

Enhancing Genomic Research in US Through the Lens of Indigenous Data Sovereignty

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Abstract

As biomedical science advances and generates immense amounts of data, stricter mechanisms of control are emerging by Indigenous Peoples who seek to exert stronger oversight over data about them. Many previous studies have offered no benefit and, in some cases, were misaligned with tribal priorities, thus generating deep mistrust of researchers. In addition, ethical regulations in the US lack community engagement and control requirements. In an effort to be engaged in research, Indigenous Peoples have developed tribal codes, research review boards, and protocols; research principles; and Indigenous data sovereignty networks to refocus the locus of control with Indigenous Peoples. The shift to exerting rights and interests over biospecimens and data have brought attention to the need to develop policies, relationships, and infrastructure. This article describes the processes that Indigenous Peoples have developed for research and data governance and lays the groundwork for more fair and equitable participation in biomedical research.

Introduction

As technological advances have generated immense amounts of biomedical data, a movement is afoot that promotes Indigenous data sovereignty to exert stronger control and oversight over such data from Indigenous Peoples. Biomedical data, which were once subject to localized systems of management, are now organized and stored in numerous large-scale databases, allowing researchers worldwide to access and utilize the data for new analyses. The governance of large-scale databases, many of which adopt broad data sharing models, often stands in contrast with the stricter mechanisms of protection and relationships of trust that facilitated the original collection of these data. This disconnect is clearly evident in the case of Indigenous communities.

Historically, biomedical data may not have been collected or utilized in ways that align with community rights and interests. This has resulted in research that has offered little or no benefit to the communities from which the data originated, potential biases in the interpretations of the data, dwindling participation in genetics and genomics research, and limited oversight by the people from whom the data are collected (Garrison et al. 2019a).

In the wake of negative experiences; in the face of biomedical and data futures including big data and large scale biobanking; and in the resurgence of Indigenous self determination, a shift toward Indigenous data sovereignty (ID-Sov) is happening (Hudson et al forthcoming, Garrison et al. 2019a, Carroll et al. 2019, Rainie et al. 2019, Kukutai and Taylor 2016a, Snipp 2016). IDSoV articulates the rights of Indigenous Peoples and nations to govern the collection, application, and use of data about their peoples, communities, lands, and resources (Kukutai & Taylor 2016b, Rodriguez-Lonebear and Rainie 2016, Snipp 2016).

This article first describes the sovereign, collective rights that Indigenous Peoples have to control their biomedical data. Then drawing on lessons learned from historical misuses of data to new efforts to exert Indigenous governance over data, we illustrate how IDSoV is emerging to return the locus of control to Indigenous nations and communities from where the data come.

Tribal sovereignty and data

For the purposes of this paper, we define Indigenous Peoples in the US as American Indian, Alaska Native, Native Hawaiian, and others Indigenous to the US and its territories. The federal government recognizes 574 tribes in the US as sovereign nations with their own legal and political structures to govern their citizens and homelands (Federal Register 2019). In addition, many other Indigenous Peoples exert sovereignty as state-recognized (National Conference of State Legislatures 2019) or un-recognized nations, including those in the state of Hawai'i. Sovereignty refers to the collective powers of a nation, such as the power to grant access to the population or to negotiate treaties between nations. As sovereign nations, tribes have the power to govern via their own structures, determine their own citizenship, and regulate tribal business (Duthu 2008).

Since 2015, the assertion of Indigenous data sovereignty (IDSoV) has emerged in scholarship and practice among Indigenous Peoples worldwide (Kukutai & Taylor 2016a, Rainie et al. 2017; Rodriguez-Lonebear 2016, Rainie et al. 2019 open data, Chung & Chung). These rights of Indigenous nations to control how data are used, described, and stored are delineated in the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP), particularly articles 3, 4, 5, 15(i), 18, 19, 20(i), 23, 31, 32, 33, 38, and 42 (Davis 2016, UN General Assembly 2007). Indigenous data, whether born digital or not, include information, knowledge, specimens, and belongings about Indigenous Peoples or to which they relate at either the individual or collective levels (Rainie et al 2019; Lovett et al 2019). IDSoV returns authority over data about Indigenous nations and their citizens, communities, and resources (wherever they may be located) back to the tribes from whom the data derive (Kukutai and Taylor 2016b).

IDSoV is an aspiration to be reached through the processes of decolonizing data and Indigenous data governance (Carroll et al. 2019). Decolonizing Indigenous data occurs as tribes and other data agents supplant non-Indigenous values and priorities with Indigenous systems that define data and guide how data are collected, analyzed, and used. Walter (2016; 2018) describes how 5D data, data defined by the state and researchers primarily to measure Indigenous difference, disparity, disadvantage, dysfunction and deprivation, have dominated Indigenous data narratives. There's an abundance of 5D data which are inaccurate,

inconsistent, and irrelevant for Indigenous purposes (Rainie et al. 2017). Simultaneously, a scarcity of data for Indigenous decision-making and innovation exist (UN 2018).

Indigenous data governance is when tribal ways of knowing and doing guide Indigenous decision-making and control of data (Rainie et al. 2017b, Walter et al. 2018). Tribes exercise IDSov through mechanisms of data governance—that is, tangible processes and instruments that direct how data are collected, managed, and used. There are two ways in which this can be achieved: 1) tribal governance of tribal data; and 2) influencing how others steward tribal data (Rainie, Rodriguez-Lonebear, and Martinez 2017). Other entities that steward Indigenous data include governments, non-profits, corporations, and research institutions. In response, some tribes have created additional protocols for data management, access, and stewardship to exercise control over Indigenous data (Rainie et al. 2017, CITE).

Indigenous data governance and tribal research governance complement one another; some data are research data and are subject to both data governance and research governance. Indigenous Peoples have always been “researchers,” asking questions, observing and collecting information, and analyzing for decision-making, transfer of knowledge, and other uses. Persistent and ongoing colonialism disrupted, co-opted, and suppressed Indigenous research methodologies and methods (Smith 2012). Today, tribes continue to rebuild and enhance their engagement with research through *tribal research governance*. Tribal research governance occurs when an Indigenous nation harnesses its own ways of knowing, doing, and being to set the agenda, determine the methodologies, control the processes, and direct the outcomes of the nation’s research ecosystem. Thus, Indigenous research governance becomes a mechanism for enhancing Indigenous data governance as tribes assert IDSov.

