Supplemental Information to the NIH Policy for Data Management and Sharing: Responsible Management and Sharing of American Indian/Alaska Native Participant Data
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Key Dates

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Related Announcements

NOT-OD-22-064 – Request for Public Comment on DRAFT Supplemental Information to the NIH Policy for Data Management and Sharing: Responsible Management and Sharing of American Indian/ Alaska Native Participant Data

NOT-OD-22-213 - Supplemental Information to the NIH Policy for Data Management and Sharing: Protecting Privacy When Sharing Human Research Participant Data

NOT-OD-21-013 – Final NIH Policy for Data Management and Sharing

NOT-OD-21-014 – Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan

NOT-OD-21-015 – Supplemental Information to the NIH Policy for Data Management and Sharing: Allowable Costs for Data Management and Sharing

NOT-OD-21-016 – Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research

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Office of The Director, National Institutes of Health (OD)

Purpose

NIH is committed to increasing its focus on the health of American Indians and Alaska Natives (AI/AN) through enhancing capacity for research in Native communities, promoting opportunities for the next generation of AI/AN researchers, and disseminating transparent and culturally responsive information about NIH and biomedical and behavioral research.[i] This Supplemental Information to the NIH Policy for Data Management and Sharing (DMS Policy) describes considerations and best practices for the responsible and respectful management and sharing of AI/AN participant data under the DMS Policy. This Supplemental Information was developed in response to Tribal Nations' input received through Tribal Consultation and public comments from AI/AN organizations and community members, researchers, institutions, data providers and users, research participants, infrastructure developers, and others to further promote culturally respectful and effective research partnerships.

Background

As a steward of the Nation's biomedical research, NIH champions policies that support responsible, transparent, and robust data management and sharing practices for biomedical research. In 2020, NIH further advanced this commitment through the issuance of a final NIH Policy for Data Management and Sharing (DMS Policy).[ii] The DMS Policy promotes the management and sharing of scientific data generated from NIH-funded or conducted research by requiring submission of Data Management and Sharing Plans (hereinafter Plans) and compliance with NIH Institute, Center, or Office (ICO)-approved Plans. The DMS Policy also emphasizes the importance of good data management practices and establishes the expectation to maximize appropriate sharing of scientific data generated from NIH-funded or conducted research, with justified limitations or exceptions. Additionally, NIH builds flexibility into its policies to allow researchers to comply with Tribal laws, regulations, policies, and preferences in support of trustworthy and responsible biomedical research practices.

In developing the DMS Policy, NIH engaged Tribal Nations, Tribal Leaders, AI/AN organizations and community members, researchers, institutions, data providers and users, research participants, infrastructure developers, and others for their perspectives and input to support a robust data sharing ecosystem that prioritizes responsible data sharing and management practices and promotes stewardship of scientific data. NIH recognizes that conducting biomedical research with AI/AN Tribes, including data management and sharing, must be predicated on respecting Tribal sovereignty, with an acute recognition that our failures to honor sovereignty have caused stigmatization and other harms to AI/AN Tribes[iii] and communities.

NIH sought input directly from Tribal Nations through a Tribal Consultation on the draft DMS Policy in 2019, and the resulting recommendations were released in the Tribal Consultation for Data Management and Sharing Report.[iv] In addition, the final Policy, which was developed in collaboration with NIH's Tribal Health Research Office (THRO), was informed by input from the NIH Tribal Advisory Committee (TAC). NIH supports the recommendations received and, in response, developed this Supplemental Information to:

- support researchers in the submission of a Plan under the DMS Policy with appropriate data management and sharing, when conducting research with AI/AN Tribes;
- promote an understanding of Tribal sovereignty;
- recognize the historic harms to AI/AN Tribes in relation to inappropriate data use and misuse and participant risks;
- provide best practices to mitigate potential risks (e.g., group harm, stigmatization, and privacy vulnerabilities) to AI/AN Tribes; and
- facilitate respectful, sustained, mutually beneficial, and equitable partnerships between AI/AN Tribes, researchers, and the biomedical research enterprise.

