“We’re not just raw material for research”: Understanding the Cultural Beliefs of Indigenous Communities to Ensure Culturally-Sensitive Genetic Research Engagement

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Abstract

"We're not just raw material for research": Understanding the Cultural Beliefs of Indigenous Communities to Ensure Culturally-Sensitive Genetic Research Engagement

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Historical, political, and cultural factors have contributed to the underrepresentation of Indigenous communities in genetic research. Few studies have explored Indigenous perspectives on important factors to promote stronger engagement between researchers and Indigenous communities. This thesis examines Indigenous perspectives to identify the key cultural factors affecting genetic research participation. Semi-structured interviews with health professionals, policy experts, and tribal leaders in the US were analyzed using a modified grounded theory approach and conventional content analysis. An important consideration for an individual's decision to participate in genetic research is influenced by his or her beliefs about genetics and biospecimens; these beliefs are shaped by one's spiritual understandings and cultural teachings. Considerations about the appropriate handling of biospecimens are also important, as people expressed concerns about respectful handling, control and ownership of biological samples, specimen disposal, its intended purpose, and potential health benefits. Researchers can utilize this knowledge to facilitate improved, culturally-sensitive genetic research engagement with Indigenous populations, and the findings can create increased opportunities for advancing the health of Native communities through the clinical benefits of genomics research.

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DEDICATION

To my parents,

For all of the sacrifices that you’ve made and the hardships that you’ve endured,

so that I can have the opportunities that you didn’t.

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INTRODUCTION

The Underrepresentation of Indigenous Communities

American Indian, Alaska Native, and Native Hawaiian populations constituted only 0.05% of total genome-wide association studies (GWAS) by 2016; to compare, individuals of European ancestry comprised 81% of total GWAS (Popejoy & Fullerton, 2016). GWAS are a type of genetic study that aim to identify genetic variants associated with a specific disease by investigating the entire genome of large populations of individuals (Genome-Wide Association Studies Fact Sheet, 2015). The underrepresentation of Indigenous communities means that any potential clinical benefits derived from these genomic studies may not be as applicable to these populations; this severely limits the clinical utility of applicable research findings for non-European populations and compromises the knowledge and ability to address the health needs of these populations.

Advancements in genomic research have transformed modern medicine, directing the field toward precision medicine, an approach that tailors clinical decisions and treatments to individual patients based upon their genetic profiles (Ginsburg & McCarthy, 2001). Since genetic information is unique from person to person, with the exception of identical twins, these genetic profiles can yield valuable insights about genes that may predispose an individual toward a specific condition or reveal pharmacogenomic implications affecting drug metabolism, both which are crucial to informing clinical decision-making and improving health outcomes. Even though this genetic information is relatively unique from person to person, individuals from the same ancestral background often share genes inherited from common ancestors (Genetics Home Reference, 2018). These shared genes may carry mutations that contribute to a higher genetic risk for certain diseases or affect the effectiveness of specific drug treatments. However, knowledge of these genetic variations and its clinical implications for Indigenous populations is limited since genomic studies have been conducted primarily within European populations. This suggests that the knowledge derived from these studies may not be as applicable to Indigenous populations. Gaining a better understanding about why Indigenous communities are underrepresented in genomics research will facilitate the development of strategies to increase that representation. In doing so, genetic research can generate findings that can lead to improved clinical applications that are better directed and targeted to the health needs of Indigenous populations.

The following sections will explore some of the historical, political, and cultural factors that have impacted research participation among Indigenous populations and contributed to their underrepresentation in genomics research. Examples of beneficial and successful biomedical research partnerships will also be presented.

A History of Past Research Harms

Throughout history, there have been several instances of research abuse against minority populations, including Indigenous communities (Brandt, 1978, Hodge, 2012, McGregor, 2007, NACE, n.d., Solomon & Randall, 2014). Some Indigenous communities have had traumatic experiences with research participation, and the history and memory of those past research harms remain among these communities, contributing to a distrust of the research process and hesitancy and reluctance to engage in future research endeavors. The experiences of the Nuu-Cha-Nulth and Havasupai Tribes are two examples of research partnerships gone wrong due to issues about the misuse of samples, lack of consent and confidentiality, and a failure to return results to the participating community.

In the 1980s, the Nuu-Cha-Nulth people of Canada submitted over 800 blood samples to Dr. Ryk Ward, a researcher at the University of British Columbia (UBC), to study rheumatoid arthritis (Dalton, 2002, NCAI, n.d.). This disease had a high prevalence in this community, and tribal members were motivated by altruistic desires to address this pressing community health issue. Ward eventually left UBC in 1986, taking these samples with him to two other universities. Unable to find a genetic basis for rheumatoid arthritis, Ward collaborated with other researchers, sharing and using the samples for other unconsented studies about HIV/AIDS, migration studies, and drug abuse. Producing over 200 publications from these research projects, he never reported findings or returned results back to the community. It wasn't until roughly twenty years later in 2000 that the tribe became aware of these research abuses. This generated great anger and unrest among the community, thus prompting them to work with university officials and researchers to track down and have their samples returned. The Nuu-Cha-Nulth people were finally able to reclaim their samples in 2004 (Wiwchar, 2004).

The Havasupai Tribe experienced a similar situation in 1989 through their research partnership with Arizona State University (ASU), wherein samples were collected for the purported purpose of conducting association studies on diabetes (Mello & Wolf, 2010, NCAI, n.d., Sterling, 2011). The Havasupai experienced increasingly high rates of type II diabetes and, like the Nuu-Cha-Nulth, wanted to understand why this disease was afflicting their people. Ultimately, the research proved unsuccessful in finding a genetic link for diabetes risk, and the samples were used for other studies, including schizophrenia, inbreeding, and migration studies, topics which are taboo subjects for this community. Awareness about the unconsented use of these samples was made in 2003, when a Havasupai member and former research participant attended a lecture held at ASU and learned that Havasupai samples were used in a study on human population migration (Dalton, 2004). Upon further pressing, she learned that her samples and those of other tribal members were utilized in many research studies without the tribe's knowledge (Harmon, 2010, Rubin, 2004). A lawsuit was brought against the university on the grounds of the lack of informed consent, violation of confidentiality, and the misuse of DNA samples and data (*Havasupai Tribe of the Havasupai Reservation v. Arizona Board of Regents and Therese Ann Markow,* 2004). Ultimately, the parties in the case reached a settlement, but the experience left a lasting negative impact on many tribal communities.

Tribal Sovereignty

Tribes are sovereign nations; though they exist within the physical boundaries of the US, they have their own system of governance, with their own distinct policies, laws, and regulatory processes (Harding et al., 2012, Solomon & Randall, 2014). This sovereignty extends to research regulation as well, as many tribal communities have established their own research codes or institutional review boards (IRBs) to oversee and manage these research processes. Most of these tribal IRBs have been established according to the Common Rule federal regulations, which mandate the protection and ethical treatment of human research participants (Office for Human Research Protections, 2016). Tribal IRBs may also specify additional requirements for conducting research within a specific tribal community, such as publication agreements or protocol reviews by community elders (Kelley et al., 2013). As such, any form of research engagement must adhere to the policies and review processes of that tribal community. Research proposals that do not adhere to those policies or deemed potentially harmful to the community will not obtain approval from the tribal government.

