

Research With American Indian and Alaska Native Individuals, Tribes, and Communities

Deana M. Around Him
Francine C. Gachupin
William L. Freeman

Abstract

Research with American Indian and Alaska Native (AI/AN) individuals, Tribes, and communities requires special considerations and processes. This chapter offers guidance to IRB and human research protection program (HRPP) personnel about reviewing such research. This chapter presents information about AI/AN peoples, Tribal sovereignty, and self-governance; reports brief histories of research that harmed or benefited them; shares best practices to minimize harms and maximize scientific and community benefits; analyzes a realistic case study; recommends shared governance and oversight for repositories; and discusses research with urban Indians. Many best practices also apply to research with other marginalized populations.

Introduction

Of the total U.S. population, an estimated 1.7%, or 5.6 million people self-identify as American Indian or Alaska Native (AI/AN) alone or in combination with one or more other races (U.S. Census Bureau, 2016). AI/AN peoples are the Indigenous peoples of North America. As of May 2020, there are 574 self-governing, federally recognized AI/AN Tribes and several state-recognized Tribes (U.S. Department of the Interior, 2020). Names of Tribes include Nations, Pueblos, Rancherias, Bands, or Villages, and each Tribe has its own culture and

history. More than half of the AI/AN population lives in urban areas, most outside of federally designated tribal lands and reservations (Snipp, 2013).

TERMINOLOGY

This chapter uses “AI/AN Communities” to refer to Tribes, AI/AN urban communities, and Tribal-based entities (e.g., Tribal Colleges/Universities [TCUs]).

The complexity and diversity of the AI/AN population affect the ethical conduct of research with AI/AN Communities, whose experiences with and perspectives on research and research oversight processes vary widely. Although research may be with a single Tribe or geographic context (e.g., reservation, urban community), many AI/AN individuals have connections to multiple Tribes and geographic areas. For example, they may have lineage to more than one Tribe; live or work in an urban area while maintaining a close relationship to their Tribe and Tribal homeland(s) through frequent visits; live or work on a reservation different from their own; be Tribal intermarried; or self-identify as an urban Indian. Research activities or approaches thus are not completely generalizable from one AI/AN Tribe, community, or situation to another, although some general commonalities exist.

Most AI/AN Communities are underserved and experience health inequities and discrimination in general society and health care. However, many AI/AN Communities have abilities and assets to contribute to research and scholarship not recognized by outsiders. Their life experiences, values, concerns, and identified needs differ from those of many researchers and members of most IRBs. AI/AN collective history includes both positive and negative experiences with research. Their experiences offer important lessons for the ethical oversight of research with AI/AN Communities today, especially for IRBs, HRPPs, and Community Action/Advisory Boards (CABs).

The primary goals of this chapter are as follows:

- Provide historical examples of *unethical* research as well as *beneficial and ethical* research with AI/AN Communities.
- Describe the importance of Tribal sovereignty and self-governance for IRBs and HRPPs (e.g., researchers, data and safety monitoring committees, institutional officials, funders, bioethicists, lay public), especially in reference to the three principles of the *Belmont Report*.
- Outline best practices by IRBs in the ethical oversight of research involving AI/AN Communities.
- Present a case study illustrating a research plan and IRB response that implemented those best practices.
- Discuss several issues related to best practices, including shared governance and oversight of repositories, the 2018 revisions to the Common Rule, “going beyond the Common Rule,” and research with AI/AN urban communities.

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Brief History of Unethical Research With AI/AN Communities

Groups that suffer discrimination, experience disparities, or are disadvantaged—e.g., racial and ethnic minorities, orphans, women, or the economically disadvantaged—have often been subjects in unethical research. Instances of

research injustice have important lessons for IRBs/HRPPs, and some cases have spurred improvements in research approaches and oversight. Although not as well known, the experiences of AI/AN Communities in unethical research also have important lessons for IRBs/HRPPs.

Except for the I¹³¹ and Indian markers cases (described later), most unethical research involving AI/AN Communities has harmed primarily the *whole community*, not just the individual subjects. “[R]esearch . . . designed to study a group or that retrospectively implicates a group may . . . result in members of the group facing, among other things, stigmatization and discrimination in insurance and employment whether or not they contributed samples to the study” (National Bioethics Advisory Commission, 1999), a harm now widely recognized (Weijer, 1999; Weijer & Emanuel, 2000). Group stigmatization can even occur in meta-analyses of primary studies (Gribble & Around Him, 2014).

