

The background of the cover features a large, light blue circle containing numerous stylized human figures. Each figure is composed of a grey circle for a head and grey lines for limbs, arranged in various poses. The figures are scattered throughout the circle, creating a sense of a diverse community.

Ensuring Community-Level Research Protections

Proceedings of the 2007 Educational Conference Call Series on Institutional Review Boards and Ethical Issues in Research



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About the Organizations That Supported This Report

Community-Campus Partnerships for Health promotes health (broadly defined) through partnerships between communities and higher educational institutions. Founded in 1996, CCPH is a growing network of over 1,700 communities and campuses across North America and increasingly the world that are collaborating to promote health through service-learning, community-based participatory research, broad-based coalitions and other partnership strategies. What ties CCPH members together is their commitment to social justice and their passion for the power of partnerships to transform communities and academe. CCPH advances its mission by disseminating information, providing training and technical assistance, conducting research and evaluations, developing and influencing policies, and building coalitions. Learn more about CCPH at <http://www.ccpH.info>

The Tuskegee University National Center for Bioethics in Research and Health Care promotes racial and ethnic diversity in the field of bioethics and in public debates about bioethical issues. Established in 1999, its mission is to promote equity and justice in health and health care. The Bioethics Center is the nation's first bioethics center dedicated to addressing bioethical issues of importance to African Americans and other underserved populations. It is also the only bioethics center at a Historically Black College and University. The Bioethics Center carries out its mission by conducting education and training programs, fostering respectful community partnerships, advancing interdisciplinary research, and advocating public policies that improve the health and health care of all Americans, particularly the underserved. Learn more about the Bioethics Center at <http://www.tuskegee.edu/Global/category.asp?C=35026>

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Continuing the Conversation

CCPH and the Bioethics Center invite anyone interested in community-based participatory research (CBPR) and research ethics issues to join our ongoing electronic discussion group. For more information, visit CCPH's CBPR & Research Ethics Webpage at <http://www.ccpH.info>



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Introduction

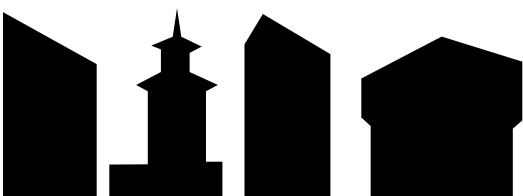
Community-Campus Partnerships for Health (CCPH) and the Tuskegee University National Center for Bioethics in Research and Health Care (the Bioethics Center) sponsored an Educational Conference Call Series on Institutional Review Boards (IRBs) and Ethical Issues in Research that took place between February 2007 and June 2007, which advanced their shared goal of meaningfully involving communities in decisions made about every aspect of research. The call series was intended to increase understanding of the role of IRBs and other mechanisms for assuring that human subjects research is ethical and appropriate – both at individual and community levels.

The idea of the call series grew from observations by CCPH – through its conferences, workshops and electronic discussion groups – that community members and researchers engaged in community-based participatory research (CBPR) were grappling with a number of challenges related to the research ethics review process. These included concerns about inconsistent community membership on IRBs, difficulties gaining IRB approval for studies employing CBPR approaches, and conflicts between the protection of individuals participating in research and the protection of communities in which research takes place. Reinforcing these observations were related concerns being raised in the peer-reviewed literature:

Community IRB Members & Their Role on IRBs: The inconsistency of community representation on an IRB through a non-affiliated or non-scientific member is prominent in the literature. In a study by DeVries and Forsberg (2002), the authors found that the majority of IRBs they examined did not meet the National Bioethics

Advisory Commission recommendations that non-scientists should compose at least 25% of membership and at least 25% of members should be nonaffiliated with the institution.¹ Even with the appropriate representation of nonaffiliated and scientific members, also known as community members, their roles are often unclear and they may not feel respected. Dyer argues that in order for the participation of the community member to be effective, their roles must be clear.² Sengupta and Lo found that many lay members have felt that scientists often disrespected their opinions and that their presence was tolerated because of a federal mandate.³ Moreover, the authors found that only 22% of the lay participants in their study had formal training, and those who did have training felt it gave them confidence in their role as community IRB member. The literature demonstrates that most IRBs may not have the recommended number of community members, and even with the requisite membership, community members may not have the necessary tools to fulfill their role.

Tensions Between CBPR and IRB Review: The Belmont principles that guide IRB review of human subjects research do not appear to cover the scope of ethical considerations that arise in CBPR, and thus the IRB's application of these principles may not provide a relevant or thorough ethical analysis. IRBs, designed to protect the rights and welfare of individual study participants, are neither expected nor equipped to protect the rights and welfare of communities involved in research. 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 also begins with a research topic of importance to the community and has the aim of combining knowledge



with action and achieving social change. An underlying assumption of CBPR is that through active and meaningful community involvement, community benefits are maximized and a range of potential harms to individuals and their communities can be prevented. CBPR thus represents a shift from regarding individual community members as *research subjects* to engaging community members and the organizations that represent them as *research partners*. These features of CBPR contribute to ethical considerations that can differ from those encountered in more traditional research approaches. Human protections concerns in CBPR are not just about the individual, but also inherently concern the respect, beneficence, and justice for the community as well.

Studies of CBPR researcher experiences with research ethics review reveal deep concerns about the ethics of partnership processes, social justice, and the need to expand ethical analysis to include community level considerations. Malone et al. (2006) found many challenges to getting IRB approval for CBPR because her university's IRB did not recognize the role of the community researchers; instead, they saw them as subjects.⁴ Other researchers, such as Gilbert (2006), Shore (2006), and Flicker et al. (2007), have found the need for a broader scope of ethical review than is included in traditional IRB review—review that includes community considerations with regard to respect, beneficence, and justice.^{5 6 7} CBPR considerations are often missing from university-based IRB application forms, for example. A recently published content analysis of 30 IRB forms found that while all of the forms inquired about scientific rationale, none asked about the involved community's perception or input regarding the justification for the study (Flicker 2007). Only 4 forms asked about community or societal level risks and benefits, and only 5 forms inquired into how the research findings would be disseminated.

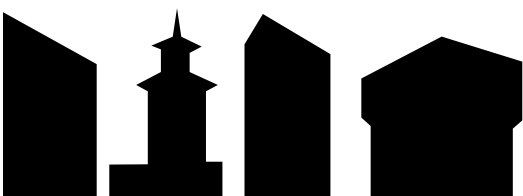
The Emergence of Community Mechanisms for Research Ethics Review: A number of community groups and community-institutional partnerships have established their own community-based mechanisms for research ethics review that operate independently or in parallel with institution-based IRBs. Many of these models are common in Native American communities, including tribal IRBs that may require review and approval at multiple levels.⁸ While there was reference to the existence of various community mechanisms in the literature,⁹ there was not a documented source for how a community and/or a community-higher education partnership might develop a mechanism for community-level considerations.

CCPH and the Bioethics Center concluded that an educational conference call series would serve to gather and raise awareness of community level protections among a diverse group of stakeholders, including community members, academics, IRB administrators and committee members. The series consisted of six moderated conference calls, each featuring a panel of expert speakers followed by audience participation. Call #1 covered the historical events leading to human protections regulations and IRBs. Call #2 delved into the issues of community membership on IRBs. Call #3 explored the tensions between the IRB process and CBPR, including the frequent difficulty in gaining IRB approval of CBPR, especially in traditional biomedical research institutions. Calls #4 and #5 explored options for incorporating community concerns into the research ethics review process, including by establishing community advisory boards and community IRBs. Call #6 concluded the call series by highlighting recent research findings that advance a broader scope of ethical considerations in CBPR. With over 500 participants, the call series indicated a significant level of interest in the topics covered.

The series sought to create not only a forum for discussion, but also a clearinghouse of resources that could help to advance community level protections. This proceedings report is intended as one such resource. Additional resources, including audio files, presentations and handouts from each call in the series, are available on CCPH's CBPR & Research Ethics Webpage at <http://www.ccpb.info>. We encourage readers to continue the conversation by joining the free CBPR & Research Ethics Electronic Discussion Group (listserv). Visit the CCPH website, above, for instructions on how to subscribe.

Frequently Used Acronyms

CAB	Community Advisory Board
CBPR	Community-Based Participatory Research
CBR	Community-Based Research
CCPH	Community-Campus Partnerships for Health
CDC	Centers for Disease Control and Prevention
CHC	Center for Healthy Communities
DHHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
IHS	Indian Health Service
IRB	Institutional Review Board
KSDPP	Kahnawake Schools Diabetes Prevention Project
OCAPICA	Orange County Asian and Pacific Islander Community Alliance
OHRP	Office of Human Research Protections
PATH	Promoting Access to Health
PHAT	Protecting the Hood Against Tobacco
PRC	Prevention Research Center
PRIM&R	Public Responsibility in Medicine and Research
REACH	Racial and Ethnic Approaches to Community Health
REB	Research Ethics Board
SSG	Special Service for Groups
UCLA	University of California - Los Angeles
UCSF	University of California - San Francisco
WCCHC	Waianae Coast Comprehensive Health Center
YVFWC	Yakima Valley Farm Workers Clinic



What is an Institutional Review Board (IRB) and What Purpose Does it Serve?

