal?



CASE STUDY



Curriculum Next Steps

- Conference workshops and IRB trainings beginning in Fall 2010
- Curriculum freely available online in 2011
- Curriculum released through CITI in 2011



How You Can Get Involved

Let CCPH know--

- of any cases or innovations that we could include in the curriculum
- if you're interested in on-site training
- what other resources would be helpful

Send CCPH your email to receive a notice when the curriculum is released



Tap into CCPH Resources

www.ccpsh.info

- Report: Ensuring Community-Level Research Protections
- Call Series: CBPR ethics
- Online Curriculum: Developing & Sustaining Community-Based Participatory Research Partnerships
- Listserv: CBPR and CBPR ethics



Citations

Blumenthal D (2010). Community-Based Participatory Research. Presented at AAHRPP Conference.

Chapman SA, Shore N, Eder M, Alt P, and Cook D. Module 3 – Ethical Review of Community-Engaged Research Protocols. In: IRB-REB Workgroup. IRB-REB Workgroup. IRB-REB Curriculum on Ethical Considerations in Community-Engaged Research, Community-Campus Partnerships for Health, 2010.

Hatch J, Moss N, Saran A, Presley-Cantrell L & Mallory C. (1993). Community Research: Partnership in Black Communities. *AJPM* 9 (suppl), 27-31.

Grignon J, Wong KA and Seifer SD. Ensuring Community-Level Research Protections. Proceedings of the 2007 Educational Conference Call Series on Institutional Review Boards and Ethical Issues in Research. Seattle, WA: Community-Campus Partnerships for Health, 2008. Available at <http://www.ccph.info>



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