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November 26, 2019

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Re: *All of Us* Research Program Tribal Consultation

Sent by email to: AoUTribal@nih.gov; francis.collins@nih.gov

Dear Director Collins and Director Dishman:

We are writing to provide our **formal input to the tribal consultation on the *All of Us* Research Program** that was initiated in a letter from the National Institutes of Health (NIH) Director Francis Collins on May 24, 2019. Thank you for responding to our letter on September 30, 2019 with our request to extend the period of tribal consultation until November 30, 2019. The *All of Us* Research Program is a complex endeavor and more time was needed by tribal nations to review the program and discuss recommendations, especially since this program may have a significant impact on American Indian and Alaska Native (AI/AN) tribal citizens.

The National Congress of American Indians (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 that is conducted on tribal lands or with tribal citizens falls under the purview of tribal governance, and in accordance with the Federal Policy for the Protection of Human 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, to publication, must follow tribal research laws and policies. Also, every tribal nation, as a sovereign nation, has the right to determine how research is governed when it involves their citizens and lands even if they do not have specific research laws in place.

Tribal Consultation

We began our input on the importance of tribal consultation to the NIH *All of Us* Research Program on August 21, 2017 when we invited Dara Richardson-Heron to visit NCAI and met with our Executive Director and our Director of NCAI's Policy Research Center. During that meeting, we were disappointed to learn that the program was already substantially developed and recruitment was starting. Dara stated she was visiting for the purpose of "community engagement." We advised her that tribal consultation needed to start immediately on a government-to-government basis and that recruitment of AI/ANs needed to be put on hold until the tribal consultation was completed. We also advised her that it was unlikely that there would be a one size fits all solution given the diversity of the 573 federally recognized tribal nations.

Dara told us that *All of Us* Research Program was looking for a compromise so that they would not have to modify their plans for every tribal nation. We repeated that tribal consultation needed to start immediately, a one-size fits all solution was unlikely, and that the *All of Us* Research Program's Tribal Collaboration Working Group, composed of academics and tribal representatives, did not represent government-to-government tribal consultation. **It took almost two years for the NIH to initiate tribal consultation from our initial request in 2017.** We are mentioning this timeline because we have heard complaints from NIH staff and NIH contractors that the tribal consultation is taking too long or is delaying the *All of Us* Research Program from moving forward with recruitment of AI/ANs. If NIH had initiated a tribal consultation in 2017, we would be a lot further along and tribal nations should not be blamed for "slowing things down."

NIH should have been aware that tribal consultation was required for a program of this significance and potential impact on tribal nations. The Department of Health and Human Services (HHS) Tribal Consultation Policy states that "before any action is taken that will significantly affect Indian Tribes it is the HHS policy that, to the extent practicable and permitted by law, consultation with Indian Tribes will occur." The policy also states that "...that HHS seek consultation and the participation of Indian Tribes in the development of policies and program activities that impact Indian Tribes." Even though NIH does not have its own formal tribal consultation policy, the HHS Tribal Consultation Policy states that "each HHS Operating and Staff Division shall have an accountable process...to ensure meaningful and timely input by Indian Tribes in the development of policies that have Tribal implications."

The NIH *All of Us* Research Program is already recruiting, and while we are grateful that active recruitment of AI/ANs is now on hold for the tribal consultation, we are concerned that at least 1,600 AI/ANs have been recruited through the *All of Us* Research Program recruitment processes. We do not know how many wrote down a tribal affiliation or how many are tribal citizens. For those that identified a tribal affiliation, their tribal nations likely do not know that they have enrolled and how their data is being handled. The NIH Tribal Advisory Committee provided strong input at one of their meetings this year to stop public release of information about AI/ANs who had already been recruited until tribal consultation could occur.

We thank you for holding tribal consultation sessions at meetings and conferences in the past year and hope that the input you have received is helpful as you consider how to incorporate input from tribal nations. We understand that the *All of Us* Research Program is going to prepare a report of the input received during the consultation, and we hope you can share that document with us as soon as possible along with how you have decided to incorporate the input into changes and modifications to the *All of Us* Research Program that meet tribal governance requirements. All input received as of November 30, 2019 should be included. We also repeat from our prior letter that **tribal consultation is meant to be government-to-government between tribal nations and the federal government.** The Tribal Collaborative Working Group, the Request for Information from the public on the consultation, and input from researchers and other individuals are not to be considered tribal consultation activities. While their input may be valuable or useful, tribal consultation is between the federal government and tribal nations.