Call #1: February 14, 2007

Speakers:

- **Shirley Hicks, Director, Division of Education and Development, Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services (DHHS)**
- **Bill Freeman, Director of Tribal Community Health Programs & Human Protections Administrator, Northwest Indian College, Bellingham, Washington (Presentation prepared by Francine Romero, former co-chair of National Indian Health Service IRB & Member of Secretary's Advisory Committee on Human Research Protections, OHRP)**

Moderator: Vanessa Northington Gamble

Overview:

This call set the stage for the series by providing background on the advent of human protections and the role of IRBs. **Shirley Hicks** discussed the historical events that led to the formation of policies and regulations to ensure human protections in research. Shirley also focused on the role of IRBs in providing these protections. **Bill Freeman** presented a case story by Francine Romero that illustrated the role of human subjects review and IRBs in ensuring protections for individuals and considerations for broader community protections.



Shirley Hicks, Director, Division of Education and Development, Office for Human Research Protections, OHRP, DHHS

Shirley Hicks provided background on a number of landmark historical events, such as the Nuremberg Trials and the U.S. Public Health Service's Syphilis study, to demonstrate the importance of human protection in research and health care. As part of the verdict of the Nuremberg Doctor's Trial after World War II, the court set forth standards that should be in place for experiments involving human subjects. With more questionable studies during the 1960s, the U.S. federal government began to implement policies designed to ensure the protection of human subjects involved in government-funded research.

"Protecting human subjects is a shared responsibility and each one of us involved, no matter what our role, has an obligation to help protect these subjects. It is a privilege to do research - it is not a right to do research."

—Shirley Hicks, Director,
Division of Education and Development,
Office for Human Research Protections

The U.S. Public Health Service's Syphilis study was a turning point for human protections. The subjects in this study, all African American men, did not know that they had syphilis, and when a treatment for syphilis became available, they were not offered treatment. News of this study resulted in hearings on the quality of health care in human experimentations and led to the National Commission for the Protection of Human Subjects and the requirement of IRBs at institutions receiving support from the DHHS. In 1979, the Commission released the Belmont Report, as well as DHHS regulations to protect the rights and welfare of human research subjects. The Belmont Report

articulated three basic principles and guidelines for the protection of human subjects: 1) Respect for persons: the person has the right to make an informed choice; 2) Beneficence: it is our obligation to maximize the benefits of the research and minimize the harms; and 3) Justice: there must be equitable distribution of the benefits and burdens of research—or proper consideration for who has an opportunity to participate and who is excluded.

Shirley also described how an IRB provides protections as outlined in the Belmont Report, and is charged with reviewing research to assure that the rights and the welfare of subjects are adequately protected. The IRB performs an objective review of proposed research by considering the risks, ensuring that informed consent is adequate, participation is voluntary, and there is no coercion. Please visit OHRP's web site at www.ohrp.org for specific regulations, guidance, and frequently asked questions.



Bill Freeman, Director of Tribal Community Health Programs & Human Protections Administrator, Northwest Indian College, Bellingham, Washington

Bill Freeman presented a case of a community-based study that involved screening school children in primary and secondary school for risk factors associated with type II diabetes. The study utilized individual screening and a system-wide approach in examining all the factors that contribute to type II diabetes, such as the resources available, communication, and health education. The purpose of this case was to identify elements essential to protect individuals and communities and to understand the procedures for approval of research in Indian Country. An IRB is charged with reviewing the research to assure that the rights and the welfare of subjects are adequately protected. Though not in the federal regulations, Bill highlighted a fourth basic ethical principle: respect for communities. This case shows the level of community involvement and participation in all phases of the research that is necessary in Indian Country, as well as in the review of the research that often is otherwise done through a university IRB, for example. The IRB review process can enhance CBPR, or hinder it, depending upon the IRB's understanding of the philosophy behind CBPR. In this case, the IRB was not seen as an impediment but rather an enhancement of the community's role in research.

Resources

If you are in the US: Learn more about IRBs by reviewing the Office for Human Research Protections IRB Guidebook at http://www.dhhs.gov/ohrp/irb/irb_guidebook.htm

If you are in Canada: For more information about REBs, visit the National Council on Ethics in Human Research at <http://www.ncehr-cnerh.org/english/home.php>





Conducting Ethical Reviews in Native American Communities

Bill Freeman, Northwest Indian College

Francine Romero, Jemez Health and Human Services Department

The process of conducting community-based ethics review in Indian Country can be viewed as a model for IRBs that review CBPR. The overall goals of these ethics reviews are to enhance the communities' role in research, minimize adverse impacts of research by minimizing potential harms, and maximize potential benefits to individuals and the community. Although tribes each have their own individual system of reviewing research proposals, reviews in many locales need to go through up to eight different levels of approval before research can take place. In comparison, most research elsewhere has only two (usually the researchers' host institution IRB and funding agency). In tribal communities, these levels can include:

- Tribal Health Director
- Tribal Health Committee or Board
- Tribal IRB (e.g., Cherokee Nation IRB, Choctaw Nation IRB, Navajo Nation IRB)
- Tribal Council
- University IRB
- Indian Health Service Area IRB
- Indian Health Service (IHS) National IRB
- Funding Agency (occasionally, e.g. National Institutes of Health, Centers for Disease Control and Prevention)

The reason for all these approvals is that involvement of the community in the process of the research is important to Native Americans. The IHS IRB wants the tribes to insist through their own approval process that the research first be presented to the tribe, the tribal council, health board, or health program before any research plans and publications can move forward. This is required so that tribal sovereignty is both respected and maintained.

The IHS National IRB tries to be sensitive to the cultural appropriateness of the study design, questions and implementation of the study, and tries to incorporate in the IRB itself community specific knowledge, norms and world views. In the recent past, seventy percent of the IHS National IRB members have been of Native descent – that is, American Indian or Alaskan Native. Just as important, the members come from a diversity of backgrounds and perspectives, whether they are lay tribal members, medical doctors, nurses, or those with expertise in another subject area.

One example that illustrates the tension that can arise between research outcomes and benefits to the community that participated in that research is a study involving Type II diabetes screening among the youth of a particular Native reservation community. The proposed research study was to examine the factors in the local community that contributed to the prevalence of Type II diabetes in youth, such as the availability of healthy food, access to appropriate places for exercise, and the support of family members that also exercised. When the IHS National IRB reviewed this study, the obvious concerns that arose had to do with the stigmatization of the Native community that could develop after study results were released. In another words, the overall result of the research might do more harm than good to the community, as the study would make the community is vulnerable. This particular reservation, as many others, is not wholly accepted by the surrounding community of the majority society. Depending on the way the research was done and what was presented, it could place the reservation community in a very bad light.

Highlighting the Importance of the Community IRB Member

Call #2: March 14, 2007

Speakers:

- **Elda Railey and Mary Lou Smith, Co-Founders, Research Advocacy Network, Arlington Heights, Illinois**
- **Lucille Webb, Director, Strengthening the Black Family, Raleigh, North Carolina and North Carolina State Department of Public Health IRB Non-Affiliated (Community) Member**
- **Gigi McMillan, Director, We Can Pediatric Brain Tumor Network, Los Angeles, California and University of California – Los Angeles IRB Non-Affiliated (Community) Member**

Moderator: Vanessa Northington Gamble

Overview:

The purpose of this call was to discuss the role of the non-affiliated and non-scientific IRB members, also known as community members. **Elda Railey** and **Mary Lou Smith** provided an overview of the role of community IRB members and results of Research Advocacy Network-sponsored focus groups with community members and IRB administrators regarding the role of community IRB members, training needs, and retention tools. **Lucille Webb** and **Gigi McMillan** each shared their experiences as community IRB members and the importance of training and recognition.



Elda Railey and Mary Lou Smith, Co-Founders, Research Advocacy Network Arlington Heights, Illinois

Elda Railey provided an overview of how the rights of research participants, or human subjects, are protected. Regulations require that all IRBs must have at least one member “whose primary concerns are in nonscientific areas” (non-scientific) and at least one member “who is not otherwise affiliated with the institution” (non-affiliated).¹⁰ Although they are often referred to as “community” IRB members, the non-scientific member and the non-affiliated member ensure language and other aspects of a research study make sense to the layperson. In 2001, the National Bioethics Advisory Committee recommended that non-affiliated members of each IRB should comprise 20% of its membership. This is not the norm, however.

Elda discussed how community members bring unique viewpoints to the IRB—nonaffiliated members are not biased by employment, and non-scientific members are not biased toward the research question. Community members play an important role in evaluating the benefits and risks to the research participant and providing comments on the informed consent process to ensure protections of subjects. Yet there are various barriers to community members’ participation on IRBs, such as community members not having a clear definition and understanding of their role, as well as the complexity and amount of information to be reviewed. Community members recognize many of these constraints and see the chairperson of the IRB as the key to community members feeling accepted and valued. Training has proven to be an important aspect of community members being competent in their roles on IRBs. In addition to recruitment and training, recognition and feedback are important for retaining community members.





Lucille Webb, Director, Strengthening the Black Family, Raleigh, North Carolina and North Carolina State Department of Public Health IRB Non-Affiliated (Community) Member

Lucille Webb discussed her role as a “community lay person” on the North Carolina Division of Public Health IRB. In her experience, the chair of the IRB was influential in her being accepted, and she was included with all other IRB members in an extensive IRB member training. Community members have an important role in helping their fellow IRB members understand how the community might view the issue at hand. The community member’s role goes beyond reviewing consent forms to also include reviewing protocols and making presentations. In order to understand the information and the protocols, Lucille stressed the leadership of the chair and proper investment in and training of community IRB members to operate as full members of the team.

