



Community IRBS & Research Review Boards: Shaping the Future of Community-Engaged Research



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The Bronx Health Link is a non-profit 501(c)3 organization based in the Bronx borough of New York City. TBHL seeks to reduce racial health disparities in the borough, focusing on infant and maternal health. TBHL's mission is to promote

Health Equity and Social Justice by:

- Connecting community residents to health and social support services;
- Engaging community residents, health providers and other Community Based Organizations (CBOs) through research, advocacy, and programs; and
- Providing information to consumers, providers, and policymakers to improve quality of life for all

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Community-Campus Partnerships for Health

Transforming Communities & Higher Education

Community-Campus Partnerships for Health promotes health equity and social justice through partnerships between communities and academic institutions. A non-profit organization founded in 1996, 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. CCPH members from diverse community, academic, government and philanthropic settings are advancing these goals in their work on a daily basis through service-learning, community-based participatory research and other community-academic partnerships. By mobilizing knowledge, providing training and technical assistance, conducting research, building coalitions and advocating for supportive policies, CCPH helps to ensure that the reality of community engagement and partnership matches the rhetoric. Learn more at <http://ccph.info>

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Context

A growing number of community groups are implementing ethics review processes to determine whether and how research is conducted in their communities (Grignon 2007). These community-based review processes operate independently, in parallel or in partnership with institution-based Institutional Review Boards (IRBs) and in some cases are community-based IRBs.¹

In 2009, with grant support from the Greenwall Foundation, Community-Campus Partnerships for Health (CCPH) completed the first systematic study in the U.S. of community-based review processes through an online survey of community groups and community-institutional partnerships involved in conducting research involving human participants and/or advising on its conduct (Shore 2010, Shore 2011). The study identified 109 ethics review processes that mainly function through community-institutional partnerships, community-based organizations, community health centers and tribes, with 30 more in development. These processes primarily formed to ensure the involved communities are engaged in and directly benefit from research, and are protected from research harms. They routinely examine issues that institution-based IRBs typically do not, such as community risks and benefits of the research and the cultural competency of the research team and study design. Their primary benefits were giving communities a voice in determining which studies are conducted in their communities and

ensuring that studies are relevant, feasible and build community capacity. Time and resources were primary challenges.

In follow-up to the initial study, CCPH is collaborating with study participants to conduct in-depth case studies of their research review processes. At the same time, The Bronx Health Link and Albert Einstein College of Medicine have established a community research review board and expressed a desire to learn from more experienced boards. Familiar with each other's work, the three organizations decided to collaboratively convene a meeting on March 7, 2012, in New York City of representatives of 9 community-based IRBs and community research review boards. The goals of the meeting were to celebrate successes, identify promising practices, address challenges and plan collaborations. This report summarizes the dialogue that took place at the meeting.

Introductions

During introductions, participants shared what they hoped to gain from the meeting. Their hopes included:

- Identify ways to sustain the review process
- Discuss strategies for evaluating and funding the review process
- Learn from each other and share stories
- Identify challenges and ways to address them
- Learn about the implementation of community IRBs
- Gain information and ideas to bring back home

Presentations

Each of the participating groups briefly presented an overview of its review process.

Community IRBs

The presentations began with the four groups that have a community IRB that is registered with

¹ An institutional review board (IRB) is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving human participants. In the United States, federal regulations have empowered IRBs to approve, require modifications in planned research prior to approval, or disapprove research. We refer to IRBs that are operated by community-based organizations and community coalitions as “community IRBs” to distinguish them from IRBs operated by research institutions such as universities and hospitals.

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the U.S. Office of Human Research Protections. These groups were Special Service for Groups, the Hispanic Health Council, Papa Ola Lokahi and The North Carolina Commission of Indian Affairs.



Special Service for Groups Los Angeles, CA

Represented by: Eric Wat, Director
of Research and Evaluation

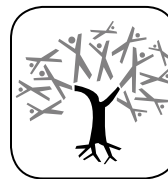
SSG is a non-profit organization that operates over 25 programs serving diverse populations, including some of the most vulnerable populations in research, such as mental health consumers, ex-offenders, and people who are homeless. Beginning in the mid-1990's SSG began a series of efforts to collaborate and build strategic partnerships with other community-based organizations and groups. In an era of uncertain resources and economic instability, SSG-led Community Collaborative Projects have become a well-known and respected agency trademark.