Past genetic research experiences

Historically, Indigenous communities have been subjected to extensive research with little, if any, input into the research process, study results, or in decision-making about how those data are described in publications and presentations (Smith 2012). In many cases, the harms from Indigenous participation in research have far outweighed any benefit, as exemplified in the cases of genetic research by Arizona State University (ASU) with the Havasupai Tribe and the University of British Columbia (UBC) with the Nuu-chah-nulth First Nation. In the two high-profile examples, the Havasupai and Nuu-chah-nulth tribes experienced a multitude of harms, and in one case resulted in a lawsuit filed by the Havasupai Tribe.

In the early 1990s, approximately 400 Havasupai Tribe members donated blood samples for a Diabetes Study. In 2003, Carletta Tilousi, Havasupai Tribe member and study participant, learned that subsequent studies with those samples were conducted on schizophrenia and human migration without the tribe’s knowledge. During recruitment, researchers did not disclose potential future uses. The Havasupai Tribe filed a lawsuit in 2004 over lack of informed consent and misuse of genetic materials (2004). The investigative Hart Report found that Dr. Therese Markow and her research team purposefully hid their intentions to study schizophrenia from the Havasupai Tribe and study participants. The informed consent form stated, “the purpose of the research is to study the causes of behavioral/medical disorders” (Hart and Sobraske 2003a).

When the lawsuit started, the Havasupai Tribe issued a Banishment Order barring all researchers (Bommersbach 2008). The case ultimately settled in April 2010 in which 41 named tribal members received a \$700,000 settlement, and the Tribe received funds for a clinic, a school, and scholarships. The remaining blood samples were returned to the Tribe (Harmon

2010). A small group of Havasupai members traveled to ASU to retrieve the DNA samples from the university's freezers, and took them home and buried them with a ceremony.

Similarly, the Nuu-chah-nulth First Nations Tribe in Canada participated in a genetic study on rheumatoid arthritis in the 1980's. Over 800 blood samples were collected by Dr. Ryk Ward, a genetic researcher at the UBC (Dalton 2002). When Dr. Ward later moved to different universities, the samples moved with him. He was unable to identify a genetic basis for arthritis and subsequently shared the samples with collaborators for research on human migration, retroviruses, and drug abuse (Wiwchar 2004). The Tribe never gave approval nor did individuals consent to having their biological samples used in research other than the arthritis study (Wiwchar 2004). Although Dr. Ward published over 100 papers, he did not return or report the results to the Tribe. When the Tribe found out about the subsequent research in 2000, many tribal members were furious and demanded explanations for the unapproved research. After Dr. Ward's sudden death in 2003, UBC officials and researchers partnered to retrieve blood samples from his collaborators and returned them to the Nuu-Chah-Nulth in 2004 (Garrison et al 2019).

Responses by Tribes to increase research oversight

Tribal research review boards have emerged as a key mechanism of data governance because they re-center the locus of control to the Indigenous oversight committees and away from researchers or universities. Additionally, tribal research review boards often enforce tougher requirements than university-based IRBs by expanding the content under review beyond just human subjects, assuring researchers' adherence to cultural protocols, and asserting that resulting data from a study belongs to the tribe and should be returned when the study is over (Sahota 2007). To mitigate future research harms, the Nuu-chah-nulth formed their own Research Ethics Committee in 2003 to review and oversee all future research projects involving within their community (Wiwchar 2004).

As these two cases have shown, biomedical researchers have a long history of disrespecting Indigenous communities, thus inflicting group harms, and spreading distrust of researchers to other Indigenous communities. These examples also demonstrate how university-based IRBs and their ethical regulations are unable to adequately prevent disputes about the collection and use of Indigenous data in research. The resulting tribal research review boards have emerged as a mechanism to exert stronger Indigenous oversight over the research data and results.

While the Havasupai and Nuu-chah-nulth cases brought unethical research in Indigenous communities to the forefront of many disciplines, concerns about lack of engagement, fear of exploitation, and group harm in genetic research are long standing (CITE). The intersection of biomedical research and the protection of Indigenous Peoples is particularly fraught, as evidenced by the magnitude of past transgressions. It is also a space where the exercise of IDSov by tribal nations and respect for IDSov by non-Indigenous researchers and non-tribal entities can make tremendous headway (Garrison et al. 2019a, Hudson forthcoming).

As tribes took note of the research misconduct that took place with Havasupai and Nuu-Chah-Nulth biospecimens, many enacted restrictions or bans over a wide range of research within their nations (National Congress of American Indians Policy Research Center 2006, American Journal of Medical Genetics 2010). Yet, not all research is seen as harmful. Even after the Havasupai settlement, Tilousi stated, "I'm not against scientific research. I just want it to be done right. They used our blood for all these studies, people got degrees and grants, and they never asked our permission" (Harmon 2010). Many Indigenous Peoples are generally

supportive of the idea of research, especially if it can benefit individuals or the community, but want to be in control of how their samples and other types of data are used and re-used (CITE). This is not only a matter of individual informed consent, but also the collective rights of Indigenous nations based in tribal sovereignty and self-determination.

IDSov acknowledges collective, nation-based rights to Indigenous data. As such, tribal cultural norms and protocols must guide the governance of Indigenous data. Integral to this is a focus on cultural rigor. This concept was developed in 2013 to address the tension between scientific rigor and integration of AI/AN cultures and sovereignty in program evaluation (Tribal Evaluation Workgroup 2013). Cultural rigor, a mechanism for enacting IDSov, also applies to research and data in Indigenous communities. The concept of cultural rigor demands tribal oversight that provides meaningful input, governance, and control over Indigenous data. Before a research study begins with a tribe or including tribal identifiers, the tribe must define if and how biospecimens or resulting digital data should be stored for future use, or returned or destroyed at the end of the study. Additionally, researchers should also ask individual participants the same questions (given the parameters set by the tribe).

