NIH TRIBAL CONSULTATION REPORT

NIH DRAFT POLICY FOR DATA MANAGEMENT AND SHARING

National Institutes of Health

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National Institutes of Health

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PREFACE

Dear Tribal Leader or Urban Indian Organization Leader:

We recognize that American Indian/Alaskan Native (AI/AN) communities are facing tremendous hardships as a result of the COVID-19 pandemic. We aim to continue advancing biomedical research to improve health outcomes for the future of all AI/AN communities. As you may recall, last April NIH announced plans to work in partnership with Tribal Nations to solicit input on NIH's proposed data management and sharing policy efforts[1]. We are pleased to share with you the attached final report from this Tribal Consultation and update you on NIH's plans for implementing activities in response to Tribal leaders' recommendations.

NIH specifically acknowledges the historic experiences and harms related to data oversight and privacy concerns of AI/AN populations and strives to partner with Tribal Nations to inform responsible research practices. Moreover, NIH recognizes Tribal sovereignty and is committed to soliciting input in accordance with the *HHS Tribal Consultation Policy*[2] and the *NIH Guidance on the Implementation of the HHS Tribal Consultation Policy*[3]. Following these policies, NIH initiated the 2019 Tribal Consultation on a new policy proposal for the management and sharing of data resulting from NIH-funded or conducted research. Specific details of the Tribal Consultation process and outcomes are outlined in the Tribal Consultation report that concludes the Consultation process. We encourage you to share this report broadly across your community. It will also be provided publicly at https://osp.od.nih.gov/scientific-sharing/engaging-tribal-nations/.

NIH supports the recommendations received through Tribal Consultation and intends to emphasize the role of Tribal sovereignty in a future data management and sharing policy. To supplement the policy, NIH intends to develop and disseminate guidance that promotes research partnerships between researchers, Tribal Nations, and urban AI/AN communities and helps researchers respectfully manage and share data. Through this guidance, NIH will work to educate researchers on best practices for ethical data management and sharing, along with strategies for mitigating potential risks to AI/AN communities.

NIH is committed to building partnerships with Tribal Nations. We are deeply appreciative for the thoughtful dialogue and engagement of Tribal leaders in this important topic and hope this will be the first of many productive conversations in the future. Ultimately, working together to enhance trust, we can increase AI/AN representation in biomedical research which will lead to improved health outcomes for Tribal communities.

Sincerely yours,

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Carrie D. Wolinetz, Ph.D.
Acting Chief of Staff and Associate Director for Science Policy, NIH

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[1] https://dpcpsi.nih.gov/sites/default/files/NIH_Dear_Tribal_Leader_Letter-Data_Sharing_Management_508.pdf
[2] https://www.hhs.gov/sites/default/files/iea/tribal/tribalconsultation/hhs-consultation-policy.pdf
[3] https://dpcpsi.nih.gov/thro/policy

TRIBAL CONSULTATION REPORT

NIH COMMITMENT TO RESPONSIBLE DATA MANAGEMENT & SHARING

NIH's Mission and the Importance of Data Sharing

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. NIH strives to facilitate the inclusion of American Indian and Alaska Native (AI/AN) populations in biomedical and behavioral research studies, as this representation is critical for translating scientific discoveries into improved prevention and treatment strategies useful for the diverse needs of these communities.

Sharing scientific data is critical to NIH's mission, which ultimately relies on ensuring that scientific findings are widely available to improve health outcomes and advance healthcare. By increasing access to data, NIH promotes the validation of study design and research findings, enables the reuse of hard-to-generate data, and stimulates new lines of research inquiry. Access to scientific data is also imperative to honoring research participants' contributions to science, as it maximizes the potential for turning research discoveries into medical advancements for the individuals who volunteer and the communities they represent. Of course, data sharing must be balanced with appropriate data protections, and NIH has long recognized the importance of protecting research participants' privacy, confidentiality, and autonomy through policies, informed consent practices, and infrastructure for protecting and securing sensitive data, (e.g., controlled access mechanisms, Certificates of Confidentiality[4]).

