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Ethics review for a multi-site project involving Tribal Nations in the Northern Plains

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Abstract

Increasingly, Tribal Nations are forming ethics review panels, which function separately from institutional research review boards (IRBs). The emergence of strong community representation coincides with a widespread effort supported by the Department of Health and Human Services and other federal agencies to establish a single IRB for all multi-site research. This article underscores the value of a tribal ethics review board and describes the tribal oversight for the Safe Passage Study - a multi-site, community-based project in the Northern Plains. Our experience demonstrates the benefits of tribal ethics review and makes a strong argument for including tribal oversight in future regulatory guidance for multi-site, community based research.

Keywords

Tribal IRB; Communication in Research; Multiple IRB Review; Community IRB; Research Ethics Committee; CBPR

Increasingly, researchers are using community-based approaches to study complex public health issues. Community-based research (CBR) involves collaboration between the researchers and local community representatives in the study design, implementation, interpretation, and dissemination of findings (Israel, Schulz, Parker, & Becker, 1998). This progressive and democratic approach empowers the community, builds infrastructure and provides resources to address pressing problems beyond the scope of the research (Goodman, Dias, & Stafford, 2010; Israel et al., 2010) .

CBR methodology has complex and unique challenges, notably in the ethics review and oversight process (Wolf, Walden, & Lo, 2005). Institutional review boards (IRBs) need to be cognizant of the needs of the community, as well as those of the individual (Friedman Ross, 2010), affecting informed consent procedures, interpretation of results, data sharing, and ownership (Friedman Ross et al., 2010). In addition, communities may mistrust conventional IRB review processes. Previous exploitations such as the Tuskegee Syphilis Study (Thomas

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& Quinn, 1991) and Havasupai Tribe vs. Arizona State University (Sterling, 2011) support the perception that some investigators and institutions put their own interests above those of the community.

In an attempt to exert more control and influence over research, communities are progressively establishing their own ethics review panels (e.g., tribal review boards) (Horowitz, Robinson, & Seifer, 2009). These should be distinguished from Community Advisory Boards (CABs) that often provide insight from a cultural perspective, but are not empowered by the tribal government to regulate or approve research. These ethics review boards speak directly to the local perspective regarding beliefs, community norms and customs and provide direct oversight from a community perspective (Community IRBs and Research Review Boards: Shaping the Future of Community Engaged Research. Albert Einstein College of Medicine, 2012).

Ironically, the emergence of a strong community presence coincides with a widespread effort to centralize the IRB review process for multi-site studies. Inconsistent institutional requirements, duplication and investigator burden leading to project delays, are some of the major reasons behind this change. Over the last few years, both the Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) have supported a central IRB review for multi-center clinical research(Menikoff, 2010). Recently, the National Institutes of Health (NIH) expanded this recommendation and issued a draft policy proposing that *all* NIH-funded domestic multi-site studies use a single IRB (NIH, 2014).

While the idea of a single IRB review is appealing, it undermines tribal governance and oversight. A tribal review committee adds tremendous value by providing input regarding the local laws, culture and values. It may be argued that a local perspective may be sought through a consultant or representative knowledgeable about American Indian tribal culture. However, the notion that a single individual with knowledge of ‘American Indian culture’ can speak for a tribe or several tribes is flawed. There isn’t one single language or spiritual tradition that represents all tribal nations or communities (Kelley, Belcourt-Dittloff, Belcourt, & Belcourt, 2013). While a tribal review process may be challenging in the absence of a designated regulatory entity, a tribally established review committee can help streamline the research review by providing a defined pathway for communication and approval process for investigators.

The objective of this paper is to underscore the benefits of community involvement in research ethics review. We will report on our experience in navigating ethics review for the Safe Passage Study, a large, multi-site, community-based research project involving academic, hospital or other IRBs and tribally based review processes in the Northern Plains. We will discuss ways in which we streamlined the IRB review process. We will highlight our interactions with the Oglala Sioux Tribe Research Review Board (OSTRRB) and the positive impact of their direct oversight that improved the research process. We conclude by suggesting strategies that encourage collaboration across institutions for research oversight in community based multi-site studies. These strategies could be used to inform future researchers and guide policy in the field of CBR. In this paper, ‘local’ IRB refers to ‘community’ or ‘tribally’ based IRB.

