

TRIBAL IRBS: A FRAMEWORK FOR UNDERSTANDING RESEARCH OVERSIGHT IN AMERICAN INDIAN AND ALASKA NATIVE COMMUNITIES

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Abstract: Tribal Institutional Review Boards (IRBs) and other entities that oversee research for American Indians and Alaska Natives are important and unique. They reflect and respond to community needs, changes in research, and revisions to research policy. We provide a framework to capture this dynamism by building on existing work and offering a way to describe the scope of entities that oversee tribal research. As federal research regulations are revised, and policies are developed in response to a rapidly advancing research landscape, it is critical that policy makers, IRB professionals, researchers, and tribal communities have clarity regarding the Tribal IRB.

BACKGROUND

Scholars and leaders in American Indian and Alaska Native (AI/AN) communities have noted that the work of mainstream university and medical center Institutional Review Boards (IRBs) alone is inadequate for ensuring research protections for AI/AN peoples (Champagne & Goldberg, 2005; Deloria, 2003; Freeman, n.d.; Harding et al., 2012; LaFrance & Crazy Bull, 2009; National Congress of American Indians [NCAI] Policy Research Center, 2017; n.d.). As a result, several tribes have established their own processes for oversight of research activities on their lands and with their citizens. In addition, other entities that serve AI/AN individuals and communities, on and off tribal lands, have also established processes for research oversight. The goal shared by many of these entities is often two-fold: to ensure protection within and benefit from research participation for both AI/AN individuals and communities (Fort Peck Institutional Review Board, n.d.; Navajo Nation Department of Health, n.d.; Oglala Lakota College, n.d.; Salish Kootenai College, n.d.; Sisseton-Wahpeton Oyate Research Office, n.d.-a; Southwest Tribal

Native American Research Center for Health [NARCH], n.d.; Tribal Nations Research Group [TNRG], n.d.).

Population and Historical Context

The AI/AN population in the United States is in truth a collective of several populations represented by 573 federally recognized tribes (Bureau of Indian Affairs, 2019) and several tribal nations not officially recognized by the federal government (i.e., state-recognized tribes). These populations are spread across 326 federally recognized reservations, off-reservation trust land areas (U.S. Census Bureau, 2018), and urban and rural communities throughout the United States. Federally recognized tribes are sovereign; therefore, each has a government-to-government relationship with the United States, creating a unique context for research oversight and policy (U.S. Department of the Interior Indian Affairs, 2019). This manuscript summarizes primary mechanisms for research oversight in AI/AN communities and the related considerations for upholding ethical research for these populations. Throughout the manuscript the terms *tribe* and *tribal community* are used in addition to *American Indian and Alaska Native (AI/AN)* to refer to communities and groupings of AI/AN peoples in the United States. The term *tribally based research* refers to research involving individuals residing on tribal land, or research utilizing a tribe's natural, historical, or cultural resources.

It has been a little over 50 years since the establishment of U.S. laws to protect human participants in research. These national laws were established in response to national and international recognition of research abuses and in response to the development of global research ethics standards and review processes (Maloney, 1984; Rice, 2008). U.S. IRBs were established to protect the rights and welfare of people participating in research studies, and the requirement for IRBs and IRB review evolved from a policy directive in 1966 issued by U.S. Surgeon General William Stewart (Breault, 2006; Office of the Surgeon General, U.S. Public Health Service, 1967). A little more than a decade later in 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research drafted the Belmont Report, which outlines ethical guidelines for research involving human participants (U.S. Department of Health and Human Services [USDHHS], n.d.). Subsequently, through efforts in 1981 and 1991, the Belmont Report was incorporated into the U.S. federal research policy known as the "Common Rule," or 45 CFR Part 46.

Present Day Relevance and Intended Audience

Even after the establishment of federal research policies and the IRBs tasked with implementing them, AI/AN peoples have continued to experience research abuses—indicating that mainstream ethical standards, policies, and IRBs have not been successful in preventing research-related harms to tribes (Fixico, 1980; Garrison & Cho, 2013; Hodge, 2012; LaFrance & Crazy Bull, 2009; Manson, Garrouette, Goins, & Henderson, 2004). Research violations involving AI/AN populations have only recently been publicly recognized and contribute to a long history of oppression experienced by these populations (Brave Heart & DeBruyn, 1998; Office of the Surgeon General, 2001; Whitebeck, Adams, Hoyt, & Chen, 2004). The history of research ethics violations includes multiple accounts of research conducted without permission and research conducted without participation of the relevant AI/AN communities in the research process (Morton et al., 2013; Norton & Manson, 1996; Solomon & Randall, 2014). Significant harms have resulted from these research violations, and they have occurred at both the individual and community levels (Morton et al., 2013; Norton & Manson, 1996; Solomon & Randall, 2014).

