

**IHS Tribal SELF-GOVERNANCE ADVISORY COMMITTEE**  
**c/o Self-Governance Communication and Education**  
**314 W. 14<sup>th</sup> Place, Tulsa, OK 74119**  
**Telephone (918) 302-0252 ~ Facsimile (918) 423-7639 ~ Website: [www.tribalsegov.org](http://www.tribalsegov.org)**

Sent via email: [AoUTribal@nih.gov](mailto:AoUTribal@nih.gov)

November 27, 2019

Francis S. Collins, M.D., Ph.D.  
Director, National Institutes of Health  
U.S. Department of Health & Human Services  
9000 Rockville Pike  
Bethesda, MD 20892

**RE: Comments on Tribal Engagement with the NIH All of Us Research Program;  
Data Sharing and Management Draft Policy; and Intellectual Property Policy**

Dear Dr. Collins:

On behalf of the Tribal Self-Governance Advisory Committee (TSGAC), I write to response to the National Institutes of Health's (NIH) "Dear Tribal Leader and Urban Indian Organization Leader" letters regarding the rollout of the *All of Us* Research Program and to provide comments to the Data Sharing and Management and Intellectual Property policies. Established in 1996, the TSGAC provides information, education advocacy and policy guidance for implementation of Self-Governance within the Indian Health Service (IHS).

The TSGAC appreciates NIH's outreach to Tribal leaders and researchers during consultations and listening sessions on these three important initiatives. An ongoing process that provides for meaningful consultation and upholds the sovereignty of each Tribal Nation is of utmost importance to the TSGAC. However, we are greatly disappointed in the lack of transparency, slowness of pace and the overall piecemeal approach with which the agency has adopted Tribal suggestions throughout the consultation periods. While we acknowledge that the NIH in recent months has embargoed the data of individual Tribal members and expanded the timeframes in which it will accept Tribal input on its policies, the agency has done so only upon vigorous Tribal outcry.

The TSGAC looks forward to working with NIH as it finalizes the *All of Us* and policy consultations at the end of the year, and as it gears up for Tribal consultation on the draft of its first ever Tribal Consultation Policy.

### **Background**

Since April of this year, NIH has conducted consultations or listening sessions on three separate programs and policies, as outlined above. We are concerned that NIH, as it continues to gather Tribal input, is failing to adhere to the NIH Guidance on Implementation of the Health and Human Service Department (HHS) Tribal Consultation Policy (TCP) that the agency issued in 2013.<sup>1</sup> NIH created the guidance to facilitate the implementation of the HHS TCP by the more than 25 NIH Institutes and Centers, and the Office of the Director.

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<sup>1</sup> NIH THRO, NIH Guidance on Implementation of HHS Tribal Consultation Policy (2013), <https://dpcpsi.nih.gov/thro/policies-and-guidance>

NIH further demonstrated its commitment to Indian Country by forming the Tribal Health Research Office (THRO) in 2015, as provided for in the implementation guidance. Duties of the THRO include coordinating Tribal health research-related activities across NIH; serving as a liaison to and NIH representative on Tribal health-related committees; and coordinating the NIH Tribal Advisory Committee (TAC).

The NIH TAC has advised the agency on the *All of Us* Program during biannual in-person meetings and during monthly phone calls. In addition, the NIH sought the expertise of key TAC members to create the Tribal Collaboration Working Group (TCWG) Report,<sup>2</sup> which outlines in great detail Tribal concerns about NIH's health research policies, and provides detailed recommendations about how NIH should proceed in interacting with Tribes and gathering Tribal data – with utmost respect and in the most culturally sensitive manner possible. The TCWG Report highlights, in part:

- “Strategies for collaborating with Tribal Nations, clinics, and organizations to enable AI/AN participation in the program;
- Unique considerations, such as Tribal sovereignty, cultural beliefs and traditions, and historical trauma that NIH should be aware of as they seek to engage Tribal populations; and
- Ethical, legal, and social issues that should be considered prior to enrollment of AI/AN individuals.”<sup>3</sup>

The working group report has proven to be a valuable resource to the TSGAC, the HHS Secretary's Tribal Advisory Committee (STAC), and to Tribal Organizations nationwide, as we seek to educate on the Tribal implications of NIH policies.

