NIH RFI - Re: Proposed Provisions for a Draft NIH Data Management and Sharing Policy

Deadline: December 10, 2018

Submission via NIH website: https://osp.od.nih.gov/provisions-data-managment-sharing/

NCAI Policy Research Center responses

I.   The definition of Scientific Data

Response: For the purpose of the NIH Data Management and Sharing Policy, in Section I, Definitions, the definition of "Scientific Data" should be modified to include….."data used to support scholarly publications **and scholarly presentations.**" Often scientists conduct research that may not be submitted or accepted for publication and use scholarly presentations as a method to disseminate their data to advance scientific knowledge. Scholarly presentations share data to help advance the field of knowledge, which is fundamental to the definition of research. This definition should also note that American Indian and Alaska Native tribes, as sovereign nations, have the right to determine their own definition of data in their own data sharing and management plans and tribal research codes. The NIH Common Rule affirms that researchers with federal funding must follow tribal research codes, which can be more restrictive than the Common Rule. Nothing in this data management and data sharing policy should conflict with the ability of a tribe to establish its own definitions in its own research codes and data management and sharing policies for researchers it chooses to partner with on research. NIH should consult with American Indian and Alaska Native tribes on this draft NIH Data Management and Sharing Policy before a final policy is implemented and report back on how their input was incorporated into the final version.

II.   The requirements for Data Management and Sharing Plans

Response: For the purpose of the NIH Data Management and Sharing Policy, in Section IV, "Requirements for Data Management and Sharing Plans," at the end of the first paragraph, the following should be added: "All Plans involving research and Scientific Data with American Indian and Alaska Native tribe(s) should include specific information on how the Plan complies with their tribal research codes, documentation of official tribal approval(s) for the Plan, and should describe in detail how the Plan implements tribal requirements and preferences on data management and sharing to ensure that tribal nation(s) and their citizens, lands, and resources are protected, along with how the Plan will implement any tribal restrictions to data sharing."

Under "Plan Review and Evaluation", add a new bullet at the end of the list that states the following: "For all Extramural Grants, Contracts, NIH Intramural Research Projects, and Other funding/support agreements, the Plan should be determined to be "unacceptable" by reviewers or NIH staff if the Plan involves data from American Indian and Alaska Native tribes and does not include specific information on how the Plan complies with tribal research codes, documentation of official tribal approval(s) for the Plan, and detailed descriptions of how the

Plan implements tribal requirements and preferences on data management and sharing to ensure that tribal nation(s) and their citizens, land and resources are protected, along with how the Plan will implement any tribal restrictions to data sharing."

Under "Plan Elements", add a new number 4 that states the following: "All Plans should indicate if their data includes data and information from American Indian and Alaska Natives tribes or individuals, and if so, the Plan should include a one page addendum that describes in detail how the data was obtained, whether there is/was documentation of American Indian/Alaska Native tribal approval to obtain the data, and documentation of approval(s) from American Indian and/or Alaska Native tribes for the Plan for data sharing. The Plan should describe for each element listed above how the Plan will implement any tribal requirements or restrictions relevant to each element of the Plan. The Plan should have documentation that the tribe(s) affirmatively approve each element of the Plan." Examples of how the tribe may approve each element of the Plan include the following: the tribal must approval all types of data that may be collected and shared, and reserves the right to not approve certain or any types of data to be shared; the tribe must approve all other information, including relevant associated data, that may be shared; the tribe must approve the methods of how the data will be processed or analyzed; the tribe must approve any standards used in data collection and sharing. Even though some tribes may value and encourage data sharing, any Plan should clearly include information that affirms any tribal approvals, requirements, restrictions, or denials of any or all elements of the Plan. NIH should consult with American Indian and Alaska Native tribes on this draft NIH Data Management and Sharing Policy before a final policy is implemented and report back on how their input was incorporated into the final version.

III.   The optimal timing, including possible phased adoption, for NIH to consider in implementing various parts of a new data management and sharing policy and how possible phasing could relate to needed improvements in data infrastructure, resources, and standards.

Response: NIH must consult as soon as possible with American Indian and Alaska Native tribes on any data management and sharing policy before implementation. According to the Department of Health and Human Services Tribal Consultation Policy, which applies to all Divisions in the Department including NIH, "Before any action is taken that will significantly affect Indian Tribes it is the HHS policy that, to the extent practicable and permitted by law, consultation with Indian Tribes will occur. Such actions refer to policies that… have tribal implications and have substantial direct effects on one or more Indian Tribes…" NIH's draft Data Sharing and Management Policy meets this definition of an action that will significantly affect Indian tribes and thus requires tribal consultation before it is implemented.

To our knowledge, NIH has received a large amount of input from American Indian and Alaska Native tribes and other individuals with related expertise on the importance of developing its Data Sharing and Management plan in partnership with tribes and the importance of incorporating the input and recommendations of tribes to protect their sovereign rights to govern research and data that involves their citizens, lands, and resources. As of the date of this submission, American Indian and Alaska Native tribes and others have expressed in public

forums their dissatisfaction with NIH's efforts to date to incorporate tribal recommendations into this draft policy.

We recommend that NIH immediately consider this draft NIH data sharing and management policy to represent a Critical Event, affirm that it impacts all 573 American Indian and Alaska Native tribes, and immediately initiate tribal consultation through a process that begins with a letter to all tribes with the current draft of the policy attached. NIH should understand that a Request for Information released to the public is not a form of tribal consultation. NIH should initiate a tribal consultation on this draft policy as soon as possible and should not wait for the draft NIH tribal consultation protocol under development by the NIH Tribal Research Office to be finalized. NIH should allow for in-person tribal consultation, should carefully review tribal input, and should communicate with all tribes how their recommendations will be reflected in the final draft of the NIH Data Sharing and Management Policy and give tribes one more opportunity at that point to consult that the final draft. All input received by tribes to date should be summarized by NIH and shared with tribes at the onset of this tribal consultation. NIH should understand that tribal consultation is a policy of the Department of Health and Human Services and that any policies developed without tribal consultation represent a litigation risk to the agency, the Department, and individual investigators. The topic of data sharing and management is a priority topic for American Indian and Alaska Native tribes who must have the opportunity to exercise their sovereignty over data management and data sharing, both of which have potential significant risks to their citizens, lands and resources.

Finally, the NCAI Policy Research Center submitted comments on the Draft NIH Genomic Data Sharing Policy in 2013 and in those comments the following five overarching principles were highlighted:

- Tribal nations have sovereignty over research conducted on tribal lands and with tribal citizens;
- Researchers must secure active tribal approval for the collection, use, and sharing of tribal data;
- There are successful models of tribally-driven data sharing that serve to both protect and benefit Native people;
- Research ethics need to acknowledge the importance of community consent alongside individual consent; and
- Research ethics need to include protections for biological samples collected from both living and deceased human beings.

Given that American Indian and Alaska Native tribes have experienced the harmful effects of inappropriate research and data sharing, and in some cases continue to experience those harmful effects, ensuring that a meaningful tribal consultation on the NIH data management and sharing policy is of utmost importance and urgency. Tribes understand the importance of research and data to eliminating disparities and can be helpful in developing recommendations and solutions to data management and sharing policies that respect their sovereignty, the government to government relationship between tribes and the federal government, and the rights of tribes to enter into respectful partnerships with researchers on data management and data sharing.