



Ethics Review of CBPR

Options & Models





Citation for this Presentation

Seifer SD. Ethics Review of Community-Based Participatory Research: Options and Models. Oral Presentation to the Secretary's Advisory Committee on Human Research Protections, October 2009.



Community-Campus
Partnerships for Health

Mission

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



Goals

- **Combine knowledge, wisdom & experience** in communities and in academic institutions to solve major health, social and economic challenges
- **Build capacity** of communities & higher educational institutions to engage each other in authentic partnerships
- **Support communities** in their relationships & work with academic partners
- **Recognize & reward** faculty for community engagement & community-engaged scholarship
- **Develop partnerships** that balance power & share resources equitably among partners
- **Ensure community-driven social change** central to service-learning & community-based participatory research (CBPR)

What is CBPR?

“...a partnership approach to research that equitably involves, for example, community members, organizational representatives, and researchers in all aspects of the research process; with all partners contributing their expertise and sharing responsibility and ownership to enhance understanding of a given phenomenon, and to integrate the knowledge gained with interventions to improve the health and well being of community members.”

Israel, BA Annual Review of Public Health, 1998

What is CBPR?

“A collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community and has the aim of combining knowledge with action and achieving social change...”

W.K. Kellogg Foundation, 2001

“Scientific inquiry conducted in communities in which community members, persons affected by condition or issue under study and other key stakeholders in the community’s health have the opportunity to be full participants in each phase of the work – conception, design, conduct, analysis, interpretation, conclusions and communication of results.”

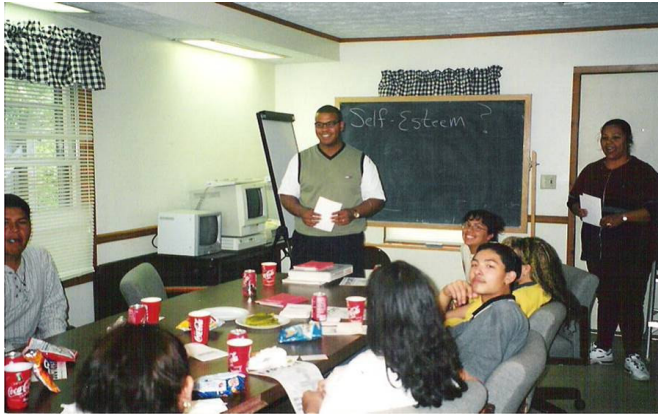
Federal Interagency Working Group on CBPR, 2003



CBPR & Research Ethics Program

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

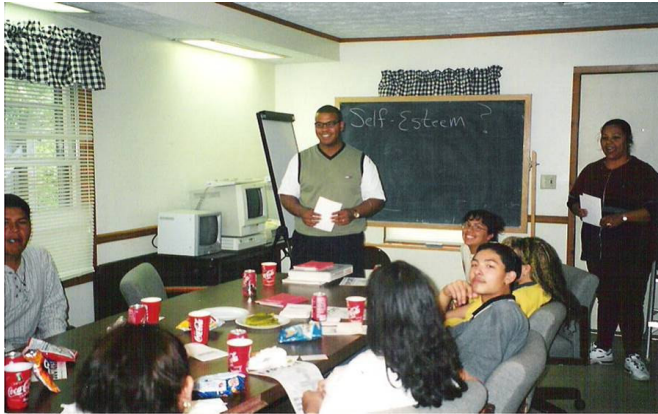
**co-sponsored with Tuskegee Bioethics Center*



Options & Models

Institution-Based

- IRB expands #/role of community members
 - HIV REB at University of Toronto, co-sponsored with Ontario HIV Treatment Network (50% + 1)
- IRB revises process for reviewing CBR
 - University of Washington
- IRB forms specific committee to review CBR
 - Michigan State University
- IRB serves as IRB for community partner
 - Silent Spring Institute and Brown University IRB



