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Access, Relevance, and Control in the Research Process: Lessons From Indian Country

SPERO M. MANSON,

University of Colorado Health Sciences Center

EVA GARROUTTE,

Boston College

R. TURNER GOINS, and

West Virginia University Health Sciences Center

PATRICIA NEZ HENDERSON

University of Colorado Health Sciences Center

Abstract

Objective—To illustrate successful strategies in working with American Indian (AI) and Alaska Native (AN) communities in aging and health research by emphasizing access, local relevance, and decision-making processes.

Methods—Case examples of health studies involving older AIs (50 years) among Eastern Band Cherokee Indians, a federally recognized reservation; the Cherokee Nation, a rural, nonreservation, tribal jurisdictional service area; and Lakota tribal members living in Rapid City, South Dakota.

Results—Local review and decision making reflect the unique legal and historical factors underpinning AI sovereignty. Although specific approval procedures vary, there are common expectations across these communities that can be anticipated in conceptualizing, designing, and implementing health research among native elders.

Conclusions—Most investigators are unprepared to address the demands of health research in AI communities. Community-based participatory research in this setting conflicts with investigators' desire for academic freedom and scientific independence. Successful collaboration promises to enhance research efficiencies and move findings more quickly to clinical practice.

Keywords

community-based participatory research; health; American Indians; elders

Participatory research, community based, collaboration, partnerships, public-academic liaison—all are familiar terms in the ongoing dialogue about appropriate forms of scientific inquiry in today's world. Although relatively new to conversations in the health arena,

spurred in part by recent attention to racial and ethnic disparities, the need for different approaches to how research is conducted has long been debated, oftentimes with great rancor, in American Indian (AI) communities. Witness the scathing critique by Vine Deloria (1969), a Lakota social scientist, of anthropologists more than 30 years ago in *Custer Died for Your Sins*. He asserted that researchers “derive all the benefits and bear no responsibility for the ways in which their research is used” (Deloria, 1991, p. 457). Deloria (1995) subsequently expanded his argument to include the scientific process as a whole by questioning not only the manner in which scholars pursue their research among native people, but the very nature of the questions they ask and the tools they employ in searching for answers. His work foreshadowed a growing literature on this topic specific to AI/Alaska Natives (ANs) (Byers & Hubbard, 1997; Macaulay et al., 1999; Norton & Manson, 1996; Wax, 1991), which has been fueled, in turn, by similar concerns in the more general professional codes and federal regulations regarding scientific conduct (Fisher et al., 2002).

The costs of business as usual with respect to research in this special population have proven to be enormous. They range from stigmatizing communities to undermining their economic viability. An example of the former includes early references to the Hantavirus pulmonary syndrome as Navajo flu. More serious are examples of the latter, of which the Barrow Alcohol Study is best known (Manson, 1989). In this instance, the premature press release of the limited results of a survey conducted among a largely Inupiaq community in Northern Alaska led to sensational headlines in leading Eastern newspapers that characterized Barrow as a city of alcoholics. The municipality’s Standard and Poor bond rating dropped sharply soon thereafter precluding financing for a number of important community projects.

Unlike in other communities, however, exhortations to adopt more empowering, participatory approaches to research have been quietly accompanied by a dramatic political revolution in Indian Country. Exerting their authority as domestic dependent sovereignties, many AI/AN communities, assisted by the Indian Health Service (IHS), have developed agencies that function not only as institutional review boards (IRBs) but also control access to the entire population within their jurisdiction. They demand that proposed research show relevance to local priorities, reserve the right of review and approval of all publications prior to dissemination, and claim ownership of the data generated by these studies. The emerging presence of such entities and the new codes of research conduct that they embody pose a very different set of challenges and opportunities for scientists and study participants than one is likely to encounter in other communities.

This article shares lessons learned from studies of elder health in which we collaborated to varying degrees among ourselves and with tribal and federal authorities. Although conducted in distinct parts of Indian Country involving three different tribes, these efforts reveal striking similarities in the process of negotiation, approval, and subsequent support despite marked variation in local governance structures. Their similarities suggest that investigators can anticipate specific issues surrounding the participation of AI/AN communities in health research—a predictability that springs from the increasing incorporation of tribal values such as sovereignty, respect, self-determination, mutuality of interests, full participation, reciprocity, collective benefit, and long-term commitment in the research process.