“As the community member, I have the voice that helps the IRB understand how the community might view the issue, when the researcher may view it in a different way.”

—Lucille Webb, Director, Strengthening the Black Family, Raleigh, North Carolina and North Carolina State Department of Public Health IRB Community Member



Gigi McMillan, Director, We Can Pediatric Brain Tumor Network, Los Angeles, California and University of California – Los Angeles IRB Non-Affiliated (Community) Member

Gigi McMillan discussed her role as community member on several IRBs and the need to know what was expected of her and how to do the job. In her presentation, Gigi detailed her informal discussions with community IRB members across the country, and provided helpful tips for how a community member can ask for help and guidance from their IRB administrator. In addition to designing an IRB community member track at a Public Responsibility in Medicine and Research (PRIM&R) conference, Gigi worked with her IRB administrator at UCLA to make some practical changes within the IRB. The IRB administrator and staff have since designed a step-by-step guide for how to review a protocol from a layperson’s perspective. The IRB administrator uses this guide to provide training to community members on issues to look out for when reviewing a protocol. For the second part of the training, the group reviews a hypothetical protocol together to practice their skills.

Resources

Find resources for IRB community members on The Community IRB Member: Neighbor and Partner page on the U.S. Department of Energy website at <http://www.ornl.gov/communityirb/default.htm>.



Gigi McMillan and We Can
Founder and Executive Director
We Can, Pediatric Brain Tumor Network

I wear a lot of hats. We Can - Pediatric Brain Tumor Network is a non-profit organization based in Los Angeles and we empower families to manage their medical situation and to become part of the “process” as their children go through treatment. There are almost 600 families in the We Can Network in California. I’m also on two IRBs at the University of California, Los Angeles (UCLA)-one as a community member and one as a subject representative for the cognitively impaired. I also sit on the National Cancer Institute’s Central IRB that reviews children’s cancer studies and am a member of a subcommittee for Secretary’s Advisory Committee on Human Research Protections (SACHRP). UCLA was my first experience with an IRB and it took me two years before I finally began to feel comfortable doing my job. Two years is too long of a learning curve. As I became more involved with research issues and the review process, I looked back and wondered how things could have been done differently. Three years ago I began asking community IRB members and other non scientific members around the country how they felt about what they do, what goes on at their institutions, what they hoped for regarding their IRB participation. I asked specific questions about their “job product” and what would they change if they could. I began to see a big picture with recurring themes. I realized that people like me, lay members, were not being properly utilized in the committee process, not because the administrators or IRB chairs or other IRB members did not like us or appreciate us. They simply did not know what to do with us.

I have not seen a document that explains how the federal regulations translate to the committee table. The lack of this specific, practical instruction poses a problem. I want to know what’s expected of me, how to do the job, and I want someone to tell me if I met the goals and parameters of the project. I came up with a list of what I could do as a non-affiliated, non-scientific IRB member to be more comfortable with that process. I knew I had to take the initiative -- to empower myself, to truly become part of the process. I used the same skills that we teach to our families at We Can. I asked my IRB administrator for information I could use to educate myself-were there conferences I could attend? At conferences, I talked to other people like myself and identified specific needs. Input from these many people led to designing a “Community Member Track” for the national Public Responsibility in Research and Medicine conference (www.primr.org). Over three days, this track included workshops on the history of human subject protection, value and skills that a layperson brings to an IRB committee, a discussion of the psychology of a meeting, how to review protocol, and finally, a chance for community members to grill an actual IRB chair with questions. Every community member who attended the track received a certificate of competency and a letter was sent to the IRB chair at their institution congratulating them on the success of their community member at the PRIM&R conference.

I learned many things at conferences and I wanted to bring this knowledge back to UCLA. I made it easy for my IRB administrator to help me. I asked her to hold a community member luncheon for members of all five of the UCLA IRBs. More than half of the invited members and staff attended. We met each other for the first time and as a group, we came up with a “wish list” that boiled down to three things that we would want from the program at UCLA: a peer mentor, specific training, and a sense of community. These requests complemented what I had already learned from other community members around the country. I asked my Administrator to offer specific training. She designed a short curriculum that addressed “how to review a protocol” from the lay person’s perspective. This evolved into a two-hour workshop where community members are walked through the “review process”. First, the administrator goes through each page of a sample protocol with the group and illustrates, inviting discussion, the kinds of things that lay people should be looking for. Then, as a group, the lay people have a chance to practice their new skills on another sample protocol. This workshop was part of PRIM&R’s 2007 Annual Human Research Protection Programs Conference.

In summary, I think there are five things community members want when they join an IRB: training, mentoring, respect, feedback, and a sense of community. It’s important for IRB administrators to nurture community members’ passion by getting them involved, teaching them what to do, and telling them when they do a good job. In turn, community members need to take responsibility for voicing their needs and helping their institution to help them, the laypeople, fully participate in the review process.

Community-Based Participatory Research Proposals and the Human Subjects Review Process: Methods for Working with University IRBs

Call #3: April 18, 2007

Speakers:

- **Sherril Gelmon, Professor of Public Health, Mark O. Hatfield School of Government, Portland State University, Portland, Oregon**
- **Ruth Malone, Professor, School of Nursing, University of California San Francisco, San Francisco, California**
- **Elleen Yancey, Director, Morehouse School of Medicine Prevention Research Center, Atlanta, Georgia**

Moderator: Vanessa Northington Gamble

Overview:

The purpose of this call was to provide insight into promising practices and challenges for getting IRB approval of CBPR projects. **Sherril Gelmon** provided helpful tips for getting a CBPR proposal through an IRB. **Ruth Malone** provided an example of challenges in getting IRB approval of CBPR proposals at a traditional biomedical institution. **Elleen Yancey** discussed approval of CBPR proposals at a Prevention Research Center at a historically black university, and the value of a community advisory board.



Sherril Gelmon, Professor of Public Health, Mark O. Hatfield School of Government, Portland State University, Portland, Oregon

Sherril Gelmon detailed how the role of the IRB is not to redesign data collection instruments, except where those have implications for the rights and welfare of human subjects. With any kind of research, including CBPR, writing a clear proposal is a challenge to getting IRB approval. Sherril discussed the importance of educating IRB staff members on CBPR and the role of community research participants in providing individual and community protections. IRB members may not be as familiar with CBPR, so it is important that it is carefully presented and that proposals consider concerns and risks and explain any unfamiliar methods. There seem to be many challenges in IRB review of CBPR proposals at academic health centers, where a biomedical model and quantitative research methods prevail as gold standards. If you have heard that your IRB has not been responsive to CBPR proposals, you must find ways to negotiate the IRB through such means as consulting with IRB staff and reviewing examples of previously approved proposals.



Ruth Malone, Professor, School of Nursing, University of California San Francisco, San Francisco, California

Ruth Malone presented a case study of the Protecting the Hood Against Tobacco (PHAT) Project, in which there were challenges in getting a CBPR proposal through a traditional biomedical research institution's IRB.⁴ In this case, researchers experienced a "hot potato" referral process from the IRB to the University's risk management office and back to

the IRB. It was not clear to the researchers whether the IRB sought to protect the university or the subjects of the research study. IRBs are essential for evaluating and managing risks in research, but it is important to be aware that power dynamics are embedded in all ethical decision-making. If CBPR is to be encouraged, IRBs may need to expand their ethical horizons. *See sidebar for more on Gigi's story.*



Elleen Yancey, Director, Morehouse School of Medicine Prevention Research Center, Atlanta, Georgia

Elleen Yancey talked about her experience with the Prevention Research Center (PRC) at Morehouse and how ongoing communication and collaborations have helped the IRB to understand the concepts and processes that characterize CBPR and be supportive

of moving research forward. The theme of the PRC is “Risk Reduction and Early Detection in African American and other Minority Communities: Coalition for Prevention Research.”

Elleen described how the PRC is governed by a community coalition board that has a majority of community residents as members, and serves as a governing body for policy-making. One of the questions always asked of researchers seeking approval from the coalition board for community based research is, “How will the community benefit?” The PRC incorporates the local knowledge of the health problems and community members’ interests into the design of interventions. The PRC makes an effort to convey these concepts to members of the university IRBs and to discuss how the PRC conducts CBPR. The coalition board provides campus-wide workshops across university departments, in an effort to market CBPR as a collaborative process of research that both engages and involves the researchers and community representatives alike.

“The bottom line for the community members is how will the community benefit from participating in the research? How does this translate to better health practices and better health outcomes?”

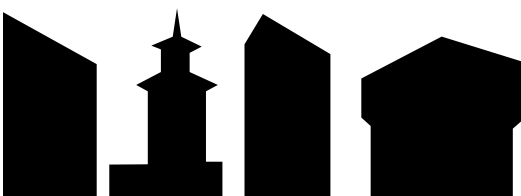
—Elleen Yancey, Director, Morehouse School of Medicine Prevention Research Center

In reference to considerations of the community IRB in review of CBPR proposals

The coalition board has established a community IRB based upon identified priorities, and it has established a set of values to determine whether proposed PRC research addresses the needs of the partner community (i.e., right to self-determination, community equal partner at every level). All of the proposed research must have prior approval from the community IRB. Once researchers have gone through the challenges of community IRB, it makes it less difficult to receive approval from the institutional IRB.