Overview of Public Comments

The Supplemental Information was informed by input received during Tribal Consultation, engagements undertaken during the DMS Policy development, and review of published literature and best practices. NIH solicited direct feedback from the NIH TAC and Tribal Leaders before the draft was issued for public comment on January 25, 2022. NIH received 12 responses to the "Request for Public Comments on the DRAFT Supplemental Information to the NIH Policy for Data Management and Sharing: Responsible Management and Sharing of AI/AN Participant Data" (NOT-OD-22-064).[v] Changes reflected in the final Supplemental Guidance in response to the request for public comment are summarized below.

Discussion of Public Comments

Relevance of Supplemental Information for All Indigenous Populations Participating in Research

Several respondents noted that the scope of the Supplemental Information should be clarified and that it should pertain to research with any Indigenous peoples, including but not limited to urban AI/AN communities, non-Federally recognized Tribes (e.g., state recognized Tribes) and populations (e.g., Native Hawaiians), and Indigenous communities outside the United States, in addition to Federally-recognized Tribes.

The Supplemental Information was developed in response to Tribal Consultation and, accordingly, refers to research involving Tribal Nations within Tribal jurisdiction. The Supplemental Information is not intended to be responsive to other Indigenous peoples' research considerations. However, the final Supplemental Information clarifies that the presented best practices for responsible research may be useful for research involving any Indigenous peoples.

Clarity in Intended Use of Supplemental Information

Some respondents requested clarity about the document's intended audience. The Supplemental Information is intended to be used by researchers subject to the DMS Policy who are planning to conduct research involving Tribal Nations. The final Supplemental Information was updated to clarify that it could contain helpful ideas for researchers conducting biomedical research with any Indigenous peoples. Additionally, while the Supplemental Information was designed to encourage prospective planning for the management and sharing of scientific data consistent with the DMS Policy, the final Supplemental Information clarifies that the suggested best practices could be considered when researchers unknowingly collect AI/AN data (i.e., inadvertent inclusion of AI/AN participants) and may be appropriate even after research is underway.

Need for Additional Researcher Resources and Training Materials

Public comments sought clarification about how this Supplemental Information was developed and requested that NIH provide additional resources for researchers on implementing and promulgating responsible research with AI/AN Tribes.

The final Supplemental Information outlines the iterative process undertaken to develop these considerations including incorporating Tribal Nations' input from Tribal Consultation, collaborating with NIH THRO, obtaining input from NIH TAC, and considering public comments from a broad range of stakeholders across the biomedical research enterprise, including but not limited to Tribal Leaders, AI/AN organizations and community members, researchers, and institutions. Importantly, NIH is committed to continued engagement with Tribal Nations on data management and sharing and will update this Supplemental Information as needed.

Supplemental Information to the NIH Policy for Data Management and Sharing:Responsible Management and Sharing of American Indian/Alaska Native Participant Data

Introduction

AI/AN communities bear a significant burden of health disparities, yet there remains a lack of meaningful research to alleviate this burden.[vi] AI/AN community members are underrepresented in biomedical research. Inclusivity of AI/AN communities in biomedical research is essential for benefitting from research outcomes, developing prevention and treatment strategies responsive to AI/AN community members' health needs, and learning from these communities' strengths and resiliencies. NIH is committed to supporting trustworthy and responsible biomedical research practices, prioritizing research participants as partners in the research enterprise, and supporting respectful, sustained relationships with AI/AN Tribes.

This Supplemental Information provides considerations for all researchers that are subject to the DMS Policy prior to conducting NIH-supported research projects. By increasing awareness and understanding of the considerations of AI/AN Tribes and their data amongst researchers, NIH seeks to mitigate instances of irresponsible use and unintentional collection of AI/AN data in ongoing research projects. While this

Supplemental Information only addresses data management and sharing considerations when working with AI/AN Tribes, it may contain useful ideas for any researchers who, as part of their research, share and manage data in partnership with urban AI/AN communities, non-Federally recognized Tribes (e.g., state recognized Tribes), communities (e.g., Native Hawaiians), and Indigenous peoples outside the United States.

