

Compiled Request for Comment on the
NIH Data Sharing and Management
Policy draft Supplemental Information:
Responsible Management and Sharing of
American Indian/Alaska Native
Participant Data

Guide Notice Number: NOT-OD-22-064

January 25, 2022 – April 28, 2022

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ID: 1895

Submit date: 02/26/22

I am responding to this RFI: On behalf of myself

Name: Andrew

Name of Organization: Kualaaau

Type of Organization: University

Role: Scientific researcher

Comments:

I appreciate how AI/AN tribal nations are considered and given rights and afforded representation in research, as this supports rigor and reproducibility across studies. However, I find that I am generally disappointed when Native Hawaiians are not afforded the same level of consideration or representation. This could possibly be because the U.S. government never recognized Native Hawaiians as a Peoples deserving of self-determination. Nevertheless, I believe the NIH could make efforts to recognize this inequity and make efforts to address it.

Email: akualaaau@gmail.com

ID: 1954

Submit date: 03/21/22

I am responding to this RFI: On behalf of myself

Type of Organization: University

Role: Scientific researcher

Comments:

Thank you for seeking input on this important topic. One question I have and would appreciate more explicit information on within this document is how involved in the NIH Tribal Health Research Office and NIH THRO Tribal Advisory Committee was in the development and approval of this document. Also, this document only focuses on tribal nations, what are the considerations for urban AIAN peoples? This is an important topic to include given that the majority of AIAN peoples live off tribal lands and in urban or non-reservation settings.

ID: 1955

Submit date: 03/23/22

I am responding to this RFI: On behalf of an organization

Name: Claymore Kills First

Name of Organization: Brenden-Colson Center for Pancreatic Care

Type of Organization: University

Role: Medical provider

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/rfi2022_tribal/uploads/CFqIbzQFLK.pdf

Description: NIH DMS Comments - Brenden Colson Center

Email: killsfir@ohsu.edu

ID: 1958

Submit date: 03/26/22

I am responding to this RFI: On behalf of myself

Name: Susan Brown Trinidad & Wylie Burke

Name of Organization: University of Washington

Type of Organization: University

Role: Bioethicist

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/rfi2022_tribal/uploads/nwzQJpcThg.pdf

Email: sbtrini@uw.edu

ID: 1959

Submit date: 03/28/22

I am responding to this RFI: On behalf of myself

Type of Organization: Tribal Nation or Tribal Organization

Role: Institutional official

Comments:

The drafted policy is highly supportive of researchers respecting tribal sovereignty. Will NIH also support tribes/tribal IRB's if they must implement consequences for researchers that do not respect tribal codes, processes, and procedures? A statement to this effect will greatly assist tribes/tribal IRB's when pursuing compliance and/or legal action. Also a statement supporting Tribal datasets, for consideration in secondary research, shall require the researcher to submit protocol to the particular tribes IRB for review and approval. (This process may be developed through NIH tribal partnerships)

ID: 1961

Submit date: 03/28/22

I am responding to this RFI: On behalf of an organization

Name: Andrew Boyd, M.D.

Name of Organization: University of Illinois Chicago

Type of Organization: University

Role: Institutional official

Comments:

We are pleased to see the addition of guidance and recommendations for researchers working with AI/AN communities. As a public urban university on the historical lands of three Fire peoples, the Ojibwe, Odawa, and the Bodéwadmi peoples, we believe we have a specific obligation to ensure that we find ways to engage with the AI/AN community, to see them represented in our institution and our research, and to ensure that our work continues to benefit them. While we support the draft guidance, there are several areas that we believe would benefit from additional clarification or further support and guidance. Recognition of Urban AI/AN The Tribal Consultation document reports drawing upon community leaders, but it is unclear whether community groups in urban areas were included in this cohort. A significant majority of AI/AN people do not live on tribal land and many live in urban settings like Chicago. Urban AI/AN communities may therefore not live within the jurisdiction of a particular Tribal nation. Therefore, it is essential that community affiliation groups such as the Chicago American Indian Community Collaborative (CAICC) which provide resources and can proactively engage with AI/AN communities, providing a translational bridge between researchers and community members. We recommend modifying the language in the AI/AN guidance to specifically point out these community groups as local authorities in addition to the Tribal governance structures for consultation and collaboration. Eliminating erasure in statistical presentation AI/AN individuals are often not identified in health research, due to the lack of inclusion in the demographic categories captured in research, or demographic data being incorrectly captured in health records by healthcare employees. Further, where AI/AN identity is documented, there are often so few participants that researchers collapse or in other ways obfuscate them in statistical or graphical presentation, erasing their presence or avoiding notation of their absence in data. This is compounded where AI/AN individuals have multiple identities and are grouped by those instead. While we deeply appreciate the expanded need for the protection of individual participants who are at a much greater risk for re-identification, this has the harmful effect of erasing their presence entirely or further alienating them by grouping them as an “other” with other underrepresented groups. We recommend guidance for researchers to explicitly represent whether they asked for AI/AN demographics and, where no AI/AN participants are represented, to specifically notate that on charts to better represent and promote community awareness. Education of Researchers While this guidance provides an excellent starting point for researchers who are seeking to collaborate with AI/AN communities, as a solo document it is insufficient to address other lack of training about partnering with these communities and understanding cultural practices. The NIH should collaborate with the Tribal and AI/AN-led Community groups to develop training materials which will further prepare researchers to build genuine collaborations with native communities, to expand mainstream

