



# HHS Public Access

Author manuscript

*Am Indian Alsk Native Ment Health Res.* Author manuscript; available in PMC 2022 February 25.

Published in final edited form as:

*Am Indian Alsk Native Ment Health Res.* 2021 ; 28(2): 77–97. doi:10.5820/aian.2802.2021.77.

## URBAN AMERICAN INDIAN AND ALASKA NATIVE DATA SOVEREIGNTY: ETHICAL ISSUES

**Emily A. Haozous, PhD, RN, FAAN [Chiricahua Fort Sill Apache] [Research Scientist],**  
Pacific Institute for Research and Evaluation in Santa Fe, NM.

**Juliet Lee, PhD [Senior Research Scientist and Study Director],**  
Prevention Research Center at the Pacific Institute for Research and Evaluation in Berkeley, CA.

**Claradina Soto, PhD, MPH [Navajo and Jemez Pueblo] [Assistant Clinical Professor]**  
Keck School of Medicine at the University of Southern California in Los Angeles, CA.

### Abstract

This paper examines the ethical issues underlying research with urban American Indians and Alaska Natives (AI/ANs) through the lens of tribal sovereignty. There are 574 federally recognized tribes within the United States. Each of those tribes is recognized by the federal government as having sovereign status, an important political designation that ensures that decisions impacting tribal peoples must be made after consultation with those nations. Most AI/AN people live away from their designated tribal lands, yet their sovereign rights are frequently only recognized when living on tribal lands. These urban AI/ANs are still considered citizens of their sovereign nations, yet they lack the protections afforded to those who live on tribal lands, including protections surrounding research with their tribal communities. We explore the Belmont Report and related documents and demonstrate their inadequacy in considering the cultural and ethical concerns specific to protecting urban AI/ANs. We also provide several solutions to help guide future institutional policies regarding research with urban AI/ANs that honors Indigenous data sovereignty, including consultation, partnership with community advisory boards, employment of data use agreements, and ensuring informed consent.

### INTRODUCTION

In the United States, there are currently 574 federally recognized American Indian and Alaska Native (AI/AN) tribes in 34 states (Bureau of Indian Affairs, 2021). Federally recognized tribes are distinguished by the U.S. government as sovereign nations, a status that has historic roots stemming from early encounters with European colonizers and subsequent treaties that were negotiated with AI/ANs. Currently, U.S. and state governments are directed by multiple Supreme Court decisions, Executive Order 13175, and a January 2021 Presidential Memorandum to recognize tribal sovereignty through a process of participation, consultation, and accountability when considering policies that may impact tribal communities (Biden, 2021; Exec. Order No. 13,175, 2000; Wilkins & Adams, 2019).

#### CONFLICT OF INTEREST DISCLOSURE

The authors declare they have no conflicts of interest.

Due to a series of historic, economic, and personal factors, as many as 70% of AI/ANs live in urban areas and away from their home tribal community, reservation, or recognized territorial lands. Despite having status as citizens of sovereign nations, AI/ANs who are not physically on tribal land are not protected by the rights of sovereignty (from this point, we will refer to this population as “urban AI/ANs,” recognizing that this label encompasses a wide diversity of reservation to non-reservation living situations). Yet, unless their specific tribe retracts citizenship, AI/ANs who are members of federally recognized tribes are sovereign citizens regardless of where they live.

In health research, this can have far-reaching implications, as tribes are protective of the rights and data of their tribal members, but the extent of the protections of sovereignty for urban AI/ANs are still undefined. Furthermore, although the ethical foundations of current human subjects’ protections regulations in the United States guide institutional review boards (IRBs), they do not always reflect the values of many AI/AN peoples.

The purpose of this paper is to examine the ethical issues underlying research with urban AI/ANs through the lens of Indigenous data sovereignty and governance. Through this examination, we argue that the ethical researcher will adopt additional strategies of consultation, partnership with community advisory boards, employment of data use agreements, and guaranteeing informed consent to ensure that urban AI/AN sovereign citizens’ rights are recognized and protected.

## Background

Sovereign Indigenous Nations have their own governance and rights over their lands, cultural knowledge, peoples, and resources. With those rights come the ownership of information, or data, that describes their peoples, activities, and all aspects of their communities (Rainie, Rodriguez-Lonebear et al., 2017; Tsosie, 2020). With ownership comes the control of how the data are used. Indigenous data governance describes the right to self-determination, controlling how tribal data are gathered, accessed, and used (Tsosie, 2020).

When tribes maintain their own data, the data are more complete and provide a better understanding of the nuances that are seen in tribal communities that would not otherwise be observed (Rainie, Schultz et al., 2017). For example, racial misclassification in cancer surveillance data is a well-established problem, and the true extent of cancer morbidity and mortality in AI/ANs is yet to be known (Bruegl et al., 2020; Jacobs-Wingo et al., 2016; Melkonian et al., 2020; White et al., 2014). Cancer surveillance data are improved when cancer registry data are linked with IHS and tribal enrollment records, requiring partnership with tribes and honoring of tribal data sovereignty (Weber et al., 2019). The outcome to this linkage is greatly enhanced surveillance data, which then more appropriately directs funding and cancer control efforts at the local, tribal, state, and federal levels.

Tribes who control their data also manage how samples obtained through research are used. This component of Indigenous data governance is a critical component of Indigenous data sovereignty, as it embodies exactly why these data must be protected (Tallbear, 2013). Having control over their own data allows tribes to dictate exactly how the data will be used,

interpreted, and written about. In practical terms, this means tribes can control the narratives about their own people.

When a tribe practices data sovereignty through data governance, they also take immediate control over the cultural assets contained within the data that are collected by researchers. Many large, mixed-methods studies conducted with AI/ANs include extensive qualitative interviews. There is always potential for participants in these studies to share cultural information that may not be intended for publication (Tsosie, 2007). With data governance, participating tribes can engage in research activities knowing their sacred cultural information will not be exploited by researchers, and all cultural information is reviewed prior to dissemination to ensure the tribe's cultural practices are shared respectfully. Likewise, with data governance, all tribal data is reviewed prior to dissemination to protect the participating communities from inappropriate or exploitative reporting by researchers (Oetzel et al., 2015; Rainie, Schultz, et al., 2017).