Federal government research oversight in the age of IDSov

Garrison et al. (2019a) compiled research policies for US, Canada, New Zealand, and Australia and assessed the following with respect to genomics research with Indigenous Peoples: Community Engagement, Rights and Interests, Institutional Responsibilities, Ethical/Regulatory Oversight. The analysis included the NIH Genomic Data Sharing policy and the Federal Policy for the Protection of Human Subjects, also known as the 'Common Rule' (Office of Human Research Protections 2017, National Institutes of Health 2014). The US policies only addressed 8/18 topics coded, while Canada addressed 17/18 and Aotearoa New Zealand and Australia addressed 15/18. While addressing each of the broad topic areas, the US failed to stipulate expectations around community engagement in protocol development before collection of samples; did not address issues of Indigenous rights and interests including community approvals for secondary use, cultural review, nor commercial applications; and lacked delineation of institutional responsibilities for ongoing research updates to communities, community review of study findings before release, and the need to develop Indigenous guidelines for the research.

The shortfalls of the US policies both present challenges for Indigenous Peoples and biomedical futures, as well as opportunities for Indigenous innovation to change how research happens for equity and to the benefit of Indigenous Peoples.

Indigenous Peoples and Biomedical Futures

IDSov requires heightened consideration in projects that evoke a government-to-government relationship, such as federally funded projects that seek to recruit large numbers of Indigenous Peoples nationwide. In these cases, strong relationships and effective data governance systems at the tribal level are paramount for ensuring equitable participation in federally funded research and culturally rigorous results. Yet at the same time non-tribal institutional policies and practices must also evolve to promote and protect the sovereign rights and interests of Indigenous Peoples.

Management of Large Biobanks

In 2016, the National Institutes of Health launched *All of Us*, a precision medicine research program that aims to recruit individuals across the US, with a particular effort targeted at AI/AN Peoples through the Banner Health system and the University of Arizona. Discussions are

underway to make the cohort representative, with special emphasis on over-sampling AI/AN populations as they have been historically underrepresented in biomedical research (2017). Analysis of representation in genome wide association studies shows that Indigenous Peoples make up only 0.02% (2019) to 0.06% (2009) of published studies worldwide (Popejoy and Fullerton 2016, CITE). Pervasive distrust continues to negatively influence the participation of AI/AN people in research, especially biomedical research. A critical success factor for increased participation of Indigenous Peoples toward equitable health outcomes in biomedical research is building relationships with AI/AN tribes and communities, both urban and rural (Hudson et al. forthcoming, Garrison et al. 2019a, Claw et al.)

The *All of Us* program's ambitious recruitment plan targets the inclusion of AI/AN individuals through methods like oversampling. Oversampling may help to achieve a more representative sample. However, it cannot replace the importance of developing tribal partnerships and community engagement. Moreover, the complexity of Indigenous identity, the colonial legacy of displacement, and the continued reality of urban relocation must be considered (Lucero 2010, Straus and Valentino 1998). AI/AN populations are not simply ethnic or racial groups, nor are they vulnerable or 'special' populations. AI/AN peoples maintain a unique political status; AI/AN peoples are citizens of tribal nations regardless of whether they reside on tribal lands or in urban settings. This political designation is the foundation for IDSoV; yet, the inclusion of AI/AN peoples in urban areas challenges the reach of tribal oversight of research over enrolled tribal members.

Approximately 78% of self-identified American Indian and Alaska Native individuals live off tribal lands, and approximately 60% primarily reside in urban areas (CITE YEAR). Thus for Indigenous people that live off tribal lands, questions arise such as how tribes will govern information about them when the data reside outside the jurisdictional boundaries of the tribal nation, and how other institutions, such as intertribal non-profit organizations in metropolitan areas and universities, will steward and protect data about Indigenous Peoples. To this end, there are more questions than answers. How does one reconcile individual rights with those of AI/AN tribes? How can tribes maintain oversight or extend protections to their tribal members who live off reservations (i.e. in urban settings)? What happens when a tribe opposes the program (or has a moratorium on certain types of research), but individual members of the tribe want to participate? Will participation in these large studies allow the benefits reach all the way to the historically disadvantaged and be truly equitable?

Additionally, when aggregated Indigenous data are collected, presented, or shared (e.g., AI/AN *not* tribal identifiers) ethics review and data oversight procedures become complex. The twin histories of negative research experiences and negative data experiences raise concerns with respect to the deficit narrative that emerges from aggregate data (Walter 2018). Who has oversight for aggregate Indigenous data? Can university, IHS, and other institutional review boards be trusted to protect Indigenous Peoples in the aggregate? This is dubious given the findings of Garrison et al. (2019) that show, compared to recommendations in Aotearoa New Zealand, Australia, and Canada, the US Final NIH Genomic Data Sharing Policy (2014) and the Federal Policy for the Protection of Human Subjects (2017) lack community engagement and control requirements.

The *All of Us* program raises questions to which there are no clear answers. The recognition of IDSoV by NIH is an important first step. An additional step is the development of culturally rigorous Indigenous data governance principles and mechanisms at the tribal level for use by non-tribal entities. Tribal partnerships and community engagement support the relationships necessary for creating mechanisms, policies, and procedures that respect IDSoV, adhere to

tribal principles for the governance of Indigenous data, and are culturally, ethically, and scientifically rigorous. Relationships take time to build and sustain, and developing them can sometimes delay research timelines. However, relationships remain a critical component of robust research with Indigenous peoples and tribes.

Data Sharing and Tribal Sovereignty

The NIH Genomic Data Sharing policy requires federally-funded investigators to deposit de-identified data into federal databases to promote secondary analyses (National Institutes of Health 2014). However, the current policy allows a data sharing exception that recognizes some tribal laws may not permit broad data sharing. Some tribal laws and policies dictate that all data generated from a research study is property of the tribe and, when a study ends, all data must be returned to the tribe. A resulting concern about the data sharing policy is that the allowable exceptions are not clearly understood or recognized by all researchers, institutions, or journal editors. For example, some investigators who have collaborated with Indigenous communities to carry out research have been asked by journal editors to submit their data to the federal databases, even when the agreement with the tribe is to not share data.