Clarifying data sharing and management best practices for research with AI/AN Tribes is intended to mitigate related risks, build trustworthy and sustainable partnerships, and increase research transparency for AI/AN Tribes. A responsible Plan, which is respectful to Tribal Nations, is a singular component of designing a research project, and researchers should ensure that the Plan is one part in a broader, culturally appropriate, and responsive project design that aligns with relevant Tribal laws, policies, regulations, and preferences. Some Tribal Nations may have preferences for data governance beyond, and complementary to, the FAIR (Findable, Accessible, Interoperable, and Reusable) principles,[vii] for example, the CARE (Collective Benefit, Authority to Control, Responsibility, and Ethics) Principles for Indigenous Data Governance.[viii] AI/AN Tribes may also have preferred research practices that focus on partnership building, community inclusion, and continuous collaboration such as Community Engaged Research or Community-Based Participatory Research.[ix] [x]

This Supplemental Information responds to the Tribal Consultation with NIH for the DMS Policy by emphasizing respect for Tribal sovereignty and trust building between researchers and AI/AN Tribes regarding data management and sharing practices.[xi] NIH is committed to continuing the conversation about responsible data management and sharing practices with AI/AN Tribes to ensure researchers respect Tribal Nations through the responsible management and sharing of AI/AN data.

Considerations for Researchers Working with Tribal Nations

Tribal sovereignty. The United States recognizes Indian Tribes as sovereign governments under the Constitution of the United States, treaties, statutes, Executive Orders, and court decisions.[xii] Sovereignty refers to the authority to self-govern. The essence of Tribal sovereignty is the ability to govern and to protect and enhance the health, safety, and welfare of Tribal citizens within Tribal jurisdiction.[xiii] Researchers must recognize Tribal sovereignty throughout the research process by developing partnerships with Tribal Nations that align with relevant Tribal laws, regulations, policies, and preferences when the research occurs within Tribal jurisdiction or the Tribal Nation is engaged in performing human subjects research.[xiv] Tribal Nations have unique rights associated with Tribal sovereignty to control how biomedical research can be performed within Tribal jurisdiction, including how their data can be collected, used, managed, and shared.[xv]

Tribal research laws, regulations, policies, preferences, and processes.Tribal sovereignty includes the right for each AI/AN Tribe to establish and enforce Tribal laws, regulations, and policies for biomedical research that respond to Tribal needs and expectations. AI/AN Tribes may set expectations beyond the requirements of the Common Rule.[xvi] If research is conducted within the jurisdictions of multiple AI/AN Tribes or has participants from different Tribal Nations with the Tribal Nations engaged in the human subjects research, researchers should understand each relevant AI/AN Tribe's Tribal laws, regulations, policies, and preferences and engage with each AI/AN Tribe prior to conducting research. Tribal Nations often employ a variety of strategies to protect their communities. For instance, Tribal Nations may have Tribal laws that require review of the research by a Tribal-designated Institutional Review Board (IRB[xvii]) or Tribal research review committee as well as other research review processes, including presentation and publication review[xviii] to assess the benefits and risks of research within Tribal jurisdictions. Other Tribal Nations may have other processes that include oversight by a Tribal Leader or a designated Tribal entity conducting Tribal reviews of prospective research plans to promote beneficial use and prevent inappropriate use or misuse of AI/AN data. Tribal laws, regulations, and policies may be available in Tribal Research Codes and/or individually available on Tribal websites.

Historical awareness.Because research exploitation and data misuse have often resulted in undermining trust between AI/AN Tribes, Federally-funded researchers, and the research enterprise, awareness of past research abuses perpetrated against AI/AN Tribes, including instances of data misuse, is important for comprehending each AI/AN Tribes' understanding of research and respecting their research related concerns. The sharing of biospecimens is often a concern of AI/AN Tribal Nations. While not applicable to the DMS Policy, biospecimens, if collected, should be proactively discussed at the earliest stages of research in parallel to Plan development. Proactive and transparent conversations with Tribes around how data will be managed and shared are of paramount importance to earning trust and cultivating productive relationships between Tribal Nations, NIH awardees, and the NIH.