A person's AI/AN enrollment is based on the eligibility of their specific Tribe, Pueblo, or Nation. Geography and proximity do not define an AI/AN identity or ability to maintain enrollment status in most tribes (Haozous et al., 2014). Ostensibly, an enrolled AI/AN member is considered a sovereign citizen of that tribe. Even so, under the current practices of tribal sovereignty in the United States, geography is the sole determining factor for protections under sovereignty. An AI/AN living on their home tribal land will maintain all protections as a member of their Nation, yet an AI/AN from that same Nation living off tribal lands likely lacks those same protections. This land-based sovereignty is made more complicated for those AI/AN Nations for whom tribal land is reduced to allotments, as is the case for certain tribes in Oklahoma (Kiel, 2019; Tsosie, 2000).

The authors of this article (Haozous, Lee, and Toya) were part of a team that was involved in research with multiple urban AI/AN community organizations. The team included experienced AI/AN and non-AI/AN researchers who were familiar with the principles of Indigenous data sovereignty. In collaborating with urban AI/AN populations, we recognized that the protections offered through sovereignty are only within the limitations of established, federally recognized tribal communities on tribal land. This did not change the concerns regarding Indigenous data governance for urban AI/ANs, who still wanted to protect their data from the same concerns of misuse, exploitation, misrepresentation, and protection from inaccurate narratives. Recognizing this lack of protection by way of territorial sovereignty led us to investigate the ethical foundations and data governance-linked mechanisms for protecting Indigenous data.

## **ETHICAL FOUNDATIONS FOR PROTECTING INDIGENOUS DATA**

In the United States, the Federal Policy for the Protection of Human Subjects (Protection of Human Subjects, 2018) sets the standard for all research with humans. Although not entirely so, the ethical foundation of the Common Rule is drawn from the Belmont Report (Ryan et al., 1979). The Belmont Report breaks medical bioethics into three basic concepts: justice, autonomy, and beneficence. Much of the ethical foundations of the Belmont Report are recognized as universal, but there are limitations. When considering AI/AN communities,

the Belmont Report does not accommodate collective cultures, and it is based entirely on a European/Western concept of knowledge (Tsosie et al., 2019). While IRB members may receive some training on the importance of looking beyond the European, and largely Christian, values that underpin the Belmont Report, there is nothing within the Common Rule that specifically instructs an IRB or researchers to consult with community leaders, tribal members, or other cultural experts when working with AI/AN tribes (Adashi et al., 2018; Parker et al., 2019; Tsai, 2008; Williams et al., 2010).

According to Beauchamp and Childress (2001), there are four concepts that guide modern medical bioethics: justice, beneficence, nonmaleficence, and autonomy. The Belmont Report does not include nonmaleficence, instead including this with beneficence. Outside the United States, there are several guiding documents that assist in formulating a broader perspective on bioethics. These documents may assist researchers and IRB members when considering the special circumstances of AI/ANs within the United States, both reservation-based and non-reservation-based. For the purposes of this paper, the documents that we focus on are the International Ethical Guidelines for Health-Related Research Involving Humans, authored by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO); the Ethics of Research Related to Healthcare in Developing Countries, authored by the Nuffield Council on Bioethics; and the United Nations Declaration on the Rights of Indigenous Peoples (Calman et al., 2002; CIOMS, 2016; United Nations Declaration on the Rights of Indigenous Peoples, 2007). We are focusing on documents that center ethical issues in developing and international communities due to the power differentials between large institutional researchers and AI/AN communities, which share many qualities with those found in developing nations.

## Justice

Although not explicitly classified under the same categories as Belmont or Beauchamp and Childress, all documents contain guidelines that can be clustered thematically within the same concepts of justice, autonomy, beneficence, and non-maleficence. As stated previously, domestically authored publications focus on the individual as the decision-making body. In striking contrast, those documents that consider Indigenous and developing populations consistently share a common characteristic: the firm insistence that the community in which the research is being conducted is an equal partner with all research-related decisions, from the first ideas to dissemination to data storage and ownership. This equitable partnership is seen as an issue of justice, as is described in the Nuffield guidelines in their observation that local context is critical to the safe and equitable conduct of research (Calman et al., 2002). In this report, justice and respect are synonymous, with recognition that there is always the possibility for those researchers from wealthy countries to exploit economic, political, and educational vulnerabilities, even unintentionally. For this reason, collaboration and constant consultation with community representatives are protective mechanisms to prevent this exploitation.

The Belmont Report defines justice as an equitable distribution of the benefits and burdens of research (Ryan et al., 1979). This simplistic definition is insufficient when the research

endeavor includes populations with great income inequality, limited access to resources, and great distance between the researcher's home institution and the research site. Looking at quantifiable conditions of disparity, global research in developing nations is like research in Indian Country. It is those disparities that make Indian Country so appealing as a setting for health research because AI/AN communities appear ripe for measurable change through intervention. In research with developing nations, investigators are cautioned to avoid over-representing marginalized populations in research, considering the difficulty those populations will have in naturally accessing the benefits of research in daily life (CIOMS, 2016). Likewise, issues of health care access and payment, as well as generations of disenfranchisement and the resulting mistrust, have led to a highly limited utilization of health care resources across AI/AN communities, in reservation and urban areas alike.

For AI/ANs living in urban areas, there are additional concerns that add to the Indigenous data sovereignty discussion. AI/ANs living in urban areas who utilize Urban Indian Health Programs (UIHPs; Indian Health Service, 2021) are recognized within research circles to be easily recruited and engaged to provide data without having to obtain permission from critical tribal Councils, tribal review boards, or tribal leaders (Yuan et al., 2014). Unfortunately, although UIHPs may wish to regulate data with the same principals of data sovereignty as to protect AI/ANs living on or near reservation land, they do not have the same legal protections afforded to reservation residents.

