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Fostering Ethical, Legal, and Social Implications Research in Tribal Communities – The Center for the Ethics of Indigenous Genomic Research

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Abstract

Genomic research raises unique ethical concerns among Alaska Native and American Indian (AN/AI) people and their communities. The Center for the Ethics of Indigenous Genomic Research (CEIGR) was created to foster research that takes these concerns into account while considering the sovereign status of AN/AI tribal nations. Relationships developed within CEIGR have allowed for effective, collaborative research among individuals who come from diverse cultures, political and historical backgrounds, and academic disciplines, and who work for organizations with varying resources, capacities, and expectations. The CEIGR framework may inform other groups seeking to conduct social science research related to genomic research with tribal people and their communities.

Keywords

ELSI; Alaska Native; American Indian; Genomic Research; academic-community partnership

INTRODUCTION

The scope and potential clinical applications of genomic research are expanding daily, as is the promise for improving individual and community health. Stemming from earlier successes in the Human Genome Project and the International HapMap Project, interest and investment in genomic research are growing (Consortium, 2003; Green, Watson, & Collins, 2015). For example, the National Institutes of Health (NIH) continues its effort in the *All of Us* program to collect the genetic data of 1 million research participants to build a biospecimen and data repository that represents the diversity of the U.S. population to

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support research into the genetic links between disease and health (Sankar & Parker, 2017). This has created a new impetus to include Alaska Native and American Indian (AN/AI) populations and renewed attention to the ethics of research with these communities, particularly in the absence of tribal consultation prior to national recruitment (Kaiser, 2019).

Among AN/AI people, historic distrust of health research is intertwined with distrust of federal and other non-tribal organizations that have a record of forced assimilation and mistreatment of AN/AI people over hundreds of years (Dillard, Caindec, Dirks, & Hiratsuka, 2018; James et al., 2014; Kelley, Belcourt-Dittloff, Belcourt, & Belcourt, 2013; Pacheco et al., 2013). The U.S. federal government has a trust responsibility to provide AN/AI tribes and tribal people with health care services, but these health care services have historically been severely underfunded, which has resulted in grave health disparities compared to the general U.S. population (USCCR, 2018; Warne & Frizzell, 2014). Compounded with distrust of federal institutions is distrust with health research. A recent example is the Arizona State University case, in which samples collected from an Arizona tribal community for genetic studies on type 2 diabetes – a community health priority – were used in multiple unrelated and unapproved genetic studies. Unethical genetic research conducted by university-based researchers exacerbated concern among AN/AI people and their tribal governments regarding participate in genetic research (Garrison, 2013; Pacheco et al., 2013).

In addition, the availability of genetic counselors nationwide is a concern as genomic medicine is implemented in clinical care (Bernhardt, 2014). Within AN/AI communities access to primary care services is limited due the chronic underfunding of the tribal health care system by the federal government (USCCR, 2018). In turn, access to specialty care, genetic counselors included, may be lacking or not available. Next, the comparatively small size and unique genetic profile of some AN/AI populations may make it easier to identify individuals and communities from whom genetic data had been collected. Furthermore, ancestry information gleaned from research results or increasingly accessible direct-to-consumer genetic tests can negatively impact an individual's sense of belonging within a tribal community and challenge the origin beliefs of a tribe (Garrison, 2013).

At the same time, failure to engage in emerging health technologies poses its own risks, including the continued use of clinical tests, treatments, and therapies that may be less effective or appropriate for AN/AI persons because the initial research did not include AN/AI people (Popejoy & Fullerton, 2016). As a result, many tribal governments have called for a measured approach to genetic research—one that balances the profile of risks and benefits unique to their communities (Pacheco et al., 2013). Here we describe a collaborative approach to achieve this balance through systematic inquiry into tribal concerns on genomic health research that can inform policies. We give an overview of the creation of a multidisciplinary research consortium focused on genomics in AN/AI communities, note the contributions this center has made to scholarship and practice in Indigenous genomics, describe some challenges and best practices for multi-site collaborative projects, and provide a roadmap for our future research efforts.

