

***All of Us* Research Program
Briefing Webinar for Tribal Nations
National Institutes of Health (NIH)
National Congress of American Indians (NCAI)
June 3, 2019**

Meeting Summary

Webinar Speakers

Eric Dishman, Director, *All of Us* Research Program

Spero Manson, Ph.D., Co-Chair, Tribal Collaboration Working Group of the *All of Us* Research Program Advisory Panel

Aaron Payment, Ed.D., Chairperson, Sault Ste. Marie Tribe of Chippewa Indians; First Vice President, National Congress of American Indians; Chairperson, NIH Tribal Advisory Committee

Yvette Roubideaux, M.D., Director, National Congress of American Indians Policy Research Center; National At-Large Technical Advisor, NIH Tribal Advisory Committee

Meeting Agenda

- Welcome and Opening Remarks
- What Is Precision Medicine?
- Data Access
- Tribal Engagement
- Tribal Collaboration Working Group
- Comments from NIH Tribal Advisory Committee Chairperson Aaron Payment, Ed.D.
- Questions and Answers

Welcome and Opening Remarks

Yvette Roubideaux, M.D., of the National Congress of American Indians (NCAI), opened the webinar at 3:04 p.m. with welcoming remarks. Dr. Roubideaux, director of NCAI's Policy Research Center, presented an overview of the agenda, noting the webinar speakers and the opportunity to submit questions and comments via the webinar attendee interface. A recording of the event will be available soon on NCAI's YouTube page and its website. Dr. Roubideaux next turned the discussion over to Eric Dishman, director of the *All of Us* Research Program.

What Is Precision Medicine?

Mr. Dishman noted that feedback from the NIH Tribal Advisory Committee (TAC) has changed the course of the *All of Us* Research Program. As director, Mr. Dishman moved the process too slowly, and now the program seeks to make up for lost time. With help from TAC, the program team has scheduled Tribal consultations and listening sessions throughout the country.

The spirit of the program is precision medicine, said Mr. Dishman. Rather than giving patients a one-size-fits-all approach to managing health or treating disease, the *All of Us* Research Program seeks to create

individual care based on a person's unique biology, lifestyle, and environment. Researchers still seek answers on how these elements come together to address most conditions and diseases. As with a pair of eyeglasses, researchers aim to develop a unique "prescription" to treat patients for cancer, diabetes, and other conditions.

The *All of Us* Research Program is intended to be a national resource that will help scientists get to the science faster. A national resource of 1 million or more volunteers from around the country will help scientists work more efficiently. The data from this resource will inform a range of conditions and studies. NIH wants thousands of scientific studies to leverage this national resource to identify cures more quickly.

Nearly a quarter of a million people have begun to participate in the research program since it launched on May 6, 2018. More than 150,000 people have completed all the steps of the initial protocol, and 80 percent of them are from groups that are underrepresented in biomedical research. More than 50 percent of those are racial/ethnic minorities. This research program continues to embrace unprecedented diversity in medical science.

Mr. Dishman said the program is not currently recruiting American Indian/Alaska Native (AI/AN) participants. People choose to sign up on their own, but NIH partners will not actively recruit in Tribal communities until the consultation process ends and program leaders identify appropriate outreach strategies.

No data is available to researchers yet. NIH anticipates releasing the first set of data in early 2020. NIH created a data browser, but on the basis of TAC recommendations, researchers cannot analyze or assess data by race, ethnicity, Tribal affiliation, or ZIP code.

Data Access

Mr. Dishman said NIH wants a broad set of researchers with appropriate credentials to use the data. Researchers will have access by tiers: Those who want access to information that could reidentify an individual must complete additional steps, including completing human subjects training and other protocols. NIH will conduct audits and provide public reports, and the scientists must report their data use publicly. NIH stores the data in a secure enclave in the cloud. All researchers must use a credentialed process to access the data. Researchers cannot download or copy data. A Research Access Board and a Committee on Access, Privacy, and Security will govern access.

