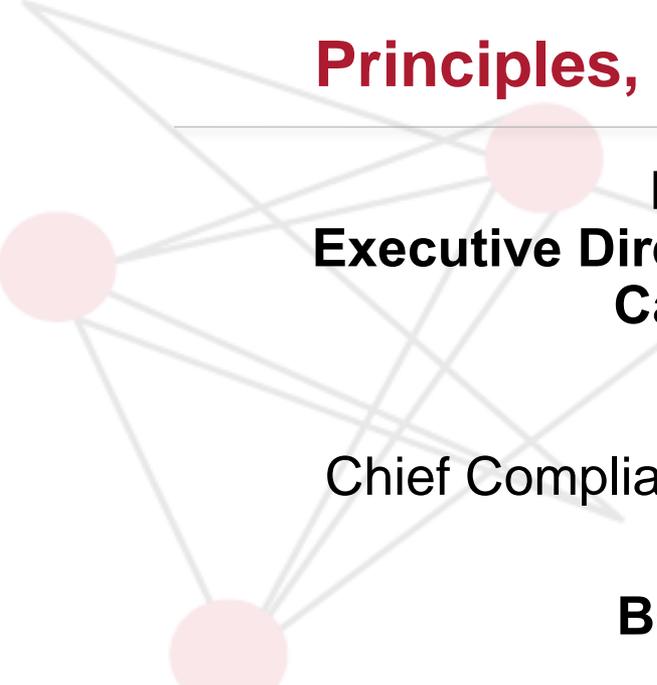


OHRP Research Community Forum
*Protecting Human Subjects in Research:
Blending Regulatory Requirements and Best Practices*
**Community-Engaged Research (CEnR) and the
Institutional Review Board:
Principles, Challenges, and Opportunities**



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Boston, MA June 21, 2011

Overview of Presentation

- What is Community-Engaged Research (CEnR)?
 - CEnR terminology and historical context
 - The continuum of CEnR
- Who is the community?
- Why engage in CEnR?
- Risks and ethical issues for CEnR

What is CEnR?

- “A fundamental premise of community-engaged research is that community-based organizations have credible, legitimate, and intimate understandings of the assets, concerns, values and activities of their constituents and communities.”
- “Community engagement is about relationships, and relationships between researchers and community representatives can be described as taking place along a continuum.”

