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# ACCESS AND MANAGEMENT: INDIGENOUS PERSPECTIVES ON GENOMIC DATA SHARING

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As genomic researchers are encouraged to engage in broad genomic data sharing, American Indian/Alaska Native/Native Hawaiian (AI/AN/NH) leaders have raised questions about ownership of data and biospecimens and concerns over emerging challenges and potential threats to tribal sovereignty. Using a community-engaged research approach, we conducted 42 semi-structured interviews with tribal leaders, clinicians, researchers, policy makers, and tribal research review board members about their perspectives on ethical issues related to genetics in AI/AN/NH communities. We report findings related to perspectives on genetic research, data sharing, and envisioning stronger oversight and management of data. In particular, participants voiced concerns about different models of data sharing, infrastructure and logistics for housing data, and who should have authority to grant access to data. The results will ultimately guide policy-making and the creation of guidelines and new strategies for tribes to drive the research agenda and promote ethically and culturally appropriate research. *Ethn Dis.*2019;29(Suppl 3):659-668; doi:10.18865/ed.29.S3.659

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## INTRODUCTION

Sharing biospecimen samples and data within the scientific community has become a common practice to reduce the time and expense associated with sample collection and to advance scientific discovery. Despite the advantages offered by broad genomic data sharing among researchers, some research participants have expressed concerns with granting broad consent for a wide range of secondary data uses.[1,2] In particular, Indigenous peoples have been reluctant to allow sharing and secondary data uses because of past research misconduct, including inadequate informed consent procedures, uses unauthorized by tribal organizations, and stigmatizing interpretations of data.[3-7] Indigenous communities and scholars have articulated that Indigenous data comprise knowledge, information, and data (including biospecimen samples) about peoples, lands, resources, and cultures at both the individual and collective levels.[8,9] These issues pose conflict with federal policies for sharing genomic data.

The NIH Genomic Data Sharing (GDS) Policy set forth expectations for researchers to obtain broad, rather than study-specific, consent from participants for future research utilizing their biological materials.[10] Federally funded researchers who collect genomic data are required to submit a data sharing plan describing a timeline and process for depositing data into a repository, such the Database of Genotypes and Phenotypes (dbGaP).[11] Prior to submission, data are de-identified, removing personal identifiers including names, addresses, zip codes, birthdates, and social security numbers. Requests to access individual-level genotype data in dbGaP go through the NIH Data Access Committee (DAC) with a description of how researchers will use the data, who will have access, and how they

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will ensure proper data usage and management.[11] Composed of federal employees, the DAC oversees ongoing data usage to ensure that data uses are consistent with the original consent forms and reduce privacy risks to participants. Tribes have raised concerns about the lack of tribal representation on the DAC.

As sovereign nations, tribes have the power to govern, define citizenship, and regulate research. Furthermore, the United Nations Declaration on the Rights of Indigenous Peoples Article 31 states that "Indigenous peoples have the right to maintain, control, [and] protect… [their] human and genetic resources…" (p.10), underscoring Indigenous rights and interests in genetic research and data.[12] However, in the United States, assertion of these rights are complicated by federal recognition, or the lack thereof, of particular communities of American Indian, Alaska Native, and Native Hawaiian (AI/AN/NH) peoples. The US has a government-to-government relationship with 573 tribes in the lower 48 states and Alaska, and a number of states engage in such relationships with approximately 60 tribes not federally recognized. Many other US-based Indigenous peoples are not recognized by federal or state governments, including in the state of Hawai'i. While recognition does not define a tribal nation's sovereignty, it can provide rights and benefits. This authority extends to research endeavors and data governance.

Many tribes view knowledge and intellectual property, including genomic information, as belonging to the collective group rather than an individual, contrasting with mainstream Western frameworks of property ownership.[13-16] To ensure culturally appropriate oversight, many tribal organizations have developed research oversight committees and Institutional Review Boards (IRBs) or have partnered with Indian Health Service IRBs.[7] They have also developed regulations to govern research, research agreements that limit or prevent data sharing, and researcher-signed contracts detailing terms like pre-review of presentations and publications and returning data to the tribe at the end of a research study.[17-19] But with advances in genetic and genomic research and the move toward broad data sharing and open data, new mechanisms are needed to protect the rights and interests of Indigenous peoples.