Health disparities.AI/AN communities bear a significant burden of health disparities, yet there remains a lack of meaningful research projects to alleviate this burden. Sufficient inclusivity of each AI/AN Tribe, and the subpopulations within, remains a pervasive challenge, along with limited datasets of sufficient quality and reliability to draw meaningful conclusions. In other instances, the benefits of research do not meet the needs or are inaccessible to AI/AN communities, further perpetuating health disparities. AI/AN organizations such as the National Congress of American Indians (NCAI) and other groups have advocated for data disaggregation and analyses of AI/AN data, while respecting Tribal sovereignty, to facilitate understanding of health disparities, protective health factors, and health outcomes of AI/AN communities.[xix],[xx] NIH's inclusion policy may also apply, which requires reporting of cumulative subject accrual and progress in conducting analyses for differences by race and ethnicity.[xxi]

Best Practices for Researchers

Proactively engage AI/AN Tribes in planning for data management and sharing. Establishing partnerships with AI/AN Tribes prior to initiating a research project is an important step toward building trust, facilitating mutually beneficial and equitable partnerships, and developing a culturally appropriate Plan. Researchers should not only develop and proactively discuss the Plan with Tribal partners when preparing an application for funding but also engage Tribal partners when updating Plans throughout the research process. Engagement with AI/AN Tribes prior to initiating research equips researchers with a greater understanding of any Tribal laws, regulations, policies, or preferences prior to developing a Plan under the DMS Policy. The DMS Policy also allows researchers the opportunity to disclose any applicable NIH policy expectations prior to project initiation and involve AI/AN Tribes as research partners throughout all stages of the project. Note that in some cases, researchers may include in their budget requests costs for Tribal Nations that partner with researchers to develop a Plan and Tribal Nations may be reimbursed by the award recipient for their role in data management and sharing consistent with NIH rules for pre-award (pre-agreement) costs.[xxii] These data management and sharing costs may be proposed by researchers in their budgets, and researchers should notify AI/AN Tribes that such reimbursement is dependent on the actual award. AI/AN Tribes or organizations receiving an award may also be eligible to have pre-award costs covered based on the NIH rules.

Establish mutual understandings of goals for data management and sharing. While the goals of a research project may be well documented, it is also important for researchers to understand the motivations and expectations of research participants/communities who engage in research and form equitable partnerships around a shared understanding of research goals, including those for data management and sharing. For instance, Tribal Nations may have expectations regarding how their data will be used and shared. Research agreements should describe planned data management and sharing practices, including when data sharing limitations are appropriate, to ensure mutual agreement about data management and sharing that aligns with AI/AN Tribes' preferences. Researchers should convey relevant data management and sharing agreements in the Plan (i.e., who made the agreement; applicable Tribal laws, regulations, and policies, etc.) and obtain Tribal letters of support, Tribal resolutions, and/or other forms of written documentation when required and if possible. Agreeing to present research findings to communities, particularly before research results are broadly disseminated, can be one strategy for researchers to sustain relationships with AI/AN Tribes and increase trust. It is also helpful to proactively discuss any Tribal preapproval processes that AI/AN Tribes may use to review manuscripts or the dissemination of research findings.

Incorporate AI/AN data management and sharing practices and preferences in Plans. Prior to submitting a Plan to NIH, researchers and AI/AN Tribal partners should consider whether data generated will be stewarded by Tribal Nations, researchers, or a trusted third party. The DMS Policy strongly encourages the use of an established data repository to the extent possible but does not specify use of a particular data repository or which entity manages the data repository selected. NIH is committed to supporting Tribal data science resources, including data repositories, through efforts such as NIH-supported data centers, the Centers of Biomedical Research Excellence research infrastructure, and the NIH Office of Data Science Strategy's data science training. Note that as a project evolves, Plans, including the repository(ies) selected, may be updated with NIH funding ICO approval of the Plan to accurately describe how scientific data will be managed and shared.

