REDEFINING RESEARCH ETHICS REVIEW:
CASE STUDIES OF FIVE COMMUNITY-LED MODELS

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CCPH Mission

To promote health equity & social justice through partnerships between communities & academic institutions
Community Network for Research Equity & Impact (CNREI)

- Mission is to ensure communities have a significant voice in decisions about research practice and policy, are true partners in research, and fully benefit from the knowledge gained through research.
- Open to community leaders & community-based organizations.
- Agenda for action:
  - Leadership Development
  - Accountability
  - Institutional Review Boards (IRBs) & Ethics
  - Research Funding & Policy
  - Training & Mentoring
• Funding agencies, researchers and community groups increasingly recognize CEnR as a critical approach to understanding and addressing disparities.

• Communities are developing research review processes to ensure the ethics of research in which they are engaged.

• Our case study demonstrates how these review processes function, how they compare to institutional IRBs, and how they impact research ethics, integrity and rigor.
Specific Aims

• To articulate the research ethics and integrity considerations, experiences and outcomes of community-based processes for research ethics review.

• To assess similarities and differences in the research ethics and integrity issues raised by community-based processes for research ethics review and those raised by institution-based IRBs.

• To identify and disseminate promising practices for assuring the ethics and integrity of community-engaged research to community groups, researchers, institutional IRBs, funding agencies and policy makers.
CCPH partnered with 5 community groups operating a research ethics review process

<table>
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<th>Name of Organization</th>
<th>Location</th>
<th>Type of CRP</th>
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<td>Center for Community Health Education Research and Service, Inc. (CCHERS)</td>
<td>Boston, MA</td>
<td>Emerging review committee</td>
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<td>Galveston Island Community Research Advisory Committee (GICRAC)</td>
<td>Galveston Island, TX</td>
<td>Research review committee</td>
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<td>Guam Communications Network (GCN)</td>
<td>Long Beach, CA</td>
<td>Research review committee</td>
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<td>Papa Ola Lokahi (POL)</td>
<td>Honolulu, HI</td>
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<td>Special Service for Groups (SSG)</td>
<td>Los Angeles, CA</td>
<td>Community IRB</td>
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Methods

Year 1: Case studies of each partner’s review process (CRP):
• Interviews:
  - CRP chairs and administrators
  - Researchers who submitted proposals to the CRP
• Focus groups: CRP members
• Document analysis: Practices and policies guiding the CRPs
• Observations: CRP meetings in action

Year 2: Cross-case analysis involving the study team. Key questions included:
• How do the CRPs compare to each other,
• What are the key issues the CRPs consider?
• How do the CRPs compare to institutional IRBs?
Open Q&A

Please submit your questions via the question box on your GoToWebinar panel
PAPA OLA LOKAHI’S INSTITUTIONAL REVIEW BOARD

Serving to Protect Native Hawaiians while Advancing Health

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Building Parity
Catching Different Waves
Race for Knowledge

Multitrillion Dollar Industry
Institutionalized

- Bureaucracy
- Institutes
- HMO’s, Insurance Co., Drug Co.
- Experts/Scientists
- Funding

Long Standing Relationships
Highly Competitive
Time Constrained
Regulated
Studies are chosen & constructed by the industry
Race for Survival

Obstacles
1. Informally organized
2. Few resources
3. Burdened with diseases & inadequate health care
4. Surviving in a predatory social/economic milieu

Resiliency
Living Cultural identity
Innate connection to their birth place & environment
Non-competitive, strength in numbers
“Ka Meheu ‘Ohu O Ka Honu”-mystical knowledge of the Path
Research Industry Responsibility

Build cultural sensitivity into protocol
Invest in working within the context of the culture
Invest in Community Infrastructure Building
Community Responsibility

*Be Aware of community needs, opportunities*
- Be willing to invest time, energy, experience, resources
- Be willing to mentor
Come together
Drink
Sacred Awa Bowl
A Case Study of Special Service for Groups’ Institutional Review Board: Research Equity Is Community Protection

Eric C. Wat, MA
Director, Research & Evaluation
Special Service for Groups (SSG)
Special Service for Groups, Inc. (SSG) is a nonprofit organization founded and incorporated in 1952.

SSG has over 25 programs and affiliate organizations, primarily in Los Angeles, but also in Orange County and San Francisco.

SSG programs serve vulnerable populations, including people with HIV/AIDS, older adults, limited English speaking (LEP) immigrants/refugees, indigent, re-entry and homeless individuals.

Program areas primarily include mental health, behavioral health, youth development, family functioning, occupational therapy, basic needs, and increasingly primary care.

SSG has a long history of conducting **community-based participatory research (CBPR)**, particularly on health disparities.

SSG has a Research & Evaluation unit (R&E) that provides capacity building through program evaluation, community assessment, and CBPR to SSG programs and their partners. This unit administers the **SSG-IRB**.
Why was the Community IRB started?