> *Although tribes recognize the efficiencies that data sharing may offer, tribal partners noted that the current approach to data sharing as reflected in federal policy[10] does not allow for the oversight tribal leaders need to execute this responsibility.*

To address concerns and begin building pathways for genomic research, collaborators of a university-tribal partnership gathered in 2012 to discuss NIH genomic data sharing policies and the unique concerns it raises for tribal entities.[20] Tribal partners noted that tribal organizations have a fiduciary responsibility to ensure that research is conducted and reported responsibly and uses of data conform to tribal priorities. Although tribes recognize the efficiencies that data sharing may offer, tribal partners noted that the current approach to data sharing as reflected in federal policy[10] does not allow for the oversight tribal leaders need to execute this responsibility. They noted that consultation between tribal and federal governments is needed to develop appropriate collaborative approaches to data governance.[20] The NIH GDS Policy allows data sharing exceptions for "compelling scientific reasons,"[10] and could serve as the basis for discussion of alternative governance approaches. Although the sovereignty of federally recognized tribes is an important justification for considering alternative approaches, it is important to note that the concerns about past research misconduct and the need for community oversight are shared by Indigenous groups that lack federal recognition, such as Native Hawaiians, or lack sovereignty, such as urban American Indians.[3,21]

As concerns emerge, Indigenous data sovereignty concepts and new governance models have gained traction to assert more comprehensive tribal control over data derived from Indigenous peoples and promote productive partnerships with researchers.[8,22,23] Tribal sovereignty empowers governance across tribal jurisdictions of peoples, lands, and interests, raising opportunities and challenges for tribal oversight of research and governance of data.[24] With the emergence of large, national cohorts and studies – such as the *All of Us* precision medicine cohort that aims to oversample underrepresented populations, especially AI/AN/NH peoples[25,26] – the issue of appropriate governance of stored data and biological samples takes on greater importance. The limited community involvement typical of most data repositories is insufficient to address Indigenous concerns about research oversight.[27] Although some guidance around conducting genetic research with tribes has been developed,[28,29] there is an important need to generate stronger guidance and policy language to ensure more comprehensive controls over data derived from Indigenous peoples and support productive partnerships with researchers.

This study aims to better understand the specific concerns held by AI/AN/NH leaders and researchers who are engaged in tribal, regional, and national discussions about genetic research as the basis for informing collaborative approaches to data management. Here, we examine perspectives and concerns about data sharing, access, and management in the context of genetic and genomic research.

**Table 1. Sample interview questions**

| |
|---|
| What guidelines or policies are necessary to ensure appropriate research? |
| What should researchers do with data after a study has finished? |
| Should tribes participate in data sharing? |
| Who should manage the use and access to the data? |

## METHODS

### Participant Recruitment

Discussions about genetics and genomics research in tribal communities have taken place at multiple national and regional conferences, often aimed at tribal leadership and policy makers. To engage these stakeholders further, we recruited tribal leaders, health professionals, and policy experts to participate in semi-structured interviews. Tribal leaders included elected officials, elders, and leaders of professional organizations serving AI/AN/NH communities. Health professionals included scientists, clinicians, nurses, epidemiologists, and public health care workers. Policy experts included tribal, state, and federal policy analysts and tribal IRB members. Participants were targeted if they were engaged in public discussions or scholarship about genetics, recruited with permission at conferences focused on genetics with tribal communities, or referred through snowball sampling, and invited in person or through a recruitment e-mail with one to two follow-up attempts. Brochures with study information and a flyer with interview questions were distributed at conferences or emailed to approximately 200 people between June 2016 and March 2018. Potential participants were asked to share perspectives on genetic research and identify priority areas for development of guidelines, strategies, and policies for tribes to govern and ensure ethically sound genetic research based on their knowledge and expertise with tribal communities. The study was approved by the Seattle Children's Hospital IRB.