understanding of native presence in all communities, and to better engage in ways that are truly reciprocal and respectful of Indigenous cultures and traditions. Additionally, we recommend drawing upon the training materials created by our Canadian colleagues through the First Nations Information Governance Centre (FNIGC) program, who have a much more robust and established set of requirements and training material for collaborating with Indigenous groups. Training can build upon their established principles of OCAP (Ownership, Control, Access, and Possession) in addition to the CARE Principles to create greater understanding of shared obligation between researchers and AI/AN participants. Community Based Participatory Research Community Based Participatory Research (CBPR) approaches have been the gold standard for conducting research with the AI/AN community for approximately twenty years and should be further promoted through this guidance. Researchers' commitment and plans for adherence to CBPR should be documented in the grant proposal if they need to deviate from them, how they will continue to follow the principles of CBPR. We recommend going beyond the facilitation of "respectful partnerships" and instead focus on the creation of genuine collaboration and engagement. We strongly recommend establishing the requirement that researchers draw upon the AI/AN community as not only for recruitment or data collection but throughout the entire research process. We have many examples of drawing upon community organizations to serve not only as assistants for recruitment but also as connectors to hire members of the community to gather data and learn about data analysis. This must also lead to data sharing and accounting for these projects to move away from an extractive form of research towards one where our work buttresses what the community needs are. We have successfully done this for projects such as the CHI-Tracing program related to COVID-19 and can use this as a way to hire community members, train them, and help them connect with a pathway towards further education or work experience. This reflects our work as a university investing in our local community and seeking to directly improve that community health. Recognize the ongoing need for consideration of who is included in AI/AN community and authority structures While researchers may be able to identify Tribal structures, it is critical that they also consider the current disagreements about membership, such as the exclusion, for example, by some tribes of the descendants of people who were enslaved by the tribes. We encourage the NIH to review the guidance with an eye towards identifying where black and Native members or other minority members may be excluded and provide guidance on better inclusion of all members of the AI/AN community. Additional review should also consider where tribal authority structures may not include the engagement of elders or women and girls who may be more directly impacted by certain research projects. Underfunding and Power Differentials While AI/AN communities should always be given autonomy to determine whether they wish to participate in a research project, we recognize that some groups are so significantly underfunded that any research which may be perceived to come with financial benefit may seem appealing. This runs the risk of these groups being over-surveilled or put into situations where they do not feel they can turn down external researchers. Particularly where financial remuneration is provided to individuals or to a community, the NIH should identify mechanisms to hold researchers accountable for ensuring true collaboration with communities both in their leadership structures and with individuals participating in the research. Center the Research Questions and Benefit of the Community NIH has the specific authority to make requirements of researchers collaborating with the AI/AN community or performing research that includes AI/AN participants with regards to returning benefit to the community. We believe these requirements are needed to develop research questions and shape research design in a way that ensures reciprocal benefits. We encourage the development of parameters for review in partnership with Indian Health Service and other federal groups which address

AI/AN individuals to identify benefits of research to the community and ensure those studied populations will not be excluded or left behind. We want to highlight the work of this nature already being done by the NIDA and hope it will expand to the other NIH Institutes and Centers. Guidance on the Ownership of Data by Institutions The majority of research institutions claim ownership of data created through federally funded research projects, which creates obligations for the institution to ensure veracity, curation, and preservation. However, for AI/AN Communities, increased data capture has not been correlated with support, but instead led to systematic exclusion and erasure. Further, there is a lack of understanding of the importance of cultural and spiritual aspects surrounding physical samples like hair, DNA storage and sequencing, etc, that needs to be more comprehensively addressed in policy and education. In relation to AI/AN research and collaborations, institutions may need to relinquish primary ownership and instead serve only as the steward of the data on behalf of the community. We recommend further engagement with the Tribal leader and community leaders such as CAICC to establish best practices and standard data use agreements to clarify data responsibilities so that it may be more generally consistent across organizations and not reliant on relationship or power imbalance.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/rfi2022_tribal/uploads/GopqncbSUq.pdf

Description: NOT-OD-22-064 Response UIC

Email: pearsong@uic.edu

ID: 1962

Submit date: 03/28/22

I am responding to this RFI: On behalf of an organization

Name: Kristin West

Name of Organization: COGR (Council on Governmental Relations)

Type of Organization: Other

Role: Member of the Public

Comments:

Our comments, submitted on behalf of COGR and its member institutions, are set forth in the attached letter.