AI/AN Communities have experienced all six types of research harms identified by the National Bioethics Advisory Commission (NBAC) (NBAC, 2001), listed here. This chapter adds a seventh research harm: *relational*.

- *Physical*: In 1955–1956, the U.S. Air Force’s Arctic Aeromedical Laboratory used radioactive iodine (I¹³¹) to study the thyroid function of 102 Alaska Natives from interior Alaska to see if they survived Alaska’s cold by having a metabolism different from European Americans. Three of the 26 women were breastfeeding, and one was possibly pregnant (National Research Council, 1996).
- *Psychological*:
 - *Self-stigmatization by AI/AN individuals*. Researchers studied the adverse effects of alcoholism in Barrow, Alaska, and then announced the bleak results at a news conference in Pennsylvania (Klausner & Foulks, 1982; Manson, 1989). In addition to having economic implications for the town, the results of the research study produced feelings of shame and self-stigmatization among the Inupiaq people, even those living far away, which was still strongly felt decades later: “I felt that I was, and we were, bad people” (Inupiaq Elder who never drank, from a village outside Barrow, personal communication, n.d.).
 - *Disruption of the Tribe’s values*. Research has made public to the outside world information that was private Tribal knowledge—a problem with some anthropological studies. Parsons, for example, observed private cultural ceremonies and subsequently published detailed accounts without authorization of the southwestern Tribe (Parsons, 1925).
- *Social: External stigmatization of the group*. Epidemiologists studied an outbreak of congenital syphilis in a southwestern American Indian Tribe (Gerber et al., 1989). The State Health Department publicly named the Tribe, and after local newspapers publicized it, reservation children were called derogatory names in off-reservation schools, and AI/AN people were prohibited from using restrooms in nearby gas stations (Freeman, 1998).
- *Economic: Loss of economic status by AI/AN Community*. See study of alcoholism in Barrow, Alaska described previously.
- *Legal: Public policy on genetic determinism*. A Tribal agency misappropriated an external study’s results of genetic determination of “Indian markers” among Tribal members and used the results to expel members lacking those markers (study’s principal investigator, personal communication, 1996). See also the proposed bill by the Vermont General Assembly Committee on Health and Welfare, “An Act Relating to DNA Testing and Native Americans” (Vermont General Assembly, 2000).

- *Dignitary:*
 - *Violation of AI/AN individual and Tribal privacy.* Researchers robbed AI/AN graves of human remains and sacred objects during the 19th and 20th centuries (Native American Graves Protection and Repatriation Act, 1990).
 - *Violation of Tribe's sovereignty and self-governance.* A researcher used DNA from a study of severe atypical arthritis among the Nuu-chah-nulth First Nations people, Canada, to conduct migration studies without their consent (Tymchuk, 2000). The dispute resulted in a code of research conduct in British Columbia, Canada (Garrison et al., 2019). See also Arizona State University (ASU) research with the Havasupai, next.
- *Relational, vis-à-vis research or health care:*
 - *Distrust of health research.* ASU researchers obtained the approval of the Tribal government to research diabetes among the Havasupai Tribe, and more than 200 Havasupai members consented and participated. Without notice, Tribal approval, or individual consent, researchers conducted unrelated studies of topics contrary to Havasupai cultural and religious beliefs—population migration, schizophrenia, and inter-relatedness—using study DNA plus data from illegal access to medical records of all Tribal members (Drabiak-Syed, 2010; Garrison et al., 2019).
 - *Distrust of public health activities and care.* In late spring 1993, an outbreak of an unknown illness with a high mortality rate emerged on the Navajo reservation. Intense sensationalist media coverage fostered widespread fearful shunning of Navajo people (Stumpff, 2010; Pottinger, 2005). The Centers for Disease Control and Prevention (CDC) rapidly identified the viral cause. The Navajo Nation, Navajo Nation Division of Health (NNDoh), CDC, and area State Departments of Health partnered to marshal political and public health resources, determine chain of transmission, and institute Navajo-specific and general public health education and measures to prevent more infections (Centers for Disease Control and Prevention, 1993a, 1993b). Unfortunately, that partnership was violated by the first two publications about the epidemic in prestigious scientific journals (Nichol et al., 1993; Childs et al., 1994), both of which used Navajo place names for locations of infected humans or animals despite NNDoh's explicit and repeated requests to CDC to not use them to avoid increasing the existing external stigmatization and contraventions of Navajo privacy. The two violating publications led the Navajo Nation to develop its own Research Code and establish the first Tribal IRB, the Navajo Nation Human Research Review Board (Federal-wide Assurance of Compliance [FWA] number 00008894).

