Redefining Research Ethics Review:
Case Studies of Five Community-Led Models

Citation

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Acknowledgments

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 ʻohana (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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Glossary of Frequently Used Acronyms and Terms

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

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

Nancy Shore, Alice Park, Paige Castro, Eric Wat, Lola Sablan-Santos, Mei-Ling Isaacs, Elmer Freeman, John M. Cooks, Elaine Drew and Sarena D. Seifer

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.[1-10] 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.[11-13]

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.[3-5,8-10] 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.[14-20] 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.[15-16] 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.[17]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.[18-20] 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.[22] 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.[22] 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.[13, 23-31, 37-38]

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.[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.[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."[21] National organizations that represent community groups are also identifying community review of research as a priority for their members.[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:

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

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

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.

Our main audience for this report is CBOs that are interested in developing or strengthening a research review process. By packaging these pieces together, our aim is provide CBOs with a rich set of review process examples, promising practices, and key considerations that can inform their work.

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Papa Ola Lokahi's Institutional Review Board: Serving to Protect Native Hawaiians while Advancing Health Research

Mei-Ling Isaacs, Nancy Shore, Alice Park and Sarena D. Seifer

In the back of the room [at an ethics training] this woman raises her hand…and she says, 'by ethics do you mean if a researcher like a genetic researcher came into our community and wanted to take blood samples and skin samples to do a genetic study, does that person need to have informed consent?'

…[The ethics trainer] said 'yes you do.'

And she said 'well our family was told they have a genetic disease that is incurable, there's no treatment and researchers and doctors came and took blood and skin samples at our family reunion. We haven't heard from them in two years. We don't know where it is, what's going on. They just disappeared.'

These are really innocent people and they were going oh wow maybe there's a cure as they have known about this since 1860 as there tends to be this recurrence of a physical disability among certain family members at a young age and they die usually by 40.

<div align="right">

-POL-IRB Administrator

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Stories such as this underscore the importance of Papa Ola Lokahi's (POL's) commitment to protect and empower Native Hawaiian communities to ensure ethical research. POL's federally registered Institutional Review Board (IRB) reviews research with a commitment to apply both the human participant federal regulatory considerations expected of IRBs *AND* a deep understanding of Native Hawaiian communities. This case study report provides an overview of POL including the history behind the development of its IRB, how it operates, as well as its successes and challenges. The report furthermore looks at how POL-IRB compares to institutional IRBs, as well as its relationship with these IRBs. The report concludes with a set of recommendations for community and institutional IRBs. The report is based upon findings from an analysis conducted in 2013 of key documents guiding POL-IRB, an observation of a POL-IRB meeting, a focus group conducted with seven POL-IRB reviewers, and separate interviews with 1) the POL-IRB Administrator, 2) the POL-IRB Chair, and 3) three researchers who submitted their protocol to both POL-IRB and an institutional IRB. This case study is one of five conducted as part of the National Collaborative Study of Community-Based Processes for Research Ethics Review. The study aims and methods are further described in the first chapter of this report.[1]

Overview of POL

Papa Ola Lokahi (POL) is a 501(c)3 non-profit organization in Honolulu, HI founded in 1988 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. Native Hawaiians refer to individuals who can trace their ancestry to Hawaii prior to western contact. 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 Native Hawaiians. POL's research infrastructure includes: a clearinghouse for research and training opportunities, resources, and publications regarding Native Hawaiians 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 (CBPR) methods; and administration of its federally registered POL-IRB.

Overview of POL-IRB

History of review process
'Imi Hale, POL program funded by the National Cancer Institute (NCI) in 2000, provided an educational platform to develop Native Hawaiian researchers and to educate Native Hawaiian communities about cancer prevention and control. These budding researchers needed an IRB that understood and supported culturally relevant and tailored research in Native Hawaiian communities, and Native Hawaiian communities wanted to understand their role as partners and advisors to these researchers. The POL-IRB was established to provide the greater community with an IRB that had the capacity to educate researchers planning to do research in Native Hawaiian communities. The IRB reviews protocols of direct interest to Native Hawaiians. Groups or organizations that submit protocols to POL are the 5 Native Hawaiian Health Care Systems (NHHCS) centers, 'Imi Hale Community Cancer Network, the University of

Hawaii (the Department of Native Hawaiian Health and the RMATRIX Research Group), Chaminade University, Queen Medical Center (in partnership with 'Imi Hale), and the Hawaii Youth Drug Coalition. POL-IRB also reviews studies funded by POL. POL-IRB Fact Sheet (2013) states "with initial technical assistance from the Indian Health Service IRB and ongoing guidance from the NIH Office for Human Research Protection (OHRP), the POL-IRB held its first meeting on May 10, 2000." POL-IRB meets on an as needed basis, with approximately 26 protocols reviewed each year.

The POL-IRB Fact Sheet indicates that, "the purpose of the POL-IRB is to maximize the benefits and minimize the risks of research in Native Hawaiian individuals and communities. Additionally it was recognized that existing IRBs within the state of Hawaii were inappropriate to address the needs of the Native Hawaiian Health Care Systems and lacking in awareness of potential harms to Native Hawaiian communities." Another aim of POL-IRB is to educate Native Hawaiian researchers to build capacity within communities to participate in and partner with research projects that address existing community health concerns.

The goals of the POL-IRB are to protect Native Hawaiian communities from exploitive and demeaning protocols by:

- Increasing cultural awareness of the researcher and opening pathways in which the Native Hawaiian community can assist, advise, and partner with the researcher.
- Delving into the implications of the scientific construct, especially for genetic studies, and determine cultural safeguards.
- Increasing knowledge, building collaboration and improving upon relationships with universities and other educational groups who conduct research among Native Hawaiians.
- Educating independent researchers who plan to do research in Native Hawaiian communities.

Infrastructure

The POL-IRB has developed policies to guide its work and address concerns of Native communities, such as group harm and participation in genetic studies. Several key documents are discussed below. Please contact the POL-IRB Administrator to request copies of policies and forms specific to the review submission and overall process. The Administrator's contact information is listed at the bottom of this report.

IRB application

POL-IRB's application orients the researcher by including its mission statement in the application instructions: "To make sure human participant research on Native Hawaiians and all related activities are done in a respectful, culturally appropriate, ethically, and legally responsible manner." Also included in the written instructions is a timeline for the review process, indicating that researchers must submit their materials at least four weeks prior to the scheduled IRB meeting. Researchers must respond to all questions and submit required attachments including certification of Human Subjects Protection training. The instructions mirror content one would expect to see in institutional IRBs (i.e., "consent form may only be used if it has been date stamped," "actual instruments that are going to be used must be reviewed, current and up-to-date copies must be included.") Perhaps unique to POL-IRB is the request to see feedback from any other involved IRBs, and the recommendation to share its "Participant Bill of Rights" with potential participants prior to their signing informed consent documents. The "Participant Bill of Rights" reiterates content usually required in informed consent documents, per the human participants federal regulations and standard IRB practices. As an example, one point states that participants have the right to "refuse to participate, for any

reason, before and after the research study has started." POL-IRB adopted this document from the Indian Health Services IRB.

The actual application consists of eight over-arching questions, which require the applicant to reflect on questions traditionally included in institutional IRB forms. These include questions requiring the applicant to "outline objectives and methods" as well as "summarize all involvement of humans in this [research] project (who, how many, age, sex, length of involvement, frequency, etc.) and the procedures they will be exposed to." In terms of questions related to potential harm and benefits, the application primarily asks the researchers to reflect on individual-level considerations. More specifically the application questions are:

- How will you detect if greater harm is accruing to your subjects than you anticipated? What will you do if such increased risk is detected?
- Briefly describe the benefits that will accrue to each human subject or to mankind in general, as a result of the individual's participation in the project, so that the committee can assess the risk benefit/ratio.

Although not specified within the application researchers complete for POL-IRB review, the review process itself clearly examines community-level concerns. Of note, the POL-IRB Reviewer Checklist prompts the IRB reviewer to assess whether the proposed research will "comply with best practices and POL policies." As part of their determination, reviewers must answer: "Does it minimize harms and maximize benefits to Native Hawaiians by Participatory Research?" Verbatim sub-parts to this question are: Whether or not participatory research, does the research plan to: 1) work with communities to identify and minimize harms, 2) report timely results to the communities and POL, and 3) have the

POL review all publications? Community-level concerns are included in the continuing review/final report form that researchers complete, specifically within Part C-Presentations and/or Reports. This form asks researchers to report on how findings and/or progress have been shared with various audiences including NHHCS organizations, other Native Hawaiian communities, lay groups, as well as research participants or their families. Researchers are asked a similar set of questions in the Status Report and Renewal Application Report Form.

IRB administrator

Central to the functioning of the POL-IRB is a 0.5 FTE IRB Administrator. Across several of the documents the "required characteristics/considerations/charges" for the IRB Administrator position are spelled out. Some of these qualities are specific to working at POL, given its mission statement. These include knowledge of Native Hawaiian communities and culture, and knowledge of Native Hawaiian health and concerns that affect minority populations.

The current IRB Administrator was asked to recall what were the qualifications and experiences discussed when she applied for the position. Examples of the requirements and "characteristics" recalled included someone with an understanding of Native Hawaiian culture, as well as someone who practices these traditions. The ideal candidate also needed to have relationships with communities residing on the different islands and training in public health specific to Native Hawaiians.

The IRB Administrator's responsibilities are to:
- Oversee, manage, and evaluate assigned projects and programs for Papa Ola Lokahi.
- Provide training and technical assistance in program management and evaluation to Papa Ola Lokahi board members and staff, Native Hawaiian community, and the general public.
- Initiate research and training projects in conjunction with Papa Ola Lokahi Research Director.
- Seek funding through grants to support Papa Ola Lokahi sponsored projects and programs.
- Provide ongoing education on CBPR to Residents/Interns and first year medical students on how to work with Native Hawaiian communities.

The IRB Administrator is involved in a wide range of activities, including serving on task forces assigned by the Executive Director. The reporting structure at POL mandates that the IRB Administrator report to the Executive Director. The Executive Director in turn is responsible for key actions including, but not limited to, handling appeals to IRB decisions, making final determination on IRB membership, removing IRB members as needed, and designating the IRB chair and vice-chair. As explained by the IRB Administrator, this structure is appropriate for community-based IRBs given that the Executive Director is responsible for keeping the organization afloat and remaining responsive to the "board, community people, and the feds." At times this includes navigating challenges when the IRB's decisions are contested or questioned. As the IRB Administrator shared, the potential exists for the "IRB to be a trigger for political things in the community."

POL staffing specific to its IRB also includes one half-time Program Administrator. This position reports directly to the IRB Administrator. The Program Administrator is responsible for a wide range of supportive activities including maintaining documentation of IRB activities, retaining records in accordance with Code of Federal Regulations, preparing for and documenting IRB meetings, as well as maintaining the IRB database. Qualifications for this position include "knowledge of Native Hawaiian communities and cultures."

Structure

Type of research reviewed

The POL-IRB reviews research involving Native Hawaiians on diverse topics including behavioral health, diet, exercise, traditional healing, cancer, mental health issues, transgender populations, epigenetics, and genetics. Involvement of Native Hawaiians must be justifiable, or as the POL-IRB Policies and Procedures states "there shall be sufficient reason for the proposed research in NH [Native Hawaiian] community populations as opposed to conducting the research in non-Native groups." The reviewed protocols do not always focus solely on Native Hawaiians. As an example, POL-IRB reviewed an exercise protocol for an elementary school. The protocol did not solely focus on the Native Hawaiian children, but POL-IRB opted to review given there was a large population of Native Hawaiian families at the school.

Membership

Community members sit side by side with scientists and health professionals on the IRB with equal weight given to their manaʻo (thoughts). As the IRB Fact Sheet states, "because of the underlying principal of POL and the NHHCS is to promote the self-determination and cultural integrity of Native Hawaiian people, the POL-IRB includes Native Hawaiian members, whose concerns are primarily in nonscientific areas, and specifically in the culture and social situations of Native Hawaiians." Members receive NCI and NIH certification in research ethics, and hold 5 year staggered terms. New members are further prepared to review protocols by observing a POL-IRB meeting prior to becoming a voting member. New members are also given a binder of key human participant regulatory and POL specific documents, and are oriented by the IRB Administrator.

Members are recruited in part through recommendations from Native Hawaiian communities, current POL-IRB members, and Papa Ola Lokahi. Per the POL-IRB Fact Sheet, "members are selected for their expertise in one or more of the following fields: 1) Native Hawaiian cultural beliefs and practices; 2) biomedical research; 3) behavioral research; 4) medicine (allopathic); 5) public health and 6) legal. Additionally, members come with local expertise regarding their islands or catchment areas." POL's policies further require that at a minimum 50% of the membership must be of Native Hawaiian ancestry. Currently POL-IRB exceeds this minimum with over 80% of its membership being Native Hawaiian. As one reviewer shared, the "prized group" is the *akamai*. These are cultural practitioners or individuals who are "culturally astute…[and] know what's going on in the community." Two reviewers shared why they believed they were recruited to serve on the POL-IRB:

> *I was asked to join by Uncle. My background is not medicine at all or health. I think I was asked to join because of my work as a community activist. I come out of a community organizing background. I've always seen my role such as it is to simply look at some of the ethical and moral issues and think about how they affect our community.*
>
> *So when [the IRB Administrator] asked me it was one Kokua with Puʻukohola—reciprocal help. I am sure I will need her help one of these days for something or another. But that's a lifestyle. When people ask, ayou just help out that's just how it is whether it is me or someone else. That's our nature. And because you can always learn something. For me coming as a Hawaiian cultural practitioner, living the practices on a daily basis and living in aan extremely rural community. I think those are the two visions and perspectives that I can bring to the table.*

In thinking about how to further diversify the membership, suggestions included recruiting young Native Hawaiian researchers as well as individuals from different neighbor islands. One person envisioned the ideal membership comprised of at least one quarter of the members from neighbor islands. Per the POL-IRB Policies and Procedures, appointments must be approved and renewed "at the Executive Director's discretion upon recommendation of the POL-IRB Administrator." In regards to the importance of thinking about the IRB composition, particularly in terms of community members, the IRB Administrator shared "make sure they are people who actually live in the community and understand the ways of the people. Choose them well because they're the only ones in the IRB that can actually stop or veto a protocol." This position reflects POL's stance that the review process belongs to the community.

Budget

The total budget for the IRB is $102,000, with the majority of funds covering salaries and benefits for the IRB Administrator and IRB Program Administrator. Additional budget items listed in order of cost include rent, technical assistance workshops, health promotion/education, phone, dues/subscriptions, insurance, supplies, equipment lease, supplies, and postage. Funds supporting the POL-IRB are primarily from Public Health Service funds. The risk of POL-IRB having to cut back on its programs due to budget cuts is a challenge with this financial arrangement. Ideally funds to support POL-IRB would be a line item in POL's overall budget, thus providing a more reliable source of funding. The IRB Administrator is not paid for teaching and training provided to learners such as the medical residents from the John A. Burns School of Medicine at the University of Hawaii.

Submission Process & Review Considerations

Prior to the submission of a protocol, the IRB Administrator encourages researchers to contact her and discuss the study plan. As she explains, "we want them to call us first. And we talk about the process and we talk about how we would like to help them through the process because we want it to be successful for them as well as for us." This may entail talking about "what they have in mind, what their goals are who they are working with, are they engaging the community."

To submit a protocol to the IRB, the researcher completes an electronic application. The IRB Administrator completes an administrative review of the IRB application for completeness and accuracy, and the researcher is consulted if it is incomplete or has resolvable problems. The IRB Administrator completes the reviews for possible protocols that may be exempt or expedited. In some instances the IRB Chair reviews exempt and expedited protocols. If a protocol requires full review, the IRB Administrator assigns a primary and secondary reviewer, and a consultant is secured if needed, particularly for genetic protocols. The primary and secondary reviewers are selected with the intent to match reviewers' expertise with the substantive focus of the protocol under review. The primary and secondary reviewers along with the consultant, if applicable, submit a written report to the IRB Administrator. In instances where the report identifies significant concerns, the IRB Administrator may work with the researcher on addressing these concerns prior to the IRB Board convening. The researcher has the opportunity to respond to the reviewers' concerns and make changes to the protocol. The IRB Administrator sees her role as a facilitator between the researcher and the IRB committee. The IRB Administrator

is the only one who communicates directly with the researcher, and she does not disclose to the researcher who completed the written reports. This ideally allows the reviewers greater freedom to objectively write their reports.

All IRB members then receive the electronic version of the protocol, the written reports, and any possible revisions made by the researchers based upon the reports. An IRB meeting is then set within 2-3 weeks to discuss the protocol and the reviewers' reports.

IRB meetings occur on an as needed basis, depending upon when protocols are submitted. At the meeting, members attend in-person at the POL office located in Honolulu. Travel support is offered for reviewers coming from other islands, as well as parking compensation for those driving to the meeting. A dial-in option is provided for reviewers who cannot attend in-person. Previously, researchers attended the meeting when their protocol was discussed, however the policies and procedures were changed due to challenging encounters with having the researcher present. The POL-IRB Administrator now serves as the primary liaison between the POL-IRB committee and researchers.

As observed during a POL-IRB meeting, the meeting begins with an opening prayer, or pule wehe. Minutes from the previous meeting are discussed and voted upon, announcements are made, and then the review of the protocol begins. The primary reviewer provides an overview of the study, identifying key concerns. The secondary reviewer is invited to provide additional feedback. The IRB chair then asks for additional comments regarding the study, followed by a lengthy discussion of the proposal. The outcome of the discussion includes a list of possible contingencies and/or recommendations required in order for the

proposal to be approved, assuming the proposal is something that potentially could be approved. Contingencies represent items that must be changed, while recommendations are suggestions that the researcher may want to consider. Once the list of contingencies and recommendations is determined, a vote is taken. While the policies specify a vote to be taken, some of the reviewers describe the process as being more about arriving at consensus. As a reviewer stated, "it is [consensus], the Hawaiian way. It is the local way." The IRB Administrator shares the decision with the POL Executive Director, then informs the researcher in writing of the IRB decision. There is an opportunity for re-submission if the protocol is deferred or denied. Of note, the vast majority of protocols are ultimately approved. Once a protocol has been approved and implemented, a final report to the IRB is required as well as a community meeting to report findings.

Worth noting is that rarely are protocols exempted, even when the involved institutional IRB deems a protocol as exempt. As an example, the involved university's IRB deemed one protocol exempt on the basis that the Native Hawaiian participants did not represent a "vulnerable population." POL-IRB disagreed and required review "as potential study participants are viewed as vulnerable, particularly related to past negative research experiences, i.e., never seeing study findings." In this instance the study required an expedited review with a list of contingencies. Due to the history and complexity of genetic and epigenetic studies, POL-IRB has also developed biological specimen handling requirements. Researchers who intend to collect or store biological materials must agree to these requirements prior to the review of their protocol. Researchers are required to sign off on the biological specimen handling form, which contains requirements for the current study as well as any future studies generated from the collection of these same specimens.

In instances where a protocol requires review by both POL-IRB and another IRB, the POL-IRB Policies and Procedures document specifies the "POL-IRB shall require certification that the research proposal submitted for review has not been denied by any other institutional review board. A research proposal pending approval or having been denied by the POL-IRB may not proceed with the approval of another institutional review board." The Policies and Procedures document further states that "disapproval of an activity, suspension or termination of a previously approved activity, or imposition of conditions or requirements for approval shall not be voided or modified by any other authority if the POL-IRB actions were the result of a process in conformance with written POL-IRB procedures." To facilitate possible multiple review, the POL-IRB application requests that researchers, if applicable, submit letters of approval from other involved IRBs. More specifically, the application states "if your protocol has been reviewed by another IRB, it would help if you shared their comments with us. Many times they will have concerns similar to ours and by letting us know how they were addressed, we can avoid duplication." The application furthermore clearly states that the POL-IRB decision takes precedent over all other IRBs' decisions.

In instances where a protocol requires multiple reviews, a protocol approved by POL-IRB would likely receive automatic approval by the institutional IRB. However, approval from the institutional IRB does not necessarily equate to approval by the POL-IRB. The following example shared by the POL-IRB Administrator exemplifies this:

We have another protocol [that] had to do with genetics… And their board [referring to the institutional IRB] exempted it, actually it was administratively exempt. It went right through the hopper, whereas we denied it… the taking of specific tissue and the analysis of the tissue using perhaps a standard and getting results that does not speak to some biological variable…And she [referring to the university IRB director] said …it's such a low risk thing. Well it may be if you are looking at just anybody, but if you are looking at Hawaiians, this isn't a low risk, this is a very high risk deal.

Perceptions of high risk were based upon historical and ongoing unethical research practices involving Native Hawaiians as well as important cultural beliefs regarding the meaning and use of any body part.

Researchers also must seek continuing or renewal approval from the IRB. This process requires in part that the researchers speak to how they have shared findings with the involved communities. The IRB Reviewer Checklist also prompts reviewers to determine whether or not researchers presented findings back to the community and to POL in a timely manner. POL-IRB also has instituted a publication review policy, which requires researchers to submit any reports generated from their study to POL-IRB for approval. In the POL-IRB Policies and Procedures document, it specifies that publication review requires a quorum. Similar to an actual IRB review of a protocol, the publication review requires "a majority of members, including the Chair or Vice Chair, a scientific representative, and a Native Hawaiian community member whose primary concerns are in non-scientific areas must be present. This quorum shall be present at the beginning and throughout the period of deliberation and decision-making."

Review criteria
As observed during the POL-IRB review meeting, it is clear that POL-IRB reviewers consider issues dictated by the federal human participants regulations and traditional IRB practices, as well as

community-specific and cultural considerations. Some of the more traditional considerations focused upon issues of understandability. More specifically looking at the consent form, questions raised include: is the form written at the appropriate reading level, are all the acronyms spelled out, is the intent of the study and its requirements clearly articulated. Other examples of traditional considerations focused upon issues of data safeguards (i.e., how is data stored, who has access to data, how long is data stored, and when and by whom is data destroyed), disclosure of financial interests, and HIPAA considerations.

The POL-IRB places significant emphasis upon community or cultural concerns that are not necessarily assessed by institutional IRBs. These considerations were discussed at great length during the observed POL-IRB meeting, as well as discussed in-depth during the focus group with the POL-IRB reviewers. Some of the key documents mentioned above also prompt reviewers to assess community or cultural considerations. Examples of these types of questions include:

- Who is doing the research? Are they Native Hawaiian? Are they culturally aware?
- How is the community involved?
- Are there cultural harms in this research?
- Does it minimize harms and maximize benefits to Native Hawaiian individuals and communities by participatory research?
- What new information will be generated, and how will it be used?
- How is permission from the community group demonstrated, e.g., is there a memorandum of agreement?
- Are partnership terms equitable/satisfactory to the community?
- Who are the community facilitators or gatekeepers?
- How is the community kept informed as the research advances?

- Is there sufficient funding/budget to complete the research?
- How is the participant/community informed if there is an adverse event?
- Who owns the data?

To further elaborate upon some of the more community-specific considerations, one reviewer explained how at times they might recommend that the researcher add a community education component. This would translate to not only a community benefit (i.e., learning opportunity), but also potentially to strengthen the research. As an example, in the observed POL-IRB meeting the proposal being reviewed assumed that the community knew what CBPR was, and what were its underlying principles. The reviewers questioned this assumption, and suggested that a community forum on CBPR would ensure that community members were aware of their rights. This awareness would help the community in both current and future research endeavors. This in turn may minimize the possibility of research *on* rather than *with* the community. With knowledge of CBPR, the community would also be better positioned to answer this researcher's study questions, thus potentially strengthening the study design. Another question aimed at understanding the intended community benefit entailed reviewers asking what happens after the study is completed other than the researcher receiving a PhD? If best practices are identified, will they be shared with the community or perhaps buried in a professional journal resulting in no actual change? As an example of community risk, reviewers talked about the potential harm of findings from a study that looked at a few Native Hawaiian communities being generalized to represent the Native Hawaiian perspective. Another potential community harm entailed asking whether the study outcomes might create unnecessary and potentially damaging barriers to doing research with particular communities. POL-IRB's intent is not to stop research from occurring; instead it is to ensure research is done respectfully.

The importance of community members is underscored in POL-IRB's policy that states community reviewers are the only ones that have the power to veto a proposed study regardless of whether other reviewers support the research project.

Comparison of POL-IRB & Institutional IRBs

Researchers identified similarities between the community and institutional IRB due to adherence to the same federal regulatory requirements for human participant protection. One researcher who had submitted the same protocol to both POL-IRB and an institutional IRB commented the two involved IRBs were very interchangeable in terms of the materials requested and the application questions. Another researcher indicated similarities by describing both the involved IRBs as fair.

Researchers and the POL-IRB reviewers also identified differences between POL-IRB and the involved institutional IRBs. One researcher interviewed perceived the institutional IRB as more anchored in science, while the POL-IRB seemed to operate from a political agenda. Another difference discussed was POL-IRB's focus upon the wellbeing of Native Hawaiians, while the institutional IRB's focus appeared more on the wellbeing of its host institution and the participants in the study. POL-IRB's in-depth focus on Native Hawaiians was a theme throughout many of the discussions with the reviewers. For example, one reviewer shared:

> *That's our mandate to protect cultural beliefs and prevent harm as a result of violating these beliefs, and yet we still have to do the science as well, so we got a double whammy coming at us.*

In thinking back to the comments received from the involved institutional IRB and POL-IRB, some of the researchers identified differences in actual feedback received. One researcher recalled the POL-IRB feedback focusing more on developing a plan to address possible participant distress and ensuring the informed consent document was written at an age-appropriate level. In contrast, the institutional IRB feedback was more focused upon data safety considerations. Another researcher described the POL-IRB feedback as overly focused on re-writing the proposal as compared to the involved institutional IRB focus on issues of feasibility and researcher expertise. Another researcher did not recall receiving feedback from either IRB, perhaps due to the lower risk nature of the proposed study. Conflicting feedback from the involved institutional IRB and POL-IRB emerged for only one researcher, resulting in the study not being able to move forward due to denial by POL-IRB.

In comparing their experiences going through both the involved institutional IRB and POL-IRB, two researchers did not point out major differences. Both felt the institutional IRB feedback was nothing "unusual" and did not require major changes to their study. One of these researchers was appreciative of the POL-IRB focus on cultural considerations given her desire to "not offend anyone" while the other researcher felt POL-IRB could have been even "more rigorous" and "more in depth." The other researcher described the institutional IRB more positively by characterizing it as "challenging, but useful."

A reviewer further differentiated the POL-IRB and institutional IRB process by adding that POL-IRB is not driven by grant money. By not being dependent upon grant dollars, the reviewer asserts that they can remain focused upon critical cultural considerations. This POL-IRB member shared:

> *[Institutional IRBs] don't take into consideration cultural issues. The educational IRBs are really designed to push through research projects*

because it means money for the institution. So they're going to put through, and they are going to exempt, expedite whatever they can. They will ignore cultural issues because it just holds them back. They're not under any kind of mandate they feel, to recognize cultural issues.

Relationship Between POL-IRB & Institutional IRBs

The POL-IRB has Federalwide Assurances with the 5 NHHCS and Chaminade University, as well as a memorandum of agreement with Chaminade. In addition, they assess protocols reviewed by the University of Hawaii School of Medicine, Queens Medical Center and Western IRB (an independent, for-profit IRB). While no formal agreement exists between the POL-IRB and the involved institutional IRBs, there is a strong relationship with two people from Chaminade who sit on the POL-IRB. In addition, the POL-IRB works closely with the Department of Native Hawaiian Health and the RMATRIX staff at the University of Hawaii (RMATRIX is an NIH-funded Research Center in Minority Institutions). For instance, they hold joint study groups with RMATRIX in preparation for PRIM&R certification as an IRB professional and the POL-IRB Administrator presents to their medical students every month.

Suggestions to improve the relationship between the POL-IRB and involved institutional IRBs include working to ensure POL-IRB has access to the key decision-makers within the University, and that these decision-makers not only understand the role of the IRB but also how a partnership with POL-IRB could be mutually beneficial. Strategies are also needed to deal with conflicting assessments, for example when POL-IRB disagrees with a University IRB's decision to exempt a study due to perceived minimal risk. As

discussed in the challenges section below, tension can exist between POL-IRB and the involved institutional IRBs.