NIH will address stigmatizing research in two ways: First, each researcher must clearly identify their data use and purpose. Second, a committee will watch for signs of inappropriate use. Regular assessments via computer will also identify stigmatizing research.

Mr. Dishman noted that the research program does not yet have any genetic or sequencing data on any participants. NIH continues to work on the policy and infrastructure to provide such data.

Tribal Engagement

Tribal engagement efforts launched in 2016. The Tribal Collaboration Working Group (TCWG) has played a key role in that effort, said Mr. Dishman. Once the consultations and listening sessions are complete, NIH will review the input, explore Tribal partnership opportunities, and develop or make changes to protocols and policies based on the feedback received.

Tribal Collaboration Working Group Spero Manson, Ph.D., Co-Chair

Spero Manson, Ph.D., led a presentation on the TCWG. Dr. Manson, co-chair for the TCWG, is associate dean for research at the Colorado School of Public Health in Aurora, Colorado. Dr. Manson, Pembina Chippewa from the Turtle Mountain Reservation in North Dakota, also directs the Centers for American Indian and Alaska Native Health.

The working group offered insight into some of the appropriate strategies needed to develop meaningful and culturally sensitive collaboration with Native communities. The group sought to describe the challenges and unique considerations, with a special emphasis on identifying possible solutions. Members envisioned the effort as a first step toward informing the consultation process. The working group, which launched in 2017, was composed of 16 people, including Tribal leaders, scientists, providers, community and consortia representatives, and *All of Us* Research Program staff. The group met nine times and completed a report in April 2018.

The working group requested that the *All of Us* Research Program engage a series of Tribal organizations in listening sessions between April and June 2018. Those organizations recommended that the research program proceed directly to the Tribal consultation process. Staff posted a final working group report on the *All of Us* website in August 2018. NIH decided to sunset the working group, but members remain available to provide advice on the engagement and retention of Native people.

The report does not include consensus recommendations; instead, the document offers a collection of input from working group members, who offered an array of solutions that *All of Us* Research Program staff can use. There were four overarching considerations:

- Start from the position of respecting Tribal sovereignty.
- Acknowledge the history.
- Engage urban Tribal leaders.
- Remain responsive.

In its deliberations, the working group focused on the following key focus areas:

- *All of Us* Research Program governance
- Tribal sovereignty and consent
- Ethics, institutional review boards (IRBs), biospecimen storage and access, and protection and benefits
- Partnership and engagement opportunities

The working group called for Tribal representation at all levels of *All of Us* Research Program governance, including the advisory panel, the dedicated single IRB, the Research Access Board, and

future committees, boards, and task forces. AI/AN representation should include leaders, advocates, patients, family members, scientists, and health providers. This effort should also coordinate with such organizations as NCAI, the Indian Health Service (IHS), and the National Indian Health Board.

The working group also recommended that the *All of Us* Research Program obtain Tribal approval when recruiting and enrolling participants within Tribal lands and jurisdictions. Although the enrollment of urban Indians does not require Tribal consent, *All of Us* Research Program staff should send courtesy letters to Tribal leaders, including urban Tribal leaders, to inform them of the program in any region where the program is recruiting participants. The program could also produce educational videos featuring Tribal leaders, providers, researchers, and community members/potential participants discussing the program.

Dr. Manson highlighted the critical issue of identifying Tribal affiliation. Options range from not asking about Tribal affiliation to a variety of graded responses. No matter how the program collects this information, NIH must recognize that Tribal affiliation is a matter of great sensitivity. The program must safeguard this information and carefully consider how others should access and interpret this information. The working group also proposed tiered consent so participants can opt out of certain types of studies.

Ethics is the third area of concern. Although the *All of Us* Research Program has a single dedicated IRB, many Tribal Nations also have IRBs that serve a wide variety of purposes. The working group recommended that these Tribal review boards have equal footing with the *All of Us* Research Program's dedicated IRB. Further, the IHS has jurisdiction in off-reservation programs where its staff, resources, or facilities remain involved in any matter related to the engagement, recruitment, and retention of Native people in this initiative. Dr. Manson also noted the enormous amount of discussion about biospecimen storage and access, as well as protection and benefits.