Because of its many years of experience in community-based research, particularly in racial and ethnic health disparities, SSG established its own community IRB in 2004 as the cornerstone of its research ethics review process. The IRB was developed as part of a Centers for Disease Control and Prevention funded project. Part of the motivation was the growing trend of community-based participatory research and recognition that the University IRBs had minimal community representation. Concerns existed that these IRBs were not positioned to evaluate community-level considerations. SSG's IRB reviews studies it is directly involved in as well as studies that involve numerous Asian-American serving community organizations in the Los Angeles area. Research proposals reviewed by SSG's IRB have also been reviewed by IRBs at the University of California-Los Angeles, the Rand Corporation and California State University-Fullerton.

SSG's review process has a dedicated staff person. Training for reviewers include observing the

review process and completing a course offered through the local University. All reviewers have participated in community research (i.e., principal investigator, participants) and are recruited largely from local organizations. Currently it is an internal review board for SSG programs, affiliated organizations, and community partners. Researchers come to the review meeting where the reviewers engage in dialogue. The intent is for the conversation to result in a stronger research design. Meetings are held quarterly.

The importance of the review process includes providing guidance on protections, empowering community programs to be equal research partners, giving voice to under-represented communities regarding research, and building capacity.



Hispanic Health Council Hartford, CT

Represented by: Joan Cruz,
Director of Special Projects and
Laura Victoria Barrera, Chair,
HHC's IRB

HHC is a non-profit organization founded in 1978 to improve the health and social well-being of Latinos and other diverse communities. HHC works to achieve its mission through community-based research, evidence-based direct services, training and policy advocacy. Community-based research has been core to HHC's work since its inception and served as a vehicle for development and testing of community interventions and policy change initiatives.

Throughout its 34-year history, HHC has conducted research independently and in partnership through its strong collaborative relationships with researchers at academic and clinical institutions, including the University of Connecticut and Yale University. HHC's IRB was developed in the mid-1990s and has served the organization continuously since then. HHC's IRB reviews and approves all research



initiatives involving human participants in which the organization is directly involved, regardless of sponsorship. HHC's IRB consists of a multidisciplinary group of stakeholders dedicated to ensuring that the rights and welfare of human participants involved in research activities are protected and consistent with federal regulations. Its diverse membership has community participation at its core. They review primarily socio-behavioral and anthropological research. They have established policies and procedures, adapted from the University of Connecticut and the State. As part of the review process, HHC asks if a proposed project will benefit their organization or harm their clients. HHC also wants to see how the research will be disseminated to the community. Anyone who wants to conduct research with HHC clients must submit an application for IRB review, including researchers, students and HHC staff. By having an IRB, HHC can also receive federal funding and offer funding for its projects.

Challenges to operating an IRB identified by HHC include 1) maintaining consistent staff; 2) relying on its own resources; and 3) not having resources to send staff to IRB trainings. To address some of these challenges HHC has considered joining other IRBs connected to an institution or community-based organization. The future for HHC's IRB depends on funding. While HHC has a federally negotiated indirect rate, the IRB is neither funded through indirect cost recovery nor a line item in the HHC budget.



Papa Ola Lokahi
Honolulu, HI

Represented by: Mei-Ling Isaacs,
Program Director

POL is a 501(c)3 non-profit organization founded in 1988 to improve the health status and well-being of Native Hawaiians (NH) and others by advocating for, initiating and maintaining culturally appropriate strategic actions aimed at improving the physical, mental

and spiritual health of NH and their 'ohana (families) and empowering them to determine their own destinies. Through its Research, Education and Training Department, POL provides an infrastructure for health research, education, and training programs that addresses the disproportionate burden of chronic diseases among NH. POL's research infrastructure includes: a clearinghouse for research and training opportunities, resources, and publications regarding NH health; stipends and internships for Na Liko Noelo, "budding Hawaiian researchers" in cancer prevention and control; training and mentorship in cancer epidemiology, research design and methods, proposal development and implementation, evaluation, and publications; advocacy and technical assistance to operationalize community-based participatory research methods; and administration of the federally registered Native Hawaiian Health Care Systems Institutional Review Board (NHHCS IRB).



