



## Beyond Belmont: Ensuring Respect for AI/AN Communities Through Tribal IRBs, Laws, and Policies

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# Beyond Belmont: Ensuring Respect for AI/AN Communities Through Tribal IRBs, Laws, and Policies

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We concur with Friesen and colleagues (2017) that it is timely to reflect on the history of the Belmont Report and its role in the development of research regulations, especially its failure to account for harms to communities and transparency in research. We would like to amplify the authors’ comments about the relevance of these failures as they pertain to American Indian and Alaska Native (AI/AN) communities—and clarify a few important nuances. Transparency and trust are key issues that continue to beleaguer AI/AN communities and their perception of scientific research (Havasupai Tribe of the Havasupai Reservation v. Arizona Board of Regents and Therese Ann Markow 2008; *American Journal of Medical Genetics [AJMG]* 2010). It would have been fitting for the Belmont Report to address “respect for communities” in response to the harm caused to the African American community by the Public Health Service Tuskegee Syphilis Study,

especially given that the study was an important catalyst in the establishment of both the National Research Act and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1974. Realistically, however, it seems unlikely that the Belmont Report, a historical document that has stood intact for nearly 40 years, will be revised to formally incorporate a new principle that focuses on community respect and trust—which makes it all the more important to understand how the interests of AI/AN communities can be protected under the newly updated U.S. federal regulatory framework (“the final Common Rule”).

Friesen and colleagues (2017) acknowledge that the issue of community harms is relevant to AI/AN tribes through their inclusion of case examples and alluding to the sovereign authority that tribes have to establish research regulations. However, their concern that it is

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difficult to define “community” is less relevant for AI/AN tribes, whose identity is determined by formal criteria, in addition to self-definition, shared vulnerabilities, health outcomes, and histories. There currently are 567 federally recognized AI/AN tribes<sup>1</sup> whose status has been determined by a detailed and arduous set of requirements related to their autonomous governance structure and historical identity and continuity (per 25 CFR Part 83). The sovereign authority of AI/AN tribes to self-govern, which has been recognized in the U.S. Constitution, treaties, case law, executive orders, and other federal policies, provides the grounding for updated references in the final Common Rule that acknowledged tribal laws.

Friesen and colleagues also correctly point out that AI/AN tribes are permitted under the final Common Rule to establish additional research protections. Specifically, the final Common Rule clarifies that its various references to state and local laws and regulations now must be construed to include any tribal laws that were passed by an official tribal governing body. As the executive summary further states:

Thus, if the official governing body of a tribe passes a tribal law that provides additional protections for human subjects, the Common Rule does not affect or alter the applicability of such tribal law . . . In addition, for purposes of the exception to the single IRB review requirement for cooperative research, relating to circumstances where review by more than a single IRB is required by law, Sec. \_\_.114(b)(2)(i) specifies that tribal law is to be considered in assessing whether more than single IRB review is required by law. (Federal Policy for the Protection of Human Subjects/Final Rule 2017, 7158, Executive Summary ILE.2)

Many tribes utilize the national or one of the regional Indian Health Service institutional review boards (IRBs), their own independent tribal IRBs, or other oversight mechanisms such as tribal research review committees and presentation and publication (“P&P”) committees that provide protections beyond those required by the Common Rule. For example, some tribes require review and approval of all publications and presentations and have developed policies to limit the use of community identifiers, such as the name of their tribe, in research publications (Chadwick et al 2015). These requirements are more expansive than the Common Rule’s relatively narrow focus on individual identifiers, helping to address a potential source of community harm that tribes are particularly concerned about. The final Common Rule now explicitly acknowledges the validity of such policies that have been passed by official tribal governing bodies, and other tribes may be interested in exploring similar policies that advance community protections that are not otherwise addressed in the U.S. federal regulatory framework (Angal and Andalcio 2015; Morton et al. 2013).

1. It is worth recognizing here that there are communities who self-identify as Native American tribes but have not been formally recognized by federal or state governments.

