


## Perspective

# Codesigning a community-based participatory research project to assess tribal perspectives on privacy and health data sharing: A report from the Strong Heart Study

Cynthia Triplett<sup>1,2</sup>, Burgundy J. Fletcher<sup>3</sup>, Riley I. Taitingfong<sup>1</sup>, Ying Zhang<sup>4</sup>,  
Tauqeer Ali<sup>4</sup>, Lucila Ohno-Machado<sup>5,6</sup>, and Cinnamon S. Bloss <sup>1,2,6,7</sup>

<sup>1</sup>Herbert Wertheim School of Public Health and Longevity Science, University of California, La Jolla, California, USA, <sup>2</sup>Center for Empathy and Technology, University of California, La Jolla, California, USA, <sup>3</sup>Department of Ethnic Studies, University of California, La Jolla, California, USA, <sup>4</sup>Department of Biostatistics and Epidemiology, A Center for American Indian Health Research, University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma, USA, <sup>5</sup>Veteran Affairs San Diego Healthcare System, San Diego, California, USA, <sup>6</sup>Department of Biomedical Informatics, University of California Health, La Jolla, California, USA and <sup>7</sup>Department of Psychiatry, School of Medicine, University of California, La Jolla, California, USA

Corresponding Author: Cinnamon S. Bloss, PhD, Herbert Wertheim School of Public Health and Longevity Science, University of California, 9500 Gilman Drive MC 0896, La Jolla, CA 92093-0896, USA; [cbloss@eng.ucsd.edu](mailto:cbloss@eng.ucsd.edu)

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## ABSTRACT

Broad health data sharing raises myriad ethical issues related to data protection and privacy. These issues are of particular relevance to Native Americans, who reserve distinct individual and collective rights to control data about their communities. We sought to gather input from tribal community leaders on how best to understand health data privacy and sharing preferences in this population. We conducted a workshop with 14 tribal leaders connected to the Strong Heart Study to codesign a research study to assess preferences concerning health data privacy for biomedical research. Workshop participants provided specific recommendations regarding who should be consulted, what questions should be posed, and what methods should be used, underscoring the importance of relationship-building between researchers and tribal communities. Biomedical researchers and informaticians who collect and analyze health information from Native communities have a unique responsibility to safeguard these data in ways that align to the preferences of specific communities.

**Key words:** health information privacy, tribal consultation, community-based participatory research (CBPR), indigenous populations

## INTRODUCTION

In November 2019, the US National Institutes of Health (NIH) released a draft policy outlining a new requirement that all NIH-funded investigators make their datasets available to other researchers.<sup>1</sup> Aimed at facilitating and promoting collaboration and data sharing among research groups, this draft policy presented both opportunities and challenges that varied by the characteristics of the data and the populations those data represent. Specifically, it was

unclear how the draft policy would be implemented for studies involving data from American Indian tribes. Since 2000, federal agencies in the United States have been charged by Executive Order 13175 to engage in open, continuous, and meaningful consultation and collaboration with tribal officials when developing any policies that have tribal implications.<sup>2</sup> The Department of Health and Human Services (HHS) later codified this into a Tribal Consultation Policy (TCP).<sup>3</sup>

Organizationally situated under the HHS, the NIH recognizes tribal sovereignty and currently uses tribal approval to develop processes governing data originating from American Indian tribes, including processes for health data collection, sharing, and use in research. In April 2020, the NIH initiated a Tribal Consultation on the proposed draft data management and sharing policy, and subsequently released a report summarizing three themes and eight consultation recommendations.<sup>4</sup> Based on these recommendations, the NIH released their final NIH Policy for Data Management and Sharing in October 2020,<sup>5</sup> noting that they are still in the process of developing supplemental information for researchers who plan to work with Native communities.