CENTER FOR THE ETHICS OF INDIGENOUS GENOMIC RESEARCH

Formation and Purpose

To support AN/AI communities in determining how to approach genomic research, the University of Oklahoma (OU) collaborated with research groups based in AN/AI communities to seek NIH funding to establish a Center of Excellence in Ethical, Legal, and Social Implications (ELSI) Research (Table 1). Established in 1990 as part of the Human Genome Project, NIH's ELSI Research Program funds ongoing research on the myriad societal impacts of genomic research and medicine. Centers of Excellence in ELSI Research (CEERs) were created to support development of multidisciplinary ELSI research teams, to facilitate translational research, and to cultivate a new generation of ELSI scholars (McEwen et al., 2014).

Staff at OU had prior professional experience partnering with AN/AI communities in conducting community-driven health research, including genomic research. Upon funding, the OU CEER formally adopted the Center for the Ethics of Indigenous Genomic Research (CEIGR) as a name. CEIGR is multidisciplinary consortium dedicated to investigating the ELSI research in AN/AI communities. These research goals are being pursued by OU in partnership with three research groups based in AN/AI communities led by Indigenous researchers experienced in conducting research in tribal settings: the Chickasaw Nation Department of Health's Research and Public Health Division; Missouri Breaks Industries Research, Inc., an American Indian-owned private research organization; and Southcentral Foundation, a tribal health organization based in Anchorage, Alaska. Tribal community partners and OU staff equitably prioritize CEIGR activities. For example, OU is directly awarded the CEER funds, but has allocated a majority of the funding to partner sites through subaward agreements. In addition, CEIGR has an external advisory committee comprised of Indigenous and non-Indigenous researchers and clinicians with direct experience in genomics, research, and health care with AN/AI populations and biobanking who bring additional expertise to the Center on a consultant basis. As described below, the research agenda has been determined by the community organizations. The external advisory committee does not direct the CEIGR research agenda but provides ELSI-specific contextualization of CEIGR efforts.

AN/AI Community Partner Sites

Chickasaw Nation Division of Research and Population Health—The Chickasaw Nation's Division of Research and Public Health (DRPH) was established in 2011 to provide public health and research services including epidemiology, health promotion and disease prevention, clinical informatics, and research and Institutional Review Board (IRB) support. Over the past seven years, DRPH has developed and strengthened academic partnerships that provide benefits and services to the Chickasaw Nation through tribally-driven research. DRPH houses the research protections program, which includes a federally registered IRB responsible for reviewing all research that takes place within the Chickasaw Nation. DRPH has also fostered an environment supportive of ethical research by developing policies to guide genetic research and pursuing certifications and training on protections for research participants. The research protections program is pursuing several research questions,

including how tribal sovereignty relates to the NIH's single IRB policy and the management and ownership of genomic data and biospecimens (Hull & Wilson, 2017).

Missouri Breaks Industries Research, Inc.—Missouri Breaks Industries Research, Incorporated (MBIRI) was established in 1995 and is a private, American Indian-owned organization. MBIRI conducts research in partnership with tribal communities in North and South Dakota, with the goal of empowering AN/AI people to choose healthier lifestyles through tribally specific and validated health care standards and locally informed interventions. For the past 23 years, MBIRI has carried out research in tribal communities in North and South Dakota on population health projects. MBIRI has no formal ties to any specific tribal institution or government, allowing it to work across institutional silos and in partnership with all entities committed to improving community health outcomes. MBIRI's staff members are knowledgeable about research as well as community issues, have experience in community engagement methods, and have established trust with tribal entities. Approximately 85% of permanent MBIRI employees are enrolled tribal members of various federally recognized tribes.