Current Research Review Process in the US

The current system for the protection of human research subjects in the US is governed by federal regulations, most notably DHHS 45 CFR 46 subpart A, also known as the 'Common Rule', which outlines the basic requirements for IRB review, informed consent, and assurances for protection of human subjects(DHHS, 1991). The Common Rule permits IRBs to exercise their own discretion regarding the classification and conduct of research in certain situations, such as appropriateness of informed consent language and processes, level of risk, referral procedures and adequacy of safeguards to protect confidentiality. IRBs are held accountable to make informed decisions relevant to local context (Byerly, 2009). Thus, the basic framework of ethics review in the US creates potential for variances in interpretation and application of regulations and policies.

Multi-site IRB review

Multi-site research often involves an independent IRB review by each participating institution. Multiple IRB reviews are known to be burdensome due to administrative redundancy, conflicting requirements and variation in interpretation of risks; all three result in increased cost (Burman et al., 2003; Emanuel & Menikoff, 2011; Pritchard, 2011). Variation in interpretation of regulations results from the unique composition of members within each individual board. IRBs may be inconsistent with their interpretation of federal and local regulations and vary in the time they take to review studies (Abbott & Grady, 2011), complicating and delaying study activities. While current federal regulations allow IRBs to reduce the burden of review through an IRB Authorization Agreement - a contract between two institutions which allows one institution to assume responsibility and oversight of the research study on behalf of the other - institutions are often reluctant to cede review to another IRB (Klitzman, 2011a, 2011b). Thus, multi-site review poses significant logistical challenges.

Single IRB review

In single site review, the institutions designate a single IRB, commonly known as the 'IRB of record,' to oversee the research on behalf of all participating locations. The IRB of record format is often idealized as a more "streamlined" approach, where review time is reduced and decisions are expedited and consistent. This approach has worked successfully for clinical trials and the FDA has guidance documentation for industry to aid in establishing this process for multi-site clinical trials (FDA, 2006). However, use of a single IRB of record may not be as easily implemented for CBR.

PASS Network Ethics Review Experience

The Prenatal Alcohol in SIDS and Stillbirth (PASS) Research Network is a collaborative effort between the National Institutes of Health (NICHD, NIAAA and NIDCD); two main Clinical Site locations, one in the Northern Plains, US and the other in Cape Town, South Africa; a Developmental Biology and Pathology Center; a Physiology Assessment Center; and a centralized Data Coordinating and Analysis Center (Dukes et al., 2014). The Safe Passage Study is a large, multi-disciplinary, prospective study designed to investigate the

role of prenatal alcohol exposure (PAE) in fetal and infant mortality. The primary hypothesis of the Safe Passage Study is that PAE increases the risk for Sudden Infant Death Syndrome (SIDS) and stillbirth. Secondary hypotheses relate to factors such as maternal, placental and other environmental factors that may potentially modify the effect of prenatal alcohol on fetal and infant autonomic function, facial features, somatic growth and brain development. In total, over 12,000 women and infant pairs have been recruited from the two clinical sites – Northern Plains, US and Cape Town, South Africa. Internal network oversight is provided by a Steering Committee and external oversight is provided by an independent Advisory and Safety Monitoring Board. Ethics oversight is provided by IRBs and tribal review mechanisms linked to the participating sites. This article focuses on the Northern Plains regulatory infrastructure, due to the involvement of multiple institutions and Tribal Nations. The Northern Plains clinical sites are located on two rural and three urban locations in North and South Dakota.

Early on, we recognized the need to streamline the IRB review process and initiated authorization agreements between participating institutions. Two hospital IRBs and one academic IRB located at the Northern Plains clinical site negotiated authorization agreements. In addition, the Tribal Nations and their respective community advisory boards, provide oversight and input for their respective locations. The Oglala Sioux Tribe Research Review Board, in particular has been a pioneer in development of tribal research system in the region. Established in 2007, the OSTRRB was formed through Tribal Ordinance #07-053. The ordinance empowers the OSTRRB to review, approve or disapprove all research conducted within the exterior boundaries of the Pine Ridge Indian reservation. Comprised of a maximum of 10 members, the OSTRRB reviews all applications for research occurring on the Pine Ridge Reservation and affiliated off- reservation entities. OSTRRB also reviews publications and presentations resulting from those research projects. The board meets once a month for about four hours and reviews new protocols, protocol amendments, publications and presentations. Members on the board are appointed by the Oglala Health Administration. While the meetings are open to the public, the audience does not have input in the review process or outcomes. The meetings are closed to the public during review of adverse events, protocol deviations or other issues dealing with non-compliance.

