Deciding What Research Takes Place in their Communities: The Role of Community-Based Research Review

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Urban Health Grand Rounds, Mt. Sinai School of Medicine
April 15, 2011
Community-Campus Partnerships for Health
Transforming Communities & Higher Education

To promote health (broadly defined) through partnerships between communities & higher educational institutions
Mobilize knowledge, wisdom & experience in communities and in academic institutions to solve pressing health, social, environmental & economic challenges

Build capacity of communities & higher educational institutions to engage each other in authentic partnerships that balance power, share resources & work towards systems change

Ensure community-driven social change is central to the work of community-academic partnerships
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. Community-based participatory research 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
Why a Focus on Ethics Review of CBPR?

CBPR as an approach to research is growing dramatically.

Larry Green, based on unpublished Scopus review by Doug Brugge, 2011.
Why a Focus on Ethics Review of CBPR?

CBPR raises research ethics considerations that go beyond those normally assessed by IRBs

- Shift from regarding individual community members as research subjects to engaging community members and the organizations that represent or serve them as research partners

- Iterative, participatory nature of study design & implementation

- Institution-based IRBs are designed to protect the rights and welfare of individual study participants, not the communities involved in research
IRB expands #/role of community members
- HIV REB at University of Toronto, co-sponsored with Ontario HIV Treatment Network

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
CBPR Ethics Review

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 (CIHR)
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
CBPR Ethics Review
Community-Based

- Community-based IRB
  - Tribal nation: Navajo
  - CBO: Special Services for Groups, Los Angeles
  - Community health center: Waianae Coast, Hawaii

- Based in community-university partnership
  - Detroit Urban Research Center Community Board
  - University of Pittsburgh Community Research Advisory Board

- Based in community organization
  - Yakima Valley Farmworkers Clinic, WA
  - Access Alliance, Toronto
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
Understanding Community-Based Processes for Research Ethics Review
CCPH & University of New England (UNE)
Funded by Greenwall Foundation

- **Aim:** To identify and 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:** University of Washington & UNE IRBs
- **Study team:**
  - CCPH: Sarena Seifer, Kristine Wong, Lisa Moy, Andrea Corage-Baden
  - Medical College of Wisconsin: Ruta Brazuaskas, Elaine Drew
  - UNE: Nancy Shore, Kirsten Cyr, Jocelyn Ulevicus
- **Study advisory committee:** next slide
Study Advisory Committee

- **Bonnie Duran**, Indigenous Wellness Research Institute, Univ of WA
- **Sarah Flicker**, York University
- **Bill Freeman**, Northwest Indian College
- **Kelly Edwards**, Dept. of Medical Ethics, Univ of WA
- **Helen McGough**, Retired IRB Administrator, Univ of WA
- **Ann-Gel Palermo**, Harlem Community and Academic Partnership
- **Michelle Proser**, National Association of Community Health Centers
- **Linda Silka**, Policy Research Center, University of Maine
- **Stephen Sodeke**, Tuskegee Bioethics Cetner
- **Eric Wat**, Special Services for Groups in Los Angeles IRB
Methods

• Online survey
  – Reasons for developing the review process
  – Types of research reviewed
  – Review process functioning
  – Review process challenges and benefits
  – Relationship with institution-based IRBs
  – Interest in participating in collaborative research network
Study Participants

• Database construction
  – Bibliographic and funding databases
  – Online program conference agendas
  – Relevant list servs

• 172 respondents who met study criteria
  – 109 respondents with a review process
  – 30 respondents planning to establish a process
  – 33 respondents with no plans for establishing a process
Study Participants

- **Affiliation**
  - Community-Institutional Partnerships 34 (31%)
  - Community-based Organizations 24 (22%)
  - Non-profit Organizations 13 (12%)
  - Community Health Centers 13 (12%)
  - Tribal Organizations 8 (7%)
### Types of Research Reviewed
(n=109)

<table>
<thead>
<tr>
<th>Research Approach</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community-based Participatory Research</td>
<td>95 (87%)</td>
</tr>
<tr>
<td>Social and Behavioral Research</td>
<td>60 (55%)</td>
</tr>
<tr>
<td>Health Services Research</td>
<td>52 (48%)</td>
</tr>
<tr>
<td>Clinical Research</td>
<td>39 (36%)</td>
</tr>
<tr>
<td>Quality Improvement</td>
<td>36 (33%)</td>
</tr>
</tbody>
</table>
## Types of Research Reviewed
(n=109)