The urban AI/AN population can be difficult to locate due to conditions of economics and racial misclassification (Bird et al., 2007). Drawing from national datasets, there exist some estimates on the overall health of urban AI/AN populations, but these estimates have significant flaws, including concerns with racial misclassification contributing to undercounts of the numbers of AI/ANs overall, small sample sizes forcing AI/AN numbers to be aggregated with other small populations in the data, or concerns regarding inclusion of AI/ANs who identify with more than one race or ethnicity (Urban Indian Health Institute, 2016).

Unlike reservation-based AI/ANs, urban AI/ANs have a greater range of educational, economic, and lifestyle heterogeneity (Austin, 2013). The UIHP population is the easiest to access within urban settings, but there are concerns of data skewing when samples are drawn exclusively from UIHPs. This is a special concern for those UIHPs that serve a high number of clients without private insurance. If justice is the equal distribution of both the positive and negative effects of research, yet all data is collected through a UIHP, the ultimate result is an unequal distribution of the outcomes. Additionally, those urban AI/ANs whose data are not represented have no collaborative or consultative voice in the research process, effectively denying their sovereignty.

### **Autonomy**

Community-based participatory research (CBPR) is the collaborative research approach suggested by the Nuffield and CIOMS guidelines. This is the approach most known in the United States and is critical in guiding researchers on important cultural insights necessary for maintaining autonomy in the consent process. Those insights include providing information on how best to approach the individual or collective regarding who should

provide informed consent, as the person from whom data are being collected may not be considered the responsible party in all cultures. In the United States, this concept is well understood when obtaining informed consent in research with children, as it is well accepted that children cannot give independent consent, they are quite capable of giving assent. Within the domestic borders of the United States, we have Indigenous communities for whom group consent would be the best cultural model, with many variations therein. For example, tribal leaders may be the primary decision-makers, or tribal elders, or other tribal members for whom great traditional responsibilities are given, yet in the dominant culture these individuals are decision-making equals to their adult children (Smith, 2013; Tallbear, 2013). The idea of individual consent is conceptually incomprehensible (and extremely disrespectful) in many traditional AI/AN contexts (Christian, 2019; Kovach, 2021). The Nuffield Council provides excellent guidelines on obtaining consent within collective communities, suggesting that individual *consent* is sought from the research participant, but only after community consultation with *assent* obtained from the most appropriate representative of the community (Battiste, 2008; Calman et al., 2002).

Researchers engaged in the consenting process expect that the participant can make independent, goal-oriented decisions (Ryan et al., 1979). Autonomy depends on the individual to devise and act upon personal goals. Autonomy is provided with the caveat that those individuals who are deemed “vulnerable” must be protected, yet the definition of vulnerable populations is frustratingly vague. 45 CFR § 46 specifically defines vulnerable populations as children, prisoners, people with impaired decision-making ability, or economically or educationally disadvantaged persons (Protection of Human Subjects, 2018). Specifically, there is no clear definition for the subjective categories of “economically or educationally disadvantaged persons,” leaving those determinations for the IRB overseeing the research. This creates potential for populations that have been marginalized through unbalanced reporting of population-based statistics to have their decisional capacity removed. Indigenous communities, whether urban or reservation-based, may rate poorly on standard measures of income and academic education, yet their cultural understandings of what consists of knowledge and worth could be substantially different (Smith, 2013). Regardless of their Indigenous definitions for economic and educational achievement, these external and often artificial measures are imposed on AI/AN communities without their consent or consultation, thus denying those communities agency in deciding whether they can consent to participate in research (Creighton University, 2013; Kwon, 2018; Medical College of Wisconsin, 2021). Without self-determination, there is no autonomy. In IRBs where AI/ANs have a blanket determination of “vulnerable,” the institution has usurped the AI/AN populations’ self-determination without consultation, removing their autonomy.

In a population that has been systematically denied self-determination through generations of unjust federal and state policies, the potential for true Indigenous autonomy is rare. For this reason, tribes are exerting their sovereignty so they may govern how their data are used and shared. AI/ANs not living on or near their tribal lands do not cede their status as citizens of sovereign nations, yet they lack the protections of local sovereign governance, and thus their ethical rights as autonomous beings are at risk when engaging in biomedical research. Some may argue that the protections for vulnerable populations required within 45 CFR § 46 make research more ethical for AI/ANs, but it is our assertion that the paternalistic stance of

institutional oversight is not a just replacement for community engagement and appropriate consenting processes. Indeed, denying community input by deeming specific populations vulnerable based on externally applied metrics is a clear violation of autonomy.

### **Beneficence**

Ultimately, it is the researchers' responsibility to maximize all potential benefits in the research endeavor. The consenting process plays an important role in ensuring research informs potential participants of all possible risks, so they may weigh the risks against the possible potential benefits of the research. Frequently, consent documents will feature only the immediate personal risks and benefits such as side effects or symptoms and possibilities for data breaches, with little explanation of the long-term outcomes. Consent documents rarely state the potential collective risks and benefits which may result from the research processes and reports, including potential negative impacts as well as how the community may benefit from the program. While there may be a sentence describing publication intentions, few community participants know how their data will be used in reporting, particularly how their data can be manipulated to exploit negative narratives about their communities.

Therapeutic misconception and therapeutic optimism are also known factors that cloud participants' ability to provide true informed consent. Often, participants' judgement regarding consent is based on personal factors such as an immediate health need, or a belief that they will be randomized to the intervention group, indicating a poor understanding of clinical research and characteristic of therapeutic optimism (Jansen, 2011). Another characteristic of therapeutic misconception is the confusion between the overall generalizability of research results regardless of participants' personal benefit (Bhutta, 2004; Henderson et al., 2007). These two barriers to informed consent allow a poorly informed public to be unintentionally coerced into participating in research activities. In communities in which health literacy is already an issue, such as is the case with many AI/ANs (Willing et al., 2018), therapeutic misconception and therapeutic optimism at the time of consent conflict with the ethical principles of beneficence.