Many tribal leaders recognize the benefit of academic research partnerships,<sup>6</sup> and there has been agreement between tribal leaders and the entities who work with them that certain core values should be acknowledged when conducting research with tribal communities. These include an acknowledgment that Indigenous or American Indian knowledge(s) are valid and should be incorporated into the project, that there is no such thing as culturally neutral research, and that responsible stewardship includes a shared interpretation of the data collected.<sup>7</sup> Although the new final NIH policy takes these core values into account, it is unclear how they can be implemented in practice so that American Indian populations are both included in the research, and so that their data are shared according to these core values. In this context, we also note that around the world, Indigenous Peoples are leading movements aimed at Indigenous Data Sovereignty (IDSov), or, “the right of a nation to govern the collection, ownership, and application of its own data [...] deriv[ing] from tribes’ inherent right to govern their peoples, lands, and resources.”<sup>8</sup> IDSov movements are well underway in the United States, Aotearoa/New Zealand, Australia, and Canada, where Indigenous leaders and scholars are pushing for self-governance of data, including biomedical and genomic samples and information, in alignment with Indigenous communities’ collective values and interests.<sup>9–11</sup>

The new NIH policy is of particular interest to both researchers and participants involved with the Strong Heart Study (SHS), the largest epidemiologic study of American Indian health in the United States.<sup>12,13</sup> Although the SHS began as a study focused on cardiovascular disease, over the years, it has expanded to include other health research on cancers, liver diseases, inflammatory conditions, genetics, and genomics. Through this work, the study has resulted in the production of a large amount of personally identifiable information, including personal health information. Investigators affiliated with the SHS are committed to the doctrine that research requires full partnership and ongoing consultation with tribal communities.<sup>14</sup> The authors of this paper comprise one research team working on a study ancillary to the SHS (integrating Data for Analysis, anonymization and Sharing, or iDASH-SHS, NHLBI R01 HL136835). The goal of iDASH-SHS is to facilitate shared access of clinical and genetic data of tribal populations to researchers who are approved to conduct a study or query by developing a framework to move the analysis code to the data rather than moving the data outside the SHS enclave.<sup>15</sup> To inform the development of this framework, we sought to gain an understanding of SHS tribal members’ data sharing expectations and preferences, while keeping in mind the themes and recommendations articulated through tribal consultation, together with the requirements and goals of the NIH data sharing policy.

In line with calls for collaborative research practices among researchers and communities,<sup>16–20</sup> we opted to take a community-

based participatory research (CBPR) approach. CBPR focuses on the development of equitable partnerships to coproduce and cointerpret knowledge in order to realize shared benefits.<sup>21–23</sup> Under the CBPR framework, community members function as full and equal partners in the research rather than having a limited role as participants of the investigation. This approach allows a greater diversity of voices to be heard, which is particularly useful for research involving moral and/or ethical complexities that must be addressed collaboratively. In the case of genomic data sharing, for example, risks of harm are unique due to the population group being highly identifiable and the implications for critical issues such as sovereignty, kinship, and ties to land.<sup>19</sup> The harms faced by Indigenous communities when these key considerations are overlooked in research are well documented, for instance in the cases of the Human Genome Diversity Project,<sup>24</sup> Barrow Alcohol Study,<sup>25</sup> or Arizona State University versus Havasupai lawsuit,<sup>19,26</sup> which prompted a range of concerns including consent, handling of biospecimens, and the potential for patenting and commercialization of genetic data.

We designed our general approach with 3 phases: (1) Phase 1—Conduct a workshop with tribal leaders to discuss privacy and collaboratively identify a process to work with tribal members (ie, codesign a research project to assess tribal perspectives on privacy and health data sharing); (2) Phase 2—Implement the codesigned approach identified in Phase 1; and (3) Phase 3—Hold a roundtable discussion with tribal leaders to cointerpret the results collected from Phase 2.

In this paper, we describe Phase 1 of this work: a collaboration between researchers from the University of California San Diego (UCSD), the SHS Coordinating Center at the University of Oklahoma Health Sciences Center (OUHSC), and a subset of American Indian tribes and their leaders who have been participating in the SHS for over 30 years. We report the results of our Phase 1 workshop conducted in December 2019 that was focused on bringing tribal leaders, tribal members, and SHS researchers together to codesign a research project to assess tribal perspectives on privacy and health data sharing. The types of data of focus were clinical and genetic data.