Engaging Tribal Nations in Responsible Data Sharing Practices

NIH is committed to improving the health of AI/AN communities by supporting research that will benefit these populations, recognizing that Tribal Nations have sovereignty. Accordingly, NIH established the NIH Tribal Health Research Office (THRO)(https://dpcpsi.nih.gov/thro) to facilitate engagement between the NIH and Tribal Nations, and to ensure meaningful input is solicited and incorporated into NIH programs and policies. NIH routinely seeks to engage Tribal Nations in conversations around responsible data sharing in culturally sensitive ways as part of NIH's commitment to responsible data sharing and in alignment with the goals outlined in the NIH Strategic Plan for Tribal Health Research (https://dpcpsi.nih.gov/sites/default/files/2019_THRO_StrategicPlan_508.pdf).

Over the course of the past decade, NIH has sought and received input from Tribal Nations on its data management and sharing policies and continues to incorporate feedback to date. NIH actively engages both the NIH's Tribal Advisory Committee (TAC) and the Department of Health and Human Services (HHS) Secretary's Tribal Advisory Committee to discuss future policy

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[4] Certificates of Confidentiality (CoCs) protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations. For more information see NIH Notice NOT-OD-17-109.

proposals and exchange information about its intended priorities. For example, NIH worked to solicit Tribal feedback on the Agency's proposed Genomic Data Sharing (GDS) Policy[5] and Single institutional Review Board (sIRB) Policy[6], and incorporated feedback pertaining to Tribal law and policy prior to their finalization.

Most recently, NIH initiated a new Tribal Consultation to inform the Agency's proposal for a NIH-wide policy for data management and sharing, and in accordance with the HHS Tribal Consultation Policy (https://www.hhs.gov/sites/default/files/iea/tribal/tribalconsultation/hhs-consultation-policy.pdf) and the NIH Guidance on the Implementation of the HHS Tribal Consultation Policy (https://dpcpsi.nih.gov/thro/policy). NIH intends for this report to summarize feedback received through the Tribal Consultation process and propose potential strategies for addressing concerns raised in developing an NIH-wide policy for data management and sharing.

Impetus for Undertaking Tribal Consultation for Data Management and Sharing Policy

Including AI/AN and other historically underrepresented populations in biomedical research is paramount to ensuring scientific discoveries are translated into improved prevention and treatment strategies for the diverse needs of these communities. NIH strives to partner with Tribal Nations to inform responsible research practices and increase AI/AN representation in biomedical research studies capable of improving health outcomes. However, NIH also recognizes AI/AN communities' concerns regarding the risks of exploitation by participating in research. Thus, NIH is eager to work with Tribal Nations to alleviate these concerns and mitigate potential risk.

NIH also acknowledges and respects the importance of Tribal sovereignty in the collection, management, and secondary use of the resulting research data. Input from AI/AN communities and Tribal leadership is essential to inform the development of any new policy and to build relationships of trust between NIH, the research enterprise, and AI/AN communities. Related to the current Tribal Consultation, NIH initially sought input on its Proposed Provisions of a Draft Policy for Data Management and Sharing (https://osp.od.nih.gov/wp-content/uploads/Data_Sharing_Policy_Proposed_Provisions.pdf) and received input from Tribal organizations. NIH also recognizes the historic experiences and harms related to data oversight and privacy concerns of AI/AN populations, and thus undertook the current Tribal Consultation to ensure the appropriate consideration of Tribal sovereignty and AI/AN community input into data management and sharing practices.

