



USET

SOVEREIGNTY PROTECTION FUND

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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 the United South and Eastern Tribes Sovereignty Protection Fund (USET SPF), we write to provide comments to the National Institutes of Health (NIH) regarding its Tribal consultation on the *All of Us* Research Program. While we appreciate the opportunity to provide additional comments to the agency on this topic, we note that NIH continues to demonstrate a lack of understanding of Tribal Nations, our communities, and our priorities. The consultation questions posed by NIH are inappropriate as NIH has yet to fully address issues related to community protections and Tribal sovereignty that have been [raised in prior consultations](#), despite committing to many protective actions in the “All of Us Research Program Tribal Consultation Final Report.” USET SPF appreciates that NIH acted on several requests from Tribal Nations in the original consultation period, such as prohibiting recruitment and engagement on Tribal lands and not including American Indian and Alaskan Native (AI/AN) in available program datasets while developing a Tribal engagement plan. However, USET SPF asserts that there are outstanding issues with NIH’s current policies and philosophies regarding engagement with Tribal Nations and communities.

USET Sovereignty Protection Fund (USET SPF) is a non-profit, inter-tribal organization advocating on behalf of thirty-three (33) federally recognized Tribal Nations from the Northeastern Woodlands to the Everglades and across the Gulf of Mexico.¹ USET SPF is dedicated to promoting, protecting, and advancing the inherent sovereign rights and authorities of Tribal Nations and in assisting its membership in dealing effectively with public policy issues.

¹ USET SPF member Tribal Nations include: Alabama-Coushatta Tribe of Texas (TX), 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), Mi'kmaq Nation (ME), Mississippi Band of Choctaw Indians (MS), Mohegan Tribe of Indians of Connecticut (CT), Monacan Indian Nation (VA), Nansemond Indian Nation (VA), 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), Upper Mattaponi Indian Tribe (VA) and the Wampanoag Tribe of Gay Head (Aquinnah) (MA).

Because there is Strength in Unity

Policies and Protections for Self-Identified AI/AN Participants

USET SPF maintains that NIH continues to focus almost exclusively on individual protections in the program rather than Tribal sovereignty and community protection. While it is unquestionable that individual protection is important, NIH continues to largely ignore the need for community informed consent in the *All of Us* Program. We remind NIH that Tribal Nations count all our citizens regardless of where they reside – not only those living on our homelands. Regardless of whether research occurs on or off Tribal land or if an individual AI/AN participant has given their consent, if the research involves our citizens, it has the potential to impact our Tribal Nations – a principal NIH explicitly acknowledged in the “*All of Us* Research Program Tribal Consultation Final Report.” In the Final Report section titled “Community Protection and Informed Consent,” NIH states that it “emphatically agrees with the need to protect communities as well as individuals,” yet will not implement our previous recommendation to require AI/AN participants to actively choose to continue participating (“opt in”) in the program and does not offer any other actionable policies to address our concerns.

USET SPF continues to assert that in order to mitigate potential harms to Tribal communities and uphold its obligations to Tribal Nations, NIH must implement stronger informed consent requirements for continued AI/AN participation in the program. Offering educational materials to participants and the option to withdraw is not sufficient, and we disagree with NIH’s assessment that an active “opt in” requirement would place undue burden on individual participants. Tribal Nations and our communities stand to be put at risk if individual concerns are placed over the potential of community harm, and this necessitates more stringent consent requirements – even if those requirements require additional engagement with current and future AI/AN participants. When it comes to ensuring the protection of Tribal citizens from unethical research practices, NIH has an obligation to protect the whole of our communities, not just individual AI/AN people.

Further, NIH must remember that Tribal Nations and our people have an inherent political status and should not be viewed as a racial or ethnic group for these purposes. Regardless of our racial backgrounds, Tribal Nations, our citizens, community members and others eligible for federal Indian programs and services have a unique political status due to the centuries-long trust and treaty relationship established with the federal government and Tribal Nations’ status as inherently sovereign political entities. As such, NIH should view its engagement with Tribal Nations for research purposes through the lenses of diplomacy and the Nation-to-Nation relationship. What protections and policies would govern NIH’s engagement with citizens of another sovereign? Tribal Nations must have the ability to authorize and regulate research done on Tribal Nations, our citizens, and our communities, and NIH has an obligation-to facilitate and uphold this sovereign right.