## METHODS

We convened a workshop to codesign a research study to assess tribal preferences pertaining to health data privacy. Formal workshop participants included a facilitator (BJF; a researcher and citizen of another tribe in Oklahoma), four researchers, and nine tribal community members (SHS tribes). Community members included retired SHS staff, community health advocates, elders, physicians, and tribal presidents and chairs. We utilized elements of design thinking in our approach. Design thinking is a formal method that encourages both practical and creative solutions by asking stakeholders to thoughtfully generate as many ideas as possible in response to specific prompts.<sup>27</sup> A high-level goal of the workshop was to plan a research project that would generate knowledge of SHS tribal community perspectives about privacy and health data sharing by ensuring that the right questions are posed to the most appropriate groups of people.

### Cultural safety

Prior to the conduct of the workshop, we sought feedback on our study design and methods from a tribal research consultant. Our study was also reviewed by the SHS steering committee, which

includes an Ethics Sub-committee led by Native investigators. Together, they provided cultural safety training during monthly meetings. Members of our team also met multiple times per month with SHS investigators, who have a long history and experience working with the tribes in the SHS.

### Reflexivity statement

Members of our research team hold unique positionalities, relations, and experiences that shaped our approach to this work. Five members of our team identify as female (71.4%), and education ranges from having obtained a bachelor's degree (one individual) to having obtained a doctoral degree (five individuals). From a disciplinary standpoint, our team has expertise in public health, ethnic studies, communication, biomedical informatics, medicine, clinical psychology, and epidemiology. The workshop prompts were shaped by team members' expertise in qualitative research, as well as lived experiences of team members from marginalized identities.

### Community consent

Prior to initiation, this project received tribal consent from the Southwest Oklahoma Intertribal Health Board (SWOIHCB), which is comprised of representatives from each of the seven Oklahoma SHS-participating tribes. The SWOIHCB reviews all newly proposed projects, and if approved, provides the team with a Resolution of Support. Investigators are then responsible for presenting progress reports at monthly SWOIHCB meetings to keep tribal representatives up to date.

### Workshop process

#### Informal welcome

All participants were greeted at the door by research staff who were familiar to them. Food that was purchased locally was provided for invited participants as well as their accompanying guests. There was a brief time of conversation prior to the consent process where participants could, at a relaxed pace, catch up with each other and with SHS staff.

#### Individual consent

Given the robust body of literature showing a correlation between poor consent processes and research mistrust,<sup>28,29</sup> we sought to ensure all individuals were adequately informed about our study, including any potential benefits and risks to themselves or their communities. To this end, we endeavored to review the consent document thoroughly and communally. Specifically, we projected an enlarged version of the consent form onto the wall and reviewed it with all participants simultaneously. The facilitator read the consent form section-by-section as participants followed along on their own printed copies, stopping periodically to ask if anyone had any questions. The facilitator also pointed out key information, defined particular academic or scientific terminology, and periodically invoked their own community affiliation as a citizen of another tribe in Oklahoma. This approach addressed the individual consent processes required of our institutional IRBs, while creating shared space for participants to ask questions and discuss the implications of their participation. Particular emphasis was put on how to opt out of the study and with whom to speak if a participant had any concerns or questions about the study. All nine community participants who were present agreed to participate.