NIH TRIBAL CONSULTATION PROCESS

On April 17, 2019, NIH initiated a Tribal Consultation and an Urban Confer on provisions of a Draft Policy for Data Management and Sharing

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[5] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html
[6] https://grants.nih.gov/grants/guide/notice-files/not-od-16-094.html

(https://dpcpsi.nih.gov/sites/default/files/NIH_Dear_Tribal_Leader_Letter-Data_Sharing_Management_508.pdf), recognizing that there may be unique concerns for AI/AN communities regarding broad data sharing, including circumstances in which broad data sharing may not be appropriate (i.e., particularly sensitive data or data restricted by certain Federal, Tribal, state, and local laws, regulations, etc.). Thus, the Tribal Consultation aimed to solicit input from Tribal Nations on responsible data management and sharing practices and strategies, along with the identification of any additional resources that may need to be developed to assist researchers working with these communities to successfully implement these practices. NIH also engaged the National Congress of American Indians on May 2, 2019 to promote awareness of the Tribal Consultation and solicit input from Tribal leaders early in the process (archive posted at https://www.youtube.com/watch?v=ZmbVKQw7IrM&feature=youtu.be). This webinar also served to promote awareness of the Tribal Consultation and encouraged Tribal Nations' involvement in the conversation.

Through this Tribal Consultation, NIH engaged Tribal Nations in three HHS Regional Consultations. Locations and dates are provided below and further information can be found at https://osp.od.nih.gov/scientific-sharing/engaging-tribal-nations/:

- **HHS Regional Consultation (Region 9)** – June 20, 2019; Sacramento, California
- **HHS Regional Consultation (Region 10)** – July 11, 2019; Spokane, Washington
- **HHS Regional Consultation (Regions 6, 7, & 8)** – August 21, 2019; Denver, Colorado

On November 11, 2019, NIH released a Draft NIH Policy for Data Management and Sharing and Supplemental Draft Guidance for public comment ([84 FR 60398](#)). Specific outreach was made to Tribal Nations through the NIH Tribal Health Research Office (THRO) to request input on the draft Policy and the development of guidance for researchers seeking to work with AI/AN communities (https://osp.od.nih.gov/scientific-sharing/engaging-tribal-nations/).

NIH CONSULTATION SUMMARY & ANALYSES OF FINDINGS

Input from this Tribal Consultation, including written feedback, was analyzed by NIH staff and shared with the NIH TAC for additional discussion. Some of the Tribal Consultation recommendations are broader than the scope of a data management and sharing policy and thus not included in the analyses for the purposes of this report. Themes and activities specifically directed towards the data management and sharing practices of NIH-funded and supported research included:

Theme 1. Strengthen engagement built on trust between researchers and Tribal Nations
- Build trust by appropriately acknowledging Tribal sovereignty and emphasizing the essential role Tribal governance plays in determining how AI/AN data should be managed and shared regardless of whether a Tribal Nation has data management and sharing laws and/or policies in place.

- Ensure oversight mechanisms and procedures are in place to prevent unauthorized AI/AN data use or publication beyond the approved research plan.
- Urge researchers to increase communication with Tribal governments, Institutional Review Boards (IRBs), and communities regarding their plans for data management and sharing at all stages of the research project (i.e., before research studies are initiated, plans for research publications, and dissemination back to study participants).

Theme 2. Train researchers to responsibly and respectfully manage and share AI/AN data

- Develop plans for data management and sharing that acknowledge and respect Tribal sovereignty, cultural beliefs, and traditions prior to undertaking a study that involves Tribal members in biomedical research. Explore formal mechanisms for agreement where appropriate and ensure communications from researchers in regard to these plans are clear.
- Educate researchers and IRBs on how to develop clear consent documents in accordance with Tribal laws and agreements, indicating how data will be managed and shared, how it will be used and for what purpose, and who will have access.
- Acknowledge Tribal sovereignty by supporting data management and sharing resources for Tribal Nations who wish to manage and share their own data.
- Encourage documentation of AI/AN community risks and benefits of research and data sharing and communicate these concepts to AI/AN communities prior to research.

