



USET

SOVEREIGNTY PROTECTION FUND

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Andrea Jackson-Dipina, Dr.PH
Director of the Division of Scientific Data Sharing Policy
Office of Science Policy
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Re: Request for Public Comments on a DRAFT NIH Policy for Data Management and Sharing and Supplemental DRAFT Guidance

Dear Dr. Jackson-Dipina,

The United South and Eastern Tribes Sovereignty Protection Fund (USET SPF) is pleased to offer comments to the National Institutes of Health (NIH) regarding the agency's *Request for Public Comments on a Draft NIH Policy for Data Management and Sharing and Supplemental Draft Guidance*. USET SPF recognizes that sharing data among the scientific community is imperative for scientific discovery and advancement. However, as NIH advances its policy regarding data management and sharing, the agency must recognize the historical relationship between scientific study and Tribal Nations, where researchers committed ethical violations against our communities and our people. We underscore that NIH must seek to prevent these violations from ever occurring again by ensuring all NIH policies are reflective of the federal government's obligation to honor, protect and uphold Tribal sovereignty by requiring explicit consent from Tribal Nations.

USET SPF is a non-profit, inter-tribal organization representing 30 federally recognized Tribal Nations from the Canadian border to the Everglades and across the Gulf of Mexico¹. 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 Indian Health Service, which contains 36 IHS and Tribal health care facilities. Our patients receive health care services both directly at IHS facilities, as well as in Tribally-operated facilities under contracts with IHS pursuant to the Indian Self-Determination and Education Assistance Act (ISDEAA), P.L. 93-638.

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), Chickahominy Indian Tribe (VA), Chickahominy Indian Tribe—Eastern Division (VA), 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), Pamunkey Indian Tribe (VA), Passamaquoddy Tribe at Indian Township (ME), Passamaquoddy Tribe at Pleasant Point (ME), Penobscot Indian Nation (ME), Poarch Band of Creek Indians (AL), Rappahannock Tribe (VA), 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).

Because there is strength in Unity

Native people and Tribal communities continue to face negative impacts from previously unauthorized and unpermitted use of genomic data without Tribal Nation informed consent (*Arizona Board of Regents v. Havasupai Tribe*). Despite Tribal efforts to require informed consent regarding the use of Tribal data, NIH has continued to advance certain initiatives, including a Tribal Consultation Policy, without engaging in meaningful consultation with Tribal Nations. In August 2018, USET SPF provided comments to NIH regarding the agency's inadequate Tribal consultation on three initiatives, including proposed provisions for the Draft NIH Data Management and Sharing Policy. In our comments, we note NIH's ineffective and insufficient consultation practices with Tribal Nations which are in violation of the U.S. Department of Health and Human Services (HHS) Tribal Consultation Policy. While we recognize some improvement with the addition of clear deadlines and a request for broader guidance on research with our population, we remain focused on the results of these efforts. As stated in past communications, we expect NIH to engage in consultation with Tribal Nations in a transparent and meaningful manner to resolve outstanding concerns from Indian Country to ensure sovereignty is upheld and past abuses never happen again. This includes taking active steps to implement the recommendations and guidance of Tribal Nations. In addition to our below recommendations, we continue to underscore that NIH must consult with Tribal Nations on an ongoing basis regarding the agency's research, data sharing, and data management policies to ensure the privacy of Tribal Nation communities, as well as American Indian and Alaska Native (AI/AN) individuals.

Draft NIH Policy for Data Management

Within the Draft NIH Policy for Data Management, the 'Effective Date' seems to include only research to be conducted in the future. Because of the historical research abuses outlined above, USET SPF believes that ALL projects, current and future, be required to submit a Data Management Plan. There is an opportunity to ensure that data currently being collected and utilized is protected. Under the 'Compliance and Enforcement' section, USET SPF insists that an oversight mechanism, specific to Tribal Nation data, designed consultation with Tribal Nations, be included. This mechanism would detail Tribal Nation data protection best practices, procedures, ensure researcher compliance, and recommend consequences for violations.

Supplemental Draft Guidance: Elements of an NIH Data Management and Sharing Plan

USET SPF appreciates NIH's forethought of requiring a data management and sharing plan as part of all research funded or conducted in whole or in part by the NIH. As part of the federal 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, USET SPF's recommendations 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 and collection. This element should be designed through ongoing consultation with Tribal Nations.

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 memorandums of understanding with a 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;
- Community risks and benefits of the research and any potential data sharing

- Specimen use, storage, and destruction policy;
- Work product ownership and sovereignty;
- Data use provisions for future studies; and
- Data sharing and use provisions for NIH-maintained databases (i.e., genomics).

USET SPF notes 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 of its trust obligation to ensure that Tribal Nations can protect our citizens and data, and this obligation supersedes any data sharing interests.

NIH Institutional Review Boards

In addition to the comments above regarding data sharing, USET SPF strongly recommends Native representation on all NIH Institutional Review Boards (IRB) reviewing studies that include AI/AN people. Without this unique perspective advising the IRB, Native people and communities will not be adequately protected from research abuse.

Conclusion

Based on NIH's previous practices, USET SPF continues to be deeply concerned that the final policy may not contain necessary protocols for integrating Tribal Nation protection and sovereignty concerns into common research practice. As we seek to protect, regulate, and maintain ownership over the data of our citizens and Nations, NIH has a legal and moral trust obligation to uphold the sovereign status of Tribal Nations. Because data management and sharing policies have significant implications for Tribal governments and their citizens, NIH must seek formal Tribal Consultation on this and all other issues. We look forward to the opportunity to partner with NIH to ensure research conducted and data collected in our communities and with the Native population is done in a way that reflects our sovereign status and seeks to reconcile our difficult history with the scientific community. From study development and design, approval, ethical review, data collection/analysis, result interpretation, and reporting research within the Native community cannot be ethically conducted without Native representation and consent at all stages of the research process. Should you have any questions or require further information, please contact Ms. Liz Malerba, USET SPF Director of Policy and Legislative Affairs, at LMalerba@usetinc.org or 202-624-3550.

Sincerely,



Kirk Francis
President



Kitcki A. Carroll
Executive Director