The NCAI membership recently passed resolution ABQ-19-061 that calls on NIH to consult with tribal nations, provide a process for tribal nations to have oversight over any data and biospecimens from their tribal citizens, and restrict use of data associated with tribal nations until tribal oversight is in place. The resolution was passed by consensus of the NCAI membership and is attached. Tribal consultation should continue until the concerns of tribal nations are addressed.

Community Based Participatory Research

NIH has stated publicly on numerous occasions that it supports community based participatory research. However, we have concerns that the *All of Us* Research Program may have been developed as a way around the need to conduct research in partnership with tribal and other racial and ethnic minority communities to advance precision medicine research efforts. While it is true that racial and ethnic minorities are underrepresented in clinical trials and precision medicine research, **NIH has a responsibility to address this disparity in partnership with the diverse communities it is recruiting, including tribal nations.**

We recognize that precision medicine may result in therapies that can be tailored to the needs of individuals and has the potential to further address health disparities, but so far, the therapies from precision medicine research are expensive and in many cases out of reach for underserved racial and ethnic minority groups. AI/ANs face significant health care access challenges along with significant underfunding of the Indian Health Service (IHS), which is the healthcare system that provides services to over two million AI/ANs from federally recognized tribal nations. IHS, tribal, and urban Indian health programs operate under significant funding restrictions and likely cannot afford expensive therapies developed from precision medicine research.

Tribal nations need to hear from NIH that they will ensure that the positive results from precision medicine are made available and accessible to AI/ANs at a price that they can afford. Otherwise, the *All of Us* Research Program will result in widening the health disparities tribal communities already face. The *All of Us* Research Program cannot use the data from underserved communities to develop novel therapies that only the privileged can afford. **NIH has a responsibility to take a leading role to ensure that tribal nations have access to the same benefits and potential new therapies as all other participants in the *All of Us* Research Program.**

Human Subjects Protections and Tribal Research Oversight

We do not believe that the *All of Us* Research Program has sufficient protections for human subjects. We understand that NIH believes that the first phase of the *All of Us* Research Program, the recruitment and collection of data, is exempt from Human Subject Protections, primarily because NIH believes that the data it is collecting from participants is not identifiable. This determination was made by the NIH Institutional Review Board (IRB), which we believe is a serious potential conflict of interest. **Since the data collected from participants includes tribal affiliation and genetic material, it is identifiable for both individuals and tribal nations.** We have reviewed this issue with geneticists and they agree that genetic material is identifiable to the individual. Tribal affiliation is also identifiable to the nation, and it is possible that researchers could conduct stigmatizing or harmful research that impacts individual tribal nations. NIH must partner with tribal nations to ensure that protections are in place for tribal citizens and tribal nations since they both could be identified during the research phase of the *All of Us* Research Program.

The *All of Us* Research Program also recently stated in a tribal consultation that there will be no central IRB approval or single IRB once the data is made available to researchers and is relying on the IRB reviews of the researchers' home institution when they apply to use the data. We have heard conflicting reports of whether there is or is not an IRB overseeing this research, and we understand it is very difficult for individuals signing up for the program to identify to whom they can ask IRB related questions. We also are concerned that it is not clear how participants can withdraw, and also it is not clear how they can be certain that all their data, including genetic data, will not be used after they withdraw. We understand that an entity within the *All of Us* Research Program may review research proposals to ensure that the proposed research is not stigmatizing, but it is unclear how this review group will be trained to recognize the significant risks of stigmatization and harm associated with research conducted with tribal data or how many individuals with expertise in tribal research will be involved. In addition, few university IRBs understand the issues and potential harms that can occur to tribal citizens and tribal nations. **NIH must be transparent about how it will ensure that researchers and all staff receive training to understand how to conduct research with tribal nations, understand the additional tribal review requirements, and agree to work with tribal nations to minimize any potential harms from the research.**

We are uncomfortable with the *All of Us* Research Program relying on IRBs from the researcher's home institution to do the work of NIH to ensure human subjects are protected when researchers access and analyze data that includes AI/AN participants and that is identifiable for individuals and tribal nations. **NIH must immediately and clearly explain to tribal nations how it is protecting human subjects during the entire *All of Us* Research Program process, including during recruitment, the consent process, data collection, data storage, the proposal process for researchers to access data, the conduct and analysis of those studies, and any presentations or publications of the results. Representatives from tribal nations should also be members of any review or oversight committees in the *All of Us* Research Program. Also, more than one tribal representative should serve on any advisory or oversight committees.**