Practically, oversight measures NIH must pursue are the establishment of Tribal-designated Institutional Review Board (IRB) review, or approval through local Tribal IRBS if a significant number of AI/AN individuals are within the research pool for a particular area. Tribal-designated IRB review should be a required step before research commences in any Tribal community, unless expressly waived by a Tribal Nation. As stated previously, Tribal Nations consider all of our citizens as part of our communities regardless of where they reside, and therefore, review by a Tribal-designated IRB should apply to all AI/AN participants in the *All of Us* Research Program. This review process must include informed-consent procedures that outline publication permissions, as well as community informed consent procedures and potential impacts on Tribal Nations. While NIH states in the “*All of Us* Research Program Tribal Consultation Final Report” that it has “AI/AN representation” on its single program-wide IRB, USET SPF asserts that NIH must abide by other commitments in the Final Report and engage with Tribal Nation-designated IRBs whenever research involves AI/AN participants.

Engagement and Outreach with Tribal Nations and AI/AN Participants

USET SPF asserts that any engagement on Tribal lands, including materials sent to individuals, should be created and approved in consultation with each individual Tribal Nation. Outreach on lands and communities that overlap with Tribal lands must be conducted through a community consent lens. This is not simply an issue impacting individuals. There is a long history of predatory and exploitative research practices involving Tribal Nations and communities, and this necessitates both a higher level of care and a thorough understanding of the federal government's obligations to protect our people and communities. While developing agreements with individual Tribal Nations would undoubtedly create more work for NIH and may potentially slow or delay *All of Us* deployment in areas that overlap with Tribal communities, those are necessary efforts. NIH itself states in the "All of Us Research Program Tribal Consultation Final Report" that "*All of Us* will recruit on tribal lands only in cases where it has a partnership agreement in place with that specific tribe" and that "recruitment on tribal lands or association of a specific tribal affiliation in the *All of Us* dataset is explicitly prohibited and will never be allowed without approval from Tribal Nations and their respective or designated institutional review boards (IRBs)." Therefore, USET SPF asserts that in these situations where zip codes overlap with Tribal lands, NIH must deliver upon its own commitment and enter into agreements with each affected Tribal Nation.

Avoid Standardized or Generalized Policies Regarding AI/AN Communities

In the consultation request, SAMHSA posed a question about "conducting a traditional blessing ceremony" for biosamples of self-identified AI/AN participants when those participants withdraw from the All of Us program. Unfortunately, this question starkly underscores SAMHSA's continued and significant lack of understanding of Tribal Nations and our communities. Indian Country is not a monolith, and NIH itself acknowledges in the Tribal Consultation Final Report that "there is no consensus position or singular source" that can represent Tribal Nations and communities. Knowing that the range of "traditional blessing ceremonies" is extremely vast and that ceremony is often unique and personal for Tribal Nations, SAMHSA's suggestion that it could standardize an "intertribal ceremony" is concerning and indicates a fundamental misunderstanding of how to engage with Tribal Nations. As is the case with many of these consultation questions, this is a matter that must be determined in consultation with each individual Tribal Nation.

Task Force and Further Tribal Consultation

USET SPF urges NIH, as we have in prior comments, to move forward with the creation of a task force that would review all research proposals focused on AI/AN data and other considerations within the *All of Us* program. 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.

In addition, there are several issues that require further Tribal consultation before NIH moves forward with this program. The educational materials that NIH claims that it will provide current and future AI/AN *All of Us* participants – including the information provided during the withdrawal period and the information provided prior to consenting to participate in the program– must undergo Tribal consultation. Additionally, NIH must engage in Tribal consultation regarding the required training for researchers. USET SPF maintains that all researchers should undergo annual training that is specific to AI/AN community protection, Tribal sovereignty, and the unique nature of the relationship between the U.S. and Tribal Nations, and that this training should also be developed in consultation with Tribal Nations.

Conclusion

USET SPF acknowledges that this consultation period is another step forward in the relationship between NIH and Tribal Nations, and is, in some ways, an improvement upon prior policies and engagement.

However, despite repeated requests in prior Tribal consultations, NIH continues to overly concern itself primarily with individual AI/AN participants and has rejected actionable recommendations for improving community consent and protection. USET SPF strongly encourages NIH to engage in further Tribal consultation on the All of Us Research Program and work to implement the commitments it made to Tribal sovereignty and engagement in its program reports. 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 615-838-5906.

Sincerely,



Kirk Francis
President



Kitcki A. Carroll
Executive Director