### Data Collection and Analysis

Designed to last 60 minutes, semi-structured interviews were conducted in-person or via telephone and audio-recorded with verbal consent. Although the interview guide was designed to solicit perspectives and experiences about genetic research and data and results from genetic research studies, participants also shared perspectives about genomic research and data. We report on questions that prompted responses about data and data sharing (Table 1).

Participants completed a brief demographics survey that included questions about their self-reported tribal affiliation(s) and occupation. Tribal identifiers were collected to track representation across tribes but were not reported to maintain anonymity. The participants' occupations were reclassified as tribal leaders, health professionals, or policy experts to enhance anonymity. Participants were compensated for their participation with the option of a $50 gift card or a travel mug decorated with an Indigenous Pacific Northwest design paired with a box of Navajo tea.

Audio files were transcribed by a HIPAA-compliant transcriptionist. Transcripts were de-identified by removing names, tribal identifiers, place names, and project or grant names. The codebook was developed and iteratively refined until agreement was reached. Transcripts were coded by two investigators using NVivo v.10 qualitative analysis software (QSR International) and coding discrepancies were resolved by consensus discussion until 100% agreement was achieved or settled by a third investigator. Theme identification and data analysis was based on a modified grounded theory approach.[30,31]

## Results

### Participants

Fifty-nine individuals were formally invited to participate in an interview. Of these, 17 declined or did not respond to invitations. Those who actively declined gave reasons such as being too busy or preferring to refer colleagues whom they felt were better positioned to comment on the topic. Interviews were conducted with 42 individuals affiliated with tribes across the United States; however, most of the respondents reported affiliations with tribes in the Southwest and Pacific Northwest. While we strived to achieve representation across tribes (not reported to maintain confidentiality), some tribal affiliations were reported more than once. Thirty-seven (88%) participants identified as AI/AN/NH. The five (12%) participants who did not identify as such described strong personal and/or professional ties to a tribal community where they had worked for 10 or more years. Participants were health researchers, professors, clinicians, tribal research review board members, directors of health organizations, and policy analysts, many of whom have worked in or with tribal communities for many years. Based on self-reported job titles, we classified 23 (55%) participants as health professionals, 14 (33%) as policy experts, and 5 (12%) as tribal leaders, though many had overlapping roles (i.e. a clinician who also serves on a tribal IRB). The majority of participants were between the ages of 46-60 (n=19, 45%) or 45 and under (n=14, 33%) (Table 2). Thirty-eight (90%) participants had advanced degrees and 25 (61%) identified as female. More than half (n=23, 55%) self-reported knowing more or much more about genetics than others. Interviews took place in-person or by telephone between June 2016 and March 2018. Recruitment ceased when no new themes or concepts emerged. Most interviews lasted about 50 minutes but ranged from 30 to 195 minutes.

**Table 2. Demographics**

| Age (yrs) | n (%) |
|---|---|
| 31-45 | 14 (33) |
| 46-60 | 19 (45) |
| ≥61 | 9 (21) |
| Gender | |
| Male | 16 (37) |
| Female | 25 (61) |
| Two-Spirit/LGBTQ | 1 (2) |
| Education level | |
| Some college/bachelor's degree | 4 (10) |
| Masters/doctorate degree | 38 (90) |
| Knowledge about genetics | |
| More/much more than others | 23 (55) |
| As much as others | 13 (31) |
| Less/much less than others | 6 (14) |