Options & Models

Institution-Based

- IRB serves as IRB for CBOs
 - HIV REB at University of Toronto, co-sponsored with Ontario HIV Treatment Network
- IRB coordinates with community-based IRB
 - University of New Mexico & Navajo IRB
- IRB coordinates with community review process
 - Morehouse Medical School and its Prevention Research Center Community Committee
- Funder adopts additional ethics protections
 - Institute for Aboriginal Peoples' Health, Canadian Institutes of Health Research

Options & Models

CIHR Guidelines for Health Research in Aboriginal People

Community jurisdiction and approval

Research partnership methodology

Collective and individual consent

Confidentiality (collective and individual) and privacy

Respect for individual autonomy and responsibility

Inclusion of Indigenous knowledge in research

Protection of cultural knowledge

Benefit sharing

Empowerment and capacity development

Right to control collection, use, storage and potential use of data

Biological samples considered licensed to the researcher

Interpretation of results

Dissemination of results



Options & Models

Community-Based

- Community-based IRB
 - Tribal nation: Navajo
 - CBO: Special Services for Groups, Los Angeles
 - Community health center: Waianae Coast, Hawaii
- Community research review process
 - Yakima Valley Farmworkers Clinic, WA
 - Detroit Urban Research Center Community Board
 - Access Alliance, Toronto
 - Mayor's Health Task Force, Lawrence, MA



Understanding Community- Based Processes for Research Ethics Review

*CCPH & University of New England (UNE)
Funded by Greenwall Foundation*

Aim: To identify & describe community-based mechanisms for research ethics review through an online survey of U.S. community groups and community-institutional partnerships involved in human subjects research

Ethics review: Study reviewed by IRBs at University of Washington, and UNE, and by Study Advisory Committee of community and academic experts in ethics and CBPR

Citation: Shore N, Wong K, Bajorunaite R, Drew E, Moy L, Corage Baden A, Cyr K and Seifer SD. Understanding Community-Based Processes for Research Ethics Review: An Exploratory Study. Manuscript under review.



Topics Asked About in Survey

When & why the process was established

How the process functions, criteria, challenges and benefits

Who serves as reviewers, their training, how decisions are made

Who “staffs” the process, how it is funded

What types of research are reviewed

Relationships with institutional IRBs

Policies and other documents that guide/support the process

Interest in participating in collaborative research network



Understanding Community-Based Processes for Research Ethics Review

*CCPH & University of New England
Funded by Greenwall Foundation*

Identified 109 community-based processes for research ethics review,
30 in development

Most formed between 2000-2008

Most review from 2-10 proposals annually

They exist in 31 states, the District of Columbia and Puerto Rico

Six serve multiple states, six are national.

Type of organization:

Community-institutional partnership: 31%

Community-based organization: 22%

Non-profit organization: 22%

Community health center: 12%

Tribal/indigenous organization: 7%

Other (health dept, school, etc): 16%

Research reviewed

Type of research	CBPR 87%	Social and behavioral 55%	Health services 48%	Clinical research 36%	Quality improvement 33%
Focus	Health disparities 63%	Diabetes 42%	Cancer 41%	Obesity 39%	HIV, Mental Health 32%
Population	Adults 83%	People of color, women 70%	Men 57%	Adolescents, Seniors 51%	Children 50%
Geography	Urban 61%	Rural 35%	Suburban 24%	Tribal 14%	Non-specific 13%
Race/ethnic group focus	African American, Latino 44%	Mixed 30%	No particular group 24%	American Indian, Caucasian 21%	Pacific Islander 14%
Federal funding	NIH 62%	CDC 44%	HRSA 30%	HIS 13%	Other 22%



Reasons for establishing process

- To make sure community directly benefits from research – 85%
- To make sure community is engaged in research process – 75%
- To protect community from possible research risks – 68%
- To respond to growing # of researchers asking to support or participate in their research – 41%
- To set own research agenda – 17%