Tribal concerns about data use and data sharing have generated many discussions in federal agencies, universities, professional societies, and Indigenous communities. These discussions have also spurred questions about sharing samples with other researchers and institutions, which is a practice that has become more common due to the time-consuming and expensive nature of sample collection. These arrangements have purported to accelerate scientific discovery. But, at what cost?

In 2012, collaborators of a university-tribal partnership met to discuss data sharing concerns of the tribal partners in order to explore pathways to building long-lasting, trusting relationships to promote ethical and engaged research (James et al. 2014). Key themes that emerged from this discussion include the importance of recognizing tribes as sovereign nations that may have their own research oversight boards; acknowledging that many tribes view knowledge and intellectual property as belonging to the collective group rather than an individual, in contrast to a western framework of individualism; and that scientific practices such as data sharing may not be in a tribe's best interest. Further, tribal governments have a distinct legal status with the federal government that requires specific recognition for tribal rights; data-sharing policies may thus fall under a tribe's protection. Additional discussions in the workshop brought attention to the concerns, such as stigmatization or discrimination, that some communities may have regarding how their data are used for broad research purposes.

In a set of interviews of tribal health professionals, policy experts, and tribal, respondents shared range of views about whether tribes should share research data and if so, what data sharing should look like (Garrison et al. 2019b). Some believe data should be shared openly, whereas others believe it should be restricted. Many believed that tribes should have oversight over the data, but recognize their capacity limitations. The interviews participants identified a need for richer and continued discussion of data access, management, and sharing. This is increasingly important as biomedical and genomics research moves toward broad data sharing policies.

In genomics, much of the data that are derived from DNA samples are deposited into the online Database of Genotypes and Phenotypes (dbGaP). Researchers who receive federal funding are required to submit a data sharing plan stating when and how their study data will be deposited into dbGaP. Data submitted to the database must be stripped of all personal identifiers such as names, addresses, zip codes, birthdates, and social security numbers. Researchers who wish

to use the individual-level genotype data in dbGaP must submit a request to the NIH Data Access Committee (DAC) with a description of how they will use the data, which members of their research team will have access, and how they will ensure that the data are used and managed properly. Additionally, the DAC oversees on-going uses of data in order to ensure appropriate use and to reduce risks to the individuals from whom the data were derived. However, membership to the DAC is limited to federal employees and does not allow for tribal members to participate in influencing how data in dbGaP are used that come from tribal citizens. Thus, some tribal representatives feel that federal employees should not be the only oversight authorities that determine how data in dbGaP are used if the databases include data derived from their tribes.

Changes to the Common Rule

The Federal Policy for the Protection of Human Subjects, also known as the 'Common Rule,' issued a final and updated rule in early 2017 that encourages broad data sharing of biological materials (Office of Human Research Protections 2017). Recent efforts to systematize how samples are used for genetic studies include the earlier proposed changes to the Common Rule to require at least broad consent for secondary research with existing specimens (Office of Human Research Protections 2015) and the Genomic Data Sharing (GDS) Policy that requires consent for broad uses of genomic data (National Institutes of Health 2014). These efforts offer many opportunities to explore the concerns of Indigenous research participants and researchers who work in these communities, to further contextualize the issues, and explore ways to maximize tangible benefits. Of note, the GDS Policy allows a data sharing exception for "compelling scientific reasons" (National Institutes of Health 2014). One of these reasons may be that some tribal laws may not permit broad data sharing. It is important to note that many now assert that if a tribe does not have a law, that the tribe still must be allowed to decide whether or not to share data (among other issues) (TCWG 2018, NCAI 2019).

As noted above, broad consent has the benefit of allowing researchers to conduct a wide range of studies without having to return to participants for new consent for each new project. Importantly, however, the sort of broad consent that has been proposed in these policies would fail to resolve the concerns raised by the Havasupai case, precisely because it does not demand explicit consent for specific future research. In other words, per the policy of broad consent, researchers can conduct secondary research that unintentionally inflicts harm on Indigenous communities, unless particular uses are explicitly prohibited. One group has reported that many people appreciate being asked for new consent (Ludman et al. 2010). While the practicality of seeking new consent is arguable, given the difficulties in recontacting the sources of the samples in the future and the need to retain identifiers if such recontact is desired, specific consent to use existing samples for new studies can be a more cost-effective and less time-consuming option than initiating an entirely new study and sample collection. Moreover, seeking specific consent may be particularly important to preserving the trust of certain populations. It is also clearly preferred to litigation and repairing trust in the scientific community following transgressions. Notably, even if the regulations do not require specific consent, tribes, on the basis of their sovereign powers, could demand specific consent as a condition of engagement in research (National Congress of American Indians 2012, James et al. 2008).

Indigenous Peoples' Increased Oversight of Biomedical Research

The current structures that are in place for federal biomedical data governance, in particular the Common Rule and the DAC, fail to align with the rights and interests of Indigenous nations and communities. Rather than demanding that representatives of Indigenous communities

participate in these existing structures of governance, we argue for sovereign control—that is, Indigenous nations controlling ownership, governing and/or maintaining storage, and dictating parameters for data use and reuse. We also promote policy innovations for other institutions that both adhere to tribal sovereignty and protect Indigenous Peoples living off tribal lands or included in research at aggregation (i.e., the identify is “AI/AN”, Indigenous, etc., not tribal affiliation).

This section introduces innovations in IDsov and governance, tribal efforts, and other institutions’ strategies that support Indigenous efforts to reclaim control and oversight of data, including physical specimens collected from Indigenous peoples’ bodies.

Indigenous Data Sovereignty and Governance

IDsov finds its roots in OCAP®—ownership, control, access, and possession—now a registered trademark of the First Nations Information Governance Centre (FNIGC.ca). Developed in 1998 as the data governance mechanisms for the First Nations Regional Longitudinal Health Survey in Canada, OCAP® outlines information governance principles as standards for conducting research with First Nations communities (FNIGC 2014). As OCAP® gained traction in Canada and as Indigenous Peoples became increasingly self-determining, a movement enacting IDsov across the globe arose (Carroll et al. forthcoming). Since 2015, there has been increasing interest in decolonizing Indigenous data and developing methods of Indigenous data governance via the IDsov framework (Kukutai & Taylor 2016, Carroll et al. 2019, Lovett et al 2019).