### **Application of the HHS Tribal Consultation Policy**

In an era in which Tribes' political status has seen challenges from special interest groups and certain federal government actors, it is more important than ever to emphasize long-established law and policy, including the U.S. Constitution, which make clear Tribes hold political status, are sovereign Nations, and are not racial groups. The Executive branch, like *all* of the federal government has a trust responsibility to Tribes, as well as safeguards for Tribal engagement that we urge NIH, as an executive agency, to follow. The HHS Tribal Consultation Policy (TCP),<sup>4</sup> calls on the HHS operating staff and divisions, including NIH, to have an accountable process to ensure meaningful and timely input by Indian Tribes in the development of policies that have Tribal implications, to the extent practicable and permitted by law.

In addition, an effective consultation between HHS and Indian Tribes *“requires trust between all parties which is an indispensable element in establishing a good consultative relationship. The [...] extent of consultation will depend on the identified critical event. A*

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<sup>2</sup> NIH THRO, Considerations for Meaningful Collaboration with Tribal Populations (Apr. 4, 2018), [https://allofus.nih.gov/sites/default/files/tribal\\_collab\\_work\\_group\\_rept.pdf](https://allofus.nih.gov/sites/default/files/tribal_collab_work_group_rept.pdf)

<sup>3</sup> NIH, Tribal Consultation and Listening Sessions on the All of Us Research Program (2019), <https://allofus.nih.gov/about/tribal-engagement/national-institutes-health-tribal-consultation-and-listening-sessions-all-us-research-program>

<sup>4</sup> HHS, Tribal Consultation Policy (2010), <https://www.hhs.gov/sites/default/files/iea/tribal/tribalconsultation/hhs-consultation-policy.pdf>

*critical event may be identified by HHS and/or an Indian Tribe(s).*” In practice, this means that once Tribes identify a “critical event,” NIH must communicate clear and explicit information on the means and time frames for Tribal Nations to engage in consultation, to submit comments, and when to expect the agency’s response. As stated in the first paragraph of our letter, it does not appear that NIH adhered to the HHS Tribal Consultation Policy upon distribution of the Dear Tribal Leader letters on the three data initiative; this is because the NIH has through the course of the *All of Us* consultation expanded the timeframe for commenting, yet has not directly responded to Tribes’ requests that the agency provide a final due date.<sup>5</sup> Deadlines matter to Tribes. Knowing the discussion topic, proper protocols, and comment deadlines allow Tribes to adequately prepare for dialogue with NIH on critically important matters such as DNA research, policy, and protocols.

Additionally, TSGAC respectfully reminds NIH that TAC meetings and regional listening sessions are not substitutes for Tribal consultation. Since NIH has not given Tribes the HHS’s TCP’s proper 30-day notice of consultation timelines and, by extension, discussion topics, the agency has made the unfortunate mistake of conflating consultation sessions and listening sessions. Tribal participants may show up to an *All of Us* consultation, for example, only to discover that NIH will instead informally discuss the draft data management policy, if not multiple policies.

To busy Tribal leaders, this can be confusing at best, and misleading at worst. Tribes are also not clear on the turnaround time for receiving responses to their concerns or whether the agency’s responses will be posted in a public place. NIH’s last-minute schedule changes and vagueness of timelines for accepting Tribal comments in one sense showcases NIH’s flexibility and willingness to collect Tribal viewpoints at all possible venues. At the same time, this approach prevents meaningful Tribal participation and is counterproductive to building trust and consensus with Tribes.

## **I. All of Us**

A pillar of the *All of Us* Research Program is to recruit participants who have been historically underrepresented in the science of precision medicine. It is TSGAC’s understanding that scientific research using *All of Us* participants’ data has not yet begun, although the research database may be open to the public as soon as Winter 2019. At the recent STAC meeting (September 11-12, 2019) in Washington, D.C., representatives from NIH’s THRO assured Tribes that the DNA or biological samples of self-identified American Indians/Alaska Natives (AI/ANs) is embargoed – or, not available to researchers who have completed NIH ethical use training – until the agency concludes its meetings with Tribes at the end of the year.