The purpose of this manuscript is to acknowledge the diversity of mechanisms for research oversight that presently exist in AI/AN communities and present a framework to help clarify the role and scope of the various entities involved in such activities. The recent growth and dynamism of tribal research oversight warrants acknowledgement and deeper understanding. This manuscript is intended to serve as a tool for many, including those engaged in tribal research or research oversight with tribal communities, tribal policy makers, federal policy makers, and research funding agencies. To ensure that AI/AN peoples are both adequately protected within and benefit from research, it is important that all existing tribal research oversight processes are recognized and more clearly understood. While we acknowledge that it is likely we are not aware of all tribal IRBs or research oversight processes serving AI/AN peoples, this manuscript documents those known to the authors and for which there is publicly available information. We provide the most comprehensive published listing to date (Table A1 in Appendix), and we anticipate that our proposed framework will be amenable to the continued growth of tribal research oversight processes in the future.

Author Perspectives and Experience

The authors represent, or were previously affiliated with, the Collaborative Research Center for American Indian Health (CRCAIH), Tribal Nations Research Group (TNRG), and Sisseton-Wahpeton Oyate Local Research Review Board (SWO LRRB). The primary content of the manuscript is based on insights derived from our individual and collaborative experiences with Tribal IRBs and other AI/AN research oversight entities. CRCAIH has provided education, tools, and technical support for the establishment of new Tribal IRBs and the growth of existing Tribal IRBs (Angal & Andalcio, 2015; Elliott et al., 2015). These services are part of the larger aim of the center to facilitate and support the building of tribal research infrastructure, with the goal of addressing health inequities experienced by American Indian communities in South Dakota, North Dakota, and Minnesota (Collaborative Research Center for American Indian Health, 2013; Elliott et al., 2015). TNRG is an organization created to promote high quality research relevant to the Turtle Mountain Band of Chippewa Indians, to “improve the quality of life for all Tribal Members, through culturally competent, custom-fit research,” and for the promotion of public and private economic development and opportunity (TNRG, n.d.). TNRG provides a variety of research and data collection services. TNRG also founded and manages the system of tribal research oversight for their Tribal Nation, the Turtle Mountain Band of Chippewa Indians Research Review Board (TNRG, n.d.). The SWO LRRB is a part of the Tribal Research Office established by the Sisseton-Wahpeton Oyate Tribal Council. This board provides research oversight for the Sisseton-Wahpeton Oyate Tribal Nation by reviewing research proposals and granting permission to researchers to conduct research on the Lake Traverse Reservation (Sisseton-Wahpeton Oyate Research Office n.d.-a).

Current Mechanisms for Understanding Research Oversight in AI/AN Communities

Tribal Nations are currently using research to address the health of their communities (Crazy Bull, 1997; Fisher & Ball, 2003; Mariella, Brown, Carter, & Verri, 2009; National Institutes of Health [NIH] Center for Research Capacity Building, 2015; Swisher, 1992) and lead initiatives to ensure that tribally based research is beneficial to both the individuals who participate and their communities (Crazy Bull, 1997; Harding et al., 2012; Manson et al., 2004; Solomon & Randall, 2014; Swisher, 1992). However, the mechanisms of research oversight in AI/AN communities are wide-ranging. A comprehensive review of the literature (Angal, Petersen, Tobacco, & Elliott,

2016; Brugge & Missaghian, 2006; Gribble & Around Him, 2014; Harding et al., 2012; Henderson, 2018; Kelley, Belcourt-Dittloff, Belcourt, & Belcourt, 2013; LaFrance & Crazy Bull, 2009; Manson et al., 2004; Morton et al., 2013; NCAI Policy Research Center, 2017; Saxton et al., 2015; Yuan, Bartgis, & Demers, 2014) and engagement with several entities involved in tribal research oversight has revealed a clear gap in characterizing these diverse and evolving mechanisms.

A decade ago, LaFrance and Crazy Bull (2009) identified three distinct entities engaged in research oversight in AI/AN communities: 1) Indian Health Service (IHS) IRB, 2) Tribal College IRB, and 3) Tribal IRB. Since LaFrance and Crazy Bull’s characterization, there has been tremendous growth in the number of entities involved in providing research oversight for AI/AN peoples. Use of the term *Tribal IRB* has become widespread, and it is commonly used to describe many entities that provide oversight of research involving AI/AN peoples. In addition, use of *IRB* in the name of a research oversight entity is sometimes thought to signify a federally registered review body and other times is not formally linked to a federal designation. This array of interpretations poses challenges for many, including tribal and non-tribal entities that provide research oversight, those involved in tribal research more broadly, and those involved in policy development. It leads to cross communication and general confusion around research oversight in AI/AN communities, and it could potentially contribute to inadequate oversight of research involving AI/AN peoples.

AN UPDATED FRAMEWORK

We propose an updated framework (Table 1) that expands the structure provided by LaFrance and Crazy Bull (2009) to account for the current landscape of research oversight in AI/AN communities and to improve understanding for those engaged in research oversight, the conduct and funding of research, and related research policy development. As noted above, these revisions are necessary for several reasons. The updated framework offers greater clarity and recognizes the growing variety of entities engaged in the important work of research oversight for AI/AN peoples. Our hope is that it will further ensure adequate and appropriate research oversight is provided in a streamlined process—a benefit to AI/AN peoples and the research community at-large.

