



USET

SOVEREIGNTY PROTECTION FUND

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Transmitted Electronically to:
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October 16, 2020

Josh Denny, M.D., M.S.
Chief Executive Officer, *All of Us* Research Program
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Denny,

On behalf of United South and Eastern Tribes Sovereignty Protection Fund (USET SPF) we write to provide feedback on the *All of Us* Program's Draft Tribal Consultation Report. While we appreciate the Program's efforts in drafting the Report and developing its Tribal commitments, we note that both fail to offer adequate protections for Tribal Nations and our communities. While there is much focus on the protection of individual American Indian and Alaska Native (AI/AN) people, NIH must remember its trust and treaty obligations to Tribal Nations. This includes an obligation to prioritize the protection of our communities (including our citizens who live away from home) as research protocols are developed.

USET SPF is a non-profit, inter-tribal organization advocating on behalf of 30 federally recognized Tribal Nations from the Northeastern Woodlands 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.

USET SPF has repeatedly raised issues related to community protections and Tribal sovereignty in its comments to NIH on *All of Us* and other initiatives. We remind NIH that Tribal Nations count all our citizens, regardless of where they reside—not only those living on our homelands. Whether research occurs on or off Tribal land, if it involves our citizens, it has the potential to impact our Tribal Nations. With this in mind, it is time for NIH to offer concrete steps that will demonstrate commitment to upholding its obligations to our governments by implementing Tribal guidance. To that end USET SPF offers the following recommendations:

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

Institutional Review Board Approval

Tribal-designated Institutional Review Board Review (IRB) must be a requirement before any research commences within any Tribal community, unless expressly waived by Tribal Nation leadership. This review process must include informed-consent procedures that outline publication permission, as well as community protection informed consent and procedures.

Informed Consent for Current and Future AI/AN Participants

While USET SPF commends NIH on its plan to retroactively apply informed-consent procedures to allow current AI/AN participants to learn about potential harms to their respective Tribal communities, we remind NIH that the *All of Us* research program began enrolling AI/AN participants before undergoing Tribal consultation in violation of its obligations to Indian Country and the Department of Health and Human Services' Tribal Consultation Policy. For this reason, USET SPF believes that all current and future AI/AN research participants should actively choose to continue participation ('opt in') in *All of Us*, instead of withdrawing if in disagreement ('opt out'). Furthermore, this informed consent must be a documented requirement of continued participation and not simply 'materials offered.' Development and finalization of all stages of this process—including educational materials—must also undergo the Tribal consultation process.

Training for Researchers

All researchers must undergo required annual training regarding the need for AI/AN community protection, as well the unique nature of the relationship between the US and Indian Tribal Nations, and the concepts of indigenous data sovereignty. This training must be developed in consultation with Tribal Nations.

Task Force

USET SPF supports and urges the NIH to move forward with the creation of a task force that would review all research proposals focused on AI/AN data. We stress the individuals serving on this task force should be AI/AN, with extensive knowledge of research within Indian Country, and without conflicts of interest, such as being a federal employee or researcher on a federally-funded project.

Broad Consent and Secondary Research

As discussed above, NIH does an admirable job of protecting the rights of the individual, but pays scant attention to Tribal community protection. In the case of *All of Us* Tribal Consultation Report, the procedures associated with secondary use of de-identified samples and data need additional clarification and, likely, a additional oversight and protections. For this reason, USET SPF advises that until these concepts are explored more fully, secondary research should not be NOT conducted on AI/AN data or samples.

Disciplinary Actions for Violations of the Data User Code of Conduct

USET SPF supports the notification of the Tribal Advisory Committee (TAC) in cases where the Data User Code of Conduct is violated. We would like to extend that notification to the proposed task force, and to the affected Tribal Nation(s). In addition, it might be helpful to report on all violations (not just those involving AI/AN data) to the TAC at the semi-annual meetings.

Conclusion

USET SPF acknowledges this draft Tribal Consultation Report as a step forward in the relationship between NIH and Tribal Nations. However, we insist that NIH must modify the focus of the Report to uphold its obligations to Tribal Nations—including the obligation to protect the whole of our communities from unethical research practices—instead of only concerning itself with individual AI/ANs. It is our hope that with some improvements, NIH's commitments to Tribal Nations can be more reflective of these obligations. 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. 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,

A handwritten signature in black ink, appearing to read "K. Francis", with a long horizontal flourish extending to the right.

Kirk Francis
President

A handwritten signature in black ink, appearing to read "K. A. Carroll", with a long horizontal flourish extending to the right.

Kitcki A. Carroll
Executive Director