Tribes are appreciative that NIH has heard and responded to Tribal concerns about the *All of Us* Research Program, but the issues are far from resolved. Specifically, we have the following concerns:

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<sup>5</sup> See United South and Eastern Tribes Sovereignty Protection Fund (USET SPF), Comment Letter to NIH (Aug. 27, 2019), [http://www.usetinc.org/wp-content/uploads/2019/09/USET-SPF-Comments-to-NIH\\_All-of-Us\\_Draft-Data-Sharing\\_IP-FINAL-8\\_29\\_19.pdf](http://www.usetinc.org/wp-content/uploads/2019/09/USET-SPF-Comments-to-NIH_All-of-Us_Draft-Data-Sharing_IP-FINAL-8_29_19.pdf)

- **Lack of respect for Tribal data sovereignty.** Data sovereignty involves a Tribe's right to govern the collection, ownership, and application of their own data. Because the parameters of *All of Us* are broad and ambiguous, Tribes feel unsafe and unwilling to partake in the research.
- **Lack of cultural sensitivity training and failure to adhere to data ethics.** Under the *All of Us* program rules, any researcher would have access to data that is shared by volunteers, on the condition that the researcher completes an ethics training, signs a data use agreement, and posts on the NIH website the parameters of their research project. While the research project information would be publicly available, Tribes feel that they should not be put in the position to have to analyze or monitor the scientific community's proposed research projects and the potential impact to Indian Country.

For this reason, Tribes recommend an **Expert Tribal Advisory Committee** to determine the Tribal impact of *All of Us*. The committee would consist of AI/AN scientists and researchers.

- **Lack of clarity in the consultation process.** Tribes are concerned that NIH is conflating Tribal consultation sessions with listening sessions. Additionally, Tribes have reported that the agency has attempted to hold consultation sessions for three different initiatives at once: the *All of Us* program, the Draft Data Sharing and Management Policy, and the Intellectual Property Policy. Holding meetings with Tribes about all three of these very different issues, without notice, makes it impossible for Tribes to adequately prepare for meetings with agency officials and have their voices heard. Furthermore, it does not follow the consultation procedures outlined in the HHS TCP and in Executive Order 13175, "*Consultation and Coordination with Indian Tribal Governments*".
- **Lack of respect for the rights of Tribes regarding research on members living in urban areas.** American Indians and Alaska Native peoples who do not live on Tribal lands should not be viewed or treated as "fair game" for research. Regardless of whether or not Tribal members live on Tribal lands, NIH should respect the data sovereignty rights of Tribes and all self-identified AI/ANs and request consent before moving forward with any use of data.
- **Lack of anonymity.** Although NIH has explained to Tribal leaders some of its procedures for anonymizing data so that the data of individual AI/ANs cannot be matched with the Tribe of origin or to a particular region of the United States, the examples the agency provided were not well thought out and instead instill fear and uncertainty in Tribal Nations.

The TSGAC and member Tribes support advancements in the science of precision medicine that will, over time, serve Tribes and American Indian/Alaska Native people, but we do not support the process that NIH is following to achieve that end. This issue is far from resolved.

## II. Data Sharing and Management Policy

The *All of Us* Program and the Data Sharing and Management are very much entwined. The overall sentiment from Indian Country is for NIH to exercise caution in how it approaches these issues with Tribes. TSGAC acknowledges that AI/AN health disparities represent a loss of individual and societal potential that could be reduced through inclusion in research. Unfortunately, AI/AN individuals have been severely underrepresented in clinical trials and often are not included in sufficient numbers in national research studies. The FDA recognized this discrepancy in a recent request for information on draft guidance to broaden the eligibility requirements for clinical trial participants.

The intent of the draft guidance, “Enhancing the Diversity of Clinical Trial Populations: Eligibility Criteria, Enrollment Practices, and Trial Designs,” was to encourage increased diversity in clinical trials by broadening eligibility criteria, so they better reflect underrepresented populations likely to use the drug once approved.<sup>6</sup> Without mentioning American Indians and Alaska Natives specifically, the FDA guidance observed that some communities may be historically mistrustful of government-sponsored clinical trials. It also recognized this in its *Minorities and Clinical Trials* page.<sup>7</sup>

TSGAC supports federal research initiatives that are meant to improve Tribal health outcomes and elevate the health status of Tribal peoples. However, we highlight FDA’s request for information here, to encourage the THRO to be vigilant of other agency efforts to cultivate AI/AN data and to speak out on behalf of Tribal interests not just within the National Institutes of Health, but across the federal government, where the office finds the opportunity to do so. The TSGAC is prepared to provide technical assistance to support THRO in its government-wide advocacy on behalf of Tribal Nations.