Brief History of Ethical Research With AI/AN Communities

AI/AN Communities have also experienced several research projects with one or more important characteristics. These projects can be characterized as follows:

- *Were innovative* in the research topic or in the strength and closeness of collaboration between academia and the AI/AN Community
- *Addressed* a high health priority
- *Directly benefited* the AI/AN Community in the research with actionable results

- Were strengths based
- Incorporated the Community's values

The examples listed are in chronological order:

- *The People Awakening Project (PAP), 1997.* Alaska Native people proposed a research project on alcoholism to Dr. Gerald Mohatt, Director of Psychology at the University of Alaska, Fairbanks (UAF). They wanted not another negative pathology study like that at Barrow but rather a partnership of AN people and UAF researchers focused on AN strengths and resilience in confronting alcoholism. Like many AI/AN Tribes, a higher percentage of AN people were abstinent from alcohol than the U.S. general population (May & Gossage, 2001), an indication of AN strengths. PAP was an AN-initiated, AN Community-Based Participatory Research (CBPR) study from its inception (Mohatt et al., 2004a) and throughout (Rasmus, 2014). It was successful scientifically (Mohatt et al., 2004b) and directly benefited the AN people by leading to an effective intervention to expand strengths and resilience against alcoholism (Allen et al., 2018).
- *White Mountain Apache Tribe Suicide Surveillance and Prevention System, 2001.* Following the loss of several youth to suicide, the White Mountain Apache Tribe collaborated with researchers at the Johns Hopkins Center for American Indian Health (JHCAIH) to establish a community-based surveillance and case management system for suicide prevention (Cwik et al., 2014). One of few community-based suicide surveillance systems in the United States, the system addressed a top priority of the Tribe, was an evidence-based effective intervention for this highly sensitive and critical health disparity, and served as a mechanism to conduct important research to further refine prevention and intervention activities. The JHCAIH and Tribal community researchers continue to respectfully collaborate to contribute knowledge and skills essential for successful benefit sharing for both parties.
- *The Safe Passage Study, 2006.* The Safe Passage Study (PASS) prospectively investigated prenatal exposure to alcohol and smoking on Sudden Infant Death (SIDS). PASS enrolled almost 12,000 pregnant women in two geographic areas with high rates of prenatal drinking and SIDS; one in the Dakotas included two AI reservations, and the other in Cape Town, South Africa. Governance and oversight of PASS's science and ethics was by the participating research institutions and their IRBs, the two Tribal governments, and the Oglala Sioux Tribe Research Review Board (OSTRRB), a Tribal IRB. PASS addressed a topic that was a priority of the Tribes, yet was also psychologically sensitive and had potential stigmatizing harms. To help minimize both harms, OSTRRB required that it review and approve publications and future uses of specimens by the PASS Network (Angal et al., 2016). Results showed that exposure to smoking and alcohol together after the first trimester was associated with a 12 times higher rate of SIDS, much higher than that of smoking or

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THE COMMON RULE AND GROUP HARMS

"The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility" [45 CFR 46.111(a)(2)]. Some people believe this sentence prohibits IRBs from considering "group harms." We disagree, for three reasons. (1) NBAC (1999) did not interpret that section to prohibit consideration of group harms; (2) the Office for Human Research Protections (OHRP) has repeatedly and publicly stated that minimizing group harms can be an important part of IRB responsibility; and (3) the group harms described previously in the section Brief History of Unethical Research with AI/AN Communities occurred immediately after the research finished; i.e., they were not "long-range effects."

drinking alone (Elliott et al., 2020). These findings should lead to beneficial, community-based, public health messaging and actions.

- *American Indian and Alaska Native Head Start Family and Child Experiences Survey (AI/AN FACES), 2015.* FACES has surveyed Head Start programs annually since 1997; however, the 145 programs that served predominantly AI/AN children were not included. Instead, AI/AN FACES was conducted for them in 2015. The planning workgroup for AI/AN FACES included Tribal Head Start directors and researchers; it planned the “design, implementation, and dissemination of findings and ... added questions regarding children’s experience of Native language and culture” that were actionable (Administration for Children and Families, 2019). For instance, the survey found that 35% of children were in classrooms that never used the Tribe’s Native language, in part due to hiring policies that disqualified Tribal members fluent in the Tribe’s language. That finding led to proposals to change the policy (Sarche et al., 2020).
- *The Alaska Area Specimen Bank, 2010.* The Alaska Area Specimen Bank contains residual biological specimens from over 83,000 persons who participated in clinical testing, public health investigations, and research projects dating back to the early 1960s; about 85% of samples are from Alaska Natives. Prior to 1997, the bank was managed by the CDC and another federal agency. When Alaska Natives established responsibility for management of their healthcare system, the Bank transitioned to management by a tribal–federal partnership. That partnership developed the Bank’s governance and oversight system and implemented a structure that combines the expertise of Tribal, state, and federal partners. Parkinson et al. (2013) described this innovative specimen repository with linked clinical data and included the Bank’s policies and procedures in supplemental materials.