Resources

Learn more about Morehouse School of Medicine’s Prevention Research Center and its Community Coalition Board at <http://web.msm.edu/prc/>





Ruth Malone
Professor, School of Nursing,
University of California San Francisco
The Protecting the Hood Against
Tobacco (PHAT) Project



**Carol McGruder, Community
Co-Principal Investigator,
PHAT Project**

The PHAT Project's CBPR Approach

The PHAT project was a CBPR project in the Bayview-Hunters Point community of San Francisco focused primarily on African Americans, who are disproportionately affected by tobacco-related disease. In this community, 55% of the African American residents felt that health and wellness were beyond their control compared to 15% of the white residents. We decided a community participatory approach emphasizing empowerment would be useful for addressing the issue of tobacco in this community. As part of the CBPR model, community research partners participated in all phases of the research, including designing the study. Community partners were particularly interested in smoking cessation, and through a community survey found that the practice of selling “loosies,” or single cigarettes, were an obstacle to cessation. For someone trying to quit smoking, it was cheaper than buying a pack, and they were readily available at most convenience and liquor stores in the community.

Modifying the Protocol & IRB Review

The community research partners decided they wanted to look at the issue of single cigarette sales, and they began to map convenience and liquor stores in the community. We submitted modifications to the IRB for our protocol for an observational study of the stores looking at their advertising density and store sales practices, including single cigarette sales. Yet after we got approval, it was clear that an observational study would not work. There is no loitering allowed at these stores, and it can be dangerous to just hang around, so our research partners decided they wanted to try and buy single cigarettes. We revised our study and returned to the IRB with this modified protocol.

We assured the IRB that we would never identify any individual store, clerk or owner in our data, and we would only report the findings in the aggregate. The IRB refused our modification, and they did not understand that our research partners were paid researchers on the team. They said that we would be soliciting them to commit an illegal act. They said that trying to buy a single cigarette would constitute entrapment of store personnel.

“Hot Potato” Referral & Power Dynamics in Ethical Decision-making

We experienced a “hot potato” referral process from the IRB to university risk management and back to the IRB. It was not clear whether the IRB sought to protect the university or the subjects of the research study. According to the biomedical view, there were risks for the store clerks, yet according to the communitarian view, the risk was actually for the stores. And in this study, there were negligible risks for the stores, given the protections, compared to potential benefits to the community from the knowledge generated. This “hot potato” referral seemed to indicate that the university feared a legal situation, where they might be vulnerable to lawsuits.

After multiple appeals, the IRB denied us. Our community partners felt the IRB decision was a betrayal and a decision that served to protect community predators. The community research partners actually broke off from our project to carry out the study independently because as interested citizens not working with the university, they did not need IRB approval to go and ask people if they could buy a cigarette. They gained knowledge about single cigarette sales, but it could not be published or reported as a finding of the PHAT project. We could not help them disseminate this knowledge. IRBs are essential for evaluating and managing risks in research, but it is important to be aware of the power dynamics that are embedded in all ethical decision-making. Additionally, there may have been institutional conflicts of interest influencing decision-making. If CBPR is encouraged, IRBs may need to expand their ethical horizons.



Elleen Yancey

Director, Morehouse School of Medicine Prevention Research Center

The theme of our Prevention Research Center (PRC) at the Morehouse School of Medicine is risk reduction and early detection in African American and other minority communities, with an emphasis on a coalition for prevention research, including multiple community partners as well as academic and agency research partners. Through collaboration and ongoing communication with Morehouse School of Medicine's IRB, the IRB has learned the concepts integral to CBPR proposals and has been supportive in efforts to move our research forward.

The focus of the PRC is on identified health needs and priorities for the coalition partners. We make sure that at least annually (and sometimes more often) we have assessments within the community to understand the health priorities. The community residents identify these needs through surveys, focus groups, and individual interviews and communication with our prevention research center staff and faculty. The PRC is governed by a community coalition board that has a majority of community residents as its members. This is important in that it has a governing body and policy-making arm which is different from many of the prevention research centers, as well as other areas in other academic areas of community-based research.

From our community's perspective as well as our institution's perspective, CBPR must be culturally sensitive and designed to effectively translate into applicable methods of health promotion and disease prevention. This information must go beyond general publications directly into the communities. One of the questions that is always asked of researchers seeking the approval of our coalition board is, "How will the community benefit?" It's important to convey these concepts to the members of the IRBs and to talk about how we do CBPR. So our PRC actively participates university-wide in grand rounds talking about community-based prevention research. We market our approach through campus-wide workshops and face-to-face interactions.

Community members are involved in the process and the products of our research as well. Prior to submission for publication on any of our research findings, a draft goes to our community board and there is an ad-hoc committee on the community board that reviews the publication, and gives their input. Only then do we go forth with submitting to journals. In addition to this, the community members are invested in the dissemination and the use of the research findings, so ultimately their goal is a reduction in health disparities. The Morehouse PRC Community coalition Board developed three primary priorities that guide the direction of our PRC research and a set of nine community values to determine whether the proposed PRC research is appropriate to and addresses our partner communities. All of our proposed research must have prior approval by our community IRB. So once we've gone through the challenges of our community IRB, it makes it less difficult for approval with the institutional IRB.



Beyond the University IRB: Understanding Alternative Models for Human Protection, Part I: Supplementing the IRB for Community Protection with a Community Advisory Board

Call #4: May 7, 2007

Speakers:

- **Otsehtokon Alex M. McComber (Mohawk), Former Training Coordinator, Kahnawake Schools Diabetes Prevention Project, Kahnawake Mohawk Territory Quebec, Canada**
- **Vickie Ybarra, Director of Planning and Development, Yakima Valley Farm Workers Clinic, Yakima, Washington**

Moderator: Vanessa Northington Gamble

Overview:

The purpose of this session was to explore examples of community advisory boards (CABs) that have been created for additional community protections, but work collaboratively with university IRBs. **Alex McComber** described the impetus for creating the Kahnawake Schools Diabetes Prevention Project's CAB and code of research ethics. **Vickie Ybarra** discussed how the Yakima Valley Farm Workers Clinic created an internal research review committee that developed policies and procedures for determining priority projects in which to engage with academic institutions and other outside investigators.



Otsehtokon Alex M. McComber (Mohawk), Former Training Coordinator, Kahnawake Schools Diabetes Prevention Project, Kahnawake Mohawk Territory Quebec, Canada

Alex McComber provided the historical context of the Iroquois Nation and belief system as a backdrop for the Kahnawake Schools Diabetes Prevention Project (KSDPP), which seeks to address high rates of diabetes. Kahnawake embarked upon a community-university partnership to create a program with research that would give back to the community. A community advisory board (CAB) was established to conduct activities such as monitoring the project's intervention activities and participating in the evaluation process. The decision-making model built into KSDPP mirrors traditional Mohawk decision-making, with the CAB as the advisor. In partnership with university researchers, the CAB established a code of research ethics, which facilitated collaboration between the Kahnawake community, the CAB, and the university IRB.



Vickie Ybarra, Director of Planning and Development, Yakima Valley Farm Workers Clinic, Yakima, Washington

Vickie Ybarra discussed how the Yakima Valley Farm Workers Clinic (YVFWC) became interested in taking a proactive stance with universities and researchers interested in studying their community, and shared the process they put in place for a local agency research review committee. Yakima County has the highest concentration of Hispanics and of migrant and seasonal farm workers. Due to this fact, it many researchers wanted to do research on this population, without much benefit to the community. YVFWC had no structure or procedures in place to approve these projects, which were often based upon individual interests.

Vickie described some of YVFWC's negative experiences in the 1990s when several research projects diverted resources away from patient care. As a result, YVFWC was prompted to rethink how it interfaced with researchers and to implement policy changes. YVFWC developed a policy on research involvement, which states that their primary responsibility is to provide primary care for patients, and that they are interested in partnering with researchers who are interested in issues that are priorities for YVFWC. The policy on research involvement sets out a specific expectation that YVFWC has approval rights over any research that comes into the organization. YVFWC has adopted principles of community-based research and developed a research review committee, which also functions as the Health Insurance Portability and Accountability Act (HIPAA) privacy board. The research review committee reviews applications, which must be supported by a clinic sponsor (liaison between researcher and organization) according to considerations outlined by policy such as cost and benefit for the organization, sustainability, and proof of approval by the institutional IRB. The committee also considers whether the researcher has followed the principles of CBPR, such as early involvement of the community and an outcome that should benefit the community.

“We saw that researchers and academics would build upon individual relationships they had with individual clinicians and would find ways to get [approval to do their research in] in our organization in an informal way. We had no structure for approval. So often, these projects would be based largely on individual interests.”

—Vickie Ybarra, Director of Planning and Development, Yakima Valley Farm Workers Clinic

She was discussing the impetus for her organization developing research protocols and a research review committee.