Case Example 1: Disability and Long-Term Care Use

Little is known about physical disability and use of long-term services among rural AI/ANs. Compared to Whites, AI/AN elders have a higher rate of chronic disease and disability (Goins, Tincher, & Spencer, 2003; IHS, 1997). Because of the growing number of AI elders, the need for long-term care services is expected to increase (Chapleski, 1997; Finke, Jackson, Roebuck, & Baldrige, 2002). The purpose of this study was to compare older, rural AIs and Whites on extent of physical impairment as well as assess their awareness and use of local long-term care services.

All study participants were community-dwelling, older adults residing in Western North Carolina. The AI sample consisted of members of the Eastern Band of the Cherokee Indians (EBCI), a federally recognized tribe. The majority of EBCI lands are known as the Qualla Boundary, which spans three counties. According to the EBCI Tribal Enrollment Office, 12,723 persons are currently enrolled, with approximately 8% of them aged 65 years or older. The White sample resided in or near Robbinsville, North Carolina, which is approximately 42 miles southwest of the main population center of EBCI.

In this cross-sectional survey, 62 EBCI and 64 White rural elders were interviewed. They were randomly selected from the past 12 months of outpatient visits at the Cherokee IHS hospital and a rural primary health clinic. Participants were 65 years old and diagnosed with diabetes and one additional chronic disease. Interviewers were hired from each community to administer an augmented version of the Older Americans Resources and Services (OARS) Multidimensional Functional Assessment Questionnaire (Fillenbaum, 1988; Fillenbaum & Smyer, 1981).

Obtaining approval for this study occurred in two distinct phases: (a) local stakeholder discussions and (b) multiple IRB approvals. Personal visits to the community by the investigator (R. Goins) aided in the identification of key individuals whose input would ensure the success of the study. These individuals included the EBCI IHS service unit clinical director, the EBCI tribal medical director, and the executive director of the tribally operated home health agency. The service unit clinical director questioned the cultural relevance of the OARS, not concerning specific items per se, but rather whether the OARS had been used with other AI populations. The investigator provided documentation of previous studies that used this instrument with other AI elderly populations. Also during this phase, the executive director of the tribally operated home health agency and tribal medical director expressed their desire to know the extent of unmet long-term care needs among the tribe's elderly members. As a result, the investigator augmented the OARS instrument with additional items regarding awareness and use of specific local home- and community-based long-term care services.

Because sample selection required cooperation of the local IHS hospital, the approval process was rather complex given the layers of bureaucracy inherent in a federal agency. The investigator began the process by communicating with the regional and national IHS IRBs in addition to several local tribal governance entities. IRB approval was needed from the EBCI Health and Medical IRB, the EBCI Cultural Resources Committee (which introduced the

research request to the tribal council on behalf of the investigator), the EBCI IHS service unit, the regional IHS, the national IHS, and the West Virginia University. Obtaining approval from the EBCI Health and Medical IRB, the EBCI Cultural Resources Committee, and the West Virginia University IRB was relatively straightforward. Interestingly, approval by several IRBs depended on documentation of the others' approval. Fortunately, after telephone conversations with each, the respective chairs were willing to process our request contingent upon documentation of all necessary approvals prior to initiating the study.

Before obtaining IHS IRB approval at the service unit and regional levels, the study had to be approved at the national IHS level. Discussions were initiated simultaneously with the EBCI service unit director, the service unit clinical director, the area Privacy Act officer, and the director of nursing about sharing names and contact information of eligible study participants. The EBCI service unit director and staff were concerned about violating the Privacy Act of 1974 as well as patients' personal preferences. The investigator subsequently approached the national IHS IRB chair to determine how the Privacy Act related to the request of names and contact information drawn from EBCI IHS hospital records. After consultation with IHS legal counsel, the national IRB chair determined that the EBCI and service unit could provide patient contact information to the investigator without prior consent of the patient provided four requirements were met: (a) the investigator complied with the routine use for research of the IHS implementation of the Privacy Act and the area Privacy Act officer approved the procedure, (b) the IHS service unit determined that it is not practical or feasible for them to contact the patients instead of the investigator, (c) the IRB approved the procedure by assessing and stating in writing that the research plan and circumstances met all applicable conditions of the Privacy Act's regulations, and (d) both the tribe and the IHS service unit agreed that potential benefit of the procedure outweighed the potential harm. A service unit agreement was developed by the investigator, which consisted of a written statement guaranteeing that the study met these four criteria, and was signed by the investigator, the service unit clinical director, the area Privacy Act officer, and the chair of the Nashville area IHS IRB.