All of these examples addressed high health priorities and were guided by innovative, respectful partnerships that enabled research to directly benefit the AI/AN Communities and incorporate fundamental Community ethical values. Most examples focused on Community strengths and resilience and produced immediately actionable knowledge—all characteristics of CBPR (Wallerstein et al., 2018).

Tribal Sovereignty and “Full Scientific and Cultural Rigor”

Potential harms and benefits of any study are defined not only by researchers and IRBs, but also by the *subjects of the research*, per the Common Rule definition of “benign behavioral interventions” in which “the investigator has no reason to think the *subjects* will find the interventions offensive or embarrassing” [45 CFR 46.104(d)(3)(ii)], emphasis added). Researchers and IRBs thus must include in their ethical assessments the potential harms and potential benefits as defined by the AI/AN Communities involved.

Beneficial and ethical research involving AI/AN Tribes differs from ethical research with other groups in one significant aspect: the active role of Tribal governments in research oversight. AI/AN Tribes reviewed and approved the ethical research listed earlier; engaged in conducting the research, from research development and modification (in the cases of the PAP and suicide prevention projects) through Tribal governance and oversight; and reviewed and approved articles that reported results. The active role of Tribal governments in overseeing research is based on *Tribal sovereignty* and *self-governance*. As self-governing,

sovereign political entities, federally recognized Tribes have legal authority to permit or prohibit research and entry by researchers to/from their reservation or Tribal lands. Many Tribes have established policies and procedures to review and approve or disapprove proposed research, and some have their own IRBs (Around Him et al., 2019).

In their review, AI/AN Communities may require that research plans incorporate their own Indigenous values (National Institutes of Health [NIH], n.d.). One set of values of many Communities concerns their worldview. The AI/AN worldview varies between and within AI/AN Communities, but one aspect is common to most and is relevant to research with them: the worldview's two realms. One realm is the environment. Many AI/AN Communities consider that they are related to and accountable for the entire environment—e.g., animals, plants, land. “They are our relatives” is often expressed, and many AI/AN people feel a responsibility to respect and maintain not only the various components of the environment but also their spiritual relationships with them. In the other realm, the human realm, many AI/AN people feel accountable to past, present, and future generations. That is, they feel a responsibility to honor and respect their ancestors and their recent and current Elders (“Past”), their own generation (“Present”), and their children and grandchildren “unto the seventh generation” (“Future”) (public communication, Marilyn Scott, Upper Skagit Indian Tribe Elder and leader, 2019).

Another set of values concerns the purposes of research. Many AI/AN Communities want research to have both “full scientific rigor and full cultural rigor” (A. Echo-Hawk, Director, Urban Indian Health Institute, public comment, 2019). AI/AN Communities increasingly insist that research focus on their strengths and assets that can be grown or expanded to improve the Community. AI/AN Communities want respectful Community-researcher engagement, in which both sides truly listen to and collaborate with each other. AI/AN Communities want to fully implement the vision of the Belmont Report; IRBs are essential in doing so.

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Many non-AI/AN IRBs/HRPPs and researchers do not recognize or interpret potential harms or benefits in the same way that AI/AN Communities do. We recommend that those IRBs/HRPPs engage with AI/AN Communities and include one or more AI/AN persons from a nearby Community as IRB members or consultants to help the IRB more accurately assess AI/AN-specific individual and group harms and benefits. The AI/AN Community review systems are an important resource that can assist IRBs, HRPPs, and researchers in understanding and respecting the worldviews and values of AI/AN peoples related to research. The structures of these systems typically are the Tribal government, Tribal or AI/AN Community IRBs, and related committees and offices. The membership and procedures of these structures help ensure that the AI/AN Community's values guide its review of risks and benefits of participation, for the following reasons:

- Membership includes largely community members, often traditional healer[s] and representative[s] from the Tribal Council.
- Final Tribal approval often requires approval by both the IRB and Tribal Council/Leadership.
- All proposed research is reviewed from an individual, family, and community perspective when assessing potential harms and benefits.
- All proposed research is often reviewed by the governing body and entire IRB, irrespective of the Common Rule's categories of “not research,” “exempt,” and “expedited”—categories that were developed without considering harms to groups/Community.