Resources

Learn about the Community Research Advisory Board at the University of Pittsburgh Center for Minority Health at http://www.cmh.pitt.edu/research_crab.asp





Alex McComber and the Kahnawake Schools Diabetes Prevention Project (KSDPP)
Former KSDPP Training Coordinator

Historical Context of the Mohawk People and KSDPP

The Kahnawake Schools Diabetes Prevention Project exists within a context of traditional Iroquoian history and belief system. The Iroquois’ foundation include The Great Law of Peace -the Kaianereko:wa - and the Creation Story and ancient ceremonies. These reflect key teachings-the importance of the balance of society between men and women, the equality of all human beings in the society, and the emphasis on responsibilities of men and women in not only taking care of today, but providing for the seven generations ahead. The strength of the Iroquoian spirit is demonstrated in Kahnawake Mohawk Territory from the 1960s to today with events such as the reemergence of traditional government within the community, parents coming together to control of the educational system, and community members taking control of health, community and social services. Within that context, there is the Kahnawake Schools Diabetes Prevention Project. In the mid-1980s, doctors at the local hospital documented the high rates of diabetes-12% of the adult population. When they brought this information back to the community, elders said, “We have diabetes, and we have to live with this, this is our problem. But please do something so the children don’t get it. Prevent it in the children.” The doctors believed there was need for research to move it forward and approached the local Kahnawake Education Center, the Kateri Memorial Hospital Centre (KMHC), McGill University, and the Université de Montréal. From this came a community - university team that developed a project proposal that in 1994 received funding to set up KSDPP. KSDPP includes nutrition and physical activity programs and an elementary school diabetes prevention curriculum (which was developed by KMHC personnel).



As history demonstrates in Indigenous communities: “Outside research teams swooped down from the skies, swarmed all over town, asked nosy questions that were none of their business and then disappeared never to be heard of again.”- Louis T. Montour MD, 1987. Kahnawake embarked upon a community-university partnership to create a program designed to be a different approach to research-research that would give back to the community.

Community Advisory Board

This community-university partnership established a Community Advisory Board (CAB) to monitor the project’s intervention activities, to work with the research team, participate in the evaluation process, and to participate in developing a code of research ethics. The decision-making model that was built into KSDPP mirrored traditional Mohawk decision-making. In the longhouse, there is the well, in which issues are generated and put out for discussion. The group agreed that the agenda fell to the staff, so that interested researchers and community members would contact the staff to present requests and research proposals. Then, it would go to researchers to discuss, and finally, the CAB would deliberate, discuss and confirm the decision.

With this kind of decision-making process, KSDPP set out to establish a code of research ethics. It came from the consensual decision-making that is part of Mohawk/Iroquoian culture, and it also came from the CBPR world. The Code of Research Ethics explains the relationship for working with universities, researchers and institutional review boards. In KSDPP’s experiences of working with new research proposals, there has been wonderful collaboration between KSDPP and its CAB and the institutional review boards. As a community, this demonstrates Kahnawake’s interest in research and their efforts to ensure respect of community members, the community itself and a collaborative research process.



Beyond the University IRB: Understanding Alternative Models for Human Protections, Part II: Creating an Independent Community IRB - When is it Right for You?

Call #5: May 24, 2007

Speakers:

- **Sheila Beckham**, Preventive Health Services Director, Waianae Coast Comprehensive Health Center, Waianae, Hawaii
- **Jacqueline Tran**, Program Manager, Orange County Asian and Pacific Islander Community Alliance, Garden Grove, California
- **Eric Wat**, Data Manager, Special Service for Groups, Los Angeles, California
- **Bill Freeman**, Director of Tribal Community Health Programs & Human Protections Administrator, Northwest Indian College, Bellingham, Washington

Moderator: Vanessa Northington Gamble

Overview:

The purpose of this call was to explore examples of independent community IRBs that have been created to serve the needs of their communities. **Sheila Beckham** discussed the development of a research review and community IRB serving a native Hawaiian community. **Jacqueline Tran** and **Eric Wat** described how they created an independent community IRB and how it is maintained. **Bill Freeman** discussed the impetus for creating community IRBs and important, practical considerations in their formation.

“Some researchers may question the need to obtain community IRB approval when they’ve already received university/hospital IRB approval. In order to overcome challenges [in getting your community IRB recognized], it is necessary to get Office for Human Research Protection’s ‘stamp of approval.’”

—Bill Freeman, Director of Tribal Community Health Programs & Human Protections Administrator, Northwest Indian College



Sheila Beckham, Preventive Health Services Director, Waianae Coast Comprehensive Health Center, Waianae, Hawaii

Sheila Beckham discussed the context and climate surrounding Waianae Coast Comprehensive Health Center’s (WCCHC) establishment of a multidisciplinary research committee in the 1990s to review research involving patients, staff, or community residents. The committee’s purpose is to ensure all proposals approved are ethnically and culturally sensitive, and is relevant to community needs. The research committee reviews a particular proposal before it is submitted for funding. If funded, the proposal then goes to the formal IRB, which WCCHC established in 2005, after noting that many researchers continued to bypass the review committee’s non-binding system.





**Jacqueline Tran, Program Manager,
Orange County Asian and
Pacific Islander Community Alliance,
Garden Grove, California**



**Eric Wat, Data Manager,
Special Service for Groups,
Los Angeles, California**

Special Service for Groups IRB

Jacqueline Tran and Eric Wat described how they noticed that many of the underserved communities with which SSG and OCAPICA work were not represented on university IRBs. After identifying a need for a community IRB and a year of developing protocols and procedures, in 2004, they received approval by the U.S. Department of Human Services for a community IRB. Jacqueline and Eric discussed the formation of the community IRB from a nationally-funded Centers for Disease Control and Prevention (CDC), Racial and Ethnic Approaches to Community Health (REACH) 2010, PATH (Promoting Access to Health) for Women project. This REACH 2010 PATH for Women project addressed disparities amongst breast and cervical cancer in Southeast Asian and Pacific Islander communities. The purpose of the IRB is to empower community programs and partners in the IRB process and as equal research partners and to give a voice to under-represented communities regarding research, especially involving human subjects. Jacqueline and Eric described the concrete steps and processes they took to establish and maintain the IRB once it became operational. The IRB seeks to empower the community's role through a transparent review process—thereby increasing the capacity of community organizations, increasing networking and collaboration in the community, and improving the ways of doing community outreach and education. Starting an IRB is an investment, and there have been many rewards both in terms of providing a voice for the community, and for community researchers who feel strongly about the community IRB's role in creating equity between community researchers and their community partners.



Bill Freeman, Director of Tribal Community Health Programs & Human Protections Administrator, Northwest Indian College, Bellingham, Washington

Bill Freeman described the impetus for most community IRBs—a growing trend to ensure that a community “has a voice,” to ensure that the special features of the community are protected, or to ensure truly informed consent by community members. Common motivators for starting community IRBs include having a bad experience with research in the community, or as a result of a need to assert control over its destiny in terms of what kind of research is appropriate. Bill highlighted some of the practical challenges for getting a community IRB started, such as staffing, creating policies and procedures, and the investment of time to get it up and running. One of the solutions to these challenges include borrowing policies and procedures from other community IRBs willing to share their policies and registering your IRB. The IRB can go beyond what the regulations state and what university IRBs normally do to consider harms and benefits to communities. An important step for formalizing one's IRB is to register with the Office for Human Research Protections (OHRP) and obtain OHRP's Federal-Wide Assurance of Compliance, which ensures power to make researchers comply with the IRB. In addition, a researcher and community organization can come to an agreement about terms of research in the community. It is important for a community organization/IRB to get a lawyer to ensure written agreements include the appropriate legal requirements.

Resources

Learn more about the Navajo Nation Human Research Review Board, “Indigenous people and researchers: building collaborative partnerships and the importance of responsibilities, ethics, and values of research on the Navajo Nation,” at <http://www.nnhrrb.navajo.org/>



Sheila Beckham and the Waianae Coast Comprehensive Health Center (WCCHC)
Preventive Health Services Director, WCCHC

The Waianae Coast is home to the fourth largest number of native Hawaiians in Hawaii and has long been a focus of researchers desiring to study native Hawaiians, collect data, and leave when funding ends. In 1990, the Waianae Coast Comprehensive Health Center (WCCHC), a Federally Qualified Community Health Center, entered into a joint research relationship with the University of Hawaii’s Cancer Research Center to implement the Waianae Cancer Research Project.

Research Protocols, Principles, and Guidelines

The Waianae community established and published a set of research protocols, principles and guidelines for participatory research in 1992, and a protocol for the dissemination and publication of data in 1995 that would guide future community-based research. WCCHC’s multidisciplinary research committee was established around this time to assume responsibility of reviewing any research that might involve patients, staff, or community residents. The research committee’s primary purpose is to ensure all proposals approved by the committee are sensitive to diverse groups of cultures, ethnicities, and communities on the coast, and the secondary purpose is to ensure that the research is relevant to the needs of the community. An important distinction between the research committee and the IRB is that the research committee reviews a particular proposal before it is submitted for funding and before providing the valued letter of support.

Community IRB

If the proposal is funded, it will then come to our formal IRB, which was established to protect the special features of our community and to ensure that the community has a voice. WCCHC decided to establish its own recognized IRB in 2005 after noting that many researchers continued to bypass the non-binding review system of our research committee in hopes of obtaining expedited approval for a proposal. Many researchers have questioned the need to obtain approval from our IRB when they’ve already received approval from what they consider to be a “gold standard” university or medical center-based IRB. Our community-based IRB has intimate knowledge of our community and its residents, and it is in a position to determine successful elements related to community-based research. We prefer to see a proposal come through the research committee at its inception.