The updated framework includes two of the three distinct types of AI/AN research oversight denoted by LaFrance and Crazy Bull (2009) and, in addition to renaming the third type, adds a fourth. We narrowed the “Tribal IRB” designation provided by LaFrance and Crazy Bull (2009) to specify recognition of research oversight authorized by a “Tribal Nation.” We also introduced the designation of “Tribally Based or Focused Organization/Department.” Entities within this type were not distinct in the LaFrance and Crazy Bull (2009) framework; they may not have been in existence or well-known at the time. Furthermore, we have provided a conscious re-ordering of the categories placing entities that provide research oversight for Tribal Nations first: 1) Tribal Nation, 2) Tribal College, 3) Tribally Based or Focused Organization/Department, and 4) IHS. For each mechanism in the framework, there are special cases where an entity may engage in more than one type of research oversight, and these are described in detail below.

Table 1
Framework for understanding oversight in AI/AN communities

Tribal Nation	Tribal College	Tribally Based or Focused Organization/ Department	Indian Health Service (IHS)
Entity authorized to provide the ethical review and monitoring of research for one Tribal Nation or for a single reservation home to more than one Tribal Nation	Entity that provides the ethical review and monitoring of research for a Tribal College or University (TCU)*	Entity in an existing organization or department that provides the ethical review and monitoring of research for that organization or department and is within a Tribal Nation, and/or serving a Tribal Nation or Nations, and/or serving AI/AN peoples	An entity designated by IHS to provide the ethical review and monitoring of research conducted in IHS facilities within IHS regional or national designations

*Includes tribally and federally chartered colleges and universities. See the “Tribal College Research Oversight” section for further information.

Several factors were taken into consideration in determining how to organize this updated framework. For example, components of jurisdiction, including geography, content, and authorizing entity, each factored into our conceptual thinking. Ultimately, we decided the most collaborative, respectful, and effective approach was to acknowledge and build on what exists and may be easily recognized among those engaged in AI/AN research and research oversight. In this spirit, we have retained the names proposed by LaFrance and Crazy Bull (2009), as well as the names that existing tribal research oversight entities have given themselves. Thus, the primary

characteristics highlighted by the nomenclature in this framework are a combination of geographic and structural jurisdiction. This concept is explained in more depth below under the heading “Jurisdiction, Authority, and Other Considerations.” Furthermore, it is important to note that this framework introduces terminology that is recommended for use *in addition to* the existing names of entities providing tribal research oversight. See “Applying the Framework” below for more detail. A table listing AI/AN research oversight entities known to the authors at the time of publication, and according to this framework, is provided in the Appendix.

Tribal Nation Research Oversight

Tribal Nation research oversight may be used to describe research oversight by a board or committee authorized by a tribal government to provide the ethical review and monitoring of research on behalf of a tribal nation or for a single reservation home to more than one tribal nation. It is the only mechanism in this framework that denotes the explicit legal authority of a tribal government to provide research review and monitoring on behalf of an entire Tribal Nation or reservation. This research oversight entity may be the tribal governing body applying its own research code, such as the Tribal Council of the Confederated Tribes of the Coos, Lower Umpqua, and Siuslaw Indians (The Confederated Tribes of the Coos, 2002), or a Business Council, such as that of the Confederated Tribes of the Colville Reservation (The Confederated Tribes of the Colville Reservation, n.d.). It may also be a separate board with primary responsibility for the ethical review of tribally based research for the Tribal Nation, such as existing boards that carry the name “Tribal IRB” or “Tribal Research Review Board (RRB).” Examples of these types of boards serving a single Tribal Nation are the Tribal Nations Research Group (TNRG, n.d.), the Sisseton-Wahpeton Oyate Local RRB (Sisseton-Wahpeton Oyate Research Office, n.d.-b), and the Choctaw Nation of Oklahoma IRB (Clark, 2016). The Fort Peck IRB, like the Tribal Council of the Confederated Tribes of the Coos, Lower Umpqua, and Siuslaw Indians (mentioned earlier; The Confederated Tribes of the Coos, n.d.), serves a single reservation home to more than one tribal nation (i.e., the Assiniboine and Sioux Tribes; Fort Peck Institutional Review Board, n.d.). It is important to note that this description and the additional examples in the Appendix refer to entities authorized by tribal governments (e.g., in a research code or law); however, as sovereign nations, all tribal governments have the power and authority to provide research oversight in the absence of having authorized another entity to do so (Deloria, 2003).

Tribal College Research Oversight

The *Tribal College* mechanism refers to entities that are commonly referred to as “Tribal College IRBs.” These entities typically review research based at their tribal college and/or college facilities, and/or research in which the college students, staff, or faculty are engaged. Note that this designation primarily refers to tribally controlled colleges; however, it also includes colleges that operate under the authority of the federal government, such as Haskell Indian Nations University. Examples of *Tribal College* IRBs are the Oglala Lakota College IRB and Institutional Animal Care and Use Committee (Oglala Lakota College, n.d.), the United Tribes Technical College IRB (United Tribes Technical College, n.d.), and the Salish Kootenai College IRB (Salish Kootenai College, n.d.). See Appendix for additional examples.