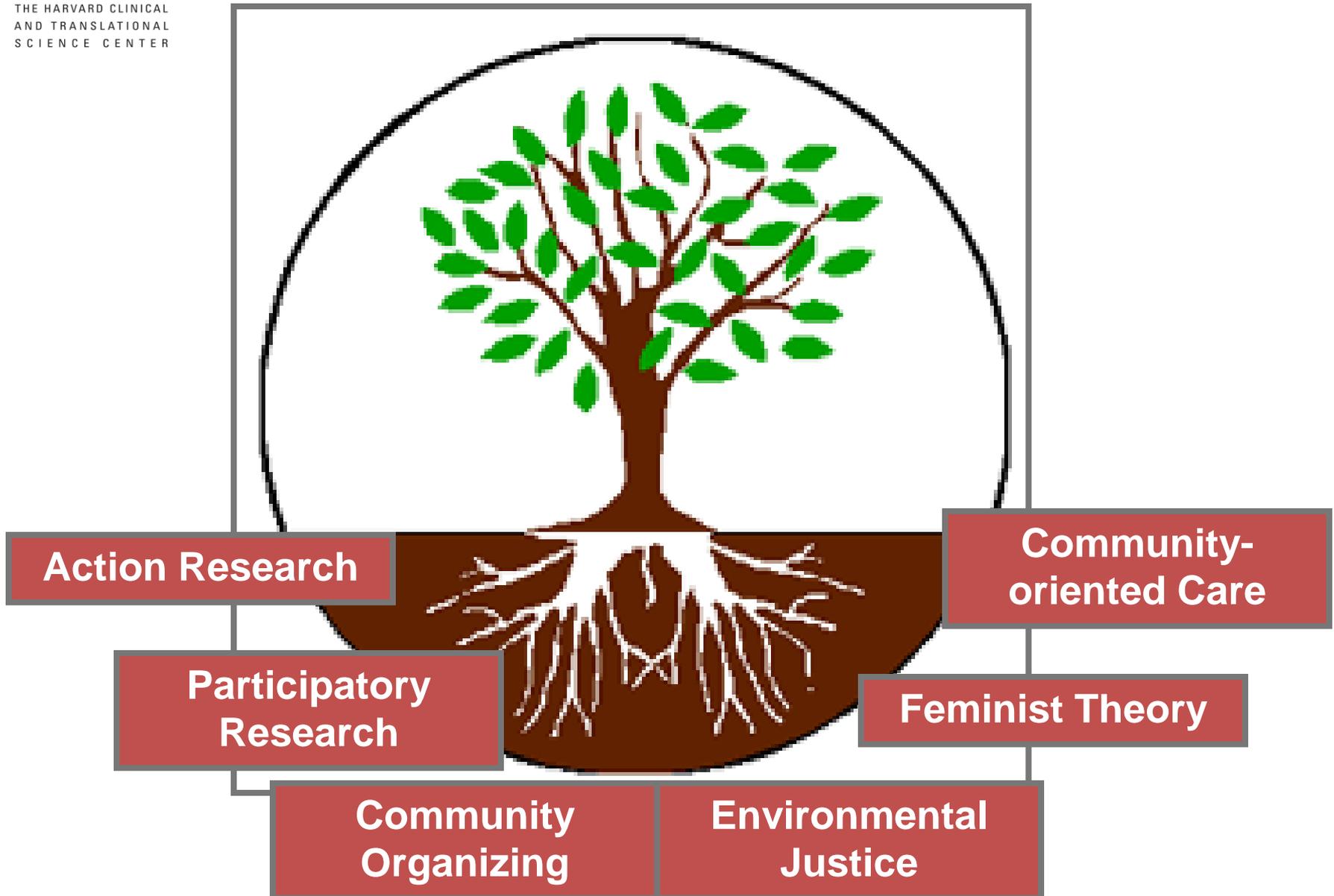
Transition of terminology

- Historic differences in terminology
- NIH Roadmap
 - Encourages improved communication and cooperation between researchers and communities
 - Standardized terminology to represent level of participation
- The term “community-engaged” is broad
 - includes the full spectrum of approaches that involve the community in the research process

Historical Roots

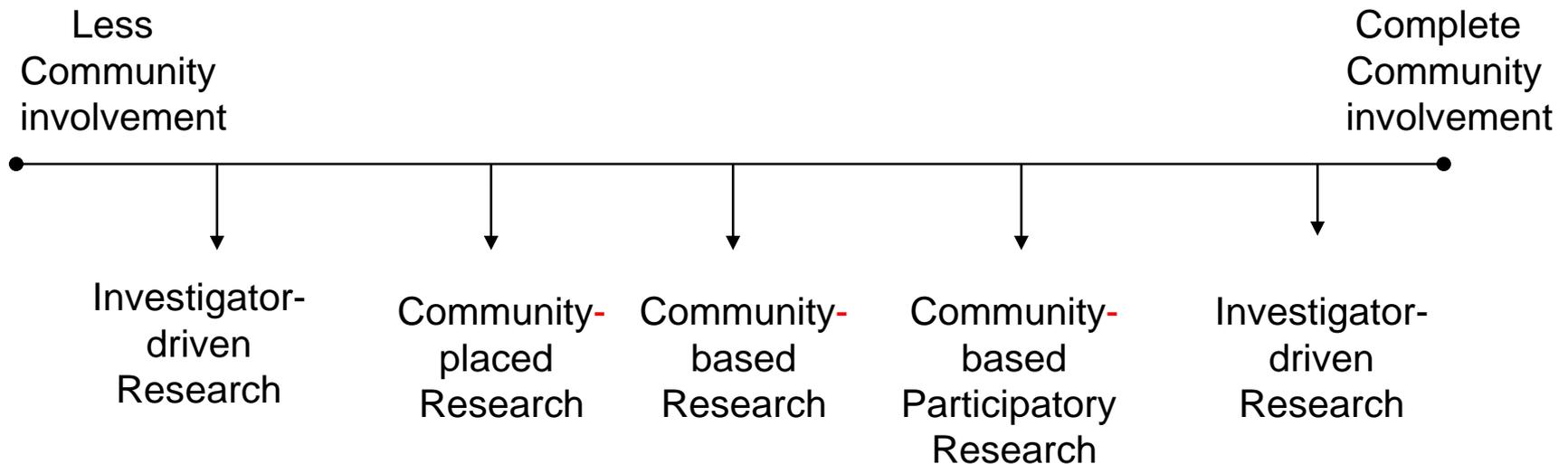


THE HARVARD CLINICAL
AND TRANSLATIONAL
SCIENCE CENTER



Community Engaged Research Continuum

(clinical & social/behavioral)



VCU Center for Clinical and Translational Research

VCU Center for Clinical and
Translational Research

Descriptive

- “Impact of Immigration and Customs Enforcement on Immigrant Health”
Hacker K, Chu J, Leung C, Pirie A, Brahim M, Beckmann J, English M, Acevedo-Garcia D, Marlin R. *Social Science & Medicine*, *In Press*.