We have also provided input to the *All of Us* Research Program that we believe the program falls under the Common Rule requirements for Broad Consent, even though NIH officials have tried to argue otherwise or state that since the program started before the new provisions in the Common Rule went into place, Broad Consent does not apply. We are very disappointed that NIH would take these positions since the updates to the Common Rule are meant to further protect human subjects. **The process of recruiting and consenting individuals to participate in the *All of Us* Research Program and the use of that data for numerous unknown future studies is the exact reason that following the rules of Broad Consent are important.**

The consent form for the *All of Us* Research Program does not meet the standards of Broad Consent required in the Common Rule: the consent form does not provide a description of future secondary research studies and uses of the data; and does not provide information on how the data will be stored and protected. We are aware that many tribal nations have opted to not allow Broad Consent in any research studies they approve and some tribal research laws may prohibit it. In addition, many tribal nations do not allow for exempt or expedited research and require full review for every proposed project. **We believe that NIH is in violation of tribal research laws, policies, and review practices by declaring the first phase of the *All of Us* Research Program to be exempt or expedited, and may also be in violation of the Common Rule requirements.**

We also understand that there has been little outreach to the IHS, and that their National IRB has not received an application from the *All of Us* Research Program. Conducting research with AI/ANs who receive care in the IHS requires IHS National IRB approval to access to IHS medical records. Also, tribal nations require research review or approval of any research conducted with their citizens or on their lands. If a participant provides the *All of Us* Research Program with a tribal affiliation, they could be a tribal citizen. At that point, the *All of Us* Research Program must determine the research review process of that tribal nation, and then seek IRB or research review approval from that tribal nation. If the tribal nation has research laws in place, NIH could be out of compliance those laws.

Given the many responsibilities of NIH to protect human subjects during the *All of Us* Research Program and the need to identify tribal requirements for research review and approvals, **NIH and the *All of Us* Research Program should immediately involve multiple tribal representatives on advisory or oversight committees throughout the entire *All of Us* Research Program protocol and process, or develop a separate advisory and/or oversight mechanism for research conducted with AI/AN individuals and about tribal nations.**

The NIH Tribal Advisory Committee was established to provide advice to the NIH Director. We recommend that once the report on the input from the tribal consultation is completed, a copy be sent to the NIH Tribal Advisory Committee members and technical advisors, and **the NIH Director and the Director of the *All of Us* Research Program be in attendance during a phone call or in-person meeting of the NIH Tribal Advisory Committee to review the input received during the tribal consultation and to discuss possible solutions.** Once NIH makes a decision on proposed changes to the protocol of the *All of Us* Research Program to address the concerns of tribal nations, another letter should be sent to tribal nations to allow for an additional round of comment on the proposed solutions.

Data Ownership and Intellectual Property

Tribal nations, as sovereign nations, have the right to ownership of any research data from their citizens or about their nations, and reserve the right to any intellectual property that results from the research. Tribal nations are increasingly codifying these rights into tribal research laws, codes, or policies. However, even if a tribal nation does not have a law in place, it still is a sovereign nation with rights to data ownership and intellectual property that results from research. If data is used in the *All of Us* Research Program from tribal citizens or that identifies the tribal affiliation of the individual, **NIH must include requirements in its protocol to ensure that tribal nations have the right to data ownership and rights to any intellectual property that results from the research.** All researchers applying to use the *All of Us* Research Program data must understand the data ownership and intellectual property rights of sovereign nations and must be willing to negotiate how it handles data about tribal nations and its citizens in its proposed research. It is not enough to rely on tribal nations to pass research laws – NIH must implement safeguards so that the rights of tribal nations are respected by all researchers. Given that precision medicine is resulting in expensive therapies and many researchers may be motivated by potential profit, there is a high risk that tribal data ownership and intellectual property rights may be violated. Tribal nations have the right to own the data on their tribal nation and its citizens and to benefit from its use.

Cultural Protections

Many tribal nations have described their cultural beliefs around data and research and often have concerns about how biospecimens are handled during the research and disposal process. **NIH and the *All of Us* Research Program must consult with tribal nations whose citizens are enrolled in the program on how to respectfully handle biospecimens, such as blood samples, during all phases of the research and disposal process.** NIH must ensure that tribal cultures and beliefs are respected in the *All of Us* Research Program and these beliefs may vary among different tribal nations.