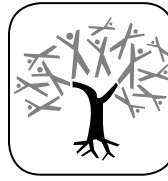
In the late 1990s a native cancer researcher had "had enough" with how academic researchers were interacting with the community. She wanted for her community to be the ones to determine what would be studied, how it would be studied, who would own the data, and how findings would be disseminated. Concerns also existed that none of the existing IRBs understood the community interests and cultural norms. The desire was to develop a community IRB that reflects the community's cultural values and is rigorous.

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The purpose of the NHHCS IRB is to maximize the benefits and minimize the risks of research in Native Hawaiian individuals and communities but additionally to educate researchers to build capacity within communities so that communities can participate in and partner with research projects that address existing community health concerns. Community members sit side by side with scientists and health professionals on the NHHCS IRB with equal weight given to their mana`o (thoughts). Ongoing and rigorous IRB training is provided for all IRB members. The NHHCS IRB has developed policies to guide its work and to address issues of concern to native communities, such as group harm and participation in genetic studies. It takes a grassroots approach by going out and asking the community if they really want a particular research project. At this point, community members will direct researchers back to NHHCS if they haven't received the board's approval.

The NHHCS IRB has reviewed studies that are also reviewed by the University of Hawaii. Challenges can exist as the NHHCS IRB may review a proposal concurrently with the University IRB. At times this results in differences, which prompt discussions. Ultimately the University IRB must respect NHHCS IRB's position if they want the research to move forward.

Researchers are educated so they know NHHCS' expectations regarding partnership (i.e., equal voice at the table). Researchers are also mandated to hold a community forum at the end of the project, and produce a community report. If the community has concerns, the researcher must abide to the feedback prior to publishing. Expectations also exist pertaining to compensation. Researchers, for example, must allocate funding for the effort to review the proposal and some of the community capacity building (i.e., funding to support screening for women, training youth on how to do research). NHHCS charges universities to conduct a review.



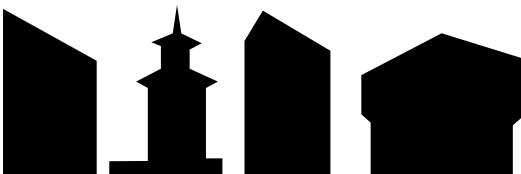
The North Carolina Commission of Indian Affairs Raleigh, NC

Represented by: Missy Brayboy,
Program Director

NCCIA was created by state statute as an agency for American Indians. North Carolina has the largest Indian population east of the Mississippi, with eight tribes and four American Indian organizations. The NCCIA administers programs for the tribes and organizations that address health, employment, training, education, housing, and career services utilizing state and federal resources.

Seven tribes do not have an IRB, nor do urban Indian groups. Problems arise when researchers go to a tribe, and the tribe agrees to participate without fully understanding the issues (i.e., problems associated with not getting the data, lack of reporting back to the community). Upon realizing the extent of these issues, the Commission opted to act as a gateway to the tribes. After convening a task force, the Commission decided to form an IRB. As the Commission could not do this as a State agency, they formed the North Carolina American Indian Health Board (NCAIHB). The NCAIHB is a state-wide research review committee that performs research ethics and integrity reviews of how research is conducted in North Carolina. The board also provides advocacy on behalf of NC Indians and make recommendations to state health agencies on American Indian health matters. It is comprised of members from each of the different tribes, doctors and non-clinicians, public health workers, and individuals from the Commission of Indian Affairs. The board provides training for its members.

The NCAIHB has reviewed research proposals that have also been reviewed by IRBs at the University of North Carolina-Chapel Hill and the Indian Health Service. NCCIA has strong collaborative relationships with American Indian



communities in NC and an exemplary reputation among American Indian communities across the country. These relationships are invaluable for disseminating study findings and products.