For the White comparison sample, telephone conversations were held with a rural health clinic's head administrator. The investigator visited the clinic to establish logistics for obtaining names of eligible participants and to become familiar with relevant procedures and policies. Shortly thereafter, following an in-service training about the impending implementation of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, the clinic withdrew from the study. Although HIPAA had yet to be instated, the clinic preferred to start compliance in advance. A second rural health clinic was approached, found willing to participate, and West Virginia University IRB approval was obtained. The HIPAA Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. Currently, the Privacy Rule permits use and disclosure of protected health information for research as long as certain criteria are met (Office for Civil Rights, 2002). However, the present difficulty for investigators is that this legislation can be interpreted differently by different organizations. Thus, whereas one group may be reluctant to disclose protected health information, another group may not.

Data collection went smoothly with both the EBCI and White elderly samples. Among the EBCI, data collection began in February 2002, approximately 13 months after initial planning and negotiations. Using the IHS computerized patient information system, the EBCI IHS service unit generated and forwarded patient names and contact information based on the study's selection criteria. A joint letter was sent to 256 individuals from the investigator, EBCI service unit director, and clinical director. This letter explained the study and contained a form to sign and return to the investigator if the recipient wished to participate. Interviewers contacted those who agreed to participate, scheduled face-to-face interviews, and obtained informed consent. Data collection for the White sample began in October 2001, 8 months after initial planning and negotiations. Names of eligible patients were forwarded to the investigator who used the clinic's computerized patient information system to confirm their eligibility. Interviewers contacted potential study participants similar to the interviewers for the EBCI sample. Strong visible support for this research by the clinic's head doctor helped to obtain a high response rate.

This experience illustrates several key points that must be taken under consideration when working with tribes. By approaching the community, there can be a useful exchange of information; the community members can inform the investigator about their most pressing needs, and the investigator can offer his or her professional knowledge and skills. By engaging local community stakeholders in discussion, the investigator can translate widely held concerns into a research question and design a corresponding project. This professional exchange requires several site visits along with multiple telephone and written correspondences prior to submission of a formal research protocol. It is crucial to be clear about what the community will gain in terms of practical applications of the findings. Local personnel can invariably shed light on important methodological and substantive issues, including the cultural appropriateness of the study design. Before finalizing a study protocol, investigators should realize that conventional research instruments are not usually developed for or with tribes and may require modification to reflect tribal concerns.

The investigator who wants to work in Indian health must have a strong commitment to the project. He or she may confront a large number of organizations that must give formal approval, and these organizations may not be interconnected. It often falls to the investigator to coordinate communication and cooperation between these entities. Also, investigators must allow significant lead-time to accommodate the multiple authorities that will participate in the review process. Investigators should have at least minimal acquaintance with legislation (e.g., Privacy Act and HIPAA) that may circumscribe their activities. Finally, they should even be aware of new legislation (or differing interpretations of such legislation) that may affect the investigation, and they need to be flexible and willing to amend research plans as needed.

Case Example 2: Provider/Patient Communication in Medical Encounters

Effective provider communication is strongly associated with patient satisfaction, medical adherence, and improved health outcomes (Roter & Hall, 1993). Although the available evidence suggests that both ethnicity and age can significantly influence medical communication, there are *no* studies of health communication among AI elders comparable

to those in the general population. Accordingly, this study focused on older Cherokee patients among whom the need for culturally sensitive health communication may be most pronounced.

With more than 200,000 citizens, the Cherokee Nation is the second-largest tribe in the United States. The Cherokee Nation does not comprise a reservation but a tribal jurisdictional service area extending across 14 counties in northeastern Oklahoma. Under a 1990 self-governance agreement with the federal government, the Cherokee Nation plans, administers, and delivers health services to tribal members. The county in which the research was conducted has approximately 40,000 people—68% White and 20% AI (mainly Cherokee). The area embraces numerous small, predominantly Cherokee communities that include many full-blood members who speak Cherokee as their first language and who maintain their cultural practices.

The study sought to describe communication patterns that characterize health care providers' interactions with older Cherokee patients. It employed the Roter Interaction Analysis System to relate communication style to patient and provider characteristics and explore the association of communication style with patient satisfaction. The sample included seven primary care providers and 115 patients 50 years old. Their medical encounters were audiotaped over 11 clinic days in July and August 2001.