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- Abstracts, presentations, articles, and reports are also reviewed prior to dissemination to minimize harms to the AI/AN Community.
- Many Tribes require Tribal ownership and control of data access and data sharing.
- Many Tribal IRBs require that the researcher's home IRB concurrently review and approve the research.

Collectively, these structures and procedures reflect both the unique standing of Tribes as sovereign nations as well as the deeply embedded value systems present in Tribal cultures. These systems therefore are a valuable resource for non-AI/AN IRBs, HRPPs, and researchers to better understand how to minimize harms and maximize benefits of research with AI/AN Communities.

What IRBs Should Do When Research Involves AI/AN Communities

This section has recommendations to IRBs on how to strengthen their ethical oversight of research with AI/AN Communities.

- *Assist and require the researcher to engage the AI/AN Community.*
The IRB should require that researchers who conduct research with AI/AN Communities show evidence in their IRB application that they engaged the AI/AN Community and report the results of their engagement. Such evidence may include the following (Gachupin, 2012):
 - Dates of meetings with Tribal program representatives and Committees of the Tribal government, with accomplishments
 - Letters of support from the programs and Committees showing that the study requirements, burden to community programs or services, and community involvement are understood
 - Formation of a Community Action/Advisory Board (CAB) in which the research team and community will continue to partner

We recommend that the IRB develop a checklist and procedures, both to assist researchers in how they engage the Community and to aid the IRB

RESOURCES TO ASSIST IRBS WITH DEVELOPMENT OF AI/AN COMMUNITY ENGAGEMENT PROCEDURES

- **Collaborative Research Center for American Indian Health (CRCAIH)**, especially its IRB Toolkit and Data Management Toolkit
- **Indigenous Wellness Research Institute (IWRI)**, especially its Research Ethics Training for Health in Indigenous Communities (rETHICS) curriculum, a culturally adapted version of Collaborative Institutional Training Initiative's (CITI's) human subjects training
- **National Congress of American Indians (NCAI) Policy Research Center**, especially its *Research That Benefits Native Peoples: A Guide for Tribal Leaders* curriculum
- **Native American Cancer Prevention Center—Outreach Core Resources**, especially researcher guidelines and *How to* resources in the publications library
- **Public Responsibility in Medicine and Research (PRIM&R)**. See resources developed with the NCAI Policy Research Center, Northwest Indian College, and others, especially several free webinars (search for "Tribal" and "Indian" within past and archived webinars)
- **Urban Indian Health Institute (UIHI)**, especially support and materials for Urban Indian Programs.

in assessing applications for research with AI/AN Communities (see Box: Resources to Assist IRBs With Development of AI/AN Community Engagement Procedures).

- *Assist and require formal AI/AN Tribal-Community approval.*
Tribes have legal authority to approve or prohibit researchers and research projects from their Tribal lands under Tribal sovereignty and self-governance. Researchers thus must obtain formal approval by the Tribal government. (TCUs are covered by the Tribe that chartered them [U.S. Court of Appeals, Ninth Circuit, 2017]: Non-Tribal urban AI/AN Communities are discussed later in this chapter.) Tribes increasingly require that the researcher's institution sign a legally binding Data and Material Sharing and Ownership Agreement (DMSOA) for control of all future uses of the research data and specimens (e.g., DNA) from their member research subjects.

The IRB should require that researchers obtain formal AI/AN Community approval of the proposed research. IRBs can assist researchers by outlining the steps for researchers:

- Obtain formal approval by the Community's HRPP system, e.g., its IRB/review committee.
- Obtain formal approval by the Tribal Council ("Tribal Council," "Business Council").
- Offer to have the research institution and Tribe develop and sign a legally binding DMSOA. (The IRB can show researchers a prior or sample DMSOAs.)

If more than one Community is involved, researchers should follow the steps for each entity. Around Him and colleagues (2019) present a framework for IRBs to understand the Tribal, TCU, Tribally based, and IHS IRBs. The IRB should require that the research begin only after researchers have obtained *all* required AI/AN Community approvals, a signed DMSOA if required, and of course approval by their own IRB.