The PASS Network's relationships with the communities have been built over a decade. Our participants have the assurance that the research protocol has direct oversight from their tribe, which likely contributed to our success with participant recruitment and retention (Dukes et al., 2014). In an effort to engage the community, extensive input was sought from the local review boards throughout the planning, implementation and data collection phases. In particular, the OSTRRB played a direct and crucial role in the research. Discussions with OSTRRB, as described by each phase of the study below, helped to create measures sensitive to cultural needs while maintaining scientific integrity, thereby strengthening the sense of trust and partnership between the researchers and IRBs.

Planning and Study Setup

The OSTRRB requires all investigators to present new research protocols in person. This is particularly important for relationship building and demonstrates readiness to engage with the community. Our initial discussions with the OSTRRB resulted in creating options on the consent form to allow a subject to decline participation in certain study components (e.g., specimen collection or facial images) based on individual choices or cultural beliefs. In subsequent discussions, the board provided input regarding consent language specific to use of specimens for research, genetic studies, and storage for future use by other researchers so that it was locally understandable and acceptable.

Another key outcome of OSTRRB's direct involvement in research review was the development of separate addendums for use of specimens for future research. From the perspective of community protection, the OSTRRB determined that Oglala Sioux Tribe members would not participate in broad sharing of de-identified specimens with undisclosed investigators for future research. However, the board approved future use of specimens by the PASS Network, with the stipulation that OSTRRB approval would be necessary prior to implementation of additional research. Given these contingencies, we developed separate consent forms for participants from the Oglala Sioux Tribe. In the absence of input from the board, we may not have had an opportunity to create separate addendums, thus denying members of the Oglala Sioux Tribe an opportunity to benefit from future research.

In addition to input on consent language and use of specimens, the OSTRRB provided valuable input on recruitment and sampling strategies. Specifically, the board recommended additional recruitment locations which would allow outreach to tribal members receiving care at tribally run clinics outside the reservation.

Implementation and the data collection phase

During the study implementation, the investigators had a frequent in-person presence at OSTRRB meetings (at least twice per year). This provided an opportunity for the board members to ask questions and review study progress. These interactions helped to address concerns and resolve issues quickly. This also provided a mechanism for providing feedback to the community about the research and its impact within and outside the local community. The OSTRRB meetings are usually open to the general public and provide a first hand opportunity for tribal members to learn about research in their communities. Thus, the local ethics review mechanism is able to serve a dual purpose of providing oversight and education.

Research results and publications

In contrast to most academic IRBs, tribal ethics review boards and Indian Health Service area IRBs, also review presentations and manuscripts prior to publication. Past instances of misrepresentation and stigmatization of tribes in research publications have prompted many tribal IRBs to require a pre-review of manuscripts and presentations. Review of publications is also a mechanism for the tribes to be informed of research results and how these results are communicated to other investigators and the public (Sahota, 2007). A frequent concern with research with tribes is the potential for stigmatization through the discovery of

potentially 'negative' findings. In our experience, the tribes that participated were very interested in using research to bring areas of concern to the forefront.

To simplify the publication review process, the OSTRRB asks investigators to submit a 'lay summary' along with the manuscript and requests that the investigators be available via phone to respond to questions, if necessary. It is an opportunity to disseminate research results and obtain feedback on critical issues surrounding identification of tribes in publications.

Data ownership and future use of data

With the research community moving towards broad sharing of data for public benefit, the issue of data ownership and future use is of vital importance to the tribal communities. Previous experience with misuse of tribal data, as occurred with Havasupai Tribe data, has motivated most tribal communities to unequivocally endorse research data as tribal property (Williams et al., 2010). Tribal partners in the PASS network have also stipulated that research data will ultimately need to be returned to them and any future use or secondary data analysis will require additional approvals. These stipulations, in part, reflect a cost-benefit analysis from a perspective of 'community harm' and reinforce the need for local perspective to understand issues within a local context. By allowing for input from independent community review boards, we felt the research was strengthened and the subjects were protected in ways they may not have been possible through a single IRB of record.

Discussion

In CBR, we believe it is crucial that local review boards have a strong voice in the approval and ongoing review of the research being conducted in their community. Nonetheless, we recognize that there are benefits in having a streamlined review process, such as establishing an IRB of record, to reduce inefficiencies and duplications often encountered in multiple IRB reviews.

Training and Educational Implications

As an alternative to mandating a single IRB format for *all* types of research, we propose strategies that encourage institutions to work collaboratively while allowing for local IRB review through use of joint reviews and authorization agreements. In an effort to increase communication and collaboration across IRBs, joint reviews for initial submission, continuation review and adverse event reports should be encouraged. This will help address any disagreements early in the process, and reduce inefficiencies and overlap. Issues relating to rights, data ownership, publication and confidentiality should be discussed early in the research process and must be documented. Institutions engaged in tribally based research should actively seek documentation of tribal approvals to ensure tribal rights are not circumvented. (See Table 1).