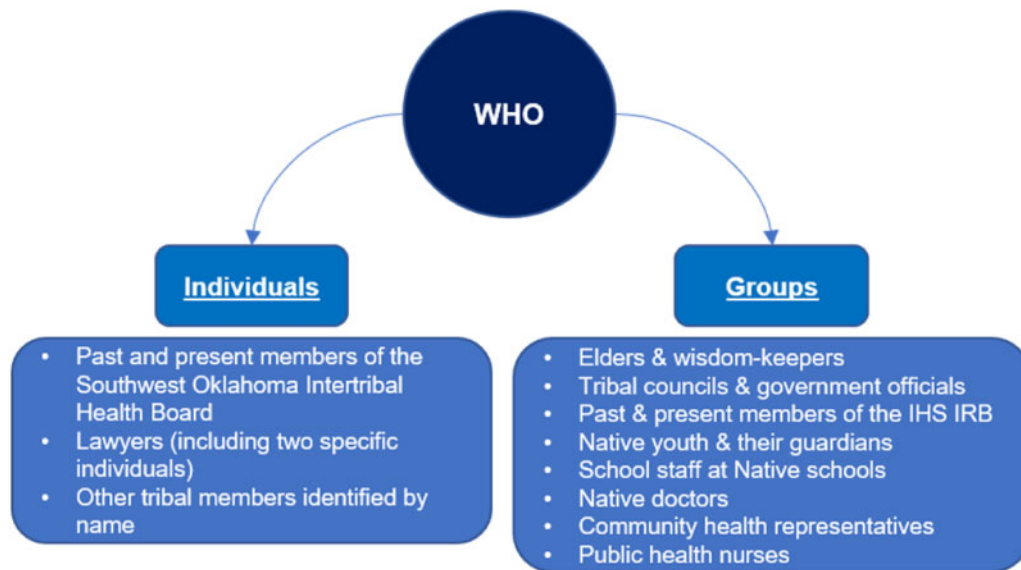
The discussion then began with roundtable introductions. This was intentionally designed to be an unhurried time of sharing, start-

ing with the nine tribal community leaders and members seated around the table, and then expanding to the other individuals (family members of tribal members, researchers) in the room. Participants were asked to share their names, titles, tribal affiliations, connection to SHS communities, and their reason for being in attendance. It should be noted that no one was rushed through the introductory process as the goal was to create a relaxed, collaborative environment. After introductions, the facilitator led a generative discussion in response to three major questions intended to codesign Phase 2 of the study: (1) Who should we talk to? (2) What should we ask them? and (3) When, where, and how should we talk to them? These questions were intended to help us broach conversations and potentially sensitive topics about inclusive ways to recruit participants, what facilitators should know about engaging participants, and what format might help people feel more comfortable talking about health data privacy. Members of the research team took written notes during the workshop; the session was not audio or video recorded. The research team provided their personal contact information and university email addresses for follow-up thoughts. The group discussions related to each of the aforementioned questions are described below. The data that support the findings of this study are available from the corresponding author upon reasonable request.

## RESULTS

During the introductions, many participants shared information related to their personal and professional ties to the SHS, either as study participants, current and/or former employees, or sometimes both participant and employee. They candidly shared their thoughts on the opportunities and the challenges of such a long-running and ever-expanding federally funded research study and shared ways in which they could envision current and future SHS investigators engaging with communities in ways that are focused on specific research questions. Participants voiced that the continuation of the SHS was crucial to the health of their respective communities, signifying their personal investment in the success of the study. This portion of the workshop suggested that participants were taking the call to collaboration seriously.

As the facilitator moved the discussion toward the first of our three main questions (ie, who we should talk to for this research), it quickly became apparent that participants expected and recommended that a wide swath of individuals be consulted. Participants named specific individuals (eg, two individuals who are attorneys) as well as groups of people (Figure 1). For the second question (what should we ask participants), workshop attendees initially had difficulty imagining the content of specific research questions, but ultimately suggested that researchers start by asking people how important privacy is to them. During the brainstorm, the group voiced wonderings about the policies governing existing data versus data that had not yet been collected and warned that there might be cases in which tribes have hard limits on data sharing, and that those limits may not be expressly articulated in any easily accessible written documents. The third and final question that was posed to participants involved logistical questions about when, where, and how to best engage members of American Indian communities. The workshop participants provided several suggestions rooted in their cultural practices (Figure 2). These suggestions emphasize the importance of relationship-building through both formal (eg, structured meetings and presentations) and informal (eg, cultural events



**Figure 1.** Who in the community should be included in the research?

and local communal spaces) activities, and practices that foster inclusivity and accessibility of information.