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/rfi2022_tribal/uploads/ASdpyzVcZo.pdf

Description: COGR's response to NIH NOT OD 22 064

Email: KWest@cogr.edu

ID: 1964

Submit date: 03/28/22

I am responding to this RFI: On behalf of myself

Name: lancer stephens

Name of Organization: Tribal Member and Researcher for OUHSC

Type of Organization: University

Role: Scientific researcher

Comments:

Please see attachment and let me know if any clarification is desired. Mvto- lancer

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/rfi2022_tribal/uploads/JgTtvuNLsB.pdf

Description: Public Comment for DMS with AIAN populations

ID: 1966

Submit date: 03/28/22

I am responding to this RFI: On behalf of myself

Name: Janis Geary

Name of Organization: Arizona State University

Type of Organization: University

Role: Scientific researcher

Comments:

NIH should consider how researchers might determine if the guidelines are relevant to the research they are conducting and the data they are collecting. In what circumstances would a researcher be required or expected to adhere to these guidelines? If the guidelines are only applicable to research projects identified at the funding stage as being "AN/AI focused", is NIH going to consider best practices like "Proactively engaging AI/AN communities in planning for data management and sharing" to be a prerequisite for gaining funding? Are researchers required to self-identify their research as AN/AI focused, or is someone else going to review their study to determine that? What if the researcher is collecting data from a source that has a large population of Tribal members or other Indigenous populations, what are the expectations for adhering to the best practices? If the researchers are primarily studying a topic that relevant to a broader population, but intend to report on outcomes or variables stratified to include Indigeneity, are they required to follow these best practices? The Canadian Tri-Council Policy Statement on the Ethical Conduct of Research outlines scenarios in which researchers would be considered to be conducting Indigenous Health Research, and are therefore required to follow specific guidelines. This document may be useful in thinking through scenarios in which NIH would expect their guidelines to be applied. Without clear expectations of when the best practices are expected to be implemented, researchers may look for loopholes to avoid activities that cost time and resources.

Email: jdgeary@asu.edu

ID: 1968

Submit date: 03/30/22

I am responding to this RFI: On behalf of myself

Name: Mary Marcus

Type of Organization: Other

Role: Patient advocate

Comments:

As a patient and RN the abuses related to Project Nightingale - what I am following up on and is making me upset is my falsified EKG report by an Ascension Health cardiologist saying I sustained a recent anterior wall MI requiring an immediate chemical stress test (major complication cardiac arrest) up to a cardiac catheterization. My EKG 7 days later in the ER was normal. Google software through "Project Nightingale", an AI predictor model hooked up to my PHI, allowed them to falsify test results on a google linked EKG machine. The ER EKG didn't have the Google connection, so the findings were normal... no MI. data should not be shared right now it is being monetized by Google and Ascension Health.

Email: maryma1@comcast.net

ID: 1971

Submit date: 4/3/2022

I am responding to this RFI: On behalf of myself

Type of Organization: University

Role: Scientific researcher

Comments:

As a Native researcher, I am opposed to any form of oppression vis a vis mandatory data sharing. We are sovereign Nations and as Native People, we will make the determination what data will or won't be shared and in what way.

ID: 1982

Submit date: 4/15/2022

I am responding to this RFI: On behalf of myself

Type of Organization: Government Agency

Role: Government official

ID: 1994

Submit date: 04/28/22

I am responding to this RFI: On behalf of an organization

Name: Kenneth Lokensgard

Name of Organization: Washington State University

Type of Organization: University

Role: Institutional official

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/rfi2022_tribal/uploads/DcyFDcTcTL.pdf

Description: Comments upon DSMP from Washington State University Tribal Relations, Native Health Sciences, and Human Research Protection Program

Email: kenneth.lokensgard@wsu.edu

ID: 1995

Submit date: 04/28/22

I am responding to this RFI: On behalf of an organization

Name: Paul Spicer

Name of Organization: Center for the Ethics of Indigenous Genomic Research

Type of Organization: Other

Role: Scientific researcher

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/rfi2022_tribal/uploads/mWUHpVhwBg.pdf

Description: CEIGR Statement

Email: paul.spicer@ou.edu