Applying international guidelines such as CIOMS for AI/ANs, both those on and away from tribal lands, would promote research methods that are scientifically sound and have local applicability with a clear endpoint that promotes health at the individual, community, or policy level (CIOMS, 2016). The conditions described previously can incentivize research that does not ensure the participants are fully informed of the risks and benefits to the community, an important consideration in collective cultures. Furthermore, the Nuffield guidelines describe social and cultural context as components necessary for informed consent, both of which would aid in avoiding therapeutic misconception and optimism (Calman et al., 2002).

In urban AI/AN communities, researchers may mistakenly assume the participants are more assimilated to the dominant culture, thereby lacking the same cultural tailoring of consent or other population-specific considerations they would make with a rural, reservation-based community. Although AI/ANs living in urban areas may be required to develop coping strategies that allow them to enjoy their lives in whatever settings they live, many are still

strongly oriented to their worldview from an Indigenous perspective. Considerations of urban AI/ANs' cultural needs should include consideration of community-based consent and a community-oriented worldview.

### **Non-maleficence**

Few would argue with the assertion that research should do no harm and should actively work to avoid harm through unintentional negligence (Beauchamp & Childress, 2001). This appears simple on the outset, but the art of avoiding harm by negligence is much more nuanced. Most health researchers have written a research plan they believe water-tight, only to encounter countless issues once data collection begins. This is the rub of unintentional negligence; not only addressing those complications as they occur, but meeting them with interest, recognizing that cultural norms vary, and knowing that research design can change according to the context of the location (Calman et al., 2002). The ethical researcher understands that research has a footprint in the community, and a negative experience with one researcher will leave a lasting impression for many years to come.

Although non-maleficence is appreciated as an ethical ideal, the argument that “we did not know” still allows researchers to continue with what many would consider unacceptable practices. In preparing for this paper, we found a document published by the United States National Endowment for the Humanities (NEH). This document, purporting to be a code of ethics for projects involving Native Americans, only suggests that grant recipients work in collaboration with AI/AN participants. The document fails to recognize tribal sovereignty and tribal ownership of data and has an outdated understanding of tribal hierarchical relationships and governments, going so far as to suggest that completed works be “deposited with the Native representatives of the elders and traditional leaders of the community” (NEH, 2018). While this text is well-intentioned and does not exclude urban AI/AN communities, it overlooks the highly sophisticated structures many tribes have in place for reviewing and storing tribal data, including the wide network of tribal libraries and the many tribal human subjects review boards and research review committees (Brugge & Missaghian, 2006; Hull & Wilson Dine, 2017; James et al., 2014; Morton et al., 2013). A grant recipient following these guidelines could claim ignorance to the wide body of scholarship on data sovereignty and data governance and might publish what tribal members consider sacred or protected cultural information (Holkup et al., 2004). There is precedent for the publication of sacred information across the range of academic research, and because U.S. statute protects personal property but does not consider cultural property of value, the harms caused by the release of this information are experienced without recourse (Portman & Garrett, 2006; Tsosie, 2007). These protections extend as well to urban AI/ANs.

## **SOLUTIONS**

We propose four ethical practices that researchers adopt when conducting research with urban AI/AN communities. The first is the integration of data use agreements (DUAs) in all research that include AI/AN data as a reportable outcome. In this context, DUAs are formal documents that describe the process by which the researcher or research team intends to collect, analyze, report, and store all data, with any negotiated plans for returning data



to the Tribe or urban community made explicit. Frequently, a DUA will be reviewed and signed or included in a tribal resolution or Memorandum of Understanding prior to data collection. When an AI/AN organization is included in a contractual agreement with a research organization or funder, the DUA can be attached as a component of the negotiated contract. If the research is a collaboration with a UIHP or urban AI/AN Community Center, the organization can require a DUA for access to their patient or client population. If there is no intermediary and the research is conducted through a university, DUAs may not be applied unless there are collaborating partners within the project, in which case the agreement is between researchers and not with the data sources. In this case, the most accountability the researcher has with the urban AI/AN is to clearly describe how the participants' data will be used in the consent form. Incidentally, all consent forms should already include a description of how the collected data will be used.

The benefit of DUAs for AI/AN communities is that Tribes or urban AI/AN organizations can define how their data are used, stored, disseminated, and destroyed prior to data collection. This process allows AI/AN groups to review dissemination products to ensure that information about their communities reflects a balanced perspective about community concerns, provides context when there are disparities that need reporting, and protects communities against having sacred or protected cultural information inadvertently released and shared to the larger public. The benefit for external research and sponsoring organizations is that the community's needs and concerns are identified and addressed well in advance of the project beginning. This process itself builds relationships between these external organizations and AI/AN communities. A well-articulated statement of benefits to the community, with risks identified and addressed, enhances buy-in and ownership of the research, which in turn can support recruitment and retention of research participants.

The Urban Indian Health Institute in Seattle, Washington has published guidelines for data collection in all AI/AN communities, including urban AI/ANs (UIHI, 2020). Included in these guidelines is the recommendation to secure tribal permission according to the conditions of a DUA when any tribal-specific data might be released. This recommendation affords protection to tribal members when working directly with specific tribes but is less applicable when working in an urban setting, where tribal representation can be diverse and seeking DUAs with all tribes represented in a research project ceases to be logistically practicable. The state of Arizona has an early childhood education initiative that includes a large data collection component. This program, titled "First Things First," created a DUA that clearly describes how data that is collected on tribal lands will be used (First Things First Institute, 2020). This DUA is comprehensive, with sections regulating data collection, analysis, communication, privacy and confidentiality, data review and publication, tribal data access, and a sample data request form. Although this agreement is intended to be used between the agency and tribes, it is a good example of the degree of information any DUA requires and is applicable for researchers wishing to work with urban AI/AN organizations.

