



NATIONAL CONGRESS OF AMERICAN INDIANS

September 30, 2019

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Submitted to: AoUTribal@nih.gov; francis.collins@nih.gov

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Dear Director Collins and Director Dishman:

We are writing to respond to the tribal consultation on the *All of Us* Research Program that was initiated in a letter from National Institutes of Health (NIH) Director Francis Collins on May 24, 2019. We would like to thank you for working with us to hold an in-person tribal consultation session at the 2019 National Congress of American Indians (NCAI) Mid Year Conference in Reno/Sparks, Nevada. We are glad that NIH and the *All of Us* Research Program did respond to the request from the NIH Tribal Advisory Committee (TAC) to initiate tribal consultation, especially since this program may have a significant impact on American Indian and Alaska Native (AI/AN) tribal nations and their citizens.

NCAI is the oldest, largest, and most representative national organization serving the broad interests of AI/AN tribal nations and advocates to uphold and strengthen tribal sovereignty. Research conducted on tribal lands or with tribal citizens falls under the purview of tribal governance, and in accordance with the Federal Policy for the Protections of Human Research Subjects, also known as the Common Rule, tribal research laws must be followed in human subjects research [45 CFR 46.101(f), Subpart A]. Since the *All of Us* Research Program is federally-funded, any research that is conducted, from the initial consent process, collection and storage of data and specimens, analysis, reporting, and publication, must follow tribal research laws and policies. Every tribal nation, as a sovereign nation, has the right to determine how research is governed when it involves their citizens and their lands.

While NIH does not yet have a formal tribal consultation policy, NIH must conduct tribal consultation activities under the authority of the U.S. Department of Health and Human Services (DHHS) Tribal Consultation Policy, updated on December 12, 2010. The policy requires meaningful and timely consultation, an accountable process, clear means and timeframes, and notice of the outcome of the consultation within 90 days of the final consultation.

NCAI understands that the tribal consultation was initiated and some consultation activities did occur, but we are also concerned that the timeframes are not clear and somewhat contradictory. The letter from May 24, 2019 states that input is “welcome” by August 31, 2019. However, consultation sessions with tribal nations were scheduled after that date, the *All of Us* Tribal Collaboration Working Group (TCWG) apparently met with the *All of Us* team to discuss recommendations, even though they are not officially a part of the tribal consultation process, and a Request for Information (RFI) was released to the public with the title: *Soliciting Additional Input to the All of Us Research Program 2019 Tribal Consultation*.

RFIs are not a part of the DHHS Tribal Consultation Policy, are not familiar to tribal nations, are not used by any other agencies that conduct tribal consultations, and the process of soliciting public input on the tribal consultation is irrelevant since the consultation is about the government-to-government relationship between federally-recognized tribal nations and the NIH, and not with the public. Public comments have no place in a tribal consultation – comments from tribal nations and their representatives are all that should be considered since tribal consultation is a government-to-government relationship. In addition, the timeline for final comments to this tribal consultation is not clear, and there is no timeline for follow up or decisions by the NIH.

The NIH TAC recently met by phone with the NIH Tribal Health Research Office and passed a motion recommending that the NIH extended the tribal consultation deadline from August 31, 2019 for two more months, which would be to October 31, 2019. We recommend that the tribal consultation is extended through the end of November 2019 and that clear timelines be published to include the end of the comment period and the timeline to NIH’s announcement of the decision and outcome.

NCAI also wants to remind NIH and the *All of Us* Research Program that the *All of Us* TCWG is not a tribal consultation group, is not a part of the tribal consultation process, and that any recommendations they make must be vetted and reviewed by the NIH TAC and tribal nations prior to the close of the consultation. NIH must not rely solely on the recommendations of the *All of Us* TCWG unless tribal nations have the opportunity to review, comment on them, and concur with them. Implementing recommendations from the *All of Us* TCWG without tribal input does not satisfy the requirement for meaningful government-to-government consultation with tribal nations. The input must be from tribal nations, not a group that includes a large number of academic researchers, even if some of them are individuals who happen to be American Indian or Alaska Native. The tribal consultation is with tribal nations, not individuals.

NCAI has additional comments and specific, detailed recommendations about the *All of Us* Research Program and we will submit another letter soon. We interpret the May 24, 2019 letter to not have had a firm deadline for comments and encourage NIH to provide a more specific timeline for the tribal consultation.

Until the tribal consultation timeline is completed, NIH and the *All of Us* Research Program must suspend any use of data for individuals who self-identify as American Indian or Alaska Native and/or those that indicate a tribal affiliation. The data must always be kept in the most protective category and not released to researchers or the public until tribal nations are satisfied that they have been able to consult in a meaningful manner, their tribal research laws are respected, and their requirements for data ownership, confidentiality, research review and approval, and other needed protections are honored. Each tribal nation has the right to determine how data about their nation and their citizens are used and protected in the *All of Us* Research Program.

We also have serious concerns about the lack of adherence to the Common Rule requirements of broad consent in the *All of Us* Research Program consent forms. The determination that the *All of Us* Research Program activities are not research is not consistent with the right of tribal nations to regulate all activities associated with research that may impact them. Tribal nations deserve to have input on the entire process for the *All of Us* Research Program. Tribal nations and individual AI/ANs need to have clear and accurate information on the process and oversight of the secondary uses of their data after primary collection in the *All of Us* Research Program. Even though NIH has taken the position that the primary data collection portion of the *All of Us* Research Program is exempt from Human Subject Protections and IRB review, many tribal nations do not allow research projects to be “exempt” and would not allow the *All of Us* Research Program to claim that its activities from recruitment to entry of the data into a data set for future use by researchers are exempt. These activities are still a part of the research process since they represent primary data collection.

All researchers that utilize federal funding must follow the Common Rule which states that these researchers must also follow tribal research laws. The concerns of tribal nations include the concerns of institutional review boards on human subject protections at the individual level, but tribal nations also are concerned about protections at the tribal or community level.

The *All of Us* Research Program must be responsive to the concerns, needs, and requirements of tribal nations when research is conducted on their lands and with their citizens. Unfortunately, it is unlikely that a single rule for how to deal with tribal data will result from the tribal consultation. Tribal nations are sovereign, and have the right to define their own research governance requirements. The *All of Us* Research Program will need to implement steps for tribal oversight of any research conducted with tribal citizens or on tribal lands.

The NCAI Policy Research Center recently published a series of research updates on provisions in the updated Common Rule that impact or relate to research conducted with tribal nations. We encourage NIH and the *All of Us* Research Program staff to review these updates during the tribal consultation to better understand the input received from tribal nations. You can access these updates at: <http://www.ncai.org/policy-research-center/research-data/prc-publications>.

Thank you for consulting with tribal nations on the *All of Us* Research Program. We ask you to consider our comments and announce any updates to the timeline for the tribal consultation as soon as possible. We plan to submit additional detailed comments in October 2019 in response to the tribal consultation, and not the RFI, the latter of which in our opinion is not an official part of the tribal consultation process.

Sincerely,

A handwritten signature in black ink, consisting of several overlapping, fluid strokes that form the name 'Kevin J. Allis'. The signature starts with a large, sweeping initial 'K' and extends horizontally across the page.

Kevin J. Allis
Chief Executive Officer
National Congress of American Indians