• SSG’s long history of CBPR projects
  – Part of an effort on a nationally-funded CDC project since late 1990s (REACH 2010)
  – Community voice was lacking in university-based IRBs
  – Encouraged by academic partners to look into community-based IRBs

• Growing trend of CBPR projects (with or without academic partners)
  – Need to increase SSG’s own capacity in leading CBPR projects and in supporting our community partners
How was the Community IRB started?

• Support of SSG and other community leadership as well as academic partner
• A year’s work in research and development (2002-2003)
  – dedicated staff (Dr. Jacqueline Tran, OCAPICA)
  – Reviewed other community research ethics review models
  – Developed policies and procedures
    • IRB application, review, and renewal forms (and associated forms, as appropriate)
    • Meeting protocols
    • Review guidelines
    • Training tools for IRB members and organizational programs
• Coincided with the establishment of SSG Research & Evaluation Unit in 2003 – which went on to register and administer the SSG-IRB in 2004
What is the purpose of the Community IRB?

- Engage and educate community programs and partners on the importance of research ethics
- Provide guidance for human subjects and community protections in CBPR projects
- Empower community programs and partners to be equal research partners through IRB process
- Give a voice to under-represented communities regarding research, especially involving human subjects
- Build capacity to do CBPR
How is the Community IRB maintained?

- **Structure**
  - Staff person (IRB Administrator) coordinates all efforts and requests
  - SSG-IRB members are volunteers (i.e., not financially compensated)
  - SSG’s executive director is the IRB Institutional Official (IO).
  - SSG provides in-kind support (e.g. staff salary, meeting costs, etc.)

- **Roles and Responsibilities of IRB administrator**
  - Maintain record of all applications
  - Document all processes of the IRB
  - Coordinate application review requests and process
  - Communicate with IRB application contact person for materials and review process
  - Provide workshops and TA on research design, methodology and human subjects protection
What are the benefits to the community?

- Community organizations and members become more aware of the IRB and research process
  - Improve research design by sharing best practices, methods and tools, and solutions to common challenges

- Community organizations can use this process to demand more equitable relationship in CBPR projects
  - Methodology, working with community members, data ownership, authorship, community dissemination, etc.

- SSG can serve as a conduit to provide oversight on human protections
What are some common issues addressed by the Community IRB?

- Community involvement in all phases of research process (not just subject recruitment and data collection)
- Community dissemination (not just publication in peer-reviewed journals) and data ownership
- Benefits and harms to the community, not just individuals
What are some common issues addressed by the Community IRB?

• Informed consent
  – Voluntary – subjects can still receive service even if they don’t participate
  – Sensitive topics: HIV/AIDS, criminal activities
  – Contact people and information
  – Length and format of consent form
  – Data use and dissemination

• Language (e.g. conversational and non-scientific) – translation, interpretation, verbal consent
What are some common issues addressed by the Community IRB?

- Subject recruitment and selection (e.g. experimental design, etc.)
- Role conflict for provider-researcher (e.g. mandated reporting, confusion to subjects, etc.)
What are the Limitations of the Community IRB?

• Funding for staff
  ❖ Would like to follow-up with projects to monitor progress (e.g. community-academic partnership) and gather CBPR lessons learned and more training!

• Voluntary board members
  ❖ Limited pool of available community partners who are already trained in CBPR
  ❖ Limited number of protocols reviewed
  ❖ Limited diversity to address protocols we do not have specific cultural competence for

• Having teeth: How to truly hold academic partners accountable?
Things to Consider when Considering a Community IRB

- Review and assess your resources, e.g.
  - How many community members familiar with CBPR who can serve as IRB members?
  - Do you have academic allies?
  - How many projects will need to be reviewed?
- Research existing IRB models – consider the resources to develop, conduct, and maintain the IRB
- Explore and learn about other options - IRB is not the only research ethics review process available to communities.
Resources


Thank you!

Contact Information

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Envision a healthcare system based on social justice and racial equity for optimal health of most vulnerable populations and communities of society.

- Equitable healthcare system
- Academic community health center model
- Community oriented primary care
- Commitment to vulnerable populations
- Eliminating health disparities … promoting health equity

To engage institutions, communities, community health centers and other healthcare providers in education, research and service partnerships to redirect health professions education, improve healthcare delivery, and promote health system change.
Institutional Partners

- Boston Medical Center
- Boston Public Health Commission
- Boston University School of Medicine
- Northeastern University Bouve College of Health Sciences*

*Host institution and sustaining partner
Community Health Center Partners

- Bowdoin Street
- Brookside
- Codman Square
- Dimock
- Dorchester House
- East Boston
- Gieger/Gibson
- Harvard Street
- Mattapan
- Neponset
- Roslindale
- South Boston
- Southern Jamaica Plain
- Uphams Corner
- Whittier Street

Certified as a primary care practice-based research network by the Agency for Healthcare Research and Quality and recognized by the National Institutes of Health
CCHERS Research Goals

