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The IRB/REB Curriculum on
Ethical Considerations in
Community-Engaged
Research



Community-Campus Partnerships for Health

Mission

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





TUSKEGEE
U N I V E R S I T Y

Tuskegee University
National Center for
Bioethics in Research
and Health Care

Mission

Promoting equity and justice in health and health care for African American and other underserved populations.

Terminology

Community-Engaged Research (CEnR)

- Community Based Participatory Research (CBPR) is one type of CEnR
- CEnR the term used by the NIH's Clinical Translational Science Awards (CTSA)



Terminology

- **REB Canadian
Research Ethics Board**





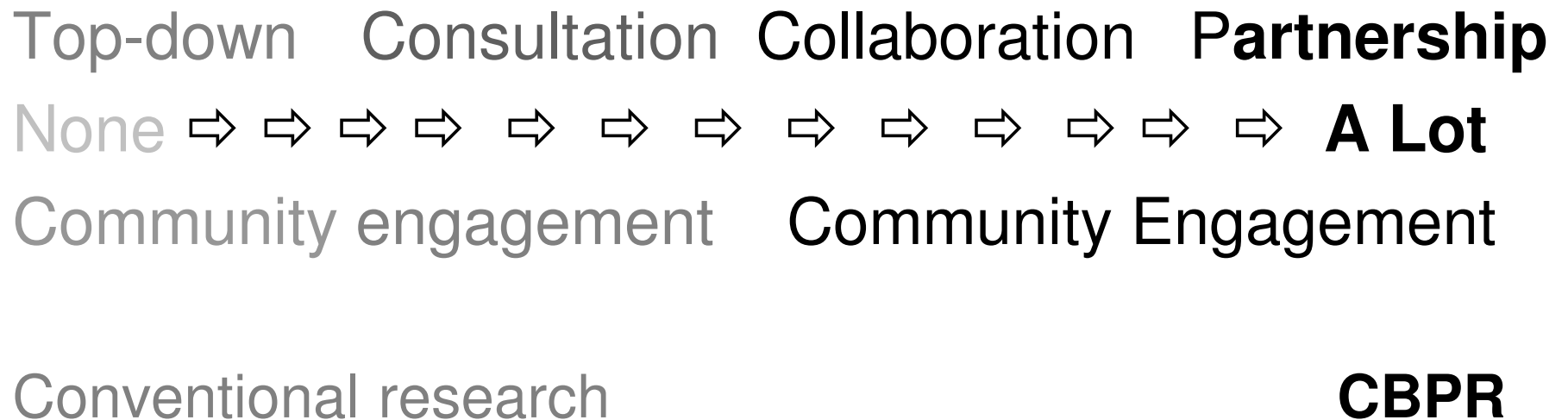
Why Do Community-Engaged Research?

Health interventions have often not been as effective as they could be...

- Not tailored to the concerns & cultures of participants
- Rarely include participants in all aspects of intervention design, implementation & evaluation
- Focused narrowly on individual behavior change with less attention to broader social & structural issues



The Community- Engaged Research Continuum



References: Winer and Ray, Anucha



CCPH's CBPR & Research Ethics Program

- 2007 Call Series “Ensuring Community-Level Research Protections”*
- CEnR & Ethics Listserv
- Oct 2008 --JERHRE Theme Issue -
- 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 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 Development Process

- Late 2007 Call for volunteers
- January 2008 Writing group convened &
- Advisory & Review Group assembled
- Objectives, format and group process developed
- January 2009 draft material evaluated
- 2009 Reorganized into 3 modules and revised
- December 2009 two day meeting at Tuskegee National Bioethics Center
- 2010 Revisions



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



Audience

- Administrators and members of IRBs and REBs
- United States and Canada





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



Intended Outcomes

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



Module 1 Learning Objectives

- Describe principles of a community-engaged research approach
- Describe different concepts of “community”
- List ways that researchers’ roles are different in CEnR compared to conventional research
- Summarize ways that research can benefit from collaboration among researchers and community partners



Module 2 Learning Objectives

- Examine how the regulatory framework that applies to human subjects research applies to CEnR
- Describe the ethical considerations of CEnR re: informed consent, participant privacy and confidentiality, data ownership and risk/benefit analysis
- Explain the importance of using an emergent design in CEnR



Module 3 Learning Objectives

- Identify measures to increase diverse representation of community members on IRBs/REBs
- Identify & appraise measures to maximize the CEnR expertise of all IRB/REB members
- Identify & evaluate measures to modify existing IRB/REB structures, policies and review processes to ensure ethical considerations for CEnR



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



Curriculum Next Steps

- Draft is currently under peer-review
- Will be Pilot tested & revised
- Curriculum release in Summer 2010
- Conference workshops and IRB trainings beginning in Fall 2010
- Produce as on-line modules



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.ccph.info

- CCPH conference, May 12-15, 2010 in Portland, OR
- Pre-conference workshops on CEnR ethics, Roadmap to CEnR Funding at NIH
- Online Reports & Toolkits
- Developing & Sustaining CEnR Partnerships
- Electronic Discussion Groups



How to Cite this Presentation

Seifer S., McDonald MA. The IRB/REB Curriculum on Ethical Considerations in Community-Engaged Research. Oral Presentation, Association for the Accreditation of Human Research Protection Programs, Atlanta, GA, April 2010.

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