The Navajo Nation was the first tribe to establish its own IRB (Brugge & Missaghian, 2006). Institutionalized in 1996, the Navajo Nation Human Research Review Board (NNHRRB) “regulates, monitors, and controls all research within the boundaries of the Navajo Nation,” and ensures that potential research endeavors and partnerships promote the interests and values of the Nation (Navajo Nation Human Research Review Board, 2009). In exercise of tribal sovereignty and authority over research regulation, the Navajo Nation enacted a moratorium on genetic research in 2002 after many years of deliberations about whether or not it should be allowed and the recognition that there was no policy in place (NCAI, n.d.). Though the ban is currently still in effect, the moratorium is being reconsidered, as efforts are being led by the Navajo Nation toward a development of a policy on genetic research that ensures future research will be conducted under tribal terms and values (Reardon, 2017). Nonetheless, tribal sovereignty may be another factor contributing to the underrepresentation of Indigenous populations in genomics research (Harding et al., 2012, Norton & Manson, 1996). Each tribal government may be organized differently, and researchers wanting to engage these populations in research must recognize and operate under the policies of that tribal community.

Cultural Factors

In addition to the historical and political factors, cultural dynamics have also affected the research engagement of Indigenous communities. These cultural dynamics include spiritual and traditional teachings. Spiritual traditions are beliefs about an individual’s connection to another spirit or soul; this can include connection to a superior being like nature or a deity (HeavyRunner & Morris, 1997, Watkins et al.,2013). Traditional beliefs come from cultural teachings of a specific community which have been passed down from generation to generation, or have some significance rooted to the past (Gosselin, 1975). These beliefs include origin and creation stories, which are cultural explanations based in oral history describing how a community came to be, such as how they emerged from the land where they currently live (Nelson, 1997). These spiritual and traditional teachings possess great cultural significance and value for the specific tribal community.

Some tribal community members have spiritual beliefs about the sacredness of their bodies. For many Native people, there is no separation between the physical and the spiritual (Arambula Solomon & Randall, 2014). For example, Hawaiian peoples believe that each part of the body contains a life force called *mana*, and the disruption of *mana* can cause disease (Bowekaty & Davis, 2003, Santos, 2008). Other communities have beliefs about the connectedness of their physical body to spiritual notions about maintaining wholeness and preparing for the afterlife. For some communities in the Southwestern US, amputations and organ donations are believed to contribute to body fragmentation—or the "separation of body parts from the body-self"—and this fragmentation compromises an individual's wholeness, which can adversely impact the transition into the afterlife (Sahota, 2014). Other tribal communities in the upper Midwest echoed similar beliefs about organ donation affecting the ability of the body to enter the spirit world after physical death (Danielson et al., 1998). These cultural beliefs about the body may influence decisions about the donation of different tissue types from the body, including donation for research purposes. Thus, if tribal communities holding these spiritual beliefs deemed that their participation in a research study may somehow conflict with their cultural values, it can negatively impact their willingness to participate.

Cultural factors can affect the willingness to engage in other types of non-medical genetic research, such as genetic ancestry testing. Many tribal communities have had limited experience with genetic research, with participation in ancestry research being the primary type of genetic research experience for these communities. These experiences have led to an opposition to participation in ancestry and migration studies due to these studies producing stigmatization and unwanted results, such as findings being used to disprove origin stories (Royal et al., 2010, TallBear, 2007). Scientists who have led recent genetic ancestry projects, such as the Human Genome Diversity Project and the Genographic Project, have been particularly interested in recruiting American Indian, Alaska Native, and Native Hawaiian populations because these "isolated indigenous populations…were viewed as highly unadmixed", and therefore assumed to be ideal sources for providing definitive genetic evidence of human evolutionary and migratory history (Cavalli-Forza et al., 1991). Yet these projects have been problematic in many ways, including raising concerns about the protection of Indigenous culture and the exploitation of Indigenous people who are assumed to be "endangered" and "inevitably going to disappear" (Greely, 1999, Harry, 1995). These projects have also produced narratives that the ancestral origins of all human populations are rooted in African origins, which has been used to challenge the origin stories of Native Americans (TallBear, 2007). Similarly, other ancestry testing has connected Native Americans to Asian populations through the Bering Strait theory (Li et al., 2008, Reich et al., 2012). Thus, these types of studies have led to results challenging the cultural teachings of these Indigenous populations, and these conflicts with cultural beliefs can impact decisions about future research participation.

Other Tribal Experiences with Genetic Research

Despite past harms, some genetic research has been beneficial and successful partnerships with tribal communities have emerged. Most of these types of studies have been focused on biomedical research to promote health. These include the Strong Heart Study (SHS), the Sioux Cancer Study, and the Center for Alaska Native Health Research (CANHR) obesity study. Started in 1988, the SHS began by investigating cardiovascular disease (CVD) and its risk factors in American Indians in thirteen tribal communities in Oklahoma, Arizona, and North and South Dakota (Strong Heart Study, 2017). SHS continually engaged its participants throughout the research process, enabling participating tribes to provide input into the study design and implementation. Investigators also ensured that participants were fully informed throughout their engagement, frequently presenting results to the communities and providing educational materials as needed. Participants also received clinical examinations, referrals, and medical advice (Solomon & Randall, 2014). Through effective engagement, the study has yielded important insights about CVD-related morbidity and mortality and genetic links contributing to CVD risks.

The Sioux Cancer Study was an ancillary study of SHS that investigated cancer risk factors among three Sioux tribes in North and South Dakota (Welty, 1993). Women study participants received screening for breast, cervical, and rectal cancer whereas male participants were screened for prostate and rectal cancer. These screenings identified relevant participants for follow-up consultation and referral for surgical procedures, allowing participants to undergo these procedures earlier than they would have had without participation in the study (Solomon & Randall, 2014). The Sioux Cancer Study demonstrated the importance and clinical utility of cancer screening program within the Sioux tribal community, and participants diagnosed with cancer were able to gain access to medical interventions to address their health needs.

Another example, the CANHR study recruited the Yup’ik people of Alaska in order to investigate gene-environment interactions that influence risk for obesity and related diseases, such as CVD and type II diabetes (CANHR: Genetics of Obesity, 2017). Specifically, the CANHR researchers studied the effects of activity levels and a polyunsaturated fatty acid-rich diet upon disease risk and the genetic variants affecting that interaction. Polyunsaturated fatty acids (PUFAs) are a type of fat required for various physiological processes and moderate consumption is important to healthy outcomes (Ander et al., 2003). Through the study, the researchers determined a PUFA-rich diet was protective against type II diabetes, more active individuals displayed healthier biometric outcomes, and some genetic variants contributing to obesity risk were identified. All three studies, the SHS, the Sioux Cancer Study, and the CANHR study, are examples of genetic research studies that have yielded important knowledge about the respective chronic health conditions affecting tribal communities.

Purpose of this Study

More recent studies have begun to utilize community-based participatory research (CBPR) approaches to engage Indigenous communities and highlight the need for culturally-appropriate engagement (Bowekaty & Davis, 2003, Brockie et al., 2017, Burhansstipanov, Christopher, & Schumer, 2005, Cochran et al., 2008, Fong, Braun, & Tsark, 2003, Tobias, Richmond, & Luginaah, 2013). However, there is limited in-depth knowledge about the cultural factors that need to be understood and respected in genetic research engagement. Specifically, there is a knowledge gap about how specific Indigenous traditional and spiritual beliefs influence decisions about participation in research requiring biospecimen collection, and considerations for ensuring respectful handling of these biological specimens. There have been few studies that have analyzed Native American perspectives on biospecimen collection and disposition. In one, Sahota (2014) concluded that some tribal members who identified as traditional ("an emic category use in the community") were more likely to believe biospecimens should be returned to the participant at the end of a study and not be used after a participant's death due to concerns about body fragmentation. Haring et al. (2018) surveyed members of the Haudenosaunne tribe and determined that that 25% of participants indicated that they would be very likely to donate biospecimens, 46% of participants were somewhat likely to donate, and 27% of participants were neutral to donate, with factors such as trust, having culturally-appropriate recruitment materials, and informed consent impacting these perspectives. We set out to further explore the perspectives of Indigenous stakeholders to identify the key cultural factors affecting research participation in order to develop culturally-focused approaches for increasing research engagement with Indigenous communities.