All health-related research projects involving Cherokee tribal members must pass review by the Cherokee Nation IRB, which possesses sole approval authority. It is responsible for ensuring the research is safe, ethical, well designed, feasible, culturally appropriate, and conducive to the best interests of the tribe. The board comprises representatives of the medical professions, the tribal council, and local community. Outside opinions may be sought for proposals involving specialized interests or knowledge.

The investigator (E. Garrouette) began initial project negotiations regarding a markedly different health-related research project—focusing on the relationship between spirituality and health status as well as functioning—by approaching the tribe's executive director of health at a national conference. This individual generously invested time and knowledge to develop a proposal she felt would produce useful results. Additional communication with several individual IRB members confirmed the board's interest in working with investigators and their willingness to review the project. Inquiries showed that it was not customary or desired for the investigator to attend the IRB meeting to present the study or meet with IRB members in advance.

Surprisingly, at the least to the investigator, after formal review of the proposal by the full IRB, the body voted to disapprove the project. Their decision reflected several concerns including (a) the research might be infeasible because it depended, in part, on gathering information from elders regarding a sensitive subject and (b) the project, although showing scientific merit, did not imply obvious, immediate, *practical* benefits to the tribe. The IRB did, however, invite future project submissions and emphasized their commitment to research that contributes to the reduction of health disparities among Indian people.

The failure of the initial proposal suggested including a wider range of advisors and key decision makers in formulating a more broadly acceptable research focus. In particular, the rejection letter noted that the IRB had invited the opinion of special consultants (not formally members of the board but experts in culture and spirituality). Telephone inquiries revealed that IRB members and other tribal personnel (some previously known to the investigator, others not) would graciously accommodate personal visits and discussions. Particular attention was paid to speaking with the special consultants who had raised important concerns so that the investigator could determine ways to revise the study to address their reservations. The executive director of health and the principal chief were also included in our discussions and offered useful perspectives and information. In all these meetings, the investigator benefited from the active participation of an older Cherokee family member. Her presence underscored that the investigator maintained ties to the local Cherokee community, and her cultural knowledge ensured that the requests for advice were properly pursued.

Personal visits identified two individuals who, by virtue of their position on the IRB and specific personal commitments, were willing to invest in shaping a useful study. They revealed a particular concern for enhancing care at tribal clinics by examining issues related to patient satisfaction and culturally sensitive health services. The IRB and other consultants mentioned that the tribe had recently conducted focus groups that explored these subjects and shared the results. They suggested that a potentially welcome study would pursue this previous work by focusing on understanding communication between Cherokee patients and their health care providers (who may or may not be AIs). IRB staff also emphasized that acceptable projects do not merely avoid offending tribal values, nor do they simply promise to promote scientific knowledge in some long-term, general way. Such studies should also yield *direct and immediate benefits to Cherokee people*. An immediate benefit of investigating provider-patient communication, they offered, might be a practical, empirically based handbook, which the tribal clinics could make available to their health care providers. Based on this advice and information, the original study was discarded and replaced with a new one on medical communication.

As the new study took shape, continuing communication with IRB members who had shown particular interest in the project proved important. It not only confirmed that IRB recommendations had been properly understood but also yielded additional information (as, for instance, when individuals remembered new documents relevant to the study). Stressing that no individual IRB member speaks for the IRB as a body and that proposals could only receive final approval through a formal, collective-decision process, these consultants were nevertheless extremely important in ensuring the study's potential success. Last, before the second IRB submission, personal courtesy notes were mailed to tribal council members representing the Cherokee Nation voting district in which the proposed research project would occur. The notes introduced the investigator, briefly outlined the proposed study, and explained its potential benefits to clinic patients.

This second proposal was approved provided that (a) the investigator spend 2 weeks at the site prior to initiating the study to learn about the clinic function, requirements of medical records and their regulations, and doctor/patient relationships and (b) additional simple, but

important, arrangements be instituted to protect patient privacy and conform to the clinic's record-keeping requirements. Once the IRB was assured, in writing, that these provisions would be satisfied, the study began immediately. Approximately 6 months passed between initial discussions with the executive director of health and final IRB approval.

The IRB's approval was accompanied by their full support and attention to the project's success. On the investigators' arrival at the site, a leading IRB member arranged for a gifted, bilingual (Cherokee-English) translator to volunteer his services. This obviated the need to hire someone for this important role and saved considerable money, because the individual resolutely refused compensation. The same IRB member also introduced the investigator to clinic administrators and personnel. Clinic administrators responded by offering a variety of local resources including two additional staff members (one bilingual) to assist with tasks.