As the formally guided discussion came to a close, participants encouraged investigators to keep abreast of and in compliance with Indian Health Services (IHS) regulations and other legislation that impacts tribal-researcher relations. The conversation then turned to a discussion of whether researchers, especially those who might access data from tribal communities under the new NIH policy, would be aware of the history of Presidential Directives about tribal consultation.<sup>2</sup> One participant who self-identified as a retired medical professional and US veteran expressed that all researchers working with tribal communities need to recognize tribal sovereignty and should understand the position of tribal governments within the larger structure of American government prior to initiating any research. Participants cited examples of noncompliance, leading to lawsuits against federal agencies in which the tribes were victorious. Further questions were raised about whether NIH leadership and staff were aware of this history and whether it would be taken into account in the final policy (given that this workshop was conducted after the draft policy came out but prior to the release of the final policy). Lastly, the group provided several ‘cultural tips’ for investigators (Table 1). These tips are specific to the participating SHS communities with whom we partnered, and may not be generalizable to other groups or Native communities.

## DISCUSSION

Informaticians and biomedical researchers who collect and study health information from Native communities have a unique responsibility to safeguard these data in ways that align to the preferences of specific communities. Here, we describe how a multidisciplinary, NIH-funded research team applied an early-stage CBPR approach to begin to ascertain community preferences and codesign further research to inform data collection, data sharing practices, and safeguards for a biomedical informatics research effort. The insights learned, while not generalizable to all Native communities, are the result of a process that represents a valuable approach for research-

ers in the informatics community who are working with (or seeking to work with) tribal communities and their data.

As participants provided guidance about potential topics to discuss and individuals to consult, we were struck by the inclusivity of the suggestions. For example, the response to one of our main questions (“Who should we talk to?”) was essentially “everyone”—from elders and tribal councils to Native youth and their guardians. Likewise, the response to logistical questions of when, where, and how we should speak to those identified was essentially “in as many ways as possible”—individually, in groups, more than once, and with the option of collecting written responses. This input suggests that all members of tribal communities (ie, “everyone”) should be consulted about the privacy of tribal health information, including those individuals from whom we might not immediately think to solicit input (eg, Native youth). While it may be difficult in practice to consult every individual within a large, diffuse tribal community or nation, workshop participants’ desire for researchers to be as inclusive as possible in such efforts is clear.

The communal nature of some American Indian tribal cultures stands in contrast to individualistic Western conceptualizations of privacy, and by extension, research about privacy. Western approaches are focused at the individual level; Western definitions of privacy are synonymous with self-governance and individualism, and existing regulations are designed to protect against individual-level risks. However, the focus on individual autonomy is incongruent with “Indigenous communitarian ethics”<sup>30</sup> and research has suggested that privacy and consent policies fall short in protecting tribal communities as group entities.<sup>31–34</sup> Indeed, Native and Indigenous researchers have emphasized the importance of collective well-being and protection in tribal communities, pointing out the high stakes of research outcomes that may affect the entire tribe (eg, genomic research that is or can be used to disenroll tribal members<sup>35</sup>). Our findings suggest that individual tribal members desire to have highly inclusive collective discussions when making decisions about their health data privacy, pointing to the need for additional studies about Native perspectives on the use of health data for research.<sup>36</sup>

Furthermore, there is a need for researchers to seriously consider familial and kinship ties when developing research plans that involve