Consider additional protections and appropriate limitations to future data sharing.AI/AN Tribes have legal rights to determine the conditions by which their data are shared when data are collected within their jurisdiction, including requiring Tribal approvals or participating in research review requests. More information on data sharing limitations can be found in the DMS Policy FAQs.[xxiii] Researchers and AI/AN partners are encouraged to jointly consider data sharing expectations, and any appropriate limitations on data sharing for secondary research. The DMS Policy recognizes that other factors (e.g., ethical, legal, and technical) may shape permissibility of data sharing, and these factors should be described in the Plans. Examples of factors to be considered include applicable Tribal laws, regulations, policies, and agreements governing participant research and resulting data; and distinct, culturally embedded, or spiritual values that inform Tribal preferences regarding the extent to which data are shared. Tribal laws, regulations, policies, and preferences, for example, may apply to de-identified data not protected under U.S. Federal regulations. Data sharing may also be limited in instances in which AI/AN Tribes wish to manage and share their own data, and no appropriate repository exists or is accessible.

Incorporate data management and sharing plans in the informed consent process.The DMS Policy strongly encourages researchers to communicate data sharing and future use limitations to research participants in the informed consent process. This includes accessible descriptions of conditions and oversight processes and safeguards on secondary research (e.g., whether all secondary research or secondary research beyond a prespecified scope will be reviewed by an oversight body), plans related to return of secondary research results (e.g., whether results of secondary analyses will be returned to individuals and/or Tribes), and/or stipulations of the data repository used (e.g., whether certain secondary research domains or questions are acceptable and how long data can be made available for secondary analyses). NIH released points to consider on "Informed Consent for Secondary Research with Data and Biospecimens" to support researchers when developing accessible and transparent informed consent processes.[xxiv] Additionally, researchers should ensure that when partnering with an AI/AN Tribe to conduct research within Tribal jurisdiction that the informed consent is accessible, responsive, and consistent with the preferences of the Tribal Nation and the preferences of the anticipated research participants. For example, individual AI/AN Tribes may have IRB policies that specifically prohibit broad consent practices. The DMS Policy does not have specific expectations about the consent process, such as broad consent, and emphasizes honoring appropriate sharing limitations in the informed consent process.

Safeguarding against future risk.The DMS Policy indicates that, in developing Plans, researchers should describe how participants' privacy, rights, and confidentiality will be protected. Accordingly, NIH has developed supplemental information on protecting privacy when sharing research participant data.[xxv] Unique populations, including AI/AN Tribes, are at greater risk of privacy vulnerabilities and/or stigmatization if participant protections are not appropriately planned for and implemented (e.g., easier data re-identification, or stigmatization resulting from misuse).[xxvi] To mitigate the potential for group harm to AI/AN Tribes, both individual and community data protections (e.g., deidentification of Tribal affiliation or other group identifiers and controlled access review) should be considered. In explaining participant protections in Plans, researchers partnering with AI/AN Tribes are recommended to include in Plans considerations of Tribal sovereignty by describing their compliance with expectations from any relevant Tribal law, regulation, policy, and/or preferences. Tribal IRBs and/or other relevant AI/AN research oversight entities may specify for researchers the data sharing preferences of relevant AI/AN Tribes. Compliance with the Plan is determined by the funding NIH ICO and may be reviewed during regular reporting periods, e.g., at the time of annual Research Performance Progress Reports (RPPRs). Breaches in compliance may result in enforcement actions consistent with the established NIH policies of the funding ICO and NIH, which could include additional special terms and conditions or termination of the award and may affect future funding decisions.

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[xiii] NCAI Tribal Governance https://www.ncai.org/policy-issues/tribal-governance.

[xiv] Code of Federal Regulations. Protection of Human Subjects. To what does this policy apply? See 45 CFR 46.101 https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46

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[xvii] See IHS listing of "Independent Tribal Institutional Review Boards" https://www.ihs.gov/dper/research/hsrp/instreviewboards/

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