



# Creating Research Capacity Through a Tribally Based Institutional Review Board

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Tribal groups work tirelessly to maintain sovereignty rights, preserving and upholding tribal authority and protection over their land, people, businesses, and health. Moreover, the conduct of health science research by outsiders has had its share of an unethical, misguided, and abusive past.

Tribally based institutional review boards (IRBs) are addressing these issues in an effort to control new health science research, set their own research agenda, and protect their people in the same spirit as has been accomplished through the perpetuation of sovereignty rights.

We describe the success of a tribally based IRB at creating new capacity for health research and enhanced levels of trust, including bidirectional cultural education between academic researchers and tribal IRB committee members. (*Am J Public Health*. 2013;103:2160–2164. doi:10.2105/AJPH.2013.301473)

## CONCERNS REGARDING THE

conduct of scientific research within one's community are universal. Nevertheless, according to Bozeman et al.,<sup>1</sup> societies' attempts to control research ethics have historically amounted to "disaster response," with no preventive action. As a consequence, they have

called for internal reform of and systematic research on institutional review boards (IRBs) and their operations.

American Indian/Alaska Native (AIAN) communities have a long history of unethical scientific research, despite the existence of formal IRBs since the mid-1960s. The literature contains many examples of the exploitation of tribal groups by research scientists. Distrust of outside researchers continues to pervade tribal communities. A well-known contemporary example is the lawsuit between the Havasupai Tribe and Arizona State University, in which the tribe alleged that its members' DNA was used without proper consent.<sup>2</sup> The case against the university, which was settled in 2010, plainly illustrates a crucial role for tribally based IRBs.

Drawing on Bowekaty's insider view of Indian Country as a former governor of Zuni Pueblo, Bowekaty and Davis<sup>3</sup> expertly describe the history and experience of hundreds of years of theft and lack of respect since first contact with Europeans in his recommendations on how to succeed in genetic research with AIAN people. The list of breaches is well-known to tribal communities and mainstream society but remains startling when presented in such a straightforward manner: theft of land, culture,

language, children, sovereignty, natural resources, artifacts, and ancestral bones and native symbols, as well as lack of respect for values, culture, tribes, elders, individuals, religion, and sovereignty. From this perspective, avoiding participation in research would seem the only reasonable response for the individual as well as the larger tribal community.

However, a contemporary generation of AIANs, many of whom have become research scientists themselves, is helping to precisely define and share cultural information that will delineate fresh ideas and encourage collaborations to bring much-needed evidence-based research to tribal communities that experience serious health disparities.<sup>4–6</sup> Along with Bowekaty and Davis,<sup>3</sup> Burhansstipanov et al.<sup>7</sup> have provided a clear list of reasons why tribal members are disinclined to be "guinea pigs," including the following beliefs: researchers cannot be trusted; researchers receive career advancement and tribal communities get poorer; researchers are disrespectful of cultural practices; researchers feel that tribally based organizations are too unstable to be reliable partners in research; results are not shared with the tribal community; studies are actually designed to harm Indians; participation in disease studies may

cause that disease to manifest in one's family or community; benefits of a study rarely reach tribal members; when the study results are presented to the community, they are too technical to be understandable. Besides constituting priceless cultural information, these insights provide a road map for conducting successful scientific research in Indian Country.

## INDIAN HEALTH SERVICE IRBs

Although the Indian Health Service (IHS) has provided a national IRB since 1991 to protect all US tribal people, it requires that any research conducted in IHS facilities or with IHS staff or resources must be approved by an IHS institutional review board along with an approval letter from the appropriate tribal government(s). Moreover, if a tribe has its own IRB but is conducting the research in IHS facilities, then approval from both the IHS and the tribal IRB are required. This cumbersome process has been known to take up to years to gain the required approvals. In some cases, the IHS institutional review board requirements have unintentionally created barriers to possible beneficial research and discouraged non-Indian scientists from becoming involved. The IHS



does, however, currently support the creation and expansion of tribally based independent IRBs.