METHODS

Design

A cross-sectional qualitative design was chosen because there is limited knowledge about how Indigenous traditional and spiritual beliefs influence participation in biomedical research, and this study will provide greater context about these beliefs in the realm of genetic research (Starks & Trinidad, 2007). Each participant was interviewed once during the interview period, capturing the participant's perspectives at that particular time. Semi-structured interviews were utilized to elicit stakeholder perspectives. The semi-structured nature of the interviews provides a standardized set of open-ended questions for discussion about specific issues around genetic research participation, with follow-up probes allowing for more in-depth exploration of these topics. Nonetheless, participants were able to discuss new ideas as necessary, allowing for a range of perspectives related to the traditional and spiritual beliefs about biospecimen handling to be captured. Utilizing a modified grounded theory approach, conventional content analysis was employed to ensure the knowledge gained is grounded in the data and reflective of participant perspectives (Starks & Trinidad, 2007, Hsieh & Shannon, 2005).

Participants

Study participants were English-speaking individuals (18 years or older) with a professional interest in genetics, ethics, and policy and who identify as or have strong affiliations with American Indian, Alaska Native, and Native Hawaiian communities across the US. These stakeholders included those of AI/AN/NH heritage, as well as non-AI/AN/NH individuals who have worked extensively with tribal communities and are familiar with the issues pertaining to genetic research within Indigenous communities. Possessing a wide array of educational backgrounds, professions, tribal affiliations, and experiences, participants are characterized into three main subgroups: 1) tribal leaders, 2) policy experts, and 3) researchers and health professionals (Table 1). Tribal leaders were individuals with decision-making authority or influence about health research in their tribal communities; some examples of individuals categorized as tribal leaders were elected officials, tribal elders, and medicine men/women. Policy experts were individuals with professional experience in the development and/or implementation of health policies in their tribal communities; some examples of individuals categorized as policy experts were policy makers and analysts, and IRB members. Health professionals were individuals with an advanced degree in a biomedical profession whose experience interfaced with genetics and tribal communities; some examples of individuals categorized as health professionals were scientists, physicians, and nurses.

Table 1. Stakeholder Characteristics

Stakeholder Group	Definition	Professions
Tribal Leader	Individuals with decision-making authority or influence about health research in their tribal communities	Elected officials Tribal elders Medicine men/women Tribal healers/knowledge keepers Professional organization leaders
Policy Expert	Individuals with professional experience in the development and/or implementation of health policies in their tribal communities	Policy makers Policy analysts Institutional review board (IRB) members Tribal IRB members
Health Professionals and Researchers	Individuals with an advanced degree in a biomedical profession whose experience interfaced with genetics and tribal communities	Scientists Clinicians (physicians and nurses) Epidemiologists Public health care workers

Recruitment

The study received approval from Seattle Children's Institutional Review Board. Widely used in qualitative research, a purposive sampling technique is the identification of individuals who are "especially knowledgeable about or experienced with a phenomenon of interest"

(Palinkas, 2015). Purposive sampling was utilized to ensure recruitment of participants who were knowledgeable about the issues of genetic research engagement in Indigenous communities. This sampling was achieved through the different recruitment methods: 1) direct invitation based on relevant publications or previous public talks, 2) at national research conferences (Table 2), 3) referrals from the Advisory Council, and 4) through snowball sampling, wherein participants referred potential participants to the study. The Advisory Council consists of individuals who have expertise about the issues surrounding genetic research in Indigenous communities, and who are also well-connected to stakeholder groups and have facilitated introductions for study recruitment. Participants have also been recruited at national research conferences and annual tribal meetings, and through snowball sampling. Participants were approached in-person or through email for recruitment. The informed consent process entailed providing participants with written documentation outlining the study purpose, the risks and benefits of participation, plans for protecting confidentiality, and an Information Sheet that serves as a consent document. We identified and sent invitations to 43 participants who were eligible for the study.

Table 2. Research Conferences for Recruitment

Conference Name	**Location**	**Date**
Native Research Network conference	Cherokee, NC	June 2016
National Congress of American Indians mid-year conference	Spokane, WA	June 2016
Regional American Indian/Alaska Native Tribal Dialogue Conference on the All of Us Research Program on Precision Medicine	Chandler, AZ	May 2017
National Congress of American Indians mid-year conference	Uncasville, CT	June 2017

Summer internship for INdigenous peoples in Genomics (SING) workshop	Tucson, AZ	July 2017
National Indian Health Board conference	Bellevue, WA	October 2017

Data Collection

Participant perspectives were elicited through semi-structured interviews with open-ended questions and probes (Appendix A). At the time of recruitment, participants were given an informational brochure about the research project, a list of interview questions, and the Information Sheet. Designed to last 60 minutes, interviews were conducted in-person or via telephone in a confidential manner and were audio-recorded with verbal consent. Each participant also completed a brief survey of demographic information at the conclusion of the interview. The demographic survey also asked participants to report their tribal affiliation(s) and occupation. Tribal identifiers were used to ensure representation across the tribes, but were not reported. Two team members re-categorized the participants into the three stakeholder subgroups. Participants were compensated for their participation with the option of a $50 gift card or a travel mug decorated with a Pacific Northwest design paired with a box of Navajo tea.

Data Analysis

Audio files were transcribed by a HIPAA-compliant transcriptionist. Investigators de-identified the transcripts to maintain participant privacy and confidentiality. In addition to confirming transcription accuracy, the de-identification process entailed removing various identifying information, such as the names of individuals, tribal identifiers, specific locations, and project or grant names. Transcripts were uploaded to the qualitative analysis software program, NVivo v.10 (NVivo Qualitative Data Analysis Software, 2012). Initial coding by the investigators identified emerging themes that informed development of the preliminary codebook, the document that defines and describes the identified themes. Containing definitions and code-specific examples, this document provided guidelines for organizing the transcript data into codes. Transcripts were independently double-coded by two investigators, and any coding discrepancies were resolved by consensus discussion until 100% agreement was achieved. Any unresolved coding discrepancies were settled by a third investigator. The codebook was iteratively refined until agreement was reached (Appendix B). Theme identification and data analysis was based on a modified grounded theory approach (Starks & Trinidad, 2007). The analysis focused upon the following codes: barriers to participation, community identity, ownership, pathways to participation, reluctance to participate risks and benefits, tribal engagement, and spiritual connection to DNA codes. For the selected quotes, interviewee utterances were removed to enhance content clarity and readability. Examples of utterances removed include “you know”, “and yeah”, and “I think” (when presented in a repetitive nature).