As a mechanism to exert stronger oversight over Indigenous data, the United States Indigenous Data Sovereignty Network (USIDSN) formed in April 2016 to “ensure that data for and about Indigenous nations and peoples in the US (American Indians, Alaska Natives, and Native Hawaiians) are utilized to advance Indigenous aspirations for collective and individual wellbeing” (Rodriguez-Lonebear and Rainie 2016). The Network’s founders recognized the need to create a transdisciplinary community of practice to share research information and policy advocacy that safeguard the rights and promote the interests of Indigenous nations and peoples in relation to their data. While the USIDSN Advisory Council and network members individually pursue data projects, policy, and advocacy, the USIDSN hosts gatherings for educational purposes and to discuss and develop policy and recommendations. Towards this end, the Network has established a web site, listserv, and collaborative presentations and research projects.

The USIDSN is modeled after and collaborates with the Aotearoa New Zealand-based *Te Mana Raraunga* (temanararaunga.maori.nz), the Maori Data Sovereignty Network, which was formed in 2015 (Te Mana Raraunga 2015). *Te Mana Raraunga* argues that data that are collected about Indigenous people should be subjected to the laws of the nation from which they are collected, including tribal nations. For example, as biobanks continue to grow, Maori stakeholders have begun to express ethical concerns and developed a model that incorporates Maori values, protocols, and practices into a framework for biobanking governance (Beaton et al. 2017, Hudson et al. 2016). Other IDsov networks include the *Maiamnyri Wingara* Aboriginal and Torres Strait Islander Data Sovereignty Collective in Australia formed in 2017 (<https://www.maiamnyriwingara.org/about-us/>), and nascent networks for Pacifica, in Canada, for the Sami, in Latin America, and in Southeast Asia.

In 2017, the three IDsov networks formed the International Indigenous Data Sovereignty Interest Group at the Research Data Alliance (RDA) to focus on “more robust and coherent international collaboration to achieve impactful outcomes at the intersection of IDsov,

Indigenous data governance, and research” (RDA 2017). This group served as a catalyst for enriching global connections and for developing internationally applicable mechanism for Indigenous data governance within research environments. In 2019, the group released the ‘CARE Principles for Indigenous Data Governance’ (RDA IG 2019) and the national-state based IDSoV networks in partnership with other IDSoV allies launched GIDA, the Global Indigenous Data Alliance.

GIDA has direct impact through international Indigenous data governance policy development and integration at national and global levels. With challenges being particularly pervasive in health and genomics, especially in relation to the offenses by researchers at ASU and UBC, transformations in institutions, IRB boards, researcher and data storage policies, must be addressed through systematic Indigenous-led change (Garrison 2013, Garrison et al. 2019a). GIDA endeavors to create transformational change in data practices to enhance Indigenous Peoples’ control of their data.

The CARE Principles define the relationship of Collective benefit, Authority to control, Responsibility, and Ethics, to engagement with and secondary use of Indigenous data (RDA IG 2019). The CARE Principles enhance and extend the ‘FAIR Principles’ for data findability and reuse, Findable, Accessible, Interoperable, Reusable (Wilkinson et al. 2016) by centering equity and ethics as core guiding principles alongside those set out by FAIR. The CARE Principles reflect the crucial role of data in advancing Indigenous innovation and self-determination by focusing on people and purpose-oriented standards to be used with mainstream data guidelines.

The CARE Principles are in the early stages of implementation, with some entities leading the way by collaborating with GIDA to detail operationalization pathways and mechanisms, including the Open Data Charter, the RDA, the Smithsonian Institution (Carroll et al. forthcoming). Adopting the Principles within data policies and practices begins to shift the underlying values, however, implementation also demands tools for operationalizing IDSoV with data ecosystems and collections. Such mechanisms include metadata tagging for provenance, transparency, the assertion of rights, and the protection of knowledge; transforming institutional policies and practices, such as ethics review and data governance; and trainings on the CARE Principles and metadata tagging initiatives.

Institutional Responsibilities

Universities, for and non profits, and other institutions also must institute policies and procedures for engaging with Indigenous data that they generate, steward, and use. Today in the US, these policies are rare. However, development policies is occurring across a broad range of entities, with some protections already put in place at urban Native serving organizations and universities.

For example, to protect tribal data and Indigenous Peoples in metropolitan areas, the Urban Indian Health Institute (UIHI; [add website](#)) developed a research and data governance structure for use by 32 Urban Indian Health Programs (UIHP) serving urban Indians in 19 US States and 100 counties. UIHPs’ research and governance structures allow for a systematic approach to engaging in research by establishing formal partnerships via Memorandums of Understanding, implementing a research application process that ensures the project meets clinic priorities,

dictating collaboration on methodologies, mandating community/clinic interpretation of the data, limiting secondary data analysis, and ensuring community authorship and dissemination.

Tribal Research Governance

Increasingly over the past 50 years, some tribes in the US have developed policies and procedures for the oversight of research within their nations. In addition, some tribes rely on tribal colleges, tribally based or focused organizations, or the IHS to provide research oversight on their behalf (Arouns Him et al. 2019). We draw on tribal nations’ laws and policies regulating research (Table 1) to illustrate how these official documents assertions of IDsov may influence or even conflict with *genomics research* using the *All of Us* Program for discussion throughout.

Table 1. Tribal Laws and Policies Regulating Research for this discussion

Research Code of the Mandan, Hidatsa, and Arikara Nation
Pascua Yaqui Research Protection Code
Chickasaw Nation
Colorado River Indian Tribes
Navajo Nation
Cherokee Nation
Sisseton Wahpeton Oyate
United Houma Nation
White Earth Nation
Ho-Chunk Nation’s Tribal Research Code
Akwesasne Community
Confederated Tribes of Siletz
Confederated Tribes of Coos, Lower Umpqua and Siuslaw Indian
Turtle Mountain Band of Chippewa Indians

As noted above, tribal sovereignty is the inherent authority of tribes to self-govern on matters related to their citizens, territories, and common affairs. Some tribal research codes are explicit in describing the nature of tribal sovereignty. For example, the Research Code of the Mandan, Hidatsa, and Arikara Nation recognizes the Tribe’s “prior, proprietary rights and interests over all air, land, and waterways, and the natural resources within their territories that they have traditionally inhabited or used, together with all knowledge and intellectual property and traditional resource rights associated with such resources and their use” (CITE YEAR). More closely connecting sovereignty to research oversight, the Pascua Yaqui Research Protection

Code outlines the Tribal council's duty to "protect the people, culture and natural resources of the Tribe and the Tribe's future generations from unauthorized research" (CITE YEAR).

