



USET

SOVEREIGNTY PROTECTION FUND

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

Transmitted via email to:
Dave.Wilson2@nih.gov

February 9, 2018

David R. Wilson, PhD
Director, Tribal Health Research Office
Division of Program Coordination, Planning, and Strategic Initiatives
Office of the Director, NIH

Dear Dr. Wilson,

In response to a request for information from the National Institutes of Health (NIH) regarding the “All of Us” research program protocol that was published on August 4, 2017 requesting feedback and recommendations on topics for consideration by the program, the United South and Eastern Tribes Sovereignty Protection Fund (USET SPF) offers the following comments and questions to consider.

USET SPF is a non-profit, inter-tribal organization representing 27 federally recognized Tribal Nations from Texas across to Florida and up to Maine¹. 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 citizens 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 acknowledges the potential for wide-reaching benefits as a result of the innovative, individual-focused approach to research that NIH has proposed in the ‘All of Us’ Core Protocol V1. This approach, as well as the depth and breadth of this project, is likely to lead to great breakthroughs in health-related knowledge. However, before USET SPF can share ideas with NIH regarding potential research questions and projects, as requested, we’d like to remind NIH that, as an agency of the federal government, it has a legal and moral trust responsibility to Tribal Nations. This includes upholding the sovereign status of Tribal Nations, as we seek to protect, regulate, and maintain ownership over the data of our citizens and Nations.

We continue to urge NIH to consider the shameful and deeply unethical history between research and Tribal Nations, as well as opportunities to ensure that past abuses never happen again. Any proposals moving forward that include Tribal Nation or American Indian and Alaska Native (AI/AN) data must be Tribally-guided. And Tribal Nations must have full confidence that research will be conducted in a way that

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), 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), 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).

acknowledges and seeks to correct past abuses, including through the use of Tribal Institutional Review Boards, community-based participatory research, and informed consent. In review of the initial project protocol, USET SPF found that it raised a multitude of currently unanswered questions and concerns, which are broadly categorized below. USET SPF contends that NIH must, through broad and extensive Tribal consultation, develop a protocol or guidance that addresses Tribal concerns and ensures the unique status of Tribal Nations is taken into account before the 'All of Us' protocol can be utilized in Tribal communities and among the AI/AN population.

Special Populations

Within the 'Vulnerable Populations' section, which we suggest re-titling to "Special Population", there is no mention of American Indian/Alaska Native (AI/AN) citizens. The United States trust obligation to Tribal Nations is unique and should be emphasized in this section, along with an explanation of past abuses of research in Indian Country.

Issues of Data Sovereignty

Tribal Nations have rights to data about their lands and citizens. Throughout the document, there is extensive focus (as there should be) on data, including datasets, tissue samples, publications, and electronic health records access by the study participants, researchers, health providers, etc. However, a glaring omission in the document is regarding the sovereignty of Tribal Nations over all the data types included in this project. While Tribal Nations are concerned about the protection of the individual study participant, we are equally concerned with community protection. A litany of past research abuses have negatively impacted and continue to impact Tribal Nations across the country. USET SPF cannot stress enough the need to ensure that this never happens again. Tribal Nations must have the ability to authorize and regulate the research done on Tribal Nations and Tribal citizens. This includes maintaining ownership over

USET SPF has concerns regarding the protocols and regulations that govern data oversight and protection. The protocol mentions that NIH is seeking guidance on where and who should govern this data from its internal General Counsel and the Office of Civil Rights. NIH must also seek this guidance from Tribal Nations and its Tribal Advisory Committee. Tribal Nations, as sovereign nations, must have the governing authorities over any projects that include Tribal Nations both individually and collectively.

Overall Recommendations

- The NIH Tribal Advisory Committee's 'All of Us' subcommittee must have the opportunity review and provide specific recommendations that address AI/AN and Tribal Nation concerns.
- A formal, exhaustive Tribal consultation must be undertaken to ethically include Tribal Nations in this project and before any access to any Tribal Nation or AI/AN data is authorized under this project.
- This document reflects the need for educational opportunities for program officials at NIH regarding the unique nature of the trust obligation that the United States has with federally recognized Tribal Nations, data sovereignty, and community protection. This training should be developed in consultation with Tribal Nations and be required for ALL researchers funded or supported by NIH.

USET SPF appreciates the opportunity to provide recommendations and looks forward to formal Tribal consultation on this and other issues related to research in Indian Country. 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 stroke extending to the right.

Kirk Francis
President

A handwritten signature in black ink, appearing to read 'K. A. Carroll', with a stylized, cursive script.

Kitcki A. Carroll
Executive Director