



Council On Governmental Relations

An Association of Research Institutions

March 28, 2022

Submitted via Email to: <https://osp.od.nih.gov/rfi-data-sharing-management-policy-of-native-participant-data/>

Office of the Director
National Institutes of Health (NIH)

RE: Comments in Response to NIH NOT-OD-22-064

To Whom It May Concern:

The Council on Governmental Relations (COGR) is an association of almost 200 public and private U.S. research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions. One area of significant interest and expertise among COGR member institutions is the ethical conduct of research involving human participants and support for the broad dissemination of information obtained from such research. We write today to submit comments in response to NIH's issuance of the [NOT-OD-22-064, Request for Public Comments on DRAFT Supplemental Information to the NIH Policy for Data Management and Sharing](#) ("Notice").

COGR recognizes that fostering participation in research by historically under-represented groups improves the quality of the research and the equitable distribution of any resulting benefits. Yet, certain under-represented communities, such as American Indian and Alaskan Native Tribes ("Tribal Nations"), have historical or other reasons to distrust the scientific enterprise. Thus, COGR also recognizes the imperative to solicit and understand these communities' perspectives on the ethical conduct of such research and the sharing of research results. Further, we deeply respect Tribal Nations' sovereignty, and the rights conferred by that sovereignty to control the conduct of research under their jurisdiction. Accordingly, we appreciate NIH publishing the Notice as part of its "commitment to building partnerships with American Indian/Alaska Native communities" ("AI/AN Communities"), and we hope that COGR's comments here will help in achieving that goal.

Specific Comments:

Our comments concern two paragraphs in the Notice, noted below in italicized text:

Paragraph 1:

Establish mutual understandings of goals for data management and sharing. Researchers and AI/AN communities are encouraged to form equitable partnerships with a shared understanding of goals for data management and sharing. While the goals of a research study may be well documented, it is important for researchers to understand the motivations and expectations of research participants who engage in research. For instance, communities may have expectations regarding how their data will be used and shared. Agreeing to present research findings to communities can be one strategy for researchers to sustain relationships and increase trust. It is also helpful to proactively discuss any Tribal preapproval processes that will be used to review manuscripts or the dissemination of research findings. Researchers should convey agreements for data managing and sharing in the Plan (i.e., who made the agreement; applicable Tribal laws, regulations, and policies, etc.) and consider obtaining Tribal letters of support, Tribal resolutions, and/or other forms of written documentation when possible/required.

Comments:

- (a) The Guidance includes examples of actions that researchers may take to clarify appropriate data management and sharing when conducting research with AI/AN populations (e.g., presentation of findings, manuscript preapproval). We appreciate these suggestions and understand the importance of working with AI/AN communities to develop data sharing/management plans that prevent data misuse and appropriately consider Tribal Nations' histories (including past interactions with researchers), as well as their sovereignty over research conducted within their territories. Nevertheless, we recommend clarifying to researchers that use of the listed approaches are not required, and that other unmentioned approaches may be equally or more suitable. In this regard, we suggest adding the following sentence to the end of this paragraph: "Researchers should be aware that the approaches set forth in this paragraph to promote mutual understanding of data sharing/management goals are suggestions, not requirements, and that, in any specific situation, there may be different approaches not mentioned here that are equally or more effective."
- (b) As the Guidance notes, Tribal Nations have separate legal authority to regulate research under their jurisdiction, including the possibility of pre-review of manuscripts and/or data prior to dissemination. Yet, differences between Tribal Nations requirements and researcher/funding agency expectations/requirements may hamper or prevent the research from being conducted in a manner that meets all requirements, and thus must be identified early on. For example, unlimited pre-review of academic publications (as opposed to limited pre-review, such as for the protection of proprietary information) is not the norm, and NIH has set forth in its data sharing and management policies a general expectation that researchers will broadly share resulting data and conclusions, subject, of

course, to protections for participant privacy/confidentiality. COGR believes that trust with Tribal Nations is best promoted through proactive, frank discussions between researchers and Tribal Nations regarding any substantive differences between Tribal requirements and researcher/funding agency requirements/expectations in this area, ideally before a proposal is submitted. Accordingly, we respectfully suggest adding the following text to the end of this paragraph to acknowledge the possibility of disharmony and the need for resolution before the research begins:

In addition to addressing participant expectations regarding how their data should be used and shared, researchers should likewise provide information to Tribal Nations on their scientific discipline and funding agency standards and expectations for data sharing and management. Researchers and Tribal Nations should frankly discuss any substantive differences between these requirements/expectations and Tribal requirements/expectation and determine whether differences can be satisfactorily resolved to permit the research to proceed. For example, if the Tribal Nation requires pre-publication review, researchers and AI/AN communities are encouraged to discuss the scope of those reviews prior to commencing research and consider both the need to accurately describe U.S. and tribal history and to protect tribal traditional knowledge or sensitive identifying information.

Paragraph 2:

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

Comments:

As previously noted, researcher and funding agency expectations/requirements regarding data sharing and management may substantively differ with those of Tribal Nations. We appreciate NIH's recognition of this possibility and the listing of factors that may be considered in determining/limiting the scope of data sharing. Along these lines, it would be helpful if NIH would provide examples of any data sharing restrictions or limitations that NIH would not permit for NIH-funded projects. This information would assist researchers and Tribal Nations in

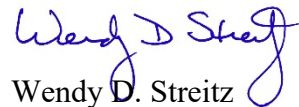
framing their discussions, determining if the research can proceed, and if so, jointly developing mutually acceptable plans, preferably during the proposal process.

Conclusion:

COGR appreciates the opportunity afforded by NIH to submit these comments. We support all efforts to encourage active, positive research partnerships among NIH, Tribal Nations, and academic institutions, and we value the Notice's contributions to work towards this especially important goal.

For questions regarding letter, please contact Kris West, Director, Research Ethics & Compliance at KWest@cogr.edu.

Sincerely,

A handwritten signature in blue ink that reads "Wendy D. Streit". The signature is fluid and cursive, with a large, stylized "S" at the end.

Wendy D. Streit
President