Southcentral Foundation Research Department—Southcentral Foundation (SCF) was incorporated in 1982 and is a tribally owned and operated health care organization based in Anchorage, Alaska. SCF serves the health care needs of more than 65,000 AN/AI people. SCF also co-manages the Alaska Area Specimen Bank with federal and tribal partners (Parkinson, Hennessy, Bulkow, & Smith, 2013). The SCF Research Department was instituted in 2006 to conduct health research on behalf of the AN/AI community by pursuing research aligned with SCF's family wellness objectives (Dillard et al., 2018). The Research Department currently employs 25 interdisciplinary research staff, 76% of whom are of AN/AI descent (Hiratsuka et al., 2017). Prior to the inception of CEIGR, the SCF Research Department had conducted participatory research to assess the understanding, perceptions, and expectations of AN/AI people with respect to genetic research, pharmacogenetics, and the use of genomic testing to inform substance misuse treatment (Avey et al., 2016; Beans et al., 2018; Dirks et al., 2019; Hiratsuka, Brown, Hoeft, & Dillard, 2012; Shaw, Robinson, Starks, Burke, & Dillard, 2013).

Research Approach

As noted earlier, researchers have recently broken trust with AN/AI communities by using the health information of participants for purposes other than those agreed upon in informed consent documents (Garrison, 2013; Mello & Wolf, 2010). Elsewhere, research has been conducted in ways that were disrespectful of cultural values and beliefs and that resulted in stigmatization and harm to AN/AI communities (Foulks, 1989; Goins, Garrouette, Fox, Dee Geiger, & Manson, 2011). These experiences compound and are entangled with the larger historical traumas committed against AN/AI people by the U.S. federal and state governments during colonialization (Fisher & Ball, 2003; LaVeaux & Christopher, 2009). In response to such events, some tribal governments have restricted the scope of genetic research involving their community members (Garrison, 2013). To create a positive working relationship and acknowledge past research harms, this Center follows the tribal community sites' lead to address research priorities of interest identified by each community site. For

example, each of the partners has conducted focus groups and interviews with community members to identify areas of concern in their respective communities (the results of which are beyond the scope of this article), foregrounding and centering AN/AI community experiences in the conduct of research. This community-based endeavor has proven to be time consuming but is crucial in changing the narrative in AN/AI communities' experience with research and views towards genetics and genomics research.

Research in tribal contexts is also unique in that the U.S. federal government has recognized the sovereignty of tribal governments as well as the rights—including self-governance and self-determination—that flow from this sovereign status (Harding et al., 2012; Manson, Garrouette, Goins, & Henderson, 2004). As sovereign nations, tribes have the right to develop research regulations to protect their interests and those of their citizens. For example, tribal governments can regulate research that involves tribal members or takes place on tribal lands. A key component of recent approaches to tribal regulation of research is the use of tribal IRBs (Morton et al., 2013). Whereas university and other IRBs focus on protection, informed consent, and minimizing risk for the *individual* study participant, Tribal IRBs expand this protection to also consider impact of the research on the *community* (Hull & Wilson, 2017; Morton et al., 2013). Other approaches to research regulation in tribal communities may include requirements for community review and approval of research before individual recruitment and informed consent can be pursued (Angal, Petersen, Tobacco, Elliott, & Network, 2016; Gilbert, 2006; Hiratsuka et al., 2017). Researchers interested in conducting research involving AN/AI communities have an obligation to recognize the authority of tribal governments and their research review processes when engaging AN/AI people and communities in health research (Fisher & Ball, 2005). Collaborative work within CEIGR includes research review by the three partner sites' local research review processes in addition to local tribal and/or Indian Health Service IRB approvals. Delineating and revisiting each collaborative project timeline are required to ensure CEIGR work moves forward with all required approvals, and to consult with community members to ensure their concerns are represented in the research process.

Finally, AN/AI communities are extremely heterogeneous in their languages, cultures, historical interactions with other tribal and non-tribal nations, health services infrastructure, and public health and health care needs (Goins et al., 2011). Research conducted in tribal settings must employ methods that are adapted to AN/AI communities. Methods appropriate for non-Native communities may not be appropriate for AN/AI communities, nor is research adapted to the character and needs of one specific AN/AI community necessarily well-suited to use in another AN/AI community. To explore the ethical, legal, and social implications of genomic research utilizing data and biospecimens from AN/AI people, it is imperative to have this work led by researchers with real-world experience in the tribal community setting (Greenbaum, 2013). To this end, CEIGR relies upon the Indigenous leads of the partner sites to conduct empiric data collection and interpret findings for research and clinical care.