## CURRENT TRENDS IN INDIAN COUNTRY HEALTH RESEARCH

In both the United States and Canada, tribally based IRBs, acting in collaboration with community-based committees, are both becoming more numerous and establishing ethics codes over scientific research conducted in their communities. There is a concerted effort to address the issues and to control new health science research, influence the research agenda, and protect their people in the same spirit as has been accomplished through the perpetuation of sovereignty rights.<sup>8-12</sup> Both AIANs and non-Indian scientists and allied health professionals want to improve the climate for more beneficial research in Indian Country. Professional research organizations such as the Native Research Network, established in 1997, advocate for scientific research that is multidisciplinary and collaborative, embodies the principles of trust, respect, and ethical conduct, and, most importantly, builds capacity. Creating rules to monitor ethically conducted research is the first, best step. Forging beyond this stage and building research capacity, both within the AIAN community and with outside collaboration, is also essential to ending the many long-standing health disparities in tribal communities. It is necessary to foster the idea in a tribally appropriate way, where research results can assist with solutions and help inform health practice and the delivery of appropriate and effective health services.

Dickert and Sugarman<sup>13</sup> presented a framework for the 4 ethical goals of community consultation: enhanced protection, enhanced benefits, legitimacy, and shared responsibility. Although IRB goals and procedures center on protection, informed consent, and minimizing risk, community consultation in the context of a tribal IRB is embedded within the characteristics of the tribal IRB committee members and their families and community relationships. Therefore, in an effort to present the extended value of a tribal IRB beyond its fundamental purpose, we propose that Dickert and Sugarman's<sup>13</sup> framework can be appropriately applied to the working activities of a tribally based IRB. We use this framework to illustrate as a case study the success of a tribally based IRB and its contribution related to building research capacity at Indian Health Council, Inc (IHC), a tribally owned and operated health clinic in southern California.

## INDIAN HEALTH COUNCIL TRIBAL IRB

The IHC tribal IRB was conceptualized in 2001 when the clinic received one of the original grants for a Native American Research Center for Health (NARCH), funded by the IHS and the National Institute of General Medical Sciences. The ongoing NARCH initiative supports partnerships between academic institutions and tribes or tribally based organizations conducting behavioral, biomedical, and health services research. One of the 3 major goals of the NARCH initiative was to increase partnerships

to reduce the distrust of AIAN communities toward research, although no mandate has ever been issued to any NARCH grantee that a tribal IRB be created. Technically, tribes are not ethnic minority groups but sovereign nations within a nation, with their own governments, courts, licensing, taxation, and law enforcement systems, and members carry dual citizenship.

California has no clinics or hospitals owned or operated by the IHS, and it is generally not standard practice for tribal councils or tribal health boards to create specific IRB-like protocols, regulations, rules, or procedures for the conduct of health science research involving tribal individuals or the larger tribal community. Tribal health concerns concentrate on providing health services to their tribal members, and tribes do not generally conduct large research projects. When tribal councils or clinics without their own IRBs are approached by outside investigators, permission is given on a case-by-case basis and the tribal board relies on the fact that any scientists who are applying to conduct research in their tribe must have IRB approval from their own institutions. Although this non-Indian institutional approval ensures an academic level of acceptable scientific standards and methodology, it does not necessarily guarantee that the proposed research addresses specific cultural considerations.

As with all tribal reservation-based health clinics in California, the IHC is owned and operated by a consortium of tribes in the local area. The IHC received NARCH funding and currently serves as

a home for new health science research projects conducted in its clinic. In 2004, it therefore decided to establish its own IRB in order to create new levels of trust and a more beneficial atmosphere for research and recruitment. The IHC provides the required IRB federal-wide assurance and thus holds final approval for all scientific research conducted through the clinic among its tribal consortium members.

