The National Collaborative Study of Community-Based Processes for Research Ethics Review

Redefining Research Ethics Review: Case Studies of Five Community-Led Models
About the Report Cover
During a study team meeting, co-investigator Mei-Ling Isaacs proposed a fish as a metaphor to represent communities in research that strongly resonated with the rest of the team.

I imagined...the outline of a fish. You have that main bone going all the way from the tail all to the head. And connecting to all these outlying bones...there are similarities, which was the main bone of the fish, leading from the beginning, the tail to the head...it signals everyone is on a developmental line, ending with what we consider self-determination. And what are those main things that we're all trying to do here? It has to do with research, need, protection, authority, advocacy, and making it all work. Because the whole fish is really 'research' and how we can make life better for all of us. The whole fish really is bringing together our communities with science and scientists.

In thinking about the shared guiding core values of the “fish”, team members spoke about the importance of communication, advocacy, community-centeredness, protection, cultural appropriateness, self-determination, and transparency. The fish metaphor further touched upon the importance of a healthy environment, or as one study member shared, “we had to be careful what you put in the water so that it promotes growth and healthfulness and thriving and try to eliminate the toxicity.”

Continuing with the fish metaphor, the study team displayed an interactive poster at Community-Campus Partnerships for Health’s 13th International Conference, April 30-May 3, 2014 in Chicago, IL. We asked conference attendees that walked by to write on a colored construction paper fish what matters to them in ensuring that community-engaged research is done right. The photo on the cover of this report shows the result. The core values and practices that resonated with the study team were echoed and expanded upon by the more than forty people who participated. Their responses included:

• Nothing about us without us!
• We don’t work for free.
• All the community-based participatory research work must lead to change…policy, systems, institutional or social change.
• Listen to the community. Respect the people. Show up. Follow through.

A copy of the poster along with a complete list of participants’ responses can be found at: https://ccph.memberclicks.net/conference-presentations.
About the Co-Sponsoring Organizations

Community-Campus Partnerships for Health (CCPH) is a national non-profit membership organization that promotes health equity and social justice through partnerships between communities and academic institutions, including those that involve research. CCPH's strategic goals are to leverage the knowledge, wisdom and experience in communities and in academic institutions to solve pressing health, social, environmental and economic challenges; ensure that community-driven social change is central to the work of community-academic partnerships; and build the capacity of communities and academic institutions to engage each other in partnerships that balance power, share resources, and work towards systems change. http://ccph.info

The University of New England School of Social Work embraces a comprehensive definition of health as a state of complete physical, emotional, social, and spiritual well-being and not merely the absence of disease or infirmity. We believe that health, defined in this way, is a universal right. The majority of human suffering is embedded in inequity in the distribution of resources, with vulnerable populations at greatest risk. Thus, our focus is on changing those structures and relationships that foster the inequities that undermine the promotion of health. The School realizes this goal by teaching empowering theories for practice and developing collaborative relationships based on mutuality and respect, at all levels, from direct practice to societal movements. http://www.une.edu/wchp/socialwork

The Center for Community Health Education Research and Service, Inc. (CCHERS) is a community-based organization that is a community/academic partnership established in 1991 with a $6 million grant from the W.K. Kellogg Foundation's Community Partnerships in Health Professions Education initiative. The partnership is comprised of Boston Medical Center, the Boston Public Health Commission, Boston University School of Medicine, Northeastern University Bouvé College of Health Sciences and an established network of fifteen community health centers serving the racially and ethnically diverse populations of the City. Northeastern University serves as its host institution and sustaining partner. http://cchers.org

The Galveston Island Community Research Advisory Committee (GICRAC) is the brainchild of a devoted community researcher and concerned community members in Galveston, TX. Serving as gatekeepers for the health and well being of the African American community in the Galveston County area, GICRAC strives to bridge the gap between community and research through bidirectional education and meaningful and relative engagement in community-based participatory research activities.

Guam Communications Network (GCN) facilitates increased public awareness of the issues concerning the Chamorro people and culture through education, coalition building and advocacy. While we focus our efforts on the Chamorro community, we collaborate with other community-based service organizations in order to foster solidarity in our diverse communities and work together toward common goals. http://www.guamcomnet.org/

Papa Ola Lokahi's (POL) mission is to improve the health status and wellbeing of Native Hawaiians and others by advocating for, initiating and maintaining culturally appropriate strategic actions aimed at improving the physical, mental and spiritual health of Native Hawaiians and their 'ohana (families) and empowering them to determine their own destinies. One of its programs, POL Institutional Review Board (IRB), seeks to offer community and cultural perspectives that are lacking in other IRBs, an objective that is critical in light of the distrust by Native Hawaiians of researchers and the research process. The POL-IRB recognizes that, despite past wrongs, research focused on improving health programs is valuable for Native Hawaiian communities. http://www.papaolalokahi.org/