We also understand that one use of biospecimens in the *All of Us* Research Program may be for genetic analysis, and tribal nations may have concerns that need to be addressed before that use. In particular, the NIH announced that the Navajo Nation did not allow the ECHO Program to do genetic studies in their data sharing agreement. **Has the NIH consulted yet with the Navajo Nation on the use of Navajo citizens' biospecimens for genetic research in the *All of Us* Research Program?** NIH must immediately consult with all tribal nations about how to handle cultural concerns about the use of biospecimens and any other parts of the protocol for the *All of Us* Research Program. **Since genetic data is potentially identifiable for an individual and a tribal nation, tribal nations have the right to have oversight over any potential genetic studies proposed by researchers.**

NCAI is also interested in whether the *All of Us* Research Program has modified its recruitment and consent process to ensure that individuals with English as a second language and those with lower health and general literacy truly understand the risks and benefits. We recommend that

translation services be available and that the consent process not proceed until they are available for individuals needing those services. NIH should consult with tribal nations on these issues.

Summary

NCAI understands that precision medicine research has the potential to address health disparities for AI/ANs. **However, the *All of Us* Research Program must immediately implement changes to its policies and protocols to allow for tribal oversight of any research conducted with AI/ANs who may be tribal citizens. These changes include the following recommendations:**

- NIH must continue to consult with tribal nations until the *All of Us* Research Program is in compliance with tribal research laws, policies, research review requirements, and preferences;
- NIH must do more to protect human subjects and comply with the requirements of the Common Rule on Broad Consent;
- NIH must also modify its protocol for tribal nations that do not accept research conducted under Broad Consent;
- NIH must develop a plan to complete IRB review requirements with the IHS and all tribal nations and notify all tribal nations of this plan and a timeline for completion;
- NIH could develop a separate review or oversight process for AI/AN data and researcher proposals that aim to use AI/AN data or tribal affiliation information;
- NIH should include multiple tribal representatives on its advisory and oversight committees;
- NIH should immediately share a summary of all tribal consultation input received with the NIH Tribal Advisory Committee and schedule time for discussion with the NIH Director and the *All of Us* Research Program Director before final decisions are made, and then send those proposed decisions out to tribal nations for comment before implementation;
- NIH must practice community based participatory research with all diverse communities represented in the *All of Us* Research Program;
- NIH must work to ensure that any research results and new therapies developed with research data from the *All of Us* Research Program are affordable and accessible to AI/ANs and other underrepresented communities;
- NIH must develop a plan to protect identifiable data, including genetic data, for its AI/AN individual participants and tribal nations;

- NIH must develop a plan to implement protections for the cultural concerns of tribal nations;
- NIH must immediately clarify how potential participants can decide to withdraw from the *All of Us* Research Program at any time and ensure that their data, including genetic data, will not be used once they decide to withdraw;
- NIH must develop policies to ensure that tribal rights and policies on data ownership and intellectual property are respected and followed;
- NIH must ensure that *All of Us* Research Program staff and researchers using its data are trained to understand how to conduct research with tribal nations and to avoid harms; and
- NIH must hold all data on AI/ANs in the most stringent protection until these issues are resolved.

NIH must consult in a meaningful way with tribal nations and must not use any data from AI/AN individuals or allow any use of the tribal affiliation variable until these protections are in place. The NIH Tribal Advisory Committee must be involved in the tribal consultation process and has the expertise necessary to assist NIH with meeting the needs of tribal nations. We have attached the NCAI resolution and selected NCAI Policy Research Center Research Updates on topics mentioned in this letter. If you have any questions, please contact our Policy Research Center at research@ncai.org.

Sincerely,



Kevin Allis
Chief Executive Officer
National Congress of American Indians

Attachments:

- 1) NCAI Resolution #ABQ-19-061 – Calling Upon the National Institutes of Health to Consult with Tribal Nations and Establish Policies and Guidance for Tribal Oversight of Data on Tribal Citizens Enrolled in the *All of Us* Research Program;
- 2) NCAI Policy Research Center Research Update – Intellectual Property Rights and Tribal Nations (October 2019)
- 3) NCAI Policy Research Center Research Policy Update – Final Rule: Part 3 – Informed and Broad Consent (January 2019)
- 4) NCAI Policy Research Center Research Policy Update – Final Rule: Part 5: Tribal Research Codes (January 2019)