The 2-week residence, required by the IRB before commencing data collection, addressed important goals such as meeting key clinic personnel. The visit enabled us to observe patient flow and the division of patient care duties among clinic personnel, craft minimally disruptive data collection procedures, and accustom clinic personnel to the presence of a research team. Clinic personnel appreciated learning about the study and its benefits. As a consequence, data collection was completed in a timely, efficient manner.

Many lessons learned from this experience apply to navigating large organizations. Personal visits are more likely to produce desired results than the impersonal submission of documents by an unknown person. Even though we met with the executive director of health before submitting our first study, our failure to do so with IRB members (even though encouraged not to) probably contributed to our initial difficulties in formulating an acceptable study.

Simple gestures of courtesy and goodwill are important. Thank-you notes for the help of consultants and informal updates to those who showed interest—such things were remembered. The same is true of offering to help with extra work that the study may create. Learning that our activities involved additional duties for medical records clerks, upon our departure, we arranged to stay late to help.

It also pays to remember that practical decision-making power does not necessarily follow the organizational flow chart. The interest and assistance of an individual at the highest level of the organization (the executive director of health) was invaluable; she offered encouragement, helped us get started, advised on procedures for submitting a proposal, and pointed us toward necessary resources. At the same time, our failure to seek the opinions, ideas, and values of individuals at other levels of the organization proved a mistake, because it was these latter individuals who ultimately decided the status of our project. Similarly, we learned that, at times, individuals who do not appear at all in a formal organizational hierarchy may contribute to relevant decisions, and the only way to identify them is to ask if final decisions will incorporate others. Thus, although a personal visit does not guarantee IRB approval, it can assist investigators in identifying a research idea that is relevant to tribal needs and the people whose judgment will be central to that determination.

Other lessons are more particular to working with Indian tribal organizations. For us, a central lesson involved the importance of research that yields practical, short-term deliverables. In academic contexts, knowledge is valued for its own sake, and we sometimes forget that this position is a luxury afforded us by our relatively privileged position. Tribes, on the other hand, have many very immediate concerns and may be unwilling to support research that fails to address them. Although we were aware of this tribal value, our own ideas about practical utility did not coincide with those of the IRB and its advisors; our discussions with the IRB members pointed us toward a specific research product that they readily agreed would be of value to the tribe.

Another lesson involved establishing credibility. In most professional contexts, an adult person who was accompanied by an elderly relative to a professional meeting would be met with confusion, if not outright suspicion. In the current example, the investigator's specific inclusion of an elder relative to support her in seeking advice from tribal personnel was helpful because of this individual's cultural knowledge and relationships in the community and because Indian people often place particular value on the opinions of elders. Yet another lesson was the importance of respecting the knowledge, judgment, and experience of the IRB. Although we were initially surprised by the requirement of a 2-week, initial residency at the clinic, this was an appropriate length of time to complete necessary tasks. Other IRB advice proved equally valuable.

The last and the most important lesson was that IRB approval was attended by extensive IRB support. The IRB did not simply approve the study but made significant efforts to ensure its success. Although negotiations required more advance time than anticipated, the result was a better, more efficient, well-supported study.

Case Example 3: Smoking Knowledge, Attitudes, and Beliefs

The smoking prevalence among AI elders is among the highest in the nation with rates as high as 45% (U.S. Department of Health & Human Services, 2000; Welty et al., 1995). This smoking rate, nearly 20% greater than that observed in the U.S. general population (Piani & Schoenborn, 1993), has been accompanied by increasing mortality from cardiovascular disease and lung cancer and is the leading cause of death among older AIs/NAs (Welty, Zephier, Schweigman, Blake, & Leonardson, 1993). Despite these trends, important potential factors such as knowledge, attitudes, and beliefs related to tobacco use remain underinvestigated in this special population. Hence, the overall goal of this study was to explore the knowledge, attitudes, and beliefs regarding tobacco use (secular and ceremonial) among AI elders and subsequently employ this information to better measure their tobacco use.

The study was conducted in Rapid City, an off-reservation town of 60,000 residents in Western South Dakota, 20% of whom are AIs, largely members of surrounding Lakota tribes. The two-phase study included Lakota adults 50 years of age living in Rapid City. These AI community members were chosen for this study because of their rich and complex history with ceremonial and secular tobacco use, the high rates of smoking among their

elders, the investigator's (P. Henderson) previous work in a smoking-related research project, and the community's interest in addressing tobacco-related issues.