These rights and duties of tribal governments to administer their territories, manage their resources, maintain their cultures, and protect their citizens furnish a policy framework for ensuring responsible research within tribal communities and beyond. With respect to research on tribal lands, a growing number of tribes have set up mechanisms and procedures to review and approve proposals (Around Him et al. 2019). For example, the Chickasaw Nation, Colorado River Indian Tribes, Navajo Nation, and the Cherokee Nation operate specialized Institutional Review Boards (IRBs) or research review boards. In contrast, the Nez Perce Tribe has a review process managed by the Tribe's Executive Committee as one among other administrative duties (NP Code YEAR). Though showing some differences in methods of review, the tribes listed require formal approval before any research activities begin, such approval most often signified by an official permit. These approval procedures are typically distinct from any other review procedures undergone by researchers at sponsoring institutions, as noted, for example, in regulations adopted by the Chickasaw and Navajo Nations as well as by the Colorado River Indian Tribes.

The 2018 *All of Us* Research Program Advisory Panel Tribal Collaboration Working Group report, *Considerations for Meaningful Collaboration with Tribal Populations* (TCWG Report) recognized the exercise of tribal sovereignty through separate tribal research review processes. The report points to the inadequacy of the AoU IRB to ensure full review of tribal research given its narrow reliance on human subject protections as codified in the federal Common Rule (TCWG 2018). Accordingly, the report calls for the AoU Research Program to "also obtain approval from a tribal and/or [Indian Health Service] IRB, as applicable," emphasizing further that tribal IRBs, where they exist, have precedence over Indian Health Service IRBs (TCWG 2018, 16). In late 2019, the National Congress of American Indians (NCAI 2019) asserted that even in the absence of formal tribal approval processes, researchers must establish a process to obtain approval that allows for tribal oversight of tribal data. Furthermore, the NCAI membership passed a "resolution ABQ-19-061 that calls on NIH to consult with tribal nations, provide a process for tribal nations to have oversight over any data and biospecimens from their tribal citizens, and restrict use of data associated with tribal nations until tribal oversight is in place," (NCAI 2019).

Research beyond Tribal territory. The fact that most tribal citizens reside, and may participate in research, off tribal lands (CITE YEAR) raises unique challenges to Tribes' exercises of sovereignty for ensuring responsible research. The tribes have sought to address this governance challenge by extending the application of their research codes beyond tribal lands in two situations: (1) use of materials to which Tribes have a legal claim and (2) participation of Tribal citizens.

Some tribes include language describing conditions under which their codes might apply outside tribal territory. Hence, on the one hand, the Colorado River Indian Tribes explicitly restrict the application of their code to "human research which will occur within [their] territorial jurisdiction" (CITE YEAR). On the other hand, the Gila River Indian Community requires compliance with its research ordinance if the tribe has "a legal or equitable claim of intellectual, cultural or other ownership or a claim of control" to materials used in research, wherever the materials are located (CITE YEAR). The Sisseton Wahpeton Oyate, United Houma Nation, and White Earth Nation use similar language (CITE YEAR). Acknowledging the complexities of overlapping sovereignties with local, state, and federal governments

outside tribal lands, the Gila River ordinance (like several others surveyed) qualifies claims of tribal ownership and control by including the phrase, “to the extent applicable law permits” (CITE YEAR). As noted earlier, sorting out the complex legal effects of overlapping sovereignties is a challenge for research governance and the TCWG (2018) Report specifies this area as a potential topic for further formal consultation. In summary, some tribes extend the protection of their citizens and interests beyond their territories by linking the exercise of their sovereignty to the physical location of research materials to which they have a claim.

Another way tribes address research governance challenges beyond their territories is to link the exercise of sovereignty to participation of their citizens in research, particularly in studies that implicate aspects of their tribal membership in some way. For example, whereas the Ho-Chunk Nation’s Tribal Research Code does not cover citizens “who participate in research off the Nation’s lands outside the parameters of [the] Code”, the Navajo Nation authorizes its IRB to review “human research which will occur within [its] territorial jurisdiction ... *or which otherwise concerns Navajo individuals as an identifiable group*” (emphasis added) (CITE YEAR). The Confederated Tribes of Siletz likewise require a permit for “any type of project on Tribal lands *or directly affecting the Tribe, Tribal lands, or Tribal members*” (emphasis added). Similarly, the Pascua Yaqui Tribe’s code regulates research activity “on the Reservation *or with [T]ribal members*” (emphasis added) (CITE YEAR).

The TCWG (2018) Report acknowledges the complexity of governing research involving tribal citizens living in urban areas and other locations outside tribal territory. The report records varying positions voiced by tribal leaders and other Working Group members on the relationship between the rights of individual tribal citizens and those of the tribe. Options ranged from binary positions privileging either individual or tribal rights to intermediate positions that allowed enrollment without disclosure of tribal affiliation or enrollment as American Indian/Alaska Native without stating specific tribal citizenship (TCWG 2018). Though acknowledging the knotty issues involved in engaging tribal citizens based off tribal lands, the TCWG (2018) Report emphasizes that the physical separation of tribal citizens from tribal territories is not to be viewed as an opportunity “to circumvent tribal oversight” (TCWG 2018, 16). This cautionary note is consistent with evidence from tribal research codes showing a clear intent on the part of tribes to protect their communities and citizens from potentially harmful research.

Tribal Rights in Specimens and Data. A key element of the *All of Us* Research Program is the collection of biological specimens and health data to study the genetic, environmental, and lifestyle factors crucial to understanding precision medicine. For a long time, but perhaps most visibly with the case of the Havasupai in Arizona, tribes have been taking steps to address the misuse of their specimens and data in research. The research codes and policies surveyed show that strategies for protecting collective tribal interests and individual citizenship rights in specimens and data fall into three broad categories: (a) ownership claims, (b) control through biobanking and data-sharing agreements, and (c) review of publications. There have also been (d) recent developments in specimen and data governance.