Benefits & Impact

A major benefit [of POL-IRB] is we are protecting Native Hawaiians. Universities are really blind to cultural aspects of what is happening in the community.

We are all stakeholders as well. The members on the board are a cross-section of the communities and we bring to the table our own expertise.

One way we generally approach [our review] is to try to represent the community's… to make sure that there's a benefit back to the community. Sort of speaking as an agent for the community.

The POL-IRB protects the Native Hawaiian community from problematic research through careful deliberation guided by requisite information, cultural awareness, and a belief that harms and benefits must be considered on both the individual and community-level. The POL-IRB seeks expert consultation when proposals include complex methodologies or require specialized knowledge. As an example, reviewers described instances when geneticists were consulted to help assess the risks and benefits of a proposed genetic study. The POL-IRB is able to critically think about the "cultural aspects" due to its policies regarding committee composition. At a minimum, the POL-IRB must be comprised of 51% Native Hawaiians representing the different islands. As one reviewer stated,

We have a stronger tap into the community in general, whether it is very rural Hawaiian communities or even urban Hawaiians as well.

And also I think in general stronger cultural background and agenda kind of to assuring that those aspects rate very high in terms of importance when it comes to research and protecting the cultural integrity and the practices of the participants and the culture in general.

This insight translates to reviews that help raise cultural considerations to the forefront, which is often not the case when research is reviewed by institutional IRBs. As an example, one reviewer commented,

We are not stopping [researchers]. But we want you to handle it in a different way, how you handle this kind of tissue is important to us, how you destroy it is important to us, who keeps it is important. We are not saying stop. We are saying you must be aware of what we consider to be sacred and handle it in a way that we will approve.

The need to approach the analysis through a cultural lens is critical given researchers tend not to be culturally attuned. In other words, POL-IRB's attention to "cultural and spiritual impacts" likely is not considered by the "traditional university researcher." The POL-IRB also requires researchers to explain how findings will be reported back to the community, and what are the potential benefits of participating to both the individual and the community. For example, the POL-IRB continuing application asks several questions such as "who have you and your team reported results or progress to about the research during this period?" Prompts to this question include NHHCS organizations, other Native Hawaiian community organizations, lay groups, and research participants or their families. These review considerations and application questions help to ensure that communities do benefit from the research, countering

the experiences described at the beginning of this report of researchers taking tissue and blood samples and raising the community's hope for a cure, but returning none of the findings to the family members.

Another perceived benefit of the POL-IRB is its ability to enhance the methodology or strengthen the proposal overall. This may occur when proposals appear somewhat haphazard, and the reviewers prompt the researchers to further streamline their process and sharpen the focus. In other instances the reviewers identify potential risks and require researchers to think through how to either minimize these risks, or implement strategies to address possible harm. As one researcher shared, "what we did for the study was we administered several questionnaires to the participants so they [POL-IRB] wanted to know what the plan was to address any psychological or emotional distress that may arise from answering some of the questions. Not simply stating 'they don't have to complete the survey.' They [POL-IRB] wanted an actual plan." Other examples of how overall study design were strengthened included feedback on the consent form's reading level, strategies to engage community leaders, and measures to ensure confidentiality. These examples highlight how the POL-IRB focuses on BOTH cultural AND regulatory AND scientific considerations. Through the process, researchers gain understanding and "insight into a different world." As one researcher commented, "it makes me a better researcher." POL-IRB has received additional positive feedback informally from other researchers. As part of the POL-IRB Administrator's job description, she also provides training. This includes frequently speaking to medical students on working within the Native Hawaiian community.

Outcomes of the POL-IRB review that go beyond strengthening research proposals and educating researchers include increased use of CBPR

particularly in rural communities, empowerment of communities, increased recognition of the POL-IRB and benefits to the reviewers. As evidence to the increased recognition of POL-IRB, one reviewer shared how different communities have demanded that researchers go through the POL-IRB. As the reviewer commented, these communities in essence say, "don't even come to us unless you've come through the POL-IRB. We don't care who exempted you, if you don't get through Papa's [POL] we aren't talking to you." In reference to being exempt by other IRBs, reviewers shared how the POL-IRB, unlike institutional IRBs, are not dependent upon research grants to sustain their activities. This perceived independence from grant reliance contributes to the POL-IRB's ability to focus on prioritizing cultural and community considerations. Lastly, as the POL-IRB continues to review proposals, it has also gained increased recognition within its parent organization becoming a permanent fixture on the organizational chart. In describing the impact of serving on the POL-IRB, reviewers spoke in terms of enjoying the process and the value gained in fulfilling a "real duty to protect people."

Challenges

Three broad categories of challenges to the POL-IRB emerged: Challenges related to institutional practices, researchers, and membership expertise. Challenges with the involved institution (i.e., university, hospital) typically refer to the different standards used to determine a proposed study's risk level. A powerful story was shared how an involved university IRB declared a study exempt, contradicting the POL-IRB assessment. The proposed study entailed further analysis of tissue samples without re-consent. As shared by a reviewer,

[The institution IRB] said that nobody cares, doesn't matter. Well it does matter, it matters to Hawaiians that you re-consent them before you go off and take tissue samples for a totally different study.

In another example of different standards, reviewers shared how the involved university determined a study exempt due to classifying the study materials, placenta, as medical waste. This classification as "medical waste" contradicts Native Hawaiian beliefs that honor the significance of the placenta. In fact, Hawaii became the first state in 2006 to expressly give women the right to take their placenta home after childbirth. This stance recognized cultural rights. Challenges associated with different standards can be escalated when institutional IRBs "think they have the key to the kingdom and the secret to life." Other challenges associated with working with institutions are university policies that may, for example, be driven by research dollars rather than the cultural values and priorities that guide POL policies.

Researcher beliefs and actions can also translate to other impediments to the POL-IRB's ability to protect the wellbeing of Native Hawaiians from unethical research practices. More specifically, some researchers may try to avoid the POL-IRB process, while others may IRB hop. As one reviewer shared, "IRB hopping [is] if you don't get what you want from one IRB, you go to another." These actions may be a result of the POL-IRB's reputation as being difficult to gain approval or lack of familiarity with the POL-IRB process. Interestingly, several of the researchers interviewed discussed how they anticipated or desired more feedback from the POL-IRB. In these instances questions emerged regarding whether the review process was

sufficiently rigorous. Other researchers may believe that a community advisory board is sufficient for their community-engaged research. As one reviewer stated, "we need to help the researcher community to see the IRB process as more than an obstacle." This need ties into the ideas put forth regarding the importance of educating researchers.

A final category of challenges focused upon membership expertise. Many of the protocols submitted to the POL-IRB are genetic studies that require specific expertise. In other words, "some of the challenges really kind of rear its head like when we're dealing with difficult protocols, like genetic protocols, because we may not have the expertise on the board to really truly understand." Another reviewer also pointed out that "just because we're Native Hawaiian doesn't mean we necessarily understand all of the cultural context." While these comments were framed as challenges, one can also interpret them as a strength. In numerous instances across the focus group discussion and interviews, the POL-IRB practice was described as seeking consultation from experts in the field on an as needed basis. These consultants provide critical feedback, but do not vote. In other instances reviewers provide peer education opportunities on issues encountered in the review process. As an example, during the observed POL-IRB meeting, a reviewer who is a cultural practitioner provided a PowerPoint presentation that carefully outlined the historic and contemporary Native Hawaiian beliefs regarding the sacredness of the placenta. A final related challenge discussed was the potential for community-based IRBs in general to lack the same scientific expertise as institutional IRBs, such as specialization in biostatistics.

Recommendations

Recommendations for institutional IRBs
Four main recommendations were suggested for institutional IRBs. The first is to move beyond the idea that having one non-affiliated member provides sufficient expertise in understanding the communities often engaged in research. As one reviewer stated, "the one token native person on the IRB with 15 researchers is not enough to fully prepare an IRB to knowing how to make decisions about a protocol." An increased percentage of community members can help address potential power imbalances as well as provide a more comprehensive understanding of the involved communities. Without a more comprehensive understanding, the concern remains that institutional IRBs "are seriously unequipped to deal with the comprehensive issues that a community must have to face in regards to community consent as well as historical trauma and historical harm." A second recommendation was to compensate community reviewers. Academics are expected to fulfill university service requirements as part of their contracts. Community reviewers typically volunteer to serve on the institutional IRB and add this service to their already overloaded work schedules. To ensure an even more comprehensive understanding of the communities involved in the proposed research, a third recommendation was for institution-based IRBs to hire paid community consultants. This recommendation parallels the approach POL-IRB already takes when they seek consultants to help understand complex protocols.

Lastly, institutional IRBs should increase their understanding of CBPR and incorporate community-level considerations into their reviews. In thinking about CBPR, the researchers interviewed identified key ethical issues that may not be considered in institutional IRB reviews. These included such questions as: what is the proposed study's impact on the community, how is the community involved in the research process including designing and implementing the study, what is the researchers' relationship to and/or experience with the involved community, what are the critical considerations that must be addressed regarding cultural practices, possible historical harm, and beliefs regarding community consent?

Recommendations to strengthen the POL-IRB

Both researchers and reviewers generated recommendations specific to POL-IRB. The ability for POL-IRB to continue to grow and develop requires a greater operating budget. An increase in budget would allow for more frequent trainings on an array of topics, and the ability to attend relevant conferences such as PRIM&R. Currently training occurs only every other year. In addition to ethics and regulatory training, reviewers identified research methodologies as a desired training need. More specifically, one reviewer suggested a training on "how do we evaluate if this research method is in fact appropriate or not." Another reviewer recommended working with other indigenous researchers to gain greater understanding of how to ethically and respectfully engage with native communities, and how indigenous research methodologies differ from western research methodologies. Training would address a concern raised by a researcher that the "Native Hawaiian IRB may not be fully skilled and trained to look at the depth and complexity they should be looking at."

A larger operating budget would also allow reviewers to attend relevant conferences, such as PRIM&R. Another suggestion was to create opportunities for reviewers to convene with members of other community-based IRBs. This would allow community-based IRBs to learn from each other and support their continued growth. Working together, community-based IRBs may also identify strategies to ensure that funders, researchers, and institutional IRBs recognize their rigor and value. A concern exists that some entities and/or individuals may question whether a community-based IRB can sufficiently review research proposals. In response to this concern, reviewers discussed how the POL-IRB effectively assesses both scientific rigor and cultural relevance. As discussed in the challenges section, experts in the field are consulted when reviewers need assistance in assessing complex proposals.

The challenge remains, however, that POL-IRB is underfunded and at risk of more budget cuts due to such factors as federal sequestration and not having a dedicated line item in POL's overall budget. A recommendation was to advocate for and secure a more reliable funding stream to ensure its sustainability.

Recommendations specific to the POL-IRB process also included developing questions for their IRB application focusing on community engagement and benefit that parallel those appearing on the Reviewer Checklist. Suggested questions included: How was the research question derived, how much will the community be involved, what will be the benefits to the community? As part of the review, one reviewer also recommended assessing the proposed study's budget to determine whether there's a justifiable and equitable budget. This would allow reviewers to minimize the possibility of "wasting money" when "limited resources [exist] that come and reach the community." Given the scarcity of resources, this reviewer felt strongly that the budget ought to be viewed as an ethical issue.

Other recommendations to facilitate the review process focused upon strategies to better prepare researchers to engage with Native Hawaiian individuals and communities. In addition to requiring traditional ethics training (i.e., CITI),[2] reviewers discussed the value of developing an ethics guidebook or manual for researchers. This manual would expand upon the content covered in traditional ethics trainings by introducing how these ideas translate into working respectfully with Native Hawaiians. Along with the materials to prepare researchers, one reviewer also suggested that the POL-IRB increase its marketing. More specifically, this reviewer stated, "we could do a better job of letting researchers know that we're there, that we really are trying to educate and not trying to block you."

In addition to building relationships with academic-based researchers, a recommendation was also

put forth to continue dialoguing and working with institutional IRBs. Several examples of partnership efforts between POL-IRB and local university IRBs are mentioned above in the section, "Relationship between POL-IRB and institutional IRBs." In addition, an institutional IRB has invited the POL-IRB Administrator to join its accreditation process activities. Additional work, however, must occur for some of the local institutional IRBs and their reviewers to gain greater understanding of and respect for Native Hawaiian priorities and concerns that inform research practices with Native Hawaiian communities and shape POL-IRB's approach. Supporting the need for this increased awareness were the examples shared when POL required a review of a research proposal while the involved institutional IRB deemed it exempt. In these instances POL-IRB and the involved institutional IRB held different opinions regarding what groups constitute a vulnerable population and what is sacred. A commitment to engage in dialogue and teach others about Native Hawaiian values and practices is aligned with POL's mission. Ideally, continued engagement between POL-IRB and surrounding institutional IRBs will prove to be mutually beneficial, and most importantly of value to Native Hawaiian communities.

Recommendations for other community groups interested in developing their own IRB

Researchers and reviewers identified specific recommendations for community-based IRBs in general, both for existing as well as developing ones. Roughly these recommendations can be grouped into five categories: community awareness and respect, infrastructure, committee considerations, relationships, and researcher specific recommendations.

Community awareness and respect: Community-based IRBs must have a deep understanding of the communities they serve. This includes "what they think about research and what they want done, how they want it done, what's important to them,

how they want to be treated, all those things." Developing this deep understanding takes time, and must be done with respect. The IRB application questions must be infused with this awareness and respect.

Infrastructure: Community-based IRBs require ongoing financial support. As discussed above, money must exist for training reviewers and supporting the work they do. Given the costs of developing and sustaining a community-based IRB, one reviewer suggested that communities consider collaborating to co-manage a community-based IRB. One reviewer added that the host agency support for the community-based IRB is absolutely critical to the IRB's sustainability as well as having a passionate and well-respected IRB Administrator.

Committee considerations: Assess reviewer expertise and identify gaps. Expertise related to understanding and connection to the community is essential. As one reviewer commented, "make sure they are people who actually live in the community and understand the ways of the people." The need to recruit Native Hawaiian youth is an example of a gap identified by the POL-IRB. Another example was the need for reviewers with statistical expertise in order to ensure scientific rigor. Other committee considerations focused upon the importance of the committee remaining critically self-reflective in order to recognize and address potential biases and overreach. For one interviewed researcher, the question emerged as to whether committees ought to involve themselves in the re-design of protocols, or if this extends beyond their purview. Another committee recommendation was to ensure all reviewers remain engaged. More specifically, even if there is a primary and secondary reviewer, everyone must read the protocols and be prepared to discuss them at the meeting.

Relationships: Build relationships with other community-based IRBs to create a learning

community. Developing relationships of open communication with the researchers' affiliated institutions is also important. Partnership or relationship building can help address potential sources of conflict, build shared resources (i.e., training opportunities) and perhaps result in shared agreements. A final key relationship is ensuring that one's community-based IRB continue to nurture and grow the relationship with the diverse communities it serves. As one reviewer pointed out, it is also important that "the parent agency of [the community-based] IRB is well respected not only locally, but also statewide, nationally, and internationally."

Researcher specific recommendations: Researchers who submitted the same proposal to both a community- and institutional IRB recommended that the involved IRBs consider using the same or similar forms to help streamline the process. Secondly, that the involved IRBs enhance their communication with each other, and share mutual learning opportunities. This ideally would result in a decrease in conflicting requirements. A strong call was also made for community-based IRBs to be rigorous, countering some of the concerns that community-based IRBs may lack scientific capacity. More specifically, one researcher shared, "there should be no lack of scientific rigor on a community IRB, [and] there should be an added rigor of having community viewpoints put on it." A final recommendation was to reject a proposal rather than require changes that might fall outside the perceived scope of IRB reach. Concerns were raised that it is "unethical to try and change proposals."

Summary Reflections

POL-IRB's emphasis on community and cultural respect was consistently observed throughout the interviews, focus group discussion and observation of an actual POL-IRB meeting. This commitment is further reflected in many of the key documents including the checklists that guide the reviewers

and policies related to membership and voting practices. POL-IRB's materials for researchers clearly indicate that their approach is guided by these commitments to protect and empower the Native Hawaiian community. While a question was raised as to whether POL-IRB operates from a political agenda, one could also re-frame this question to see POL-IRB's orientation as a response to past abuses and a commitment to ensuring research occurring within Native Hawaiian communities is respectful, beneficial, and just. It is not to contradict the guiding ethical principles in the Belmont Report, but rather to infuse these principles with a meaningful cultural context.[3]

In regards to adherence to federal human participants regulatory requirements, POL-IRB does so through a thoughtful and critical cultural lens. This approach translates into a review of added rigor where researchers must demonstrate the value and ethics of their proposed research based on more than the regulatory considerations. Assessment of scientific rigor or appropriateness is also examined, and at times requires POL-IRB to seek external consultants. Perhaps over time the need for consultants will decrease given Ime Hale's mission to support the development of young Native Hawaiian researchers. Ideally these emerging researchers will share their cultural wisdom and scientific training as future POL-IRB members.

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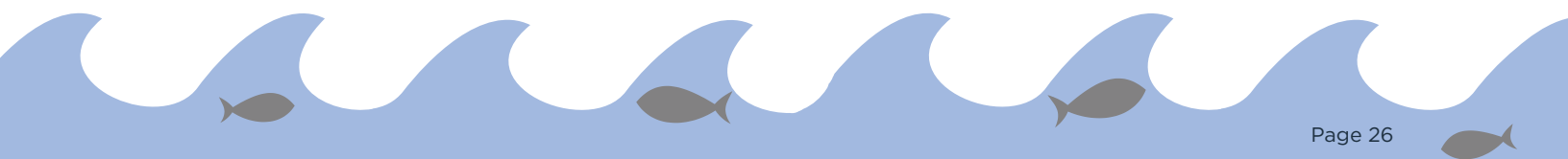
Special Service for Groups' Institutional Review Board: Research Equity *Is* Community Protection

Eric Wat, Alice Park, Nancy Shore and Sarena D. Seifer

…The processes that I've been involved in the past with institutional IRBs…the language and the jargon…make it a little too formal and they ask you to do things in a more complicated way. And I think that with the SSG IRB we are very grounded…we want to be able to use the language of the people so they can understand what it is that we are asking of them…even with community based organizations who may be very fluent and much more articulate in the language…For me that is really important because I was always so lost I had to go back to the dictionary and go, what did they mean by this? …Why don't you just tell me it is just a fork? Why do you tell me it is this utensil, make it more complicated?

-SSG IRB reviewer

The above quote illustrates how the community-based Special Service for Groups' (SSG) Institutional Review Board (IRB) differs from typical institutional IRBs. This case study report provides an overview of SSG including the history behind the development of its IRB. The report also describes how the SSG IRB operates, as well as its successes and challenges. The report furthermore looks at how the SSG IRB compares to institutional IRBs, as well as its relationship with these IRBs. It concludes with a set of recommendations for community-based review processes and future directions for the SSG IRB. The report is based upon findings from an analysis of key documents guiding the SSG IRB, an observation of a SSG IRB meeting, two focus groups conducted with the SSG IRB reviewers (one in person with five reviewers and one by phone with two reviewers), and individual interviews with the SSG IRB Administrator, the SSG IRB Chair, the SSG IRB former Chair and five researchers who submitted protocols to both the SSG IRB and an institutional IRB. This case study is one of five conducted as part of the National Collaborative Study of Community-Based Processes for Research Ethics Review. The study aims and methods are further described in the first chapter of this report.[1]

Overview of SSG

SSG is a 501(c)3 non-profit organization in Los Angeles, CA founded in 1952 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. In 2003, SSG established a Research and Evaluation Unit (R&E). The R&E seeks to build the capacity of SSG programs and their community partners in using data effectively for program planning, policy advocacy and organizational development through training and technical assistance. The program provides on-the-ground training for community members to design and conduct research in their own communities and has a track record of conducting community assessments for larger institutions, such as hospitals, clinics, and foundations.

Overview of SSG IRB

History of review process

With its many years of experience in community-based research dating back to the late-1990's, particularly in racial and ethnic health disparities,

SSG established its own community IRB housed within R&E in 2004.

The IRB was developed as part of a Centers for Disease Control and Prevention (CDC) funded research project, based on SSG's experience with institutional IRBs and encouragement by academic partners. Establishing the IRB was motivated in part by growth in SSG's involvement in community-based participatory research (CBPR) and the recognition that university IRBs had minimal community representation and were not positioned to evaluate community-level considerations of research.

While no specific incident prompted SSG's decision to create a community IRB, a combination of factors led to its formation. Through discussion with the Papa Ola Lokahi (POL) IRB in Honolulu, a community IRB was envisioned as a mechanism for SSG to ensure ethical research that practiced community-based participatory principles. SSG's desire was to create a community IRB where community researchers would serve on the board as a means to engage the community, ensure community voice and ethical research. Through a year's work in research and development and much guidance from the POL-IRB, the SSG IRB was formed.

Review process goals and functions

The goals of the SSG IRB are to:

- Respond to the growing number of community-led research projects involving SSG or its partners, regardless of whether there is an academic partner; and
- Advocate for and build research and research ethics skills among community partners, especially in community-campus collaboration, by making sure they are engaged or consulted throughout the research process.

The multi-pronged purpose of the SSG IRB is to:

- Engage and educate community programs and partners on the importance of research ethics;

- Provide guidance for individual participant and community protections in CBPR;
- Empower community programs and partners to be equal research partners through the IRB process;
- Give a voice to under-represented communities regarding research, especially research that involves human participants; and
- Build capacity of SSG programs, community partners and community members to do CBPR.

Type of research reviewed

The SSG IRB reviews research that SSG programs and community partners are directly involved in. Three to four meetings are typically held each year with one protocol reviewed per meeting. The research is mostly CBPR involving vulnerable populations and people of color. Specifically, studies have focused on older adults, Asian, Southeast Asians and Pacific Islanders, Latino, African-American, individuals who are HIV positive, ex-offenders, torture victims, immigrants, people who have experienced trauma, refugees and sex workers. The research is typically social/behavioral in nature, although the IRB also reviewed studies that are program evaluation, exploratory/needs assessment and clinical trials.

Almost all of the research is driven by the community partners' research agenda, sometimes involving an academic partner. Some research proposals reviewed by SSG's IRB have also been reviewed by the academic partner's IRB. These have included IRBs at the University of California Los Angeles, University of California Irvine, University of Southern California, Cal State, Fullerton and Rand Corporation. For studies involving SSG programs that have an academic partner, it is not a requirement to use the SSG IRB. As described by the IRB Administrator, "with our SSG programs, we tell our programs that if you feel comfortable with your academic partners' IRB you don't have to go through our SSG IRB. We are an option for you."

Type of education provided

As part of its goal to build research and research ethics skills among community partners, the SSG IRB provides free workshops and technical assistance on various aspects of community-based research including informed consent, conducting focus groups, community-based research methodology and program evaluation. The R&E Unit of SSG provides research training that complements the IRB's activities.

The SSG IRB also gives presentations, provides technical assistance and shares resources about its community-based IRB model and the nuts and bolts of starting an IRB. During its start-up phase, the SSG IRB benefited from other community IRBs sharing information with them, and as explained by a former reviewer, they have been "paying it forward and sharing it with others and working with other organizations to identify and assess if this is something they can and want to develop and, if they did, how they would go about doing that…advise and share resources like our policies and protocols." When a person based in Appalachia contacted the SSG IRB for assistance in reviewing their study, the IRB Administrator explains, "in those cases [when the inquiry is from outside of our geographic area], we've tried to provide resources…here's a group we've heard of locally. Maybe you want to contact them first because we don't know if we're the most appropriate." Former reviewers continue "to educate other community researchers and community members about the existence of the IRB and why that's also an important part of empowerment within our community's engagement, especially for conducting research."

Infrastructure

Policies and procedures

The SSG IRB has developed policies and procedures to ensure its reviews focus on community concerns and are compliant with federal research ethics regulations. Key documents include: initial and renewal applications, conflict of interest policy, checklist and sample informed consent forms. To obtain copies, please contact the SSG IRB (see contact information at the end of this report).

Membership

As outlined in its Policies and Procedures, the SSG IRB must have a minimum of five members with diverse backgrounds, and include laypersons as well as scientific researchers to reflect the cultural and ethnic representation of study populations. The IRB may invite consultants to aid in the review of issues that require expertise beyond that available on the IRB, however these individuals do not have a vote.

Currently nine individuals serve on the SSG IRB with alternates. Five have community affiliations, two represent institutions, and two have other affiliations (i.e., private consultants). All have community expertise regardless of where they are housed. The reviewers have all previously worked for SSG or their community partners, and nearly all members have served on the SSG IRB since its inception. New reviewers were recruited upon the IRB Administrator's recommendation, who identified individuals based on membership needs expressed by the reviewers. There are no reviewer term limits.

The selection process for reviewers is critical for the functioning of the SSG IRB so they may, as explained by a reviewer, "integrate the rigorous academic review process together with [SSG's] community mission and spirit." SSG is fortunate to have a ready pool in Los Angeles of diverse individuals with both community and scientific knowledge from which to recruit.

Reviewers are required to receive research ethics training to become certified as an IRB member. All reviewers completed their IRB training through

existing institutions, however the SSG IRB has developed a training tailored for community IRB members that provides an overview on research ethics, the review process, community-based action research and community IRBs. All of the reviewers are familiar with community-based research and additional training occurs through "on the job" learning at IRB meetings. Reviewers commented on how educational the meetings are in and of themselves.

The SSG IRB membership has been sufficient for the volume and focus of the proposals the IRB currently reviews. In thinking about how to further diversify the membership, suggestions from reviewers included recruiting someone coming from a church or a temple, a young and older adult, and perhaps having more turnover of reviewers to ensure "a new influx of folks…so that everyone has a chance."

Budget

The budget for the SSG IRB is paid for entirely from SSG internal discretionary funds, as they do not charge for reviewing proposals or build IRB costs into grants. The funds pay for a portion of an R&E staff person's time to serve as part-time IRB Administrator. Due to the limit imposed on the number of proposals reviewed by the SSG IRB, the R&E staff person estimates 5% of his time is devoted to IRB activities. Additional budget items for operating the SSG IRB consist of meeting room space, food, phone, conference call line (reviewers are permitted to participate in meetings by phone when necessary), training, copying, supplies, and postage.

Organizational support

The key support that exists for the reviewers is having a staff person, the IRB Administrator. As described by reviewers:

The IRB administrator provides support and training to the IRB members to help ensure that they feel they can fulfill their roles and responsibilities as a board … if there is a question on how things should be done the IRB administrator will remind folks about the process and the protocols or review and then help to implement them…

I don't think this IRB can really do it without that [IRB administrator] and this was advice that [person from an established community IRB] gave us early on. She said you must have a staff member staff this and they have to be not only extremely organized, but they have to really truly believe in this process because they're going to implement it and be accountable back. You have to take this extremely serious and what this means. It's not just passing people, it's taking it seriously.

Submission Process & Review Considerations

Prior to submission of a study protocol to the SSG IRB, the applicant typically receives an orientation with the IRB Administrator by phone or email that covers questions about the process and determines whether the protocol needs to be reviewed. To submit a protocol, the applicant completes an electronic application that has nine questions covering four areas: research project background summary, research goals, organizational capacity and research protocol. Applicants must complete all questions and submit required attachments including curriculum vitae for key research staff, all research materials (study instruments, consent forms, etc.) and any memoranda of understanding with partnering organizations. Unique to the SSG

IRB application and aligned with SSG's mission of fostering self-sufficiency are questions regarding community engagement/benefit and technical assistance needs. The application contains a question regarding what type of technical assistance the applicant anticipates needing during the course of the research project and that the SSG IRB offers free workshops on various aspects of community-based research, such as methodology and program evaluation. Application questions pertaining to community engagement and benefit include:

- Describe the characteristics of the community that highlight the importance of the research questions.
- Describe how the process and anticipated outcomes of the research project can benefit the community and its various stakeholders (e.g. community leaders, parents, youth, child care providers, etc.).
- Describe how you've solicited community input to determine research project goals, research questions and potential benefits to the community.
- Describe any experience the organization has in engaging community and its various stakeholders. Identify any organizational strengths derived from this experience.
- Is the organization partnering with other community-based organizations for this research project? If so, what would be the role and responsibilities of each partnering organization? (Please include their memoranda of understanding).
- How is the organization involving community members in the planning, implementation, and/or participation in the research project (e.g. community advisory group, etc.)?

