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.
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

- 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
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 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
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

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
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%
Non-profit organization: 22%
Tribal/indigenous organization: 7%
Community-based organization: 22%
Community health center: 12%
Other (health dept, school, etc): 16%
## Research reviewed

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

<table>
<thead>
<tr>
<th>Consideration</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research methods that are appropriate to the community</td>
<td>2.95 (0.21)</td>
</tr>
<tr>
<td>Good fit with the community’s agenda</td>
<td>2.87 (0.34)</td>
</tr>
<tr>
<td>Culturally appropriate recruitment strategies</td>
<td>2.87 (0.41)</td>
</tr>
<tr>
<td>Plans to share findings with the communities involved in the research</td>
<td>2.87 (0.36)</td>
</tr>
<tr>
<td>Culturally appropriate informed consent</td>
<td>2.86 (0.40)</td>
</tr>
<tr>
<td>Community-level risks and benefits</td>
<td>2.85 (0.30)</td>
</tr>
<tr>
<td>Community consent</td>
<td>2.85 (0.30)</td>
</tr>
</tbody>
</table>
## Review considerations

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

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

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>9 (8%)</td>
</tr>
<tr>
<td>1-24%</td>
<td>23 (21%)</td>
</tr>
<tr>
<td>25-49%</td>
<td>5 (5%)</td>
</tr>
<tr>
<td>50-74%</td>
<td>6 (6%)</td>
</tr>
<tr>
<td>75-99%</td>
<td>13 (12%)</td>
</tr>
<tr>
<td>All</td>
<td>53 (49%)</td>
</tr>
</tbody>
</table>
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.”

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