## ETHICAL GOALS

In proposing their 4 ethical goals, Dickert and Sugarman<sup>13</sup> had specifically defined settings in mind, such as "disease communities" (e.g., those with cancer or HIV) or indigenous groups, emergency settings, international collaborations, and communities conducting community-based participatory research. We use here the 4 ethical goals of community consultation as the framework to present the unique characteristics of the IHC institutional review board and show how its work has increased and strengthened the research capacity of the clinic. Moreover, we propose that a tribally managed IRB can serve as an additional resource and a structured support system alongside community consultation activities, particularly in tribal communities where research is not always seen as beneficial.

### Enhanced Protection

The first goal of Dickert and Sugarman<sup>13</sup> illustrates the importance of having community input to further protect participants' welfare and minimize risk beyond the original vision of the researchers, who may or may not have had prior



community experience, contact, or relationships in the tribal community. Some risks may not be readily apparent to outside researchers.

With the creation of a tribally based IHC institutional review board, enhanced protection is evident through several mechanisms. The first is the IHC institutional review board Committee membership structure, which includes clinic administration and staff, tribal community members, and members of the clinic Board of Directors, representing the consortium tribes who own and operate the clinic. The IHC chief executive officer, the medical director, and the director of community health services serve on the IRB, along with 2 members from the clinic Board of Directors and 2 community members with a long history of tribal government involvement. All are tribal members and thus cultural experts who represent the larger community. Only 1 IRB committee member, the chairperson, is non-Indian. Because this person is a university-based research scientist and professor affiliated with the California Indian Culture and Sovereignty Center at California State University, San Marcos (a NARCH partner), tribal and academic collaboration is promoted.

The second mechanism is unusual for any traditional university-based IRB. After consensus based on the committee chairperson's recommendation is reached, research applicants may be invited to appear before the IRB Committee and have the opportunity to explain the purpose, methods, and details of their research protocols, including

questionnaires, particularly when their protocol may be complicated. The exchange and interaction of research scientists with tribal people, who may be quite skeptical of research and nontribal scientists, is exciting. Both groups learn from one another; scientists gain valuable cultural input and perspective regarding appropriate recruitment, relevant phrasing of questionnaires, and culturally appropriate data interpretations. Tribal members begin to release their historically generated negative concepts of universities and university scientists, ease their generalized cultural hostility toward nonnatives, and increasingly understand how research can benefit their people. They gain a new appreciation of the level of educational preparation, dedication, and hard work of scientists who want to understand their tribal culture and contribute to the eventual eradication of health disparities. This process is an invaluable bidirectional cultural education that encourages a more trusting tribal communitywide atmosphere.

The third mechanism providing greater protection is the clinic staff's awareness of the IRB Committee and its function. Clinic staff members understand that, along with provision of service and care of their patient population, research is being conducted at the clinic, using clinic resources. Because clinic staff members are aware of specific projects being conducted, they may take an interest in and assist with recruitment and referrals, thus increasing overall project success. Moreover, all recruitment materials posted in the clinic must carry the stamp

of the tribal IRB. Staff members, cognizant of this requirement, have several times identified "stray" flyers or brochures from outside sources recruiting in the clinic whose projects did not receive prior IRB approval or permission. IHC administration can then investigate and stop unidentified or unapproved projects, thus promoting empowerment and the protection of participants' welfare.

Western culture encourages researchers to share their results,<sup>14</sup> and most scientists publish journal articles or books on their research projects, thus making the information free to all. By contrast, according to Tsosie,<sup>15</sup> publication of specific information about the tribe may be inappropriate and cause harm. This cultural belief becomes apparent when research is conducted in tribal communities. The most recent example of these discordant beliefs is the Havasupai Tribe and its conflict with faculty from Arizona State University over the publishing of articles on schizophrenia, inbreeding, and the geographical origins of the tribe, when tribal members mistakenly believed they had given permission solely for a study about diabetes.<sup>2</sup>

The IHC institutional review board has 2 unique requirements to prevent possible replication of the Havasupai situation and enhance protection. The first is that all draft manuscripts written from study results conducted through the clinic must be reviewed by the IRB before submission and potential publication. No specific tribal names can be used in any publication for any reason, and a pseudonym for the IHC is

required in all manuscripts. Additionally, the manuscript must not contain any statements on any topic that could possibly harm or cast a negative light on any of the tribes, its members, or the clinic. For relatively small tribes and their organizations, any negative published information could lead to a cascade of severe consequences—a breach of confidentiality and anonymity regarding study participants being the least of them.