Some tribal claims of ownership over specimens and data are made in the context of broader statements about tribal sovereignty. For example, the Mandan, Hidatsa, and Arikara Nation Research Code includes a general principle of prior rights that recognizes, among other rights, “proprietary rights and interests over... all knowledge and intellectual property” associated with their resources (CITE YEAR). Similarly, the United Houma IRB Ordinance codifies the rights of the Tribe, “as a self-governed and self-determined people,” to “all data and information

generated and produced by ... research” conducted in the community (CITE YEAR). Other codes couch the tribe’s claim to ownership of specimens and data in narrower terms (e.g., Pascua Yaqui Tribe, Confederated Tribes of Siletz, Sisseton Wahpeton Oyate), while others stress the need for researchers to respect those claims (e.g., Akwesasne community, Cherokee Nation) (CITE YEAR).

Some codes protect not only Tribal (i.e., collective) but also individual citizens’ claims to ownership of specimens and data. For example, the Tohono O’odham Nation’s Research Code protects both Tribal and individual ownership and control of specimens in research (CITE YEAR). The Colorado River Indian Tribes’ Human and Cultural Research Code protects an individual citizen’s “right to ... information and intellectual property that is provided to Researcher[s]” (CITE YEAR). Of note in the preceding excerpt is the adoption of intellectual property concepts in Tribal codes to support individual and collective claims of ownership in specimens and data (other examples include regulations from the Akwesasne community, Ho-Chunk Nation, Navajo Nation, and Turtle Mountain Band of Chippewa Indians) (CITE YEAR).

The majority of the tribal research codes presented here require applicants to sign agreements as a condition for being issued a research permit. Such agreements are useful for maintaining a measure of control over specimens and data outside tribal territory. For example, the Gila River Medical and Health Care Research Ordinance states that researchers, their sponsors, or their funders may be required to sign an agreement to allow enforcement of Tribal rights and interests in specimens or data outside Tribal lands (CITE YEAR). The Mandan, Hidatsa, and Arikara Nation Research Code preserves Tribal jurisdiction over specimens stored outside the community’s boundaries (CITE YEAR).

However, Tribes can take a more active role in protecting their specimens and data outside their territories. A case in point is the Akwesasne community, which reserves the right to have researchers store specimens at a repository of its choosing (CITE YEAR).

Other issues covered by research agreements with regard to specimens include whether and how collected specimens will be disposed of after the research project; whether other uses are being considered for collected specimens; and who will have access to the collected specimens. On the question of access to collected specimens, the Mandan, Hidatsa, and Arikara Nation, Tohono O’odham Nation, and Turtle Mountain Band of Chippewa Indians require separate agreements with any third parties with whom the researcher plans to share collected specimens (CITE YEAR).

Issues in research agreements pertaining to data reflect broadly tribal concerns about specimens. Additional points include the need to describe specific means of preserving confidentiality of individual and tribal data, including Assurances of Confidentiality (e.g., Akwesasne community, Gila River Indian Community, Ho-Chunk Nation); the need to provide data disposal plans (e.g., Cherokee Nation); and the need to describe conditions that would allow researchers to breach their duty of confidentiality under signed agreements (e.g., Akwesasne community; Ho-Chunk Nation) (CITE YEAR).

Based on a history of exploitative research with tribal communities, the ability of tribes to review inaccurate, harmful, or stigmatizing information before publication or dissemination is crucial both to preventing the misuse of their data and to supporting sound scientific practice (Garrison et al. 2019a). Most research codes presented here show that this right to pre-publication review is a condition for application approval and is often part of the research

agreement signed by successful applicants. Researchers who fail to comply risk losing IRB approval and may face other sanctions. The avenues of publication and dissemination covered under pre-publication review include manuscripts for scholarly articles, theses, and dissertations as well as abstracts or content intended for conferences and other presentations.

Criteria for review vary among the tribes presented here typically include a mix of form and content. For example, the Chickasaw Nation's review body assesses manuscripts for "technical content and validity, organization of content, general readability, adherence to established policy, and assurance that the publication is high quality", but also checks whether "publications represent the Chickasaw Nation without unfair stigma or harm to the [Nation's] overall community, culture, or heritage" (CITE YEAR). Similarly, the Colorado River Indian Tribes' review board ensures that material considered "sacred" or "inaccurate" is removed or addressed, in addition to content judged to be "in violation of CRIT's intellectual property rights" (CITE YEAR). The Confederated Tribes of Coos, Lower Umpqua and Siuslaw Indians take their review a step further, reserving the right to require inclusion of the Tribes' official responses in materials approved for publication (CITE YEAR).

Echoing the necessity and intent of the preceding code provisions, the TCWG Report recognizes the need for "greater input and oversight by tribal communities on data and biospecimens policies, beyond those for other groups" (TCWF 2018, 8). The report marks out regulations on data access as well as on secondary uses of specimens and data as warranting particular compliance. However, it is critical to note that challenges for remain even once tribes assert oversight. For example, the Navajo Nation Human Research Review Board (NNHRRB) has a 12-step process for granting Institutional Review Board approval for research; a required element includes rigorous engagement of the community partners. At the conclusion of a study, the NNHRRB requires that all investigators turn all resulting data over to the Navajo Nation. After years of having data returned and stored, questions have emerged about what to do with all of it. In June 2016, the Diné Policy Institute and the Navajo Studies Conference, Inc. hosted the "*Siihasin* Summit: Reflecting on Research and Data Management in the Navajo Nation" with the goal of identifying what data are available about Navajo citizens, where the data are held, and how to more effectively manage the data (Diné Policy Institute 2016). While the Navajo Nation owns extensive research data, a data governance challenge they are grappling with is developing processes that enable new analyses with existing data.