Randomized Community Trial

- “A Promotores de Salud Intervention to Reduce Cardiovascular Disease Risk in a High-risk Hispanic Border Population (2005-2008)”
Balcazar HG, de Heer H, Rosenthal L, Aguirre M, Flores I, Puentes FA, Cardenas VM, Duarte MO, Ortiz M, Schulz LO. *Preventing Chronic Disease* 2010;7(2).

Who is community?

- A group of people linked by social ties who share common perspectives or interests, and may also share a geographic location (MacQueen et al.)
- Examples of communities
 - Boston residents
 - Brazilian immigrants
 - Primary care physicians
- Communities are *not* homogeneous and seldom speak with a single voice

Why engage?

- Traditional research can be limited
- Despite research in key areas, health disparities persist
- Community members want research to address their needs
- Community involvement can lead to innovation
- Research findings can be applied directly to develop interventions specific for communities

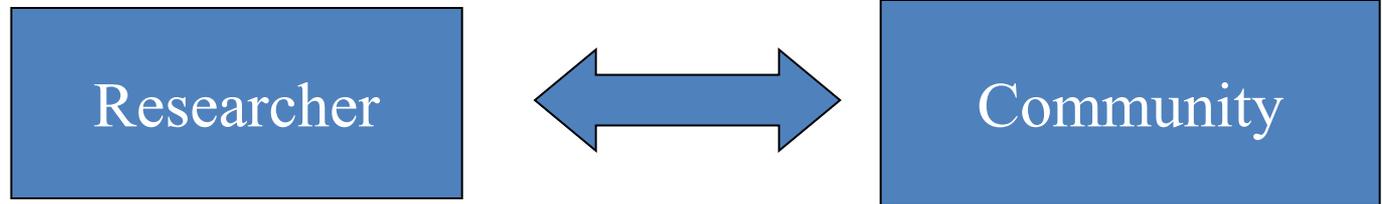
The Spectrum of Engagement

- **Low engagement**
 - Intercepting potential participants on the street
 - Conducting random phone sampling
- **Moderate engagement**
 - Solicitation of a community-based organization (CBO) to assist in implementing a study design
 - A CBO provides the setting for a partnering clinic staff member to draw blood or do another lab test on-site
- **High engagement**
 - Community advisory board
 - Community and researcher act in partnership to jointly explore a problem

Traditional vs. Community Engaged Research

	Traditional	Community-Engaged	CBPR
Research Objective	Based on epidemiologic data and funding priorities	Community input in identifying locally relevant issues	Full participation of community in identifying issues of greatest importance
Study Design	Design based entirely on scientific rigor and feasibility	Researchers work with community to ensure study design is culturally acceptable	Community intimately involved with study design
Instrument Design	Instruments adopted/adapted from other studies. Tested chiefly with psychometric analytic methods.	Instruments adopted from other studies and tested/adapted to fit local populations	Instruments developed with community input and tested in similar populations
Data Collection	Conducted by academic researchers or individuals with no connection to the community	Community members involved in some aspects of data collection	Conducted by members of the community, to the extent possible based on available skill sets. Focus on capacity-building.
Dissemination	Results published in peer-reviewed academic journals	Results disseminated in community venues as well as peer-reviewed journals	Community members assist academic researchers to identify appropriate venues to disseminate results (public meetings, radio, etc.) in a timely manner and community members involved in dissemination. Results also published in peer-reviewed journals.

Characteristics



- CEnR requires
 - Partnership development
 - Cooperation and negotiation
 - Collaboration between community partners/academic researchers
 - Commitment to addressing local health issues

Why are there Community Risks?

- Structure and function of communities
 - Communities have unique politics, beliefs, and values - research may affect these elements
 - Communities may make decisions collectively, and informed consent from individuals may conflict with the political structure, social networks
 - Disease treatments may conflict beliefs regarding traditional healing

(Weijer 1999)

Unique Ethical Issues

- Insider/outsider conflicts
- Risks/consequences to the community
- Assuring equitable participation in all aspects
- Data ownership
- Dissemination

An exploration of the intersection of human subjects regulations and community engagement

“In response to SACHRP’s recent identification of future priorities, this is the first of what may become several panels on regulatory perspectives on Community Based Participatory Research (CBPR).

This initial discussion will have a broad focus, exploring the intersection of regulations and the nature of CBPR generally; questions to be explored include whether CBPR would benefit from regulatory guidelines or FAQs, and whether current human subjects regulations are overly onerous for CBPR investigators.