A potential challenge for the NCAIHB is that it will not supersede sovereign rights of the tribe. Yet at the same time the board recognizes that at times a tribe does not have the expertise to make decisions regarding research without the board's input. The board offers to serve as a facilitator for the tribes and as an entity where tribes can come to ask the board to review research for them. Challenges can also surface working with the University. There's an ongoing push for researchers to be more inclusive in the research process. The board can help set parameters around these relationships and partnerships.

Community Research Review Boards/Committees

The next three presentations were from groups having a community research review board or committee. These included: the Community Research Advisory Board, the Galveston Island Community Research Advisory Committee, and the Bronx Health Link Community Research Review Board.



Community Research Advisory Board Pittsburgh, PA

Represented by: Angela Ford,
Executive Director, Center for

Health Equity and Rev. Brenda Gregg, Member,
Community Research Advisory Board

The CRAB is based in the Center for Health Equity (CHE) at the Graduate School of Public Health at the University of Pittsburgh and was originally convened in 2001 by the Center for Minority Health, which was established in 1994 and became the CHE in 2011. The CRAB was

established as a result of (a) community members saying they wanted more input regarding health research being done by the University of Pittsburgh and (b) investigators wanting advice on designing, recruiting for, and conducting their research. The desire was to see more community-informed research.



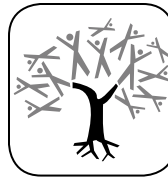
The CRAB consists of both academic and community stakeholders – individuals of various ‘walks of life’ – coming together for the purpose of building both academic and community capacity to conduct and contribute to research by: (1) Increasing community stakeholders’ awareness of various aspects of research studies, their benefits and implications; (2) Providing feedback and consultation to investigators regarding their proposed or on-going research, related to cultural and linguistic competency, relevance, and sensitivity; recruitment strategies; community education; and the translation of findings into practice; (3) Sharing knowledge and transferring information - based on research findings - to improve health outcomes; (4) Creating opportunities for further collaboration and partnership between research investigators and the communities/individuals most impacted by racial and ethnic disparities in health. CRAB members are encouraged to share information on research studies they want to support with others in the community at large, including identifying opportunities for others to learn about the problem being addressed and opportunities for

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participation in the research; and (5) Encouraging community-informed research and the basic spirit and philosophy of the Ten Commandments of Community-based Research (Browne 1995) to be applied to both new and on-going research investigation (e.g., “value process as you value outcome” and “do not cover the community data”).

The review board facilitates communication between researchers and the community, fosters respect for diverse perspectives, assists with building partnerships, and ensures researchers understand cultural norms. The process entails the investigator completing a research summary, presenting to the CRAB (15 minute presentation, informal without PowerPoint), providing copies of all documents two weeks in advance of the meeting, and answering questions. Researchers receive both written and verbal feedback. The University IRB has begun to refer researchers to the CRAB, which was taken as a strong sign of the CRAB’s effectiveness and value. The IRB also worked with the CHE to educate CRAB members about protection of human subjects and informed consent.

Challenges include not being a regulatory board and the potential to be used as a vehicle to legitimize what investigators are already doing wrong. The continued evolution of the CRAB must be informed by an evaluation of the experience of both CRAB members and investigators. The CRAB also must increase its visibility and build the capacity of members to raise greater awareness of research at the community level. Issues identified in proposed research include study materials not sensitive to culture or literacy, problematic consent forms, lack of diversity on research teams, as well as researchers not understanding importance of building relationships nor the community’s cultural norms and assets. Researchers have provided positive feedback on the review process and indicate that National Institutes of Health (NIH) reviewers have reflected positively on their participation with the CRAB.



The Galveston Island Community Research Advisory Committee Galveston, TX

Represented by: John Cooks, Chair

GICRAC was formed in 2005 and its mission is to serve as gatekeepers for the health and well-being among African Americans in Galveston County. A 501(c)3 nonprofit organization, it is committed to advocating, participating, and endorsing health research and related services, by participating in the selection, design, implementation and results sharing of research. GICRAC partners with the University of Texas Medical Branch at Galveston. The review board is comprised of 13 community volunteers and 7 research affiliates. The group educated itself on principles of community-based participatory research and research in general. It was awarded NIH Partners in Research funding. The review board has secured a Federal-Wide Assurance (an agreement with the federal government assuring ethical research involving human participants will take place).



GICRAC’s activities have ranged from proposal review and consultation to participant recruitment in mammogram screening. A milestone for the board was to be awarded a NIH grant through the Partners in Research Initiative in 2008. The board’s mantra is “What we will be will be determined by what we are willing to do” – Reverend Charles Wheat, first chair of GICRAC.



GICRAC identified the need to be listed within grants in order to assure compensation for such tasks as assisting researchers to conceptualize their grants and providing training/education. The stance is that GICRAC's work must be compensated, and therefore they need to be listed in the budget. In some instances this results in being listed as a line item. Funds are also needed to cover infrastructure costs.

The vision for the future is to build community capacity so that GICRAC can eventually knock on the door of the university to say what they want. The university will know GICRAC exists. Additionally GICRAC wants to have a line in the budget for projects they are involved in and wants to be invited to the table.

Challenges faced by GICRAC include 1) working within the constraints of the partnering academic institution, 2) helping institutions understand how GICRAC works; and 3) continuing to partner with local medical/research institutions that have different agendas.

GICRAC sees itself as steadily morphing, adding new members, constantly checking the pulse of its environment (i.e., asking if GICRAC represents the community), and always remembering its mantra.



The Bronx Community Research Review Board Bronx, NY

Represented by: Francisco Martin del Campo, Community

Health Educator; Bernice Williams, BxCRRB member and chair, Community Board 5's HHS committee; Anthony Day, BxCRRB member; Jannie Armstrong, BxCRRB member and member, Community Board 6's HHS committee; Rosalyn McMullin, BxCRRB member and Taariq Spruill, BxCRRB member

The Bronx Health Link, founded in 1998 as a 501(c)3 non-profit community-based

organization, is a one-stop source for consumers and health and human service providers on health issues facing the Bronx. The organization's focus is on improving the health of Bronx residents through community education and outreach, distribution of health promotion information, community-based research, policy work, community review of academic research, and advocacy. The Bronx Health Link and Albert Einstein College of Medicine have come together to educate the Bronx community about what research is and how it can benefit the community. This is being done through the project that developed the BxCRRB. The Bronx Health Link was also awarded a NIH Partners in Research grant to develop its BxCRRB and secured a Federal-Wide Assurance (an agreement with the federal government assuring ethical research involving human participants will take place).

The BxCRRB was recently developed, and began reviewing proposals from researchers at Albert Einstein College of Medicine in summer 2011. Motivation to create the research ethics review process was in part due to the many researchers wanting to do research within the community. The surrounding community attracts researchers due to the high rates of poverty, disparities in health outcomes across a variety of categories, and having a large and diverse immigrant population.

As part of the recruitment effort for the board, project leaders assessed how people were involved in different community organizations. The intent is for the BxCRRB membership to reflect the demographics of the community. Once recruited, trainings were held on the review process and bioethics.

The board represents the voices of the diverse communities of the Bronx to researchers. The board's pledge is to educate the public about what research is and how research findings can help close the gap in health disparities. At the same time, this is a body that listens and provides feedback to researchers about how Bronx

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residents feel about research. The board reviews and discusses research proposals with researchers. It then provides recommendations that these researchers can include in their studies. Researchers complete the required forms, and with the clear expectation that they need to use accessible language (i.e., not using overly medical terminology). Reviewers sometimes meet as a group prior to meeting with the researchers to prepare their questions and discuss concerns. As part of this group meeting, reviewers would ask such questions as what are the benefits and the action plan. Projects must address a health concern in the community.

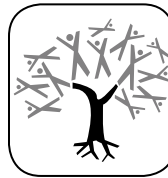


Plans for the future include recruiting and training new members. Current reviewers will also serve as mentors to the new members. In the future the BxCRRB is open to having other research institutions go through their review process, not just Einstein (The Bronx Health Link is subcontracted by Einstein on an NIH Clinical and Translational Science Award and CTSA supplement grant for its hosting of BxCRRB).

Emerging Community Research Review Boards/Committees

The final two presenters were Community Health Education Research and Service (CCHERS) and West Harlem Environmental Action (WE ACT).