- *Offer to engage with other IRBs.*
Collaborations between Tribal IRBs and academia-based IRBs have often resulted in each IRB learning from the other and together producing more helpful, relevant, and complete reviews. For example, the potential to identify subjects in AI/AN research is much higher than in most settings due to the small size of most AI/AN Communities; collaboration of the IRBs may result in a better solution to protect identity and ensure privacy than by either IRB alone. Both IRBs often come to better understand and respect each other and to share their respective skills.
- *Engage their institution's HRPP.*
IRBs can assist their HRPP to issue an effective policy that respects Tribal sovereignty. IRBs can then implement the policy by widespread and recurrent dissemination, education, oversight, correction, and enforcement as part of those activities to implement the Common Rule. The HRPP must clearly support the IRB's efforts.



Case Study: A Collaborative Project

This case study is a composite of several research projects the authors have been part of or observed over more than a decade. It illustrates that AI/AN Community research can truly maximize benefits and minimize harms by collaborative planning.

A multidisciplinary research team applies to its IRB for an ethnographic, behavioral, pathophysiologic, and genomic study of emotional stress among the AI of a reservation, with the goal to reduce debilitating chronic stress. The researcher had conducted her doctoral dissertation there 27 years earlier. The reservation has two population centers: one more "traditional" in the reservation's western hills, the other more "acculturated" in its eastern plains.

Research methods include qualitative ethnography, quantitative surveys of current stressors and prior related factors (e.g., childhood sexual/physical abuse), and measurements of stress hormones and genetic variants associated with chronic emotional stress. Research hypotheses are (1) self-reported stresses, related factors, and stress hormones will be higher in the "more traditional" population, but (2) the prevalence of genes associated with stress will be similar in both. The study will return all clinically meaningful results to subjects as required by state law.

The university IRB's policy is that research with Tribes must be approved by the Tribal government and by the Tribal IRB with which it collaborates closely. The Tribal IRB notes six serious potential harms not minimized or addressed and two conditions always required for this type of research as follows:

- Results could disrupt intra-tribal relationships between the two populations.
- Self-stigmatization by individuals interpreting their genetic results as "defective."
- No plan to manage rare but expected adverse reactions to survey questions on sensitive topics.
- No plans and written agreement[s] with the Tribe's Counseling Service for emergency response to subjects with acute psychological reactions.
- Some questions from standard surveys have ethnocentric terms unfamiliar to many Tribal members.
- Consent document is too long and complex.
- In all "multicenter research," each center chooses its experts for the research team—the Tribe's choices include spiritual leaders and Elders widely respected in the Tribe.
- The Tribe requires a legal DMSOA signed by Tribe and university that the Tribe controls all use of specimens and data from its members.

Concurrently, the university IRB requires that the researcher do the following:

- Show how she engaged with the Tribe.
- Answer all concerns by the Tribal IRB and gain its approval.
- Sign a legal agreement not to identify any research subject, subject's relative, or their genome by any means, e.g., social media (Gymrek et al., 2013).
- When returning results of tests to individuals, minimize potential harms by providing the university's telemedicine genetic counseling service if requested by any subject, subject's family, researcher, or Tribal clinician.

The university IRB also gives the researcher its handout "Engaging with AI/AN Communities in Research."

The collaborating IRBs learn from one another as follows:

- The university IRB learns that intra-community conflict is a potential harm, behavioral counseling services are scarce on this reservation, and concrete plans and agreements are needed to respond to adverse events.
- The Tribal IRB learns that identification of individuals using multiple databases and social media is a potential risk and genetic counseling can be provided by telemedicine.

After 7 months of intense respectful engagement, the researcher answers all concerns of both IRBs, with one exception. She acknowledges that the Tribe and its approval of research had changed from 27 years ago and admits that the research plan now is scientifically and culturally much improved, will be more beneficial to the Tribe, and is more likely to achieve its purpose. The unanswered issue is the DMSOA. The Tribe and university agree on its terms, but the funder requires all data and specimens be deposited in a large national repository named Research in Environmental and Genomic Interactions For new Therapies (REGIFT).

REGIFT aims to have specimens and linked clinical data of more than 100,000 subjects age 18+ years from the research studies contributing to it. Its purpose is

to develop new preventive and treatment interventions by discovering previously unknown genetic–disease interactions. REGIFT hopes to receive an oversample of Tribal and racial/ethnic minority populations to find genetic–disease interactions more common among them.

REGIFT has a 10-member single IRB with four lay members whose primary education and expertise are nonscientific, two of whom are people of color. REGIFT's Scientific Review Board (SRB) is composed entirely of scientists respected by the U.S. scientific community. The SRB governs the scientific uses of the repository; it approves/disapproves all applicant researchers and their proposed projects. REGIFT has no procedure for a nonscientist Tribal government or any donor population/stakeholder to participate in the governance and oversight of the scientific uses of the repository.