Consortium Activities

Consortium Meetings—The first consortium meeting took place in November 2016 at OU's Health Sciences Center campus. This included representatives from CEIGR

community partner sites, faculty from OU, the Oklahoma Medical Research Foundation, and the CEIGR external advisory committee. During the first meeting, CEIGR leadership sought to address two potential research topics through dialogue and deliberation: (1) What is the clinical utility of genomic knowledge for tribal communities? and (2) How can this research be conducted in such a way that AN/AI communities are protected from risks, including the misappropriation of materials, data, and knowledge?

Deliberation is an approach to community engagement that has proven fruitful in other contexts (Abelson, Blacksher, Li, Boesveld, & Goold, 2013; O'Doherty & Burgess, 2009) but has seen less examination in AN/AI communities. Deliberation has taken many specific forms in health research and other contexts, but can be generally defined as an inclusive process of respectful discussion and analysis of a topic, often aided by a facilitator, with the aim of producing well-reasoned recommendations or policy choices (Abelson et al., 2013; Burkhalter, Gastil, & Kelshaw, 2002).

When discussing coordinated data collection, it became clear each partner site was starting in a different place in relation to the proposed questions and had different priorities. For example, the Chickasaw Nation has not engaged in genomic research, and was interested in creating a biobank. MBIRI had assisted with data collection for a few genomic research efforts and had taken some preliminary steps to establish a biobank. SCF had engaged in ELSI and genomic research and was already actively engaged in co-managing a biobank (Parkinson et al., 2013). In response, the consortium decided that each site would pursue individual local priorities during the first year addressing CEIGR's research topics local importance related to the Center's goals. This meant that CEIGR's coordinated data collection efforts were delayed, pending the outcomes of the local research. A second meeting in February 2017 at OU focused on possible common questions related to the conduct of genomic research, with a focus on possible survey tools as the consortium began to articulate common protocols.

Additionally, consortium meeting discussions underscored the need to prioritize questions related to the *conduct* of genomic research over those of its potential *value*, since the question of clinical utility still remains largely unresolved (Stark et al., 2019). Nonetheless, genomic research is proceeding, even in the absence of evident clinical value. Indeed, the identification of possible clinical utility rather than the pursuit of specific identified goals remains one of the major justifications for ongoing genomic research, such as the *All Of Us* project, formerly the Precision Medicine Initiative (Sankar & Parker, 2017; Scherr et al., 2017).

SCF hosted a third consortium meeting in Anchorage in August 2017. During the meeting, researchers from OU, MBIRI, and Chickasaw Nation's DRPH met the SCF Research Department and toured SCF's Anchorage Native Primary Care Center and the Alaska Area Specimen Bank. Consortium partners also presented progress on site-specific research activities, undertook practical training in deliberative democracy to prepare for future work involving community dialogue and deliberation, and discussed the purpose, design, and content of a cross-site survey to determine community perspectives on genomic research and related concepts. A fourth CEIGR meeting was hosted by the Chickasaw Nation DRPH in

December 2017. Consortium partners met to discuss common interests in biobanking in AN/AI community settings and federal Indian law pertaining to biobanking.

In addition to these consortium meetings, CEIGR partner sites participated in weekly conference calls to build rapport among individual researchers, develop an understanding of the socio-political and clinical context of partner site tribal communities, discuss ongoing and planned CEIGR research projects, and develop a shared research agenda. Although it took more than a year to get to this point, this working relationship led to a gradual convergence around central research questions and common data collection approaches, even as we remain open to local differences in the individual questions to be pursued.

The Benefits and Challenges of Inter-Partner Diversity

Educational Implications—The most important work products to emerge from the initial phase of the consortium’s work are the strong inter-partner relationships. These relationships positioned consortium partners to conduct effective, collaborative research among individuals who come from different cultures and political and historical backgrounds, are trained in different academic disciplines, and work for organizations with varying resources, capacities, expectations, and priorities.

An early example of this partnership’s commitment to collaboration was the change of the Center’s name from the “Center on American Indian and Alaska Native Genomic Research” to the “Center for the Ethics of Indigenous Genomic Research” in response to concerns among partner sites that the original name did not properly emphasize the role of ethics as foundational for genomic research and suggested the Center existed to promote genomic research in tribes. The revised name was arrived at through deliberation among partners and emphasizes the fundamental role of ethics and community processes in the Center’s work. This example illustrates CEIGR’s dedication to participatory practices as manifested through its broad and early use of stakeholder engagement and shared decision-making among partners.