[Trially-controlled Biobanks – potential section]

Discussion and Recommendations

Employing data governance principles and mechanisms that support IDSov is forward thinking. Aligning research practices and priorities with ever-evolving ethics and rights based frameworks provides a solid foundation for the work and findings to stand the test of time. Tribal code provisions, TCWG Report observations, and the CARE Principles demonstrate a need not only to recognize tribal rights and interests in their data but also to respect tribal authority to control such data. Existing and emerging tribal data governance and policy frameworks are informing the expectations of other governing bodies and institutions regarding implementation of data identifiers in resources such as biological specimens and health data (RDA IG 2019, Carroll et al. forthcoming). Those working with tribal data are responsible for ensuring that the creation, interpretation, and use of those data uphold and remain respectful of tribal Nations' sovereignty,

rights, and interests. To uphold these rights in potential future uses and to minimize future harm while maximizing future benefits, metadata should acknowledge purposes, limitations, or obligations regarding secondary use, including issues of consent and prior engagement.

Throughout our discussion, we have noted, on the one hand, the principle of inherent tribal sovereignty and the inter-sovereign relationship between the US and tribes. Together, these legal notions frame tribal engagement with biomedical research. On the other hand, we have pointed out the limits of tribal laws and policies to oversee research with tribal citizens residing outside of tribal territory. These limits are defined by the nature of overlapping jurisdictions that can result in governments (local, state, federal) adopting varying standards for responsible research (e.g., the federal Common Rule, as noted in the TCWG Report earlier).

In addition to jurisdictional differences, the inevitably gradual process of passing and harmonizing laws means that the emerging legal norms and best practices we have observed across tribal research codes may be slow in finding legal expression outside tribal territories. This reality counsel a broader approach to policy and procedure regarding tribal participation in biomedical research. In other words, ethics requirements for research under federal law need to be complemented by evolving ethics requirements in tribal communities, whether or not such norms have been codified as law. There is an evolving body of scholarly literature¹ analyzing legal and non-legal norms from tribal communities that has become a rich resource for informing research policy and processes affecting Tribes.

Recommendations. As discussed above and in the TCWG (2018) Report, normative differences and jurisdictional overlaps can be difficult to navigate, especially in as large and complex an undertaking as the *AoU* Research Program. This challenge makes the federal consultation requirement all the more crucial because consultation provides a structured opportunity to align expectations between federal and tribal governments regarding the goals, costs, risks, and benefits of biomedical research.

1) *Tribal Law and Policy*: Research institutions, researchers, and funding agencies follow appropriate federal, state, and local laws. Likewise, these institutions must follow proper engagement and consultation procedures with tribal nations to uphold tribal laws pertaining to research, data, and specimens. These laws and processes need to be part of robust planning and policy for research institutions and programs. Additionally, as asserted in the TCWG (2018) Report and by NCAI and its members (NCAI 2019), when no laws exist, it is the responsibility of research institutions, researchers, and funding agencies to engage in a process with participating tribal nations to obtain approvals.

2) *International, Federal, and Institutional Guidelines*: Many governments and institutions now have requirements for free prior and informed consent through full

¹ For example, Sharp, R. R., & Foster, M. W. (2002). An analysis of research guidelines on the collection and use of human biological materials from American Indian and Alaskan Native communities. *Jurimetrics*, 165-186; Bardill, J. (2017). Comparing tribal research and specimens policies: models, practices, and principles. *The International Indigenous Policy Journal*, 8(4), 4; Claw, K. G., Anderson, M. Z., Begay, R. L., Tsosie, K. S., Fox, K., & Nanibaa'A, G. (2018). A framework for enhancing ethical genomic research with Indigenous communities. *Nature communications*, 9(1), 2957; Him, D. A., Aguilar, T. A., Frederick, A., Larsen, H., Seiber, M., & Angal, J. (2019). Tribal IRBs: A framework for understanding research oversight in American Indian and Alaska Native communities. *American Indian and Alaska Native Mental Health Research*, 26(2), 71-95; and Garrison, N. A., Hudson, M., Ballantyne, L. L., Garba, I., Martinez, A., Taulii, M. Arbour, L., Caron, N. R., & Rainie, S. C. (2019). Genomic research through an indigenous lens: understanding the expectations. *Annual review of genomics and human genetics*, 20, 495-517; Carroll et al. forthcoming; Hudson et al. forthcoming.

engagement and tribal consultation. The United Nations Declaration on the Rights of Indigenous Peoples, the US Department of Health and Human Services (HHS), other US federal agencies, and some universities (e.g., the University of Arizona) require consultation with tribes. These federal and international laws and policies around informed consent necessitate the engagement of tribal laws and research review processes as collective consent to participate in research programs, regardless of existing or delineated processes at the tribes.

3) *Evolving Ethical Practices*: The development of tribal research codes and Indigenous ethical guidelines provides direction on the expectations of community involvement in research and ethical review processes. It behooves the researchers, the NIH, and other research institutions to engage with existing and evolving tribal laws and policies as well as other relevant Indigenous guidelines, through inclusion of such principles in research practice. For example, in New Zealand, the principles within Te Ara Tika Guidelines for Maori Research Ethics are being integrated into the National Standards for Health and Disability Ethics alongside Western bioethical principles (CITE YEAR). In the US, federal and institutional guidelines must adopt and embed tribal expectations for free, prior, and informed consent, consultation, and embed broad standards, such as the CARE Principles for Indigenous Data Governance, within their own policies and procedures.

Conclusion

After two centuries of broken treaties and medical neglect, tribal nations and Indigenous Peoples are reclaiming their cultural value of conducting research, gathering information, and analyzing data. In exercising their right to IDSov in biomedical research, they are recognizing that biological samples not only carry sacred spirit and meaning, but also contain valuable information about them that should be honored and protected through rigorous tribal oversight. Formalized structures, networks, and communities of expertise, such as USIDSN, tribal research review boards, and other mechanisms are emerging and expanding to protect data that are valued or viewed as sacred by Indigenous Peoples. In modern times, tribes and others use culturally rigorous methods supplemented by western science. A central belief of Indigenous Peoples is making a better world for the next generations, a promise that precision medicine heralds. However, as evidenced by past unethical research practices, precision medicine efforts need to move cautiously forward. Researchers, tribes, and Indigenous communities must invest in activities that enhance trust and build mutually beneficial relationships to ensure high quality translational biomedical science that emerges as tangible benefits for tribes and rural and urban Indigenous communities.

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