The final Common Rule’s revised regulatory language was informed by public comments on the emergent versions of the proposed rule (i.e., the advance notice of proposed rulemaking [ANPRM] and notice of proposed rulemaking [NPRM]) that were submitted by individual tribes and various tribal organizations at various stages in the rulemaking process, as well as a consultation that took place on January 5, 2016, between tribal and federal representatives in accordance with the HHS Tribal Consultation Policy. Although some skepticism was initially expressed that the public comments submitted in response to the ANPRM and NPRM would be taken seriously (Lynch et al 2017a), the final Common Rule was indeed responsive to public comments (Lynch et al 2017b), including specific concerns that were raised on behalf of AI/AN communities. The Tribal Consultation Statement that is included in the preamble of the final rule presents concerns that were expressed about the NPRM’s failure to acknowledge tribal sovereignty and the role of tribal governments in oversight of research occurring on tribal land or with tribal citizens, its failure to address risks of research to communities, and the negative effect that the single IRB review mandate could have on the ability of tribes to oversee research involving their citizens or that takes place on their land, among other concerns (Federal Policy for the Protection of Human Subjects/Final Rule 2017, 7258). A summary of the public comments that were submitted regarding tribal research for both the ANPRM and NPRM is also included in the preamble.<sup>2</sup>

Friesen and colleagues briefly mention the ability of AI/AN tribes under the final Common Rule to “establish a single IRB,” without providing further explanation. The concern that AI/AN tribes have expressed is that the single IRB mandate for multisite studies could circumvent their ability to ensure carefully tailored ethical review of research that takes place in their communities (NCAI 2016). AI/AN tribes do not want to be required to cede oversight authority to a single IRB that is not familiar with their distinctive cultural and historical contexts and that does not have policies to adequately protect against community harms. Instead, AI/AN tribes are increasingly interested in developing their capacity to set up their own IRBs to conduct local community-based governance and oversight of research conducted on their land and with their citizens. (Morton et al. 2013) By recognizing the validity of tribal regulations, the final Common Rule helps to ensure that the single IRB mandate does not prevent tribes from conducting ethical review of research occurring within their communities when participating in multisite cooperative research.

The final Common Rule’s recognition of AI/AN authority to oversee research provides an important anchor to help promote respect for AI/AN communities through tribal IRBs, laws, and policies that are crafted both

2. The word “tribal” appears 85 times in the *Federal Register* notice that contains the final Common Rule.

to safeguard the unique values and cultural heritage of AI/AN communities and to hold researchers accountable for interacting with these communities in a trustworthy, transparent manner. This is a positive step forward toward facilitating impactful research to address significant and enduring health disparities in AI/AN populations, while preventing the kinds of community harms that these populations have historically endured from research. It is also a timely development in relation to the creation of a new Tribal Health Research Office (THRO) at the National Institutes of Health (NIH), for which the goal is to increase communication to the tribes about the potential health benefits to tribal members and tribal communities who participate in research projects and programs from the NIH (<https://dpcpsi.nih.gov/thro>). The new Common Rule language provides a stronger foundation upon which the THRO can build to assure tribes that any research plans that emerge from the NIH will be held to ethical standards set forth by the tribes involved. ■

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# Dollars and Deadlines: Rule Reforms in Short Time Frames

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In “At Last! Aye, and there’s the Rub,” Capron (2017) describes challenges related to the timing for development, adoption, and revision of the Common Rule. Capron argues that the difficulty of making changes over the 10 years required before agencies adopted the original Common Rule created an “all or nothing” atmosphere. That is, because of the effort required, agencies were loath to make incremental changes and

instead “take up every possible revision at once” with the process that culminated in the recently revised Common Rule. Here we briefly describe the efforts of one agency—the U.S. Environmental Protection Agency (EPA)—that made interim changes to its human subjects protections within a 180-day time frame, and the opportunities and challenges that such an ambitious goal created.

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