A second solution to address the issues of data sovereignty with urban AI/ANs is community oversight via a project-specific advisory board. Without a formal tribal organization to represent this population, urban AI/ANs may have their interests overlooked in the process of research, data collection, and data usage. For this reason, the Community Advisory Board

or Community Action Board (CAB) remains the gold standard for working with AI/AN data, regardless of location from which the data is obtained (Blue Bird Jernigan et al., 2020; Lewis & Boyd, 2012; Wallerstein & Duran, 2018). CABs are a foundation of community-based participatory research (CBPR) and community-engaged research (CER) and critical to any project that requires close collaboration or oversight by a community, be it urban, reservation-based, or agency-based. When partnering with a CAB, the special interests of sovereignty inherent to AI/ANs can be protected, by including a body that can provide consultation on ethical justice, ensure equitable access to research, and accurately interpret results. A trend to underutilize CABs in research lends to their role only as symbolic gatekeepers for many researchers, but for those wishing to conduct truly collaborative work with AI/ANs in urban conditions, a CAB can oversee all phases of the research to ensure maximal benefits to the community and reduce risks which may not be apparent or of concern to external agents (Oetzel et al., 2015; Wallerstein & Duran, 2006).

A CAB is not the same as a tribal government. In tribal communities, there is a nation-to-nation relationship. With that relationship comes a corresponding obligation for consultation with tribes when policy decisions are made that impact tribes. Tribal consultation between governments concerns policy making and ongoing monitoring of public programs (Wilkins & Adams, 2019). In research, a CAB functions as a consultative body but does not serve any legal function, unless specified by the terms of the research.

The role of the CAB in a research study working with urban AI/ANs has potential to guide the research through expert oversight and protection of Indigenous sovereignty, but the research team and the CAB must address certain concerns first. Membership on the CAB will require thoughtful guidance regarding knowledge and qualifications as they relate to the research. A CAB member can bring extensive knowledge and cultural guidance; it is the duty of the research team to seek out the best possible representatives from the community and then abide by their guidance. Other considerations include planning regular meeting times, meeting at locations that are convenient and culturally appropriate for the CAB members, and paying for CAB member expenses to attend meetings as needed. The CAB's involvement should consider members' qualifications, at what levels will they provide advisement, and whether they can veto decisions within the research project. Qualifications should include people with expertise germane to the research topics and methods (Lee et al., 2018; Oetzel et al., 2015). For example, a school-based intervention to improve adolescent AI/AN mental health should be overseen by CAB members with expertise in and good connections with AI/AN youth and families; such a project may also include a Youth Advisory Council for more precise insight and guidance (Lee et al., 2012). Many of these guidelines are best practice recommendations for community engagement for any population in which there is a potential power inequity with external research entities (Wallerstein & Duran, 2006, 2018). Specifically, for urban AI/AN studies, CAB membership and resourcing should address specific contours of urban AI/AN communities (e.g., include people from multiple tribes residing in community together and identify meeting spaces that are inclusive and accessible to all).

Although every project that involves AI/ANs should include a CAB, urban AI/AN-based projects will rely more heavily on a CAB for data governance purposes. For this reason, the

CAB members' qualifications, role, and ability to regularly advise holds special importance for this population. A strong partnership with a CAB will enhance a project by providing clarity regarding the priorities and boundaries within a community. In the urban setting, a CAB will also help a research team identify how this population interacts and is impacted by the larger non-AI/AN community and provide necessary context to the research findings that may emerge within the AI/AN community. A CAB can also provide the necessary feedback regarding drafting and enforcing a DUA in place of a formal tribal governmental body. Without a strong CAB relationship for this feedback, data can be published that misrepresents or exploits the study population, which is ultimately an act of injustice.

CABs integrated into the research process can also provide insight into culturally congruent approaches to building consent documents that meet the specific needs of their communities. With this guidance, investigators can formulate consent documents that address cultural congruence, therapeutic misconception, and health literacy concerns as described previously in this paper. Another approach to further enhance comprehension is the inclusion of true/false statements about research goals within the consent document (Henderson et al., 2007). This strategy helps study staff charged with consenting participants identify those individuals who need additional attention to build understanding regarding the purpose, procedures, risks, benefits, clinician role, and general protocol of the research for which they are volunteering to participate.

Finally, projects with AI/AN communities in both reservation and urban areas may benefit greatly from consultation and training processes. Federal and state agencies have formalized tribal consultation in navigating their relationships with sovereign tribes, for example in federal rule making and budgeting and state negotiations of gaming compacts, easements, health care provision, and other revenue- and resource-sharing agreements with tribes. Consultation in the form of in-person meetings may be combined with a period of public commenting on drafts of documents of high interest to AI/AN communities, made available for review online. Increasingly, urban AI/ANs are invited to participate in these consultation proceedings along with tribal government representatives. Within an urban AI/AN community, consultation should include commonly accepted community leaders, often within the structure of an AI/AN community center or UIHC non-profit board of directors or identified through less formal word-of-mouth or social networking. Community-based consent may also consist of a series of informational meetings and a period of public consultation and comment prior to the initiation of data collection (Bhutta, 2004). Staff participating on these research studies may be unaware of Indigenous research concerns, while community leaders who have not engaged in research activities may also be unaware of basic principles and best practices in risk protection. Training all participating staff and advisors on Indigenous research ethics, for example through AI/AN-specific curricula such as Research Ethics Training for Health in Indigenous Communities (rETHICS; Parker et al., 2019), can both increase awareness and support improved research partnerships (Wallerstein et al., 2018). Through this community-focused approach, the urban AI/AN population will be more informed about the larger goals of the research and more able to endorse the research within the community at large, achieving true community-based consent.