### Sharing and Accessing Genomic Data

Genetic research produces large volumes of information, raising questions about whether data should be shared with researchers and what safeguards need to be in place to offer appropriate protections. Many participants expressed a desire to have control over how their genetic data are managed and accessed for secondary studies after they are collected. When asked about whether tribes should share genetic data, some participants first questioned whether or not tribes are *required* to share data. Tribes maintain sovereignty, but many tribal programs are funded by federal dollars, thus granting some level of federal oversight. As such, questions were raised about a tribe's obligations to comply with federal policies. One respondent thought that tribes might need to comply with the federal government and NIH GDS Policy unless tribal communities take a stand against such sharing, as described here:

> *Because we're sort of under federal oversight, there's not much we can do if they want to do it, unless tribal communities stand up and say, 'No. You can't do that.' (ID 42, Policy Expert)*

Many respondents thought that tribes should be able to make their own decisions about whether to share data with other researchers. However, they believed that appropriate protections should be in place, such as privacy and confidentiality assurances for research participants. One respondent explained:

> *Yes. Again, as long as there are assurances that the information is in fact deidentified. (ID 35, Health Professional)*

Another respondent echoed that sentiment by stating that tribes already share many types of data, but elaborated on how tribes should have a more proactive role in understanding the extent to which data are shared and how they are accessed by other parties:

> *Tribes should participate in data-sharing, if they want to. […] We already participate in data-sharing to a large degree. […] We need to do a better job of understanding what that data-sharing really means, and what's done with it, who has access to it, and those type of things. (ID 5, Policy Expert)*

Other participants were less decisive about whether tribes should share genetic data, but believed that tribes should not be forced or unduly influenced to share data if they have concerns about potential misuses. While they understood that sharing data could provide benefits, they also voiced concerns about how some types of data might require stronger protections than other types. One respondent expressed apprehensive views about tribes sharing data:

> *Mm, oh geez. Yes, but at their own direction or prerogative. I would encourage it, but I would never impose upon another tribe if they aren't comfortable with sharing certain types of information. (ID 30, Tribal Leader)*

Some respondents believed that tribes should not share data and raised concerns about the lack of strict protections. One respondent elaborated by stating:

> *No. Not until more safeguards are in place. I have ensured that none of the data or biological samples of any of the projects that I've conducted in partnership with tribes have ever been placed into NIH or federally sponsored repositories. (ID 21, Health Professional)*

Across all participants in our study, there was no convergence of views regarding whether or not tribes should share data, including genetic data. While respondents recognized potential benefits, the types of concerns raised focused on ensuring the protection, privacy, and confidentiality of their tribal members. Concerns about protecting the identities of AI/AN/NH people became more apparent when discussions led to types of data access. Biorepositories and databases have different rules that dictate how the data can be accessed, ranging from open, unfettered access to closed, restricted access. Open access data may have few or no restrictions in place for people to gain access, whereas restricted access may require researchers to submit a proposal and sign data use agreements to comply with the database policies. Some databases have robust oversight mechanisms to ensure that researchers comply whereas others have limited oversight. Participants viewed the merits and pitfalls of various types of access. A minority of respondents thought that data should be made accessible as long as certain protections are established, as articulated by one respondent:

> *I think it should be shared pretty openly. Again, we just want to be careful of confidentiality. (ID 37, Tribal Leader)*

On the other hand, many respondents felt that privacy and confidentiality issues were strong enough to warrant closed access. One person described this by saying:

> *Personally, I think it should be closed. […] I've seen in certain cases where they're supposed to be deidentified at the national level even, and I ask questions […] and I said, 'I bet you I can tell who that person is.' (ID 6, Health Professional)*

Because many tribes are small, it may be possible to re-identify a tribe, community, or even person based on a few demographic indicators. Most participants tended to favor closed or restricted data access to avoid some of these potential risks to participants.