CCHERS is considering the development of its own Community Investigations Review Board (CIRB). WE ACT has created a pilot model based upon qualitative data collected to form their Community Ethical Research Review Board (CERB).



Center for Community Health Education Research and Service Boston, MA

Represented by: Elmer Freeman,
Executive Director

CCHERS is a unique organization that brings over 20 years of experience with community-campus partnerships and its leadership position in Boston in community engaged research. CCHERS was founded in 1991 with support from the WK Kellogg Foundation. The intent was to educate medical and nursing students. In 1997 the CCHERS partnership incorporated as an independent 501(c)3 non-profit corporation as the institutions, community health centers and community partners determined it to be the most equitable way of sharing power and allocating resources for the work and sustainability of the partnership. Its Board of Directors is composed of representatives of the universities, hospitals, health centers and the communities they serve. Through shared power and decision making they provide governance, make policy and determine strategic direction for the organization.

Currently there are 26 community health centers in the city of Boston, with 15 in the network. CCHERS is certified as a primary care practice-based research network by Agency for Healthcare Research and Quality, and recognized as a minority serving institution by NIH. Their research is completely based in community health centers, coined academic community health centers. Teaching and research is integrated into the centers. The intent is to be recognized as a credible center for initiating and conducting community-based health services and clinical research.



The board's research review committee determines whether the organization will support, endorse or participate in a given research project. Research proposals reviewed by CCHERS' review committee have been reviewed by IRBs at Northeastern University, Tufts University, Harvard University and many of the teaching hospitals of Boston.

Based on the varied experiences of the multiple IRBs (Institution Review Boards) with which CCHERS negotiates, it is considering establishing its own Community Investigations Review Board, or CIRB. (It was noted during the meeting that the acronym IRB was originally intended to stand for investigations review board, not institutional review board). As evidence of impact of their current review process, health centers now know that they need to direct researchers back to the review board. Becoming a recognized IRB will provide greater power to assure this occurs. The challenge however is attaining legitimacy in an environment when even the medical schools do not have enough legitimacy to push their projects through their affiliated teaching hospitals.



**West Harlem Environmental
Action
New York, NY**

Represented by: Ogonnaya Dotson-
Newman, Acting Director of
Environmental Health

WE ACT is a non-profit, community-based environmental justice organization that has worked in community-academic partnerships for the past 10 years. The organization recognized gaps in research paradigms affecting how research was being done. A desire also existed to address the questions of “who does data belong to?” and “how is the community going to benefit?”

WE ACT used qualitative interview data to develop a Community Ethical Research Review Board (CERB) pilot model for community review of environmental health science research (Watkins

2009). While it is well understood that multiple and cumulative environmental health stressors negatively impact health at the community level, existing ethical research review procedures are designed to protect individual research subjects but not communities. The CERB was developed to address increasing concerns regarding the ethical conduct of research in general and environmental and genetic research in particular and to underscore the need to expand the scope of current human subjects' research regulations and ethical guidelines to include protections for communities and increased ethics training for researchers.

A goal for the CERB is to provide a confidential mechanism for the community to file grievances regarding research practices (e.g., researchers not adhering to a signed Memorandum of Understanding). In these instances, a facilitated discussion occurs and if problems continue the funder may be informed and a new partner identified. These steps can help make researchers stay true to agreements.

The CERB was built around a model where periodic communication occurs between the CERB and a study community advisory board (CAB), as well as between the CERB and the involved IRB. This results in a more circular process where communication flows between the CAB, researchers, and field workers. The CERB can provide oversight to this process, and helps to empower the CAB. Key stakeholders include: University IRB, CAB, environmental health science researchers, field workers, and the community ethical review board itself.

WE ACT's future vision includes implementing the CERB, understanding barriers from the community perspective, engaging youth and community-based stakeholders, identifying key policy implications of the work (internally within the organization and broader policy such as at the National Institutes of Health), and translating knowledge into action.