## CONCLUSION

In examining the core ethical concepts of justice, autonomy, beneficence, and non-maleficence, we present specific concerns for AI/ANs, with a focus on urban AI/AN communities. Although this population is not specifically protected by the government-to-government relationship that federally recognized tribes operate under, those individuals who are tribal deserve the same attention to their needs and rights as sovereign citizens and the same protections of their data as though they were on their tribal lands.

Although daunting, investigators can frame this discussion as an effort to strengthen the ethical considerations of all participants while giving special thought to those issues specific to urban AI/ANs. AI/AN data are meaningful for this small population, particularly concerning allocation of resources and appreciating the size of the on-reservation and urban population of AI/ANs in the United States. This diverse population has experienced generations of misrepresentation in the lay-press and popular media, as well as by the mainstream research community, which has yet to respond at the broad institutional level (Hodge, 2012). By expressing and exerting their right to data sovereignty, AI/ANs are claiming the rights to their narratives, voicing their identities individually and as a collective. Observing the ethical principles of research as they are understood internationally will aid in appreciating and honoring Indigenous data sovereignty for all AI/ANs, regardless of physical location.

Federal research and data governance guidelines do not yet obligate research institutions, funding agencies, or IRBs to know about and ensure protection against research risks that are specific to AI/ANs. Although academic IRBs may be aware of tribal review protocols, the federal institutions that provide assurance to IRBs do not yet obligate researchers to seek out and obtain consent and oversight from tribal institutions, much less obligate researchers to ensure oversight in urban AI/AN contexts. In lieu of such policies, AI/AN communities are distinctly disadvantaged in their being assured of full protection when they participate in research programs and rely on members of the research community to inform and hold each other accountable to standards of ethics and justice due to AI/ANs wherever they reside.

## ACKNOWLEDGEMENTS

The authors acknowledge the many community members whose expertise and experience have informed this work. The authors would also like to thank the anonymous reviewers whose comments helped improve this manuscript.

## FUNDING INFORMATION

Haozous, Soto, Lee: Office of Health Equity, California Department of Public Health, Contract 16-10574, Native American Technical Assistance Provider, California Reducing Disparities Program Phase 2.

Haozous: R01 MD010292, Improving Native Elder Access to and Use of Healthcare through Effective Health System Navigation.

## REFERENCES

Adashi EY, Walters LB, & Menikoff JA (2018). The Belmont Report at 40: Reckoning with time. *American Journal of Public Health*, 108(10), 1345–1348. <https://ajph.aphapublications.org/doi/10.2105/AJPH.2018.304580> [PubMed: 30138058]

- Austin A (2013). Native Americans and jobs (#370). <https://www.epi.org/publication/bp370-native-americans-jobs/>
- Battiste M (2008). Research ethics for protecting Indigenous knowledge and heritage: Institutional and researcher responsibilities. In Denzin N, Lincoln Y, & Smith T (Eds.), *Handbook of Critical and Indigenous Methodologies* (pp. 497–509). Sage. <https://methods.sagepub.com/book/handbook-of-critical-and-indigenous-methodologies>
- Beauchamp TL, & Childress JF (2001). *Principles of biomedical ethics* (Fifth ed.). Oxford University Press.
- Bhutta ZA (2004). Beyond informed consent. *Bulletin of the World Health Organization*, 82(10), 771–777. <https://www.scielo.org/article/bwho/2004.v82n10/771-777/> [PubMed: 15643799]
- Biden J (2021). Memorandum on tribal consultation and strengthening nation-to-nation relationships. (January 26, 2021). Washington, DC: The White House. <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/26/memorandum-on-tribal-consultation-and-strengthening-nation-to-nation-relationships/>
- Bird M, Burhansstipanov L, Clinton J, Henderson JA, Joe JR, Maresca T, Trafzer CE, Trujillo MH, Slater E, Waukazo M, & Wilson CB (2007). *Invisible tribes: Urban Indians and their health in a changing world*. Robert Wood Johnson Foundation. <https://www2.census.gov/cac/nac/meetings/2015-10-13/invisible-tribes.pdf>
- Blue Bird Jernigan V, D'Amico EJ, & Keawe' Aimoku Kaholokula J (2020). Prevention research with Indigenous communities to expedite dissemination and implementation efforts. *Prevention Science*, 21(S1), 74–82. 10.1007/s11121-018-0951-0 [PubMed: 30284158]
- Bruegl AS, Joshi S, Batman S, Weisenberger M, Munro E, & Becker T (2020). Gynecologic cancer incidence and mortality among American Indian/Alaska Native women in the Pacific Northwest, 1996–2016. *Gynecologic Oncology*, 157(3), 686–692. 10.1016/j.ygyno.2020.03.033 [PubMed: 32305303]
- Brugge D, & Missaghian M (2006). Protecting the Navajo People through tribal regulation of research. *Science and Engineering Ethics*, 12(3), 491–507. 10.1007/s11948-006-0047-2 [PubMed: 16909151]
- Bureau of Indian Affairs. (2021). About us. <https://www.bia.gov/about-us>
- Calman K, Binka F, Elves M, Mathan VI, McAdam K, McLaren A, Parekh B, Parkin D, Peckham C, Riis P, Sewankambo N, Sadeque S, Smith P, & Zicker F (2002). *The ethics of research related to healthcare in developing countries* [Report]. Nuffield Council on Bioethics. <http://nuffieldbioethics.org/project/research-developing-countries>
- Christian D (2019). Indigenous visual storywork for Indigenous film aesthetics. In Archibald J-A, Lee-Morgan J, De Santolo J, & Smith LT (Eds.), *Decolonizing research: Indigenous Storywork as methodology* (pp. 40–55). ZED Books Ltd.
- Council for International Organizations of Medical Sciences (CIOMS). (2016). *International ethical guidelines for biomedical research involving human subjects*. <https://cioms.ch/>
- Creighton University. (2013). *Human research protection program: Vulnerable research populations*. [https://www.creighton.edu/fileadmin/user/ResearchCompliance/IRB/Policies\\_](https://www.creighton.edu/fileadmin/user/ResearchCompliance/IRB/Policies_)
- Exec. Order No. 13,175, 65 C.F.R. 67249 (2000). <https://www.federalregister.gov/documents/>
- First Things First Institute. (2020). *Tribal data policy*. <https://www.firstthingsfirst.org/wp->
- Haozous EA, Strickland CJ, Palacios JF, & Solomon TG (2014). Blood politics, ethnic identity, and racial misclassification among American Indians and Alaska Natives [Review Article]. *Journal of Environmental and Public Health*, 2014(321604), 321604. 10.1155/2014/321604 [PubMed: 24669226]
- Henderson GE, Churchill LR, Davis AM, Easter MM, Grady C, Joffe S, Kass N, King NMP, Lidz CW, Miller FG, Nelson DK, Peppercorn J, Rothschild BB, Sankar P, Wilfond BS, & Zimmer CR (2007). Clinical trials and medical care: Defining the therapeutic misconception. *PLoS Medicine*, 4(11), e324–e324. <https://doi.org/10.1371/> [PubMed: 18044980]
- Hodge FS (2012). No meaningful apology for American Indian unethical research abuses. *Ethics & Behavior*, 22(6), 431–444. 10.1080/10508422.2012.730788