IRB Reform: Changing Policy and Practice to Protect Communities

Call #6: June 25, 2007

Speakers:

- **Nancy Shore, Assistant Professor at the University of New England School of Social Work, Portland, Maine**
- **Sarah Flicker, Assistant Professor, York University, Toronto, Ontario, Canada**
- **Robb Travers, Scientist and Director of Community-Based Research, Ontario HIV Treatment Network, Toronto, Ontario, Canada**
- **Syed Ahmed, Director of the Center for Healthy Communities & Professor of Family and Community Medicine, Medical College of Wisconsin, Milwaukee, WI (Presentation prepared by Sarah Beversdorf, Rural Health Liaison for the Healthier Wisconsin Partnership Program, Medical College of Wisconsin, Milwaukee, Wisconsin)**

Moderator: Kristine Wong, Community-Campus Partnerships for Health

Overview:

This call explored findings from recent studies of IRBs and CBPR to provide insight into how research ethics policies and practices can be changed to provide community protections.



Nancy Shore, Assistant Professor at the University of New England School of Social Work, Portland, Maine

Nancy Shore described a growing body of literature that describes community-based review mechanisms as well as IRB/CBPR tensions. Nancy discussed several issues emerging in the literature, including IRB risk-benefit analysis and how it relates to the community context, problematic methodological assumptions or biases that privilege more traditional research approaches, and the degree to which the Belmont principles cover the scope of ethical considerations. Nancy also talked about her exploratory study entitled “Re-conceptualizing the Belmont Principles,” which focused on trying to understand the similarities and differences between the ethical considerations expressed in the Belmont Report and from the CBPR perspective.⁶ Overall, study interviewees’ responses touched upon IRB considerations, yet articulated their desire to push the Belmont Report framework further by introducing the ethics of involvement as well as emphasizing social change in community level considerations. The Belmont Report suggests a framework more consistent with traditional research where the research is more representative of objects that passively contribute to the researchers’ understanding and ability to produce individual and/or societal level benefits. Nancy draws from several authors in providing a case for widening the ethical frame of reference as compared to the regulations’ tendency to focus primarily on the individual human subject.



**Sarah Flicker, Assistant Professor,
York University,
Toronto, Ontario, Canada**



**Robb Travers, Scientist and
Director of Community-Based
Research, Ontario HIV Treatment
Network, Toronto, Ontario,
Canada**

Sarah Flicker and Robb Travers presented two recent studies conducted in Canada examining the paradigm of current research ethics boards (Canada) or IRB (United States) practices and the suitability of those to community based research.^{11 7} Sarah and Robb presented an alternative set of questions for judging community-based research studies that bridge the Tri-Council Canada Principles for ethics review (analogous to the Belmont Principles) and the principles of community-based research (CBR). Research methodologies are often insensitive, and many communities, particularly aboriginal communities in Canada, feel over-researched and that benefits to their own people are minimal. CBR is an approach to research that addresses these problems. The objectives in the two studies were to think critically about the following questions: Is CBR inherently ethical? Does it pose unique ethical dilemmas? Are those ethical dilemmas captured in current processes by IRBs? Are they using the correct procedures to assess those unique ethical issues of CBR?

“More often than not, content analysis of review forms highlighted that IRBs were mainly interested in individualized notions of risk and risk management.... What are the risks for communities? What are the mechanisms that will be used to handle unflattering results? What happens when you are working with an already stigmatized community that is written or talked about a lot in very unflattering ways?”

— Sarah Flicker, Assistant Professor,
York University, discussing questions and
considerations for how to broaden IRB review
protocols to include community considerations

The HIV Treatment Network in Toronto study by Travers et al. (2006) looked at the development of an ethics review board for community-based HIV research in Ontario.¹¹ The study involved a document review of literature about the issue of ethics review and its suitability for community-based research. The study reviewed current boards that called themselves community-based and the ways they operationalize ethics review processes and how that differs from more traditional university or hospital based processes. One of the key findings involved the ethics review processes and power imbalances inherent within these reviews. Many of these projects had developmental stages where community partners felt a real sense of ownership over their research projects until the ethics review process, where suddenly the academic partners in the CBR collaborative were in a position of privilege relative to the community partners.

Sarah Flicker presented findings from a study co-authored by Flicker and Travers et al. (2007) entitled, “Ethical Dilemmas in Community-based Research: Recommendations for Institutional Review Boards.”⁷ This study was a content analysis of research ethics board (REB) and IRB forms from select schools of health in Canada and the United States. The authors developed a scoring tool that sought evidence of community-based principles in action within REB and IRB forms. For instance, many of the IRB forms reviewed asked for background, purpose, and objectives. Researchers rarely saw the question of who benefits from the research and how in terms of a larger community approach. This study identified that research should continue to identify problems with current review paradigms, as



well as solutions. In addition, IRB and REB modes that incorporate the principles of CBR and the Tri-County or Belmont Principles are needed, and alternative review guidelines for community-based research protocols are needed for REBs and IRBs.



Syed Ahmed, Director of the Center for Healthy Communities and Professor of Family and Community Medicine, Medical College of Wisconsin, Milwaukee, WI

Syed Ahmed discussed key components of a “story session” presented the story at the CCPH conference in May 2006 and participant suggestions from a workshop both the 2006 and the April 2007 CCPH conference. This story details the challenges that the Medical College of Wisconsin experienced in working with the communities it serves. Three main questions were raised at the conference: 1) What role can academics play to enhance CBPR in their own institution? 2) How can we get communities on the same page as it relates to IRB? 3) What could the role be for a national organization such as CCPH and others to create a national dialogue?

In terms of the role academics can play to enhance CBPR, Syed discussed the importance of clear communication with the IRB. In Syed’s experience, they have developed a very receptive relationship with their IRB, which has helped to clarify from the IRB’s understanding of CBPR.¹² Syed also described the Medical College’s use of an umbrella protocol, which involves proposing future amendments as part of submitting an application to the IRB. This has helped in getting the initial IRB review approved and presenting amendments as needed. Syed also discussed the need to work with communities and have a dialogue and understanding on CBPR and the potential challenges with the IRB process. In terms of creating a national dialogue, Syed discussed conference participants’ ideas of a national organization like CCPH taking the lead on developing educational materials and toolkits on research, being a clearinghouse for information, and offering technical assistance for how academics and communities work together to solve issues of CBPR/IRB tensions.

Resources

To stay connected with an ongoing dialogue about these issues, be sure to visit <http://www.ccpb.info> for more information and for instructions on joining the e-mail listserv.

Call Series Themes & Their Implications

The Educational Conference Call Series on IRBs and Ethical Issues in Research created a forum for discussing many of the issues related to CBPR, research ethics review, and protection of communities engaged in research. A number of themes emerged from the call series that are important to consider:

The first two calls in the series covered the historical events leading to human protections regulations and IRBs. These calls also provided an introduction to the importance of community representation on an IRB and the various levels of IRB review that may be required depending upon the community and its concerns for broader protections. An important and emerging theme included **the need for formal training and mentoring of community IRB members** in their role on the IRB. By investing in the training and mentoring of community members, IRBs can benefit from the important perspectives of lay members and community knowledge in their review of research proposals.

In CBPR, human protections concerns are not just about individuals involved in research, but also concerns about the respect, beneficence, and justice for communities involved in research. The third call explored the tensions between the IRB process and CBPR and the frequent difficulty of approval of CBPR proposals by IRBs, especially those at traditional biomedical research institutions. Many of the structures built into CBPR for the purpose of community participation and protection are not understood by IRBs that by design are focused on the protection of individual research participants. The themes that emerged from these calls were

the need to recognize the power imbalances that are inherent in the research ethics review process, and the need for training IRB staff and committee members in CBPR and community-level benefits and risks of participating in research.

In the latter calls, the series delved into other ways to incorporate community concerns into research ethics review. These sessions highlighted models by which communities and community-based organizations have developed structures that go beyond minimum federal standards for human research protections. These models take into account broader community concerns.

The motivating factors behind many of these models were bad experiences with research in their communities and/or a desire to control the destiny of research in their communities.

Some community-based organizations opt for internal structures that oversee only the research performed in conjunction with organizational services, and others have opted for independent structures that cover a broader geographic or racial/ethnic community. These calls demonstrated **the value to communities of creating further protections to ensure, for example, that research is culturally competent, gives back to the community, and includes community ownership of data.**

Finally, the series demonstrated the **need to broaden the ethical considerations in research to include community-level issues.** The call series demonstrated a number of ways this can be accomplished, including through stronger community representation on IRBs, increased IRB understanding of CBPR; and the creation of community mechanisms for research ethics review such as community advisory boards and independent community IRBs.



Next Steps from the Call Series

As evident in this report, community considerations in research ethics review can take a variety of forms, and there are many avenues through which a community, research institution, or community-institutional partnership can broaden the scope of ethical considerations to include community. In Call #5, Bill Freeman provided practical guidance for how a community can start their own officially registered IRB. From the community perspective, this is a way to ensure that researchers conducting work in the local community are required to go through the community entity for approval. Other models were presented by Alex McComber and Vickie Ybarra in Call #4, such as development of a code of research ethics for one's community or a research review committee for the population served by one's community-based organization. These examples rely on good working relationships with universities and other research institutions. While many of these approaches protect the specific population to which the organization provides services, they can not provide similar protections to the entire community—whether the community is defined by its similarities in geography, culture, ethnicity, or socioeconomic status. This series has elucidated a variety of ways in which communities can strive for broader protections. Yet what does one do to ensure community considerations do not fall through the cracks with human subjects research in any community? There are many options, but no guarantees that community will be considered

in all research. Thus, policies must be developed and strengthened on the institutional side as well, through institution-based IRBs.