Thus far, CEIGR consortium lessons learned have occurred through dialogue between CEIGR partners and have been due to the need of partners disaggregating ELSI questions for their respective tribal communities. As the partner site staff began to discuss past, current, and proposed genetic research, genomic research, and genomic medicine in their respective tribal communities, differences and some similarities in the ethical, cultural, legal and social implications began to emerge. It became clear that collaboration within the Center may not be possible for all activities as the tribal communities represented by the sites had differing priorities and experiences health care. For instance, during a discussion of biological specimen repositories, the issue of jurisdiction and application of federal Indian law on trust land arose. Trust land and tribal jurisdiction varies across the three tribal community partner sites of CEIGR: Alaska, Oklahoma, and South Dakota. These differences have important legal and social implications for the ELSI activities occurring within the Center.

Best Practices—There are many challenges and opportunities when conducting ELSI and corresponding genomics research within tribal communities. As AN/AI communities have

varied cultural, political, and historical backgrounds, there are meaningful differences and similarities in perceptions of the social role and value of research. Varying organizational capacities, constraints, and objectives affect whether partners can identify and meaningfully contribute to shared research objectives. Additionally, different disciplinary backgrounds among researchers will determine how a research team approaches ELSI, genomic research, and community engagement and which outcomes are designated as successful or necessary in the conduct of the endeavor.

Researchers have noted the importance of cultural and ethnic diversity on teams, which can help fuel innovation and creativity (Gastil, 2010; Konrad, 2006). Team members of different backgrounds can provide cultural awareness and sensitivity that may be lacking in homogeneous groups, of importance for researchers working with ethnically diverse populations. The development of multidisciplinary research teams has become a higher priority in health, medicine, and the sciences as scholars and policy makers see the need for leveraging expertise in the life sciences, physical sciences, social sciences, humanities, and law to understand and solve the complex, multi-dimensional problems common in health research. Representatives from the different consortium partners are trained in the theories, standards, and tools unique to their varied disciplinary backgrounds while having lived experience as community members and in some cases, tribal members of the AN/AI community.

To address these challenges posed by cross-cultural, intertribal, and multidisciplinary work, the CEIGR team has taken several steps to foster understanding and improve communication among team members. For example, major meetings have been and will continue to be held at sites across the consortium. Team members have also attended some non-CEIGR events together, such as MBIRI's annual research meeting and an ELSI academic conference. In addition, consortium members have had social gatherings and cultural exchanges during such meeting periods, which scholars have noted is important in building cohesiveness in work groups (Gastil, 2010). Moreover, the willingness of CEIGR leadership and the flexibility of the funding agency to acknowledge and accommodate the partner sites with time to align the ELSI, genomic research, and community engagement agenda of the CEIGR partnership with each community's priorities provides space for this consortium to progress successfully.

RESEARCH AGENDA

As we continue our work together, we recognize the hope that we would now have a clear single question we could ask in all partner sites using public deliberative methods was unrealistic as the partner sites have differing experiences with genomic research. CEIGR partner sites are exploring the relevant psychological, social, cultural, behavioral, and economic factors with local AN/AI leadership as they develop site-specific ELSI and genomic research. This exploration within CEIGR sites and across sites may serve as framework for other organizations seeking to conduct interdisciplinary ELSI research, including dialogue and/or deliberation work with diverse communities, in that it seeks to maintain local priorities and interests in dialogue both between diverse communities and with institutions of higher education.