- Holkup PA, Tripp-Reimer T, Salois EM, & Weinert C (2004). Community-based participatory research: An approach to intervention research with a Native American community. *Advances in Nursing Science*, 27(3), 162–175. 10.1097/00012272- [PubMed: 15455579]
- Hull SC, & Wilson Dine DR (2017). Beyond Belmont: Ensuring respect for AI/AN communities through Tribal IRBs, laws, and policies. *American Journal of Bioethics*, 17(7), 60–62. 10.1080/15265161.2017.1328531
- Indian Health Service (IHS). (2021). Office of Urban Indian Health Programs. <https://www.ihs.gov/urban/>
- Jacobs-Wingo JL, Espey DK, Groom AV, Phillips LE, Haverkamp DS, & Stanley SL (2016). Causes and disparities in death rates among Urban American Indian and Alaska Native populations, 1999-2009. *American Journal of Public Health*, 106(5), 906–914. 10.2105/ajph.2015.303033 [PubMed: 26890168]
- James R, Tsosie R, Sahota P, Parker M, Dillard D, Sylvester I, Lewis J, Klejka J, Muzquiz L, Olsen P, Whitener R, & Burke W (2014). Exploring pathways to trust: A tribal perspective on data sharing. *Genetic Medicine*, 16(11), 820–826. <https://doi.org/>
- Jansen LA (2011). Two concepts of therapeutic optimism. *Journal of Medical Ethics*, 37(9), 563–566. 10.1136/jme.2010.038943 [PubMed: 21551464]
- Kiel D (2019). Nation v. municipality: Indigenous land recovery, settler resentment, and taxation on the Oneida reservation. *Native American and Indigenous Studies*, 6(2), 51–73. 10.5749/natiindistudj.6.2.0051
- Kovach M (2021). *Indigenous methodologies: Characteristics, conversations, and contexts*. University of Toronto Press.
- Kwon P (August 21, 2018). Special categories of research, Vulnerable human subjects' policy. Mayo Clinic. <https://www.mayo.edu/research/documents/32-special-categories-participants->
- Lee JP, Lipperman-Kreda S, Saephan S, & Kirkpatrick S (2012). Youth-led tobacco prevention: Lessons learned for engaging Southeast Asian American youth. *Progress in Community Health Partnerships: Research, Education, and Action*, 6(2), 187–194. 10.1353/cpr.2012.0022
- Lee JP, Pagano A, Moore RS, Tilsen N, Henderson JA, Iron Shell A, Davids S, LeBeaux L, & Gruenewald P (2018). Impacts of alcohol availability on Tribal lands where alcohol is prohibited: A community-partnered qualitative investigation. *International Journal of Drug Policy*, 54, 77–86. 10.1016/j.drugpo.2018.01.010 [PubMed: 29414489]
- Lewis JP, & Boyd K (2012). Determined by the community: CBPR in Alaska Native communities building local control and self-determination. *Journal of Indigenous Research*, 1(2), 6. 10.26077/9yam-v819
- Medical College of Wisconsin. (2021). IRB policies and procedures: Vulnerable populations. <https://www.mcw.edu/departments/human-research-protection-program/researchers/irb->
- Melkonian SC, Henley SJ, Senkomago V, Thomas CC, Jim MA, Apostolou A, & Saraiya M (2020). Cancers associated with human Papillomavirus in American Indian and Alaska Native populations - United States, 2013-2017. *MMWR Morbidity and Mortality Weekly Report*, 69(37), 1283–1287. 10.15585/mmwr.mm6937a2 [PubMed: 32941412]
- Morton DJ, Proudfit J, Calac D, Portillo M, Lofton-Fitzsimmons G, Molina T, Flores R, Lawson-Risso B, & Majel-McCauley R (2013). Creating research capacity through a tribally based institutional review board. *American Journal of Public Health*, 103(12), 2160–2164. 10.2105/ajph.2013.301473 [PubMed: 24134381]
- National Endowment for the Humanities (NEH). (2018). Code of ethics related to Native Americans. <https://www.neh.gov/grants/manage/code-ethics-related-native-americans>
- Oetzel J, Villegas M, Zenone H, White Hat ER, Wallerstein N, & Duran B (2015). Enhancing stewardship of community-engaged research through governance. *American Journal of Public Health*, 105(6), 1161–1167. 10.2105/ajph.2014.302457 [PubMed: 25880952]
- Parker M, Pearson C, Donald C, & Fisher CB (2019). Beyond the Belmont Principles: A community-based approach to developing an Indigenous ethics model and curriculum for training health researchers working with American Indian and Alaska Native communities. *American Journal of Community Psychology*, 64(1-2), 9–20. <https://doi.org/10.1002/> [PubMed: 31355974]