Tribally Based or Focused Organization/Department Research Oversight

Tribally Based or Focused Organization/Department research oversight is proposed to describe the type of research oversight offered by an existing organization or department within a Tribal Nation, serving a Tribal Nation or Nations, or serving AI/AN individuals, which provides the ethical review of research for that particular organization or department. This includes both reservation-based organizations and organizations based in other settings off reservations or tribal lands, including urban settings. Entities responsible for this type of research oversight are distinct from those responsible for *Tribal Nation* research oversight in that they have a more limited scope of work and usually are not responsible for the oversight of *all* tribally based research for a particular Tribal Nation, reservation, or community. For example, in some communities, a Tribal Historic Preservation Office (THPO) reviews and provides oversight for certain types of research on behalf of a tribe. An example of this is the Sisseton-Wahpeton Oyate THPO (Sisseton-Wahpeton Oyate Tribal Historic Preservation Office, n.d.). It is important to note that this designation is distinct from *Tribal College* research oversight, as tribal colleges and universities have been granted their own designation consistent with LaFrance and Crazy Bull’s (2009) original framework.

IHS Research Oversight

IHS research oversight encompasses entities commonly referred to as “IHS Area IRBs,” which provide research oversight that corresponds to the twelve geographical areas defined by

IHS: Alaska, Albuquerque, Bemidji, Billings, California, Great Plains, Nashville, Navajo, Oklahoma, Phoenix, Portland, and Tucson (IHS, n.d.-b). Typically, these entities are responsible for the oversight of research conducted in IHS facilities in tribal communities within the geographical areas defined by IHS. However, historically, IHS Area IRBs have offered to provide oversight for research in tribal communities more broadly, for example when tribal communities do not have an IRB. IHS IRBs may also be of service in situations when research requires review by a federally registered IRB, and a tribal community does not have such a designation (IHS, n.d.-b). When serving as the IRB, or “IRB of record,” for a tribal community, IHS IRBs typically require documentation of approval from the Tribal Council, or an entity designated by the Tribal Council, prior to approving any research activities (IHS, n.d.-b).

Special Cases within the Proposed Framework

There are some special cases in this proposed framework. For example, boards or committees providing research oversight for a community may provide more than one type of research oversight. The Navajo Nation Human RRB (NNHRRB) is a good example, as it provides both *Tribal Nation* and *IHS* research oversight. The NNHRRB is also referred to as the Navajo Area IHS IRB (Navajo Nation Department of Health, n.d.). Other exceptions are research oversight entities that serve a consortium of Tribal Nations. Using our framework, we will refer to these types of entities as a *Tribally Based or Focused Organization/Department*. One example of this type of Tribal IRB is the Southwest Tribal IRB, which provides supplemental review of research to tribes located in New Mexico, Colorado, and Texas (Southwest Tribal NARCH, n.d.).

Other examples of special cases are the Indian Health Council IRB and the California Rural Indian Health Board IRB. Both are IRBs that serve multiple tribal communities and according to our framework provide *Tribally Based or Focused Organization/Department* research oversight. The Indian Health Council Tribal IRB in California is part of a health care center that provides health care and social services (Indian Health Council Inc, n.d.; Morton et al., 2013). The health care center was founded by a consortium of nine tribes, and it has two clinics and several outreach programs serving the North San Diego County reservations of the Inaja-Cosmit, La Jolla, Los Coyotes, Mesa Grande, Pala, Rincon, San Pasqual, and Santa Ysabel (Indian Health Council Inc, n.d.). Similarly, affiliated with a health care consortium, the California Rural Indian Health Board IRB serves the California Rural Indian Health Board, a network of tribal health programs with

membership including Feather River Tribal Health, Inc.; Warner Mountain Indian Health Program; United Indian Health Services; Tule River Indian Health Center; Redding Rancheria Tribal Health Center; Toiyabe Indian Health Project; Karuk Tribal Health Program; and the Chapa-De Indian Health Program (California Rural Indian Health Board, n.d.-a).

APPLYING THE FRAMEWORK

It is important to note that research involving AI/AN communities may fall under the purview of more than one research oversight entity. For example, one research study may need review by more than one, and even potentially all four, types of research oversight entities in this framework – *Tribal Nation*, *Tribal College*, *Tribally Based or Focused Organization/Department*, and *IHS*. Use of this framework will support awareness of the research oversight entities that may exist for tribal communities, thus adding clarity to communications about the review of research protocols for those both within and external to such communities.

Within a specific tribal community, applying this framework could help ensure that one entity providing research oversight, such as a tribal college, is aware of the existence and scope of another entity (e.g., a Tribal Historic Preservation Office). Therefore, when a research project requires oversight from both entities, the need for collaboration will be clear. The framework could also help prevent misunderstandings when applied by external partners who are less familiar with the landscape of tribal research oversight. For example, it could deter instances of a Principal Investigator erroneously believing, and perhaps reporting in publications, that a project has been approved by a Tribe or Tribal Nation, when in fact the research was approved by a *Tribally Based or Focused Organization/Department* research oversight entity. The framework may also avert researcher requests to a Tribal Council when a separate body has been designated as the *Tribal Nation* research oversight entity within the community.

Research oversight entities within tribal communities may choose to apply the framework in practical ways, to position their work within a broader range of responsibilities or delineate a specific scope of oversight. For example, tribal entities whose primary responsibility is not research regulation or oversight, such as a Tribal Council, Tribal Historic Preservation Office, or Health Board, could insert research oversight language into their list of services provided. For instance, a Health Board that performs ethical review of research for their Tribal Nation can include “Tribal Nation research oversight” in their list of responsibilities or, if they choose,

establish a public presence as the “_____ Nation Health Board and the _____ Nation IRB.” Likewise, in cases where an entity’s scope of research oversight is limited, such limitations could be clearly specified within the entity’s name or mission. For instance, a Tribal Historic Preservation Office, which may review historical and cultural research, could reference the scope of research that it reviews using language such as, “The _____ Tribal Historic Preservation Office, which serves as the Tribal IRB for historical and cultural research,” or “The _____ Tribal Historic Preservation Office, which provides oversight for historical and cultural research.”

Use of the framework in conjunction with the existing names for tribal research oversight entities is encouraged. Thus, an entity that identifies itself as a Tribal IRB can simply clarify their scope of review or oversight by referring to themselves as a Tribal IRB that provides, for example, *Tribally Based or Focused Organization/Department* research oversight or *Tribal College* research oversight. Awareness of how the U.S. Office for Human Research Protections (OHRP) uses the term “IRB” is also important for understanding this recommendation. The OHRP is part of the U.S. Department of Health and Human Services (USDHHS), and it maintains regulatory oversight over biomedical and behavioral research involving human participants that is conducted or supported by USDHHS (USDHHS, n.d.).

Entities that review and regulate research can become federally registered through the OHRP’s established registration process. Within the OHRP’s database of registered entities, each entity is referred to as an “IRB” and assigned a number. According to a personal communication with staff from the OHRP, an OHRP registered entity responsible for the ethical review and regulation of research can have any name, and there is no requirement that the name contain the words “review” or “board” (H. Blatt, personal communication, 2014). The OHRP also lists registered entities in their database using “IRB” in the name irrespective of the entity’s actual name (H. Blatt, personal communication, 2014). Therefore, for ease of reference, we use the term “IRB” throughout the remainder of this manuscript, like the OHRP uses it, to refer to any entity reviewing research or providing research oversight.

JURISDICTION, AUTHORITY, AND OTHER CONSIDERATIONS

With growing attention to tribal sovereignty in research, issues surrounding tribal jurisdiction and enforcement of research laws have emerged as important topics of discussion at local and national levels. These concepts factored into the development of the framework proposed in this

manuscript and deserve further elaboration as part of our effort to clarify the role and scope of the diverse entities that oversee tribally based research. Insights gleaned through the work of CRCAIH, TNRG, and SWO LRRB relate to three primary types of jurisdiction used by Tribal IRBs and other entities responsible for AI/AN research oversight—*geographic*, *structural*, and *content-specific* jurisdiction—which are presented in the following sections. The importance of the authority of research oversight entities is also discussed, as well as differences in sources of authorization.

Geographic and Structural Jurisdiction

For the purposes of this framework, we define *geographic* and *structural jurisdiction* in terms of physical boundaries. Using the example of a school, jurisdiction that is *structural* in nature would be jurisdiction over research that involves the school, the school property, and/or that engages students and faculty. Another example of *structural jurisdiction* is jurisdiction over research that involves an organization (other than a school), which means that oversight is provided for research that occurs in that organization’s facilities or with that organization’s staff and other patrons. An example mentioned earlier in the paper is that of a health clinic. *IHS* jurisdiction of research oversight can also be thought of as both structural and geographic.

To understand how we define *geographic jurisdiction* for this framework, it is helpful to consider those IRBs that provide *Tribal Nation* research oversight. Some limit their jurisdiction to research activities conducted within the tribe’s reservation boundaries or tribal lands. Language like “within the reservation” or “reservation boundaries” might be used in policy, with the right to such jurisdiction based on federal law and tribal government jurisdiction over a tribe’s land. In some instances, *Tribal Nation* IRBs have considered providing research oversight for research projects that aim to recruit tribal members who reside near, but outside of, the tribe’s reservation boundaries or tribal lands. An example is research proposed in a school that exists outside a reservation’s borders but serves many tribal children who reside both within and near the reservation’s borders. The difficulty of establishing jurisdiction outside of tribal lands has been acknowledged, and one suggestion is that *Tribal Nation* IRBs and administrators of such schools establish a collaborative relationship that allows for appropriate oversight of research projects involving tribal children attending the school.

The challenge of overseeing all research involving tribal members anywhere in the United States, or in the world, has also arisen in discussions with Tribal Partners at CRCAIH, including TNRG and SWO LRRB. Among the tribes partnering with CRCAIH, the belief in such an

approach has been met with a reality of the practical challenges related to its implementation and enforcement, as it would entail trying to provide oversight of research for an enormous geographic area and on lands that may not be tribal or reservation-based. It would also entail trying to enforce tribal policy on lands and in communities outside of a tribe's legal jurisdiction. The intersection of the legal and ethical implications of this topic warrants further deliberation, especially given that tribal perspectives on and capacities to address this topic may be diverse.

Content-Specific Jurisdiction

In addition to making determinations regarding *geographic* or *structural jurisdiction*, it is important to consider that there is also *content-specific jurisdiction* for many Tribal IRBs and other entities responsible for AI/AN research oversight. Some Tribal Nations and/or Tribal IRBs have developed policies around the content of their research review and oversight. In our experience, it is helpful to do so. A challenge shared by new or developing *Tribal Nation* IRBs is determining the scope of their research oversight activities, or the content that they will review and monitor on behalf of the tribe. Several *Tribal Nation* IRBs have developed policies stating that they will review *all* research, not only research involving human participants. This means for example, basic science, conservation, environmental, animal, housing, education, historical, and cultural research.

Some *Tribal Nation* IRBs also consider all data collection activities occurring on their reservation or tribal lands to be under their jurisdiction. The Turtle Mountain Band of Chippewa Indians RRB is one example (TNRG, 2014). Furthermore, many Tribal IRBs review and provide approval for presentations and publications related to both tribally based research and non-research projects. These efforts to provide oversight beyond the mainstream understanding of human subjects' research, and beyond research in general, are to protect tribal citizens and communities from harm or stigmatization. They also are designed to ensure that both the outcome and process of the projects under review are beneficial to the community and, at minimum, do not put the community at risk.

Authority

An important distinguishing characteristic of existing Tribal IRBs is their source of authorization, or rather the entity that provides an IRB with authority to operate and have jurisdiction for research oversight. This characteristic is also a factor in the diversity of existing

tribal research oversight entities. In our framework the source of authority for *Tribal Nation* research oversight is the tribal government. The source of authority for *Tribal College* research oversight is usually the college itself, although in some cases it can be the respective tribal government. It is important to note that tribally controlled colleges are enabled by charters issued from their respective tribal governments. An exception is the case in which a tribal government has authorized its *Tribal College* IRB to provide research oversight for the entire Tribal Nation. Examples of this are the Sitting Bull College IRB, which provides research oversight for its college and for the Standing Rock Sioux Tribe (M. Mongoh, personal communication, 2016), or the Fort Peck IRB, which provides research oversight for Fort Peck Community College and the Fort Peck Assiniboine & Sioux Tribes of the Fort Peck Reservation (Fort Peck IRB, n.d.). See Appendix for more detail.

The source of authority for *Tribally Based or Focused Organization/Department* entities is usually the organization or department itself. However, it can be the tribal government, particularly if the organization or department is located on tribal land. An example of this is the Fond du Lac Band of Lake Superior Chippewa Human Services Division IRB, which received authorization from the tribal governing body, the Reservation Business Committee. Moreover, jurisdiction for this IRB is structural in nature, as it pertains exclusively to research that engages the Human Services Division (C. Bassett, personal communication, 2016).

The source of authority for *IHS* research oversight IRBs is the Indian Health Service (IHS) and, therefore, the federal government (IHS, n.d.-a). The exception to this is when authority is shared by the federal government and a tribal government, for example when a Tribal IRB is both authorized by IHS and the government of a Tribal Nation. As described earlier, the Navajo Nation Human Research Review Board (NNHRRB) aligns with this scenario (Navajo Nation Department of Health, n.d.).

CONCLUSION

Research oversight in AI/AN communities is complex. However, this complexity exists for important reasons, including the sovereign right of tribes to govern activities occurring on their lands and with their peoples and genuine interests in ensuring protection and benefits for AI/AN individuals and communities engaged in research activities. We hope this framework helps bring recognition to the variety of entities engaged in this important work. A positive outcome would be

the identification of additional Tribal IRBs, beyond those shown in our Appendix. For instance, entities not identified through our efforts due to lack of a public presence may be inspired to declare their existence and role. This could be facilitated either through the encouragement of tribal community members or others they engage within the research process, such as the research community and funders.

We also hope that by offering a framework to navigate the landscape of Tribal IRBs, we have identified opportunities to improve collaboration and efficiency both in the conduct of research and its oversight within AI/AN communities. For example, our goal is that by applying this framework diverse audiences will begin to put in place the policies and supports needed to strengthen relationships both among Tribal IRBs and between Tribal IRBs and research oversight bodies external to tribal communities, such as non-tribal academic and federal IRBs. With tribal authority over research explicitly acknowledged in the revised Common Rule (USDHHS, 2017b), clarity around Tribal IRBs will be invaluable. We anticipate that more people will become aware of the need to engage and respect Tribal IRBs in their work, and this framework can serve as a resource for orienting to the complex but necessary environment of Tribal IRBs.

Tribal IRBs and other entities that provide research oversight for AI/AN communities are essential, not only because of the negative history of research with tribes, but also because research is being used more and more by tribal communities as a tool for building capacity and improving the well-being of AI/AN peoples. Entities that fall within the framework proposed in this manuscript will continue to evolve in response to community needs, changes in the types and focus of tribally based research, and academic and federal policy revisions. The framework offered in this manuscript provides shared language and structure to account for this dynamism. It provides a simple way to describe the scope of a Tribal IRB or other research oversight entity by building on work that precedes it and using familiar terminology. The updated framework is also flexible enough to grow with the inevitable progression and change that will continue with the *Tribal IRB*, particularly in the areas of tribal jurisdiction and enforcement. In this time of rapidly developing research technology, revisions to federal research regulations such as the Common Rule (USDHHS, 2017b), and development of new research policies at places like NIH (USDHHS, 2017a, 2017b), it is more important than ever that policy makers, IRB professionals, researchers, and tribal communities have a mutual understanding and shared terminology regarding research oversight in AI/AN communities.

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APPENDIX

Table A1
Fifty known entities providing research oversight for AI/AN communities as of April 2019

Tribal Nation	Tribal College	Tribally Based or Focused Organization/ Department	Indian Health Service
1. Blackfeet Nation IRB Browning, MT	1. Aaniiih Nakoda College IRB (formerly Fort Belknap College) Harlem, MT www.ancollege.edu/online-resources/pdfs/IRB.pdf	1. California Rural Indian Health Board Sacramento, CA https://crihb.org/institutional-review-board/	1. Alaska Area IHS IRB Anchorage, AK http://anthctoday.org/airb
2. Cherokee Nation IRB Tahlequah, OK http://www.cherokee.org/Our-Government/Boards-Commissions/Institutional-Review-Board	2. Bay Mills Community College IRB (BMCC IRB) Brimley, MI https://www.bmcc.edu/about-bmcc/governance-administration/research-and-special-projects	2. Chickasaw Nation Department of Health IRB* (also known as Chickasaw Nation Research Review Board) Ada, OK	2. Bemidji Area IHS IRB (Publication Review Committee) Bemidji, MN
3. Chickasaw Nation Research Review Board* (also known as Chickasaw Nation Department of Health IRB) Ada, OK	3. Chief Dull Knife Community College Institutional Review Board Lame Deer, MT http://www.cdkc.edu/CDKC_IRB.pdf	3. Eastern Band of Cherokee Indians Cultural Institutional Review Board (CIRB)* Cherokee, NC	3. Billings Area IHS IRB* (also known as Rocky Mountain Tribal IRB) Billings, MT https://www.rmtlc.org/rocky-mountain-tribal-institutional-review-board/
4. Choctaw Nation of Oklahoma IRB Idabel, OK	4. College of Menominee Nation IRB Keshena, WI	4. Eastern Band of Cherokee Indians Medical Institutional Review Board (MIRB)* Cherokee, NC http://www.cherokee-hmd.com/MIRB/index.html	4. Great Plains Area IHS IRB (formerly Aberdeen Area IHS IRB) Aberdeen, SD
5. Colorado River Indian Reservation (CRIT) Ethics Review Board Morgantown, AZ http://www.crit-nsn.gov/crit_contents/ordinances/Human-and-Cultural-Research-Code.pdf	5. Dine College Institutional Review Board Tsaile, AZ https://warriorweb.dinecollege.edu/ICS/Faculty_Staff/Committees_Taskforces/Institutional_Review_Board	5. Fond du Lac Band of Lake Superior Chippewa Human Services Division IRB Cloquet, MN	5. IHS National IRB Rockville, MD https://www.ihs.gov/dper/research/hsrp/
6. Eastern Band of Cherokee Indians Cultural Institutional Review Board (CIRB)* Cherokee, NC	6. Haskell Indian Nations University IRB Lawrence, KS http://www.haskell.edu/IRB	6. Gila River Research Review Committee Sacaton, AZ	6. Nashville Area IHS IRB Nashville, TN

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Table A1 Continued
Fifty known entities providing research oversight for AI/AN communities as of April 2019