<table>
<thead>
<tr>
<th>Substantive focus</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Disparities</td>
<td>69(63%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>47(42%)</td>
</tr>
<tr>
<td>Cancer</td>
<td>45(41%)</td>
</tr>
<tr>
<td>Obesity</td>
<td>42(39%)</td>
</tr>
<tr>
<td>HIV; Mental Health</td>
<td>35(32%)</td>
</tr>
</tbody>
</table>
## Type of Research Reviewed (n=109)

<table>
<thead>
<tr>
<th>Federal funding sources supporting submitted research</th>
<th>N  (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Institutes of Health</td>
<td>58 (62%)</td>
</tr>
<tr>
<td>Centers for Disease Control and Prevention</td>
<td>41 (44%)</td>
</tr>
<tr>
<td>Health Resources and Services Administration</td>
<td>28 (30%)</td>
</tr>
<tr>
<td>Indian Health Service</td>
<td>12 (13%)</td>
</tr>
<tr>
<td>Environmental Protection Agency</td>
<td>8  (9%)</td>
</tr>
</tbody>
</table>
Reasons for establishing a research review process (n=109)

<table>
<thead>
<tr>
<th>Reasons</th>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>To make sure the community directly benefits</td>
<td>93</td>
<td>(85%)</td>
</tr>
<tr>
<td>To make sure the community is engaged</td>
<td>82</td>
<td>(75%)</td>
</tr>
<tr>
<td>To protect our community from possible risks</td>
<td>74</td>
<td>(68%)</td>
</tr>
<tr>
<td>To respond to a growing number of researchers asking us to support/participate in their research</td>
<td>45</td>
<td>(41%)</td>
</tr>
<tr>
<td>To set our own research agenda</td>
<td>18</td>
<td>(17%)</td>
</tr>
<tr>
<td>Other</td>
<td>23</td>
<td>(21%)</td>
</tr>
</tbody>
</table>
Factors considered “very important” when reviewing research proposals (n=109)

<table>
<thead>
<tr>
<th>Factor</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research methods are appropriate to the community</td>
<td>104 (95%)</td>
</tr>
<tr>
<td>Culturally appropriate recruitment strategies</td>
<td>98 (90%)</td>
</tr>
<tr>
<td>Plans to share findings with communities involved in research</td>
<td>96 (88%)</td>
</tr>
<tr>
<td>Culturally appropriate individual informed consent</td>
<td>96 (88%)</td>
</tr>
<tr>
<td>Good fit with community’s agenda</td>
<td>95 (87%)</td>
</tr>
<tr>
<td>Community-level risks and benefits</td>
<td>94 (86%)</td>
</tr>
<tr>
<td>Community consent</td>
<td>94 (86%)</td>
</tr>
<tr>
<td>Shared power &amp; resources among partners involved in research</td>
<td>85 (78%)</td>
</tr>
<tr>
<td>Plans to translate research findings into practice or policy changes</td>
<td>85 (78%)</td>
</tr>
<tr>
<td>Opportunities for community training or capacity building</td>
<td>82 (75%)</td>
</tr>
</tbody>
</table>
Concerns identified through the review process

- Risks & benefits
- Feasibility
- Engagement
- Relevance
Benefits of having a review process

• Ensure that the research conducted is relevant or beneficial to the involved community/organization
• Allow for greater community voice in determining which projects are approved
• Create opportunities for capacity building
  – Exposes community members to the research process and enterprise to help develop their expertise and knowledge about health issues and disparities in health
  – 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
Challenges operating a review process

• Time
• Recruitment & support of engaged reviewers
• Coordination with external entities
  – Conflict with other IRBs that do not address group harm
  – Some [researchers] are stuck in the old ways of doing research where they pay a few people and claim that they have community involvement
• Infrastructure to support the review process
### Involvement of an institution-based IRB (n=109)