The working group recommended that the *All of Us* Research Program sustain Tribal engagement by hiring a dedicated Tribal liaison and communicating with Native leaders and councils through blogs, listservs, and webinars. *All of Us* Research Program staff should also engage with Tribal Epidemiology Centers and conduct periodic visits and two-way conversations with Tribes and Tribal communities in addition to formal Tribal consultation. Finally, NIH should highlight what the program has done as a result of Tribal input and note any input the program did not adopt.

Mr. Dishman closed out this portion of the webinar with a discussion of some questions for Tribal input during the upcoming consultation:

- The *All of Us* Research Program recognizes that there are many unique considerations when partnering with Tribal Nations. What are best practices for biomedical research initiatives?
- The TCWG report outlines many points for the *All of Us* Research Program to consider. What points in the report do you support or disagree with?
 - How do you recommend we handle the issue of Tribal affiliation?
 - What guidance do Tribal Nations have for the *All of Us* Research Program to deal with individuals who enroll independently and who self-identify as AI/AN?
- What are the major research questions of most interest to your Nation or community?

- How should the *All of Us* Research Program collaborate with Tribal Nations, clinics, and organizations to enable AI/AN participation in this program? What initial pilot partnerships should the program consider?
- How may the *All of Us* Research Program help to advance research conducted by members of Tribal Nations?

Mr. Dishman also provided a list of websites that include more information about the *All of Us* Research Program.

Comments from NIH Tribal Advisory Committee Chair

**Aaron Payment, Ed.D., Chairperson, Sault Ste. Marie Tribe of Chippewa Indians
First Vice President, National Congress of American Indians**

Precision medicine can help Tribes pinpoint specific ways to improve the health of Native communities, said Dr. Payment. However, Tribal members have not always had positive experiences with research in Indian Country, so Tribal communities remain reluctant and skeptical. Tribes continue to raise questions about human samples, cultural appropriateness, and responsible data use.

The *All of Us* Research Program scheduled Tribal consultations and listening sessions on the following dates to present the research process and ease Tribal members' concerns.

Tribal consultation sessions

- June 18: HHS Regional Consultation in Sacramento, CA
- June 24: Preceding the 2019 NCAI Mid Year Conference and Marketplace in Sparks, NV
- July 16: HHS Regional Consultation in Washington, DC
- August 21: HHS Regional Consultation in Denver, CO

Listening sessions

- May 6: California Rural Indian Health Board in Washington, DC
- June 18: United South and Eastern Tribes in Nashville, TN

Planning for more listening sessions is under way. Details regarding additional sessions will be available on the NIH website.

Questions and Answers

During the last portion of the webinar, Mr. Dishman and other webinar presenters answered the following questions submitted by participants. ("Q" denotes Question, "A" denotes Answer, and "C" denotes Comment.)

Q: Regarding minimization of risk for stigmatizing research, what will be your power to terminate research that is determined to be not acceptable? And also, will a Tribal representative be on your human board that evaluates what is stigmatizing?

A (Mr. Dishman): The Research Access Board, which we are still forming, will include AI/AN representatives from our consortium. We are just starting to form that group now. They have been working on policies for a while.

There are many ways in which this program is different, but one of them is the nature of requiring the researchers to really post details about their research before they get started with it. And our Research Access Board will be able to stop research or take access away in an extreme case if someone is doing inappropriate research. But because all that is public, anybody could come along and say, “I do not really understand what this researcher is doing” and ask our Research Access Board to review the research more closely.

That is the kind of transparency that we want to make sure is out there so that anybody can look and see that something just does not make sense and the Research Access Board should take a look.

Q: How will you work with patients who are limited English speakers or who do not know how to advocate for themselves as far as activating the transparency of the research?

A (Mr. Dishman): The program is currently in English and Spanish, and we are working on six other languages as a starting point. But the translation capabilities—we will never be able to put the entire content of the program, which is enormous, in all languages. So having translation capabilities with our community partners, at our call center and others, is key to being able to try to make sure that people are consented and really understand what they are signing up for when they go through this process.