As presenters in the final call highlighted, there are different questions one can ask in the ethics review process to broaden the scope of human research subjects protections to include the protection of communities. These changes must be instituted as policy on an institutional level if substantive change is to take place. Yet, as discussed in call #1, only federally funded research is regulated – independent research performed in communities is not. Thus, there is

a need and responsibility for IRBs to protect communities, not just individuals. Similarly, there is a need for protections initiated on the part of communities to protect themselves, whether through an internal research review committee, community advisory board, or community IRB.

Unfortunately, many underserved and disadvantaged communities do not have the resources to create these structures; much work needs to be done to build capacity within these communities so that these structures can become a reality.

Through this educational conference call series, CCPH and the Bioethics Center have established a network of diverse stakeholders who are interested in issues of community considerations in research ethics review. They hope that this series, the growing clearinghouse of resources on the CCPH website, and the dedicated group of individuals working to ensure community-

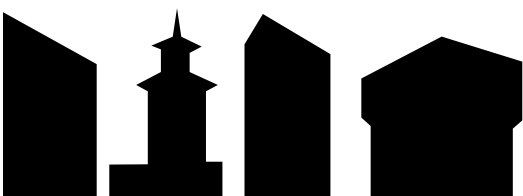
“Being a historian, one of the things that has come up [on this call and on previous calls] is the whole issue of how we deal with an IRB system that was developed to deal with clinical research and how you work with that system in terms of not just CBPR but historical and social science research.”

—Vanessa Northington Gamble,
Series Moderator and Former
Director of the Tuskegee University
National Center for Bioethics
in Research and Health Care

level research protections will provide support to organizations and communities seeking to act on the ideas presented in this report.

To help guide the continued collaboration between CCPH and the Bioethics Center and identify priorities for future activities, call series participants were e-mailed a short survey to solicit their feedback. When asked what activities they saw as priorities in follow-up to the call series, the highest ranked activity was “trainings for IRB members and administrators on CBPR,” followed by “trainings for community-based organizations on how to establish community-based mechanisms for research.” In January 2008, CCPH and the Bioethics Center convened a work group that is developing a CBPR curriculum for IRBs and REBs (Research Ethics Boards, as they are known in Canada).

Call series participants also voiced strong support for establishing an electronic discussion group (listserv) dedicated to the topic of CBPR & Research Ethics. The listserv was established in December 2007 and has over 900 subscribers (as of June 2008). We encourage readers who are interested in continuing conversations on these issues to subscribe today through the CCPH website at www.ccpb.info. In addition, a CBPR & Research Ethics Webpage was established on the CCPH website after the call series as an ongoing resource.



There are a number of tangible and practical ways that readers can respond to the issues raised in this report:

If you are an IRB member:

- View your involvement on the IRB as a critical opportunity to ensure that community-level considerations be taken into account during IRB review
- Ask the chair of your IRB for guidance, resources, and opportunities for learning and mentoring
- Network with your fellow IRB members to share experiences with each other and your collective ideas and recommendations for how the IRB can best support you
- As a seasoned IRB member, mentor novice IRB members
- If you are involved in community-based participatory research (CBPR), introduce your fellow IRB members to your CBPR colleagues and CBPR principles and approaches to, to learn more about the context for each others' work

If you are an IRB administrator:

- Provide appropriate training and protocol review exercises for all IRB members, with special attention being paid to members who may be new to research ethics review
- Clearly define the role of community members on your IRB and work to ensure this role is understood and respected by all IRB members
- Provide networking and training opportunities for community-based IRB members
- Facilitate opportunities for IRB members to learn about CBPR and the ethical challenges and considerations inherent in CBPR

If you are a CBPR researcher:

- Educate your IRB on CBPR and community ethics considerations
- Advocate for broader ethical review considerations through modifications to review forms and instructions used by your IRB
- Involve community partners early on in the IRB process
- Ensure that your community partners complete human subjects research ethics training

If you are a community member or affiliated with a community-based organization:

- Initiate a dialogue with the university or hospital-based IRBs working in your community to determine how best you can best work together
- Review the resources in your community and assess whether a community advisory board, an independent community IRB, or another community mechanism for research ethics review seems appropriate for your situation
- Follow-up with community-based speakers in the call series for advice regarding important aspects to consider in making this decision (i.e., time, resources, staffing)



Citations

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- 3 Sengupta S, Lo B. The roles and experiences of nonaffiliated and non-scientist members of institutional review boards. *Acad Med*. 2003; 78(2):212-8.
- 4 Malone RE et al. "It's like Tuskegee in reverse": A case study of ethical tensions in institutional review board review of community-based participatory research. *American Journal of Public Health*. 2006; 96(11): 1914-1919.
- 5 Gilbert SG. Supplementing the traditional institutional review board with an environmental health and community review board. *Environ Health Perspect*. 2006; 114(10):1626-9.
- 6 Shore N. Re-conceptualizing the Belmont Report: A community-based participatory research perspective. *Journal of Community Practice*. 2006;14(4): 5-26.
- 7 Flicker, S., Travers, R., Guta, A., McDonald, S. & Meagher, A. Ethical Dilemmas in Community-Based Participatory Research: Recommendations for Institutional Review Boards. *Journal of Urban Health*; 2007; 84(4): 478-493.
- 8 Freeman W. Call #1: "What is an Institutional Review Board (IRB) and What Purpose Does it Serve?" Educational Conference Call Series on Institutional Review Boards (IRBs) and Ethical Issues in Research. February 14, 2007.
- 9 Kagawa-Singer M, Park Tanjasiri S, Lee SW, Foo MA, Ngoc Nguyen TU, Tran JH, Valdez A. Breast and cervical cancer control among Pacific Islander and Southeast Asian Women: participatory action research strategies for baseline data collection in California. *J Cancer Educ*. 2006; 21(1 Suppl): S53-60.
- 10 Penslar RL. IRB Guidebook. Office for Human Research Protections. Retrieved November 4, 2007 from http://www.hhs.gov/ohrp/irb/irb_guidebook.htm
- 11 Travers, R., et al. Proposal for an ethics review board of community-based HIV/AIDS research in Ontario, an OHTN position paper. 2006. Ontario HIV Treatment Network: Toronto, ON.
- 12 Beversdorf, S., Ahmed, S., & Beck, B. (2007). Community-Academic Partnerships and Institutional Review Board Insights. *Partnership Perspectives*. 2007; IV, Issue I: 95-104. Available at <http://ccph.info/>.



Suggested Resources

Call #1 - What is an Institutional Review Board (IRB) and What Purpose does it Serve?

Code of Federal Regulations:

- Title 45 Public Welfare, Department of Health and Human Services, Part 46 Protection of Human Subjects: www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

Historical Events & Ethical Codes:

- Nuremberg Code: www.hhs.gov/ohrp/references/nurcode.htm
- Declaration of Helsinki: www.wma.net/e/policy/b3.htm
- U.S. Public Health Service Syphilis Study background: <http://www.tuskegee.edu/Global/story.asp?S=1207512>
- Belmont Report: <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>
- Washington, Harriet A. *Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present*. New York: Doubleday, 2007.

Educational Materials & Resources on IRBs:

- Office for Human Research Protections IRB Guidebook: http://www.dhhs.gov/ohrp/irb/irb_guidebook.htm
- Public Responsibility in Medicine and Research (PRIM&R) offers a course called IRB 101™: http://www.primr.org/education/2007_IRB_FUND/overview_FUND_0207.html
- Research Ethics and IRB Resources for Tribes and Researchers – by Aberdeen Area Tribal Chairmen's Health Board: <http://www.aatchb.org/epi/docs/ResearchEthics.htm>
- IRB: Ethics & Human Research Journal Available at: <http://www.thehastingscenter.org/publications/irb/irb.asp>

Relevant Websites:

- Community-Campus Partnerships for Health (CCPH) Ethics & IRBs Links Page: <http://depts.washington.edu/ccph/links.html#Ethics>
- Department of Health and Human Services, Office of Human Research Protections: <http://www.dhhs.gov/ohrp/>
- Tuskegee University National Center for Bioethics in Research and Health Care: www.tuskegee.edu/bioethics
- Public Responsibility in Medicine and Research (PRIM&R): www.primr.org



Call # 2 – Highlighting the Importance of the IRB Member

Resources for Non-affiliated/Non-Scientific Community IRB Members:

- The Community IRB Member: Neighbor and Partner, U.S. Department of Energy website: <http://www.ornl.gov/communityirb/default.htm>. Join their listserv at: <http://www.ornl.gov/communityirb/listserv.htm>
- Research Ethics Training Curriculum for Community Representatives, Family Health International. Available at: <http://www.fhi.org/en/RH/Training/trainmat/ethicscurr/retccr.htm>
- Citizens for Responsible Care and Research's listing of IRBs registered with the Office for Human Research Protections. Available at: <http://www.circare.org/info/researchbythenumbers1.htm>
- Research Advocacy Network is a non profit organization working to bring together all participants in the medical research process with the focus on education, support and connecting patient advocates with the research community to improve patient care. To learn more about the network and how to get involved, please visit: <http://www.researchadvocacy.org/about/index.php>

Recent Past Conferences and Presentations on Community IRB Members

- Public Responsibility in Medicine and Research (PRIM&R) pre-conference workshop in 2006 entitled, "What does It Mean to Represent the Community?" Description available at: http://www.primr.org/uploadedFiles/PRIMR_Site_Home/Education/Conferences/Past_Conferences/HRPP_2006/Community_Participation.pdf
- PRIM&R's educational session on recruitment and retention of non-affiliated members. Available at: <http://www.primr.org/conferences.aspx?id=752>
- Southeast Community Research Center & Tuskegee University Center for Bioethics in Research and Health Care presented a workshop in 2003 entitled, "Science By the People: Promoting Community Participation on Institutional Review Boards" Description available at: http://www.cbpr.org/index.php?option=com_content&task=view&id=18

Selected Articles on Community IRB Members:

- Anderson EE (2006). A qualitative study of non-affiliated, non-scientist institutional review board members. *Account Res* 13(2):135-55.
- Bauer PE (2001). A few simple truths about your community IRB members. *IRB* 23(1):7-8.
- De Vries R, Forsberg CP (2002). Who decides? A look at ethics committee membership. *HEC Forum* 14(3):252-8.
- Sengupta S, Lo B (2003). The roles and experiences of nonaffiliated and non-scientist members of institutional review boards. *Acad Med* 78(2):212-8.