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REFERENCES

- Abelson J, Blacksher EA, Li KK, Boesveld SE, & Goold SD (2013). Public deliberation in health policy and bioethics: mapping an emerging, interdisciplinary field. *Journal of Public Deliberation*, 9(1), 5.
- Angal J, Petersen JM, Tobacco D, Elliott AJ, & Network P (2016). Ethics Review for a Multi-Site Project Involving Tribal Nations in the Northern Plains. *J Empir Res Hum Res Ethics*, 11(2), 91–96. doi:10.1177/1556264616631657 [PubMed: 26928897]
- Avey JP, Hiratsuka VY, Beans JA, Trinidad SB, Tyndale RF, & Robinson RF (2016). Perceptions of pharmacogenetic research to guide tobacco cessation by patients, providers and leaders in a tribal healthcare setting. *Pharmacogenomics*, 17(4), 405–415. doi:10.2217/pgs.15.177 [PubMed: 26871371]
- Beans JA, Hiratsuka VY, Apok CR, Caindec K, Dillard DA, & Robinson RF (2018). Community Dissemination in a Tribal Health Setting: A Pharmacogenetics Case Study. *Am Indian Alsk Native Ment Health Res*, 25(1), 80–94. doi:10.5820/aian.2501.2018.80 [PubMed: 29671859]
- Bernhardt B (2014). Genetic counselors and the future of clinical genomics. *Genome medicine*, 6(7), 49–49. doi:10.1186/gm565 [PubMed: 25045402]
- Burkhalter S, Gastil J, & Kelshaw T (2002). A conceptual definition and theoretical model of public deliberation in small face—to—face groups. *Communication theory*, 12(4), 398–422.
- Consortium IH (2003). The International HapMap Project. *Nature*, 426(6968), 789–796. doi:10.1038/nature02168 [PubMed: 14685227]
- Dillard DA, Caindec K, Dirks LG, & Hiratsuka VY (2018). Challenges in Engaging and Disseminating Health Research Results Among Alaska Native and American Indian People in Southcentral Alaska. *Am Indian Alsk Native Ment Health Res*, 25(1), 3–18. doi:10.5820/aian.2501.2018.3 [PubMed: 29671854]
- Dirks LG, Shaw JL, Hiratsuka VY, Beans JA, Kelly JJ, & Dillard DA (2019). Perspectives on communication and engagement with regard to collecting biospecimens and family health histories for cancer research in a rural Alaska Native community. *J Community Genet* doi:10.1007/s12687-019-00408-9
- Fisher PA, & Ball TJ (2003). Tribal participatory research: mechanisms of a collaborative model. *Am J Community Psychol*, 32(3–4), 207–216. [PubMed: 14703257]
- Fisher PA, & Ball TJ (2005). Balancing empiricism and local cultural knowledge in the design of prevention research. *Journal of Urban Health : Bulletin of the New York Academy of Medicine*, 82(Suppl 3), iii44–iii55. doi:10.1093/jurban/jti063 [PubMed: 15933330]
- Foulks EF (1989). Misalliances in the Barrow Alcohol Study. *Am Indian Alsk Native Ment Health Res*, 2(3), 7–17. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/2490286> [PubMed: 2490286]
- Garrison NA (2013). Genomic Justice for Native Americans: Impact of the Havasupai Case on Genetic Research. *Sci Technol Human Values*, 38(2), 201–223. doi:10.1177/0162243912470009
- Gastil J (2010). *The group in society Los Angeles*: SAGE Publications.
- Gilbert SG (2006). Supplementing the traditional institutional review board with an environmental health and community review board. *Environ Health Perspect*, 114(10), 1626–1629. [PubMed: 17035155]
- Goins RT, Garrouette EM, Fox SL, Dee Geiger S, & Manson SM (2011). Theory and Practice in Participatory Research: Lessons from the Native Elder Care Study. *Gerontologist*, 51(3), 285–294. doi:10.1093/geront/gnq130 [PubMed: 21292753]
- Green ED, Watson JD, & Collins FS (2015). Human Genome Project: Twenty-five years of big biology. *Nature*, 526(7571), 29–31. doi:10.1038/526029a [PubMed: 26432225]