Once the IRB Administrator receives the application, it is emailed to the whole board, and the IRB Administrator sets up a date for the IRB meeting, usually between four to six weeks from when the application is received. The reviewers review the application prior to the meeting and if there are

questions, the IRB Administrator goes through them with the applicant so initial questions are addressed by the time of the IRB meeting. If the IRB Administrator feels the protocol might be eligible for exemption or expedited review, they prepare a summary for review by the IRB and the decision is made by consensus through email. If there is any disagreement, the IRB Administrator will attempt to reconcile through mediating a discussion. However, if a reviewer feels strongly that a proposal should be evaluated more thoroughly, an expedited review will not be granted. If a proposal moves forward by expedited review, the IRB Chair designates an additional IRB member to carry out the review, and the IRB Chair and designated member may approve the application. The application does not need to go to the full board unless they do not approve it.

The majority of study protocols require full review. IRB meetings occur on an as needed basis. At the meeting, reviewers attend in-person with a dial-in option provided for reviewers unable to attend. The applicant is required to attend, and if there is a partner involved, such as in a community-academic partnership, the partner is typically required to attend with the applicant. As described by a reviewer:

…We ask them to be part of the IRB meeting, to be present during the discussion and to have a dialogue with the IRB members, who come to the meeting after reviewing the proposal and have their own questions and want to find out a little bit more. We also ask that they bring a partner with them. If it's an academic partner, we especially require them to bring a community partner. If it's a community partner, we also want them to bring an academic partner. I think that's one way for us to elevate the voice for the community partner. Hopefully, that will be at least one way they can have these conversations that they might not get to have in terms of research equity and community benefits.

The community focus of the SSG IRB is exemplified in the conduct of the IRB meetings. From the SSG IRB Policies and Procedures, because people external to the IRB attend the meetings (e.g., the applicant), the meeting begins by providing an overview of the purpose and explaining the nature of confidentiality of the IRB meetings. Showing the value placed on community input and the inclusive nature of the meetings, the protocol indicates: "Toward the end, ask less-talkative people on the call if they have anything to add...Ask each Community Member in turn if she or he has anything to add."

As observed during a SSG IRB meeting, the meeting begins with introductions. The applicant may give a brief overview of their proposed study, and then the majority of the meeting is spent engaged in a discussion with the applicant about the proposal. Towards the end of the meeting, the applicant is typically asked to step out while reviewers make a final determination through consensus decision-making. In part because the SSG IRB only reviews research projects SSG or their community partners are involved in and because research projects are collaborative in nature, a reviewer may need to recuse themselves either because they serve as the PI on the study being reviewed or as a partner on it. If there is a potential conflict of interest, the reviewer can participate in the discussion, but must recuse himself from the vote. After the vote, the applicant returns to the room and the SSG IRB shares its final decision. The applicant leaves the meeting with an understanding of what needs to be modified in order to move forward. In addition, the applicant receives written notification of the determination and any required contingencies. An appeal process exists should the applicant disagree with the SSG IRB's decision, in which case the proposal would go back to the full board for review.

Due to the extensive vetting process completed by the IRB Administrator, by the time a proposed study comes to the IRB meeting for review, any non-negotiable items that may have resulted in it being denied have been addressed. As one reviewer described, "by the time... it comes to us for review it's pretty prepared where we would most likely pass it or approve it with contingency."

As a result, most protocols receive contingent approval and all approved protocols have required some changes. Contingencies include both mandatory changes in order to receive approval as well as additional suggestions for consideration. With contingent approval, the applicant submits revised materials to the IRB Administrator who ensures the contingencies are met, and the IRB Chair designates two members to conduct the final review.

An example of one of the few proposals that was denied involved a study where the applicant asked for an exemption to retroactively examine data gathered from a previous study. The SSG IRB denied the proposal because the consent process for the previous study did not provide sufficient disclosure that the data might be used for future studies or publications.

Researchers must seek continuing or renewal approval from the SSG IRB on an annual basis for research projects spanning multiple years. The renewal is completed through expedited review by the IRB Chair and one other IRB member, unless there have been significant changes to the originally approved study. In addition to providing an update on enrollment, describing challenges, explaining deviations from the protocol and indicating plans for the next year, the renewal application asks about any lessons learned or effective practices that the researcher would like to share with the SSG IRB and other community researchers.

The SSG IRB has a Year-End Evaluation Report template to be submitted once the study is complete. The report includes questions regarding

how research data is shared with the community, feedback on the SSG IRB process, and what type of technical assistance would be helpful. However, it is not a requirement to complete the year-end report, and therefore most researchers do not submit this. Some researchers share the final report for the research project with the SSG IRB, which is then distributed to all members.

Review criteria

The SSG IRB considers issues dictated by the federal human participants regulations and typical IRB practices, as well as community-level considerations. Examples of typical IRB considerations include examining the risk/benefit ratio for individual participants as well as issues of safety, voluntary participation, data confidentiality, participant privacy, informed consent, and equitable selection.

The SSG IRB checklist prompts reviewers to consider how justice is ensured for individuals, communities and families. The SSG IRB examines indirect harms and as described by a reviewer, ensuring research is "not creating more potential negative influences for those who participate." Reviewers examine ways in which the research design may affect vulnerable populations, such as people who are affiliated with the incarceration system, survivors of torture, LGBT or people with multiple identities. They consider how the community has been involved, how data will be disseminated back to the community, the research team's involvement in the community, who the community partners are, if the research idea originated from the community, and if there are concrete and discrete plans around how the community will have access to the results and be able to shape the distribution of results. Other questions the SSG IRB reviewers weigh include:

- What's the intent of this research? How is it going to help the community? What are they going to end up doing with it?

- How involved has the community been? Are they in the leadership of it or are they just translating?
- What's the value of data or research produced in the process, who owns it and what does its relationship to that ownership represent?

These IRB member quotes reflect the range of ethical issues considered when reviewing a proposed study:

I try to pay attention to the power relations that are embedded into the way that the research project has been designed as part of the broader question around participant protection…Where does this end up, what can they do with it, where does the person either retain or lose control, the way that their piece becomes part of a larger data set.

An ethical study recognizes that there's not just individual actors who are itemized and acting independently of each other on these kinds of studies but that when a research institution or even a community group decides to do a study around a community of people then it raises a second layer…of ethical questions regarding that community's relationship to the data being produced and its implications, how it's used or where it's going to go.

Of note, taking into account the history of research in communities, the SSG IRB examines proposals carefully to protect against the research unintentionally causing negative or indirect harm, and offers advice to help studies create tangible benefits for the community. For instance, not only should there be a referral list for participants in case of distress, but it must include detailed information, places where people can receive culturally appropriate services if they are uninsured or do not have a provider, and locations in close proximity to alleviate transportation issues.

Relationships Between SSG IRB & Institutional IRBs

Many proposals do not have an academic partner and are reviewed only by the SSG IRB. When an academic partner is involved, the SSG IRB does not typically maintain a relationship or have an agreement with the academic partner's IRB. The SSG IRB does have one agreement in place with the University of Connecticut for a specific study. In general, the researcher is responsible for corresponding with other IRBs in the case of multiple reviews, and ensuring adherence to all of their requirements.

Suggestions for improving the relationship between SSG and involved institutional IRBs included developing a mechanism for communicating whether a proposal is approved and any changes that were mandated. Ensuring that institutions know about the community IRB and their community focus would also be beneficial, as one reviewer observed:

> *I think what would be nice to strengthen the relationship would be for them to know more about the community IRB, what we're doing and why, the kinds of questions that we ask and how we're really thinking about culture and CBPR. I think that would be great if they would really actively seek out why we need a community IRB, why it's important to have a community IRB and the CBPR kind of lens that we do in our reviews.*

Reviewers also felt it would be helpful to have a policy in place for mediating situations in which there is conflicting feedback from multiple IRB reviews. It was also suggested that community and academic research partners be asked during the application process what would assist them in undergoing multiple IRB reviews and "what type of help do they need to negotiate" among them.

Comparison of SSG IRB & Institutional IRBs

Reviewers and researchers identified similarities and differences between the SSG IRB and institutional IRBs.

Similarities

One similarity identified was their overall purpose and adherence to the same federal regulatory requirements. Reviewers and researchers pointed out "a shared value around research" and "making sure there's good research and that people are protected." As described by a researcher, "they were similar in the sense of the general purpose of an IRB. They're similar in the sense that they both follow the same guidelines." Secondly, researchers noted that both IRBs raised some similar issues, such as voluntary participation for staff and clients of study partner organizations and concerns related to language, such as determining English-speaking ability of participants.

Differences

Reviewers and researchers highlighted differences between the SSG IRB and institutional IRBs in five areas: emphasis, inclusiveness, process of the review, community engagement and benefit, and dissemination of study results.

Emphasis: While the SSG IRB and institutional IRB may look at the same issues, both reviewers and researchers felt that each IRB has a different emphasis, resulting in a "more comprehensive review" when both review a given study. As described by a researcher:

> *Actually having these two IRBs look at the study and think about how you're going to do this was kind of a good, really useful thing… There was another set of eyes looking at this from a different*

lens. Both in terms of the [name of university] IRB were looking at the methodology and the procedure and protecting the sujects and then the community-based IRB making sure how are you going to do this thing, how is it feasible and then how are you going to protect these people, how are you going to help them get these services. It helped us think about the project from recruitment all the way through to the other side. What happens to this person once they leave our study?

As another example exemplifying the different emphasis, a researcher explained that only the SSG IRB expressed concern about stigma as it related to participating in an HIV and hepatitis study:

They were concerned about stigma, stigmatizing individuals because the study was about HIV and hepatitis. The [name of university] IRB is very concerned about risk, risk of exposure and disclosure. The community-based IRB was also concerned about that but in a different kind of way. More about the stigma of participating, less about their disclosure, so it was the same issue but phrased in a different way….

As a third example, another SSG reviewer who has experience with an academic IRB, commented that community and university IRBs have an entirely different orientation to the process. Whereas the university is primarily concerned with adhering to policies, the reviewer observed, the community IRB has a better understanding of community and views the process as the production of knowledge and advancing social goals important to the community:

The IRB process at the university level …it's become a bureaucratized layer of approval for getting a research project out the door… very rarely do you have a conversation around social

justice, around community empowerment, around data, community-based control over data and the larger good … It is a completely different orientation to the process of producing data that comes out of the community-based process, in which we the reviewers and certainly the people who are participating from the community-based organizations really see the opportunity to fill a void about the community being studied and a potential partnership between the subjects/community members and the researchers who help address social problems that are unique to that community. It's not considered something you have to go through but rather something that can really strengthen the overall objectives, not just of the study, and the production of knowledge and data, but really have potential to advance a social goal, empower the community, create a core set of knowledge or a body of work … that the community itself has identified as a problem…that sensibility is the biggest difference.

Inclusiveness: In comparison to institutional IRBs, researchers felt the SSG IRB paid more attention to the inclusiveness of the research. Researchers commented on "the special attention to highly vulnerable populations" by the SSG IRB and concerns about excluding certain groups due to the study design, including individuals experiencing homelessness, prisoners or limited English speaking persons. Regardless of whether they are the focus of the study, the SSG IRB offered suggestions to allow their inclusion whenever possible. As an example, from the SSG IRB meeting minutes, a concern was shared with a researcher regarding the proposed study's plan for "choosing stable programs and possibly excluding certain subpopulations (e.g., re-entry population)."

Related to inclusiveness, while the SSG IRB and institutional IRBs expressed concerns related to

language, the SSG IRB considered this issue in greater depth.   One researcher shared a concern raised by the SSG IRB regarding having study staff who can "speak in language" to participants on hand at any time should a participant call with a question.

Process of the review: Both researchers and reviewers identified key differences between how the SSG IRB and institutional IRBs approached the review process.   Unlike institutional IRBs, for example, the SSG IRB requires the researcher to attend the review meeting. The meeting is a conversation with the research team. As described by a researcher:

> *The [name of university] IRB doesn't interact directly with me in terms of face-to-face meeting. You submit stuff to get reviewed, it goes through committees, they give it back to you with all of their concerns, the kind of typical interaction via correspondence, sometimes telephone calls with the IRB staff if there's any questions. With the community-based IRB, it was a little different. We submitted our application and then we had to meet with the community-based IRB for them to talk to us about the project, they wanted to meet all of us, they want to meet the team, they wanted to talk through the study, they had questions they wanted us to answer. …But that was a very different part of it, that we went and actually talked face-to-face.*

Reviewers and researchers also noted a difference in terms of the timeliness of response, with the SSG IRB described as more responsive, attributed in part to the presence of the researcher at the review. This allows the reviewers and researchers to dialogue with each other and reach conclusions at the review meeting, precluding the need for back and forth phone or email correspondence. As described by a researcher:

> *They are different, I think, in the timeline. The community IRB responds faster, so it's more responsive. It's more user-friendly. The individuals, if you have a question, are accessible. That's not always the case in the academic IRB.*

Community engagement and benefit: As another point of departure, a reviewer described the SSG IRB as having a "strong emphasis on community-based research and protocols that take into account the vulnerabilities of communities," while institutional IRBs lack familiarity with community-based research.   Researchers noted the SSG IRB's concern about the community and cultural competence of the team conducting the community-based study. Researchers described the SSG IRB's desire for research to maintain a legacy, and sustaining the benefits and impact of the research, such as through training and capacity building of community members:

> *…Ensuring community benefits, sustainability was another concern of Special Service for Groups and making sure that there was a legacy that could live on. They were aware of how difficult that issue can be, but we did develop strategies to help with that, like doing co-training. All the co-training, we taught community leaders, trained along with academic experts and some of the clinical areas.*

Another way in which the SSG IRB emphasizes community is through its membership. Reviewers noted that in sharp contrast to institutional IRBs, community members make up the majority of the SSG IRB.   The SSG IRB membership also has greater racial and ethnic diversity, the result of an intentional effort. As shared by a reviewer:

I was astounded at how overwhelmingly white [the institutional IRB membership] was and how overwhelmingly the community members were folks who had very high levels of formal education. I think that's one really big difference. We have a lot of people of color on our IRB who also happen to have advanced degrees or who have formal training around data collection…We have way more racial diversity than on the institutional review boards… I also think that the other big difference … is the community member is not just one person. These are all people who I think we would, in an institutional-based setting, would be the minority…. And here what's nice …on this particular board…is that the critical mass is on the other side. The community members are the dominant group and the interface with folks who are working out of institutions and not particularly doing work or connected to the community. It's a complete reversal.

Dissemination of study results: Finally, both reviewers and researchers noted that institutional IRBs tend to deal only with the front end of studies. The SSG IRB application specifically asks about how study findings will be shared with the community and other stakeholders. A researcher pointed out the SSG IRB also asks about publication and dissemination of results from the research project in their review:

I think IRBs are mostly concerned with the front end of studies from my view or experience. It's more on the backend of things, for me, the ethical questions that come into play have to do with who gets credit for this, who publishes, who can get grants as principal investigators, who matters on the research endeavor?

Comparison of feedback provided by SSG and institutional IRB

Written feedback was compared for proposals that underwent review by both the SSG IRB and an institutional IRB. Feedback from both IRBs centered around four areas: informed consent, vulnerable populations, participant resources and study methodology.

Informed consent: Both the SSG IRB and institutional IRBs identified issues related to the informed consent process and forms, although the specific concerns were different. As an example, for one study, the SSG IRB asked for more information to be included in the consent form, such as disclosure regarding risk of potential loss of health insurance eligibility, alternative methods for receiving incentives beyond mail, clarification regarding receipt of incentive if a participant drops out of the study and information on where data will be stored and who will have access to it. The SSG IRB feedback stated "transparency would go a long way toward engendering trust between the research staff and participants" and felt these issues were "a basic tenet" and key "ethical principles (in this case, equitable participation, adequate informed consent, etc.) in community-based research" that should not be relegated to a clarification buried in supplemental information. In contrast, the institutional IRB asked the researcher to shorten the consent form and "provide any further useful information in a supplemental document - e.g. brochure, factsheet…" As described by the researcher:

[Name of institution] was concerned that we had overdone telling people about the design of the study. … since this was a group-level randomized trial with randomization at the program level, clients that were screened in a particular location, they themselves did not have a choice of the intervention…the [name of institution] IRB felt pretty strongly that we

that we should just tell them about the condition that they were enrolling in and basically, we pointed out to them that that would really not work in a study like this because it would be failing to disclose the randomization conditions even if you didn't have a choice. And given the history of the research abuses in communities of color, this would be unacceptable, not only to us but to the community.

Vulnerable populations: In other studies, the SSG IRB raised issues concerning vulnerable populations (homeless and non-English speaking), such as the format for incentives and the informed consent process. The institutional IRB was also concerned about special populations as relates to minimizing risk, and asked about protection for prisoners (e.g., changes to the consent form to make it more understandable, to indicate that participation will not affect probation or parole, and ensuring participation will not be disclosed to anyone in the judicial system).

Participant resources: Both types of IRBs raised concerns about having resources available for participants, such as a referral list in the event participation in the study resulted in distress. For one proposal, the SSG IRB was insistent about providing a detailed referral list for participants. In an interview with the researcher, it was shared that due to the persistence of the SSG IRB, a referral guide was created for the study that resulted in a valuable resource for the community. This illustrates how the SSG IRB guides researchers to provide a tangible community benefit through their studies. For this same study, the institutional IRB was additionally concerned about having resources for potential distress among those screened and not eligible for the study.

Study methodology: Both the SSG IRB and institutional IRBs raised questions about study methodology. For example, for one proposal, both types of IRBs raised issues related to voluntary participation by staff or clients. The SSG IRB had concerns regarding direct observation of workers and their work logs, and asked for clarification regarding the purpose, methods, data elements to be collected, and how data would be safeguarded against use in employment performance evaluations. The institutional IRB had similar concerns and asked for a recruitment/eligibility screening script specific for the direct observation, a description of the procedures for recruiting and consenting workers, and an explanation on the recruitment flyer that participation would involve observing their work and logs. The institutional IRB also requested clarification regarding inclusion criteria, number of recruitment attempts, procedures for safeguarding data, data destruction date, and requiring separate recruitment flyers for different groups where participation involved different methodology. Other questions raised by the SSG IRB related to this study's methodology included focus group size, and for another study, language considerations such as collecting data in the participant's language and having transcription and verification completed by a native speaker.

In summary, the SSG IRB and institutional IRBs raised similar concerns in their research reviews. The SSG IRB seemed more concerned about study accessibility and transparency, as well as more concerned with providing resources to participants to protect against potential harm.

Overall experience going through the SSG and institutional IRB process

Researchers described the experience of having their proposal reviewed by the SSG IRB as "quite positive" and a researcher credited having the IRB staff person available to answer any questions for making the process "smooth." One researcher reflected, "it was a strengthening and a sort of a cohesive factor because we genuinely felt that

we weren't doing anything in isolation, that this research project was genuinely community-participatory." Other researchers described the process as "a little stressful and it was also useful from sense that we learned some things. We've incorporated that learning into our overall operations, so we've established some capacity in this area."

Another researcher commented on the value of meeting face to face with the reviewers and the merits of hearing different perspectives outweighing the additional time involvement:

I think it's always helpful to get additional perspectives and critiques and especially having the different perspectives on things that you might not have thought of. And I especially, again, found it helpful to have the process where you're sitting down with those reviewers and discussing the comments, and sort of collaboratively discussing the trade-offs between doing things one way or another. .. there is an added time factor for sure… and there can be just added challenges when you're weighing feedback from more individuals and from more perspectives but I found it to be overall a good and valuable and really a thought-provoking, in a good way, experience.

The SSG IRB was described as more efficient and accessible than institutional IRBs. By having the researcher present during the review, s/he leaves the meeting knowing exactly what changes need to be made for the study to be approved. The process is friendlier where the researcher may engage in a dialogue with IRB members until an agreement is reached regarding modifications. As reviewers described, the work may be similar to that of institutional IRBs, but the SSG IRB is more responsive to community-based researchers.

Very quick turnaround time but with opportunities also when the group is submitting the proposal to sit around the table and in live time often work through and agree upon particular modifications or additions right then while the IRB is reviewing the application. It saves a lot of time. So it enables community based researchers to get in the field conducting the research much more quickly.

I think in the most important ways it is absolutely the same because in terms of ethics, in terms of protection. Those are always a priority. I think it's just the messaging of how it is done and maybe … it is just kind of looking at the life cycle of the project and ensuring that there's kind of a true kind of community meaning for it. In the most important ways it is absolutely similar and I think in ways that …this is kind of a funny analogy, but like casual Fridays. Okay maybe you are in a really formal legal firm you will never have casual Fridays but the work is the same but yet here we are a little bit more used to having casual Fridays but we are working around the clock doing our expertise, but we are willing to kind of just be a bit more comfortable.

Researchers tended to have positive experiences with their institutional IRB. One researcher described being "pleasantly surprised that [the institutional IRB] seemed familiar with and supportive of a CBPR approach." Another researcher shared "[name of institution] has had an IRB that is understanding of this kind of community work and has the flexibility of mindset that is very helpful in these kinds of situations." One researcher commented about learning each other's language and how to communicate since the community and the institution use different terminology. In reference to the institutional IRB, they shared it was:

…Stressful, but we learned some things and it helped us develop capacity. We learned how to communicate with scientists and how to develop our relationship with them and we learned their language. Sometimes they call people principal investigators and we call them project directors… They call it methodology and we call it how the program works. So we learned some things, I would say, on both sides.

Benefits & Impact

Reviewers and researchers noted the benefits and impact of the SSG IRB. Benefits of the SSG IRB roughly corresponded to five broad categories: alternative to the institution IRB, added value of the community lens, capacity building, enhancing study methodology and legitimizing CBPR as an approach to research.

Alternative to institutional IRB

As described by reviewers, the SSG IRB offers a "viable and very positive alternative" to institutional IRBs, for instance for "studies that don't involve institutional partners that might not otherwise have happened or known how to put together the protection review process." The SSG IRB "provides an opportunity for community-based researchers to engage in that work independently from these other kinds of institutions", particularly in situations where "there have been bad experiences where the community-based groups have felt …used and not always included as equal partners." As shared by a reviewer:

I would just affirm the value of creating community-based capacity to conduct research and having a venue for non-university-based studies and researchers who are interested in subject protection to get an approval process going… there are often studies that don't involve

institutional partners that might not otherwise have happened or known how to put together the protection review process…for those of us who are interested in that question, how do communities that are already working with a lot of people on the ground and have access to data and putting together data, how might they come together, put together a proposal for a research project and not have to navigate which is an institution that has an IRB process that's not going to subject them to the negative attributes of an institutional-based IRB.

Another benefit is creating an alternative for community reviewers, where serving on an institution IRB may be intimidating and where they may not have a genuine voice. As shared by a reviewer:

…For those of us who want to sit on an IRB because we represent some of the target populations but don't want to be in a room full of ten researchers with the MDs and PhDs, that are all part of a university hospital or university and who have been accustomed to normalize that the IRB community rep shows up, gets talked around, maybe gets a stipend sometimes, maybe doesn't, and then we get them to really rubber-stamp something that they're really, in many ways, because of either educational cost or race differences, not actually being put in the situation where they have a fighting chance to stop these people from what they want to do.

Added value by reviewing research through a community lens

Reviewers shared there is value added by the SSG IRB as it integrates "the rigorous academic review process together with that community mission and spirit." For example, beyond examining individual benefit and risks, the IRB asks about community benefit, such as community empowerment.

Researchers also credited the SSG IRB for making their research projects genuinely community-participatory. In some cases, the SSG IRB acted as a liaison for the community partner and researchers to reach an agreement about the study protocol.

Capacity building
The SSG IRB is viewed as a capacity building resource. Both researchers and reviewers cited community capacity building as an important benefit of the SSG IRB. As an example, a reviewer explained how its work has resulted in more funding for community-based activities and building community-based capacity to conduct research:

…Having a community-based IRB will now decrease the anxiety for community-based organizations who may not have gone after a big federal grant for research they are now maybe more willing to step forward and say I am willing to be a lead. Yes, we will partner together with the academic institution or the principal investigator. But we are no longer afraid because now there's been a history that a CBO can take the lead, can make sure to understand the academic process. So it is a bridging, but it also opens up funding. It's more funding for community-based activities.

In addition, more communities are involved in CBPR, and as reviewers described, "people starting to question research and how it's done," becoming "more savvy on their rights," and having "increased confidence in their ability to both meet the requirements of an IRB and see themselves as equal partners in terms of the research design with their institutional partners."

Having the IRB is also increasing SSG's capacity and recognition as a community-based organization.

One reviewer shared how there is "a deeper respect of our agency" and others commented on how the IRB has built organizational capacity and has allowed them to develop better methodology. This in turn has resulted in more research funding for SSG.

The SSG IRB is also building the capacity of researchers to engage with communities and conduct CBPR. One reviewer observed,

I think it's just made them better. I think things they didn't think about and now I think they're more sensitive to the community. But they are really, for them, everyone who has come to our IRB has really appreciated the discussions we've had with them and the suggestions we've made. It's strengthened their research and I think it's strengthened the trust that they have in the community …I think they've improved their communication with the community, but they've also gotten more resources out of it and best practices out of it by working with others.

Finally, as illustrated by the reviewer quotes below, the SSG IRB is also building the capacity of its reviewers.

Numerous benefits that I have received not only to work closely with wonderful colleagues but also to learn so much more from experts in a variety of communities about their communities and their work and I also have learned a lot more about the intricacies and challenges and solutions for safe-guarding and protecting the rights and well-being of community members who participate in research.

I thought it would be an empowering process to be able to really feel like you are at the table really trying to work with someone to try and make

some kind of social change research. It is not just research that is not applied to the real world, it is something that will actually affect people's lives for the better… I feel like I have learned so much.

Enhancing study methodology

As mentioned by researchers in their overall experience with the SSG IRB, another perceived benefit of the SSG IRB is its ability to enhance the methodology or strengthen the proposal overall, such as in the informed consent process (e.g., more explicit and acceptable language); ensuring voluntary participation; ensuring culturally appropriate recruitment, methods and incentives; and reviewing tools to reduce bias. As one reviewer explained, the SSG IRB is "dissecting things to really understand and think through the process to make sure that whatever is being presented is strengthened to better serve the community."

Legitimizing CBPR as an approach to research

By educating researchers and disseminating best practices on CBPR, the SSG IRB is "advocating for the importance of community research and ethical practices around true community engagement in research." This also benefits researchers who conduct CBPR. As one reviewer described "I think it validates the work they do which is often not validated, community-based research in an academic setting."

Challenges

Three broad categories of challenges faced by the SSG IRB emerged: those related to institutions, resources, and reviewers and staff membership expertise.

The SSG IRB may be seen as a barrier for community-academic research partnerships because it

adds another review, and institutions tend not to regard community IRBs at the same level as they do academic IRBs. Due to the lack of familiarity with a community IRB, community researchers may feel they need to only go through an institutional IRB to satisfy requirements for research ethics review. Additionally, since there are no funder or government requirements for studies to go through a community IRB, researchers may bypass the community IRB and only use their institutional IRB. As shared by a reviewer:

I think people often hold on to that feeling that… if funding is dependent upon the IRB process I have to do it the same way…I have to do it the standard way that is accepted and they may not realize that going through a community-based IRB is not different than a University based IRB because [reviewers] still have to go through the same rigorous training, the same process.

Another category of challenges relates to resources. The SSG IRB is limited in the number of proposals that can be reviewed without burdening reviewers' time and impeding the ability to do follow-up for studies approved. The IRB administrator only has 5% of his time dedicated to the IRB and there are no direct resources for the IRB. The SSG IRB would not be able to expand without additional resources.

…There would also be a hesitancy about expanding it too much because then the IRB would not be able to handle all the requests if it all came in too much. Then it is fast and furious. …so push and pull. You want to be there for everybody, but if everybody came to you all at once you would not be able to do the same service.

                                                -SSG Reviewer

Limited resources also translates into less training opportunities for reviewers.