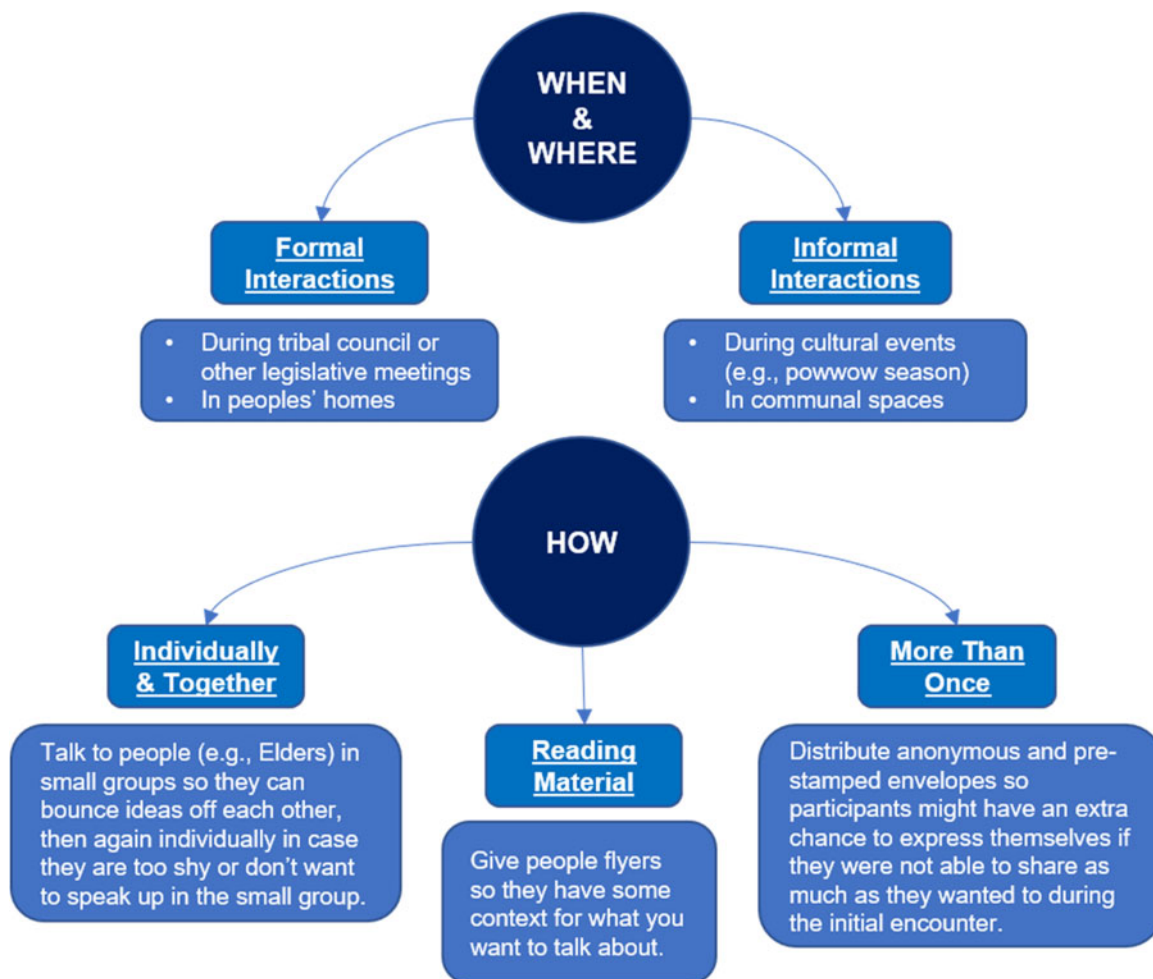


Figure 2. When, where, and how should we conduct this research?

Table 1. Cultural expectations expressed by workshop participants

Expectation	Example
Eye contact and physical touch	When interacting with elders, use a gentle touch during your hand-shake, and do not spend too much time looking them in the eye.
Boundaries around compliments	Do not verbally admire their jewelry because they may give it to you. If given a gift, put it in your pocket and look at it later.
Providing food to the community	The provision of food is an expectation—not just for the participant but for the participant’s family as well. It is also custom to offer a blessing for the food prior to eating.
Spend time in the community	Spend time and attend tribal meetings—with no agenda—just to hear and learn how business is conducted.