• To establish a sustainable practice based research network of “academic community health centers”.
• To become recognized as a credible center for initiating and conducting community-based health services and clinical research.
• To increase interest and reward of university faculty to engage in and conduct community-based research.
• To increase interest and capacity of community members to engage in and conduct community-based research.
• To develop common research agendas derived through consensus between academic and community partners.
- Harvard Medical School/Brigham and Women’s Hospital, and CCHERS as a national center for reducing disparities in asthma.
- Longitudinal study of 1000 pre-natal for genetic testing; assessment of environmental and community stressors and triggers; evaluation of current CHC asthma interventions.
- Awarded as two separate grants linked together by common research aims, training objectives and communities of focus.
- Interaction with 5 separate IRBs: 2 educational, Northeastern and Harvard; and 3 hospital, Brigham, BMC and Beth Israel.
- This was the impetus to moving to develop our own community review process and IRB.
Challenges of Community Partnered Research

- Tenuous nature of university and community relationships
- Understanding the academic research enterprise
- Building research capacity and infrastructure
- Building relationships based on trust
- Coping with differentials in power and issues of control
- Being seen as credible partners with “expertise”
- Establishing a structure and process for inclusion, communication and decision making
- Allocation of financial resources and fiscal control
- Coping with the dynamic and fluid process of community engagement

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GALVESTON ISLAND COMMUNITY RESEARCH ADVISORY COMMITTEE

Gatekeepers for Health and Well-Being for African-Americans in Galveston, TX

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GUAM COMMUNICATIONS NETWORK’S RESEARCH PROJECT REVIEW PROCESS:
Empowering our Community to Protect and Promote the Chamorro People and Culture

September 23, 2014
Lola Sablan Santos
Lourdes Flores Quitugua
WHO WE ARE

- GUAM COMMUNICATIONS NETWORK (GCN) is a non-profit 501 (c)(3) organization founded in 1993.

- Sole Chamoro (group indigenous to Guam and the Northern Mariana Island) community-based multi-service agency in the nation

- Headquartered in Long Beach, CA

- Mission Statement dedicated to facilitating increased public awareness of the issues concerning the People, Island, and Culture of Guam through education, coalition building and advocacy.
• Involved in Community-based Participatory Research (CBPR) since 1999

• Began reviewing research proposals after becoming involved as study partners in CBPR with university-based researchers

• Community review process was established to increase the Chamorro community’s involvement in CBPR.

• Developed a platform where the Chamorro community could be involved in the regulation and review of research proposals

• Set a new standard for research in the community beyond involvement as participants, but in proposal development, implementation and dissemination.
COMMUNITY RECRUITMENT

- Ensure that the research study benefits the Chamorro community as a whole
- Sought community members who were knowledgeable with the infrastructure of the local Chamorro community.
- Identified individuals with knowledge about the topic area of the research study
- Important to involve the community at each step of the review process
- Resources
- Access to Human Subject Certification
COMMUNITY RECRUITMENT

• No academic representation.
• No MEN. All WOMEN
• Six reviewers
• Two GCN staff persons who serve as review process administrators.
• The administrators facilitate the review discussion but they do not have a vote on the proposal.
• Create a pool of Chamorro community members who are knowledgeable and experience in IRB [Institutional Review Board] procedures
THE GATHERING PROCESS

• FOOD
  – Cultural significance

• Family style
  – Creates Comfort

• Talk Story, Eat
  – Creates Trust

• Reach Consensus
  – Creates decision making

• Informal setting
  – Reflects the tradition in such a way that the outcomes of the review process are genuine and true to the Chamorro people.
COMMUNITY CHALLENGES

- No budget
- No MEN all WOMEN
- Informal structure
  - Works for local Chamorro community

In the Chamorro culture, a sign of respect to the elders.
• Promoting Community Review Process with other NHPI communities
• Promoting Community IRB
  – In San Diego, CA GCN coordinating start-up NHPI Community-based Research Coalition
  – Funding received from WINCART to train community on CBPR IRB
  – Develop Formal CRP
ACKNOWLEDGEMENTS

- John Cooks, GICRAC;
- Elmer Freeman, CCHERS;
- Mei-Ling Isaacs, Papa Ola Lokahi;
- Eric Wat, SSG;
- Al Richmond, Sarena Seifer, Elaine Drew, Alice Park, Paige Castro, CCPH;
- Nancy Shore, UNE & CCPH
Si Yu’us Ma’ase

For additional information please contact:

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Paige Castro and Alice Park, CCPH

What advice would you give for other community groups looking to start or improve a CRP?
What is the relationship of your CRP to other IRBS?
What impact do you see your CRP having for researchers/research?
Open Q&A

Elaine Drew and Alice Park, CCPH

Please submit your questions via the question box on your GoToWebinar panel
Next Steps

Greenwall Foundation study
- Articulate a set of ethical principles for community-engaged research (CEnR)
- Draft revisions to Belmont Report and HHS Regulations that account for the ethical considerations of CEnR
- Develop scenarios for a system of research review that could effectively assess CEnR ethics
• Our case study report:
  https://ccph.memberclicks.net/

• Upcoming presentations:
  – American Public Health Conference: November 24th
  – PRIM&R Conference: December 6th
THANK YOU!