Review considerations

1 – not important, 2 – somewhat important and 3 – very important

Consideration	Mean (SD)
Research methods that are appropriate to the community	2.95 (0.21)
Good fit with the community's agenda	2.87 (0.34)
Culturally appropriate recruitment strategies	2.87 (0.41)
Plans to share findings with the communities involved in the research	2.87 (0.36)
Culturally appropriate informed consent	2.86 (0.40)
Community-level risks and benefits	2.85 (0.30)
Community consent	2.85 (0.30)

Review considerations

1 – not important, 2 – somewhat important and 3 – very important

Consideration	Mean (SD)
Shared power and resources among partners involved in the research	2.77 (0.44)
Plans to translate research findings into changes in practice or policy	2.77 (0.44)
Community training or capacity building opportunities	2.70 (0.57)
Community involvement in all phases of the research	2.68 (0.51)
Signed partnership agreement or memorandum of understanding	2.59 (0.61)
Plans to share findings beyond the involved community	2.44 (0.69)

Concerns identified through review process

Inadequate community engagement

Concerns regarding:

- community relevance and benefits
- researchers' cultural competence
- proposed study not feasible
- potential burden to the involved community

Lack of:

- specification of data ownership
- plans to report findings back to the community

“Inadequate safeguards for participants”

“Not enough protection for communities”

“How will this benefit our specific community – as opposed to the general good of society?”



Benefits of having process

Ensure that the research conducted is relevant, feasible and
“done the right way”

Assure community benefit and minimize risks

Allow for greater community voice in determining which
projects are approved

Create opportunities for capacity building

Greater community trust in and support for research

“Helps us to focus on research being done the right way, rather than getting steered into projects that seem like a lot of resources, but ultimately ends up hurting the community due to improper research methodology”

“Exposes community members to the research process and enterprise to help develop their expertise and knowledge about health issues and disparities in health”



Challenges of having review process

Time needed to conduct thorough review

Coordinating multiple layers of review

Recruiting, training and retaining reviewers

Working with external entities

Differences in values/priorities with institution-based IRBs

Lack of explicit funding

“It can take months and months to get tribal approvals from individual tribes because it requires visiting the reservations in person, usually multiple times before a resolution is obtained. Many funding sources do not allow time for this, or funding for all the travel required”

“Conflict with other IRBs that do not address group harm,”

“Money; there is no indirects for community health centers in most research proposals and therefore no infrastructure to support a review process.”

Percentage of proposals also reviewed by institution-based IRB

None	9 (8%)
1-24%	23 (21%)
25-49%	5 (5%)
50-74%	6 (6%)
75-99%	13 (12%)
All	53 (49%)

Main reasons for proposals also being submitted to Institution-based IRB (n=100)

Involvement of university researchers	82(82%)
Funders require it	58 (58%)
Provides an added layer of protection	47 (47%)



Next steps re: study

Subsequent phases

- Content analysis of policies and forms
- Form collaborative research network
- Conduct in-depth case study analysis

Envisioned benefits

- Support others engaged in CBPR in developing or strengthening their own review process
- Support institution-based IRBs in their efforts to better respond to CBPR

“We believe a blended system that involves both community-based and institution-based research ethics review is the ideal to strive for.

While we hope and anticipate that institution-based IRBs will, over time, routinely incorporate community considerations in their reviews of all research, we believe that the protection of communities is more appropriately situated in review mechanisms that are developed and managed by the communities involved in research.

Unfortunately, many of these communities—in particular those most affected by the social injustices and inequities that CBPR seeks to address—do not have the resources to create such mechanisms. Much work needs to be done to build community capacity to review, participate in and conduct research.”



Tap into Resources!

www.ccph.info

Upcoming Events

CCPH conference, May 12-15, 2010 in Portland, OR

Online Reports & Toolkits

Ensuring Community-Level Research Protections

Developing & Sustaining CBPR Partnerships

Outlets for Peer-Reviewed Publication

CES4Health.info

Electronic Discussion Groups

CBPR

Ethics & CBPR