Most university-based researchers are not accustomed to having an IRB review their completed manuscripts prior to submission and might consider this process a censorship of science. However, up until now, the IHC institutional review board has not needed to ask any investigator to omit any results or interpretations of data from their articles. In only 1 instance has the IHC institutional review board requested removal of information from a draft manuscript, when the authors complained extensively about the perceived extended length of time the IHC institutional review board required for approval of their project. If negative statements regarding the IHC institutional review board were allowed to be published, their credibility and power might be severely weakened, thus defeating the original purpose of this tribal IRB to create research capacity.

The second unique requirement of the IHC institutional review board is that all informed consent documents must be read aloud to the participants before they sign their names. Moreover, in many instances, the informed consent documents, already generally approved by



a university, require editing by the tribal IRB so that they are less technical and more readily comprehensible and can be read aloud in a reasonable time frame. This requirement, seemingly cumbersome at first, promotes trust and confidence among hesitant participants as well as members of the tribal IRB in their job to protect their people.

### Enhanced Benefits

The second goal, enhanced indirect or direct benefits for research volunteers, is the absolute duty of the researcher. For best overall results, benefits, while aiding both the tribal community and the researchers, need to be specifically targeted for the community.<sup>13</sup> Beneficence must always be paramount in the minds and attitudes of the researchers; at the same time, the body of research being conducted should be enhanced. Otherwise, research can be perceived as one-sided from both the scientist's and the tribe's perspectives, once again defeating the original collaborative purpose.

With the creation of a tribally based IRB, the IHC has control over how many and precisely what projects will be conducted in their tribal communities, along with the power to stop them at any time. They are the final judges as to what projects will have the most immediate as well as long-term benefit. Thus, the IRB controls the direction and the output of the research agenda. Whereas research projects using mainstream groups have large numbers of potential recruits, the IHC tribal patient population is small. Too many research projects conducted at once, with constant recruitment, could cause tribal

participants to be overwhelmed and confused by all the different protocols and eventually decide not to participate at all in any project.

Another unique IHC institutional review board requirement is that all data collected by any researcher, scientist, or student must be returned to the IHC upon completion of the project in the form of a clean, aggregate, de-identified data set ready for analyses. Researchers agree to this requirement before approval of their project is given and are allowed to keep their own copy. However, if there are new articles written after the project's completion, the draft manuscripts must still be approved by the IHC institutional review board. The return of data allows the IHC to analyze the data further—using it for comparison and looking for trends over time and possible new applications of the results. This capacity can only serve to benefit the clinic and its delivery of health services.

Moreover, all researchers are required to present their findings back to the local tribal community for all the consortium tribes to view and understand. This can be accomplished by giving an oral presentation to the clinic Board of Directors at the yearly NARCH meeting, or producing a printed document with findings in lay language that highlight their significance and beneficial application to the health of the community. This process brings the research project full circle and prevents “helicopter research.”<sup>16</sup>

The existence of a tribally based IRB can also indirectly provide enhanced benefits for tribal members through its capacity to

promote new research projects not part of the tribal clinic's long-range strategic plan. For example, one IRB-approved research project, in which data on tobacco use and environmental tobacco exposure were collected, alerted the project interviewer to the high rates of tobacco use in her own tribe. Her experience inspired her to start offering California Smoker's Helpline information to all participants who were current smokers, and to become more educated about the dangers of recreational tobacco use, particularly during pregnancy.

### Legitimacy

How better to create the legitimacy of a tribally based research project, the third goal of community consultation,<sup>13</sup> than by simply establishing a tribal IRB whose members are local tribal members and review all proposals? IRB Committee members are a subset of the primary stakeholders, have a personal and community interest in the project, and are able to express their opinions concerning any research project through the power and structure of the tribal IRB. In fact, they are appointed by the tribal health board operating the clinic and rule on behalf of that body regarding any research conducted in their tribes. They constitute the legitimate authority.