RESULTS

Participant Characteristics

A total of 30 interviews were conducted between June 2016 and July 2017, ranging from 45-115 minutes, with the interviews lasting an average of 50 minutes. The response rate was 69.8%. Participant characteristics are summarized in Table 3. The majority of participants identified as Native American (n=25), and 5 participants were not Native American but had long-standing professional and personal ties with tribal communities. There was fairly equal representation from men (n=14) and women (n=16). In terms of age group, the majority of participants belonged to the 31-45 age group (n=11) and the 46-60 age group (n=13). Though the primary roles for the majority of participants were health professionals (n=19), there was still representation from policy experts (n=9) and tribal leaders (n=2). All except three participants held an advanced degree; nonetheless, these three participants completed some college or held a Bachelor's degree. The majority of participants self-assessed their level of genetics knowledge as being "as much as others" (n=8) or "more than others" and "much more than others" (n=19); only three participants self-assessed their genetics knowledge as being "less than others".

Table 3. Participant Demographics

Category	n (%)
Identification	
Native American	25 (83.3%)
Not Native American	5 (16.7%)
Gender	
Female	16 (53.3%)
Male	14 (46.7%)
Age	
31-45	11 (36.7%)
46-60	13 (43.3%)
61 and over	6 (20.0%)
Primary Professional Role	
Tribal leader	2 (6.7%)
Policy expert	9 (30.0%)
Health professional	19 (63.3%)
Educational Level	
Some college/vocational school	1 (3.3%)
Bachelor's degree	2 (6.7%)
Advanced degree	27 (90%)
Level of Genetics Knowledge	
Less than others	3 (10.0%)
As much as others	8 (26.7%)
More than others	10 (33.3%)
Much more than others	9 (30.0%)

Culturally-Sensitive Research Engagement

Culturally-sensitive approaches are necessary to ethically engage research participants. This involves acknowledging and respecting the cultural beliefs of the community members throughout the entire research process. Respecting these cultural beliefs is an extension of respecting the research participants and their contributions to the research project beyond purely providing biological specimens. One participant asserted, “we're not just the raw material for research” (Participant 22, Researcher). This quote succinctly suggests that tribal communities are not just people who can be utilized as “raw material” for research. Rather, there are individuals behind the “raw material”, individuals with cultural beliefs that may influence perspectives and decisions about research engagement involving biospecimens. The results revealed that traditional and spiritual beliefs influence genetic research engagement, participants are concerned about the respectful handling of their biospecimen, and that additional considerations exist about biological materials, including the need to know intended purposes of their samples, and the potential health benefits derived from research on these specimens.

Traditional and Spiritual Beliefs Influence Genetic Research Engagement

Personal beliefs about genetics and biospecimens have an influence on an individual’s decision to participate in genetic research, as well as how likely an individual is to be engaged in genetic research efforts. Three primary elements have emerged as influencers that affect how participants think about genetics: the balancing of one’s cultural beliefs, incorporating one’s spiritual understandings, and embracing cultural teachings. This section will further elaborate on these three elements.

Tensions between Upholding Cultural Beliefs and Engaging in Research

There are a range of perspectives about biospecimen and research participation among the participants in this study. These perspectives are influenced by the traditional beliefs of each of the communities that the participants come from, including cultural teachings ranging from spiritual beliefs about one’s body to oral histories about the community’s creation and origins. Particularly, research engagement that includes biospecimen collection has been challenging for many communities where some tribal members hold strong spiritual beliefs about their body, often prompting them to be reluctant about donating biospecimen without additional discussion, consultation, deliberation, or assurance about the respectful handling of their biospecimen. As a result, tribal communities are struggling between wanting to uphold and respect these traditional beliefs while also wanting to engage in research efforts that may yield potential benefits for their communities. A participant described this tension that community members have struggled with in the following:

> *Their spiritual traditions tell them, '[Genetic research] is not necessarily appropriate,' and trying to weigh from a spiritual sense how much of that tradition is just because the times have changed, and the ability to collect this kind of biospecimen to analyze it, to keep it and to move it forward. The science has changed. Does that mean the tradition should change or shouldn't have changed?* (Participant 23, Researcher)

Here, "their spiritual traditions" refer to the teachings held by the researcher's tribal community. This respondent questions whether these spiritual traditions should be adapted to be more compatible with research uses to promote scientific analyses or if they should be upheld, such that the potential to "move it forward" with science may be hindered by concerns about going against traditional beliefs. In other words, the potential scientific benefits from analyzing biospecimens and translating the results into usable knowledge may not be realizable for certain tribal communities if their spiritual traditions take precedence. Some participants have echoed similar concerns, that if tribal communities are not participating in the research process, they will not have the opportunity to benefit from that process either.

Spiritual Understandings about the Body

Spiritual beliefs vary among individuals and communities. Some members of certain tribal communities hold strong spiritual beliefs about the body, whereas some individuals within these tribal communities have adopted different religious beliefs and may have different views about the human body. Some respondents explained that some tribal communities are opposed to the removal or donation of certain bodily materials, such as blood, tissues, or organs, due to their spiritual traditions about maintaining the wholeness of one's body for the afterlife, also described as "go[ing] to the Creator whole" (Participant 7, Researcher). Other participants explained that there is a belief about the sacredness of one's body, and this sacredness extended to all elements of the body and is maintained regardless of whether or not that bodily part remains physically attached to the individual. A participant described this belief:

> *There is an understanding that once tissue has left the body, that it can still harm you, if it's used in a way that's not good for [you].* (Participant 20, Researcher)

Because the bodily material originated from the individual, some believe that the tissue still remains deeply connected to the individual despite its physical detachment. As such, there is a belief that the misuse or mistreatment of the body element can still inflict harm upon the individual. Examples of harms described by participants were emotional distress or the onset of any form of physical sickness or illness. For other participants, these harms could be stigmatization, discrimination, distrust, or other harms resulting from the use of the tissue for research.

Furthermore, several participants elaborated upon the reasons for why some Indigenous community members hold this belief about a sacred connection to their bodies. In addition to the spiritual beliefs previously mentioned, some participants explained that their bodies carried their blood and genes, which served as connecting forces to other, larger entities. These included connections to other tribal members like past ancestors and future offspring, as well as connections with the larger universe. One participant described this connection as:

> *[The] gene is not a new thing [...] it's been a part of us. We try to talk about it culturally through our clan, but much bigger than that, we say we're part of the Mother Earth and Father Sky. Father Sky means the universe [...] we're connected to our past.* (Participant 27, Researcher)

Here, the participant asserts that there is a connection of the genes in his body to his clan, his ancestral history, and the universe. Many tribal communities are organized around a clan system, comprised of groups of relatives and extended families sharing an identity and descending from a common ancestor (Ross, 1996). Thus, the participant explained that these genes are ties to his past through the ancestors in his clan, but also ties to the other extended members of his clan. He also acknowledges that his genes have connections to other elements in the universe, including the earth and sky. As such, for many participants, their bodies have a sacred connection to other elements and people in the world.

Cultural Teachings about Community Origins

In addition to spiritual beliefs, many tribal communities have their own traditional teachings about their community's creation and origins. These cultural teachings vary by community and they tend to be told as stories about tribal origins that remain highly protected and valued. When asked about what types of genetic research studies would be appropriate or inappropriate, or what factors would influence research participation, the majority of participants expressed opposition to genetic ancestry testing to examine a person's lineage. A participant shared their views for an underlying reason for this overwhelming opposition:

> *Well, what if I came and decided I was going to disprove everything you know about your creation and who you are and where you come from [...] whatever your religious beliefs are or aren't.* (Participant 7, Researcher)

Because certain tribal communities have their own creation and origin stories, these stories serve as cultural explanations of their peoples' or populations' origins. Participants explained that ancestry testing is perceived as having no benefit for tribal communities; rather the findings from ancestry testing has been used to support the claim that Native Americans are not truly indigenous to the Americas, but originated elsewhere, which undermines and disproves these oral histories. Furthermore, two respondents specifically cited the land bridge theory--which theorizes that the Americas were populated by people who migrated across the Bering Strait to Alaska and south throughout the Americas--and that tribal communities are not interested in research intended to prove or disprove that theory due to perceived contradictions with tribal origin stories.