American Indian communities. For example, traditional assumptions of privacy during an individual research interview (eg, one researcher and one participant, located in a room where the

conversation is not easily overheard by others, etc.) might not be feasible nor desirable. At our workshop, one of the community members was an uninvited individual who accompanied an invited participant to the session. Participants mentioned this and explained that tribal members often invite family and friends to join them at local events, and if they live farther away from the town center, they might travel with others who also need to go into town to run errands. In these situations, participants noted, the expectation is that investigators would invite such guests to stay, eat, and participate, if willing. This kind of pivot requires flexibility and forethought on the part of the research team, for example, ensuring extra incentives, meals, and seats are prepared so as to avoid any discomfort to tribal community members.

The fact that conversation turned to US Presidential Directives is also noteworthy. After the workshop formally concluded, the same participant who raised the topic stopped to speak with CT and BJF to reiterate their points. Table 2 charts the Executive Orders and Presidential Memoranda, or “Presidential Directives,” to which this Elder referred. Our takeaway from this encounter was that Native community members are aware that researchers often come to their communities with specific priorities—priorities which, according to this participant, should be considered in light of the ongoing and meaningful consultation outlined in the Executive Orders and Presidential Memoranda. An awareness of federal directives for tribal

**Table 2.** Examples of US policy development of tribal consultation

Directive	Date	Description
Executive Order 12866 “Regulatory Planning and Review”	September 20, 1993	Outlines guidelines to improve the internal workings of the federal government and its regulatory processes so as not to be costly, ineffective, and overly burdensome on the American people, including the tribes.
Executive Order 12875 “Enhancing the Intergovernmental Partnership”	October 26, 1993	Again addresses burdensome costs of federal mandates on State, local, and tribal governments with the added intent to allow these governments the flexibility to tailor “Federal programs to meet the unique needs of their communities.”
Memorandum on Government-to-Government Relations with Native American Tribal Governments	April 29, 1994	Addressed to the Heads of Executive Departments and Agencies to “ensure that the rights of sovereign tribal governments are fully respected” by federal government officials and employees.
Executive Order 13175 “Consultation and Coordination with Indian Tribal Governments”	November 6, 2000	Addresses the unique relationship that the US government has with sovereign tribal nations. This Order defines the terms “Indian tribe,” “tribal officials,” and “policies that have tribal implications,” and outlines fundamental principles that should be upheld when interacting with sovereign tribal nations. Importantly, this Order cements the idea of “meaningful and timely consultation.”
Memorandum on Government-to-Government Relationship with Tribal Governments	September 23, 2004	A second iteration of the 1994 memorandum reiterating tribal sovereignty and tribal rights to self-govern. Again addressed to Heads of Executive Departments and Agencies, this Memorandum includes a renewed commitment to the relationship between the Federal Government and federally recognized tribes.
Memorandum on Tribal Consultation	November 5, 2009	Provides clarification on Executive Order 13175 and acknowledges that “consultation is a critical ingredient of a sound and productive Federal-tribal relationship.”

consultation, as well as historic conflicts that have arisen when research entities do not comply with them, will be particularly instructive for researchers as the NIH finalizes its supplemental information for researchers working with Native communities.

In the context of the current project, “ongoing and meaningful consultation” might include proactive efforts that seek to hear and learn from community members, inclusively welcoming participants and any guests they bring, and staying mindful of the inherent power dynamic that exists between researchers and community members. Our conclusions are aligned with the final NIH Policy for Data Management and Sharing, and we supplement that report with our own key takeaways and more specific recommendations for research with SHS tribal communities (Table 3).

## CONCLUSION

This paper describes our community-based participatory approach to design a study to understand attitudes toward health data privacy among SHS tribal community members. The workshop was the first step (Phase 1) of our project, and we believe this process of consulting with tribal elders and tribal leadership was valuable for building relationships and trust, as well as generation of ideas and design elements that were novel to the research team. A common theme across all the recommended research design elements was inclusivity and the need to talk with a diverse cross-section of the community and to use a range of methods, both formal and informal, particularly when studying a concept as complex and sociopolitically fraught as health data privacy.

