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January 17, 2020

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Francis S. Collins, M.D., Ph.D., Director
National Institutes of Health
Building 1, Room 118A
1 Center Drive
Bethesda MD 20814

Re: DRAFT NIH Policy for Data Management and Sharing

Sent by email to: francis.collins@nih.gov;
lawrence.tabak@nih.gov; carrie.wolinetz@nih.gov;
NIHTribalCommittee@od.nih.gov

Dear Director Collins:

We are writing to provide our formal input as a part of the tribal consultation on NIH Data Sharing and Management that was initiated in a letter to tribal leaders on April 17, 2019. This letter focuses on our response to the **DRAFT NIH Policy for Data Management and Sharing** that was published in the Federal Register for public comment on November 8, 2019. We did not provide comments to the Federal Register notice directly since that was intended for the general public. We strongly believe that our comments should be considered as a part of the tribal consultation process due to the government to government relationship with and the federal trust responsibility to tribal nations.

The National Congress of American Indians (NCAI) is the oldest, largest, and most representative national organization serving the broad interests of American Indian and Alaska Native (AI/AN) tribal nations and advocates to uphold and strengthen tribal sovereignty. Research that is conducted on tribal lands or with tribal citizens falls under the purview of tribal governance, and in accordance with the Federal Policy for the Protection of Human Subjects, also known as the Common Rule, tribal research laws must be followed in human subjects research [45 CFR 46.101(f), Subpart A]. Any research that is conducted, from the initial consent process, collection and storage of data and specimens, analysis, reporting, to publication, and **any plans for data management and sharing, must follow tribal research laws and policies.** Also, every tribal nation, as a sovereign nation, has the inherent right to determine how research is governed when it involves their citizens and lands **even if they do not have specific research laws in place.**

Comments on the DRAFT NIH Policy for Data Management and Sharing

We thank you for holding a tribal consultation session at the 2019 NCAI Mid Year Conference last year. However, the focus of the consultation at that time was the general topic of data sharing. Tribal nations did not have a draft policy to review or on which to provide comments at that time. Now that the Federal Register notice was released with the DRAFT NIH Policy for Data Management and Sharing, a critical event has occurred as defined by the Department of Health and Human Service Tribal Consultation Policy, and **NIH must immediately consult with tribal nations on this draft policy** since it has the potential to have significant impact on tribal nations. NIH may consider sending a new letter to tribal nations that provides information about the DRAFT NIH Policy for Data Management and Sharing and mechanisms for a meaningful consultation with tribal nations such as in-person listening sessions and a specific timeline for input.

We are disappointed that the DRAFT NIH Policy for Data Management and Sharing only has two brief mentions of tribal nations in the entire policy. The mentions include a generic statement about "...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." The only other mention is in a later section describing what should be in a plan as "...protections...that are consistent with applicable federal, tribal, state, and local laws, regulations, statutes, guidance, and institutional policies."

Tribal nations have been providing input on the data sharing policy issue for years, and these phrases are not adequate to describe the full range of issues that researchers must consider with data management and sharing when AI/AN individual participants and/or tribal nations are included in their data. In addition, as mentioned above, tribal nations have the inherent right to exert their sovereignty over data management and sharing in any research project, regardless of whether they have laws, regulations, statutes, guidance, [or] institutional policies. **The draft policy is therefore inaccurate and must be modified to ensure researchers follow the directions and preferences of tribal nations whether or not they have laws and policies in place on this topic.**

The Federal Register Notice did contain a preamble or background section that mentioned in the fifth paragraph that NIH "recognizes that sovereign Tribal Nations may have unique data sharing concerns..." Content from this section should be included in the DRAFT NIH Policy for Data Management and Sharing, and not be a part of any preamble or background section outside of the policy. For example, the wording from the background section could be included in the "Purpose" section of the policy to state: **NIH recognizes that sovereign tribal nations may have unique data sharing concerns and researchers must work in partnership with any tribal nations associated with data collection activities in their research and develop culturally sensitive data management and sharing plans that are documented to be in agreement with the tribal nation(s) involved.**