We haven't really been able to send people to training in terms of IRB. I wish I could send people to the PRIM&R Conference… We changed some of the ways we do things as a result of the things that we've learned at the conference…
                                        -SSG IRB Administratorr

Maintaining reviewer and staff expertise is also a challenge. Some reviewers commented on having a steep learning curve, having had very little exposure to IRBs prior to joining the SSG IRB. Ensuring members are fully trained on the federal regulations and reviewing research is challenging, particularly since the low volume of proposals reviewed by the SSG IRB makes it more difficult to develop competency. The number of reviewers must be kept at a manageable level to ensure everyone is fully trained. Reviewers want to make a good faith assumption about community researchers, while remembering to ask the hard questions even of research they support. As shared by a reviewer, "you have to make sure you asked these questions for your own self, even though you trust this particular provider and you think this is going to lead to good research. At some point, it just has to be asked."

If the need arose to find a replacement for the IRB Administrator, finding someone with the right set of skills might pose a challenge. Such skills include the ability to troubleshoot with the applicant to ensure the application materials are satisfactory to allow reviewers to make a determination and to synthesize the review meeting discussion into a succinct bulleted list of the issues.

Recommendations

Recommendations to strengthen the SSG IRB
Both researchers and reviewers generated recommendations for strengthening the SSG IRB.

The ability for the SSG IRB to continue to grow and develop requires a bigger budget and direct funding. This could be accomplished through increasing SSG's indirect rate and obtaining direct resources for the IRB. A number of priority activities could be undertaken with expanded resources.

An increase in budget would allow for reviewer professional development, including more frequent trainings. More specifically, one reviewer suggested a training "about using technology for research methods…staying up to date on some of the trends and some of the implications with those trends." A larger operating budget would also allow reviewers to attend relevant conferences, such as PRIM&R. Another suggestion was to create opportunities for reviewers to consult with members of other community IRBs. This would allow community IRBs to learn from each other and identify strategies to address more difficult ethical dilemmas.

Additional resources would also allow the SSG IRB to go beyond the "front-end of a review process" and develop and implement follow-up activities with researchers. Suggestions included requiring researchers to complete the Year End Evaluation Report and developing and implementing a protocol for site visits, both to ensure compliance and to learn about the outcomes of the study. One reviewer suggested that researchers attend an SSG IRB meeting to present their study findings:

All these projects we've approved, what happened to them? Even if we can't bring everyone back, just have them report back for [the IRB Administrator] or maybe a support staff saying this is what happened, this is the stuff they learned…

It was also recommended to hire additional administrative support, and build this capacity internally within SSG. As shared by a reviewer:

It would be great if we could have additional administrative resources…to share that knowledge and build that resource even internally to strengthen the work so that if the current IRB administrator were no longer there that we have the people in place to continue to carry on the great work that's being done already.

Recommendations for other community groups interested in developing their own IRB

Researchers and reviewers identified several recommendations for community IRBs in general, including both existing and developing ones. Roughly these recommendations can be grouped into three categories: infrastructure, relationships and membership.

Infrastructure: Community IRBs require ongoing financial support. As discussed earlier, money is needed for staff and for training of reviewers. A paid staff member is needed to develop and review policies and procedures, recruit members, and ensure training for members. One reviewer commented that for the IRB to be sustainable, it is absolutely critical "there are program champions in the organization that's housing it." Given the costs of developing and sustaining a community IRB, one reviewer suggested that communities consider establishing a community review process instead of an IRB. While an IRB has regulatory authority, a community review process might have great moral authority. To determine which might be the most appropriate model, a community organization might ask: Is there an existing community review process in place? Is there anything the existing community review process is it not doing well that you think a community IRB can do better? What is its relationship with institutional IRBs?

Relationships: Reviewers felt it was important for community-based organizations considering developing a community review process to build relationships and consult other community IRBs. As one observed,

…Learning from their experiences what has worked, what hasn't worked, being able to share information and resources. Some people have been very gracious about sharing policies and protocols, even tips and tidbits on how to work with other IRBs or OHRP, knowing resources through PRIM&R, CCPH and things of that nature. So…it's sharing best practices and lessons learned and being willing to share that knowledge with others.

Another reviewer commented that attending another community IRB's training was extremely helpful in understanding "what do we need to have in place, how do we maintain this and what's it going to take" to build the IRB. Examining different community IRB models and conducting an assessment to understand the resources required to develop and maintain the IRB, associated costs, and the type of staffing and knowledge required to implement and develop an IRB.

Relationships could also be strengthened with institutions, and this will ultimately strengthen the community IRB. As shared by a reviewer:

…Why does a university-based researcher go through your IRB if they're getting IRB approval from their university already? What do you add to it? …A lot of this is really building those relationships, having academic partners that understand the process and can see the value in it.

Membership: It is important to ensure you have "the right members who have that community experience." One reviewer suggested "…in the beginning it might be wise to just fill the IRB membership with people who know community-based research.

If you can just have that, that's huge. The training is going to be intense if they don't have that." Reviewers not only need to be familiar with human participants protection regulations, but they need to have the ability to offer recommendations to researchers to meet requirements. As described by a reviewer:

> *You have to follow up with...the research teams that you're reviewing. You have to have really good information back for them. If we're just saying no or yes and not providing enough details…it doesn't really help them to make sure that the research they're doing gets better.*

Recommendations for institutional IRBs

Researchers had recommendations for institutional IRBs related to their consideration of community-level perspectives and CBPR ethics. One suggestion was "having the community perspective in mind rather than just the individual level perspective." As described by a researcher:

> *I think the academic review, it's often considering the benefits and harms facing that individual participant and I think what the CBPR review process can bring is a perspective of what is this study, what are the potential harms this study might bring to the larger community? So for example, by doing this study, are you going to be stirring up conflict in the community in some way? …I think introducing a study, or even an intervention, or a study of an intervention in a community can potentially disrupt relationships, cause conflict. I think that's something that a community IRB process may often be more mindful of that the academic review may not consider.*

One researcher commented that institutional IRBs miss ethical issues related to partnering with community groups, such as joint knowledge production and credit for findings, with the ethical dilemma having to do with "knowledge … produced …that a lot of these community groups don't get enough credit for …and they're not seen as equal research partners both in terms of publications and publicity about the findings but also about research grants."

Summary Reflections

This case study documents the many ways in which the SSG IRB is achieving its goals:

1) Respond to the growing number of community-led research projects involving SSG or its partners, regardless of whether there is an academic partner.

The SSG IRB provides a thorough ethics review for community groups engaged in research without an academic partner. The SSG IRB provides consideration of additional issues beyond those specified in federal regulations for human participants research, including those pertaining to CBPR and partnerships that are not usually considered by institutional IRBs.

2) Advocate for and build research and research ethics skills among community partners, especially in community-campus collaboration, by making sure they are engaged or consulted throughout the research process.

The SSG IRB accomplishes this goal through several activities. As reflected in the SSG IRB application, it considers partnership issues throughout the life cycle of a study, from inception through dissemination. Through its proposal review and feedback process, the SSG IRB ensures that the research it approves is designed to provide tangible benefit to the community, leaving behind a legacy that is sustained. SSG IRB members – the majority of whom are community members – are provided training on research and the protection of human participants that is tailored to their roles

as reviewers. In addition, the SSG IRB provides training and technical assistance for community members more broadly.

The SSG IRB follows the federal regulatory requirements for human participants research with the added rigor of community-level considerations. Strategies to further strengthen the SSG IRB include increase funding, add more administrative support, create more opportunities for reviewer professional development, enhance follow-up with researchers on their approved studies and develop an established network of community IRBs. While its structure meets its current demands, the question remains as to whether the SSG IRB will seek to expand so that a broader set of community organizations beyond SSG and its partners may benefit from accessing its services.

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Galveston Island Community Research Advisory Committee: Gatekeepers for Health and Well-Being for African-Americans in Galveston, TX

John M. Cooks, Nancy Shore, Alice Park and Sarena D. Seifer

[GICRAC] helped me [as a researcher] build the proposal and I learned from that community review process… the knowledge that resides and emerges through a process like that, that is a true process not a rubber stamp, not a 'here's what we're going to do, sign the letter,' but really listening to how their local knowledge can inform a study is something I kind of knew but really didn't understand just how much better that could make a study. I saw that with my study and since then I've seen the same group be approached by other researchers.

The fact that they have something in place for the researchers to fill out, that the researcher has to come talk to them. I've seen protocols change. It's amazing. That kind of communication takes time to build up. You have to invest in each other for a long time so when the proposal comes down you're already ready and have the trust relationships built. If that's the case … then your study is going to be so much better.

-Researcher

This quote exemplifies the commitment of the Galveston Island Community Research Advisory Committee (GICRAC) to working collaboratively with researchers to design studies that help to actualize its mission:

We are the gatekeepers for the health and well-being among African Americans in Galveston County. We are committed to advocating, participating, and endorsing health research and related services, by participating in the selection, design, implementation and results sharing of research.

This case study report provides an overview of GICRAC including the history behind its development, how it operates, as well as its benefits and challenges. The report furthermore looks at how GICRAC compares with the local university-based Institutional Review Board (IRB), as well as its relationship with this IRB. The report concludes with a set of recommendations for community-based research ethics review processes and institution based IRBs. The report is based upon findings from an analysis conducted in 2013 of key documents guiding GICRAC,[1] a focus group conducted with seven GICRAC members, and interviews with the GICRAC Chair and two researchers who submitted study protocols to both GICRAC and an institutional IRB. This case study is one of five conducted as part of the National Collaborative Study of Community-Based Processes for Research Ethics Review. The study aims and methods are further described in the first chapter of this report.[2]

Overview of GICRAC

GICRAC traces its roots to Jesus Fit, a year-long Texas Department of Health-funded nutrition and physical intervention study in the Galveston, TX African-American community in 2004. A community advisory committee was formed at the inception of the study and became known as the Jesus

Fit committee. This committee was comprised of 7 community members partnering with a researcher from the University of Texas Medical Branch at Galveston (UTMB). As the funding ended in 2005, the Jesus Fit committee and the lead researcher decided to expand the function of the committee to include reviewing research coming out of UTMB in order to positively impact the health and well-being of the African-American community in Galveston. After operating as an informal coalition for four years, the Jesus Fit committee in 2009 became a 501c3 non-profit organization with a new name, GICRAC, which conveyed its broader purpose.

In thinking about why establishing GICRAC was important, members spoke to ethical abuses in Tuskegee as well as locally. One reviewer reflected upon the damages caused by the U.S. Public Health Service sponsored Syphilis study[3] and how it now shapes GICRAC's approach:

Tuskegee worked to the advantage of the researchers and to the disadvantage of the community, and it was years before the community realized what happened and by that time research that was supposed to be helpful had become harmful. I guess one of the worse things you could do is to know the answer to prevention and withhold it. And so I guess we are really making sure is scientific research steps up and becomes that part of the community, or that part of medical research where it does not do any harm.

Early in its development in 2005, GICRAC received training from St. Luke's Episcopal Health Charities in CBPR. This provided foundational knowledge to then begin reviewing research proposals in 2007. GICRAC also designed and implemented an extensive community needs assessment titled Listening Tours, to better understand the community's health and health research priorities. As one reviewer described,

We try to find out what's in the community, what's needed in the community by the community, from the community before someone comes to us with a research project. So when they come to us with a research project, we might already know because of those Listening Tours that this is something that the community will really be interested in pursuing, or this is something the community is going to be very accepting of and will welcome the researchers.

The Listening Tours asked key questions in a series of focus groups such as: what is health, what is healthy, and what are some barriers keeping us from being healthy? As explained by a GICRAC reviewer, "we polled nurses. We polled dock workers. We polled college students, high school students and teachers all in different groups." After gathering all the information, GICRAC held an event for the community to learn and talk about the findings. GICRAC also invited the local university President and other key university individuals. This provided an excellent opportunity to share with these university leaders the pressing health concerns and questions identified across Galveston.

Service to the Galveston community is a driving purpose of GICRAC. In part this entails ensuring that 1) the community understands the proposed study (i.e., study purpose, potential harms and benefits, participation requirements), 2) the study holds potential benefits and possible harms are minimized or prevented, 3) the study is aligned with GICRAC's mission, and 4) the researchers are provided guidance or support to strengthen their design and approach. As a reviewer also shared, "we developed it so that we would be in the know and mostly trying to, as much as possible protect the community for whatever that looks like. Be the

whistleblower if we need to be but not just blowing bad news, but blowing good news as well." GICRAC also works towards ensuring that study findings are translated into actual community benefits, which represents an expansion upon its original purpose of "gatekeepers." GICRAC also acts as an "extra voice for the community" in determining whether and how research takes place with Galveston communities.

Structure

Types of research reviewed

GICRAC reviews research coming from UTMB. Since its inception, GICRAC has reviewed 10 proposals. The research reviewed by GICRAC is generally aligned with its focus on the health and well-being of African-Americans residing on Galveston Island, extending into Galveston County. Studies reviewed have included those on depression, nutrition and exercise, and childhood obesity. Some of the studies reviewed were subsequently awarded grant funding, including from St. Luke's Episcopal Health Charities, the National Cancer Institute and the National Institute of Nursing Research. In some instances the research submitted to GICRAC has already received funding. In these cases, GICRAC first determines if the study aligns with its mission statement and whether there is an opportunity to positively influence its implementation, as stated in its policy:

Research or projects may be funded without GICRAC knowledge or even against the recommendation of GICRAC. When such projects pertain to the GICRAC mission, GICRAC will seek to positively influence project implementation later in the process.

Membership

The GICRAC chair described how the important qualities for serving as a GICRAC member are "a willingness to want to make a change and a willingness to learn about what it is we do and how the research world works." The GICRAC philosophy can be described as "we hope to 'grow people' and develop capacities." This translates into not requiring extensive research experience up-front and instead valuing a commitment to providing ongoing learning opportunities to all members. While the majority of members are from the community, people affiliated with the University including academic based researchers also serve on GICRAC. This latter group is referred to as "research affiliates." All the research affiliates were from the University of Texas System at the time of joining GICRAC. Given this commitment to capacity building, the GICRAC chair believes the current committee composition is sufficient. Depending upon the proposal under review, additional guidance may be needed in order to do a thorough and informed review and in these cases external assistance or consultation is sought.

When new members need to be recruited, GICRAC members typically make nominations. The nominating process tends to be informal, and nominees are not asked to complete an application to serve. The GICRAC Chair shares the mission and process of GICRAC with nominees in order to determine whether there is a mutual fit. Three current members shared how they came to join GICRAC:

I came on board as result of the Listening Tours.

I came on board because the founder of the group talked with me about it because I worked with the community. I had been working with youth for years at the church.

I was asked by the founder of Jesus Fit… I met her and she came to church a couple of times… she asked me why don't I be a part of the group. I said what? She said yeah. And I said you are all doctors, and teachers, and you are educators and stuff… She said you know a lot of people and there may be a time that we need to get to somebody and you'd be able to reach them quicker than we can.

There are no specified terms for the members. Currently there are 12 GICRAC members, with almost half of these individuals joining when GICRAC first formed. As the GICRAC chair reflected, members tend to be in it for the "long haul" with very little turnover. In GICRAC's by-laws the chair is elected by the GICRAC membership, and can serve up to three consecutive two-year terms.

Members are not compensated monetarily for their efforts. They do receive, however, educational opportunities to ensure they are able to complete their assessments. Examples of these opportunities include an IRB member from a local university offering training every other year to GICRAC members, and the initial training provided on CBPR. For members that were not present for the initial CBPR training, they will receive an overview of CBPR if they are unfamiliar with CBPR given it is aligned with GICRAC's beliefs regarding how research should occur. New members do not have to observe a meeting prior to gaining a vote. This decision is based upon the belief that the new members come prepared to vote with their knowledge and experiences as community members of Galveston Island.

Budget
GICRAC members are asked to pay dues to support the work of GICRAC, including the purchase of food for the meetings. Dues are $100 annually for community members, and $150 for research affiliates. Members have their dues waived for their first year of service. GICRAC seeks opportunities to raise additional funding to sustain its work. In part this entails working to secure grant funding directly or through subcontracts. Funding from UTMB's Clinical and Translational Science Award (CTSA) represents one of their main sources of income. GICRAC assists with CTSA activities and is compensated for its time and expertise. GICRAC has minimal overhead costs due to all

members, including the chair, donating their time as volunteers. A local church provides free meeting space. GICRAC, however, contributes funds to offset the church's operational costs.

Submission & Review Process

Submission process
Researchers tend to find out about GICRAC primarily by word of mouth. Most of the researchers who have submitted proposals are from UTMB. GICRAC's written policy regarding access to its review process states:

> GICRAC may be approached by researchers or community persons interested in obtaining the endorsement of their project. Such persons should approach the Chair of GICRAC with a request for support and GICRAC at large should decide 1) whether the project would be of interest to them and 2) whether it is at a stage where they can have meaningful input.

The researcher must also submit a copy of any applicable funding announcements as well as a GICRAC Letter of Support Request Form (to access the GICRAC Letter of Support and other forms, please see below for the GICRAC contact information and/or reference for a journal article that contains key GICRAC forms). Ideally the researcher submits this information before the study proposal is submitted for funding, allowing GICRAC an opportunity to be involved in the actual development of the research design.

Review and decision-making process
Once the materials have been submitted, GICRAC members determine whether they want to collaborate with the researcher. Ideally the researcher will come and present their ideas as a first step in this process. Only once has GICRAC decided not to proceed with a review. In this case, the researchers'

required timeline was insufficient for GICRAC to complete its review. When GICRAC decides to proceed with the review, a working group is created. This group, the Intervention Working Group (IWG), consists of 3-5 GICRAC members, which always includes community members and at times a research affiliate. Each IWG selects a Chair who serves as the point person for all communication with the researcher. The composition of the IWG depends upon the interests and availability of the GICRAC membership.

The IWG then meets to assess the proposal, utilizing two documents to inform its assessment: Letter of Support Evaluation Form and Questions to Guide Our Review of Research Proposals in the Community. In some instances the researcher submitting the proposal may include questions for GICRAC, specifying areas for which they are particularly interested in receiving GICRAC feedback. For example, one researcher submitted a summary of her research followed by a set of questions entitled "what I need help with" that included:

- How should parents be invited to participate, what will make it attractive for them to participate?
- If this program is going to be given to children you know, what kinds of things do the parents want to know about their children's health?
- What kinds of community support (from churches, Boys and Girls Club, Parks and Recreation Dept) is needed to get it to work?

GICRAC prefers to review proposed research that is in development, allowing for greater opportunity to help contribute to the final study design. As part of the review, the IWG may look for opportunities for payment for time spent reviewing the proposal or possibly to be a compensated study partner.

The determination of the IWG is presented to the entire GICRAC membership. As the policy states,

Deciding to provide a letter of support is a serious matter that involves the integrity of the group. The sub-group should not put the larger group "on the spot". When subgroup recommends support, a letter from the Chair will be sent from the Chair. Members of GICRAC will receive a copy of this letter.

Although the GICRAC membership generally concurs with the IWG's decision, the decision-making is described in terms of being a deliberative democratic process that entails sufficient time for discussion followed by a vote. The research affiliates serving on GICRAC can participate in the discussion preceding the vote, but do not get an actual vote. As one reviewer of GICRAC stated,

All of the "power" lies within the community. That's it and everybody comes in with the understanding that whatever the community says is the way that it's going to go relative to our actions. …because at the end of the day when we finish all of it, it's going to all be about the community so that's where all the investment is.

The policy also indicates that GICRAC members can propose a research project, and in these instances an interest group will be formed to develop the actual proposal. The interest group's function in these situations is therefore a bit different than an IWG given its emphasis on their own proposal development. The interest group will put forth a proposal to be discussed by the entire GICRAC membership.

Once GICRAC approves the proposed research, the Chair sends a letter to the researcher. This letter specifies the conditions that the researcher must meet. For example, in one letter GICRAC writes "we are pleased to work with you in this [research]

project and endorse its provisions. However, we do so with the provision, if funded, that you work with us in the development and implementation of this research project. We want to ensure that it reflects the 'cultural norms' and incorporates the special needs of participants in this community." The letter further specifies how GICRAC will "encourage the parents in our congregations and community with whom we have contact, to attend the WIC nutrition education classes."

Review Considerations

The key thing that we assess is that community piece. Always. That is the focus.

Definitely, community piece, always the community piece.

-GICRAC Reviewers

GICRAC's application and reviewer scoring sheet include questions consistent with GICRAC's community-concerned mission, which are also indicative of GICRAC's desire to be actively and meaningfully involved in shaping research. While some application questions are typical of those asked by institutional IRBs (i.e., how and who will be asked to participate in the study? Is anyone excluded? If so, why? Will their privacy be protected?), most of GICRAC's questions and scoring criteria include items not usually covered by institutional IRBs. For example, researchers are asked:

- If funded, how will your work improve the quality of research to address health issues in the African American or potentially other underserved communities?
- What efforts have you made to ensure that the research team has the sensitivity to understand the social, cultural, and environmental context of the community of focus?

- What is the racial and ethnic composition of your community of focus?

GICRAC members review each research proposal using a scoring sheet that assesses the extent of its alignment with GICRAC's mission. The reviewers' scoring is kept on file, yet the score is generally not reported out at the meetings. The scoring sheet serves as a useful tool to guide the review and discussion of the proposal. Examples of the scoring questions include:

- Does the research project/grant proposal have the potential to advance the health in the community of focus?
- Are efforts to ensure sensitivity to understand the social, cultural, and environmental context of the community of focus convincing?
- Is it a significant or pressing concern to the community?
- Is there time for us to become involved, on the study collaborative or on the planning of the study?
- What happens to study results? Will they be published? If so, where? Will there be a press release in the local paper(s)? Are community members involved in the writing of the final report or article? Will results be presented to the community? Where and how?
- Are participants involved in the presentation? Can they have input on where and how study results are made public?

GICRAC members approach their assessments with a strong community focus. This includes ensuring informed consent documents are not only understandable, but also relevant or appropriate to the community. At times this entails recommending that the researchers remove jargon, shorten the length of the form and check the reading level. As one GICRAC reviewer noted,

The jargon is very, very important. …And that does not mean that the participants are illiterate. It has no bearing on their education level because what we are working with are people in the community who have a multitude of information and knowledge. It's just getting the same vernacular on the table. Using the same English words. And for us, we are going to do it the simplicity way because there's a lot of wisdom in simplicity.

Attention to the actual consent process is also taken into consideration. When institutional IRBs require a lengthy consent document, the GICRAC members may ask researchers to create a summary sheet that highlights the key pieces potential participants need to know. As part of the proposed consent process, researchers also may be asked to attend a community gathering to be introduced to the community and to verbally share key aspects of the study.

Other review considerations include community benefit/impact, individual risks, methodology, and opportunities for compensation.

Community benefit and impact
GICRAC considers both community and individual level benefits when reviewing a proposed study. As one reviewer reflected,

I think we do it on the community basis. I feel like…just how important is it to the community? What will the community benefit from? I mean is it something we want to give a try, or put on our community, or make them a part of it?

One reviewer also reflected how institutional IRBs take into account individual-level considerations and are not positioned as well as GICRAC to

think through "how it's going to impact the entire community." Consideration of community impact takes into account both the short- and long-term impacts.

Individual risks
While the primary focus of GICRAC may be on the proposed study's community impact, they also consider individual level risks. As an example taken from GICRAC's meeting minutes, members required that the researchers include a stipulation about participants needing to seek approval from their physicians in order to participate in the study. This was due to concerns with health risks associated with participating in the study.

Methodology
GICRAC also provides feedback on the proposed methodology. This may result in adding in pieces that members describe as "back door CBPR," that allow for greater community engagement. Other examples of feedback on methodology include whether the study is appropriately inclusive and questions regarding appropriateness of the study design given the community context. Or as one reviewer shared, "oftentimes there's a different way to do [research] in a different community. So the methodology they are trying to implement is something we have to pay serious consideration to."

Community compensation
As part of the review process, GICRAC looks for opportunities to include and compensate community members as study staff and also to be included in the study as a compensated partner. This may entail recommending building in a paid position for a community person or for GICRAC. As an example, GICRAC may ask that the researchers hire someone from within the community to fill a community health worker position. This individual is not necessarily affiliated with GICRAC, but is a member of the broader Galveston Island community. In terms of seeking paid opportunities for

GICRAC, one GICRAC member shared, "based upon what we're doing and especially the work required, let's get paid for the work. … It's about the fairness of it in terms of trying to make sure that everybody's time is respected and compensated." Issues of payment were also reported in the GICRAC minutes. More specifically the minutes indicate that a proposed research project had a decrease in the agreed upon amount allocated to GICRAC due to funder cuts. The required deliverables from GICRAC, however, remained the same. The discussion amongst GICRAC members focused on whether the decreased amount represented a "fee commensurate to the work to be done."

Comparison of GICRAC & Instituional IRBs

While GICRAC members noted key similarities between their review process and institutional IRBs (i.e., "we take into account the risk to the human participants"), several perceived differences were identified. These include GICRAC's strong focus on community, desire to actively collaborate with researchers, strong faith-based and community orientation, and organic development as a review entity. In terms of GICRAC's strong community focus, one reviewer shared,

…We have at heart the community and we want to help the institutions do the right thing... Because its eventually going to benefit the community. If they do the right thing and they come through with something fantastic, it's going to ultimately benefit the community.

Another reviewer also contrasted GICRAC's community orientation with the priorities of some researchers:

There are different emphases. Their emphasis is to be able to go out and conduct the research and write a paper that's going to be accepted in various journals and what have you and maybe they will be able to conduct some research that will get them some recognition. Our emphasis is okay now you are coming to this community, now you are going to serve this community in that it is going to benefit the community in some way. I don't think they care about whether it's going to benefit the community, they care about whether it's going to benefit them.

In comparing the application process specifically, GICRAC members described how their review tends to be more collaborative as compared to institutional IRBs. As one researcher shared,

One of the researchers interviewed highlighted GICRAC's participatory process:

With GICRAC there were several pages to complete and questions to fill out, but then we met together and it was participatory as far as working through these parts together. Whereas with the IRB, you filled it out, submitted it, it felt like a black hole, an answer came back. There really wasn't any participation as far as creating how the research would be and the human subjects are structured and those kinds of things.

Because of my personal commitment and because of this proposal, it was perfect to go to this community group and say, help me develop this proposal. It was not presented to them as a finished product. In fact, we had about three meetings of a sub-group of the whole group where they looked at my proposal and the first time they did it they looked at it and said, excuse us, but we don't think this is worth the paper it's written on. Then we began to build a proposal from their ideas about what they thought it should look like and that's how it went to the community group. It went to them, it came from them, so on and so forth and, of course, it had to go to the institutional IRB because that's a requirement of my job and of the NIH application process.

Some members bring a faith-based orientation to their role on GICRAC, described by one reviewer as reflecting on the role of prayer and guidance from God as a means to determine how best to approach the review process.

Finally, unlike the more structured institutional IRBs that adhere to established federal research ethics regulations, GICRAC developed in more of an "organic" manner. Currently GICRAC has key policies and procedures established, but initially one reviewer described it as "very organic and so we made it as we went along."

Comparison of feedback received: GICRAC and institutional IRBs

Researchers were asked to compare the feedback received by GICRAC and by the institutional IRB that reviewed their study, and what occurred if they received conflicting feedback. The interviewed researchers could not recall any substantive feedback received from the IRB. For one researcher, the comments received focused more upon how to keep her study in compliance with the IRB's

deadlines and requirements (i.e., "keeping the study personnel updated"). One researcher recalled not having "many issues with the IRB after it had been approved by GICRAC."

In thinking about feedback received from GICRAC, researchers recalled questions or requirements related to cultural considerations, acknowledgement of individuals' study participation, risks and benefits of participation, sampling decision and power dynamics. As an example of cultural considerations, one researcher spoke to the feedback regarding the intervention plan and approach of a nutrition education project. This researcher shared how she "didn't have it culturally appropriate and so [GICRAC] wanted to be sure all that was in there…I always appreciated any feedback they had for me because they know the community and I don't." In terms of appropriately acknowledging the contribution of study participants, one researcher reflected,

[GICRAC] felt like I wasn't adequately acknowledging the time and effort the participants were going to put in on it, so I needed to make those changes. I don't want to say payment because it wasn't necessarily payment, but it was providing to the participants something that they would value rather than just nutrition education or something like that. So, I had gift cards. I had other types of small child toys and things for the moms that they would value to thank them for their time and effort in attending the intervention classes.