- Greenbaum D (2013). Grand challenge: ELSI in a changing global environment. *Frontiers in genetics*, 4, 158–158. doi:10.3389/fgene.2013.00158 [PubMed: 23990842]
- Harding A, Harper B, Stone D, O'Neill C, Berger P, Harris S, & Donatuto J (2012). Conducting Research with Tribal Communities: Sovereignty, Ethics, and Data-Sharing Issues. *Environmental Health Perspectives*, 120(1), 6–10. doi:10.1289/ehp.1103904 [PubMed: 21890450]
- Hiratsuka VY, Beans JA, Robinson RF, Shaw JL, Sylvester I, & Dillard DA (2017). Self-Determination in Health Research: An Alaska Native Example of Tribal Ownership and Research Regulation. *Int J Environ Res Public Health*, 14(11), 1324. doi:10.3390/ijerph14111324
- Hiratsuka VY, Brown JK, Hoeft TJ, & Dillard DA (2012). Alaska native people's perceptions, understandings, and expectations for research involving biological specimens. *Int J Circumpolar Health*, 71, 18642. doi:10.3402/ijch.v71i0.18642 [PubMed: 22663942]
- Hull SC, & Wilson DR (2017). Beyond Belmont: Ensuring Respect for AI/AN Communities Through Tribal IRBs, Laws, and Policies. *The American Journal of Bioethics*, 17(7), 60–62. doi:10.1080/15265161.2017.1328531
- James R, Tsosie R, Sahota P, Parker M, Dillard D, Sylvester I, ... Burke W (2014). Exploring pathways to trust: a tribal perspective on data sharing. *Genet Med*, 16(11), 820–826. doi:10.1038/gim.2014.47 [PubMed: 24830328]
- Kaiser J (2019). Native American groups wary of big U.S. biobank. *Science*, 364(6443), 812–813. doi:10.1126/science.364.6443.812 [PubMed: 31147498]
- Kelley A, Belcourt-Dittloff A, Belcourt C, & Belcourt G (2013). Research Ethics and Indigenous Communities. *Am J Public Health*, 103(12), 2146–2152. doi:10.2105/AJPH.2013.301522 [PubMed: 24134372]
- Konrad AM (2006). Leveraging Workplace Diversity in Organizations. *Organization Management Journal*, 3(3), 164–189. doi:10.1057/omj.2006.18
- LaVeaux D, & Christopher S (2009). Contextualizing CBPR: Key Principles of CBPR meet the Indigenous research context. *Pimatisiwin*, 7(1), 1–1. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2818123/> [PubMed: 20150951]
- Manson SM, Garrouette E, Goins RT, & Henderson PN (2004). Access, relevance, and control in the research process: lessons from Indian country. *J Aging Health*, 16(5 Suppl), 58s–77s. doi:10.1177/0898264304268149 [PubMed: 15448287]
- McEwen JE, Boyer JT, Sun KY, Rothenberg KH, Lockhart NC, & Guyer MS (2014). The Ethical, Legal, and Social Implications Program of the National Human Genome Research Institute: reflections on an ongoing experiment. *Annu Rev Genomics Hum Genet*, 15, 481–505. doi:10.1146/annurev-genom-090413-025327 [PubMed: 24773317]
- Mello MM, & Wolf LE (2010). The Havasupai Indian tribe case—lessons for research involving stored biologic samples. *N Engl J Med*, 363(3), 204–207. doi:10.1056/NEJMp1005203 [PubMed: 20538622]
- Morton DJ, Proudfit J, Calac D, Portillo M, Lofton-Fitzsimmons G, Molina T, ... Majel-McCauley R (2013). Creating research capacity through a tribally based institutional review board. *Am J Public Health*, 103(12), 2160–2164. doi:10.2105/ajph.2013.301473 [PubMed: 24134381]
- O'Doherty KC, & Burgess MM (2009). Engaging the Public on Biobanks: Outcomes of the BC Biobank Deliberation. *Public Health Genomics*, 12(4), 203–215. doi:10.1159/000167801 [PubMed: 19367089]
- Pacheco CM, Daley SM, Brown T, Filippi M, Greiner KA, & Daley CM (2013). Moving Forward: Breaking the Cycle of Mistrust Between American Indians and Researchers. *Am J Public Health*, 103(12), 2152–2159. doi:10.2105/AJPH.2013.301480 [PubMed: 24134368]
- Parkinson AJ, Hennessy T, Bulkow L, & Smith HS (2013). The Alaska Area Specimen Bank: a tribal-federal partnership to maintain and manage a resource for health research. *Int J Circumpolar Health*, 72, 20607. doi:10.3402/ijch.v72i0.20607 [PubMed: 23599909]
- Popejoy AB, & Fullerton SM (2016). Genomics is failing on diversity. *Nature*, 538(7624), 161–164. doi:10.1038/538161a [PubMed: 27734877]
- Sankar PL, & Parker LS (2017). The Precision Medicine Initiative's All of Us Research Program: an agenda for research on its ethical, legal, and social issues. *Genet Med*, 19(7), 743–750. doi:10.1038/gim.2016.183 [PubMed: 27929525]