Q: You mentioned the research being audited. Who does the auditing? Will they have the cultural sensitivities to flag when the research has the potential for cultural harm?

A (Mr. Dishman): The group who does the auditing is what you will hear us call the RAB, the Research Access Board, that we are forming. Many of them are experts in ethics and in issues pertaining to stigmatizing research.

This is going to be something in itself that we want to certainly hear from Tribal groups as well as other racial and ethnic minorities who also have been harmed by the federal government and research in the past. What should we be looking for? Computer algorithms also will look for keywords to audit the materials to make sure that something inappropriate is not occurring.

This is a great opportunity in our consultation process to seek help from Tribal communities. How do we know stigmatizing research when we see it, and what are the characteristics we should look for—both through human forms in the RAB and also that we can look for technically as well?

Q: The program must hire more than one Tribal liaison. It is a lot of work for one person to maintain good relations with the Tribes, especially for a national research program. Do you think it is possible to hire more than one Tribal liaison?

A (Mr. Dishman): I am open to all kinds of arrangements. There is no doubt that we need a village of people, some who are feds, and some who are consultants who are experts in the field. We are going to build a team that is much larger than one across all of those different kinds of capabilities.

I can tell you that in my experience, right now, it can be very challenging to hire into the federal government, so we need to be open to other ways of hiring people and getting that expertise on board. And I completely agree this is far more than one person's job.

Q: How does the research benefit each Tribal member if you did not have researchers accessing the data information?

A (Mr. Dishman): Our hope is to work with and through this consultation process and work with TAC to develop a way where many Tribes would feel comfortable with active recruitment in their own communities and Nations.

At that point, you would want the database to reflect that we had people signing up who not only self-identified as AI/AN but also were validated by their Tribe. That is another great question to address during this consultation process. What would it take for us to do Tribal affiliation correctly, to do some sort of validation?

At that point, if we can figure those things out, it will be very important to include that individual's information in the research.

Q: There is a challenging issue regarding big data sets and the possible identification of individuals based on other available data. How do you plan to protect the identification of Tribes and individuals in the data set?

A (Mr. Dishman): So we have an entire security and reidentification team as part of what we call our DRC, the Data and Research Center.

The team continues to develop anti-identification strategies across many issues, not the least of which is ZIP code, for example. You might have noticed that ZIP code, first of all, would only be accessible if you are in Tier 3 of data access as a researcher. So that is the most secure area of data access.

We are developing a set of not just policies but also algorithms and human audited activities to make sure that reidentification is not occurring. It is a bit like security and hackers. People and techniques for reidentification get better, and then we develop better techniques to keep them from reidentifying. And staying on top of that science and that technology is paramount to our success over time. We have got some of the best people in the country working on that issue. As technology changes and new data types come along, we will know how to continue to focus and not let reidentification happen.

Q: Do you plan to offer training for any researchers who access the data on the many negative experiences and the negative history of research in American Indian/Alaska Native Tribes?

A (Mr. Dishman): I cannot remember all of the training materials that we have. We already do have some materials that are not required, but we can require them as we go through it.

There is an ethics module that we are working on that can certainly include those kinds of examples. And we have been working with community partners all around the country to talk explicitly about historic examples of the absolute failure and wrongdoing of federal and other researchers on Tribal

communities and other diverse groups. We put together some materials that train people clearly to understand what new laws and protections are in place so we can never allow those atrocities to happen again.

C (Dr. Manson): If I might amplify on that, I think the report prepared by the working group, actually the first 10 pages or so, provide the equivalent of a module that individual scientists who are interested in acquiring access to data for the purpose of examining questions that might be specific or include American Indian/Alaska Native peoples should be expected to know.

I think it will highlight most of the major issues of the day within a historical context, so I think you have already got a substantial amount of material that could be reshaped for that purpose.

C (Mr. Dishman): Great idea. Thank you.

Q: How soon will you recruit on Tribal lands in the near future, and will there be consultation with those communities?