Special Service for Groups (SSG) is a nonprofit multi-service agency incorporated in 1952 that serves some of the hardest-to-reach populations across Los Angeles County. Since 2003, our Research and Evaluation Unit works with other nonprofit organizations and community members to collect and analyze information they need for planning and action. We believe that information is power, and we invest in developing these research skills within our communities. To this end, SSG established an Institutional Review Board in 2004 to ensure ethical research practices and equity between academic researchers and community members. http://www.ssgmain.org/
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The Collaborative Institutional Training Initiative (CITI): The CITI Program at the University of Miami is a leading provider of research ethics education content in the United States. Its mission is to promote the public's trust in the research enterprise by providing high quality, peer reviewed, web based, research education materials to enhance the integrity and professionalism of investigators and staff conducting research. https://www.citiprogram.org/

Community-Based Participatory Research (CBPR): CBPR is 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). http://cbprcurriculum.info

Community-Engaged Research (CEnR): In research, community engagement is a process of inclusive participation that supports mutual respect of values, strategies and actions for authentic partnership of people affiliated with or self-identified by geographic proximity, special interest or similar situations to address issues affecting the well-being of the community of focus. Community engagement is a core element of any research effort involving communities. It requires academic members to become part of the community and community members to become part of the research team, thereby creating a unique working and learning environment before, during and after the research (NIH Council of Public Representatives, 2008). http://www.nih.gov/about/copr/reports/index.htm

Community Review Process (CRP): An abbreviation used throughout this report referring to a community-based process for research ethics review, including federally recognized community-based institutional review boards as well as community-based research review boards and committees.

Federalwide Assurance of Compliance (FWA): The FWA is a contract that an organization signs with the federal government allowing research involving human subjects to take place. It is the only type of assurance of compliance accepted and approved by the U.S. Office of Human Research Protections for institutions engaged in non-exempt human subjects research conducted or supported by the U.S. Department of Health and Human Services. Under an FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR part 46, as well as the Terms of Assurance (HHS, 2011). http://answers.hhs.gov/ohrp/questions/7142

Institutional review board (IRB): An IRB is a committee established to review and approve research involving human participants. The purpose of the IRB is to ensure that all research involving human participants be conducted in accordance with all federal, institutional, and ethical guidelines. In the United States, IRBs are regulated by the U.S. Department of Health and Human Services. http://hhs.gov/ohrp

Public Responsibility in Medicine & Research (PRIM&R): PRIM&R is a non-profit organization with a global membership comprised of those working with research ethics, human research participant protections, animal care and use, and biosafety that advances the highest ethical standards in the conduct of biomedical, behavioral, and social science research through education, membership services, professional certification, public policy initiatives, and community building. http://primr.org
Community engagement is increasingly recognized by research funding agencies, researchers and community groups as an integral component of clinical and translational research, health disparities research and patient-centered outcomes research. Substantial federal investments in community-engaged research, including the National Center for Advancing Translational Sciences’ Clinical and Translational Science Award (CTSA) program and the National Institute of Minority Health and Health Disparities’ Community-Based Participatory Research (CBPR) initiative, are bringing critical research ethics issues to the fore along with the need for processes, structures and guidance to address them.

Community-engaged research (CEnR) represents a shift from viewing individual community members as research subjects to engaging community members and the organizations that represent or serve them as research partners. Institution-based Institutional Review Boards (IRBs), designed to protect the rights and welfare of individual study participants, are less equipped to protect the rights and welfare of communities involved in research. Specifically, the Belmont principles that guide IRBs do not cover the wide range of ethical issues that arise in CEnR, and thus institutional IRBs may not provide a thorough ethical analysis. For example, missing in the Belmont Report are the CEnR ethical principles of community relevance, participation, and benefit. The forms that guide institutional IRB reviews are also telling. In a content analysis of 30 university-based IRB application forms, community considerations were often missing. Although all of the forms reviewed inquired about scientific rationale, none queried the community’s perspectives regarding the justification for the study or how barriers to community participation could be minimized. Only 4 forms asked about community or societal level risks and benefits, and only 5 inquired how the findings would be disseminated. Further, studies of community-engaged researchers’ experiences with institutional IRB review reveal significant concerns about their consideration of partnership processes and community impacts. They find, for example, that institutional IRBs focus on how a study contributes to the scientific knowledge base or to society at large but do not usually consider what the benefits may be, if any, for the involved community.

With the substantial federal investments being made in CEnR, more community groups are being approached by researchers who want to conduct research in their communities, and more community groups are initiating their own research. On one level, the funding for CEnR is a welcomed sign that it is being viewed as a rigorous, legitimate and effective approach to research. On another level, it raises genuine concerns in communities that have been harmed by research and have experienced CEnR in practice as no more than being expected to recruit participants into investigator-initiated and designed clinical trials. To ensure the ethics and integrity of the research in which they and their communities are engaged, a growing number of community groups and Tribes have developed their own research ethics review processes that operate independently or in conjunction with institutional IRBs.