- Portman TA, & Garrett MT (2006). Native American healing traditions. *International Journal of Disability, Development and Education*, 53(4), 453–469. <https://doi.org/10.1080/10803540600600000>
- Protection of Human Subjects 45 C.F.R. § 46 (2018). <https://www.govinfo.gov/content/pkg/CFR-2020-title45-vol1/pdf/CFR-2020-title45-vol1-part46.pdf>
- Rainie S, Rodriguez-Lonebear D, & Martinez A (2017). Policy brief: Indigenous data sovereignty in the United States. Native Nations Institute, University of Arizona. [https://nni.arizona.edu/application/files/1715/1579/8037/Policy\\_Brief\\_Indigenous\\_Data\\_Sov](https://nni.arizona.edu/application/files/1715/1579/8037/Policy_Brief_Indigenous_Data_Sov)
- Rainie SC, Schultz JL, Briggs E, Riggs P, & Palmanteer-Holder NL (2017). Data as a strategic resource: Self-determination, governance, and the data challenge for Indigenous nations in the United States. *The International Indigenous Policy Journal*, 8(2), 1–29. 10.18584/iipj.2017.8.2.1
- Ryan KJ, Brady JV, Cooke RE, Height DI, Jonsen AR, Lebacqz K, Louisell DW, Seldin DW, Stellar E, Turtle RH (1979). The Belmont Report. (DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014). The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. <https://www.hhs.gov/ohrp/sites/default/>
- Smith LT (2013). *Decolonizing methodologies: Research and Indigenous peoples*: Zed Books Ltd.
- Tallbear K (2013). *Native American DNA*. University of Minnesota Press. <https://www.upress.umn.edu/book-division/books/native-american-dna>
- Tsai DF (2008). Personhood and autonomy in multicultural health care settings. *Virtual Mentor*, 10(3), 171–176. 10.1001/virtualmentor.2008.10.3.msoc1-0803 [PubMed: 23206885]
- Tsosie KS, Yracheta JM, & Dickenson D (2019). Overvaluing individual consent ignores risks to tribal participants. *Nature Reviews Genetics*, 1–2. 10.1038/s41576-019-0000-0
- Tsosie R (2000). Land, culture, and community: Reflections on Native sovereignty and property in America. *Indiana Law Review*, 34, 1291. [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1748720](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1748720)
- Tsosie R (2007). Cultural challenges to biotechnology: Native American genetic resources and the concept of cultural harm. *The Journal of Law, Medicine, and Ethics*, 35(3), 396–411. 10.1111/j.1748-720X.2007.00163.x
- Tsosie R (2020). The legal and policy dimensions of Indigenous data sovereignty (IDS). In Walter M, Kukutai T, Carroll SR, & Rodriguez-Lonebear D (Eds.), *Indigenous Data Sovereignty and Policy* (1st ed., pp. 204–225). Taylor & Francis.
- United Nations Declaration on the Rights of Indigenous Peoples, September 13, 2007, [https://www.un.org/esa/socdev/unpfii/documents/DRIPS\\_en.pdf](https://www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf)
- Urban Indian Health Institute (UIHI). (2016). Community health profile: National aggregate of Urban Indian Health Program Service Areas. <https://www.uihi.org/urban-indian-health-profile>
- Urban Indian Health Institute (UIHI). (2020). Best practices for American Indian and Alaska Native data collection. <https://www.uihi.org/resources/best-practices-for-american-indian-and-alaska-native-data-collection>
- Wallerstein NB, & Duran B (2006). Using community-based participatory research to address health disparities. *Health Promotion and Practice*, 7(3), 312–323. <https://doi.org/10.1177/1524902906288888>
- Wallerstein N, & Duran B (2018). The theoretical, historical and practice roots of CBPR. In Wallerstein N, Duran B, Oetzel J, & Minkler M (Eds.), *Community-based participatory research for health: Advancing social and health equity* (3rd ed., pp. 17–29). Jossey Bass.
- Weber TL, Copeland G, Pingatore N, Schmid KK, Jim MA, & Watanabe-Galloway S (2019). Using tribal data linkages to improve the quality of American Indian cancer data in Michigan. *Journal of Health Care for the Poor and Underserved*, 30(3), 1237–1247. 10.1353/hpu.2019.0084 [PubMed: 31422999]
- White A, Richardson LC, Li C, Ekwueme DU, & Kaur JS (2014). Breast cancer mortality among American Indian and Alaska Native women, 1990–2009. *American Journal of Public Health*, 104(Suppl 3), S432–438. 10.2105/ajph.2013.301720 [PubMed: 24754658]
- Wilkins DE, & Adams H (April 3, 2019). Nothing less than consent: Consultation and the diminishment of Indigenous rights. *Indian Country Today*. <https://indiancountrytoday.com/news/indian-country-today-nothing-less-than-consent-consultation-and-the-diminishment-of-indigenous-rights>
- Willging CE, Sommerfeld DH, Jaramillo ET, Lujan E, Bly RS, Debenport EK, Verney SP, & Lujan R (2018). Improving Native American elder access to and use of health care through effective health system navigation. *BMC Health Services Research*, 18(1), 464–464. 10.1186/s12913-018-3182-y [PubMed: 29914446]

- Williams RL, Willging CE, Quintero G, Kalishman S, Sussman AL, & Freeman WL (2010). Ethics of health research in communities: Perspectives from the Southwestern United States. *The Annals of Family Medicine*, 8(5), 433–439. 10.1370/afm.1138 [PubMed: 20843885]
- Yuan NP, Bartgis J, & Demers D (2014). Promoting ethical research with American Indian and Alaska Native people living in urban areas. *American Journal of Public Health*, 104(11), 2085–2091. 10.2105/ajph.2014.302027 [PubMed: 25211730]

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript