



USET

Nashville TN Office
711 Stewarts Ferry Pike, Ste. 100
Nashville TN 37214
P: (615) 872-7900
F: (615) 872-7417

Washington DC Office
400 North Capitol St., Ste. 585
Washington DC 20001
P: (202) 624-3550
F: (202) 393-5218

December 10, 2018

Office of Science and Policy
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Re: Request for Information on Proposed Provisions for a Draft Data Management and Sharing Policy for NIH Funded or Supported Research

The United South and Eastern Tribes Sovereignty Protection Fund (USET SPF) is pleased to offer the following comments on the National Institutes of Health (NIH) *Request for Information on Proposed Provisions for a Draft Data Management and Sharing Policy for NIH Funded or Supported Research*. USET SPF recognizes that sharing data among the scientific community is imperative for scientific discovery and advancement. However, it is critically important to recognize the historic relationship between scientific study and Tribal Nations, where researchers committed ethical violations against our communities and our people. American Indians and Alaska Natives (AI/AN) and Tribal communities have experienced negative impacts from the use of genomic data (*Arizona Board of Regents v. Havasupai Tribe*) without Tribal Nation informed consent. To ensure the privacy of Tribal Nation communities, as well as AI/AN individuals, USET SPF urges NIH to consult with Tribal Nations regarding its research, data sharing, and data management policies and offers the following recommendations in response to NIH's request for comment.

USET SPF is a non-profit, inter-tribal organization representing 27 federally recognized Tribal Nations from Texas across to Florida and up to Maine.¹ Both individually, as well as collectively through USET SPF, our member Tribal Nations work to improve health care services for American Indians. Our member Tribal Nations operate in the Nashville Area of the IHS, which contains 36 IHS and tribal health care facilities. Our citizens receive health care services both directly at IHS facilities, as well as in Tribally Operated facilities operated under contracts with IHS pursuant to the Indian Self-Determination and Education Assistance Act (ISDEAA), P.L. 93-638.

I. The Definition of Scientific Data

USET SPF agrees with the definition of Scientific Data as outlined in the *Proposed Provisions for a Draft NIH Data Management and Sharing Policy*. USET SPF also agrees that the definition of Scientific Data should not include 'laboratory notebooks, preliminary analysis, completed case report forms, drafts of scientific papers, plans for future research peer reviews, communications with colleagues, or

¹ USET SPF member Tribal Nations include: Alabama-Coushatta Tribe of Texas (TX), Aroostook Band of Micmac Indians (ME), Catawba Indian Nation (SC), Cayuga Nation (NY), Chitimacha Tribe of Louisiana (LA), Coushatta Tribe of Louisiana (LA), Eastern Band of Cherokee Indians (NC), Houlton Band of Maliseet Indians (ME), Jena Band of Choctaw Indians (LA), Mashantucket Pequot Indian Tribe (CT), Mashpee Wampanoag Tribe (MA), Miccosukee Tribe of Indians of Florida (FL), Mississippi Band of Choctaw Indians (MS), Mohegan Tribe of Indians of Connecticut (CT), Narragansett Indian Tribe (RI), Oneida Indian Nation (NY), Passamaquoddy Tribe at Indian Township (ME), Passamaquoddy Tribe at Pleasant Point (ME), Pamunkey Indian Tribe (VA), Penobscot Indian Nation (ME), Poarch Band of Creek Indians (AL), Saint Regis Mohawk Tribe (NY), Seminole Tribe of Florida (FL), Seneca Nation of Indians (NY), Shinnecock Indian Nation (NY), Tunica-Biloxi Tribe of Louisiana (LA), and the Wampanoag Tribe of Gay Head (Aquinnah) (MA).

physical objects, such as laboratory specimens' (referred to hereafter as 'work product') and that researchers not be required to share this information with NIH. It is important to note, however, that researchers should be expressly prohibited from refusing to share work product (and Scientific Data) with any Tribal Nation impacted by the research project.

II. The Requirements for Data Management and Sharing Plans

USET SPF appreciates NIH's forethought of requiring a data management and sharing plan as part of future application processes, proposals, cooperative research and development agreements (CRADA), or other funding agreements, or intramural research reports. As part of the US's trust obligation to federally recognized Tribal Nations, NIH has a duty to honor, protect and uphold Tribal Nation sovereignty in its efforts to 'seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.' Therefore, it is USET SPF's recommendation that all submitted data management and sharing plans require an element entitled 'Tribal Nation(s) Population' that shows, first and foremost, evidence of Tribal Nation consent for data sharing.

No Tribal Nation data should be included in any level of access without explicit Tribal Nation consent. The consent mechanism varies from Tribal Nation to Tribal Nation and may take the form of Tribal Nation Council resolutions, signed MOU's with the designated Tribal Nation leader, etc. In addition to documented Tribal Nation consent, the plan must address additional considerations between the researcher and the Tribal Nation such as:

- Data ownership and sovereignty
- Publication requirements and Tribal Nation consent procedures
- Specimen use, storage, and destruction policy
- Work product ownership and sovereignty
- Data use provisions for future studies
- Data sharing and use provisions for NIH-maintained databases (i.e. genomics)

USET SPF must note that the above list is not exhaustive, and that NIH must seek formal Tribal consultation on these recommendations, as well as on any future draft Data Management and Sharing Plan requirements. Much as 'The Belmont Report' and the National Research Act of 1974 have resulted in human subject protection as standard practice among researchers, USET SPF believes that such a required element for all NIH-funded research proposals will integrate Tribal Nation protection and sovereignty concerns into common research practice. USET SPF reminds NIH that it has an obligation to ensure that Tribal Nations are able to protect their citizens and data, and this obligation supersedes any data sharing interests.

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.

NIH must engage in formal Tribal consultation on the proposed policy provisions and proposed required elements for data management and sharing plans, as well as the subsequent draft NIH policy for data

management and sharing. These should not be considered ready for drafting or adoption prior to thorough nationwide Tribal consultation in addition to guidance from NIH's Tribal advisory committee.

IV. Compliance and Enforcement

USET SPF strongly suggests that an oversight mechanism, specific to Tribal Nation data be created by NIH. This mechanism would detail Tribal Nation data protection best practices, procedures, ensure researcher compliance, and recommend consequences for violations.

Conclusion

USET SPF appreciates this opportunity to provide comments on the NIH Proposed Provisions for a Draft Data Management and Sharing Policy for NIH Funded or Supported Research. Because data management and sharing policies has significant implications for Tribal governments and their citizens, we urge NIH to seek formal Tribal Consultation on this issue. Should you have any questions or require additional information, please do not hesitate to contact Mr. Kitcki Carroll, USET Executive Director, at (615) 467-1540 or by e-mail at kcarroll@usetinc.org.

Sincerely,



Kirk Francis
President



Kitcki A. Carroll
Executive Director