## III. Intellectual Property Policy

The Tribal Health Research Office distributed a helpful fact sheet, *Intellectual Property Rights in Biomedical Research*. TSGAC agrees with agency recommendations for Tribes that are provided in the fact sheet:

- Discussions about possible intellectual property (IP) rights should occur with (and within) Tribes before any research begins.
- Tribes must protect their patent rights prior to any kind of public disclosure on invention can occur.
- Tribes should not have substantive discussions/exchanges with any third-parties about unpublished research that could be an invention unless the exchanges are protected by confidentiality obligations.

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<sup>6</sup> See National Health Council, NHC Comment Letter: Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs—Guidance for Industry (Aug. 8, 2019), <https://www.nationalhealthcouncil.org/blog/nhc-comment-letter-enhancing-diversity-clinical-trial-populations-eligibility-criteria>

<sup>7</sup> See FDA, Racial and Ethnic Minorities in Clinical Trials (current as Aug. 6, 2018), <https://www.fda.gov/consumers/minority-health-and-health-equity/minorities-clinical-trials>

We echo THRO's recommendation that Tribal Nations and communities can develop their own policies that make clear how intellectual property rights are handled. Such policies can specify joint ownership or Tribal ownership and ensure researchers understand any requirements before entering into a research collaboration.

### **Summary of Tribal Concerns**

TSGAC supports the following Tribal recommendations:

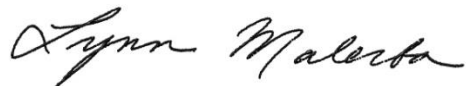
- NIH should develop a comprehensive Tribal Consultation Policy that follows the protocols in the HHS Tribal Consultation Policy and includes NIH protocol. NIH should continue to solicit TAC feedback on the draft consultation policy and, when the time is right, publish a notice in the Federal Register and also send an email to TSGAC and our partner Tribal Organizations that gives proper notice of the opening and closing of the comment period for the consultation policy, and describes how to agency will notify Tribes of the responses it receives, and creates a record of the agency's response to each Tribal recommendation.
- NIH should continue the embargo on data that includes self-identified AI/ANs and Tribal members.
- NIH should clarify the rules of consent for participating in *All of Us*. Right now, the process for withdrawing consent, at any point and for any reason, is unclear to Tribes. NIH must continue to address Tribal concerns around broad consent (i.e. how individual Tribes consent to being included in the program) because Tribal members are identifiable due to genetics and Tribal affiliation. Moreover, the agency should be required to seek consent from *all* AI/ANs, not just those living on Tribal lands.
- TSGAC supports the NIH TAC's recommendation that continued Tribal consultation should follow a two-stage approach:
  1. Solicit expert guidance. Since this issue is so complex, the TAC recommends an in-person meeting with technical experts across the 12 IHS areas to do a "deep-dive" into the *All of Us* Research Program and concerns for AI/AN participation; and,
  2. Share meeting results with Tribal leaders to inform ongoing consultation with NIH.

### **Conclusion**

In a recent phone call hosted by the Centers for Medicare and Medicaid Services, the Director of the Tribal Health Research Office, Dr. David Wilson, notified Tribal leaders that his office has provided outlines and guidance to NIH about how to respectfully and effectively engage Tribal Nations in its research initiatives. He said, "Knowledge should not leave [a Tribal] community without benefiting th[at] community." The TSGAC could not agree more and looks forward to the outcome of the consultation and listening sessions.

We thank you for the opportunity to provide these comments and recommendations. We stand ready to assist NIH as you move forward. If you have any questions or would like to discuss these comments in further detail, please contact me at [lmalerba@moheganmail.com](mailto:lmalerba@moheganmail.com).

Sincerely,

A handwritten signature in black ink that reads "Lynn Malerba". The signature is written in a cursive, flowing style.

Chief Lynn Malerba, Mohegan Tribe of Connecticut  
Chairwoman, IHS TSGAC

cc: Jennifer Cooper, Director, Office of Tribal Self-Governance, IHS  
TSGAC Members and Technical Workgroup  
Jay Spaan, Executive Director, Self-Governance Communication and Education  
Carolyn Hornbuckle, Chief Operations Officer, National Indian Health Board  
Dr. Yvette Roubideaux, Director of the Policy Research Center, National Congress of American Indians