Tribal Nation	Tribal College	Tribally Based or Focused Organization/ Department	Indian Health Service
<p>7. Eastern Band of Cherokee Indians Medical Institutional Review Board (MIRB)* Cherokee, NC http://www.cherokee-hmd.com/MIRB/index.html</p>	<p>7. Little Big Horn College Crow Agency, MT</p>	<p>7. Hopi Cultural Preservation Office* Kykotsmovi Village, AZ http://www8.nau.edu/hcpop/research.html</p>	<p>7. Navajo Area IHS IRB* (also known as the Navajo Nation Human Research Review Board) Window Rock, AZ http://www.nnhrb.navajo-nsn.gov/</p>
<p>8. Fort Peck IRB (formerly Fort Peck Community College IRB) Poplar, MT http://www.fortpeckirb.org</p>	<p>8. Navajo Technical University Committee on Institution Research (IRB) Crownpointe, NM http://www.navajotech.edu/academics/committee-on-institution-research</p>	<p>8. Indian Health Council Inc. IRB Valley Center, CA</p>	<p>8. Oklahoma City Area IHS IRB Oklahoma City, OK</p>
<p>9. Ho-Chunk Nation IRB Black River Falls, WI http://www.ho-chunk-nation.com/Laws/Title3-HealthAndSafety/3HCC3%20Tribal%20Research%20Code%2005.05.05.pdf</p>	<p>9. Northwest Indian College IRB Bellingham, WA http://www.nwic.edu/wp-content/uploads/2017/03/IRB-Manual-2013-12-02.pdf</p>	<p>9. Rocky Mountain Tribal IRB* (also known as Billings Area IHS IRB) Billings, MT https://www.rmtlc.org/rocky-mountain-tribal-institutional-review-board/</p>	<p>9. Phoenix Area IHS IRB Phoenix, AZ</p>
<p>10. Hopi Cultural Preservation Office* Kykotsmovi Village, AZ http://www8.nau.edu/hcpop/research.html</p>	<p>10. Oglala Lakota College IRB and Institutional Animal Care and Use Committee Kyle, SD http://www.olg.edu/administration/committees/irb.htm</p>	<p>10. Southwest Tribal IRB Albuquerque, NM http://www.mynarch.net/SW_Tribal_IRB.aspx</p>	<p>10. Portland Area IHS IRB Portland, OR http://www.npaihb.org/health-research/</p>
<p>11. Muscogee (Creek) Nation McAlester, OK http://www.creeksupremecourt.com/wp-content/uploads/T22-NCA10-124.pdf</p>	<p>11. Salish Kootenai College Pablo, MT http://irb.skcedu/</p>		<p>11. Tucson Area IHS IRB Tucson, AZ</p>
<p>12. Navajo Nation Human Research Review Board* (also known as Navajo Area IHS IRB) Window Rock, AZ http://www.nnhrb.navajo-nsn.gov/</p>	<p>12. Sitting Bull College IRB* (also known as Standing Rock Sioux Tribe IRB) Fort Yates, ND https://sittingbull.edu/sitting-bull-college/community/institutional-review-board/</p>		

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Table A1 Continued
Fifty known entities providing research oversight for AI/AN communities as of April 2019

Tribal Nation	Tribal College	Tribally Based or Focused Organization/ Department	Indian Health Service
<p>13. Oglala Sioux Tribe Research Review Board Pine Ridge, SD</p>	<p>13. Southwestern Indian Polytechnic Institute Institutional Review Board (SIPI IRB) Albuquerque, NM https://www.sipi.edu/apps/pages/index.jsp?uREC_ID=829035&type=d&pREC_ID=1308738</p>		
<p>14. Pascua Yaqui Tribe Research Review Committee Tucson, AZ http://www.pascuayaqui-nsn.gov/static_pages/tribal_codes/</p>	<p>14. Stone Child College IRB Box Elder, MT http://www.stonechild.edu/images/PDFs/Stone_Child_College_IRB.pdf</p>		
<p>15. Sisseton-Wahpeton Oyate Local Research Review Board Sisseton, SD http://www.swo-nsn.gov/departments/department-of-education/research-office/</p>	<p>15. United Tribes Technical College IRB Bismarck, ND https://uttc.edu/institutional-review-board/</p>		
<p>16. Standing Rock Sioux Tribe IRB* (also known as Sitting Bull College IRB) Fort Yates, ND https://sittingbull.edu/sitting-bull-college/community/institutional-review-board/</p>			
<p>17. The Confederated Tribes of the Colville Reservation Business Council Nespelem, WA https://www.colvilletribes.com/archives-records</p>			

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Table A1 Continued
Fifty known entities providing research oversight for AI/AN communities as of April 2019

Tribal Nation	Tribal College	Tribally Based or Focused Organization/ Department	Indian Health Service
18. The Confederated Tribes of the Coos, Lower Umpqua, and Siuslaw Indians Tribal Council Coos Bay, OR https://ctclusi.org/assets/57f698b2c9e22cf96e000003.pdf			
19. Tohono O’odham Nation Institutional Review Board Sells, AZ http://tolc-nsn.org/docs/Title17Ch8.pdf			
20. Turtle Mountain Band of Chippewa Indians Research Review Board Belcourt, ND http://www.tnrg.org/research-protection.html			
21. White Earth Nation Research Review Committee White Earth, MN http://www.whiteearth.com/data/upfiles/files/Judicial%20Services/ILB%20code.pdf			

^Information in this table was compiled from several sources (Indian Health Service, n.d.-b; United States Office for Human Research Protections (OHRP), n.d.; Arizona Biomedical Research Commission, 2016; California Rural Indian Health Board, n.d.-b; Montana State University, n.d.), but primarily the IHS IRBs website, the OHRP database of Registered IRBs, and the Montana State University website listing of Tribal College IRBs. There are likely additional entities responsible for AI/AN research oversight not shown in this table, and it should not be interpreted as an exhaustive list. Additionally, hyperlinks were only included for entities that have a public web presence via their own webpage or direct links to their policies, codes, or procedures.

*Designates an entity that falls under two categories, and therefore is listed twice, but is counted only once. For example, the Navajo Nation Human Research Review Board/Navajo Area IHS IRB falls within the *Tribal Nation* and *Indian Health Service* categories; however, it is a single entity only counted once for the count shown in the table’s title.