The inability of the Tribal government to control the future use of data and specimens from its members in REGIFT is unacceptable to the Tribe. The Tribe asserts that Tribal sovereignty and self-governance mean that it controls uses of its members' data and specimens. The university agrees with the Tribe. The study is at an impasse.

The two IRBs together propose a solution that draws on the agreement by the Navajo Nation and NIH for the "Environmental influences on Child Health Outcomes (ECHO)" project (NIH, 2019) and elements of the NIH All of Us Program's Tribal Consultation Report Draft (NIH, 2020). ECHO is a large multicenter, NIH-funded NIH-cooperative study, a network of 71 centers conducting long-term research in children's health outcomes. One center is the "Navajo Birth Cohort Study" (Hunter et al., 2015). In the Navajo-ECHO agreement, the Navajo Nation has shared governance and oversight of future uses of the Navajo Birth Cohort data it contributes to the ECHO data repository. If the Navajo Nation sees that a proposed study is unacceptable and the study does not change to make it acceptable, the Nation can exclude its data from that study. The Navajo-ECHO agreement concerned only data; therefore, the two IRBs additionally propose a "shared governance and oversight" system to the funder and REGIFT for the Tribe's specimens similar to that outlined in the NIH All of Us Program's Tribal Consultation Report Draft (NIH, 2020). All of Us, a research program that aims to collect data, including biospecimens, from one million or more people living in the U.S., specifies that it intends to reflect the diversity of its participants in the program's governance bodies. As such, All of Us has AI/AN representation on its IRB, Resource Access Board and Biospecimen Access Policy Task Force.

Shared Governance and Oversight of Repositories

Although genomic science has greatly advanced technologically, federal regulations and the ethical, legal, and social implications (ELSI) lag (Gachupin & Freeman, 2015). Some researchers continue to share with others or use Tribal data and biospecimens for unapproved research and deposit them in public-use repositories—without Tribal knowledge or approval (Garrison et al., 2019). IRB oversight may not apply when biospecimens are deidentified or are from people now deceased, according to **45 CFR 46**.

Many experts and international associations emphasize the importance of a repository's governance and oversight processes to maintain both the public's trust and its willingness to donate data and biospecimens to repositories (Bledsoe, 2018; Cicek, 2018; Fullerton et al., 2010; International Society for Biological and Environmental Repositories, 2018). Accordingly, some repositories involve the general public or donors of data and biospecimens in their *nonscientific* governance and oversight. For example, each location of the Mayo Clinic has a local CAB, and the Marshfield Clinic's repository has

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a CAB (McCarty et al., 2011; Olson et al., 2019). Those CABs advise the repository about the general use of biospecimens and/or researchers about how to report results in ways that are understandable and relevant to the patient/donor population.

Many repositories have *scientific* governance and oversight systems that decide which research projects are approved to use their data and biospecimens. CABs generally do not participate in the scientific governance and oversight of the repository, i.e., scientific review of applications to approve access to the repository's data and biospecimens for specific research projects.

Like many Indigenous communities worldwide, most AI/AN Communities will agree to donate their data and specimens to a repository only if the repository includes them in a shared or participatory governance and oversight system that determines the scientific uses of the repository's data and specimens (Angal et al., 2016; Hudson et al., 2020). The participation desired is more than solely to approve/disapprove a research project's application to use data and biospecimens from the AI/AN Community. Another important purpose of shared governance and oversight is to improve projects by increasing "benefit sharing"—that is, maximizing the likelihood of obtaining results that can directly benefit the Community by helping plan the project's methods and analyses.

To include AI/AN Communities in shared governance and oversight of the repository's scientific uses may appear to counter the principle of unrestricted open scientific access to the data and biospecimens of repositories (Johnson et al., 2020; Wright et al., 2019). Yet lay involvement in the scientific governance and oversight of repositories has a long history, starting in 1995; it was and remains highly acceptable to the leaders, scientists, and funders of NIH and others. The first repository with strong participatory governance and oversight was by PXE, International, self-organized by parents of, and people affected with, the rare genetic-recessive metabolic disorder, pseudoxanthoma elasticum. They did the following:

- Donated their own biospecimens and clinical data to their repository
- Carefully attended to ELSI issues
- Obtained funding for research
- Invited researchers to conduct studies using the repository with the proviso that PXE, International lay leaders were full members of the research team
- Discovered the gene
- Made all results public—thus speeding up scientific progress on the disease (Terry & Boyd, 2001)

Other advocacy groups for rare genetic diseases and consortia of groups (e.g., Genetic Alliance Registry and Biobank, Parents Like Me, Registries For All), followed (Workman, 2013). They continue to be active, make discoveries, and receive funding from NIH and others.