A (Mr. Dishman): I do not have a crystal ball, so I cannot see into the future. Certainly, this consultation process has been accelerating and widening to cover all parts of the country. We have got those four scheduled, but there are opportunities for expanding to some others as well.

I think it is important to get through that process before we even start to think through, “Okay, these are the things that we can do now. These are the things we can do eventually.” And then very transparently come back to our own Tribal Collaboration Working Group, the TAC, and then to the broad communities to say, “Here is what we are ready to do right now.” I think there will be ways that some Tribes can get involved very quickly.

That is part of the discussion and the brainstorming that we want to do during our listening sessions and consultations. I feel optimistic we can get to a place where many Tribes will feel comfortable at least with a certain amount of data capture, and then we will put additional measures in place and they will feel comfortable. I think this is part of the long-term relationship we will figure out and invent together.

Q: The screening and levels of security for access to data are good; however, historically issues regarding unauthorized, secondary data use have resulted from investigators who share data with other investigators, including students, without letting the Tribes know. How will this level of data use and sharing be monitored and prevented?

A (Mr. Dishman): That is a great concern, and one that has driven the decision to require all researchers to come to our secure domain to be able to do their research. You can imagine that is going to limit, in some cases, researchers who say, “I wanted to pull all of your data into my own tools at my university.”

We are trying to put as many common tools in place so we will not have that problem. If we did not require everyone to come to the data, then the risk that the question talked about grows higher and higher. The key decision right away was to protect all of this data in an enclave where it can be monitored again by both humans and algorithms to make sure the right thing is happening and the wrong thing is not happening.

Q (Dr. Roubideaux): So you are saying the data is going to be in the cloud and only the people who are registered can actually access it?

A (Mr. Dishman): That's right. Those tiers of access—if you are collaborating with another researcher, and you both had access to Tier 2 data, then you could share your workbench within the infrastructure. You would have to log in as your credentialed NIH infrastructure.

You can collaborate quite a lot. We have set up the space to be collaborative. What you cannot do is copy all of that out. That way, we can make sure bad things are not happening.

Q: The concerns about the public release of the data and then the release of the data to lots of researchers, and all of the concerns that American Indian/Alaska Native Tribes have about unauthorized or inappropriate use of the data—if after the consultation, Tribes only want their data to be available in the Tier 3 or controlled circumstance and do not want any American Indian data available publicly (i.e., like the most severe control), is that something that *All of Us* Research Program could deal with or accept?

A (Mr. Dishman): I think that is certainly the discussion that we ought to have, and certainly infrastructure-wise, we have some of those capabilities now and others could be built.

That is partly what we want to understand, and how, in particular—if we are doing active recruitment on Tribal lands, that is a very different scenario than somebody signing up and self-identifying as American Indian/Alaska Native. We should always make that clear, as the working group report recommends. These people are sort of self-identified.

I think at the point in which we are engaging Tribes to recruit on Tribal lands—which means you are separate, sovereign Nations—we should have discussions about the things you want to see in place to facilitate that.

Dr. Roubideaux listed these last remaining questions/comments:

- It is important to work with local universities that have experience working with Tribes and community relationships and have best practices.
- How will AI/AN samples already collected be brought in with protections indicated by the Tribal consultation?
- Do you have a list of Tribal IRBs or other research review boards that allow you to contact Tribes to get permission for use of Tribal information? Is there a way to convene IRBs or work with them?
- Are there future plans for more Tribal-based governance entities to be part of the *All of Us* Research Program?

Mr. Dishman encouraged Tribal members and communities to share best practices via email or other methods to help move the *All of Us* Research Program forward. Chairperson Payment recommended summarizing and sharing the webinar Q&A during the upcoming consultation to show the depth of questions coming from Indian Country and how the *All of Us* Research Program continues to respond to

concerns. Dr. Manson appreciated the authentic commitment and lack of defensiveness demonstrated by Mr. Dishman and NIH as the program builds partnerships with Tribal communities.

Dr. Roubideaux provided final details on links to the webinar, upcoming events, and contact email information. The meeting adjourned at 4:07 p.m.