Biospecimen Handling: Treatment, Control, and Disposal

Participants engaging in research studies requiring biospecimen collection want their biological specimens to be handled in an appropriate manner. This appropriate handling is separated into three primary areas: respectful handling of biospecimen, issues about the control and ownership of biological samples, and considerations for specimen disposal. This section will describe these three areas.

Respectful Handling of Biological Specimens

Many participants voiced concerns about biospecimen handling, its intended usage, issues of control and ownership, and methods of disposal. Given the spiritual beliefs of some tribal members, the biospecimen or research sample is still considered a part of them, regardless of whether or not it remained physically attached to the individuals. As such, the proper handling of the biospecimen is necessary to prevent harm to the individual. This respectful handling of biological samples includes using the appropriate language in discussions about biospecimen. For example, a participant recounted about an individual who referred to a donated biospecimen as “leftover” or “unnecessary”:

> *It was like it was already trash, and that was incredibly offensive to Native people [...]because they did not see their blood [like that...]. They had given it for some reason, for their own medical care. They didn't see it as 'leftover' or 'unnecessary'. They saw it as part of them, and that's when we've been unsuccessful is when we don't have proper respect for that specimen.* (Participant 7, Researcher)

The respondent explained that reference to an individual's donated blood as "leftover" or "unnecessary" was offensive and culturally-insensitive; she invoked the word "trash" as the comparable analogy of the use of those problematic words. She explained that from the perspectives of Native Americans, the biospecimen was still considered a part of the individuals, and that part had been given for their specific medical purposes and should thus be treated respectfully. For these reasons, the proper treatment of the biospecimen meant recognizing that it came from a person, respecting the individual and their beliefs, and using language that is not offensive to that individual or their beliefs.

In addition to concerns about the harms that could be inflicted upon them due to sample mistreatment, some tribal members also wanted increased transparency about how their biospecimens were handled. One participant elaborated on their preferences regarding tissue collection:

> *Especially when it comes to just the way that tissue is taken, who it's taken by, how it's stored, how people interact with it, and just culturally wanting them to be handled in a way that is respectful of indigenous people, wanting to make sure that our belief systems are upheld.* (Participant 20, Researcher)

Here, the participant listed several things that she would want to know about a tissue sample, including the institution(s) and/or researcher(s) acquiring the sample, how it was acquired, its storage details, and how the researchers or other people are using the sample. In addition to these considerations, the participant also wanted the sample to be handled respectfully, in a manner that respects her community's belief systems.

Control and Ownership of Biospecimens

Other respondents expressed concerns about the usage and control of their samples, with some respondents particularly concerned about the fate of their specimen after their deaths. One participant questioned:

> *What is gonna happen with our samples? Who's gonna have control of our samples? Why are we doing this study? What are we gonna learn from it? Is it gonna hurt our tribe [...]and what if that person does die and [researchers] still have those samples?* (Participant 14, Researcher)

This participant grapples with various concerns around biospecimens, including its use and intended purpose in a study, who maintains control of the samples, and posthumous implications. He is also worried about any potential harms from the research study from the analysis of those samples. In asking these types of questions, participants wanted to gain better knowledge about not only the handling and intended purpose of their specimens, but also what happens to their samples both post-study and posthumously, and even beyond that, having a deeper understanding of the concept of control of the biospecimens. Unease about "researchers still [having] those samples" after a person's death raises concerns about data ownership and potential unauthorized access of the sample without the person's knowledge or explicit consent. Another participant elaborated about data ownership:

> *With matters of control of the materials, particularly if they're biospecimens: 'Who owns the data? What are the intentions regarding the use and the production of this knowledge?'* (Participant 15, Researcher)

The participant explained that concerns about the control of biospecimens also encompassed concerns about data ownership, its intended usage, and the potential knowledge from analysis of the samples. Thus, the majority of participants are not only concerned about the handling and treatment of biospecimens, but also the intended purpose of the sample and control and ownership considerations.

When participants were asked what policies or guidelines need to be in place to ensure culturally-sensitive research, many participants emphasized the need for having clear research agreements, ranging from basic research protocol documents to more specific data-sharing and ownership agreements. According to these participants, these agreements should explicitly spell out various elements of the research process as it pertains to biospecimen handling in order to address the various concerns about the handling of biological samples. One participant described this agreement:

> *It's a legally binding contract between the principal investigator and [the tribal] institution that speaks to data owning, biological specimen ownership, management, just agreement that the researcher would have, cede publication review to our tribal processes, several different steps like that, again, just assert the tribal ownership and control of research.* (Participant 24, Researcher)

This participant stressed that the fundamental purpose of this research contract was the assertion of tribal ownership and control of research processes, including ownership of biospecimen and the data from biospecimen analysis. He described the different ways that tribal ownership and control were being maintained, such as through managing processes related to biospecimen and research data and reviewing research results prior to publication.

Rather than the focus being on ownership and control of biological material, other respondents explained that clear research agreements are needed as a way for increasing transparency about biospecimen handling. One participant described that part of his research agreement required annually updating the tribal community about the research project, which included updates about the specifics of biospecimen handling:

> *I'd also prepare an annual update on the research [...about] where physically all either electronic data or biological sample resides, under what conditions the samples or data reside, and what any expirations that may be tied to either [...and how long] we will retain those biological specimens to answer the questions of the study.* (Participant 21, Researcher)

This annual update included information about biospecimen storage and conditions, including the storage length and considerations dictating when those samples or data would be removed. Although these research agreements may vary in scope and focus, many participants believed these agreements are necessary to address the various concerns about biospecimen handling and treatment upfront. Through these research agreements, tribal communities and the research investigators or institutions can negotiate about issues of importance, withholding their acceptance of the agreement until conditions about proper biospecimen handling and issues of specimen control and ownership are in alignment with community values.

Biospecimen Disposal

Many participants discussed concerns about biospecimen disposal, explaining that these research agreements need to also outline protocols for biospecimen disposal. According to these participants, different tribal communities have a range of requests and expectations; some requested immediate sample disposal after data analysis, while other communities agreed to the storage of their samples for a specified period of time. Five of these participants described the importance of ensuring the proper ceremony and burial for different bodily material. A participant described this process in the following:

> *[The tribal community] are going to be sending a traditional healer to be there when the [genetic] samples are destroyed so that the proper cultural [...] ceremony that is involved happens, because they believe that these samples are still entities, living entities of their people, and so they'll come and guide it through the ceremony.* (Participant 7, Researcher)

For that particular tribal community, beliefs about the sacredness of their bodily elements as living entities of themselves and their people necessitated that those bodily elements were treated in a culturally-appropriate manner, even during the destruction process. Hence, having the traditional healer present during the disposal process to perform a prayer ensured that these samples received the proper ceremony during the disposal process. For other tribal communities, the participants clarified that the proper ceremony may involve a burial, and explained why some members of certain tribes collected placentas, umbilical cords, or displaced hair in order to keep and bury in their traditional ways. One participant recounted through his experience that one tribal community did not care about requiring a culturally-appropriate destruction process, and that incineration of the samples was sufficient. Thus, respondents explained that the proper handling of biospecimen also extended to ensuring that the proper respect is being conveyed throughout all stages of specimen handling, including the disposal and destruction phases.

