Community-based IRBs: What Researchers Should Know
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Native Americans began developing their own Institutional Review Boards (IRB) in the 1970s, and the Native Hawaiian Health Care Systems (NHHCS) IRB was established in 2000. Why have community-based IRBs been founded? What are their functions? What benefits do they provide to research? How can researchers work effectively with community-based IRBs? This article addresses these questions using a case study from Hawai`i.

Why Was the NHHCS IRB Established?

Native Hawaiians are individuals who trace their ancestry directly to the Polynesians who peopled and governed the Hawaiian archipelago prior to the arrival of Westerners in 1778. Today, about 20% of Hawaii residents are Native Hawaiians (compared to 24% Caucasian, 19% Japanese, 17% Filipino, 7% Chinese, and 13% other ethnicities). Similar to indigenous and minority groups in other locales, Native Hawaiians have a lower life expectancy and poorer health indicators than the other major ethnic groups in the state (Blaisdell, 2003; Office of Hawaiian Affairs, 2006). They are over-represented in public assistance programs and underrepresented in higher education and in medical and research careers (Braun, Tsark, Santos, Aitaoto, & Chong, 2006; Hawai`i Department of Human Services, 2006; US Census, 2000).

Despite the need for research aimed at reducing disparities, indigenous and minority communities may be reluctant to participate due to negative experiences. Native Hawaiians who have participated in research have said they felt used as “guinea pigs” and sensed they were exploited to advance the researcher’s career (Matsunaga et al., 1996; Fong, Braun, & Tsark, 2003). Research on minority communities has been criticized for focusing on researcher-identified issues (rather than community issues), for being conducted in culturally inappropriate ways, and for not benefiting the group under study (Matsuaga et al, 1996; Minkler & Wallerstein, 2003). In some cases, research findings have been harmful to communities through a failure of researchers to share financial or professional profit with the community or by attaching stigma or notoriety to the group (Green & Mercer, 2001; Fong et al, 2003; Burhansstipanov, Christopher, & Schumacher, 2005).

A goal of Papa Ola Lokahi (POL), a community-based agency dedicated to improving the health and wellness of Native Hawaiians, is to increase health disparities research by and for Native Hawaiians. One POL project, `Imi Hale - Native Hawaiian Cancer Network, aims to reduce cancer health disparities experienced by Native Hawaiians by: 1) designing, testing, and disseminating culturally appropriate interventions; and 2) developing Native Hawaiian researchers (Braun et al., 2006). A major partner with `Imi Hale in cancer programming and research are the five NHHCS, which provide health education and access services to approximately 25,000 individuals annually, the majority of whom are Native Hawaiian, on Hawai`i’s seven inhabited islands.

In anticipation of increased research activity in Hawaiian communities, POL and the 5 NHHCS established in 2000 a community-based IRB known as the Native Hawaiian Health Care Systems
Institutional Review Board (NHHCS - IRB). The purpose of the NHHCS - IRB is to maximize the benefits and minimize the risks of research with Native Hawaiians and to begin to more fully address Hawaiian communities’ concerns regarding research.

To develop the NHHCS-IRB, staff of POL spoke to staff from five different local IRBs to assess how IRBs operated within institutions in Hawai`i. Consultation and mentorship also was received from the staff of the National Indian Health Service (IHS) IRB to learn how to set up an IRB and how the IHS IRB was addressing American Indian communities’ concerns about research, such as data ownership, respect for cultural traditions and practices, confidentiality, informed consents, and group harm.

How Does the NHHCS-IRB Function?
NHHCS-IRB members include representatives from scientific and non-scientific sectors and Hawaiian communities across the state, and about 85% are Native Hawaiian (Fong et al., 2003). Members are appointed to 3-year terms. About 20 individuals serve at any given time, making up both voting and alternate members, and 10-14 attend bimonthly meetings in person or via teleconferencing. New members are identified from the community and the growing pool of Native Hawaiian researchers that have been supported by `Imi Hale to conduct and publish research and, in many cases, to earn advanced degrees and pursue careers in health disparities research (Braun et al., 2006). Meetings are bimonthly, but can be scheduled more frequently if needed. POL has a designated staff member who serves 25% time as the NHHCS-IRB administrator, and a support staff is available to assist.

Investigators wishing to conduct research with any POL program or any NHHCS must apply to the NHHCS-IRB. The application itself mirrors IRB applications of other institutions, including: the purpose and benefits of the research; funding source; methods (sample and measures); risks; and the mechanisms in place to minimize, recognize, and mitigate harm. Data collection tools and consent forms must be attached, as well as the full proposal. Maintaining some consistency among IRB forms locally makes it convenient for researchers who may need multiple IRB approvals as dictated by their research protocol.