Cross-Cutting Points

Reflecting on the nine presentations, a number of points emerged:

History

Five main reasons for creating a review entity included:

- Problematic research practices within one's community
- Growing number of researchers wanting to conduct research within one's community
- Desire to have increased input or control over what research occurs and how
- Recognition that significant research gaps exist and desire to conduct research relevant to one's community needs involving members of the community
- Concerns with institution-based IRBs, (i.e., committee composition, ability to understand community norms and community specific risks and benefits)

Structure and function

Presentations touched upon five key areas:

- *Committee composition:* Recruitment efforts include identifying diverse membership with emphasis placed on identifying members of the community (i.e., residents, representatives from different tribes, community-based organization staff).
- *Training mechanisms for reviewers:* Training approaches included relying upon internal practices (i.e., observing review meetings, educating group on relevant topics such as ethics and community-based participatory research) and accessing University sponsored courses.
- *Scope of research reviewed:* For some groups, only research affiliated with their organization or research including client populations has been reviewed. Others described how only research on health concerns relevant to the involved community is considered.

- *Review process:* Several of the review processes require the researcher to attend the review meeting. This allows the review board to engage in a dialogue, and assure the researcher has addressed such issues as community risks/benefits and dissemination plans. Examples of concerns identified during the review included lack of diversity on research teams and lack of understanding of cultural norms and community assets.
- *Infrastructure:* While adequate resources were concerns for some entities, others described mechanisms to support and sustain the necessary infrastructure. These mechanisms included charging a fee and insisting upon being included in research grant budgets.

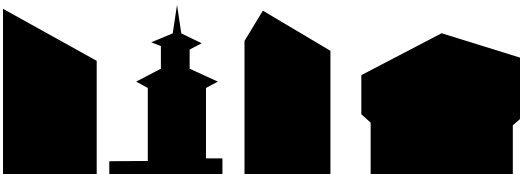
Impact

The impact of the review process included:

- Provide guidance on research protections
- Build relationships and community capacity
- Ensure cultural norms are understood
- Foster respect for diverse perspectives
- Raise researchers' awareness of community expectations (i.e., partnership will entail everyone having equal voice at the table, expectation of community forum to disseminate findings)
- Raise community members' expectations of research (i.e., community refers researchers to the review entity if their proposals have not been assessed by it)

Challenges that were identified included:

- Inadequate funding to support the infrastructure needed to operate the review process
- Conflicts with a partnering institution (i.e., different agendas, institution's IRB, difference in cultural norms and practices)
- Not being a federally recognized IRB and thus not having the level of authority that comes with it
- Helping communities recognize research that will provide community benefit



Future

For some, the future of their review process depends upon funding, prompting a conversation regarding how to negotiate indirect costs and insist upon being included within grant applications. Communities need to include the costs of operating their review process in their federally negotiated indirect rates just as universities do for their IRBs. When this isn't possible, they need to be included as direct costs.

Other future visions included:

- Increasing visibility and credibility
- Building capacity of review members
- Recruiting and training new reviewers
- Expanding the reach to include more than one academic institution
- Implementing a review entity that is now in development

Critical Issues

After listening to each other's presentations and engaging in group discussion, participants identified five critical issues to delve more deeply into. Time allowed for discussion of the first four:

- 1) Having more teeth
- 2) Community training and research
- 3) Funding and indirect costs as related to sustaining IRBs
- 4) Educating academic institution-based researchers
- 5) Community impact: assure community protections, community consent vs. community consultation

Having more teeth

Community review processes would like to have "more teeth" for researchers to go through the community review process and to hold researchers accountable throughout the life of the study. Several challenges to community review processes arise from a lack of power and authority.

Since review of research by a community review processes is usually not required, researchers may "shop" for community-based organizations to partner with or endorse the study if one organization says "no". Researchers might unilaterally remove a community group as a partner in a research study, which is compounded by the fact that the academic researcher is typically the one with the relationship to the funding program officer. A need exists to understand how some existing review processes have already found their teeth, such as the CRAB which is now getting researcher referrals from the University's IRB. This in part requires infrastructure to support the review process, thus tying into the discussion of funding.