Other Considerations: Biospecimen Types, Study Purposes, and Potential Health Benefits

Although some tribal members have beliefs about the inherent sacredness of their body and its elements, some participants revealed that the acceptability of biospecimen donation or removal is also dependent upon the biospecimen type and purpose. Specimen collection is required for various purposes, though these purposes can be generally categorized into clinical or research objective. Clinical samples are biological material taken in a clinical setting for medical examination and results are conveyed back to the patient, whereas research samples are biospecimens taken for use in a research study and results are typically not returned to individual participants. Some participants acknowledged that certain sample types were more difficult to obtain, with one participant admitting:

> *We had to do things like collect cord blood and collect placenta in some cases, so kind of touchy things/activities sometimes*. (Participant 5, Researcher)

For some tribal communities, the placenta, umbilical cord, and cord blood are considered sacred, and often buried soon after a birth to signify the individual’s relationship with that particular land (Luther, 2017). Consequently, efforts to collect these materials for clinical or research purposes may be more difficult due to the spiritual beliefs that some people have about those items. In contrast, there was less concern expressed for other bodily samples; one participant described:

> *People were much less concerned about the scrapings off their skin, the saliva in their mouth, their fecal samples, so that didn't come up as us [researchers] having a part of them.* (Participant 11, Researcher)

Here, the researchers collected specific biospecimen types for their project, and these skin scrapings, saliva, and fecal samples did not seem to create significant worry among their research participants. Given the sample type, these participants did not see the researchers as "having a [bodily] part of them," thus not having concerns about the donation of those specimens for research. In addition to the sample type, the intended purpose of the biospecimen also impacted receptivity about sample donation or removal. For example, a participant explained:

> *People go in for routine medical exams all the time where they're asked to give urine samples or blood samples [...] so that doesn't seem to be necessarily like a problem. So it depends on kind of the study and what the content of the study would be. If it's something like a cheek swab or something, that might be acceptable [...] but if it's something like undergoing surgery to remove material or something, or like for example a growth, like a cancerous growth or something and it's gonna be tied to us, it's gonna go off, that might be another discussion.* (Participant 10, Researcher)

From the perspective of this participant, urine, blood, and cheek swab samples were deemed to be generally non-problematic biospecimen types that are routinely collected in the course of for medical care. These particular biospecimen types were contrasted with the "cancerous growth" of tumors requiring more invasive surgical intervention. Therefore, the issues here were that these particular bodily elements were viewed as still being "tied to [the individual]" and the nature of a surgical removal forcibly severed that bodily material to "go off" to a laboratory. However, the participant clarified that the intended purpose for the biospecimen should also be considered, because different research purposes and studies may also factor into people's discussions and decisions about biological sample donation and removal.

Expanding upon this point, another participant explained that despite having certain traditions and customs that create challenges for genetic research, the respondent expects that people would be receptive to participating in research that addresses this cancer health issue given the cancer prevalence within his tribal community. This desire for some type of clinical health benefit is echoed by the majority of participants as affecting their considerations for research participation.

DISCUSSION

Researchers have encountered challenges with engaging Indigenous communities in genetic research efforts requiring biospecimen collection. These challenges arise from the clash of differing beliefs, as communities struggle to uphold their traditional beliefs while also wanting to engage in culturally-sensitive research efforts that may yield clinical benefits for their communities. These beliefs range from observing spiritual traditions about the body to respecting oral histories about the creation and origins of the community. The desire for these cultural teachings to be respected during research efforts, along with the knowledge or experiences of past research harms, have raised concerns among tribal communities about respectful biospecimen handling. Though participants were not specifically asked questions about biospecimens during the interview process, discussions about biospecimens emerged organically from the interviews. These concerns about biospecimens include how these biological materials are being utilized and treated, who maintains ownership and control, and how are the community's cultural beliefs are being respected throughout the handling.

In the struggle between trying to uphold traditional beliefs while also wanting to advance science and uncover health-promoting knowledge, what would happen if the tension between the two fields cannot be resolved? In other words, if the science and traditions are not compatible with each other, and neither branch of knowledge can be adapted to accommodate the other, that suggests that one has to take precedence over the other. For some communities with more restrictive beliefs about the body, that may mean that research endeavors requiring biospecimen collection may be much more challenging to achieve, and any potential health benefits arising from that analysis may not be applicable to these communities. This would only further exacerbate the underrepresentation of Indigenous communities in genetic research studies.

However, the assumption that communities with restrictive beliefs about the body will be entirely opposed to genetic research engagement requiring biological specimen may not necessarily be true. The findings indicated that there was more concern about certain biospecimen types than others. For example, there was greater concern about the collection of the placenta and other organs, than the collection of skin scrapings or saliva samples. Advancements in genomic technology have made DNA analysis possible on various sample types, presenting a wider range of techniques and methods for DNA analysis on sample that are obtained in a less invasive manner and are more acceptable or tolerable by research participants. For instance, procurement of a saliva sample requires an individual to spit into a tube, whereas a blood sample typically necessitates a more intensive and invasive collection process involving phlebotomists and needles. As such, the knowledge about the acceptability of certain biospecimen types over others, combined with an understanding of the community's cultural beliefs and values, can be utilized to better engage tribal communities in genetic research while respecting their spiritual traditions.

Because they represent cultural beliefs about the origins of the universe and their people, creation and origin stories maintain immense cultural importance to tribal communities. In addition to serving as cultural explanations for their community's origins, these creation stories also "give [the tribe] values for living, narrate [the tribe's] common history, cohere [the tribe] to a common moral framework, and tie [the tribe] to a sacred landbase (TallBear, 2007). Countering these origin and creation stories, migration studies and human evolutionary theory suggest that Native Americans migrated across the Bering Strait from Asia or through other routes from parts of the world (Benson, Petersen, & Stein, 2007, Erlandson et al., 2007, Li et al., 2008, Reich et al., 2012). Origin stories are important for reinforcing the indigeneity of Native

Americans, whose identities and origins are the products of historical, legal, and cultural factors that cannot be fully captured and explained through genetics (TallBear, 2007). This reinforcement of indigeneity—or the quality of being indigenous people “who are distinct from settler societies” —has significant political implications as well, because it establishes the right of Native Americans to exist as distinct cultures and sovereign nations (TallBear, 2007. This sovereignty grants tribal communities legal authority to define their own membership criteria, which the majority of tribes have defined through blood quantum requirements (Schmidt, 2011, TallBear, 2003). However, with direct-to-consumer ancestry tests becoming increasingly popular, there have been individuals who have tried to use their genetic ancestry test results to demonstrate affiliations to Native American lineage and seek claims to tribal membership instead of or to complement blood quantum laws (Garrison, 2018). Yet the perspectives of the participants revealed that there is much more to Native American identity than simply having the bloodline; there are spiritual teachings about the sacredness of that blood, oral histories about the community’s origin and connection with larger entities, and other cultural values that mold that identity.