The DRAFT NIH Policy for Data Management and Sharing does not clearly state that there might be circumstances where data will not be shared until far into the policy in Section VI. The language used is also not as clear as it should be. The policy must clearly state, as in the 2003 policy, that applications can describe why it is not possible to share data and that there are very good reasons why some data cannot be shared. Without these clarifications, a researcher might infer from the draft policy that all data must be shared. However, **tribal nations have the right to determine whether data can or cannot be shared, and any NIH application must specifically address tribal preferences if applicable.** The DRAFT NIH Policy for Data Management and Sharing also does not contain any references to community-based participatory research and the importance of working in partnership with communities on research and any data sharing plans.

The data sharing and management section of the policy must include a statement such as: **“Researchers must document how they are respecting the preferences of tribal nations to share or not share their data.”** In addition, the preferences or requirements of any tribal nation(s) involved in the research must be documented in the data sharing plan and be substantiated by documentation from the tribal nation, such as a tribal resolution or letter from the tribal council. A suggested phrase to add to section VI, data sharing and management plans, could be: **“Plans that involve data from AI/AN individuals or AI/AN tribal nations must include official documentation of the wishes of the tribal nation(s) on data management and sharing.”**

The Supplemental DRAFT Guidance sections provide additional details on how to implement the DRAFT NIH Policy for Data Management and Sharing but also lack guidance specific to tribal nations. The DRAFT Guidance on Allowable Costs for Data Management and Sharing must include reference to ensuring that tribal nations have adequate resources for data management and sharing since many tribal nations choose to manage the data sharing process themselves. A fourth point could be added at the end of the Supplemental DRAFT Guidance that says: **“When a tribal nation will be responsible for managing the data sharing process, researchers must include in their application budget an adequate amount of resources for the tribal nation to successfully manage the data sharing process.”**

The Supplemental DRAFT Guidance on Elements of a NIH Data Management and Sharing Plan also does not have adequate guidance specific to tribal nations. In the first section with the bulleted list of considerations, the following sentence should be added to the fourth bullet in the list: **“Data plans should include how the researcher will address the preferences and requirements of tribal nations regardless of whether a tribal law or policy is in place.”** Also, at the end of the DRAFT Guidance, in Section 5 on Data Sharing Agreements, Licenses, and Other Use Limitations, the following bullet should be added: **“Documentation of tribal nation preferences for data protection and whether or not it can be shared should be included in the form of official tribal correspondence such as a tribal resolution or letter from the tribal council.”** In Section 6, Oversight of Data Management, the tribal nation’s contact person should also be listed.

Summary

NIH must immediately consult in a meaningful way with tribal nations on the DRAFT NIH Policy for Data Management and Sharing and Supplemental DRAFT Guidance as soon as possible and before the final policy is enacted. Even though tribal consultation sessions were held last year on the general topic of data sharing, a critical event occurred when NIH published the Federal Register Notice on the DRAFT NIH Policy for Data Management and Sharing in November 2019. NIH must hold tribal consultation or listening sessions as soon as possible to allow for discussion of this draft policy. The NIH Tribal Advisory Committee must be involved in the tribal consultation process and has the expertise necessary to assist NIH with meeting the needs of tribal nations. We urge NIH to implement the comments we have proposed in this letter as soon as possible as these additions will easily address comments NIH has already received on this topic from tribal nations. However, all tribal nations must have an opportunity to consult before the DRAFT NIH Policy for Data Management and Sharing is enacted as a final policy.

If you have any questions, please contact our Policy Research Center at research@ncai.org.

Sincerely,

A handwritten signature in black ink, appearing to be 'KA', with a long horizontal flourish extending to the right.

Kevin Allis
Chief Executive Officer
National Congress of American Indians