



# **Understanding Community-Based Processes for Research Ethics Review**

Seifer SD, Shore N, Drew E, Bajorunaite R, Wong K, Moy L

# How to cite this presentation

Seifer SD, Shore N, Drew E, Bajorunaite R, Wong K, Moy L. Oral presentation at the 137th Annual Meeting and Exposition of the American Public Health Association. Philadelphia, PA, November, 2009. Philadelphia, PA.



# CCPH's 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*



# Background

- Growing investments in community-engaged research
  - CBPR key to understanding and addressing health disparities
  - Community engagement key to diverse participation in clinical research
- Recognition of challenges community-engaged researchers can encounter with institution-based IRBs
- Most IRBs don't assess community-level ethics
- Community groups and partnerships are developing review processes



# Understanding Community-Based Processes for Research Ethics Review

*Funded by Greenwall Foundation*

**Team:** Kristine Wong, Lisa Moy, Andrea Corage Baden, Sarena Seifer (CCPH); Nancy Shore, Kirsten Cyr (University of New England, UNE); Elaine Drew, Ruta Bajorunaite (Medical College of Wisconsin, MCW)

**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

**Methods:** Literature review and online survey

**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



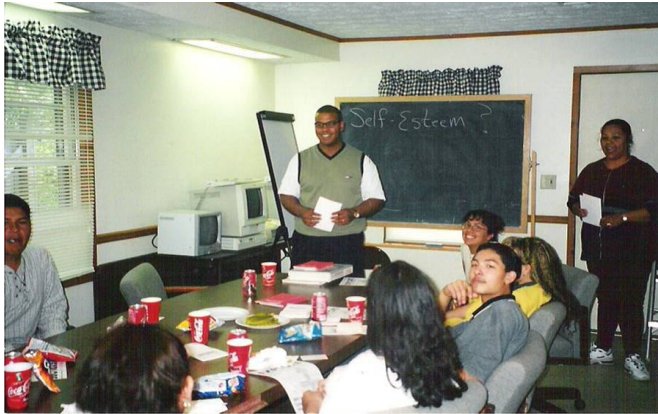
# Advisors & Supporters

## Study Advisory Committee

- Bonnie Duran
- Sarah Flicker
- Bill Freeman
- Kelly Fryer Edwards
- Helen McGough
- Ann-Gel Palermo
- Michelle Proser
- Joan Sieber
- Linda Silka
- Stephen Sodeke
- Eric Wat

## Supporting Organizations

- Association of Asian Pacific Community Health Organizations
- National Association of Community Health Centers
- National Health Care for the Homeless Council
- Public Responsibility in Medicine and Research
- Tuskegee University National Center for Bioethics in Research and Health Care



# Literature Review

*Citations available upon request*

- Community-academic partnership review process
  - Morehouse Prevention Research Center Community Coalition Board
  - Detroit Urban Research Center Board
  - University of Pittsburgh Center for Minority Health Community Research Advisory Board
- Community research review process
  - Yakima Valley Farmworkers Clinic, WA
  - Mayor's Health Task Force, Lawrence, MA
- Community-based IRB
  - Tribal nation: Navajo
  - Community health center: Waianae Coast, Hawaii



# Sample

Extensive search for community groups and community-institutional partnerships conducting, participating in, or reviewing research

- Bibliographic and funding databases
- Online program conference agendas
- OHRP and Indian Health Service IRB databases
- Listservs
- SAC and supporting organization

⇒ **1,028**



# Survey Topics

**When & why 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**



# Response

Sample = 1,028

Completed survey = 200

Met eligibility criteria = 172

**Community process for research ethics review = 109**

Process in development = 30

Non-respondents = 828

Random sample of 100 non-respondents contacted by phone:

38% did not receive study invitation (314)

Estimated effective survey sample = 714 (1,028 - 314).

Response rate =  $200/714 = 28\%$



# Findings

## **109 community-based processes for research ethics review**

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

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

<b>Consideration</b>	<b>Mean (SD)</b>
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*

<b>Consideration</b>	<b>Mean (SD)</b>
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)

# Decision making criteria

*Thematic coding of open-ended responses*

Importance of engaging community members in the decision-making process throughout the review and throughout the research itself

The research proposed must fit with the community group or partnership's priority areas or mission

The research must benefit the community directly, such as through increasing knowledge, improving resources or access to resources

The research must be feasible given the expertise, skills, resources, and time available within the community group or partnership

# 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%)

## Why also submit to IRB?

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



# Study limitations

Sample construction

Challenges with online survey

Response rate

Depth of responses



# Next steps re: study

- Content analysis of policies and forms
- Online repository of policies and forms
- Form collaborative research network
- Conduct in-depth case study analysis
  - Special Services for Groups, Los Angeles, CA
  - Mayor's Health Task Force, Lawrence, MA
  - Center for Community Health, Education Research and Service, Boston, MA
  - North Carolina Commission on Indian Affairs, Raleigh, NC
  - Guam Communications Network, Long Beach, CA
  - Native Hawaiian Health Care System IRB, Honolulu, HI
- Convenings, conferences and workshops



# Tap into Resources!

[www.ccph.info](http://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

## **Electronic Discussion Groups**

CBPR

Ethics & CBPR