- Scherr CL, Dean M, Clayton MF, Hesse BW, Silk K, Street RL Jr., & Krieger J (2017). A Research Agenda for Communication Scholars in the Precision Medicine Era. *J Health Commun*, 22(10), 839–848. doi:10.1080/10810730.2017.1363324 [PubMed: 28956728]
- Shaw JL, Robinson R, Starks H, Burke W, & Dillard DA (2013). Risk, Reward, and the Double-Edged Sword: Perspectives on Pharmacogenetic Research and Clinical Testing Among Alaska Native People. *Am J Public Health*, 103(12), 2220–2225. doi:10.2105/ajph.2013.301596 [PubMed: 24134351]
- Stark Z, Dolman L, Manolio TA, Ozenberger B, Hill SL, Caulfield MJ, ... North KN (2019). Integrating Genomics into Healthcare: A Global Responsibility. *The American Journal of Human Genetics*, 104(1), 13–20. doi:10.1016/j.ajhg.2018.11.014 [PubMed: 30609404]
- USCCR. (2018). Broken Promises: Continuing Federal Funding Shortfall for Native Americans Retrieved from <https://www.usccr.gov/pubs/2018/12-20-Broken-Promises.pdf>
- Warne DK, & Frizzell LB (2014). American Indian health policy: historical trends and contemporary issues. *Am J Public Health*, 104 Suppl 3, S263–267. doi:10.2105/ajph.2013.301682 [PubMed: 24754649]

Table 1.

Organizational Partners in the Center for the Ethics of Indigenous Genomic Research consortium

Collaborative Organizations	Organization type	Location & Alaska Native/American Indian (AN/AI) community represented	Key features related to genomic research
University of Oklahoma	Public research university	Norman, Oklahoma- no specific AN/AI community	<ul style="list-style-type: none"> • Laboratories for Molecular Anthropology & Human Microbiome Research • Oklahoma Medical Research Foundation • Native American Law Program Center for Applied Social Research • Center for Risk & Crisis Management • Native American Studies Program • Current portfolio of microbiome research with AN/AI peoples
Chickasaw Nation's Division of Research and Population Health	Federally recognized tribal government	Ada, Oklahoma- Chickasaw Nation's jurisdictional territory includes 7,648 square miles of south-central Oklahoma and encompasses all or parts of 13 Oklahoma counties	<ul style="list-style-type: none"> • Located within tribally managed research and health care systems • Federally registered IRB • Proposed genomic research proposals
Missouri Breaks Industries Research Incorporated	AI owned business	Eagle Butte, South Dakota- Cheyenne River Sioux Tribe of the Cheyenne River Reservation, Oglala Sioux Tribe, Rosebud Sioux Tribe of the Rosebud Indian Reservation, Spirit Lake Tribe, & Standing Rock Sioux Tribe of North & South Dakota	<ul style="list-style-type: none"> • Strong Heart Study field center • Development of biorepository • Current portfolio of epigenetic research
Southcentral Foundation	Cook Inlet Region, Inc. nonprofit health care organization	Anchorage, Alaska- AN/AI people living in Anchorage & the Matanuska-Susitna Borough, 55 rural villages in the Indian Health Service Anchorage Service Unit, a geographical area stretching 107,400 square miles across Southcentral Alaska – extending from the Canadian border on the east to the Aleutian Chain and Pribilof Islands on the west.	<ul style="list-style-type: none"> • Northwest Pharmacogenetics Network • Current portfolio of ELSI and pharmacogenetic research • Co-management of the Alaska Area Specimen Bank

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