Connected to the idea of appropriately acknowledging participants, one researcher also spoke to receiving feedback that pushed her to further explicate what are the benefits and burdens of the study. This information was important to share with potential participants, and required the researcher to demonstrate a critical awareness of what she was asking

participants to do. In terms of sampling decisions, this referred to feedback on how to better attain the desired representative sampling sought by the researcher. Lastly as an example of power dynamics, one researcher discussed how GICRAC provided feedback that would help ensure researchers didn't "use power to pull the wool over someone's eyes" and instead communicated in a way that everyone would understand and that leveled the playing field.

For one researcher, there were no real concerns raised at the final stage of GICRAC's review given she worked closely with GICRAC to develop the entire proposal. As this researcher reflected,

> *After our work group was finished creating the proposal, it went back to the full committee and they read it. Because their colleagues had, basically, worked to build it, read it and edited it, they didn't really have any concerns other than just how we were going to do it, the feasibility of it, given the small number of people in the coalition.*

Researchers were also prompted to think about instances where conflicting feedback was received, and how it was resolved. As an example of conflicting feedback or requirements, one researcher shared how GICRAC advocated for incentives to be paid in cash due to the perceived barriers of the originally proposed plan. Providing cash was implemented, but required the academic partner to adapt its policy to allow for such an approach. The involved researcher described having the university write a "special policy." Of note, the payment negotiations were seen more as a conflict with university-wide policy and not the IRB specifically. In order to avoid negotiating conflicting feedback, one researcher described informing the IRB that she must adhere to GICRAC's feedback in order to be consistent with the overall CBPR approach of her study. As long as there are no significant red flags in the proposed study (i.e., significant risk of harm),

the researcher believed the IRB would honor the need to adhere to community feedback.

Overall experience going through GICRAC and institutional IRB review

In thinking about their overall experience going through the institutional IRB, one researcher shared "it's pretty pro forma" while another shared, it was "just a paper process." The interviewed researchers could not think of how the IRB feedback changed aspects of their study design.

In contrast, the interviewed researchers spoke passionately about their experiences going through GICRAC and how it strengthened their proposed research. As a researcher shared,

> *Very valuable. Valuable because they give you insights that a university-based researcher really doesn't understand or doesn't see that are very valuable not only for putting it to NIH saying it's CBPR and following all the little step by step, but because it makes the research more applicable, more valuable. If you have this perfect design and study but it doesn't fit with what the community knows and how the community acts, it's never going to go anywhere. It's never going to happen.*

An example of how GICRAC feedback resulted in changes centered on sampling decisions. More specifically the researcher had proposed a sampling strategy that was based upon geography. GICRAC advocated for an approach that instead centered on sampling groups within the community. More specifically, the researcher shared how GICRAC instead proposed to do a more "cross section of folks; we're going to talk to teachers and then we're going to talk to janitors and factory workers. We're going to talk to ministers, sorority and fraternity members." Additionally GICRAC advocated for inclusion of youth as an important part of the community.

Relationship between GICRAC & Institutional IRBs

GICRAC grew out of a research project with a UTMB researcher and developed an expanded aim to review all research coming out of UTMB's Medical Center. To date there is no formal relationship or agreement between GICRAC and UTMB's IRB or any other institutional IRB. Generally researchers going through GICRAC and UTMB's IRB will submit their materials first to GICRAC. This allows the researchers to incorporate GICRAC feedback prior to UTMB IRB submission. In instances where researchers instead first submit to UTMB IRB, they will likely have to submit additional modification materials to UTMB IRB assuming GICRAC requests specific changes. If a GICRAC involved research project seeks a Federalwide Assurance, UTMB's IRB would be the IRB of record.

GICRAC members further discussed relational challenges between the broader community and UTMB post-hurricane Ike. Members pointed to the relational strain resulting largely from UTMB's hospital not being able to provide the needed services to the community after the hurricane. The strain therefore centered on the community's relationship to UTMB based upon health care provision rather then research activities.

Benefits and Impact

The benefits of GICRAC include engaging the community in the review and development of research happening on Galveston Island, working to ensure community benefits, and assisting academic-based researchers to design and conduct community-engaged research. GICRAC is a community-driven entity that not only reviews research proposals, but also aims to monitor, shape and participate in research. The involvement and leadership of community members on GICRAC, according to the GICRAC Chair, "is the strength of [GICRAC] and makes it most effective." As

another reviewer shared, "it [GICRAC] gives the community essentially an opportunity to monitor exactly what's going on in the medical community." As part of this role, GICRAC helps ensure that the broader community remains aware of what research is being proposed or conducted. GICRAC also works to ensure that the community will understand the research, helping at times to translate research jargon into layman terms.

In terms of benefits, one reviewer remarked how GICRAC tries "to link or put together an illness in the community with the search for a cure on the university level." Another reviewer reflected on the issue of community benefits by sharing "and it may turn out that there's no benefit from [the research], but at least [the community] knows that it has been reviewed and we've given it a stamp of approval in an effort to determine that this research could possibly be beneficial. And if it isn't beneficial, then the next time someone comes with this idea we can tell them right off no this isn't going to work."

Several members pointed out how GICRAC assists researchers. GICRAC members help shape the research in order to ensure the research will be relevant and received well by the community. In essence GICRAC can help add a "different perspective" due to it being a part of the community with a deep understanding of community concerns and strengths. As one reviewer noted, "we try to get the researchers to realize that some people don't go to this place. I mean you might find them better at another place or a different time and approach the whole study in a different way to get them to really participate, or want to participate." One researcher mentioned how GICRAC helped with hiring research staff, and reflected on how "the participation of GICRAC on the proposal is what got it funded because I was able to say that we did this together and this was funded … They really liked that approach, that it was jointly created."

GICRAC members provided two examples where they likely prevented problematic research from occurring. GICRAC members could not definitively state that the research projects were stopped, but believed they did not take place as GICRAC did not hear back from the researchers nor did GICRAC see evidence of these research activities occurring within the community. The first study was not approved due to concerns with the study's risks. More specifically, GICRAC members feared that the intervention would potentially place participants at risk for health complications. In the second study, the concern focused more upon the lack of clarity in the proposed research. One GICRAC member observed that "[we] haven't had many [situations where we said "no"] because generally whatever comes in, we're willing to work with them as long as they're willing to work with us. I don't remember in my history… us saying no to anything. If we did, I'm just at a loss. We're not above saying no. If it reeks, hey we can't do this. We're just not going to be a part of this."

A final benefit identified by members was the impact GICRAC service had on them. Some members gained a greater awareness of what is happening in the community and for others it has prompted personal growth. Many members spoke about the value of serving one's community especially when service is aimed at reducing health disparities. One reviewer shared "since I've joined [GICRAC], I have also joined other groups in the community. I see it as following what my mom did. She did a lot of community work. So I am happy to be here so I can help this community. Every time I come, I look forward to doing more." Another reviewer remarked, "being able to serve others makes you feel good, really good. When you can serve others." Members also gain knowledge through the various learning opportunities offered, such as training on research ethics and CBPR.

Challenges

A range of challenges surfaced across the interviews and focus groups regarding GICRAC's ability to fulfill its charge. Many of these challenges centered upon the relationship between the local university and the broader community. Members referred to "so many things have happened to us in the past" and how this contributes to lack of trust towards the local university. This includes what transpired in Tuskegee as well as locally, particularly in terms of how the university responded in the aftermath of Hurricane Ike in 2008. Focus group participants reflected upon how the university failed to address the many pressing needs emerging after the hurricane, and the impact this had on the community. Examples of the exchange between GICRAC reviewers during the focus group included:

- *[Hurricane Ike] may not have destroyed many lives, but it destroyed many minds, emotions okay. It was devastating.*
- *And [the university] never picked up upon the mental health of the community. I mean people are functioning but the mental health to go through that kind of trauma…*
- *There's no mental health from [the university]. It's just gone.*
- *After the storm the department of psychiatry got rid of inpatient psychiatry. It no longer existed out there… When we needed it the most…*
- *So the mental health issues that are facing people as a result of the storm couldn't be dealt with because there's no longer anybody here to do it.*
- *The town still suffers, it's almost like nobody cares…*
- *And once the city's population got below a certain level we didn't qualify anymore for certain government stipends, like the buses, and certain other things that cities qualify for….*
- *So when we go to interview the community, our community, this is what's on their minds. And this influences a lot of what they're saying on any subject we ask them about.*

Another relational challenge exists between the local university and GICRAC. In part, this was attributed to a lack of familiarity or understanding regarding the role of GICRAC. As one reviewer shared, "since we aren't really part of the university, trying to make sure the university understands the importance of our role." It is not mandatory for academic-based researchers to go through GICRAC, and as one reviewer shared "getting them to know our presence is a challenge" to which another reviewer added "and [getting them to know] our importance."

Sustained funding represents another broad category of challenge. This includes both challenges with securing funds to sustain community programs that were developed through the research that GICRAC was involved in and to compensate members. In reflecting upon the origins of GICRAC, members spoke to the value of the Jesus Fit nutritional and exercise program. This included encouraging participants to exercise regularly and tips regarding healthy eating. Unfortunately due to lack of funding the program ended once the grant was finished. As one reviewer shared, "I think the one thing that it might have been both the university and the community's downfall was that we weren't able to continue that [program]." Currently members are not paid, and indeed are asked to pay membership dues annually to GICRAC. Although members themselves do not identify the lack of compensation as an issue, the GICRAC Chair raised concerns about it. Ideally members would be compensated for their time spent reviewing materials and meeting as a committee. The ability to compensate would serve as a means to express gratitude and to acknowledge the community expertise they bring to their reviews. One of the interviewed researchers also spoke to the importance of factoring compensation for GICRAC members into research grants:

There's really not money for whoever sits around [GICRAC's] coalition table every other week and takes the minutes and gets the minutes back to the group. There is no money to support that kind of basic education and information transfer. There are in my grants because I'm doing a budget right now and every time there's a meeting or a transfer of information, I'm trying to write that into the budget so people can begin to see those. Those costs are there, it's just that they're being born by people will give you the shirt off their back.

The researcher noted that ensuring there are funds to cover costs to facilitate community engagement and organization is an ethical issue. Too frequently universities view community support merely in terms of writing a letter of support, failing to see the full scope of possible engagement. By financially supporting organizing activities directly or through line items in grant budgets, the researcher posits, the potential exists for the power dynamic to shift allowing the community to have a stronger voice in determining how and whether research occurs on Galveston Island.

Another challenge concerns the time demands of serving on GICRAC. As one GICRAC member noted, "the challenge is a time issue. Getting everybody at the same place at the same time around being able to do it, because it's volunteer… That is one of the main things but somehow we managed to pull it together."

Finally, challenges specific to working with researchers were also identified. One challenge centered on the tendency for researchers to use language not suited for laypeople. More specifically, a reviewer

shared "oftentimes they use acronyms and they use this and that so therefore we've got to search or try to pull it out of their heads as to exactly what they are trying to do. What is it you are trying to do? What are you trying to tell us here? And that's probably the biggest challenge for me." A second reported challenge focused upon raising awareness amongst researchers regarding the potential role of GICRAC to help shape and inform the research design. As one reviewer shared, "in the past we had situations where the researchers downplayed the role of the advisory committee and actually limited us as far as participation. Everything is already done when we get there. We want some input from the beginning, and not after everything's already been completed." Or as another GICRAC member observed, researchers needing a letter of support from a community group may approach numerous groups until a group agrees to submit a letter. As this GICRAC reviewer reflected,

What was happening was that the researchers would come to the little group or they'd get picked off one by one. They'd get a minister in the corner and they'd say hey, we're doing this study. It's due tomorrow. Will you sign this letter of support? They [the minister] were like yeah sure; we'll sign a letter of support. So we're like, how can we move the needle from that automatic response of we'll do whatever you say to show us what we're going to get in return. If we don't like the protocol, how can we change it?

Recommendations

I think both sides need to be aware from the very beginning that each other exists. The IRB needs to know about the community group that is participating, what their background is, their

research knowledge and their research experience and the community group needs to understand what a university IRB is, what kind of rules they have to follow and why it's important to have all these protections. So both sides really need an education about the other.

-Researcher

Recommendations to institutional IRBs

The majority of recommendations for institutional IRBs identified focused upon their review of CBPR. These include the need to increase IRB members' understanding of what CBPR is, and suggestions regarding types of questions to include on IRB materials to more fully assess whether the study is ethical CBPR. Examples of questions recommended include:

- How has the proposal been developed? What parts did [the community] read and have input on? How did that occur? ….How is the data going to be shared and what kind of acknowledgement is going to be given with the results via publications, the presentations?
- To what extent is your community group involved? What particular things has the community group done in the creation of this protocol and what responsibilities are the community group willing to take in order to ensure data safety?
- If this is the kind of proposal that brings in community guidance, community leadership and community resources, are they being appreciated, reimbursed and acknowledged in the spirit of respecting?

A second area of recommendations for institutional IRBs focused upon membership considerations, more specifically the required non-affiliated member specified in the federal research ethics regulations. A suggestion was to recruit individuals who are

"members of the community group that works with researchers," as compared to those who are not connected to the community groups often recruited for research. Presumably someone more connected to the community would have greater awareness of potential community considerations.

Recommendations to strengthen GICRAC
Six recommendations to further strengthen GICRAC were identified.

Increase visibility and develop relationships with researchers: Across the interviews and focus group discussions, people consistently commented on the need to increase GICRAC's visibility among researchers. Indeed, GICRAC's strategic plan includes increasing its visibility. Suggestions included scheduling time to meet with the different researchers and learn about their areas of interest and share GICRAC's mission and vision, and similarly meeting with key university leaders. Ideally building these relationships would not only increase the volume of research submitted to GICRAC, but also encourage researchers to take on more of a CBPR approach allowing for greater community input into the overall study design. Another suggestion for increasing the volume of research reviewed by GICRAC was to consider opening it up to researchers from "off the island." One reviewer also commented on the potential benefit of increased volume by stating that this would help ensure the members "don't get rusty, that they are constantly learning and doing." Ideas for increasing GICRAC's visibility in the community at large included seeking opportunities to support community activities and have GICRAC's name included on event posters or flyers.

Change the information requested from researchers: Several recommendations surfaced regarding additional questions to ask researchers. To facilitate the review process, one suggestion was for researchers to submit "a brief overview of how they came to

this research that they are about to do and what other research has been done in that area." This would help the review committee understand not only the researcher's experiences but also provide a more contextualized understanding of the proposed study. Other proposed questions included asking what kind of involvement the researchers want from GICRAC, and what benefits or compensation will GICRAC receive in return. A researcher also suggested that GICRAC ask researchers to specify how they planned to train their research staff on participant recruitment, informed consent, confidentiality and other ethical issues, since GICRAC members have heightened sensitivity to these critical training topics. More specifically, the person suggesting this line of questioning reflected,

The [institutional] IRB, basically, once the staff passes the CITI [research ethics training] it's like okay, they've met the criteria and they're okay. The community group I think would have more impact and more insight into well, our people need to know this and this is what we usually do. So if you want to do it differently, they have to be taught about that. Something really that would be more in-depth.

Adopt new policies: Two new GICRAC policies were proposed: an adverse event policy and a policy specifying the timeline for review. Currently researchers are not asked by GICRAC to report adverse events, unlike the requirement stipulated by IRBs. While GICRAC would likely hear from community members about any problems associated with the research, an actual policy would ensure that research teams would report this information in a systematic and timely fashion. A statement specifying the timeline for review was also identified as a priority. Based upon past experience, researchers tend to submit their paperwork to GICRAC with a request for a fast turnaround time (i.e., 3 to 4 days) due to funding deadlines. In these circumstances,

GICRAC has limited ability to have an actual voice in shaping the research design. One option would be to use the same submission deadlines used by the local university IRB, for example all materials must be submitted at least sixty days prior to the funding deadline.

Facilitate learning opportunities/exchanges: There are few opportunities for GICRAC members to meet and learn with their peers. Participating in meetings with other members of community-based review processes would allow for a sharing of ideas, including how different community groups approach the review of research.

Conduct an evaluation: Currently there is no systematic evaluation in place to determine the extent of GICRAC's impact. Ideally GICRAC would develop a tool to determine, for example, how it has changed the way research happens on Galveston Island. Gaining a systematic understanding of GICRAC's impact would help to secure funding and inform how they do their work.

Develop sustainable funding streams: GICRAC functions due to people's willingness to volunteer as members and pay annual dues. Ultimately GICRAC hopes to secure grant funding directly. In the meantime, GICRAC continues to identify ways to be compensated for their time and expertise. Options under consideration include charging fees for a review, requiring that researchers write GICRAC into their grant applications and dedicating a portion of the annual dues to compensate members and/or cover meeting expenses related to travel and food.

Recommendations for other community groups developing their own research review process
Four overarching recommendations for other community groups interested in developing or strengthening their own research review process emerged across the focus group and interview

discussions: create something that meets your needs, learn about and work with local university IRBs, ensure that you are paid, and educate the community.

Create something that meets your needs: Community groups should develop a review process that best meets their needs. For some this may be developing a community-based IRB if the resources and need exists. As one GICRAC reviewer shared, "do whatever works best for you." Tied to this idea was that communities should not become overwhelmed by the idea of developing their own review process. Members of GICRAC reflected upon how they found the process to be "relatively straightforward" requiring refinement over time perhaps as roles are expanded or new challenges are identified.

Learn about and/or work with local university IRBs: Local university IRBs are viewed as potential partners and resources as community groups form their own research review process. In terms of learning about local university IRBs, one suggestion was to find out about "who are the members of the IRB, what do they know about community work and what kind of community work have they done in the past." This insight may help facilitate how the community group approaches the IRB. The IRB may also help guide developing community review processes on the regulatory considerations and research ethics in general. Encouraging a member of one's own community group or organization to apply to serve on a local university IRB could enhance communication as well as help the community group to better understand and anticipate the concerns raised by the IRB.

"Make sure you get paid": Both GICRAC members and researchers agreed that community-based review processes should receive money for the work they do in reviewing and strengthening research proposals. Recommendations for community review processes include requiring a fee to review a proposed study or being written into applications

for study funding. One researcher interviewed also suggested that community review processes request that the submitted materials for review include the budget so they can assess what resources might be available for community compensation.

Educate the community: A community review process needs to educate itself as well as the broader community. GICRAC, for example, created a glossary of research terms for the community. Other suggestions included sharing information with the community about research projects currently underway and having discussions regarding what is and is not an ethical issue.

Summary Reflections

What we will be will be determined by how much we're willing to do.

-Reverend Charles Wheat,
GICRAC Founding Chair

The words of Reverend Charles Wheat represent GICRAC's mantra that drives how GICRAC approaches its work. GICRAC is committed to assessing ethical considerations AND partnering with researchers to infuse proposed studies with CBPR principles. This willingness and commitment enables GICRAC to actualize its mission:

We are the gatekeepers for the health and well-being among African Americans in Galveston County. We are committed to advocating, participating, and endorsing health research and related services, by participating in the selection, design, implementation and results sharing of research.

GICRAC's desired level of involvement requires substantial time and work, which generally is uncompensated. The success of GICRAC relies upon its members' commitment to serve their community.

As GICRAC continues to increase its visibility amongst Galveston Island researchers and potentially to "off-island" researchers, the need for increased infrastructure will be necessary. GICRAC members identified key areas for growth including policy development, evaluation procedures, and funding mechanisms. While GICRAC's structure clearly meets its current demands, the question remains as to how GICRAC will continue to evolve organically to respond to changes in its demand and role while maintaining its commitment to serve the Galveston Island African-American community.

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Guam Communications Network's Community Research Project Review Process: Empowering our Community to Protect and Promote our Chamorro People and Culture

Lola Sablan-Santos, Paige Castro, Alice Park, Nancy Shore and Sarena D. Seifer

We've had instances before us where people were being researched and [universities] would get a group of people together but nobody knew what it was about. Nobody knew that they could ask questions or even to say "stop, I don't have to participate on this." So there was no understanding of what research was or what were the processes, procedures, guidelines in being a participant in a research project. Then you have the other ones where, what do they call them? The helicopter? The catch-and-go?

They come in, do their thing and they leave.

And we never hear from them.

And community members… never get results

-GCN Review Process Administrators

Past instances such as the one described in the opening quote have left an unstable foundation for health research in the Chamorro community in Southern California, making Guam Communications Network (GCN) a crucial organization for protecting and empowering the Chamorro community. As the only Chamorro organization involved in participatory research or research review in the Continental U.S., GCN acts as a guardian for the Chamorro community. As described by its reviewers, GCN's Community Research Project Review Process assesses research with a commitment "to ensure that the research study benefits the Chamorro community as a whole", along with creating a "pool of Chamorro community members who are knowledgeable and experienced in Institutional Review Board procedures."

This case study report provides an overview of GCN, including the history behind the development of its review process. The report also outlines how GCN's review process operates, as well as its successes and challenges. The report furthermore looks at how GCN's review process compares to institution-based Institutional Review Boards (IRBs), as well as its relationship with these IRBs. The report concludes with a set of recommendations for community review processes and institutional IRBs. The report is based upon findings from GCN review process meeting notes, a focus group with one GCN reviewer and two GCN Review Process Administrators, and separate interviews with 1) two GCN Review Process Administrators, and 2) an academic researcher who submitted a study protocol to both GCN's review process and an institutional IRB. This case study is one of five conducted as part of the National Collaborative Study of Community-Based Processes for Research Ethics Review. The study aims and methods are further described in the first chapter of this report.[1]

Overview of GCN

GCN's website states "*ginen I ginaddon humuyong minaolek*" or adversity breeds beauty. This motto reflects the resilience of the Chamorro people who

have experienced significant adversity. When a series of natural disasters in 1992 left the island of Guam and its people devastated, GCN was formed in Long Beach, CA as a result to coordinate "relief efforts to provide supplies and other assistance to the people of the Island." During the crises, there was no acknowledgement by the media of the effect of the natural disasters and ensuing struggles faced by Chamorros, nor their contribution in the U.S. Once the crises passed, "the need for an organization to directly provide a focal point in the [Continental] U.S. still existed" and "GCN expanded its focus from that of addressing the emergency to that of responding to the needs of the stateside Chamorros as well as interfacing with the island."

GCN continued on to be established as a non-profit 501 (c)(3) organization in 1993 and currently employs seven staff members. GCN is "dedicated to facilitating increased public awareness of the issues concerning the People, Island, and Culture of Guam through education, coalition building and advocacy." Along with creating the first Chamorro Arts and Cultural Center in the nation, GCN provides a safe environment for community members to be involved in community-based participatory research (CBPR). GCN is dedicated to being part of the beauty that comes from adversity and to helping the Chamorro community and culture thrive.

Overview of GCN's Research Project Review Process

History of the review process
GCN began reviewing research proposals after becoming involved as a CBPR study partner with university-based researchers in 1999. Its research project review process was established to increase the Chamorro community's involvement in CBPR. By developing a platform where the Chamorro community could be involved in the regulation and review of research proposals, GCN set a new standard for research in the community beyond

involvement as participants, allowing the community to be involved in proposal development, implementation and dissemination. The community members who serve as reviewers are ensuring community protections by voicing their opinion as projected through a lens of community and culture.

Structure

With the help of GCN's organizational structure as well as the advice of trusted consultants from Special Services for Groups IRB (a community-based IRB in Los Angeles, CA that is the focus of another case study in this report),[2] GCN developed its informal research project review process. GCN provides reviewers with access to resources to become certified in the ethics of research involving human participants, support from the organization itself in the form of meeting space, identifying resources (i.e. opportunities to attend trainings and symposiums, etc.), as well as food, a culturally important aspect for gatherings.

Types of research reviewed
GCN only reviews research proposals in which the organization is directly involved as a community partner, and all proposals have involved community-academic partnerships. To date GCN has reviewed eight research proposals, typically reviewing one proposal per year. These research proposals have focused on cervical cancer, pap testing intervention, breast cancer, tobacco, HIV, lymphedema, physical activity and other health issues involving the Chamorro community.

Membership
GCN's review process currently has six members, all of whom are women. As an independent review structure for GCN, no GCN board members serve on it, although there is one staff member. There are no academic reviewers. GCN reviewers are comprised solely of community members who are knowledgeable with the infrastructure of the local

Chamorro community and their cultural values, and who may also have topical knowledge about the research proposal being reviewed. In addition to the six reviewers, there are two GCN staff persons who serve as review process administrators. The administrators facilitate the review discussion but they do not vote on the proposal.

Characteristics sought for reviewers include diversity and as described by a reviewer, a "passion for serving the community." Referrals from existing reviewers help to ensure these characteristics are met. As shared by one GCN Review Process Administrator:

I think one of the things is that we don't go for people we know real well, or people we get along with. We want to make sure that it's as diverse as we can get it. So we get a real sense of what is out there. And many times we get referrals! It's funny because the person that you know or that know about what you do, is the one that will tell you "oh yeah, maybe you should talk to so and so. Sounds like something that she would like to do."

Community members are often hesitant to become involved in research due to previous negative experiences, making the pool for readily available reviewers small. One way in which GCN addresses this challenge is by seeking out individuals who have a personal connection to the research topic, so the research is genuinely a passion for them. As described by a GCN Review Process Administrator:

And we find the people… who are either going through it themselves or being a caregiver, having family members who are… that they're taking care of so it becomes really a want for them.… One of the other things is if a person has history or knowledge of the topic either as a survivor, as a caregiver… somebody who would understand, the disease or… has experience…

Since GCN only reviews research proposals that include the organization's involvement as a community partner, GCN feels it is important to involve staff members in the review process, as they may ultimately be responsible for implementing the project. How a staff person is involved in a research project depends on both the nature of the project and the staff member's job description. Staff person's involvement in research projects have included: conducting outreach in the community; distributing surveys; facilitating pre/post tests, focus groups and key informant interviews; assisting with evaluation; and co-presenting at scientific meetings.

In the Chamorro culture, family lineage is important; each family is a clan, using the family name as identifiers. When an academic researcher approaches the Chamorro community, it is important they receive approval from the family clan leader before conducting any research in the community. GCN has helped to educate academic researchers about these cultural values and expectations. Within the tight-knit Chamorro community, once GCN opened the door and community members became more comfortable with research and academic researchers respected family structure, GCN received more referrals from community members who had participated in research. This evolution from research participant to active member in GCN's participatory research work has helped to grow enthusiasm and expand the review process from three to six members.

Budget
Currently there is no explicit budget for the GCN review process. The review process is supported by in-kind donation from GCN and reviewers. Two GCN staff are heavily involved in administering the review process. GCN also provides meeting space and reviewers typically bring food to share during the meetings.

Submission Process & Review Considerations

With GCN, it is important to involve the community at each step of the review process thus making for genuine community-engaged research. Before a proposal is submitted, GCN will work with the academic researcher to provide background information about GCN and its CBPR approach, as well as to facilitate relationships with potential community and academic partners. When the academic researcher is ready to submit the proposal for review, GCN's review process convenes to discuss and critique the proposal. Continuing with the theme of genuine community engagement, "in addition to reviewing the proposal," as explained by a reviewer, "then we ask them [referring to community members] if they would like to continue and be a member of the community advisory board for the project." If this opportunity arises, it is presented to the reviewers after the proposal has been reviewed and decided upon. By gaining GCN's input before and after the review process, an academic researcher can ensure each element included in the proposal contributes to an effective and culturally appropriate research project.

To submit a project for review, the academic researcher submits the proposal, the study instruments and the application submitted to his or her institutional IRB. GCN does not have a GCN-specific review application. The review meeting is scheduled and the researcher can typically expect to hear back about the proposal a week after it is submitted. The actual review process involves a discussion conducted in person. The academic researcher does not attend the review discussion. There is no directed process that guides the review as well as little to no paperwork involved. As described by a GCN Review Process Administrator:

You take your shoes off, and you get comfortable because then it becomes a family setting. It becomes a family circle. So then you talk about things while you're eating and someone's talking and you're thinking "hey yeah, that's right I think that'll work." Or "no, yeah I don't think that's a good idea." That's when you get everybody's input and you get a consensus. Whether "yeah it's going to work" or "nah you better throw that out the window because it's not going to work for us Samoans." Or "it's not going to work for the Chamorros" kind of thing.