There are some limitations of this work. First, it is important to note that the findings reported in this manuscript reflect the ideas and customs of leaders from six federally recognized tribes that participate in the SHS. To put this into context, there are 574 federally recognized tribes and over 200 tribes without federal recognition in the United States, each with distinct lands, histories, traditions, and languages. Our findings should therefore not be considered reflective of all tribal communities across the United States. To preserve participant privacy, we did not collect personal identifying information about the participants; we therefore cannot characterize our findings in terms of demographic traits, such as Native Americans living in urban versus rural settings. Additionally, given the CBPR approach of this work, recommendations regarding research design are specific to the context of the SHS, an epidemiological study that works with participating tribes’ clinical and genetic data. Thus, the recommendations may have less applicability for researchers working on projects that deal with different types of data. It should also be noted that some participants of the workshop were past or current SHS employees. These professional ties to the SHS may have led participants to speak more cautiously, despite our taking steps to design the workshop in such a way that would mitigate this possibility.

Recognizing that the development of new technology and analysis techniques often outpace changes to governance and policy, informaticians and biomedical researchers working with tribal communities and their data must take initiative to adhere to community wishes and preferences regarding the use of those data. The design of any research study, especially one aiming to understand tribal communities’ health privacy and data sharing preferences, should first and foremost consult with members of the communities. Our

**Table 3.** Key takeaways and recommendations for research with SHS tribal communities

## Listen to and learn from community members

- *Build in extra time on site to accommodate invitations to gather with community members for impromptu activities.* Building rapport and strengthening trust may take the form of meetings with no agendas, tours of reservation lands, or visits to cultural sites such as tribal heritage museums.
- *Seek out the opinions, ideas, and actions of Native teenagers and young children.* Both the young and the old in Native communities are held in high regard with the knowledge that each generation is critical to familial and community well-being. The opinions, ideas, and actions of teenagers and young children are heard and seen.

## Radical inclusion

- *Provide a hot meal not only for participants but for people they bring.* Like many peoples and cultures, Native Americans have long traditions of sharing food, having hot food to offer extended family, friends, visitors, or sometimes unknown travelers. The custom of eating together is a form of relationship-building.
- *Prepare extra incentives to be able to pay unexpected participants.* Consider uninvited or unexpected guests to be bonuses, rather than burdens.

## Stay mindful of the power dynamic between researchers and communities

- *Put money back into the local/tribal economy.* Demonstrating awareness of the inherently imbalanced power dynamic between researchers and community members, researchers can respectfully contribute to the flourishing of tribal communities by purchasing food from local markets, restaurants, or Native vendors.

findings also suggest that research with some tribal communities may also benefit from taking into account a relational worldview, group identity and collective privacy protection prior to initiation.

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## AUTHOR CONTRIBUTIONS

CT: methodology; investigation; formal analysis; writing—original draft; writing—review & editing; project administration. BJF: methodology; investigation; formal analysis; writing—review & editing; project administration. RIT: conceptualization; methodology; writing—review & editing. YZ: investigation; resources; writing—review & editing; supervision; project administration. TA: investigation; resources; writing—review & editing; project administration. LO-M: conceptualization; resources; writing—review & editing; funding acquisition. CSB: conceptualization; methodology; investigation; formal analysis; resources; writing—review & editing; supervision; funding acquisition.

## ETHICS APPROVAL

This study was reviewed and approved by the Institutional Review Board for the Protection of Human Subjects at the University of Oklahoma Health Sciences Center (IRB #9922). Additionally, this manuscript has been reviewed and approved by the participating SHS tribes in Oklahoma, Arizona, and the Dakotas, and their respective IHS IRBs.

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## CONFLICT OF INTEREST STATEMENT

None declared.

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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