Although AI residents of Rapid City do not have an official governing board (i.e., tribal council), all health research is subject to approval by the Aberdeen Area IHS IRB composed of non-AI and AI health professionals and AI community members. Approval from the local IHS facility may be needed if the proposed research project uses its facility for any part of the study. This was the case in this study.

The initial negotiation of the project began with a meeting between the investigator and the local IHS service unit director. Because the investigator was a resident of Rapid City and had previously worked at the local IHS facility, she was well acquainted with the IHS staff and the community. The project had proposed to use the IHS's computerized Resource Patient Management System (RPMS) to randomly select AI adults who had received care at the facility. The main issue of concern for the service unit director was protecting the privacy of patients. This was addressed by assigning an IHS computer site manager to work with the investigator. The manager advised the investigator about the importance of keeping all identifiers in a safe, locked place and destroying all the patient information upon completion of the study.

Because the knowledge, attitudes, and beliefs about tobacco use among Lakota elders had never been explored, one of the main issues for the investigator was to develop an instrument that would ask the appropriate tobacco-use questions. Using instruments from previous tobacco-related studies of both AI and non-AI populations, the investigator compiled tobacco-related questions. To assure that the questions would correspond to the values, ideas, and needs of Lakota people, several focus groups of AI elders were conducted. A local AI woman who was familiar with the Lakota culture facilitated the discussion groups using a talking-circle format. Talking circles are commonly used in the AI communities. This discussion process allows each person to speak freely without interruption but is also expected to treat all other speakers with respect even when he or she disagrees with them and acknowledges and builds on previous speakers' ideas so that there is an increasingly rich accumulation of thought and a building of consensus. Based on their own experiences and upbringing, AI elders provided valuable insight into the discrete and distinct meanings of ceremonial and secular tobacco use. One key theme that was discussed was the use of commercial tobacco in ceremonial settings. Among the Lakota, ceremonial tobacco has been viewed as a sacred plant and used in traditional ceremonies for centuries. However, over the years, commercial tobacco has permeated ceremonial practices and traditions of the Lakota people. Today in many Lakota communities, commercial tobacco has replaced or is used in conjunction with ceremonial tobacco. The focus group discussions allowed the elders and the investigator to explore these complex and intertwining issues of tobacco use in the Lakota culture. In summary, key thematic elements were identified and used to modify a measure of tobacco use. Another separate focus group then reviewed the modified instrument and provided recommendations regarding content, relevance, and comprehensibility.

Upon revisions to the instrument, the investigator submitted the proposal to the Aberdeen Area IRB and the University of Colorado IRB. Unlike the other case studies, the IRB reviewers approved the modified instrument with only a few minor changes.

To administer the modified instrument to the AI elders, the local IHS RPMS then was used to randomly select 300 Lakota adults (50 years old) who had received health care at the facility within the past 3 years. Those selected were sent a letter describing the study and inviting them to participate followed by a phone call. An AI research assistant described the study in detail and notified potential participants of the dates and place of the survey administration. Follow-up postcards were sent as a further reminder. Within 1 week of the initial mail out, 110 letters were returned undeliverable and only a handful of elders came to the designated place to fill out the survey. Taken at face value, many may have deemed the study to be a failure and the local community as little interested in the project. Had this happened, an important lesson would not have been learned. A second recruitment strategy sought to recruit 300 more eligible participants but, with local assistance, focused on those who had received care in the *past 3 months*; this strategy proved much more successful. Also, the investigator learned that many of the elders do not have transportation and/or had other obligations (i.e., providing child care). Based on this feedback, elders were given the choice to either return their completed survey in a self-addressed, stamped envelope or to visit the investigator's local office at any time. These ad hoc accommodations for the elder participants proved very successful thereby increasing participation rates to more than 50%—remarkably high in recruitment strategies of this type.

Several lessons emerged from this study. Understanding the health concerns of the community—specifically, issues surrounding tobacco use—led to an uncomplicated approval process. Moreover, although not Lakota, the investigator lived in the same city where the research was conducted, was well known to the community, and was immediately available to address concerns and issues as they arose as well as seek advice.