In the review process it is important to hear from everyone at the table. More seasoned reviewers may assist new reviewers in encouraging them to speak. As the GCN Review Process Administrators shared:

So in coming around and sitting there as a group, it makes one that is not as vocal to be able to give their input and say "yeah, I think that's a good idea." Because you find those that don't talk very much…

…we find that with everything, the person shies off, and they figure let [name of person] talk because she's the one that's good at talking. But then too, we need to see the voice of that other person to be able to come in.

And we encourage everybody… and so we all know those that have been returning know how to get other people to talk.

And we keep reminding them this is a process where we need everybody's input. So you may not think your input matters but it does.

We encourage that.

This encouragement from more seasoned reviewers as well as the growing acceptance by the Chamorro community of GCN and academic research has allowed GCN to eliminate some of the hesitancy towards the research community.

An important element in the gathering is providing food; this has extreme cultural significance. For the Chamorro community as well as many other Pacific Islander communities, food is social and creates a zone of comfort and trust. The gathering serves the Chamorro community and reflects the tradition in such a way that the outcomes of the review process are genuine and true to the Chamorro people. As described by the GCN Review Process Administrators:

> *But it's a cultural thing, too. The food. And like [name of person] says, it's important. We always try to, because I know that when we get together that that's what sets the tone, is your food. And all these years, it's worked.*
>
> *I think that was a good point that you brought up food because in our culture, food, it's an opening to things… I think with, and I'm speaking for the Chamorros, but it's true for all Pacific Islanders, that once you have the food around the table that it becomes a comfort zone for everybody. It breaks the ice. And you start to sit and you eat and the more you eat, the more comfortable you get, and the more you open up.*

Decision-making occurs through consensus. Seven of the eight research proposals reviewed by GCN to date have been approved, some requiring modification or clarification before final approval is granted. For example, in a review of a proposal aimed at replicating a program previously implemented in a Hispanic community, the meeting notes highlighted the research project would need to be tailored to the Chamorro community and its needs. This project, after modification and continued guidance from GCN, was ultimately approved and implemented. For the proposal that was denied, there were no elements suggesting a genuine partnership with GCN nor any apparent benefits to the Chamorro people.

Review criteria

The GCN review process examines typical IRB considerations, such as researcher qualifications, privacy, security, potential risks and solutions, as well as non-traditional items, such as organizational capacity and community specific or cultural considerations. Examples of questions and comments that would surface during GCN's review that may not typically be asked in an institutional IRB review include:

- Is this project relevant to the Chamorro community's needs?
- Does the community have the capacity to successfully implement the project?
- Will the community be given any kind of recognition for their input and participation in the project?
- Have all the individuals that are partners gone through all the proper training and certification?
- If conflict arises within the community during the research project, how will it be addressed?
- Are there resources available for the participants if any harm is caused?
- Are the data and final results going to be relayed back to the community after the project has been completed?
- Is there a community advisory board?

Ensuring the community's needs are met and the research methods and aims respect the culture is extremely important for GCN. As one of the GCN Review Process Administrators shared, the definition of what is ethical depends on what aspect or perspective of a research project is being considered. For GCN, community level considerations

are of primary concern, going beyond the physical or mental harm to individual study participants that institutional IRBs tend to solely focus on. In the following quote, a GCN Review Process Administrator describes how distribution of budget could potentially create an unethical situation:

> *It's not ethical… if it's top heavy with the university getting all the money and then the community only getting stipends, and very nominal stipends. And then also, the other part is what are we going to gain from this study, from this project? And the ethics and how is it going to be ethical to benefit the community, the researchers, and what is the ultimate outcome? It has to be beneficial… all around where the researchers and the community get benefit out of it because if the community don't get any benefit… If they just go in and they don't get nothing, then they're not motivated to do anything… it has to weigh out with the budget and what do they get out of this by them participating? But that's the big issue also, is that you have to weigh the budget out with whatever we need to do.*

Relationship between GCN Review Process & IRBs

In instances where a proposal requires review by multiple review processes or IRBs, it is typically reviewed by GCN first before going through an IRB. In one instance, a proposal went through both a university and a community IRB. Involved institutional IRBs have included the University of California – Los Angeles, California State Fullerton, San Diego State University and Claremont Graduate University. If a proposal must be changed to meet an IRB's recommendation, the proposal does not need to go back through the GCN review process because GCN would be a community partner involved in making the modifications. GCN and the involved institutional IRBs have

little to no interaction when reviewing the same proposals. As one of GCN's review process administrators shared, they had never met anyone from the involved institution other than the academic researchers. GCN does interact with the Special Service for Groups IRB as two GCN staff members serve as IRB reviewers. Having this interaction with a community IRB has helped build GCN's capacity as well as create a dialogue on research ethics in CBPR.

Comparison of GCN Review Process & Institutional IRBs

In comparing GCN's review process with institutional IRBs, GCN reviewers and an academic researcher identified several key differences. First, GCN's review administrators described themselves as being at a different capacity level than institutional IRBs. GCN's review process does not have a formalized, federally-recognized structure and operates at a different pace and volume of proposals than institutional IRBs. Further, GCN's review process is in its infancy. There is much for them to learn and to experience, as explained by one of the GCN review administrators. While institutional IRBs are comprised of health professionals and others well versed in research jargon, GCN reviewers include community members who are new to research. GCN's review process is gradually gaining a strong population of community members who are certified in the ethics of research involving human participants and comfortable with conversing about a research project.

The interviewed academic researcher whose proposal was reviewed by both GCN and an institutional IRB spoke to how review by the institutional IRB was necessary, particularly to obtain funding. GCN's review and ongoing engagement, however, was considered by the researcher to be essential for the success of the study. The researcher had an appreciation for the rich and in-depth

conversation that occurred during the meetings with the community partner, sharing "we'd never be as successful as we are if there hadn't been this rich conversation." By undergoing GCN's review and working with the reviewers and community partners every step of the way, the researcher gained a deep understanding for the Chamorro community and how the people operate. This contributed to creating study aims, methods, and protocols that were appropriate and effective for the Chamorro community.

While there was no conflicting feedback received from the GCN review process and the institutional IRB, the researcher highlighted the differences in review considerations and feedback received by the two entities. The institutional IRB was concerned with the privacy and protection of individual study participants. For GCN, the concerns were more extensive. As the researcher shared,

> *And the community side, they were interested in things, well, did the aims of the study meet the needs of the community? …Were the resources fairly distributed? Was the decision making process and the governance reflective of all the partners? Were the designs and methods appropriate? Did CBPR inform every phase of the study from conception all the way through analysis of the dissemination? These are things that [institutional] IRBs don't really care that much about.*

Benefits & Impact

GCN's review process has positively impacted the Chamorro community, the focus and conduct of research, the perspectives of academic researchers and funding agencies, and the organizational capacity of GCN.

Impact on community, reviewers and research

Through the research ethics review, as well as ongoing communication with the academic researcher, GCN increases positive impact on both the community and the research itself. GCN's review process has provided a safe and protective platform for the Chamorro community to become involved in research. As described by a reviewer, this has helped the community build capacity by allowing members to "get their feet wet, sit around the table and just talk about things." As explained by a reviewer, GCN's review process creates an environment where community members, especially community leaders such as family clan leaders or Chamorro social club leaders, learn about research, become comfortable with the language and the processes, and are able to confidently determine whether a research proposal "will work for our community." A GCN Review Process Administrator observed that building capacity in the Chamorro community includes serving in advisory roles and contributing to the pipeline of future researchers:

> *I think that there are more Chamorros involved in advisory or community advisory boards. We have more people involved in our projects, more young people getting involved in public health. And so there is that pipeline program where we work with [name of person] and some others in getting kids into public health.*

Along with building capacity within the community, GCN's review process has allowed the Chamorro community to have a voice in what transpires in their community. Research proposals channeled through the GCN review process allow for community members to tailor the proposal to fit the needs of the community. Rather than having outsiders tell

the community what needs to be done, the community may constructively share with researchers what needs to be done and how it may be accomplished. By tapping into the community's knowledge, this not only creates a more successful and effective research project but also creates a more genuine partnership between community and academic partners. Giving the community a sense of ownership over the research conducted in their community builds trust and gives credit where credit is due. GCN's review process has opened the door for community members, thus increasing the number of Chamorro individuals involved in research and increasing the Chamorro voice in research. In one instance, a GCN reviewer had the opportunity to give a poster presentation about research she was involved in as a participant that focused on a topic that affected her on a personal level. Research in the Chamorro population through the CBPR process is gradually becoming transformed to be more comfortable for the community and feels genuine to who they are.

GCN's review process has also had profound effects on the reviewers themselves. Not only is the academic community learning from the Chamorro community, but vice versa. As a GCN Review Process Administrator and reviewer shared:

> *It teaches me, it mentors me, and it builds my capacity. Not only to look at things on a community perspective, but as a whole with everybody involved.*
>
> *And I think for me, personally, I think just to be more educated and to help others be more involved and be educated as well.*

The GCN review process is credited with increasing research in general focused on Pacific Islanders. As explained by a GCN Review Process Administrator, this could be a result of more people serving on advisory boards and advocacy by community members previously involved in research:

> *I think also as a result of our review process, there are more projects out there that are involving or targeting other Pacific Islanders and Chamorros. And so, like [name of person] was saying, you have, in the projects that we've been involved with, you had study participants who, as a result of either their participation as a CAB member or as a study participant, they went from study participant to advocate…*

Along with the research review, GCN's community advisory board and ongoing involvement with the academic researcher has contributed to the shaping of the research as well. With the input of the Chamorro community on research that directly impacts them, they are in turn making the research more effective, beneficial, and successful for both the community and the institution.

Impact on academic researchers and funding agencies
Through GCN, the Chamorro community's increased involvement in the research review process has in turn created increased awareness and understanding of its culture and community structure. As described by a GCN Review Process Administrator, this is reflected in the culturally tailored research proposals that educate not only researchers but funders as well:

> *Having the review process also opened other people's eyes to when we look at culture and the practice of culture is how we as a community do things. And what is acceptable, what is not acceptable so it kind of helps educate the people who are actually the funders in their understanding of the communities.*

Impact on the host organization
GCN's organization capacity has grown throughout the development of the review process. As an example, with continual exposure to the review

process, GCN reviewers are more equipped to write research proposals for GCN. For instance, staff know what to look for and how to successfully critique a proposal. As shared by the GCN Review Process Administrator, the review process develops staff in a manner that promotes cross-training to ensure the organization and the review process are sustainable regardless of future transitions.

Challenges

As a small organization, the lack of resources, especially monetary, continue to be one of the many challenges to sustaining GCN's review process. With no budget supporting its review process, every meeting is conducted on donated time from community members and staff. Other challenges relate to the community, including lack of familiarity with research and associated administrative tasks, such as grant processing. When academic jargon is used in research proposals, community members feel uncomfortable or inadequate in their opinions and understanding. This has led to many potential community reviewers declining to participate in the review process. "Most of them will say they're not educated enough, they didn't go to college… those are the barriers that they use" shares one community review member.

Community members also lack trust in academic researchers who approach the community, and a level of hesitancy exists due to previous research in which academics took advantage of their community. If a research project has not been vetted and approved by the community or clan leader, there will be little to no participation in both the review process and the research project itself. What should be noted is that these community barriers stem from the negligent relationship academic researchers have had with the Chamorro community in the past, thus creating an atmosphere where trust and confidence must be re-earned.

Recommendations

Recommendations to strengthen the GCN review process

A number of recommendations for strengthening the GCN review process emerged from the focus group and interviews. These include diversifying the membership by adding men and young adults as reviewers and establishing a relationship with institutional IRBs in order to facilitate a cohesive review process.

While GCN would like to develop and grow its review process over time, staff and reviewers acknowledge that keeping the review process informal would make it most effective for the Chamorro community. In reflecting upon GCN's review process, reviewers commented on how the process is set up so that it is culturally acceptable to the community. In the Chamorro culture, there is no written language and information is relayed verbally from mother to child, hence the review revolves around a verbal discussion with food at the table and little documentation. The membership is comprised of all women; this can be attributed to how the women in Chamorro culture are the leaders of the family. GCN administrators and a reviewer shared:

Whenever you start to talk about documentation, you start to say, "okay we need to do this" or "we need to sign this" or "you need to…" But… everything with us is all verbal discussions…

I think you could say that our review process has been only a talking and not a written review?

Because our language isn't even a written language! …It's only talking! And it's our history that we have.

…Yeah talk story! Passed down from mother to child or your grandmother to your mother to a granddaughter kind of thing. So we relate that with…

…And just thinking, this review process is our community, the culture. The Chamorro culture is women leadership.

…No written policy because we're not a language! No men because men aren't the leaders of the family!

So we've been very cultural!

…Because then we're not culturally appropriate. And I think, that was the whole thing about research is that we wanted to make sure our involvement in research and especially CBPR, is because we wanted to show the academics that there is a way to research in our community. And that, what's really key is to be culturally appropriate and have everything tailored…

No forms! No sign-in sheets! Just a verbal process.

GCN participates in the Pacific Islander Community (PIC) Health Coalition comprised of Asian, Native Hawaiian and Pacific Islander researchers and community members in the San Diego area that are considering developing a community IRB for Pacific Islanders. PIC Health is looking at Los Angeles area models, specifically the SSG community IRB[2] and GCN's review process. As shared by one of the GCN Review Process Administrators:

What our ultimate goal is, because a lot of our projects work within collaboration with other Pacific Islander groups, we would like to see a Pacific Island IRB. And build the capacity there… And SSG's [IRB] is very diverse with academics and community folks and different programs, but we would like to see the same process for Pacific Islanders. So you get your researchers on the university level and then you get people involved with the aspects with various programs, from HIV to Hep B to cancer to chronic disease…

While there is interest by the PIC Health Coalition in developing a formal Native Hawaiian Pacific Islander (NHPI) IRB in San Diego, GCN reviewers feel it is important for the Chamorro community to keep its review process about conversation and the community. Although GCN's review process will continue to support and promote the development of an NHPI IRB, they have decided to maintain their GCN-specific informal review process for projects involving GCN as the community partner. When GCN has the opportunity to use the NHPI IRB, they will adhere to its policies and procedures. Reviewers expressed concern for the new NHPI IRB about the need to formalize the process, how this might feel awkward to the community and in turn, this may cause community members to decline participation in reviews and the research. In developing a NHPI community

review process, regardless of whether or not it is an IRB, GCN and its reviewers are seeking a balance between the westernized ideal of formalized policies with the cultural ideal of promoting discussion. As shared by one of the GCN Review Process Administrators:

When you run this organization and you run the IRB, okay, how much is it important to keep it in a culturally-tailored and to protect and promote the culture of your people! And how important is it to be westernized? …And so where's that balance? There needs to be a balance. Because, what we know from academics is everything, the data has to be visible. So how do you have… how do you promote data that's just based on discussion as opposed to based on paper?

Recommendations for other community groups interested in developing their own review process

GCN's Review Process Administrators recommend that community groups first determine if there is any community-based IRB nearby that could serve as its review process. If one exists, examine its viability, reliability, focus, and how often it is utilized. If no existing review process meets the needs of the community "then definitely consider starting one," but do so by consulting other established community IRBs and experts in CBPR review.

Recommendations to enhance CBPR

Based on experience working with community-institution partnerships, the academic researcher recommended the institutional partner have a representative from the institution to interface with the community partner to create an open, transparent, and healthy environment for communicating with one another. For instance, since the institution's finance department is considered part of the academic research team, they could meet in-person with community partners to dialogue on

budget issues. This will ideally lead to a more fruitful and genuine partnership between community and institutional partners rather than a top-down decision making process.

Summary Reflections

As reflected in the focus group, interviews, and meeting notes, GCN's community review process is designed to ensure that research projects are for the benefit of the Chamorro community and are ethical in all aspects, including both individual and community levels. Experiences of the past have cautioned reviewers to also ensure that research in the Chamorro community is more than just a novel project, but one that truly respects the community and provides sustainable positive outcomes.

The structure and feel of the GCN community review process reflects the traditional values of the Chamorro culture. GCN's community review process has allowed capacity building within the Chamorro community as more knowledge and exposure to health research continues to grow. Community members are able to become well-versed in scientific jargon and processes, allowing them to not only understand the research but to become comfortable critiquing and improving it.

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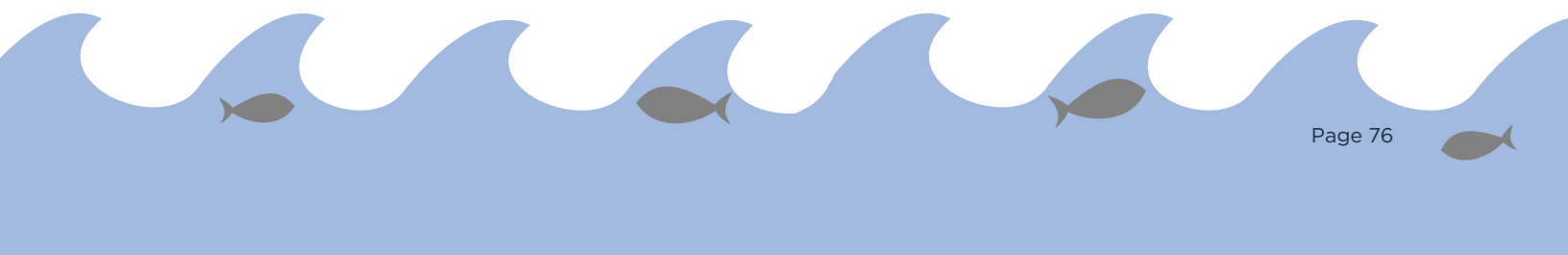
Center for Community Health Education Research and Service's Emerging Community-Based Research Committee: Practice-Based Research with Community Health Centers in Boston

Elmer Freeman, Alice Park, Nancy Shore and Sarena D. Seifer

…It's important that we start from the beginning and understand the need for individuals from the community to be a part of it through the whole complete process, and not just on paper, but to be honest and really have a percentage of participation. I've had a couple of experiences where that didn't happen, being misled, and it makes you a little hesitant sometimes in terms of how much you want to give and be a part of grants and even what level you want to be a part of it.

-CCHERS Research Committee member

Ensuring community engagement "through the whole complete process" of research is the vision of the Center for Community Health Education, Research and Service's (CCHERS) developing community-based research review process. This case study report provides an overview of CCHERS and its developing research review committee, including the history behind its development and the vision for how it will operate, as well as its anticipated benefits and challenges. The report furthermore looks at how the CCHERS committee compares to institution-based Institutional Review Boards (IRBs), as well as its relationship with these IRBs. The report concludes with a set of recommendations for community-based review processes and institutional IRBs. The report is based upon findings from an analysis of key documents guiding development of the CCHERS committee, a focus group conducted with five CCHERS committee members, and an interview with the CCHERS committee Administrator and Chair. This case study is one of five conducted as part of the National Collaborative Study of Community-Based Processes for Research Ethics Review. The study aims and methods are further described in the introduction to this report.[1]

Overview of CCHERS

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 federally qualified community health centers serving the racially and ethnically diverse populations of the City. Northeastern University serves as its host institution and sustaining partner, and CCHERS operates under Northeastern University's Federalwide Assurance. In 1997, the CCHERS partnership incorporated as an independent 501(c)(3) non-profit organization as its institutional and community partners determined it to be the most equitable way of sharing power and allocating resources for the partnership's work and sustainability. Its Board of Directors is comprised of representatives of the universities, hospitals, health centers and communities served by CCHERS. Through shared power

and decision-making they provide governance, make policy and determine strategic direction for the organization.

The mission of CCHERS is to promote the development of "academic community health centers," a term coined by the CCHERS partnership that refers to community health centers that integrate service, education and research to influence and change health professions education, improve health care delivery, and promote health systems change to eliminate racial and ethnic disparities in health. Fulfilling its mission to promote community-based health professions education, research, and service through partnerships, CCHERS has established the Edward M. Kennedy Academy for Health Careers public charter high school, a Community Health Service Corps, a Community Advocacy Program, the Boston Clinical Pharmacy Practice Network and the Community Health and Academic Medicine Partnership.

Overview of CCHERS' Involvement in Research

CCHERS first became involved in research when they were approached by Harvard to participate in an asthma grant, a topic of importance to the community. Through this research project, the community health centers involved in CCHERS began to realize there was some validity to research. Since then, CCHERS has amassed over 19 years of experience as a community-campus partnership and holds a leadership position in Boston, MA in community-engaged research. CCHERS and community health center partners have an established track record with research projects and processes that are implemented through an Agency for Healthcare Research and Quality (AHRQ) recognized primary care practice based research network. CCHERS' current research collaborations include twelve research projects, the majority involving community-academic partnerships. Areas of focus for these research projects include cancer

disparities, women's health, social and behavioral health, community research review processes, and community-engaged research. Most are federally funded through mechanisms that include R21, R01, P50, RC24 and UC1.[2]

CCHERS' research goals are:
- 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 the interest and capacity of the community to engage in and conduct academic research; and
- To develop common research agendas derived through consensus between academic and community partners.

Overview of CCHERS Research Committee

History of research review at CCHERS
CCHERS operated a Research Committee from 2009-2011 that determined whether the organization would support, endorse or participate in a given research project. The Research Committee was comprised entirely of CCHERS board members. During that time, the CCHERS Research Committee reviewed four proposals focused on asthma and social stress, racial discrimination and chronic disease, pediatric epilepsy treatment and a community health and academic partnership. These were also reviewed by IRBs at the applicable academic partner, including Northeastern University, Tufts University, Harvard University and the University of Massachusetts-Boston.

The Research Committee was dismantled when CCHERS became involved in a major

multi-partner research project requiring review by five IRBs. As described by the Research Committee Administrator, "that's when the committee sort of fell apart because we were so focused on responding to all these institutions externally that the committee [was] an added thing we didn't need…"

Re-establishment of a research committee
CCHERS decided in 2013 to re-start a process for reviewing research because of an increase in its involvement in research and demand from its partner health centers that "wanted us to have a process to vet" research through. As described by the Research Committee Administrator:

> *…We're seeing more…people trying to put their own things together, not being able to sustain it. And this isn't just the health centers, but there are community groups. … So it is pervasive throughout the community of people wanting some way of reviewing research to protect not only individual human subjects but also communities as a whole. It was just here, there and everywhere, no rhyme or reason… And because we are [in Boston], the culture where NIH dollars [are flowing], it's happening everywhere. The health centers have research fatigue as well with everybody just knocking at their door. So they want something that you can go to that legitimizes you and brings you out here if it's even relevant to what we want to do, so that's one of the reasons for the interest, sort of, the resurrection [in re-starting a Research Committee at CCHERS].*

In developing its revived research review process, CCHERS examined a variety of existing and emerging community review processes and community IRBs including those represented at a working meeting on the topic in March 2012.[3]

Envisioned role for the research committee
The CCHERS Board of Directors, under its authority in the CCHERS' by-laws, established the Research Committee as an ad hoc committee of the Board in January 2013. As described by the Research Committee Administrator:

> *The process of the charge was to look at how should CCHERS do some sort of review, some sort of vetting of research specifically for CCHERS obviously but also for the community health center partners and then there are a number of community based organizations that we partner with who have done research [and could use our review process too].*

As explained by the Research Committee Administrator, reviewing protocols "are just a small part of what the overall charge of the committee is." The Research Committee is primarily charged with developing and leading research projects at CCHERS. For example, they would be responsible for "understanding the centers and their environment and who is more likely to be engaged" for a particular research project. It is envisioned that research involving the community served by the community health centers would be generated and emanate from CCHERS itself. Another important role of the Research Committee is to provide research consultation and technical assistance for community health centers and other community groups approached to do research. In this way, the committee would serve as mediator for community-academic partnerships. As an example, CCHERS was previously approached by a community group involved in a partnership with an institution, "And they weren't playing together well so they brought us in to mediate that." As explained by the Research Committee Administrator:

So I could see groups like that coming to us as well. They get approached all the time, …[name of program] gets approached a lot with people interested in women's health and not really knowing [how to respond]. So it could possibly even evolve into us doing it for a fee that we would charge the community group who would pass it off to the academic institution…

The Research Committee is intended to become a permanent standing committee of the Board of Directors. Its intended purpose is to examine community level risks and benefits and ensure true community engagement in research, particularly in the research ethics review process, such as including the community in the institutional IRB application process. As explained by a university-affiliated committee member,

… It happens on the university side. So even if we're partners, oh I'll take care of the IRB…I know I can get it through. But me doing that or trying to get it through and doing the paperwork and wording everything how it's supposed to be because there is a lot of…legalese that needs to go through. And that's not engaging my community partner, and that's me with my institutional lens thinking about what the institution needs to hear in order to get the study through to approve it so we can get up and running.

The CCHERS Research Committee would review proposals where CCHERS is involved as a partner in the study. Northeastern University IRB would review all proposals as CCHERS' host institution, unless deferred to another IRB. In line with other standing committees created by the CCHERS Board of Directors, final decision-making on a proposal rests with the board. However, research reviews would be delegated to the Research Committee,

who would report back their proposed decisions to the board for final approval. Within the Research Committee, it is likely decision-making will occur through consensus. If researchers circumvent the CCHERS review process by going directly to the health centers or if the committee denied a proposal, as shared by the Research Committee Administrator, "there would be no role for CCHERS at all" and this would likely prevent the research from occurring. For example, while a researcher could approach one community health center, most research projects require involvement of multiple sites, and the researcher would likely need CCHERS to identify and secure additional partners. For this reason, in instances where a protocol requires multiple reviews, protocols should be reviewed by CCHERS before going through an institutional IRB. As shared by a Research Committee member,

I feel like the IRB can give approval because the study meets a set of standard criteria and has the necessary protections for human subjects but doesn't necessarily mean that you can actually do it in the real life setting or at the health centers. So I think they [referring to the IRB] could approve it, based on all that stuff, but if there's no buy-in from the health centers and there's concern from our committee that there's no beneficial impact for the patients and the health centers and the community, chances are they won't get that health center to be available.

Membership
Currently, the Research Committee is comprised of twelve members, one from a community health center, six with university affiliations and five community members who volunteer their time. Three are also CCHERS board members, hence the membership is broader compared to the previous Research Committee which was comprised entirely of CCHERS board members. There are nine females and three males serving on the committee

and the race/ethnicity of members are as follows: six African American, three Caucasian, two Asian, and one Latino. Members were recruited through referral by the Research Committee Administrator. Several members described gaining skills as their main reason for serving on the committee. As shared by one Research Committee member:

> *I'm interested in the ethics. I don't really under-stand all of this, and I feel as though by partic-ipating on this, I'm going to get some real skill and some understanding and I'm going to come out of it with something I didn't have before I went in. I can offer my information and my context and my knowledge and my experience up to date, but I think I'm really going to get out of this some real skills and it's going to enhance my understanding of the whole field. And there aren't that many places where you can get that... And I need it for things that I do. It advances me, I think it's going to advance me profession-ally; it's going to advance me in my efforts to be part of things.*

Two members viewed serving on the committee as an opportunity to bring about change, as they see the status quo as being at a "standstill." For exam-ple, a Research Committee member shared:

> *...There's a lot of things coming together around informed consent and the whole process ...and I just got very excited about this, because this is one that I felt we really did kind of better in [name of community],...and now that I'm here, I'm kind of seeing it's kind of going back, because it really was much more engagement and empowerment of the community in doing all the programs there...So this is very exciting to me because I think we are in a rut, and we need to be creative and innovative and change things.*

Moreover, one member commented that opportu-nities for community members to provide input on research is rare, and they wanted to be engaged in the solution. Two members commented they were previously or currently involved in other ethics-related projects in other cities in which they could see how community ethics review could be done effectively, and wanted to see this applied in Boston. Others saw it as an opportunity to learn from one another, to be involved in more commu-nity-related work and to realize and implement ideas for obtaining true informed consent.

Submission process and review considerations
While the Research Committee's submission process is still in development, one suggestion was to specify a timeline for when researchers should engage CCHERS for the review, such as before or after engaging the health centers as partners in the design of the study.