These "patient-powered registries and research networks" (Workman, 2013) are models for "AI/AN-powered" and "Indigenous-powered" registries and research networks with participatory governance and oversight systems, as are the Alaska Area Specimen Bank, agreement by the Navajo Nation and NIH for the ECHO project, and procedures presented in the Tribal Consultation Report Draft by the NIH All of Us Program (NIH, 2020). We propose that Tribes, other AI/AN Communities, non-AI/AN researchers, IRBs, HRPPs, and funders consider these models of participatory or shared governance and oversight as they propose, partner in, review, initiate, conduct, and publish genomic research.

The 2018 Common Rule and AI/AN Communities

The 2018 Common Rule contains two changes that benefit AI/AN Tribes:

- It recognizes Tribal authority over research [45 CFR 46.101(f), 45 CFR 46.102(k), 45 CFR 46.116(i), 45 CFR 46.116(j)]. Tribal sovereignty applied to the equivalent subsections in the pre-2018 Requirements but was not explicitly stated.
- It has an exemption process for Tribes within the single IRB review system [45 CFR 46.114(b)(2)(i)] based on Tribal sovereignty. Tribes can make sure that mandated single IRB research has minimized harm and maximized benefit to them by themselves reviewing the research.

• Section 4

The 2018 Common Rule thus helps raise awareness about Tribal sovereignty among IRBs, researchers, and HRPPs.

The 2018 Common Rule, however, may also harm AI/AN Communities by its expansion of activities “deemed not to be research” [45 CFR 46.102(l)] to include “oral history” and “[p]ublic health surveillance activities.” Many oral histories of AI/AN individuals make general statements about their Community (see Left Handed, 2018). The report of the public health investigation detailing an outbreak of congenital syphilis, described previously, harmed that Tribe. For those reasons and others already discussed, many AI/AN IRBs “go beyond the Common Rule.” For Federalwide Assurance (FWA) IRBs to “go beyond the Common Rule,” the OHRP recommends that the IRB’s institution include in its IRB policy that the IRB is to minimize harms to and maximize benefits for AI/AN Communities (DHHS, 2012, 2017).

• 5-1

• 8-1

Research With Urban Indians

AI/AN research frequently involves non-Tribal AI/AN Communities, i.e., urban Indians who constitute more than half of all AI/AN, many in larger cities (Snipp, 2013). Some IRBs and researchers believe they need not engage approval processes when research involves urban Indians, because they do not have the same legal status as do sovereign Tribal governments. Yet urban AI/AN Communities are disadvantaged and marginalized like Tribal Communities and have related life experiences, values, strengths, concerns, and identified needs.

Many large urban areas have Urban Indian Programs (UIPs), some related to health (e.g., clinics serving AI/AN people) and some nonhealth (e.g., providing social services). In many ways, their role is like that of a Tribe vis-à-vis their AI/AN population: as an interface trusted by the AI/AN urban Community regarding researchers and research. Moreover, many health-related UIPs conduct research, have a structure to engage and actively partner with researchers, have IRBs, and review and approve proposed research much like Tribes (Dominguez & James, 2018).

We therefore encourage IRBs, researchers, and HRPPs to do the following:

- Consider and relate to UIPs as similar to Tribes.
- Assist and require that researchers engage UIPs, especially health-related UIPs.
- Seek and obtain formal UIP approval of the research and a legal DMSOA if indicated.
- Have a policy that all research with urban Indians follow equivalent procedures of engagement as with Tribes.

Conclusion

When reviewing research involving AI/AN individuals, Tribes, and communities, IRBs and HRPPs should consider potential harms and benefits of the research in the contexts of the Community's values, concerns, and traditions. IRBs can, and should, promote and lead researchers to properly engage the AI/AN Community(ies) in the proposed research. IRBs can also lead their HRPP to implement the procedure recommended by OHRP that enables the FWA IRB to go beyond the Common Rule (see The 2018 Common Rule and AI/AN Communities earlier) and thus to honor Tribal sovereignty and self-governance, minimize harms, and maximize benefits in AI/AN research. The best practices of AI/AN Community-engaged research are also applicable to research with other marginalized populations.

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