<table>
<thead>
<tr>
<th>Percentage of proposals reviewed by both the community group/partnership and an institution-based IRB</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>53 (49%)</td>
</tr>
<tr>
<td>75-99%</td>
<td>13 (12%)</td>
</tr>
<tr>
<td>50-74%</td>
<td>6 (6%)</td>
</tr>
<tr>
<td>25-49%</td>
<td>5 (5%)</td>
</tr>
<tr>
<td>1-24%</td>
<td>23 (21%)</td>
</tr>
<tr>
<td>0%</td>
<td>9 (8%)</td>
</tr>
</tbody>
</table>
Communication patterns when an institution-based IRB reviews the same proposal (n=92)

<table>
<thead>
<tr>
<th></th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Our communication with the institution-based IRB varies from proposal to proposal</td>
<td>43 (47%)</td>
</tr>
<tr>
<td>We do not usually communicate with the institution-based IRB</td>
<td>31 (34%)</td>
</tr>
<tr>
<td>We usually communicate with the institution-based IRB if we have questions or concerns <em>during the review</em> of the proposal</td>
<td>20 (22%)</td>
</tr>
<tr>
<td>We usually communicate with the institution-based IRB <em>after</em> we have completed the review, and our requirements conflict with their requirements</td>
<td>10 (11%)</td>
</tr>
</tbody>
</table>
### Reasons why a proposal is not reviewed by an institution-based IRB (n=87)

<table>
<thead>
<tr>
<th>Reason</th>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The group/partnership has its own registered IRB with OHRP</td>
<td>13</td>
<td>(15%)</td>
</tr>
<tr>
<td>The group/partnership’s review process conducts a thorough review and thus an institution-based IRB is not required</td>
<td>9</td>
<td>(10%)</td>
</tr>
<tr>
<td>The group/partnership lacks access to an institution-based IRB</td>
<td>5</td>
<td>(6%)</td>
</tr>
<tr>
<td>The cost of an institution-based IRB review</td>
<td>4</td>
<td>(5%)</td>
</tr>
<tr>
<td>Lack of satisfaction with the institution-based IRB review</td>
<td>2</td>
<td>(2%)</td>
</tr>
<tr>
<td>Other</td>
<td>29</td>
<td>(33%)</td>
</tr>
</tbody>
</table>
Quality of relationship between the community review process and the institution-based IRB (n=94)

- Over half described relationship as positive
  - 24% as “extremely positive”
  - 32% as “somewhat positive”
- 40% reported relationship to be “neither positive nor negative”
- 3% reported relationship to be “somewhat negative”
## Significant challenges when working with an institution-based IRB

<table>
<thead>
<tr>
<th>Challenge</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time delays</td>
<td>22 (42%)</td>
</tr>
<tr>
<td>Institution-based IRB’s lack of understanding of CBPR</td>
<td>20 (38%)</td>
</tr>
<tr>
<td>Communication with the institution-based IRB</td>
<td>11 (21%)</td>
</tr>
<tr>
<td>No challenges</td>
<td>10 (19%)</td>
</tr>
<tr>
<td>Resolution of issues with multiple institution-based IRBs</td>
<td>7 (13%)</td>
</tr>
<tr>
<td>No contact with the institution-based IRB</td>
<td>4 (8%)</td>
</tr>
</tbody>
</table>
Study Limitations

• Study sample
• Response rate
• Questions asked
Study Implications…

• Role of communities in research
• Consideration of community risks & benefits
• Definition of ethical research
• Relationship between community-based & institution-based research ethics review
• Thorough ethical analysis in a timely manner
• Capacity issues
Planned Next Steps

• Conduct in-depth case studies
• Support CCPH learning community
• Develop practical resources
  – Online repository
  – Guidebook
  – Technical assistance


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**Selected Citations**
Upcoming Events
- CCPH 15th Anniversary Conference, Apr 18-21, 2012 in Houston

Online Reports & Toolkits
- Ensuring Community-Level Research Protections
- Developing & Sustaining CBPR Partnerships
- IRB Curriculum on Community-Engaged Research (forthcoming)

Outlets for Peer-Reviewed Publication
- CES4Health.info

Electronic Discussion Groups
- CBPR, CBPR ethics, Community partners
Community-Campus Partnerships for Health

We invite you to join a growing network of communities & campuses that are collaborating to promote health

Contact us by phone 206-666-3406 or email at info@ccph.info or visit us online at www.ccph.info
Shore N and Seifer SD. Deciding What Research Takes Place in their Communities: The Role of Community-Based Research Review. Urban Health Grand Rounds, Mt. Sinai School of Medicine, 2011.