Committee members had several suggestions for issues to be considered in their reviews of research. As shared by a Research Committee member, a key aspect of the CCHERS review will be the community health center perspective, since insti-tutional IRBs cover issues related to protection of individual study participants:

> *I think the added perspective of does it fit the mission of the health centers, does it fit the mission of the community, does it fit the mission of CCHERS? Does it benefit the community and the health center? I think those are probably the questions that we should focus on because the other nuts and bolts stuff will be covered by the institutional IRB...*

Examples of review considerations include the following:

- Does it fit the mission of the health centers?
- Does it fit the mission of the community?

- Does it fit the mission of CCHERS?
- Does it benefit the community and the health center?
- What is the composition of the research team and is there community representation?
- What was the motivation for the research and was it community-driven?
- What is the depth of involvement of all partners?
- What is the dynamics between the partners?
- Does the proposed research bring direct benefits to the community in terms of jobs, capacity, etc.?
- Does the study budget include fair compensation for community partners (including but not limited to the actual study participants) and distribution of resources among partners?
- How are communities being compensated for their knowledge and time?
- What are the proposed hiring practices?
- How are community members involved and prepared to actively engage throughout the research process?

As a way to assess the partnership, one Research Committee member suggested having the research team attend in-person:

I think it's great if people can actually come in and present and then I could see if they even brought their community partner with them. Or like who they sent and how the dynamics were…

As a way to examine the budget, one Research Committee member shared,

I think there needs to be some community organizing around research ethics and ethical issues in research and what does it mean. And what does it mean to take even $10,000 to be a consultant on a research project that's an organization, you're going to end up doing $20,000 worth of work? And it's wrong…there should be subcontracts, there shouldn't be consultancies.

Comparison of CCHERS Research Committee & Institutional IRBs

Members identified similarities between the envisioned CCHERS Research Committee and institutional IRBs in terms of how both examine risks and benefits related to research participants. However, most CCHERS Research Committee members felt the CCHERS review process would be entirely different. The CCHERS review process will be developed with the community "looking at some of these things in a very creative way to get information that's timely, and that is respectful of people and just would put the priorities in a very different place." In developing the review process, CCHERS would identify limitations with existing review mechanisms and what needs to be done differently. As shared by one Research Committee member, CCHERS would "do it in a way that would allow people to really say what's on their mind and to have it incorporated into the process. … There's nothing to lose in the push to be a little different."

The relationship between CCHERS review and institutional IRBs will vary depending on the specific institutional partner involved in the proposed study. For example, being housed at Northeastern, CCHERS might develop a formal agreement with the university's IRB that builds from the policies and procedures that were in place with CCHERS' earlier review process. As described by the Research Committee Administrator, at Northeastern "we would really have a say, and one that they will listen to" and "where Northeastern would not accept their researchers doing anything [in the community] unless they came through CCHERS." However, it is unlikely CCHERS would have formal agreements with other institutions. As observed by the Research Committee Administrator, when hospitals do not accept their own medical school's IRB, it is unlikely they would accept CCHERS' community review. However, as noted above, not having CCHERS review a proposed study could make it

very challenging for an institution-based researcher to proceed in actually carrying it out.

Envisioned Benefits & Outcomes

One, it helps to educate the researchers and give them community orientation. Two, it helps to shift this conversation around risks and benefits so that the community concerns are front and center. And third, it creates opportunities for sort of institutional power to be centered within communities so that people have colleagues, relationships, resources to underscore what they need in research.

The quote above by a Research Committee member captures many of the envisioned benefits shared by the CCHERS Research Committee Chair, Administrator and members. Benefits fell into two broad categories: ensuring a community-driven process and serving as an educational and training resource both for community members and researchers.

Ensuring a community-driven process

In thinking about the development of the CCHERS' review process, one member spoke directly to the importance and value of community in determining how and whether research occurs. As the member shared, "I mean you need experts, and the community are the experts. So why would you ever even conceive of doing anything at all without going to experts and getting their advice, and having them guide this situation?" A community driven process also could help address the concerns that the substantial research dollars awarded to institutions in Boston do not adequately engage or empower communities to address health disparities. Along these lines, one Research Committee member reflected,

I mean, if there's so much money coming into an area that's really under-resourced, why is that? Why aren't more people employed, why aren't more people getting an education? There's lots of ways you can spread that money so that it has a ripple effect and it has a way of being an investment rather than something that sort of sucks everything out of a community and goes to the suburbs.

The community-driven nature of the CCHERS review could, as shared by a member, result in "some of these disparities and these inequities are going to begin to change." The member further elaborated previous "research has not been guided by the people that need to do so in order to try to get information that can help to deal with these issues. I think we're looking at the wrong stuff a lot of the time." The CCHERS review process would have the ability to attain the goal of addressing inequities by engaging the appropriate people in the community to create change. Other envisioned impacts include "more education, empowerment, engagement and everything of an entire community so they feel not so helpless about issues."

Serving as an educational and training resource

For some committee members, the benefits of the committee extend beyond serving as a review entity to include CCHERS becoming a resource for both community and academic individuals and groups. One member saw CCHERS becoming a place that facilitates or hosts "opportunities for people to network, to engage. If you put resources together in terms of sort of funding for it, if people can have conferences and can really provide a rich resource I think for communities to have these kinds of dialogues and to sort of think, and that creates power in a sense." Another member mentioned the potential value of CCHERS being a training center for people both from the

community and academia. In terms of community training, one member felt that by serving on the Research Committee community members could become prepared to serve on institutional IRBs. This in turn would enhance institutional IRBs by bringing them more community perspectives. As this individual commented,

Using ours as a way of training people to sit on the institution's IRB. As a way of including more community, diversification, gender, race, ethnicity and the whole nine yards. So that's part of this as well. That's why I say, actually doing a review is a small part of a broader agenda. So, for instance, we're looking at some of these training grants to actually train, not only our committee, but others on how to do it. Getting people to feel comfortable taking the human subjects CITI and stuff like that.

The Research Committee was also viewed as a resource for educating academic researchers. Committee members spoke to how researchers will gain insight and possibly new knowledge by submitting their proposals through a community review process. As one member shared, "you send [your proposal] in and they give you comments back that you wouldn't have thought about. And you go…well …maybe I should do it X, Y and Z. The things that you're going to learn or you're going to get taught are not going to be the same things that one of the academic institutional boards is aware of." As an example, one member spoke to how institutional IRBs may focus more on "covering the liability of the institution," while the community process could help people think about "stigma that could come out of a research project that's related to the risk of doing work within a broader community." Another member shared that ideally over time the knowledge shared through the community review process can "create change within the institutions." Another member

anticipated the committee's role in a more formal training process for researchers, noting "I'm talking PIs getting certified and being trained by the community."

CCHERS review was seen as having the potential to impact research by generating interest on the academic side in community partnerships. This would lead to more research "done with communities and in communities…to make it more relevant." The impact on researchers might include a broader perspective that includes community impact:

I think from a researcher's perspective…it helps broaden your perspective a little bit. Sometimes you're just so focused on doing the study and trying to get the participants…But to take a step back and see the processes, and think about the impact on the community and impact on the health center as well. Sometimes we're just so focused to get it done, that we don't take a step back...

Vision for the Future

Research Committee members shared their five-year vision for the review process. Members hoped the committee would have a review structure in place, be recognized as a valuable resource, and have a long-term sustainable funding stream, preferably through independent money to protect against interests that may want to control its work. A member commented on the hope of integrating technology into the process, such as becoming less reliant on paper. Members hoped to see an impact on research as shown by "more engaged research being conducted at the health centers in the community." Members also hoped the review process would have an impact on institutions:

They're feeling our presence in a supportive way. But that they know that there's another type of review that's happening and that maybe we're even a resource for institutions as well. We're doing some consultation and training IRBs locally. And we'll train NIH.

Another hope was to see more diversity in the conversation around research ethics, such as through engaging more young adults in the 20-30 year old age group and particularly people from the community in the area, including Roxbury, Dorchester and Mattapan. As shared by a Research Committee member:

I would just say that 5 years from now, I would hope that the voices in this kind of conversation around ethics and IRB becomes diverse and that there's an infrastructure for supporting that. Diverse within communities as well as opportunities for folks in the academy and in the community to sort of talk things out and move equity forward.

Related to infrastructure, this could include hiring community-based people for research projects and developing their skill set. As shared by a member, "the best skill set to have in a city like Boston is a research skill set…there's no difference in training an undergraduate research assistant or a graduate research assistant than training a community research assistant who maybe has less than a high school degree. Because the skills that you need, you need to be personable, you need to be able to engage people, you need to be detail oriented, I mean… there's a job market for that."

Anticipated Challenges

Committee members anticipate a number of challenges related to five broad categories as the

Research Committee gets underway: developmental challenges, community compensation, previous negative experience with research, competition among non-profits and institution and funding agency concerns.

Developmental challenges
Staying focused on maintaining the vision and priorities needed to develop the Research Committee was identified as a challenge. Navigating the development of the review process must take into account the different experiences and expertise of the involved members. As one Research Committee member shared,

There'll be different levels, as with any IRB, different levels of scientific understanding, different levels of understanding the community and the health centers. It will just take us time to learn how to speak each other's languages and get around that… Trying to get everyone's perspectives and understandings, trying to have them on the same page.

A potential challenge facing the committee, according to one member, were meeting expectations based upon an unrealistic timeframe. This member spoke to the need for a planning phase to develop the infrastructure and relationships needed to make the review process effective and sustainable. Her concern was the development of the review process might be too rushed and underfunded. As she shared,

It's going to take time because you want to engage the community in how to do this right, if you're going to do it at all, and that's going to take a bit of time. So someone has to be willing to invest in an institute or whatever it is so that there's a planning phase where you really, really have

time to develop things, and I'm concerned that it will be very underfunded and then people will have the same problems over and over again. It just takes that investment initially to create something that then can be replicated if it's valuable and create…almost a cohort of people that can help to then make it more available.

Related to this developmental trajectory, other concerns were the potential for failures or glitches to derail the process, as well as the risk that the initial enthusiasm or commitment for developing the review process would wane over time.

Community compensation

Members also spoke about the challenges associated with ensuring appropriate compensation for community-based committee members and community research partners. As one member pointed out, for some, serving on the Research Committee might fall within the scope of their employment (i.e., at a university or a certain community organization), hence they would be compensated. Some community members, however, are not affiliated with an organization that can compensate them for serving on the committee. Given the workload and time commitments for members, the need to ensure greater equity in compensation exists. As one Research Committee member shared,

The other issue is that as we offer these institutes and the rest of it, and people have to review this material, they need to be compensated for their time. Because everybody is sitting at the table who are compensated by the organizations or the fact they're going to get money out of the research project or something, but the community person is expected to come and get a small stipend or no stipend and to be really up to par with all this. And they need to have a printer at home and paper at home and ink at home, you don't read this stuff off your smartphone.

Another member spoke about the importance of talking about compensation upfront in order to "make … sure that people are respected and have what they need to do the job." In addition to paying members for their time and expertise, another member discussed the value of offering certification in community-based research and research ethics that would formalize the education provided to committee members. These efforts in turn could facilitate community-based members becoming members of institutional IRBs or other community-based review processes.

Committee members also noted the unrealistic expectation for community organizations to provide in-kind support to supplement a research budget. As one member shared, "if anybody gives me any in-kind contributions, they better not, because the truth of the matter is that they can't afford it."

Previous negative experience with research

Community members may also be wary of the promise to reduce health disparities by becoming engaged in seemingly promising research projects. This wariness may be based upon seeing how these supposedly innovative approaches in fact have been attempted in the past with little success in making a difference in health outcomes. This wariness may be further compounded if people were civically engaged in the past, and sacrificed their time and energy to make a difference without seeing actual benefits. This poses a challenge both in recruiting community members to serve on the Research Committee and for implementing community-engaged research. As one Research Committee member described:

Because people forget that what happens to the community is that people will come in and say, you really need to participate in this because it will be good for you, it will be good for your family, it will be good for your community, and

you need to come to the meetings and you need to do, this is what people do, this is what communities do outside of your community. They come to the table, they work to the benefit of their community they're civically engaged, they give of their time. Well, I think that's a lot of crock because in our community, we've been doing it for years, and the same disparities and the same problems are there. Literally, there are people who are my age that can go back and look at it and recognize that this has really been a process that has been a really long process, and we're still at the same point. So I think that that's difficult. The conversation has to change because there's just too many people out there that went through that process over a number of years and know that that's not the case. Things do not change, we did give of our time, and fully of our time, often to the detriment of our own families and our own personal life and I think that they're not going for that anymore.

Different approaches to research are needed in order to see different outcomes, for example eliminating health disparities. In part this requires thinking about what it takes to build trust between researchers and communities, and to strategize on ways to "infiltrate the system to make change."

Competition among non-profits

Another challenge centered on the potential for non-profits to compete with one another over research dollars. This can be particularly challenging when non-profits are struggling to make ends meet. Ideally the development of the CCHERS review process would enable communities to come together and move beyond competing with one another. By developing more of a collaborative approach to research, nonprofits may also be better positioned to critically assess the issue of and advocate for fair compensation.

Institution and funding agency concerns

Committee members envisioned challenges stemming from how researchers and possibly funding agencies think about what it takes to develop an ethical partnership. As an example, researchers who seek letters from community "partners" last minute without ample time to work together on designing and developing the research. Institutional IRBs may also be less adept at assessing supposed community-based participatory research (CBPR) proposals, as compared to community-based review processes. In thinking about CCHERS Research Committee membership, people will be better able to think about such ethical issues as how are communities being compensated for their knowledge and time, what are the proposed hiring practices, how are community members involved and prepared to actively engage throughout the research process. One member spoke to how variance existed across institutional IRBs regarding their openness and understanding of community partnerships.

Another possible challenge for CCHERS related to institutional IRBs was described in terms of "pushback" or a questioning of what the CCHERS review process is, why it exists, and who serves on it. This triggered a discussion of the need to educate institutional IRBs regarding what are community review committees, and what purpose they serve. Pushback may also come from researchers, especially those who already have to submit their proposals to different review committees. For example, one Research Committee member shared:

So at [one university] you had to go through the IRB there, you have to go through this [CCHERS committee]. And then there's also [other institution's] Research Subcommittee, which is composed of some faculty who are at [this university] as well as faculty members at some of the health centers. So you present your research there as well, and then in order to have

a study conducted in one of the [other institution's] health centers, you have to get the signature of the executive director as well. So it would just be one more layer.

Rather than pushback, other members raised the possibility of university IRBs co-opting the review process, because "they would have the money and the power to be able to do that." Especially when the research grants flowed through their universities. They further raised the issue of "how do you fund something and allow it to really be what you want it to be without institutions and people who would be sent by their institution to control it."

Recommendations

Committee members made recommendations in three broad areas: committee recruitment, composition and support; review process procedures; and connecting to the broader context.

Committee recruitment, composition and support
Ideas for future recruitment of committee members include obtaining recommendations from the community health centers with interest in having "some of their community board members serve on it." Categories to guide membership might mirror those used by the CCHERS board, which include institutional, community health center, community, and an undesignated category. Other thoughts for membership include consideration of skill sets to ensure expertise represented in the areas helpful for the review:

So when you asked me about categories of membership I was actually thinking of going to answer about skill sets. So, for instance, I don't have a lawyer on my board at CCHERS but I would like to have a lawyer on this review

committee… Somebody who actually has some expertise with the IRB…

Recommendations on membership include increasing the number of community members on the committee. Other recommendations for membership included having a combination of community health center and consumer representation. While having representation from all health centers might be unrealistic, it was suggested to rotate health center representation to ensure the voice of the health center in which research is taking place. A couple of suggested models were proposed. One was to model the guidelines of the IRB accrediting body by specifying a percentage requirement for community and academic representation. Another model shared by the Research Committee Administrator might follow the community health center movement in that 51% of the board is comprised of patients/clients.

Recommended support for members included physical support, such as office space, computer and printer. Regular training opportunities was another recommendation, specifically on technology and attending national conferences, so members may gain exposure locally, statewide and nationally "so that they feel like they're part of a larger community." Having members involved nationally was viewed as "actually making a change nationally, because then the face of who is at those conferences begins to look different, the questions and the conversation begin to shift."

Members recommended the development of a system for member certification. Building in an educational track for members may result in increased ability to become involved on an institutional IRB or other community review

boards. Developing paid positions for community members as part of the review process activities was viewed as a means for building social capital. Funding steams could come from three sources: building into research grants, charging a fee for reviews, or tapping into hospital funds for community health initiatives.

Review process procedures

Two general recommendations emerged for CCHERS' review process as well as for institutional IRBs. The first was to allow research teams to submit letters of support in alternative formats, such as audio or visual evidence indicating the partnership. A second recommendation was to consider reviewing proposals prior to submitting for funding, as once it is funded, it may be difficult to change the protocol or have genuine input.

Connecting to the broader context

The final recommendation was to ensure the CCHERS review process fully accounts for the broader context. More specifically that the review process is not disconnected from the realities of the surrounding communities, and instead helps to foster opportunities for communities to come together and have a voice regarding existing inequities. Connection to the broader context also included the need to be aware of and engaged in relevant changes, such as staying current on changes occurring in the funding environment.

Questions members felt they should consider in developing the review process included: are there other community or academic partners that share a commitment to have a positive impact on how research is conducted in communities, do other community groups exist that might want to partner in co-developing a review process, and what funding mechanisms exist to sustain one's review process?

Summary Reflections

CCHERS has witnessed an institutional IRB process that has become increasingly convoluted and bureaucratic and a system that is more about protecting research institutions from liability than protecting study participants. For this reason and because institutional IRBs are unable to fully evaluate ethical issues related to CBPR, CCHERS is re-establishing a community research ethics review process.

CCHERS Research Committee members are eager to bring about change in the way community-engaged research is conducted in the Boston area and to assure the ethics of community participatory research projects. Some members have negative experiences where the community received no benefit from the research, while others have seen CBPR done in a more authentic manner in other cities and want to see this replicated in Boston. The Research Committee, comprised of numerous community members, has an urgent desire to address disparities and inequities that the community has faced for years and is excited at the prospect of finally having research guided by the community so they may begin to address the real issues at hand.

The impacts of the research review process could be far reaching. CCHERS hopes that through training and consultation, community members may become well versed in human participants protection so they may serve as members of the Research Committee and institutional IRBs, and they are hired to work on research projects. As more community-engaged research occurs in the Boston area, institutions would become knowledgeable on CBPR principles and IRBs would become educated on ethics related to community-engaged research.

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The National Collaborative Study of Community-Based Processes for Research Ethics Review: A Cross-Case Analysis

Nancy Shore, Alice Park, Paige Castro, John M. Cooks, Elmer Freeman, Mei-Ling Isaacs, Lola Sablan-Santos, Eric Wat, Elaine Drew and Sarena D. Seifer

The bulk of the research is from the majority of the population. … Why is it that for the groups that we represent, whether it be native groups or an ethnic group… there seems to be just that inherent thought that anything goes. So… individually we push, but I think even more so…this is a chance for us to come together and… make a group statement… to combine all of these fronts and say … business as usual is just not going to happen. …Because for so long…we're seeing all the same kinds of things…but how do we get past that? … How do we get beyond Tuskegee?

-Co-Investigator John M. Cooks, Galveston Island
Community Research Advisory Committee

In order to more fully understand the operations and impact of community-based processes for research review, Community-Campus Partnerships for Health (CCPH) and University of New England (UNE) partnered with five community-based organizations (CBOs) to conduct in-depth case studies of their community-based review processes (CRPs) and analyze the cases for cross-cutting themes and recommendations. See table 1 for the name and location of each CBO and type of CRP it operates.

Table 1. Community-Based Study Partners

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

Data collection in year one of the study included the following for each of the five 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. In year two, the study team gathered in-person to engage in a focus group discussion with the goal of further identifying CRP promising practices and making

recommendations. The discussion was informed by the study team's experiences with assessing community-engaged research and their critical review of the individual case studies. The study aims and methods are further described in the first chapter of this report.[1]

This cross-case study report discusses the similarities as well as the differences between the five CRPs; makes recommendations for key stakeholder groups, including community groups interested in developing or strengthening a review process, institution-based Institutional Review Boards (IRBs), funders and policy makers; and articulates important next steps. These recommendations and next steps aim to support emerging as well as existing CRPs and contribute to a more nurturing research environment for communities.

Similarities Across CRPs

Mission, history and commitment to capacity building

The passion in which the reviewers from across the different sites come to the table was very inspiring. There was such a clear idea of why people were at the table. Everyone could strongly point to "it's about the community, it's about doing the right thing, it's about respect, it's about justice."

-Study Principal Investigator Nancy Shore, UNE and CCPH

All five CRPs developed to ensure community voice in defining research, ensure ethical research, protect the community in their interactions with researchers and build community capacity. They shared an underlying commitment to the communities they serve and a similar history in their origins. While each CRP serves a distinct geographic or racial/ethnic community, all focus on underserved populations. Each CRP began out of concerns around

how research was conducted in their communities, with POL-IRB and GCN responding to previous research abuses. Co-investigator Lola Sablan-Santos from GCN spoke to the challenges the Chamorro community had experienced with research, drawing a connection to the history of POL-IRB,

We were all concerned with the way academic researchers were doing research on our communities… the [Native Hawaiian] women [in the POL case study] who said that researchers had come to her family and did all this research because of a genetic situation, and they weren't given any information and told anything about it. And then again, two years later they still hadn't received any information. Same like GCN, with the Chamorros… about the helicopter research. They come in… take the information and never come back…So all of us were focused on how are we going to ensure that research done on our communities is ethical, but we as a community will be able to say yay or nay we want to participate in it… We're all focused on making sure the communities are protected and that we want more community involvement.

The CRPs in our study also share a commitment to community capacity building. As co-investigator Eric Wat of SSG IRB shared,

One commonality is really capacity building on a couple of levels. One is capacity building for the organization in terms of having infrastructure to do the research. But I also see capacity building in individual community members… for those who served in the review process especially to become better researchers. But… really looking at community members, not only as research subjects, but potentially as researchers themselves, right? So their function is not just to do outreach for the academic researchers, but

potentially as researchers themselves, right? So their function is not just to do outreach for the academic researchers, but actually be involved in all the facets of the research process, from design to dissemination. So I thought that was really, is really interesting that we're all there to protect the community but we're also there to build the community up.

Similarly, the CRPs also share a commitment to building the capacity of academic researchers to enhance their abilities to effectively engage with communities. While all the review processes work with the researchers who are submitting proposals for review, POL-IRB also provides training free of charge to medical students at one of their local universities.

Ethics & Integrity Issues

Federal requirements "plus"

Ethics and integrity issues considered by all the CRPs included federal regulatory requirements as well as community, cultural and social justice considerations. The federal regulations are a requirement for the community-based IRBs (POL-IRB, SSG). All four CRPs additionally consider ethics and integrity issues beyond the regulatory requirements, which were described as inadequate particularly as relates to community-engaged and genetics research. CCHERS is also committed to considering both the traditional and more community or cultural oriented issues. As explained by co-investigator Mei-Ling Isaacs, POL-IRB,

There are two different sets... You've got the federal set and you've got the cultural set. You know these are…totally different. The federal regulations and their ethics speak to whether or not you are adhering to federal regulations. And if you are, then you're good to go. But you may be in total violation of cultural ethics. And so having community groups review is giving the researcher both the research ethics and the community or cultural ethics. They don't always agree... The federal dismissed some things, cultural say 'you can't dismiss it, that's core to who we are.'

Community and cultural considerations

Community and cultural considerations are considered by CRPs in research reviews, and may be embedded in the application questions or through the process, such as in the reviewers' checklist (SSG, GICRAC, POL-IRB) and in the requirement that the academic and community partners attend the review meeting together (SSG). The value of requiring community and academic partners to attend together, as shared by co-investigator Eric Wat, SSG IRB, is for the review committee to really "see what the dynamics are… are they on the same page about what needs to happen? Do they talk to each other? Do they seem like they have a good relationship?" In thinking about similarities across the sites, Study Coordinator Alice Park, CCPH spoke to how each of the CRPs are committed to "leave a genuine benefit to the community" noting that this is particularly important given the "history of previous research causing harm."

Table 2 illustrates the types of questions that the CRPs in the study are asking of the research proposals they review, organized by theme (pulled from CRP application forms and reviewer checklists). Many of these questions go beyond those required by the federal regulations to assess community and cultural considerations.

Table 2. Questions that CRPs Ask of the Research Proposals they Review

Theme	Questions
Justification for research	• What is the community/communities of interest for the proposed research? • How have you solicited community input to determine research project goals, research questions and potential benefits to the community? • Does it fit the mission of the health centers? Does it fit the mission of the community? Does it fit the mission of your organization? • What was the motivation for the research and was it community-driven? • Is the proposed research focused on a significant or pressing concern to the community?
Partnership and equity	• Will the community be given any kind of recognition for their input and participation in the project? • Is the organization partnering with other community-based organizations for this research project? If so, what would be the role and responsibilities of each partnering organization? • Are partnership terms equitable/satisfactory to the community? • What type(s) of technical assistance, if any, would the organization anticipate needing throughout the course of this research project?
Conflict resolution	• If conflict arises within the community during the research project, how will it be addressed? • Are there resources available for the participants if any harm is caused? • How is the participant/community informed if there is an adverse event?
Data ownership/ agreements	• Who owns the data? • How is permission from the community group demonstrated, e.g., is there a memorandum of agreement?
Budget	• Is there sufficient funding/budget to complete the research? • Does the study budget include fair compensation for community partners (including but not limited to the actual study participants) and distribution of resources among partners? • Does the community have the capacity to successfully implement the project? • How are communities being compensated for their knowledge and time?
Community involvement	• Who are the community facilitators or gatekeepers? • How is the community kept informed as the research advances? • What happens after the study is over? Will the collaborative be disbanded? Will there be an intervention? • Is there a community advisory board? • How are community members involved and prepared to actively engage throughout the research process? • What is the depth of involvement of all the partners? • Is there time for us to become involved, on the study collaborative or on the planning of the study? (continued)

Theme	Questions
Community benefit	• How does the process and anticipated outcomes of the research project benefit the community and its various stakeholders? • Does the proposed research bring direct benefits to the community in terms of jobs, capacity, etc.? • What new information will be generated, and how will it be used? • Does the research project/grant proposal have the potential to advance the health in the community of focus?
Research team composition/ experience	• What is the composition of the research team and is there community representation? • What experiences does the organization have in engaging community and its various stakeholders? • What efforts have you made to ensure that the research team has the sensitivity to understand the social, cultural, and environmental context of the community of focus? • What is the researcher's experience working in the community? With what communities? Do they have a history with this community?
Cultural considerations	• Are there cultural harms in this research? If so, how are these being addressed and minimized? • Are efforts to ensure sensitivity to understand the social, cultural, and environmental context of the community of focus convincing?
Dissemination	• Are participants involved in the presentation? Can they have input on where and how study results are made public? • What happens to study results? Will they be published? If so, where? Will there be a press release in the local paper(s)? Are community members involved in the writing of the final report or article? Will results be presented to the community? Where and how?

Community Engagement

All of the CRPs in the study share a commitment to privileging the community voice in their review considerations. One means of accomplishing this is by examining whether the community is an equal partner in the research. Protocols are reviewed with an eye towards determining whether the community has been engaged in the development, implementation and dissemination phases of the research. This may require, as co-investigator John Cooks, GICRAC describes, adding "back door CBPR" if a protocol failed to include the community in the planning phase, and offering suggestions for greater community engagement in the research moving forward. CRP reviewers consider no community involvement or lacking involvement in a meaningful way as unethical. This would include protocols written exclusively by an academic researcher with no community involvement, inadequate or non-existing stipends for the community, or lack of a mechanism for reporting study results to the community. As shared by co-investigator Lola Sablan-Santos, GCN,

> [GCN] turned down [a research proposal as] it was written by the researcher… everything was written by the researcher. Didn't have any community involvement whatsoever. There was nothing about even providing community with stipends for their participation or even a report

back and so our reviewers just said flat no…. if you're talking about CBPR … to have some researcher come in and say, 'I've got this project, I want you involved in it, here it is!' That's not right at all. And I think our communities are now savvy to this whole process.