The strategies we propose will (1) safeguard tribal oversight of research, (2) increase IRB efficiency and promote a sense of collaboration across IRB members, (3) serve as opportunity for each panel to gain a unique perspective from the institution and community,

and (4) minimize inconsistency in risk assessment; thereby, offering increased subject protection.

In conclusion, the mechanism of independent community oversight needs to be seen as an asset rather than a regulatory hurdle. The IRB review process should allow for an arrangement that fosters a bidirectional exchange of information between the participating institutions and communities to ensure human subjects' protections are comprehensive and culturally appropriate. Future regulatory guidance should include language that directs investigators and institutions working with tribal nations to obtain permission from appropriate tribal entity prior to engaging in research. These safeguards will ensure community ownership of research, and highest level of human subjects' protection.

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- PASS Steering Committee Chair (University of Texas Medical Branch): Gary DV Hankins, MD
- Data Coordinating & Analysis Center (DM-STAT, Inc.): PI: Kimberly A Dukes, PhD; *Co-PI*: Lisa M Sullivan, PhD; *Biostatistics:* Tara Tripp, MA; Fay Robinson, MPH; Cheri Raffo, MPH; *Project Management/Regulatory Affairs:* Julie M Petersen, BA; Rebecca A Young, MPH; *Statistical Programming/Data Management*: Cindy Mai, BA; Elena Grillo, MBA BS, BBA; *Data Management/Information Technology:* Travis Baker, BS; Patti Folan; Gregory Toland, MS; Michael Carmen, MS
- Developmental Biology & Pathology Center (Children's Hospital Boston): *PI:* Hannah C Kinney, MD; *Assistant Director:* Robin L Haynes, PhD; *Coinvestigators:* Rebecca D Folkerth, MD; Ingrid A Holm, MD; Theonia Boyd, MD; David S Paterson, PhD; Hanno Steen, PhD; Kyriacos Markianos, PhD; Drucilla Roberts, MD; Kevin G Broadbelt, PhD; Richard G Goldstein, MD; Laura L. Nelsen, MD; Jacob Cotton, BS; Perri Jacobs, BS
- Comprehensive Clinical Site Northern Plains (Sanford Research): *PI:* Amy J Elliott, PhD; *Co-PI*: Larry Burd, Ph.D.; *Co-investigators:* Jyoti Angal, MPH; Jessica Gromer, RN; H Eugene Hoyme, MD; Margaret Jackson, BA; Luke Mack, MA; Bradley B Randall, MD; Mary Ann Sens, MD; Deborah Tobacco, MA; Peter Van Eerden, MD
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Biographies

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Ms. Angal is currently employed as Director of Fetal and Infant Health Research at Sanford Research. She is also the Director of the Regulatory Knowledge Core of the Collaborative Research Center for American Indian Health and is a Certified IRB professional (CIP). Her research interests include research ethics and regulations in community based research. Ms. Angal provides regulatory oversight for Northern Plains clinical sites in the Safe Passage study.

Ms. Julie Petersen

Ms. Petersen has a background in epidemiology and biostatistics and works as a Project Director at Dmstat, Inc. She has experience managing multidisciplinary observational studies and RCTs. Her research interests include exposures that vary over time (e.g., substance use) and the impact of care (access to, timing and quality of) and clinical decisions on research conclusions, notably during pregnancy. Ms. Petersen serves as the Privacy Officer for the Safe Passage Study.

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Ms. Tobacco is a Project Manager at Sanford Research and is a member of the Oglala Sioux Tribe. She provides oversight for day to day research operations at the Oglala Sioux Tribe location of the Safe Passage Study, including participant recruitment and follow-up .

Dr. Amy Elliott:

Dr. Elliott is a Licensed Clinical Psychologist and is currently employed as Executive Director and Senior Scientist at Sanford Research. Her research interests include early childhood development, fetal alcohol spectrum disorders and community based participatory research. She is the Principal Investigator for the Northern Plains Clinical Site in Safe Passage Study and provides direct oversight in the design and implementation of this community based protocol.

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Table 1

Best Practices

• An independent tribally empowered regulatory entity is necessary for optimal tribal oversight for research
• Researchers should solicit and incorporate feedback from tribal reviews to build trust and long term relationships
• Open dialogue and regular communication ensures long term success of research project
• Ensure local representation on research team and at research review board meetings
• Institutions should require documentation of tribal approval as part of their review process