In essence, a tribal IRB may be thought of as its own distinctive focus group. Backed with cultural expertise and authority, they provide the first encounter at the tribal level with a fully developed research proposal, and give their concerns and comments back to the investigator, as a focus group might do. Moreover, by reviewing

questionnaires and surveys for new project applications, IRB members significantly increase their knowledge of survey development, design techniques, and research methods. Through this experience, they come to realize the creative expertise needed to write questions that will elicit the information the researcher intends to collect and, in addition, how difficult it is for an outside investigator to ask questions in a culturally acceptable way. Through this communication exchange with the investigators, IRB members influence the project methodology and survey development, thus helping to legitimize the project and increase the chances of recruitment goals being met. Because of their intimate knowledge of approved projects, IRB members may themselves become part of the pool of volunteer participants and assist further with recruitment and legitimization when asked by family and friends regarding a research project they heard about through the tribal grapevine.

### Shared Responsibility

Shared responsibility ensures an active role in the community and a sense of moral responsibility for the project by both the investigator and the community.<sup>13</sup> During the conceptualization of the research project, the IRB approval process, fieldwork, completion of analyses, and manuscript submission, the principal investigator and project staff, usually working from an office at the clinic, have continuous interaction with IHC administrative and clinic staff, ensuring a high level of collaboration. A tribal IRB fulfills the concept of





shared responsibility at the highest level, as it is the body holding ultimate authority over the comprehensive process of obtaining informed consent and disseminating results. If any negative events occur throughout the course of the research project, IRB members have the power to resolve the issue and are responsible for all ethical conduct associated with the project.

## RECOMMENDATIONS

A tribally based IRB, managed within a tribally owned and operated health clinic providing the federal-wide assurance required by the federal Office of Human Research Protection, is an invaluable asset that delivers long-term comprehensive benefits. There are no set-up costs associated with federal registration, and IRB activities can be managed with few administrative costs and with minimal clinic staff assistance. Committee members who currently serve the tribe as members of the clinic Board of Directors or of other tribal governing boards or committees can be assigned to the IRB for limited terms. With minimal cost of resources and workshops, training in research ethics and IRB functions can generate open attitudes toward new health research. Academic partners with research experience can either participate fully in IRB activities for the long term as part of their required community work or be hired as consultants in the early stages. Our experience with the IHC institutional review board has been rewarding in many contexts. We recommend the creation of

tribal IRBs for individual AIAN health clinics in California. Furthermore, the IRB structure and inherent capacity is applicable to and appropriate for any type of research involving human participants mandated by tribal councils beyond health-related interests.

## CONCLUSIONS

Building capacity for successful tribal health research in the context of academic collaboration while simultaneously maintaining respect for cultural sovereignty can be accomplished through the creation of tribally based IRBs. They provide legitimate authority and enhanced protection and benefits, and they forge a truly shared responsibility—the 4 ethical goals of community consultation as proposed by Dickert and Sugarman.<sup>13</sup> Practically speaking, because of new levels of trust and empowerment provided by tribal IRBs, research projects can provide clinic revenue through indirect costs, jobs for clinic staff, student involvement in research and clinic activities, and long-term benefits for clinic services. Bidirectional cultural education between tribal members and academic scientists becomes tailored for the tribal community, forges trust, promotes far-reaching effects for eliminating health disparities through research, and provides the ethical compass for decision-making. ■

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### Contributors

D. J. Morton conceptualized the essay, led the writing, and managed the editing. J. Proudfit assisted with drafting of the article. D. Calac, M. Portillo, G. Lofton-Fitzsimmons, T. Molina, R. Flores, B. Lawson-Risso, and R. Majel-McCauley provided significant contributions and editorial assistance.

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No protocol approval was needed as no human research was conducted.

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