The reviewers also look to ensure communities are appropriately recognized and compensated for their expertise. GICRAC and POL-IRB request researchers submit their budget to determine if the community is compensated accordingly. As co-investigator John Cooks, GICRAC reflected, "we have to say, 'is it ethical to expect me to hold these meetings every two weeks and then you not provide me the resources to do it?' Because out of those meetings is going to be everything that you are going to report back on and get tenure." Money also equates to power, hence the budget review serves as an analysis of power, an important issue particularly for partnership projects. Another example of the budget review as an ethical issue relates to in-kind, such as whether it is ethical to expect a community organization to donate weekly meeting space for a project. As explained by co-investigator Mei-Ling Isaacs, POL-IRB,

It tells you first of all, whether or not you've got the money to do the project because a lot of projects go under because they're under funded. It tells you who's getting paid. It tells you how much is allocated in the different areas… And if you are truly a partner with a community group, are they getting a fair shake here? As our review says, if you're a partner, you get one half. That's what partnerships are all about. But this is ethical for us, these are ethical questions, and we had projects go back to the drawing board to re-allocate some funds, even if it's already been set. Some of them don't come to us until after they get their money. So, they just have to go out and get more money.

In discussing the value of reviewing the budget as part of a research ethics review process, other CRPs in the study spoke to how they may now implement this as part of their review process. As co-investigator Elmer Freeman, CCHERS observed, "if we can't see the budget, we can't do a review." Along with the need to look at the budget, the CRPs in the study pointed out the importance of community groups carefully reviewing any sub-contract issued by the involved academic partner and developing more of a relationship with the partner's fiscal department. Elmer Freeman reflected upon his experiences working with academic researchers as a means to underscore the importance of understanding the fiscal policies of academic institutions:

I have one person that writes the science and then I got six other people that I deal with to get a subcontract. The researcher doesn't know anything about indirect rates. They don't know anything about off-campus indirect rates. They don't know anything about the research administration side of it. … so I put it into our review process. I think it is an educational process for the researchers to deal with the institution. Not only for the community to understand what's going on, but for the researcher to actually be able to go back and be your advocate within the institution once they get an understanding of it.

Community Benefit

All of the CRPs in the study assess whether the research will leave a sustainable and tangible community benefit. Their definition of "community benefit" includes decisions and actions that occur while the study is underway (e.g., ensuring that community partners own the data, sharing findings with community members in a timely and appropriate format) as well as longer-term benefits that may not be evident until after the study (e.g., examining whether the proposed research will build

capacity for researchers based in the community, will develop transferable skills among community-based study team members). GCN asks specifically about data ownership and control to ensure this information source remains with the community, and all the review processes stipulate that data is not used beyond the stated purpose. As another means of providing community benefit, GCN and SSG examine not only if there is an adverse event protocol that provides resources to individual participants, but request that a referral list be distributed of organizations that provide accessible, affordable services in the language spoken by participants. Such a resource list allows research to leave a tangible benefit to communities after the study has concluded.

As another means of giving back to the community, the CRPs in the study examine whether protocols exist for including the community in dissemination of study findings. Dissemination should go beyond publication in a peer-reviewed journal, and include sharing and discussion of study results in a format that is accessible to the community, such as through community forums and report-outs at community meetings. POL-IRB's progress reports ask specifically how results were shared with the community. Only POL-IRB has implemented a publications policy requiring the review of the final report and any publications resulting from a study. This allows the community a means to have a voice in how the study findings are disseminated. As explained by co-investigator Mei-Ling Isaacs, POL-IRB,

One of the reasons we have this little thing in there about reviewing final reports or publications has to do with group power. And even though we try to deal with keeping the integrity in the forefront in any research project, it's what is published, what is put in the report that is actually the last product that can cause tremendous group harm – if it isn't structured the way that is balanced or reports what it's supposed to report. Publication is, for us, very, very important in group harm.

All of the CRPs in the study also attempt to raise the community voice in research through community capacity building. Protocols are reviewed to determine if community members play a role beyond outreach or as research participants. This might occur by ensuring appropriate support and resources to have community members assist in designing the study, serve as research staff, or actively participate in the dissemination activities. This allows community members to develop valuable research skills that are also transferable to other fields, resulting in long-term benefits for the community as a result of the research.

Social Justice Orientation

All of the CRPs in the study view proposed research – and their role in research ethics review – through a social justice lens. Social justice requires CRPs to critically assess such issues as power and equity, as well as carefully examine the social, cultural, and historical context of a given proposed study. The CRPs acknowledge that a social justice orientation deviates from what is outlined in the federal human participant regulations, and goes beyond the Belmont Report's conceptualization of the principle of Justice.[2] A social justice orientation is aligned with the values and intent of the community review processes, and should not be viewed as problematically biased or less invested in scientific rigor. As shared by study principal investigator Nancy Shore, UNE and CCPH,

It's about social justice and sure, if you don't think about social justice and your norm is to just sort of think about things narrowly without context, sure what we're doing may seem political but okay fine if that's the way you want to frame it then let's embrace it. ...There's such a huge need to broaden what people think about when they talk about ethics...something that

really stood out in terms of feedback to what the POL process was about. But you consider cultural considerations, you consider historical pieces, and that's somehow deemed 'political'?… There needs to be something that addresses that narrow conception.

Differences across CRPs

The people involved in the [GCN] review process just want it to be a review process. They don't want to establish an IRB that is Chamorro-specific. They just want to review the projects and give input… they just want to be able to review the proposals that are coming to GCN and to say 'yes' this is a health disparity that we want to address. Yes we want to participate in this and they're giving us the opportunity to learn about our community. And that's what they want now. Whether or not that's still the case a year from now… I don't know. But they have control.

-Co-investigator, Lola Sablan-Santos,
Guam Communications Network

Differences among the five CRPs fell into three major areas: 1) communities served, 2) structure and 3) practices or policies. For three of the review processes, the communities served are specific ethnic groups: Pacific Islanders in the case of GCN, African- Americans for GICRAC, and Native Hawaiians in the case of the POL-IRB. For SSG, the communities served include mental health consumers, ex-offenders, and people who are homeless. Ultimately CCHERS will be serving individuals who access community health centers in Boston.

In terms of structure, POL-IRB and SSG are federally recognized IRBs, GCN and GICRAC

are community-based review processes, and CCHERS is a developing review process. Several times during the focus group discussion, the study team emphasized how becoming a community-based IRB should not be considered an end goal. As Lola Sablan-Santos explains, GCN reviewers do not currently want to become an IRB. Some of the practice and policy differences emerge due to structural differences as POL-IRB and SSG are required to adhere to the federal human participant regulations.

Other practice and policy differences emerged due to community preferences and experiences. Examples of these include:

Requirement for researchers to attend the review meeting: SSG and GICRAC require this, while POL-IRB and GCN do not. POL-IRB initially required the researcher to attend the review meeting, but based upon past experiences found that the review process moves more effectively if the POL-IRB administrator works with the researcher in advance of the meeting to sort through potential questions and concerns.

Written policies guiding the review process: SSG, GICRAC, and POL-IRB have written policies, while GCN does not. GCN's decision to have a primarily discussion-based review process reflects the Chamorro culture's oral traditions.

Membership requirements: POL-IRB and SSG reviewers reflect a combination of academic and community members, while GCN is solely community members. While GICRAC has both academic and community members, only the community members can vote on the protocol under review. CCHERS envisions a combination of community and academic reviewers.

Engagement in developing the research proposal: GCN and GICRAC review committees are

actively involved in shaping the design of the research proposal before it is reviewed. This includes ensuring proposals are aligned with a CBPR approach. If a proposal has already been written at the time of submission to GCN and GICRAC, the reviewers will work towards achieving "backdoor CBPR." CCHERS envisions this approach as well. POL-IRB and SSG influence the research design by critically reviewing proposals during their review process.

These practice and policy differences emerge mainly through experiences and context, and should not be interpreted as one way being better than the other. As discussed during the focus group, established procedures may vary across groups depending on such factors as cultural considerations and type of review model used. As an example, GCN policies and procedures are not written given the community's oral traditions. Furthermore, co-investigator Lola Sablan-Santos, GCN shared,

> *I think what's important too is that the community said… 'hey, that's the Western way. That's not our way.' And… the people who have been involved in the research that GCN has been involved with, they were very adamant that we do it our way, the Chamorro way. We take our cultural values, our traditions, and that's how we outreach into the community. So when they're reviewing proposals, why not? I mean who's to say, I mean it isn't the federal government… we can tell the federal government this isn't going to work for us. They may not fund us, but… this is how we do it. And why? It's like, how dare you tell me we don't do it this way!*

In other words, becoming an IRB is not necessarily relevant or appropriate for all community groups. This could in part be due to resource issues and desired intent of one's review process.

Challenges Experienced by CRPs

Two of the key challenges described by the CRPs in the study pertain to inadequate infrastructure and lack of respect or recognition by some within the academic community.

Infrastructure challenges

All the CRPs spoke to the challenges associated with securing and maintaining adequate resources to support their review processes. In some instances this manifested as non-existent or insufficient staffing support dedicated to the review process. Limited support negatively affects the extent in which CRPs can function. For example, co-investigator Eric Wat, SSG discussed how limited resources hamper their ability to implement post-approval site visits or even follow-up beyond the annual review requirements. In other instances insufficient support limits the number of proposals the CRP can assess, or limits the ability to provide regular training opportunities for reviewers. Only POL-IRB and SSG have dedicated funds to partially support the review process (i.e., support for CRP administrator's time). All of the CRPs, however, rely upon their reviewers to volunteer their time and expertise. In thinking about how funding challenges differ from institutional IRBs, study partners talked about how institutional IRBs are funded in part through indirect costs. Not all community-based organizations, however, have a federally negotiated indirect rate thus eliminating this potential funding source.

Legitimacy challenges

The second key challenge focused upon the struggle to be recognized and/or respected by the academic community as legitimate entities – even for CRPs that are federally recognized IRBs and thus theoretically on par with an institution-based IRB. As shared by co-investigator Mei-Ling Isaacs, POL-IRB,

We're all reaching out to science and researchers to be partners … We're recognized because of the community and then we have to look over to the federal structure because it gives us authority. It also gives us an opportunity where universities or [institution-based] institutional review boards take us more seriously… And I think we're all looking for that respect, that kind of mutual respect within our communities and between ourselves and in [institution based] institutional review boards… and beyond respect, I think is a recognition of being colleagues… we're just colleagues like everybody else and we're all moving towards the betterment of our people and…being sure research is doing that as well.

Comparison between CRPs & Institutional IRBs

[Institutional IRBs are concerned with] compliance with the grant, the funders, but the community review boards, in addition to some of those same concerns, might also be concerned about the benefit coming back to community, how dissemination happened, the ownership, respect, capacity building…

-Study consultant Elaine Drew

Similarities exist between the CRPs in the study and institutional IRBs. For example, as federally recognized IRBs, POL-IRB and SSG must adhere to the same federal guidelines as institutional IRBs.

Key differences also exist between CRPs and institutional IRBs. As described within the *Challenges* section, infrastructure resources represent one of the key differences. Overall institutional IRBs are viewed as having greater resources to support their functioning, including funds for staffing support. A second key difference centered on the underlying commitments or focus of CRPs as compared

to institutional IRBs. Table I provides evidence for the differences in types of review considerations accounted for by the CRPs. The intentional focus on community and cultural concerns differs from the types of questions prompted by the federal regulations and Belmont Report.[3] All CRPs in the study highlighted the added rigor of their review processes given their application of both traditional regulatory considerations AND community and cultural considerations.

The CRPs in the study also diverged from institutional IRBs in many of their practices and policies. Key differences include the roles they play in research beyond conducting reviews, their membership and voting policies and their practices regarding exempting protocols. Beyond reviewing protocols, GCN and GICRAC are directly involved in conducting research either in partnership with an academic researcher or on their own. GICRAC hosted Listening Tours to hear directly from the community what research should focus on. This helped to ensure community engagement through research that is relevant and useful. Understanding community priorities can then help shape the kind of research to be conducted. As co-investigator John Cooks, GICRAC shared, "I'm striving to get [GICRAC] to the point that we go knock on the [university's] door and say this is what we're concerned about, who do you have in here that can help us?" CCHERS plans to serve as a space for academic and community researchers to come together to collaboratively identify research questions. Co-investigator Elmer Freeman commented that while CCHERS will review research, the primary function of its research committee, comprised of half community members and half academics, is to "generate research and create connections between the people who are on the committee." As another example of a role beyond reviewing protocols, POL-IRB administrator teaches at the medical school to train new students on how to engage ethically with Native Hawaiians in CBPR.

Membership and voting policies differ. All the study partners require that the membership of their review committee is comprised of a majority, if not entirely (GCN), community members. POL-IRB, for example, stipulates a minimum of 50% of the membership be of Native Hawaiian ancestry. These policies contrasts sharply with institutional IRBs where there is typically one non-scientific and one unaffiliated member to fill the minimum federal requirement, who may or may not be viewed or view themselves as "community representatives."

Other practices to ensure community voice in CRP review meetings include SSG's policy that states each community reviewer should be asked in turn if they have comments. CRP voting practices also reflect a privileging of community perspectives. These include POL-IRB and SSG's policy that a protocol cannot be approved if a community reviewer disapproves. For GICRAC, community reviewers are joined by research affiliates or individuals affiliated with the local university who participate in the review committee, but do not get an actual vote. With GCN, only community members serve on the committee. All the CRPs in the study also attempt to further strengthen the community voice through training and mentoring community reviewers. Through the experience of

serving on a CRP, community members learn about research and ethics review and are ideally better prepared to become researchers as well as serve on other review committees. For example, one of the GICRAC reviewers serves on the local institutional IRB, allowing for increased community representation on it and helping to bridge communication between the institutional IRB and the CRP.

Another difference between the CRPs in the study and institutional IRBs is the frequency of research deemed exempt from human participants ethics regulations. The CRPs in the study reported that they rarely exempted a protocol. Although we did not collect sufficient data to analyze why this is the case, the CRPs felt this is likely due to the community process adding a strong community and cultural lens that identifies concerns possibly not considered by institutional IRBs. As an example, a CRP in the study described how the involved institutional IRB exempted a protocol that they deemed requiring a full review. More specifically POL-IRB required a review as the proposed study involved looking at placenta, which the involved university had deemed medical waste. For Native Hawaiians, however, the placenta holds significant cultural meaning and value, and is anything but "waste." Table 3 summarizes select practices and policies followed by the CRPs in the study.

Table 3. CRP Practices and Policies

Policy/Practice	CCHERS	GCN	GICRAC	POL-IRB	SSG
Focuses on underserved population	Yes	Yes	Yes	Yes	Yes
Requires minimum of 50% members from the community	No	Yes	Yes	Yes	Yes
Allows only community reviewers a vote	No	Yes	Yes	No	No
Requires researcher to attend review meeting	Yes	No	Yes	No	Yes
Reviews budget	Yes	No	Yes	Yes	No
Asks how results are shared with the community	Yes	Yes	Yes	Yes	Yes
Asks about data ownership	TBD	Yes	No	Yes	No
Reviews partnership considerations	Yes	Yes	Yes	Yes	Yes
Considers community capacity building	Yes	Yes	Yes	Yes	Yes
CRP approval prior to researchers publishing findings	TBD	No	No	Yes	No
Has dedicated paid staff for review process	No	No	No	Yes	Yes
Conducts research	Yes	Yes	Yes	No	No

Interaction between CRPs & Institutional IRBs

The CRPs in the study shared a number of challenges in their relationship with institutional IRBs, including not having formal agreements in place, inadequate communication, and lack of awareness and respect of the CRP. Since SSG frequently reviews research where there is no involved academic partner, it is understandable they often have no interactions with institutional IRBs. Typically CRPs rely on the researcher to act as a liaison with the involved institutional IRBs. To minimize conflict or other challenges with the involved institutional IRBs, POL-IRB requests the researcher submit the institutional IRB feedback with their application and stipulates the POL-IRB's decision takes precedence over all other IRBs. Another challenge reported by the CRPs is the lack of awareness among institutional IRBs that they even exist, which may play a role in devaluing their contributions. CRPs express a desire to be recognized as legitimate entities and colleagues by institutional IRBs.

Table 4 summarizes the interaction or relationship between CRPs in the study and institutional IRBs that review the same study protocols.

Table 4. Interactions between CRPs and Involved Institutional IRBs

Interaction with involved institutional IRBs	CCHERS	GCN	GICRAC	POL-IRB	SSG
Requires researchers to submit institutional IRB application/materials at time of submission to the CRP	Yes	Yes	No	Yes	No
Requests to see institutional IRB feedback	Yes	No	No	Yes	No
Communicates with institutional IRBs	TBD	No	No	Yes	No
Relies on researcher to communicate with institutional IRBs	TBD	Yes	Yes	Yes	Yes
Stipulates that the CRP determination takes precedence over institutional IRBs	No	No	No	Yes	No

The CRPs in the study recognize the benefits of strengthening their relationships with institutional IRBs, particularly for community-academic partnership projects that undergo both community-based and institution-based reviews. For example, cultivating these relationships might streamline the process for researchers needing to obtain multiple IRB reviews. Better communication and exchanging information might ensure consistency in the materials submitted to both review processes. The POL-IRB administrator shared how they now require researchers to submit all the materials that were submitted to the involved institutional IRB. This practice was prompted by a situation in which a researcher submitted different materials to POL-IRB causing confusion and undermining community trust. Some of the CRPs in the study are working to develop better relationships with institutional IRBs. For example, POL-IRB staff attended a training offered as part of the University of Hawaii IRB's certification and their participation has helped to build staff-to-staff relationships.

If we involve community members from design to dissemination, your research design will be better. Your methodology will be better…That we all made the improvement in how research is being carried out and that's because we brought the community voice to the table and by doing that I feel like we are educating, we are improving the way academic partners do things in the community.

Finally, CRPs facilitate greater community benefit. This might be through capacity building activities such as training of community reviewers and academic researchers, or requiring a research protocol to provide adequate resources for community partners. As shared by principal investigator Sarena Seifer, CCPH, "[CRPs] are making a difference in community capacity building and the actual changing of the research and making a difference in people's lives… co-producing knowledge and mobilizing it."

CRP Impact

The impact of each of the CRPs in the study center upon three areas: 1) strengthened research ethics, 2) improved research quality and integrity, and 3) greater community benefit. As described previously, the CRPs provide added rigor by examining research ethics that go beyond federal regulatory requirements. This in turn, as reported by both the CRPs and researchers who had submitted proposals to both a CRP and an institutional IRB, improves the research methodology. As described by co-investigator Eric Wat, SSG IRB,

Recommendations

Recommendations emerged for community groups interested in developing or strengthening a CRP, as well as for institutional IRBs. Other recommendations focused upon policy and funding stream changes.

Recommendations for community groups

Recommendations for other community groups focused on four broad categories: Infrastructure, policies/procedures, community focus and mentorship.

Assess infrastructure and identify means to ensure availability of necessary resources. Infrastructure to support a CRP can include dedicated staffing as well as funding to provide training and support to reviewers. Strategies to garner greater support include the possibility of charging a fee for reviews and advocating that the review process is included in the host organization's budget as its own line item.

Develop policies and procedures that reflect your mission and vision statement, or core principles that guide your work. Some communities may be better served with a community-based review committee rather than a federally recognized IRB depending on cultural and/or community considerations. The list below includes policies and procedures recommended for developing CRPs. Following each category of policies and procedures are examples of the types of questions or issues to be considered. As emphasized numerous times throughout the individual case studies and this cross-case report, community groups should develop a process that best meets their needs and resources while remaining open to change as new needs arise or lessons are learned.

- *Committee membership:* Will your review board include both community and academic partners? What other composition requirements are important given the involved community? How will new members be recruited? Will there be a requirement for a certain percent representation by the community?
- *Committee member training and certification requirements:* How best to ensure reviewers are prepared to assess research proposals? Will training entail completion of an established human participant research certification? Will new reviewers be required to observe review meetings prior to having a vote? What resources exist to assist with training and/or mentorship of new reviewers?
- *Application materials:* To what extent does your application materials reflect your mission/vision

statements? In addition to the traditionally required materials (i.e., recruitment materials, consent forms, data gathering instruments), what other materials might help with the review process (i.e., proposed research's budget)?

- *Review procedures:* What kinds of research will require a full review? Will there be lead reviewers assigned to each protocol? Should the academic researcher and community partner attend the review meeting?
- *Post-approval requirements:* What monitoring mechanisms should be implemented to ensure community and academic partners are adhering to the approved protocol? What publication and dissemination policies should be developed to ensure that 1) the involved community receives the research findings and benefits and 2) potential harm is minimized or eliminated?
- *Research participant bill of rights:* What are the rights and responsibilities of the research participants? What are the responsibilities of the academic and community research partners? How might community considerations be integrated into a participant bill of rights?

Listen to your community and educate researchers to ensure ethical conduct of research. Team members pointed to the Listening Tours that allowed GICRAC to hear directly from the community what research should focus on. Team members also spoke to the tremendous value of educating future as well as current researchers on how to engage ethically with the community.

Develop a system of mentorship and support. The CRPs in the study greatly benefitted from being mentored by other CRPs during their development and pointed out the benefits of CRPs building relationships and consulting with one another to create a learning community. Strengthening of CRPs and enhancing how research occurs may be achieved through mentorship, sharing advice on how to work with institutional IRBs, as well

as exchanging resources (i.e., sample policies and protocols), best practices and lessons learned.

Recommendations for institutional IRBs
Membership considerations were the primary recommendation for institutional IRBs. This includes both increasing the number of community members serving on the IRB and ensuring community reviewers are genuinely connected and/or familiar with the different communities involved in the proposed research efforts. Strengthening the community membership on institutional IRBs was felt to be an important strategy for increasing the likelihood that institutional IRBs would take community and cultural considerations into account during their reviews. CRPs are one source of community reviewers for institutional IRBs. A recommendation for both institutional IRBs and CRPs was to increase their coordination and communication. This must be bi-directional. CRPs are encouraged to initiate a relationship with institutional IRBs in their vicinity and any involved in the studies they review. Institutional IRBs are encouraged to investigate whether there are CRPs operating in their midst and reviewing the studies their researchers are involved in, and to initiate communication.

Recommendations for policy change
One recommendation for policy change focused on changing how researchers and reviewers gain certification in the ethics of human participants research. More specifically, changes are needed to the usual mechanisms of certification (i.e., CITI) often required of researchers and reviewers.[4] These training mechanisms generally do not include content regarding the ethics of respectfully engaging communities in research. Alternative trainings to CITI that focus on community-engaged research, and including a module on community-engaged research within the CITI training were both recommended. There are some examples of the former but these need to be more widely publicized and utilized. [5, 6]

Policy changes are also needed at the federal level. The Belmont principles and the federal research ethics regulations that derive from them do not adequately cover the scope of ethical issues that arise in community-engaged research. Co-investigator Mei-Ling Isaacs, POL-IRB spoke to the need to establish clearer ethics guidelines that reflect concerns experienced across diverse communities. In essence developing "a certain standard of practice" to be included in human participant research trainings that hold researchers accountable and ensure these practices or rules are "recognized and given the power of law or regulation."

Having greater community representation on the Secretary's Advisory Committee on Human Research Protections (SACHRP) was identified as an important step towards greater alignment of federal research ethics regulations and community-engaged research. As stated on the US Department of Health and Human Services' website:

> *SACHRP shall provide expert advice and recommendations to the Secretary, through the Assistant Secretary for Health (ASH), on issues and topics pertaining to or associated with the protection of human research subjects. The Committee will work to advise the Secretary on how to improve the quality of the system of human research protection programs, including the responsibilities of investigators, institutional review boards (lRBs), administrators, and institutional officials, and the role of the Office for Human Research Protections and other offices within the Department of Health and Human Services.*

Involvement of CRP administrators and chairs as SACHRP members could help to ensure that community-engaged research ethics are considered

and reflected in regulatory changes. Once these considerations are included in the regulations, the question arose as to whether an institutional IRB would be the appropriate entity to assess whether CEnR is ethical. As study principal investigator Sarena Seifer, CCPH reflected,

> *If you all of sudden change these rules to include all the community issues we care about… I don't believe university IRBs are the right place to review that. They're not constituted that way, they're already over burdened, over worked, there's no way they can take on all the community and cultural considerations.*

Greater coordination between CRPs and institutional IRBs might be the preferred system for thoroughly reviewing community-engaged research. A final policy level recommendation was to re-think the current IRB structure. As study principal investigator Sarena Seifer questioned, "Why are they even based at institutions? They should have been independent boards to begin with. They should not have been based at a university that does the research, they should've been an independent body" with no conflict of interest with the research being reviewed.

Recommendations for funding agencies

The CRPs in our study have experienced variations in funders' understanding of community-engaged research. The California Breast Cancer Research Program (CBCRP) was identified by the study team as a funder with genuine understanding of the principles of community-engaged research. For example CBCRP has separate budgets for community and academic partners, allowing community partners to be funded directly. In instances where the community partner does not have a calculated indirect rate, CBCRP pays a 25% indirect rate. We recommend that NIH and other funders look at CBCRP guidelines as a model to follow. As co-investigator Lola Sablan-Santos, GCN asked, "why

can't that [CBCRP type policies] then transfer over to NCI, NIH if they're really promoting CBPR?"

A second recommendation was for funders to invite community-academic research teams to present on their research, including partnership considerations. Similarly, successful community-academic research partnerships should speak to their funders about their experiences as a means to not only raise awareness but to encourage funders to "own" their role in supporting community-engaged research. Ideally this would lead to reinforcing the value funders place on it and ensuring their continued support.

Recommendations for mobilizing knowledge from the study

Based upon a critical review of each case study and the cross-case analysis, the study team identified a number of ways to mobilize the knowledge generated by the study. In particular, we are committed to supporting the growth and development of CRPs to enhance their reach and impact. We will collectively pursue these over the coming months:

- Create guiding documents that help community groups determine what kind of review model best fits their needs and context.
- Develop a research ethics position statement that clearly specifies core community and cultural ethical considerations. Advocate for the adoption of this position statement by national organizations and for its inclusion in federal research ethics regulations.
- Tell our stories of how communities vet research, and encourage other community groups to do the same. Speaking as a group of concerned and knowledgeable community groups will help create change.
- Develop "myth-busters" factsheets that address common misconceptions about CRPs.
- Facilitate opportunities for community groups to mentor and support each other in the development and strengthening of their CRPs.

Study Conclusions & their Implications

When we embarked on the National Collaborative Study, we knew that CRPs existed and we were familiar with a number of them through personal experiences, published papers and presentations at meetings. Little was known, however, about their operations and their impact. By examining 5 diverse CRPs in depth, we have documented the significant difference they are making both in the ethical design, conduct and impact of research as well as in the research literacy, capacity and ownership in communities. We have also documented how they differ from institutional IRBs in both their engagement of researchers in the review process and in the community and cultural lens through which they review proposed research. In the case of the two community IRBs in the study, we found they go beyond the federal research ethics regulations to include significantly more community-based reviewers and to assess community and cultural level ethical issues. Along the way, we also refute a number of misconceptions about CRPs: that they prevent research from moving forward and that they do not provide a rigorous and thorough review. We found that the vast majority of studies reviewed by CRPs are approved. CRPs are deeply invested in research that ethically engages communities and responds to community needs, concerns and assets. They take their charge seriously, including developing policies and procedures, recruiting and preparing reviewers, and investing in ongoing professional development.

Their reviews often entail a back-and-forth process between the CRP and the research team to address concerns raised by the CRPs, ultimately resulting in a more ethically sound, feasible and rigorous study design.

Our study findings point to a critically important role for CRPs in research ethics review that is not being fulfilled by institutional IRBs. For CRPs to fully actualize this role, the challenges facing their development and sustainability must be addressed. First and foremost, financial resources are needed to support them. CRPs have been creative in supporting themselves on a shoestring budget. Institutional IRBs are able to support themselves through indirect funds from research grants that CRPs are largely unable to access. We believe the federal government – as the major supporter of health research in this country – must invest in CRPs as a key component of the national research ethics review system. A promising first step would be to provide competitive grants for the start-up of new CRPs and the development/expansion of new CRPs.

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