



# USET

SOVEREIGNTY PROTECTION FUND

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June 5, 2020

Tara A. Schwetz, Ph.D.  
Associate Deputy Director  
National Institutes of Health  
9000 Rockville Pike  
Bethesda, Maryland 20892

Dear Associate Deputy Director Schwetz,

On behalf of the United South and Eastern Tribes Sovereignty Protection Fund (USET SPF), we write to provide comment to the National Institutes of Health (NIH) regarding its Tribal consultation on COVID-19 research initiatives. During the consultation, NIH representatives discussed the agency's desire to fast-track COVID-19 research in Indian Country, which would have major implications for Tribal communities during the COVID-19 pandemic and beyond. As the agency seeks to expedite COVID-19 research, USET SPF remains deeply concerned with the continued lack of NIH policies and procedures in place to protect our data, our communities, and our sovereignty. We underscore that all research, including that related to COVID-19, in Tribal communities and with Native individuals must contain protocols for integrating Tribal consent and oversight, as well as protections for Tribal data ownership and Native participants. Without these protections in place, USET SPF contends that NIH-facilitated or funded research, including on COVID-19, should not occur in our communities or with our people.

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 Mexico<sup>1</sup>. 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.

On May 21, 2020, NIH issued a Dear Tribal Leader Letter (DTLL) announcing the initiation of Tribal consultation to gather input from Tribal leaders on NIH's COVID-19 research initiatives, with a digital consultation held on May 28<sup>th</sup>. The subjects of the consultation include the Rapid Acceleration of Diagnostics (RADx) initiative and a study to identify COVID-19 antibodies in samples previously collected

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<sup>1</sup> 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).

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under the *All of Us* research program. While the nature of the virus is largely unknown, it is evident that COVID-19 has had a disproportionate impact on Tribal Nations across the country, who have been using already limited resources to mitigate the spread and treatment of COVID-19 in our communities. As such, USET SPF recognizes that research is critical in both understanding how the virus causes disease and developing strategies to mitigate illness and death in all communities. However, USET SPF and others in Indian Country are deeply concerned about the premature deployment of these initiatives within Tribal communities as an attempt to respond to the pandemic. Specifically, RADx would not only fast-track the deployment of unvetted COVID-19 laboratory tests in Indian Country, but the proposal itself is coercive and unethical in nature as it promotes access to COVID-19 testing for Tribal communities within a research project. In addition, we deeply disagree with the proposal to open access to *All of Us* data prior to the conclusion of the *All of Us* consultation.

USET SPF contends that the accelerated deployment of these, and other initiatives proposed by NIH, within Indian Country are premature, disingenuous, ill-advised, and dangerously blur the line between research and ethical practices. While it is critical that we understand how COVID-19 has uniquely affected Indian Country, it is inappropriate to propose NIH research in our communities in the absence of policies that honor, protect and uphold Tribal sovereignty.

USET SPF provides the below responses based on the specific framing questions provided by NIH in the DTLL to further convey our concerns regarding the deployment of these initiatives in Indian Country.

**1. What research questions, including around COVID-19 testing, are most important to your respective communities during the current COVID-19 pandemic?**

NIH continues to leave unaddressed the numerous concerns from Indian Country on how the agency will conduct ethical research in Tribal communities and on Native people. Therefore, it is too soon to determine further research questions around COVID-19 testing and beyond. Before exploring the possibilities of COVID-19 research in Indian Country, NIH must develop policies that respond to Tribal guidance and ensure that research is conducted ethically, using the principals of Community Based Participatory Research (CBPR).

Prior to the COVID-19 pandemic, NIH committed to refraining from sharing American Indian and Alaska Native (AI/AN) data gathered from the *All of Us* project with researchers until Tribal consultation is complete. However, NIH is now requesting input regarding a proposal to include certain *All of Us* samples from current self-identified AI/AN participants in the COVID-19 antibody analysis. If implemented, AI/AN data would ultimately be generated earlier than expected and would be made available to researchers for COVID-19 study prior to the completion of Tribal consultation. NIH justified the proposal by stating the individual COVID-19 antibody returns could provide benefits to participants. However, we are concerned NIH is attempting to use the COVID-19 pandemic to bypass the consultation process and authorize the use of Tribal data before consultation has concluded. USET SPF underscores that it is wholly inappropriate to share Tribal data without explicit Tribal Nation consent.