Theme 3. Ensure research practices are aligned with the laws, policies, and preferences of AI/AN community partners

- Understand which data types may have unique sensitivities for AI/AN communities and ensure any sensitive data types are appropriately protected.
- Ensure minimization of risks to AI/AN participants as well as the implications for the Indian Tribe or AI/AN community as a whole, including the potential misuse of data, when data are shared.
- Proactively identify and consider ethical, legal, and social issues prior to enrollment of AI/AN individuals.
- Clarify the intersection of policies for data sharing and those governing biospecimens protections.

NIH RESPONSE TO CONSULTATION RECOMMENDATIONS

NIH greatly appreciates the time Tribal leaders and AI/AN communities took in providing thoughtful input and tangible strategies for NIH implementation through the Tribal Consultation process. Specifically, in regard to the 2019 Tribal Consultation and an Urban Confer on provisions of a Draft Policy for Data Management and Sharing, several proposals for specific strategies NIH could undertake were recommended (see Table 1. Recommendations for Draft NIH Policy for Data Management and Sharing Provisions). Recommendations for actions

made throughout the Tribal Consultation process are summarized under "Tribal Consultation Recommendation" below, alongside a list of planned NIH activities to address these recommendations. These activities include policy language additions and the development of a supplemental guidance, including resources that detail complexities specific to research with AI/AN communities and allow for updates, as needed, based on Tribal Nations' input.

NIH supports the recommendations received and plans to address Tribal leaders' feedback through policy language and supplemental guidance. NIH intends to clarify the role of Tribal sovereignty in any future data management and sharing policy. Supplementing a future policy, NIH also intends to develop and disseminate data management and sharing guidance that encourages respectful research partnerships between researchers, Tribal Nations and urban AI/AN communities. Educating researchers on best practices through guidance will facilitate the participation of AI/AN communities in research while mitigating related risks and increasing research transparency for AI/AN communities. Such guidance will focus on:

- identifying culturally appropriate principles for engaging AI/AN communities in research,
- educating researchers about Tribal sovereignty considerations and AI/AN data ownership and sharing concerns, and
- ensuring researchers' data management and sharing practices align with the laws and practices of AI/AN communities.

Table 1. Recommendations for Draft NIH Policy for Data Management and Sharing Provisions.

Consultation Recommendation	Planned NIH Implementation Activities
Recommendation 1. **NIH should emphasize the essential role Tribal sovereignty plays in how AI/AN data should be managed and shared regardless of whether a Tribal Nation has data management and sharing laws and/or policies in place.**	• **Strengthen policy language**: "Applicable Federal, Tribal, state, and local laws, regulations, statutes, guidance, and institutional policies dictate how research involving human participants should be conducted and how the scientific data derived from human participants should be used; NIH also respects Tribal sovereignty in the absence of written Tribal laws or polices" • **Clarify in policy background statement**: Encourage researchers to approach studies with Tribal Nations through partnerships that respect Tribal sovereignty • **Develop AI/AN-specific guidance**: Urge researchers to engage AI/AN communities prior to beginning research to ensure deliberative inclusion of Tribal sovereignty and unique data sharing sensitivities in plans for data management and sharing

Consultation Recommendation	Planned NIH Implementation Activities

Recommendation 2.
 	
NIH should ensure data governance and oversight mechanisms to prevent unauthorized AI/AN data use.
	• **Strengthen transparency**: Increase transparency around data oversight by making data management and sharing plans publicly available and accessible to Tribal Nations
	• **Promote researcher accountability:** Make all plans for data management and sharing publicly available
	  o Facilitate the findability of plans for data management and sharing involving AI/AN research
	  o Broadly disseminate resources for accessing data management and sharing plans involving AI/AN research (e.g., NIH TAC, THRO/OSP Tribal Engagement website, THRO's future presentations)
	• **Develop AI/AN-specific guidance**:
	  o Include description of best practices for respectfully developing agreements for data use between researchers and Tribal Nations
	  o Enhance researcher awareness of processes Tribal Nations use to review prospective research (e.g., Tribal IRBs, Tribal research review boards (not registered with OHRP), or consultation with Tribal leadership)
	  o Emphasize the importance of Tribal sovereignty and open communication among governments, funders, external experts and Tribal representatives when developing data governance structures for AI/AN communities

Recommendation 3.
 	