## Appropriate Data Oversight and Management

Genomic data are stored in databases with a range of policies dictating oversight mechanisms, raising questions about how the data should be managed and by whom. Respondents identified three possible entities who could be responsible for the oversight and management of data: the federal government, university researchers, and tribes. Historically, most research data from Indigenous peoples have been collected by researchers who stored the data on their laboratory computers or university servers, but there appears to be emerging interest in seeking alternative storage databases and facilities for data about Indigenous peoples. Respondents shared a range of perspectives about what role the federal government should have in maintaining and overseeing data collected from tribal members. Some respondents were not terribly concerned about depositing individual-level and tribal-level genomic data into existing databases like dbGaP and recognized the larger benefit to society or to AI/AN/NH people. For example, one respondent said:

> *I think that tribes absolutely need to be involved in that discussion and that opportunity to share the data, because I think that any time you are pooling results, there's gonna be a significant chance that you're gonna find more important things maybe that you weren't looking for, but that raise a red flag and say 'Hey, we need to look into this further.' So I think that there's a huge benefit at a national level to data-sharing, and I hope that it's something that after further fact-based discussion here locally, that our leaders and our community would support in the long-term. (ID 2, Health Professional)*

However, most participants were wary about the idea of allowing the federal government to maintain oversight over genomic data derived from AI/AN/NH research participants. One respondent voiced this concern, suggesting an alternative to a federal repository:

> *I don't like the idea of a federal repository, and I don't think the tribe's at a level where they can maintain that data. So universities or… [consortia] where they share things in the cloud with the proper access protections. (ID 19, Health Professional)*

Like this respondent, others felt more comfortable with researchers being involved in managing the data, as has historically been the case. In these cases, respondents thought it was most sensible to continue allowing researchers to maintain oversight of the storage and management of study data as long as tribes were fully informed and in agreement. One respondent stated:

> *For practical purposes, the data should be protected and controlled by the researcher or research institution, but it should be based on an agreed upon consent process by the tribe. (ID 12, Health Professional)*

On the other hand, some respondents felt that researchers and research institutes should not provide the oversight. One respondent stated clearly:

> *It should never be the academic partner or the re-*

> *search partner, in a perfect world. (ID 4, Policy Expert)*

As more tribes have begun to develop the infrastructure and capacity to manage information technology within their own tribal nations, there has been a shift to thinking that tribes should have more control over their data:

> *The tribe should absolutely manage the use of the data. (ID 7, Health Professional)*

While most tribes lacked the ability to store their research data on tribally controlled servers, a few tribes actually had the capacity to oversee their data. One respondent described:

> *It's stored on [our] servers and kind of overseen by our Information Technology department, as well as our Data Services department. (ID 8, Health Professional)*

If federal repositories and researchers are not the answer, and in the absence of a robust data storage system within the tribe, one respondent who worked with a tribe posed a possible alternative:

> *People have talked about having a tribal repository, specifically national tribal repository. Some people are thinking outside the box. I think that's great, and a way to share that data to benefit Indian communities as a whole. (ID 42, Policy Expert)*

In summary, respondents shared a range of views about appropriate data oversight and management, but most seemed to favor granting oversight to researchers or research institutes. Respondents were less enthusiastic about delegating the responsibility to federal repositories. Finally, some respondents suggested a role for tribes to be involved in the oversight and management of data.

## Discussion

Tribal leaders, health professionals, and policy experts in this study articulated a number of concerns related to the sharing of genetic data and the implications for AI/AN/NH people. In particular, participants voiced concerns about different models of data sharing, infrastructure and logistics for housing data, and whether data access should be open or closed. Many of these responses are informed by ongoing discussions and debates taking place at the local level within their communities and at the regional and national level with tribal and NIH leadership. For example, during the course of the study, the *All of Us* research program announced a plan to oversample AI/AN/NH people in an effort to increase representation,[26] which not only raised concerns for AI/AN/NH leadership but also may have influenced interest in our study.

Although knowledgeable about genetic research and some pertinent federal policies, respondents noted gaps in guidance about how to interpret the policies. Respondents expressed a range of views about whether tribes should share research data and if so, what data sharing should look like, but there is no clear consensus as to whether they believe data sharing is beneficial to the AI/AN/NH community and participants differed in the views about the acceptability of data sharing. Many raised questions and concerns about needing policies and protections in place before data are shared and referenced the efforts of some tribes in developing policies.[22,32,33] This research identified apprehension about sharing data, confusion about whether data sharing is necessary in order to obtain certain grant funding, and recommendations for safeguards to protect privacy and confidentiality.