One suggestion was to develop formal contracts between the community partner and the researcher's institution that specify how the research is to be carried out and by whom, including the process of ethics review. Ideally, institution-based IRBs would have the capability to assure researchers follow the approved plan. If a researcher is out of compliance and his or her institution does not adequately respond, the community needs to identify effective ways to expose the problem (i.e., through the media). Another suggestion was to build a strong enough community base that could exert itself and say "no" to a researcher regardless of the existence of a contract. One ideal vision expressed at the meeting was for every researcher who is working

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with vulnerable populations to go through their institution-based IRB, and then have that IRB refer the researcher to the community review process. Another recommendation was the creation of an ombudsman position to ensure fair assessment of concerns communities may have with researchers violating contracts, memoranda of understanding, etc.



Community training and research

The benefits of training community members in research and research ethics were discussed and felt to be essential for individuals serving on community IRBs and research review boards. One option was to create a “boot camp” research training for community members. Support could also come through more experienced individuals and groups mentoring those who are less experienced. Another suggestion was to develop a National Institutes of Health funded training for community organizations engaged in research that would cover grant-writing, community-based participatory research, policy advocacy, research ethics, and cultural values.

Funding

Sustainable resources are needed to support the functioning of community-based research review processes, including for training review board staff and members, interns, and principal investigators. Support is also needed for building/sustaining other research infrastructure in communities. Community organizations are hard-pressed to

find this sort of funding. Recipients of federal research grants typically are universities, and as a result they receive the indirect funds that flow along with the grant, a portion of which supports the functioning of their IRBs.

Compounding this challenge is that oftentimes community groups do not know upfront when a grant is being written what resources they need, and may be asked by an academic partner to turn things around quickly. Community groups need to ask themselves such questions as: do we have anyone to write the grant and be the principal investigator? Do we have a reasonable idea of what the review process and any other pieces we would be responsible for would cost? Ideally there would be a community liaison to assist community groups to position themselves as the main grant recipient. Some community organizations are in a position to be listed as the principal investigator with the university listed as a sub-contractor. There is a need for training and mentorship around funding for research and for the community-based research review process.

A number of ways to fund community-based research review processes were identified: build costs into overall operating costs, secure a federally negotiated rate and include the costs of the process in that rate, charge a fee for services (i.e., for the actual review as NHHCS does, or for technical assistance), and “tax” projects needing a review (i.e., a percentage of the grant for the study being reviewed comes to the community-based review process). If funders mandate that researchers go through a community-based review, funds for the review could be included in grant budgets.

Educating academic institution-based researchers

Some academic institution-based researchers do not approach communities in the spirit of authentic engagement, participation and partnership. As a group, communities need



to determine what academic researchers need to know to work in communities and then ensure they are adequately prepared. Academic researchers could be asked upfront to identify how they are going to give back to community.

Next Steps

The group generated a range of desired outcomes for the meeting including: re- conceptualizing research (i.e., demystifying it for communities), publishing products (i.e., edited journal/book, journal manuscript), disseminating information (i.e., call-series, posting their review policies), developing a tool kit (i.e., “how to” create a review process), advocating for policy changes (i.e., changing grant mechanisms that currently privilege university applicants), and raising awareness and support of community-based review processes both within the involved community and with external entities. The first product from the meeting is this report, which the group agreed is a collective work and should not have individually named authors. A committee was charged with drafting a journal manuscript. Other products will be developed over time as resources permit.

The meeting closed with the commitment to stay connected through email and phone and to hopefully meet again in person. Participants agreed that the meeting had been a special opportunity to learn, share and network with one another and they felt validation and renewed passion and energy for the important work they are doing in their communities.

Citations

The following documents were cited in this report:

Grignon J, Wong KA and Seifer SD. Ensuring Community-Level Research Protections. Proceedings of the 2007 Educational Conference Call Series on Institutional Review Boards and Ethical Issues in Research. Seattle, WA: Community-Campus Partnerships for Health, 2008. Available at <http://bit.ly/96WwUn>

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For More Information

Questions and comments on the report may be directed to programs@ccph.info

Those interested in keeping informed of developments pertaining to community IRBs and research review boards (including additional products arising from the meeting described in this report) are invited to join the community-based participatory research ethics listserv operated by Community-Campus Partnerships for Health: <http://mailman2.u.washington.edu/mailman/listinfo/ccph-ethics>