The panel will also discuss specific ethical issues that present challenges to investigators and IRBs as they struggle to fulfill their respective roles in human subjects protections.”

- **CEnR and CBPR in particular pose unexpected challenges to IRBs**
- **Community perspective**
 - Rules of engagement
 - Special IRB considerations
 - IRB education
 - Structures for CTSAs

- Belmont Report principles and federal regulations
- CEnR challenges and opportunities to principle
- IRB operational challenges and solutions

Belmont Report: A Foundation for the Federal Regulations

- The Belmont Report informed the federal policy for the protection of human subjects
- The Belmont Report identifies three fundamental ethical principles for all human subjects research:
 - Respect for persons
 - Beneficence
 - Justice
- The Belmont Report informed the regulatory framework that focuses on the individual research subject

Belmont Report and Federal Regulations: Application of Principles

- Application of Belmont Report principles
 - Informed consent
 - Voluntary
 - Comprehensible
 - Assessment of risks and benefits
 - Nature and scope of risks and benefits
 - “benefit”, “individual”, “society at large”
 - Systematic assessment of risk and benefit
 - “balance”, “justifiability”, “reduction of risk”, “vulnerable populations”
 - Selection of subjects
 - Individual vs. community

Application of Principles: Challenges and Opportunities for CEnR

- Principles do not squarely include CEnR
- CEnR includes the community as research subject
 - Risks to individuals by group association
 - Risks to community

CEnR Challenge and Opportunities: Belmont Principle Informed Consent

Voluntariness

- How is community consent to be obtained?
- How are community leaders and groups involved in recruitment?
- What compensation is allocated to community members or groups?
- What conflicts of interest may affect community participation?

CEnR Challenge and Opportunities: Belmont Principle Informed Consent

Comprehension

- Are materials culturally and linguistically appropriate?
- How are community leaders and groups involved in key decisions in the design and conduct of the research?
- What training will be provided to community members?

CEnR Challenge: Belmont Principle Assessment of Risks & Benefits

Three categories for
risks and benefits

- Individual
- Individual by association with group
- Community
 - Disruption of community cohesion by research process
 - Risks of disseminating sensitive data in community
 - Risks of results harming community

CEnR Challenge and Opportunity: Belmont Principle Selection of Subjects

Selection of subjects

- How is the community defined?
- How are community leaders identified?
- How are community leaders involved in defining inclusion/exclusion criteria?
- What are the criteria for distribution of economic benefits?
- How are community standards of fairness applied?

IRB Operational Challenges when Reviewing CEnR

- Staff
 - Lack of experience among IRB staff and members in evaluating CEnR
- Forms
 - IRB application forms that do not require submission of necessary information
- Guidance and policies
 - IRB guidelines and policies that do not address community risks
- Process
 - IRBs that lack process for input from community leaders

IRB Operational Solutions: Potential Questions for Reviewing CEnR Applications

Global questions:

Is the proposed activity CEnR?

Does the IRB have the expertise required to review this proposal? If not, what resources are needed?

How does the proposed activity fit into the institution's goals?

The questions on slides 11 through 14 reflect the work of the Harvard Catalyst CEnR subcommittee.

The members' names and contact information may be found here:

<http://catalyst.harvard.edu/programs/regulatory/cenr.html>.

IRB Operational Solutions: Potential Questions for Reviewing CEnR Applications

Community Infrastructure and Interface (with Researcher) - Questions and Considerations:

Where will this project take place and who will it affect?

Does the proposed activity respond to the needs of this community and/or support existing infrastructure or networks?

What is the researcher's plan for engaging with this community?

How will the community be involved in the development and implementation of this particular project?

Is there a community advisory board (CAB) and who are its representative members?

What is the researcher's relationship with key stakeholders in the community?

What is the background of the researcher and what is their track record for conducting this type of work in the community?

IRB Operational Solutions: Potential Questions for Reviewing CEnR Applications

Dissemination/Accessibility- Questions and Considerations:

What plans/strategies are in place to disseminate the results and elicit feedback from community stakeholders?

Will dissemination be through multiple venues (e.g., community forums, presentations, journal articles, web sites)?

Are these venues affective and accessible to both community members/providers and researchers?

Will there be a process to inform community stakeholders about the role of the IRB?

IRB Operational Solutions: Potential Questions for Reviewing CEnR Applications

Recruitment and Informed Consent - Questions and Considerations:

Has community risk versus individual risk been evaluated properly?

Are recruitment strategies culturally/linguistically appropriate?

What role will the community partner have in recruitment?

How accessible/approachable is the researcher to the community stakeholders?

Does the proposed consent form use appropriate (linguistically and culturally) language?