Multiple, unanticipated difficulties arose during the implementation process related to recruitment and implementation of the survey that required a change of action. The proximity and familiarity of the investigator to the community; the conduct of focus groups prior to survey design and administration; the revision of conventional instruments to correspond to tribal values, needs, and concerns; and the willingness to address several barriers to participation were all crucial to the success of this project.

Discussion

In 1996, the first author (S. Manson) wrote of navigating the cultural universe of values and process in conducting research among AI communities (Norton & Manson, 1996). The values are the same today and still revolve around trust, respect, self-determination, mutuality of interests, perspective taking, full participation, reciprocity, collective benefit, and long-term commitment. The studies described above are replete with current examples. Successful collaborations with AI/AN communities continue to be distinguished by their enactment and warrant close attention. However, this now is a necessary, *but not sufficient*

condition for such success. *The process* of research has dramatically changed since then with these changes evident in the work just shared.

The changes in question reflect the increasing codification and operationalization of tribal sovereignty in terms of the research process (American Indian Law Center, 1994a, 1994b). Tribal sovereignty is a difficult concept for most non-AIs to grasp, springing from a long legal and historical tradition that accords Indian nations a unique status rooted in treaty-based relationships with the federal government (Shelton, 2001). It permeates all aspects of life in AI communities—licensing, taxation, subsistence, criminal justice, and formal governance—and speaks to the partial autonomy of tribes within the state and federal body politic. The 1968 Indian Civil Rights Act and the 1975 Indian Self-Determination Act are among the most recent precedents, further underscoring the right of AI communities to govern themselves. President Clinton carried this recognition the next step by issuing a series of executive orders between 1994 and 1998 that elevated the federal-tribal relationship to one of government to government. Consequently, federally recognized tribes regulate relationships to the outside world far beyond most outsiders' experience and expectations.

In this context, then, tribal and IHS IRBs have emerged to govern investigators and the research they seek to pursue in AI communities. Few investigators are aware of these entities, often discover them late in the course of their proposed work, and usually are stunned by the degree of local control that obtains. Indeed, referring to them as IRBs, though a self-adopted title, can be misleading, at least given the experience of most investigators, for their reach extends well beyond typical concerns regarding human participant protection and the ethical conduct of science. As illustrated in each of the case examples reported here, these bodies judge the adequacy of the proposed research with respect to its fit with community priorities and the cultural relevance of the study design as well as measurement strategies. But in our experience, they did more than judge by having joined us in making the studies possible while significantly improving their scientific merit. Witness the Cherokee Nation requirement that the investigator spend 2 weeks in the clinic prior to initiation of the study—an experience that informed the study design in important and otherwise unanticipated, but critical, ways. Likewise, guidance by the Eastern Band of Cherokee's executive director of the tribally operated home health agency and tribal medical director led to augmenting the OARS with additional items regarding awareness and use of specific local home-and community-based long-term care services to better capture the local service ecology.

In all three examples, manuscripts based on research conducted in their jurisdictions, including the present article, are reviewed and approved prior to presentation or publication—a condition that some investigators find unacceptable as a violation of their academic freedom and scientific mission. To date, our experience is that AI communities support the best science possible on matters of interest to them but insist on the opportunity to participate in the interpretation of the findings. Unfortunately, the history of scientists' relationships with AI communities in this regard has forced the latter to exert maximal control to ensure themselves such opportunities. They are willing to assume that investigators go about their business with the best of intentions but are unwilling to concede that those intentions necessarily coincide with their own.

Other AI communities have installed local review boards that exercise even more expanded authority than those described herein. In addition to the expectations noted above, the Navajo Nation Health Research Review Board, for example, requires the employment of tribal members who are subject to their labor laws, stipulates that all equipment used in the course of the research be transferred to the Navajo Nation at the study's conclusion, and claims ownership of the data specific to its members. Obviously, these requirements pose increasingly difficult challenges to investigators, their institutions, and sponsors as they attempt to sort through their own obligations to one another and to AI/AN communities.

Rather than leave this discussion disheartened at the demands of the new decision-making structures and procedures that are becoming commonplace in AI communities, we hope that the reader will recognize the concomitant opportunities. The literature on community-based participatory research is searching for ways to meaningfully involve patients, families, and local organizations in clinical and health services research. Many AI communities already provide these means with all of the attendant benefits (Israel, Schulz, Parker, & Becker, 1998). True, there are costs to investigators as there have been and continue to be for the participating communities. But our experience suggests that the trade is a desirable one.

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