The NHHCS-IRB is a registered IRB with the Office of Human Research Protection within the Federal Government of the United States and utilizes the Code of Federal Regulations (45 CFR 46) to review research for safety, confidentiality, degree of benefit, and the need for and quality of informed consent. Thus, primary and secondary reviewers assess applications against a series of questions relevant to these issues (e.g., Are risks minimized? Are risk-mitigation and confidentiality-protection mechanisms in place? Does the researcher appear to have any ethical conflict? Does the consent form include the necessary components, and is it understandable?)

As a community-based IRB, the NHHCS-IRB also incorporates procedures that promote research that is respectful of the communities served by POL and the five NHHCS. It also wants to see that opportunities are provided to build research capacity. Thus, reviewers are expected to comment on the appropriateness of the research to the community (e.g., Does the research address an issue of concern to Native Hawaiians? Are Native Hawaiians involved in conducting the research or advising on the research to the extent possible? Is the research being conducted in culturally appropriate ways? Are we assured that the research will not harm Native Hawaiian individuals and communities by causing stigma or reducing opportunities? Is it clear how Native Hawaiian individuals and communities benefit from this research?)

Because the NHHCS IRB also serves as a mechanism to educate Native Hawaiians about research, very few applications are expedited or exempted; rather they go for full review. To foster
a learning environment for both researchers and IRB members, researchers are invited to meet with the IRB and present a brief overview of their research prior to the submission of their formal application. This provides the IRB members an opportunity to offer comments that the researcher can consider and address at the formal review meeting. It also provides IRB members an opportunity to meet the researcher and anticipate the forthcoming application. Applications must be renewed at least every 12 months, and researchers must present their findings at the conclusion of their study. The NHHCS IRB does not review and/or approve manuscripts prior to their submission, but researchers must articulate in the application their plans for sharing research findings, first with the individuals and communities involved and then with the broader community.

What Are the Benefits of the NHHCS IRB?
- The NHHCS IRB assures that research is targeted to community priorities, is culturally sensitive, has tangible benefits for the community, and is attentive to group harm. Attention to these issues are lacking in other IRBs, consideration of which can strengthen the research (Table 1).
- The NHHCS IRB recognizes that, despite past wrongs, research focused on developing and improving health programs are valuable for Native Hawaiian communities. Thus this body serves as a mechanism for increasing knowledge about and involvement in research among Native Hawaiians. More Native Hawaiians can critically evaluate research and have become excited about research.
- The NHHCS-IRB supports the engagement of Native Hawaiians as equals in research. As a result, more Native Hawaiians are serving as principal investigators, co-investigators, and research associates. Other individuals have built individual research capacity by serving as cultural mentors and facilitating access to communities. Many of these individuals have furthered their education, thus increasing the pool of Native Hawaiian researchers and research supporters.
- The NHHCS-IRB has gained credibility in the scientific community and often serves as the IRB of record. For example, the University of Hawai`i tells faculty who want to conduct research in Native Hawaiian communities to apply first to the NHHCS-IRB. Because the NHHCS-IRB review is perceived as more rigorous, the UH Committee on Human Subjects usually accepts the decision of the NHHCS-IRB. Since 2005, NHHCS-IRB founders have mentored other community-based organizations in establishing their own community IRBs.

How to Work with a Community-based IRB
- Build relationships. Meet with the IRB and the community it serves before you write the proposal. Find out their priorities for health improvement. Respond to IRB comments in an open manner. Embrace opportunities for bi-directional education with IRB members.
- Build capacity through your research. Consider inviting a community member to serve as a co-investigator, establishing a community advisory group, training and employing community members as data collectors, and/or providing an honorarium to the community for its participation.
- Build trust. Always report findings to the community before disseminating them elsewhere. Communities can offer useful insights in the data interpretation process and good ideas for application of findings in the community and when appropriate, workable, follow-up research projects.

Conclusion
The growth of community-based IRBs will continue. In comparison to most university and hospital IRBs, our experience suggests that community-based IRBs are better equipped to address community
concerns that have been barriers to minority participation in research. They are more likely to provide opportunities for people to engage in research and to support research that is respectful, minimizes harm, and provides tangible benefits. Commitment to bi-directional education, communication, and deliberation may be time-consuming, but it presents the best chance of fostering positive relationships between scientists and the community and, ultimately, improving community health and wellness.

References


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