*…participants voiced concerns about different models of data sharing, infrastructure and logistics for housing data, and whether data access should be open or closed.*

In terms of data oversight and management, genomic researchers often weigh requirements outlined in federal funding policies against tribal sovereignty and tribal wishes. There are differing opinions on which of the three identified entities should be responsible for the oversight and management of data. While a few respondents were comfortable with allowing data to be shared openly, almost all believed that it should be restricted. The diversity of views expressed by the participants in this study do not paint an obvious pathway forward, likely making consensus impossible to achieve. As each tribe is self-governing, achieving consensus across all tribes is likely not necessary. Many respondents believed that tribes should have oversight over the data but recognize their capacity limitations and make determinations about data sharing accordingly.

This research was a first step in understanding AI/AN/NH perspectives about data sharing, warranting further exploration to address tribes' reluctance to participate in research when funding and publishing opportunities are contingent on the ability to share data, to understand the resource needs of tribes who want data oversight and management to remain within tribal control, and to address the privacy and confidentiality concerns that tribes have regarding access to data. Addressing these issues can reduce barriers for participation in genomic research studies.[34]

### Study Limitation

A study limitation is that some tribal leaders declined to participate because they did not actively engage in discussions about genetics and data sharing, so they referred other health professionals who tended to have advanced degrees whose knowledge and experiences may not be generalizable to all AI/AN/NH leadership. Community members were not actively recruited because we sought an informed group who were knowledgeable about genetic research as well as federal and tribal policies. Most recruitment focused on the western half of the United States, where more Indigenous representation exists, and therefore did not capture the full range of diverse views from tribes in the eastern United States. While we recognize that this limits the overall generalizability of the findings, we believe that our qualitative analysis reveals a wide range of views about data sharing, access, and management that should be explored further.

Without clear consensus about data sharing, education and communication will need to play a critical first step toward resolution. AI/AN/NH leaders and researchers will need to clarify their tribes' rights as they relate to requirements stated in federal data sharing policies. Because AI/AN/NH leaders are often left out of the discussion and not involved in federal policy development, they have missed opportunities to highlight the importance of understanding the role of tribal sovereignty in research and data interests. Steps need to be taken to improve communication and to build pathways forward.

## CONCLUSION

Clearly these leaders and researchers are interested in, have ideas about, and are concerned with data access, management, and sharing. As genomics research and data sharing forge ahead, there is a need to expand not only research participation in large studies, but also tribal research governance in order to realize equitable outcomes. It is important to include a variety of Indigenous leaders and researchers as experts in mainstream governance structures, such as the DAC, IRBs, data governance boards, and others to reflect the diversity of ideas and issues.[26] It is also imperative that free, prior, and informed consent occur at the tribal/collective level prior to research study design and commencement. For example, as a federal entity, HHS has a tribal consultation policy that requires consultation with federally recognized tribes prior to and during any action that significantly affects them. These consultations must reflect meaningful engagement that shifts the power balance so tribes can consent to and decide the terms for sharing data, such as the landmark data sharing agreement recently issued between the Navajo Nation and NIH, bolstering trust in research, benefit sharing, and accountability.[35] Finally, it will be important to bring community perspectives into these discussions to shape policies and procedures.

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## Conflict of Interest

No conflicts of interest to report.

## Author Contributions

Research concept and design: Garrison, Burke; Acquisition of data: Garrison, Barton, Mai, Burke; Data analysis and interpretation: Garrison, Barton, Porter, Mai, Burke, Carroll; Manuscript draft: Garrison, Barton, Porter, Mai, Burke, Carroll; Statistical expertise: Barton; Acquisition of funding: Garrison, Carroll; Administrative: Garrison, Porter, Mai; Supervision: Garrison

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