NIH should encourage researchers to communicate with Tribal Nations prior to developing and implementing plans for data management and sharing.
	• **Develop AI/AN-specific guidance**:
	  o Include examples of appropriate communication between researchers and Tribal Nations (e.g., before research studies are initiated, when planning for research publications, and returning results to research participants)
	  o Predicate these, wherever possible, on community engaged research approaches where tribes and researchers are equal partners in the research endeavor

Consultation Recommendation	Planned NIH Implementation Activities

Recommendation 4.
 	
NIH should ensure that data management and sharing plans provide mechanisms that acknowledge Tribal sovereignty, cultural beliefs, and unique sensitivities when involving Tribal members in biomedical research.
	• **Adopt policy language**: "Applicable Federal, Tribal, state, and local laws, regulations, statutes, guidance, and institutional policies dictate how research involving human participants should be conducted and how the scientific data derived from human participants should be used"
	• **Develop AI/AN-specific guidance**:
	   o Include broad description of historical AI/AN data sharing concerns
	   o Encourage researchers and Tribal communities to develop data management and sharing plans that specifically address how Tribal sovereignty, cultural beliefs, and unique sensitivities are addressed in plans

Recommendation 5. **NIH should include a description of practices for ethical data management and sharing of human data in informed consent language.**	• **Develop new researcher guidance**: Provide guidance to help researchers develop clear informed consent language for data management and sharing

Recommendation 6.
 	
NIH should consider data management and sharing resources for Tribal Nations who wish to manage and share their own data.
	• **Clarify in policy background statement**:
	   o Cite NIH efforts supporting Tribal data science resources (e.g., NIH Office of Data Science Strategy data science training, NIH-supported data centers, Centers of Biomedical Research Excellence research infrastructure)
	• **Plan for parallel implementation activities**:
	   o Develop and promote NIH support of data science resources and training

Consultation Recommendation	Planned NIH Implementation Activities

Recommendation 7.
 	
NIH should provide mechanisms to ensure AI/AN data is appropriately managed and protected to minimize risks to AI/AN participants when data is shared.
	• **Reference policy language**: "Applicable Federal, Tribal, state, and local laws, regulations, statutes, guidance, and institutional policies dictate how research involving human participants should be conducted and how the scientific data derived from human participants should be used"
	• **Develop new researcher guidance**: Provide guidance to help researchers navigate and employ ethical practices for managing and sharing human data, including:
	  ○ Developing clear data management and sharing informed consent language
	  ○ Deidentifying data
	  ○ Using secure data repositories with controlled data access consistent with participants' informed consents
	  ○ Identify data elements or combinations of data elements with unique sensitivity or risk for Tribal communities (e.g. Tribal affiliation, zip code)
	• **Develop new researcher guidance**: Encourage researchers to consider characteristics (e.g., data security and data deidentification) in selecting an appropriate data repository

Recommendation 8. **NIH should clarify the intersection of policies for data sharing and those governing biospecimens protections**	• **Tribal Consultation report**: Clarify that the proposed NIH data management and sharing policy does not apply to biospecimens

NEXT STEPS

NIH will work with Tribal Nations and AI/AN communities to develop the resources described above. It is important to recognize that any future NIH policy for data management and sharing will have a significant time lag between release and effective dates (~ 2 years). Throughout this time period, NIH will continue outreach activities and provide additional opportunities for NIH to continue conversation with Tribal Nations around data management and sharing and developed resources. NIH will continue to update Tribal leaders, AI/AN communities, and interested stakeholders as engagement opportunities arise.