Participants conveyed overwhelming opposition to ancestry testing due to findings being utilized to disprove and contradict the oral histories of tribal communities. However, missing from the data are the perspectives of the tribal communities who have embraced ancestry testing for various other reasons. For example, the Seaconke Wampanoag Tribe of Massachusetts have utilized genetic analysis in combination with historical and genealogical data to reconstruct their tribal history (Zhadanov et al., 2010). Another example, the Western Mohegan tribe of Vermont underwent genetic testing to prove their tribal ancestry and genetic link to other tribes in order to gain state and federal tribal recognition (TallBear, 2003). The Inupiat people of Alaska have also initiated genetic analysis to study their ancestral origins and demonstrate relatedness to ancient remains (Raff et al., 2015). Therefore, despite what our data revealed about the perspectives of participants interviewed and the tribal communities represented, the findings are not wholly generalizable to all tribal communities, and the unique perspectives and beliefs of each community needs to be determined, acknowledged, and respected with each research partnership.

Several respondents expressed concerns about the fate of their biospecimens after their deaths and wanting to ensure that their biological materials will receive a culturally-sensitive disposal. However, there was limited discussion about the participant's cultural reasons for concerns about disposal and their connection to beliefs about death, even though many participants shared their views on how spiritual and traditional teachings about the body have an influence upon their perspectives about biospecimens. In some Southwest tribal communities, members believe that a deceased person's belongings need to be destroyed in order to facilitate their transition from this world, and that these belongings included biospecimens (Sahota, 2014). Among the Zuni, a tribe in western New Mexico, there is belief in a five-stage life cycle, with death being the second stage of existence; consequently, it is necessary to ensure that all body parts are returned upon a person's death so that he or she can spiritually journey through the other stages of life with an intact body (Bowekaty & Davis, 2003). Thus, these cultural understandings about the body and death can be another source of valuable knowledge informing researchers about the importance of respectful specimen handling and disposal.

Despite the different cultural traditions that have led to challenges in the research engagement of tribal communities, the data also showed there have been many tribal communities and Native American individuals who have participated in research and have had positive experiences. Some individuals are compelled by altruistic motivations, believing that their participation will generate some type of scientific benefit for their children or community. Others wanted to support their fellow Native members, including helping them to develop professionally as researchers. Others participated in research because they trusted the investigators, who have dedicated many years into cultivating the community’s trust. Regardless of the motivating reasons, many participants want the research process to be Native-led, controlled, and owned. Recognizing the current, limited capacity within their communities, many participants acknowledged the necessity of forming research partnerships with non-Native institutions and organizations to gain the needed resources and skills. However, many participants supported efforts toward building that capacity so that these partnerships were no longer necessary. Rather, respondents want the research to fall under Native leadership who can assure that the cultural beliefs and values of tribal communities are being respected and upheld.

Limitations

The study gathered results from participants with strong affiliations with American Indian, Alaska Native, and Native Hawaiian communities across the US. However, the study was not geographically representative, as most of the participants were recruited from tribal communities primarily in the Pacific Northwest and Southwest regions. Additionally, the majority of the participants were health professionals, meaning that the perspectives of community members from other professional backgrounds were not fully captured. We targeted tribal leaders in our recruitment, but most did not respond, did not follow up, or they referred us to another person to interview, thus our study has limited perspectives from this group. Furthermore, participants were categorized into three possible stakeholder subgroups; some of the participants had overlapping professional experience and background, but were categorized into their primary subgroup by investigator discretion. Participants were also highly-educated, and the methods of recruitment at national research conferences and individuals based on relevant publications may have biased the sample.

Conclusion

Despite these limitations, the goal was to identify a range of relevant perspectives about genetic research engagement in Indigenous communities from individuals strongly affiliated with these communities. Though each particular community may be different, and the individuals comprising the community may have their own beliefs that differ from the other members within their community, these findings provide broad insight into considerations around biospecimens, and the influence of spiritual and traditional beliefs in decisions about research participation requiring biospecimen collection and handling. These insights provide a starting point for researchers seeking to establish genetic research partnerships with Indigenous or other underrepresented communities and can be further developed within the cultural context of the particular community with whom the researchers are partnering to ensure that the research engagement is conducted in a culturally-sensitive manner, one that acknowledges that these communities are more than just raw materials for researchers. The knowledge gained from these research partnerships can be utilized to facilitate improved genetic research engagement of Indigenous populations, and the findings can create increased opportunities for advancing the health of Native communities through the clinical benefits of genomics research.

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APPENDIX A

Genomics and Native Communities: Perspectives, Ethics, and Engagement

Interview Guide

Date: ____________________________
Code: ____________________________

Thank you for taking the time to talk with me today. I'm Nanibaa' Garrison / Krysta Shutske / Thyvu Mai / Leah Tanner, a faculty member / research associate / Master's student / health equity liaison at Seattle Children's Research Institute. I first want to thank you again for your time and willingness to participate. Before we begin, I want to confirm that you have received the information sheet (that I sent to you). (Review Information Sheet). Do you have any questions? _______

In this project, I will ask you about your views and opinions on genetic research with tribes. The goal is to learn about stakeholder perspectives on genetics, both from your perspective and from the perspective of your tribe (or the tribe(s) that you work closely with). We are interviewing Tribal leaders, Native clinicians and researchers, and policy makers who have a stakeholder interest in genetics. I will not ask you about your health information and ask that you do not tell me about your personal health information.

Please know that your participation in this interview is completely voluntary. Feel free at any time to let me know if you need a break or if you don't want to talk about a certain topic or if you need to stop the interview at any time. There is no right or wrong answer to the questions in this interview, I will be asking for your permission to record the interview in order to transcribe the results for analysis. The interview will take one hour to an hour and a half. We would love to thank you for your time with a $50 gift card from Amazon.com or a travel mug with a Pacific Northwest design and Navajo tea, which I/we will give/mail to you after the interview. Interviews are confidential and the contents of the interview will be de-identified. The study has been approved by Seattle Children's Institutional Review Board. Do you have any questions for me before we begin?

- If you have understood and agree to the terms on this sheet, I will need your verbal consent to participate. _______

- I also will need your verbal consent to be audio-recorded. _______ Thank you.

(Turn on recorder) I have now turned the recorder to 'on.'

Experience with genetics

To get us started, I want to ask you about your experience with genetics.

When you think about how physical or health traits are passed down in families, what does that mean for you?
Probes:
Do you think of it as bodily traits? Genetic / Familial traits?

Please describe how genetics comes up in your work.
Probes:
How has genetics come up in your job?
Have you heard of anyone else in your field encountering genetics on the job?

To what extent have you had formal or informal training in genetics?
Probes:
Have you had undergraduate or grad school courses in genetics? On the job training?
Have you attended workshops / seminars (including SING, GENA) or public talks?
Have you had coworker conversations?
Have you learned about genetics through news articles, books, or radio?

Tribes and Genetic Research

Next, please describe your main role in terms of your tribe (or the tribe that you work closely with) as it relates to genetic research:
Probes:
Are you a:
    Tribal leader / Elected official / Tribal elder?
    Clinician (Physician, Nurse, etc.) / Researcher / Public Health worker?
    Policy Maker / IRB member?

What are the health priorities of your tribe (or the tribe that you work closely with)?
Probes:
You mentioned X. Others might also mention (pick from list below). Do these resonate with you?
    Health conditions or disease (ie. Diabetes, mental health, cancer, etc)
    Improve health care access / insurance / Indian Health Service (IHS)
    Promote public health messaging
    Increase facilities / resources, Improve infrastructure (water, roads, electricity)

Where does genetics fit within the priorities that you just listed?

What discussions has your tribe (or the tribe that you work closely with) had on genetic research?
Probes:
How have they discussed whether to allow genetic research?