There appears to be growing interest among community groups in developing community-based processes for research review. In the first systematic study of these processes, investigators...
from Community-Campus Partnerships for Health (CCPH) and the University of New England (UNE) in 2009 identified 109 community groups across the U.S. with such processes in place, described their challenges and benefits, and documented the ethical issues they consider that institutional IRBs normally do not.\textsuperscript{32, 33} Findings from the study, supported by a grant from the Greenwall Foundation, revealed the important role these processes could play in ensuring the ethics and integrity of CEnR. The study not only identified 109 operational processes, but also 30 more in development.\textsuperscript{32}

Additional evidence pointing to how community groups have a growing interest in the development of community-based review processes (CRPs) includes the outcomes of the National Community Partner Forums on Community Engaged Research held in December 2011, December 2012 and April 2014. Approximately 300 community partners who attended these events indicated that “community review of proposed research” was among their four top-ranked priority topics for discussion. All the forums offered skill-building workshops on community research review. The workshops subsequently led to consultations with several emerging community IRBs. Additionally, the Community Network for Research Equity and Impact, a national network of about 300 community research partners that grew out of the first two forums, released a report in February 2013 that includes among its seven recommendations: “Funding is needed to support the start-up and continued operations of community IRBs and community-based research review boards. These entities – accountable to the communities they serve and represent – play critical roles in ensuring that community risks, benefits and feasibility of proposed research are carefully considered.”\textsuperscript{21} National organizations that represent community groups are also identifying community review of research as a priority for their members.\textsuperscript{34-36}

In order to more fully understand the operations and impact of CRPs, CCPH and UNE partnered with five community-based organizations (CBOs) that participated in the Greenwall study to conduct in-depth case studies of their review processes and analyze the cases for cross-cutting themes and recommendations (see Table 1). These review processes were selected based on their interest in the study as well as diversity in their geography, racial/ethnic makeup of communities served, research areas, and type of review process. Supported with R21 grant funds awarded in 2012 from the National Institute of Environmental Health Sciences, the National Collaborative Study of Community-Based Processes for Research Ethics Review sought to answer these critical questions:

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**Critical Questions**

- What are the structures and functions of community review processes?
- What are the core issues assessed during their reviews of research?
- How do these considerations compare to those typically assessed by institutional IRBs?
- What kinds of relationships exist between these community review processes and institutional IRBs?
- What are the review processes’ benefits and impacts?
- What challenges do these review processes encounter?
Table 1. Community-Based Study Partners

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

The National Collaborative Study team is comprised of Principal Investigators from CCPH (Seifer) and UNE (Shore), co-investigators from each of the 5 CBO partners (Cooks, Freeman, Isaacs, Sablan-Santos and Wat), a research coordinator (Park) and research assistant (Castro) based at CCPH, and a consultant (Drew). The study was reviewed and approved by four of the review processes participating in the study, deemed exempt by the UNE IRB, and the final partner’s university-based IRB secured an IRB Authorization Agreement with UNE allowing them to rely upon UNE’s determination of exemption.

Between October 2012 and May 2013, the team gathered data from key stakeholders from each community-based review process, including individuals who provide leadership and support for the review process, reviewers, and research teams who utilized the review process within the past six years. Data collection included the following for each of the case studies: 1) structured interviews with review administrators and chairs 2) a focus group with reviewers and 3) review of key documents guiding the review process. In addition, structured interviews were conducted with researchers for the four sites with an operating community review process and an observation of a review meeting was completed for two sites. The focus groups, interviews with administrators and chairs, and meeting observations were conducted in-person during site visits. The researcher interviews were conducted by phone.

For the data analysis, audio recordings of each interview and focus group were transcribed and analyzed using NVivo, a qualitative analysis software. The study PIs and study staff analyzed each transcript, identifying themes and sub-themes. The PIs, study staff and study partners engaged in ongoing discussion and reflection of the themes identified across the different study materials (i.e., interview and focus group transcripts) and their meaning. Exemplifying quotes as well as unique or contradictory information were highlighted. Ongoing discussion occurred to verify and build upon data interpretation. Based on the analysis, each study partner worked with the PIs and study staff to draft their own case study report.

The study team convened for a two-day meeting in October 2013 to discuss the similarities and differences across the individual case studies, and
to formulate recommendations for 1) community groups wanting to develop or strengthen their own review process, 2) institutional IRBs, 3) policy makers and 4) funders. The discussion was guided by a set of key questions identified by the study team. The data analysis followed the same approach used in the individual case studies.

**Overview of this Report**

This report presents the results of the National Collaborative Study and is comprised of four components:

- A glossary of frequently used acronyms and terms;
- This introduction, which explains the study rationale and methods;
- Each of the 5 case studies; and
- The results of the cross-case analysis.

**Citation**


**References**