Regulations on IRB Membership:

- Code of Federal Regulations, Title 45 Public Welfare, Department of Health and Human Services, Part 46 Protection of Human Subjects. SubPart 46.107 IRB Membership: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.107>



Call # 3 – Community-Based Participatory Research (CBPR) Proposals and the Human Subjects Review Process: Methods for Working with University IRBs

Selected Articles on IRB Review and Community-based Participatory Research or Participatory Action Research:

- Flicker S, Travers R, Guta A, McDonald S, Meagher A (2007). Ethical Dilemmas in Community-Based Participatory Research: Recommendations for Institutional Review Boards. *J Urban Health* Apr 10.
- Khanlou N and Peter E (2005). Participatory action research: considerations for ethical review. *Social Science & Medicine* 60: 2333-2340.
- Malone RE et al (2006). “It’s like Tuskegee in reverse”: A case study of ethical tensions in institutional review board review of community-based participatory research. *American Journal of Public Health* 96(11): 1914-1919.

Call # 4 – Beyond the University IRB: Understanding Alternative Models for Human Protection, Part I: Supplementing the IRB for Community Protection with a Community Advisory Board

Selected Articles on community advisory boards or similar entities:

- Burrus BB, Liburd LC, Burroughs A (1998). Maximizing participation by black Americans in population-based diabetes research: the Project DIRECT pilot experience. *J Community Health* 23(1):15-27.
- Cargo M, Levesque L, Macaulay AC, et al (2003). Kahnawake Schools Diabetes Prevention Project (KSDPP) Community Advisory Board. Community governance of the Kahnawake Schools Diabetes Prevention Project, Kahnawake Territory, Mohawk Nation, Canada. *Health Promot Int* 18(3):177-87.
- Chene R, Garcia L, Goldstrom M, et al (2005). Mental health research in primary care: mandates from a community advisory board. *Ann Fam Med* 3(1):70-2.
- Galea S, Factor SH, Bonner S, et al (2001). Collaboration among community members, local health service providers, and researchers in an urban research center in Harlem, New York. *Public Health Rep* 116(6):530-9.
- Gilbert SG (2006). Supplementing the traditional institutional review board with an environmental health and community review board. *Environ Health Perspect* 114(10):1626-9.
- Horowitz CR, Arniella A, James S, et al (2004). Using community-based participatory research to reduce health disparities in East and Central Harlem. *Mt Sinai J Med* 71(6):368-74.
- Macaulay AC, Cross EJ, Delormier T, et al (1998). Developing a Code of Research Ethics for research with a Native community in Canada: a report from the Kahnawake Schools Diabetes Prevention Project. *Int J Circumpolar Health* 57 Suppl 1:38-40.
- Quinn SC (2004). Ethics in public health research: protecting human subjects: the role of community advisory boards. *Am J Public Health* 94(6):918-22
- Strauss RP, Sengupta S, Quinn SC, Goepfinger J, Spaulding C, Kegeles SM, Millett G (2001). The role of community advisory boards: involving communities in the informed consent process. *Am J Public Health* 91(12):1938-43.

Organizations with Supplementary Models of Protections:

- Kahnawake Schools Diabetes Prevention Project, Community Advisory Board:
<http://www.ksdpp.org/elder/cab.html>
- University of Pittsburgh Center for Minority Health, Community Research Advisory Board (CRAB): http://www.cmh.pitt.edu/research_crab.asp
 - CRAB guidelines: http://www.cmh.pitt.edu/pdf/crabguidelines_dates.pdf
- Yakima Valley Farm Workers' Clinic, Community Advisory Board:
http://www.farmworkerhealth.org/newsletters/10934vol6_Newsletter.pdf
- Access Alliance: Multicultural Community Health Center:
http://www.accessalliance.ca/index.php?option=com_content&task=view&id=37&Itemid=56
- University of California San Francisco, Positive Health Program Community Advisory Board:
http://www.communityconsortium.org/about/about_cab.html
- HIV/AIDS research network community advisory boards:
<http://www.thebody.com/content/policy/art4866.html>

Call #5: Beyond the University IRB: Understanding Alternative Models for Human Protection, Part II: Creating an Independent Community IRB — When is it Right for You?

Selected articles on community IRBs and building community research capacity:

- Navajo nation IRB: a unique human research review board has three primary concerns: protecting its community, its people, and its heritage. *Prot Hum Subj*. 2003 Spring;(8):1-2. Retrieved on May 21, 2007 from <http://www.science.doe.gov/ober/humsubj/spring03.pdf>
- Braun KL, Tsark JU, Santos L, Aitaoto N, Chong C (2006). Building Native Hawaiian capacity in cancer research and programming. A legacy of 'Imi Hale. *Cancer* Oct 15;107(8 Suppl):2082-90.
- Brugge D, Missaghian M (2006). Protecting the Navajo People through tribal regulation of research. *Sci Eng Ethics* 12(3):491-507.
- Colwell-Chanthaphonh C (2006). Self-governance, self-representation, self-determination and the questions of research ethics--commentary on "Protecting the Navajo People through tribal regulation of research". *Sci Eng Ethics* 12(3):508-10.
- Hernandez JAA (2004). Blood, lies, and Indian rights: tribal colleges and universities (TCUs) becoming gatekeepers for research. Retrieved on May 21, 2007 from <http://tribalcollegejournal.org/themag/backissues/winter2004/winter2004hernandez.html>
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- Oneha MF, Beckham S (2004). Re-examining community based research protocols. *Pacific Public Health* 2.11:1
- Schrag B (2006). Research with groups: group rights, group consent, and collaborative research commentary on "Protecting the Navajo People through tribal regulation of research". *Sci Eng Ethics* 12(3):511-21.



Selected examples of independent community IRBs:

- Orange County Asian and Pacific Islander Community Alliance: <http://www.ocapica.org> - in collaboration with Special Services for Groups: <http://www.ssgmain.org/>
 - About the IRB: http://www.cbcrp.org/publications/newsletters/2006/page_17.php
 - American Public Health Association conference audio-recorded presentation: *A community perspective of CBPR methods: The Promoting Access to Health for Pacific Islander and Southeast Asian women program*: http://apha.confex.com/apha/134am/techprogram/paper_131797.htm
- Waianae Coast Comprehensive Health Center: <http://www.wcchc.com/>
 - Research and Institutional Review Board Protocols: <http://www.wcchc.com/researchactivities.aspx>
- Papa Ola Lokahi: <http://www.papaolalokahi.org>
 - Native Hawaiian Health Care System (NHHCS) – Institutional Review Board (IRB): http://www.papaolalokahi.org/hoe2/index.cfm?wwa_ID=93B99296-EF41-4D27-9ECEB62C082DD382&sub=yes
- Navajo Nation Human Research Review Board: <http://www.nnhrrb.navajo.org/>

Call #6: IRB Reform: Changing Policy and Practice to Protect Communities

Selected articles:

- Beversdorf, S., Ahmed, S., & Beck, B (2007). Community-Academic Partnerships and Institutional Review Board Insights. *Partnership Perspectives* IV, Issue I: 95-104. Available at <http://www.ccpb.info/>.
- Flicker, S., Travers, R., Guta, A., McDonald, S. & Meagher, A (2007). Ethical Dilemmas in Community-Based Participatory Research: Recommendations for Institutional Review Boards. *Journal of Urban Health* e-pub (DOI 10.1007/s11524-007-9165-7).
- Glass KC, Kaufert J (2007). Research Ethics Review and Aboriginal Community Values: Can the Two be Reconciled? *Journal of Empirical Research on Human Research Ethics*. 2007; 2(2): 25-40.
- King, N., Henderson, G., & Stein, J. (1999). *Beyond Regulations: Ethics in Human Subjects Research*. Chapel Hill: University of North Carolina Press.
- Macaulay AC, Hickner J, Sherwood RA (2006). Protecting participants in family medicine research: a consensus statement on improving research integrity and participants' safety in educational research, community-based participatory research, and practice network research. *Family Medicine* 38(2):116-20.
- Shore, N (2007). Community Based Participatory Research and the Ethics Review Process. *Journal of Empirical Research on Human Research Ethics* 2(1): 31-41.
- Shore, N (2006). Re-conceptualizing the Belmont Report: A community-based participatory research perspective. *Journal of Community Practice* 14(4), pp. 5-26.
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