How have they discussed cultural / ethical issues?
How have elders or traditional people weighed in on these discussions?

In what format(s) have discussions on genetic research taken place?
Probes:
Have discussions happened at conferences / In-person meetings / Webinars?
Have discussions happened on the Radio / Newspaper / TV / Social Media?
Have discussions happened with the tribal IRB or tribal leadership?

Has your tribe (or the tribe that you work closely with) ever been involved in genetic research?
If YES: Who initiated the project?
What was the research focus? How did it go?
Were there areas that you would do differently? What are they?
What worked well? What didn't work well?

If NO: Why not?
If never asked: What do you think the reasons were for not being asked?
If declined: Did your tribe have opportunities? Were there discussions about the decision? What were the reasons for declining?

Research Participation

If you were invited to be in a health study, what factors would be most important to you in deciding whether to participate?
Probes:
You mentioned X. Others might also mention (*pick from list below*). Do these resonate with you?

- Understanding / Transparency
- Trust / Relationship-building / Community engagement
- Health benefits to the community
- Incentives / Money / Making it easy to participate (child care, food, etc.)

What types of genetic research studies do you think you or your tribe view as appropriate? And, what types would not be appropriate for you or your tribe?
Probes:
Ancestry research, Paternity testing
Migration research, inbreeding, population genetics
Precision Medicine, personalized medicine, pharmacogenomics
Health and Disease (diabetes, arthritis, etc.)

What steps need to be in place to ensure culturally-sensitive research?
Probes:
Would these steps include any of the following?

- Protocols for ethical / culturally-appropriate research
- Collaborators / Gate-keepers
- History of trustworthy partnerships
- Pre-review of publications or presentations

What guidelines or policies are necessary to ensure appropriate research?
Probes:

Governance, oversight, tribal research review / IRB
Policies on ownership, stewardship of data

Management of Data and Results

Research studies produce a lot of data that are then analyzed and presented or published as results. Next, we want to ask some questions about the data and results.

What should researchers do with the data after a study has finished?
Probes:
How should data be managed?
How should data be shared?
What else should happen to the data?

What should researchers do with the results from a study after it has finished?
Probes:
Should results be returned to the community or individuals?
Should results be published?
What else should happen to the results?

Going back to the topic of data, who should manage the use and access to the data?
Probes:
Should data be managed by: Tribally controlled data access / Federal repositories / University controlled / Other entities

Researchers have been encouraged to share their research data and findings with other researchers. Some do this by placing de-identified data into web-based databases. Other researchers who wish to have access to that information can request access to use the data for new studies.

Should tribes participate in data sharing?
If so, who should oversee that process? If not, why not?

I know you're very busy and have to make choices about how you spend your time. I appreciate your willingness to spend time on this interview. Can you tell me what made you decide to talk to me about the issue of genetic research?

Thank you very much for your time today; I sincerely appreciate your insights. Are there any last thoughts you would like to share?

I will turn the recorder off now.

Would you like to receive a copy of our aggregate findings? Please say 'YES' or 'NO.'

We may want to contact you about follow-up research related to this study. Saying 'YES' does not mean you have to take part in any follow-up research. We are only asking if we can contact you to see if you may be interested in joining a follow-up study.

Would you like to hear about these follow-up studies? Please say 'YES' or 'NO.'

What is the best way to reach you?

Can you suggest names of people who we should contact to invite them to the study?

Which gift would you like (circle one)? Amazon Gift Card Mug & Navajo Tea
To what address should I send your gift?

Finally, I have few demographic questions to ask. The purpose of these questions is to make sure that we have representation from different perspectives. Your answers to these questions will not be linked to your interview. The first two questions are to ensure representation and will not be reported.

Demographic Questions:

1. What tribe(s) are you affiliated with?

2. What is your occupation?

3. What is your age?
   - o 18-30
   - o 31-45
   - o 46-60
   - o 61 or over

4. How do you describe yourself?
   - o Male
   - o Female
   - o Transgender

5. How much education did you complete?
   - o Did not complete High School
   - o High School Diploma/GED
   - o Some College/Vocational School
   - o Bachelor’s Degree
   - o Advanced Degree

6. Please select the one answer below that best describes your knowledge of genetics compared to other people.
   - o Much less than others
   - o Less than others
   - o As much as others
   - o More than others
   - o Much more than others

APPENDIX B

Codebook: Genomics and Native Communities As of 3-2-18

Barriers to Participation: Respondent discusses factors that prevent access to or involvement in research participation, inclusive of physical, emotional, logistical, or cultural barriers. Examples of barriers include historical trauma, past negative participation experiences, time-consuming consent or approval processes, or a failure to be asked to participate.

Community Identity: Respondent describes a shared value, belief, quality, location or perception that creates meaning, cohesion, or identification with other tribal or community members. Also use this code if respondent discusses the struggle with wanting to respect tribal perspectives, while also to be an individual.

Data Sharing: Respondent discusses access to data for researchers or tribes, or institutional or governmental agreements to share data.

Education: Respondent discusses dissemination of information to the community; This can include 1) prior to research: education about genetics, biospecimen collection, and consent forms or 2) after research: returning individual or aggregate results to the tribe and presenting summaries of research findings. Also use this code if there is a lack of education or providing information.

Genetics and Research: Respondent describes examples of genetics or biomedical-related research that respondent or tribes have engaged in or would like to participate in.

Golden Nugget: This is to be used for particularly good quotes or things that caught your eye as something important to go back and review

Governance: Respondent discusses oversight and management of biomedical data, or describes regulatory bodies or agreements involved in this process (such as Memorandums of Understanding, or MOUs).

Guidelines and Policies: Respondent describes an existing guideline/policy, discusses factors that need to be considered in guideline/policy development, or recommends changes to a process that s/he would like to see implemented.

Knowledge and understanding of genetics: Respondent discusses formal and informal education, training, or experiences contributing to their own knowledge of genetics or that of the tribes that the respondent has worked with.

Ownership: Respondent discusses beliefs regarding legal ownership of samples and data.

Pathways to Participation: Respondent discusses factors that facilitate access to or involvement in research participation, inclusive of physical, emotional, logistical, or cultural barriers.

Examples of pathways include participation incentives, tribal approval, being fully informed, or a transparent recruitment and consent process.

(Perceived) Risks or Benefits: Respondent indicates anticipated or assumed personal or collective risks or benefits from research participation. Examples of perceived benefits include altruistic beliefs that their participation helps themselves or others, and helps to advance science. Examples of perceived risks include financial or psychosocial harms, the fear of repeating past mistakes, and challenges to tribal understandings of ancestry.

Reluctance to participate in genetic research: Respondent describes unwillingness or hesitation of themselves or tribal community members in engaging in DNA testing or genetic research that involves genetic testing.

Spiritual Connection to DNA: Respondent indicates the belief that all elements of one's physical body, including DNA, possess sacred value.

Tribal engagement: Respondent discusses the process of involving tribal community members in activities and discussions aimed at benefitting and advancing the community. Examples of tribal engagement activities include utilizing tribal resources and leadership and engaging in conversations with tribal members.

Tribal health and research priorities: Respondent discusses health conditions and research goals of importance to tribes, inclusive of high and low priorities.
Trust: Respondent mentions the element of trust or distrust/mistrust, or describes a way to build or lose trust.

<u>Possible new codes:</u>
Transparency: This is a code to keep in mind as we are coding. We currently are not going to add it as a permanent code. We may be able to put this as a sub-code to Trust or may fit in under Barriers to participation.