**2. What special considerations for Tribes should be in place as we are developing funding opportunities?**

Any research in Indian Country must clearly outline how the research will benefit Tribal communities in both the short- and long-term, particularly if the research yields significant results. USET SPF underscores that Tribal Nations must see direct benefits from any research conducted in our

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communities, as “Helicopter research,” where non-Tribal researchers gather data/samples then depart the community, has been practiced in Indian Country for too long. In addition, all researchers **must** have documented consent of the Tribal Nation in any research application, including where research is to be conducted off of Tribal lands on Native people. Further, Tribal Nations **must** retain data sovereignty and must have assurances of data protection.

Further, Tribal Nations have been left out of the decision-making process within federal programs affecting Indian Country for far too long, including those within NIH. NIH must include requirements for formal coordination with Tribal Nations such as a Tribal appointment or membership within any coordinating entity overseeing those initiatives. NIH must make Tribal consent, including Tribal Institutional Review Boards (IRB), a non-negotiable element of all research applications involving Indian Country.

### **3. How can we better encourage and facilitate research partnerships to respond to the current and prepare for future public health emergencies?**

USET SPF has concerns regarding the distinction between Public Health Practice and research. We appreciate the “all hands on deck” approach that NIH has taken during this pandemic. However, NIH must ensure that taking the lead on Public Health Practice does not have unintended and harmful consequences on Tribal Nations and Native people.

For instance, Public Health Practice is often reactive—messy, quick, and imperfect—by nature, especially in a pandemic. The Indian Healthcare System is having to adjust and pivot quickly as new conditions, concerns, or risk factors arise, which does not allow for accurate research, especially regarding COVID-19 testing in Tribal communities. This is exacerbated by the chronically underfunded nature of the Indian Healthcare System, which still does not have the necessary resources to address the pandemic.

In addition, ethical research must not be coercive. Offering untested COVID-19 diagnostic tests under the RADx initiative for the purposes of expedited research on the effects on a population is harmful for Tribal communities and is a violation of the federal trust obligation to ensure the health and well-being of Native people. NIH must not capitalize on the desperate circumstances posed by the COVID-19 to conduct testing research, especially when many in Indian Country lack access to reliable testing. In general, research should never withhold the standard of care. Any tests that are being researched should also be accompanied by approved tests which must be available to all, and not as a condition of research.

#### **Continued Lack of Direct Engagement With Tribal Nations**

Based on our experiences with NIH thus far, we are concerned that the COVID-19 research initiatives will be finalized without meaningful input from Indian Country. Since 2015, NIH has repeatedly failed to seek input from Indian Country and has disregarded guidance from Tribal leaders, Tribal Organizations, and its own Tribal Advisory Committee regarding several initiatives overseen by the agency. This includes a failure to address ongoing concerns on NIH non-COVID-19 initiatives, including the *All of Us* project, Data Sharing and Management, and Intellectual Property.

As an operating division of the Department of Health and Human Services (HHS), the agency is subject to HHS’ Tribal Consultation Policy which states, “it is essential that Federally-recognized Indian Tribes and the HHS engage in open, continuous, and meaningful consultation.” However, NIH continues to engage in ineffective and insufficient Tribal consultation practices in violation of HHS’ Tribal Consultation Policy.

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Frustratingly, the continued lack of effort in engaging with Tribal Nations was further exhibited by NIH during the May 28<sup>th</sup> Tribal consultation virtual call. On the call, NIH directed Tribal leaders to submit comments and questions via a private online form, resulting in NIH hand-picking questions for response instead of an engaging in an open, comprehensive, and meaningful dialogue with Tribal leaders. As stated on the call, NIH has made various commitments to ensure an open and transparent process for the development of agency initiatives, including commitments to engage in ongoing and robust consultation with Tribal Nations. It is critical that NIH honors those commitments as an integral part of the federal trust obligation by engaging in meaningful and ongoing consultation with Tribal Nations on all matters affecting Indian Country.

### **Conclusion**

While USET SPF recognizes the importance of scientific discovery and advancement, especially during the COVID-19 pandemic, NIH has a legal and moral trust obligation to uphold the sovereign status of Tribal Nations that supersedes all other interests. With this in mind, it is critical that NIH seek to implement policies and protections that will prevent ethical violations against our communities and our people. Tribal Nations and Native people continue to face negative impacts from the unethical research practices. Therefore, it is essential that necessary policies are in place to protect the sovereignty, ownership, privacy, and use of our data prior to the implementation of any NIH research initiatives. In the absence of these policies, USET SPF cannot support NIH's proposals for COVID-19 research. 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](mailto:LMalerba@usetinc.org) or 202-624-3550.

Sincerely,



Kirk Francis  
President



Kitcki A. Carroll  
Executive Director