

All of Us Research Program

Update on the Tribal Collaboration Working Group



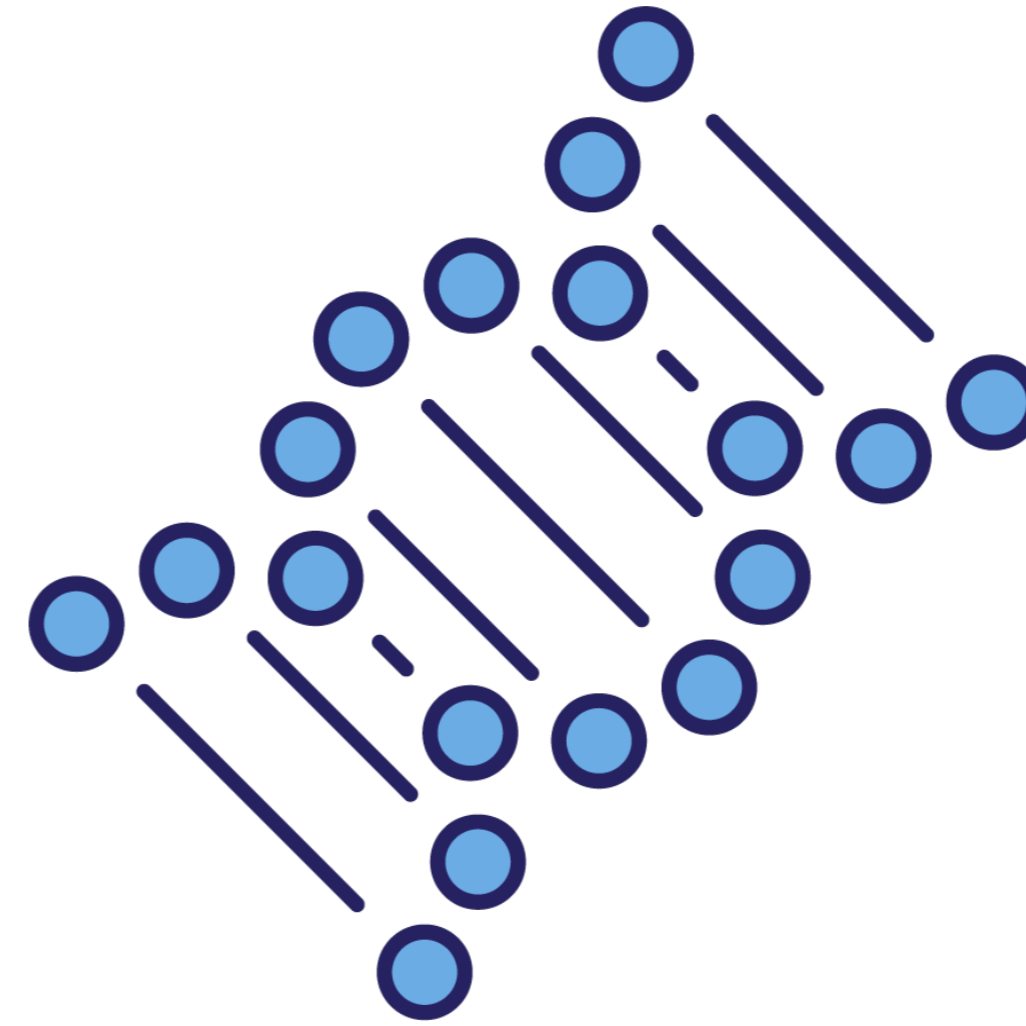
National Institutes
of Health

Lynn Malerba, TCWG Co-Chair

Dara Richardson-Heron, AOU Chief Engagement Officer

What Is Precision Medicine?

Precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in lifestyle, environment, and biological makeup. It is a radical shift in how each of us can receive the best care possible based on our unique characteristics.



The *All of Us* Research Program

- The cornerstone of the larger PMI – led by the NIH
- One million or more volunteers, reflecting the broad diversity of the U.S.
- Opportunities for volunteers to provide data on an ongoing basis
- Data will inform a variety of research studies
- Currently in beta testing; national launch anticipated this spring



Summary: Version 1 of Protocol Currently Underway



Enroll, Consent & EHR

- Recruit 18+ years old initially; plan to include children in next iteration
- eConsent or paper long-form
- Participants complete additional authorization to share EHR data



Surveys

- Three initial participant provided information modules: The Basics, Overall Health, & Lifestyle



Physical Measurements

- Blood pressure
- BMI
- Heart rate
- Height
- Hip circumference
- Waist circumference
- Weight



Biosamples

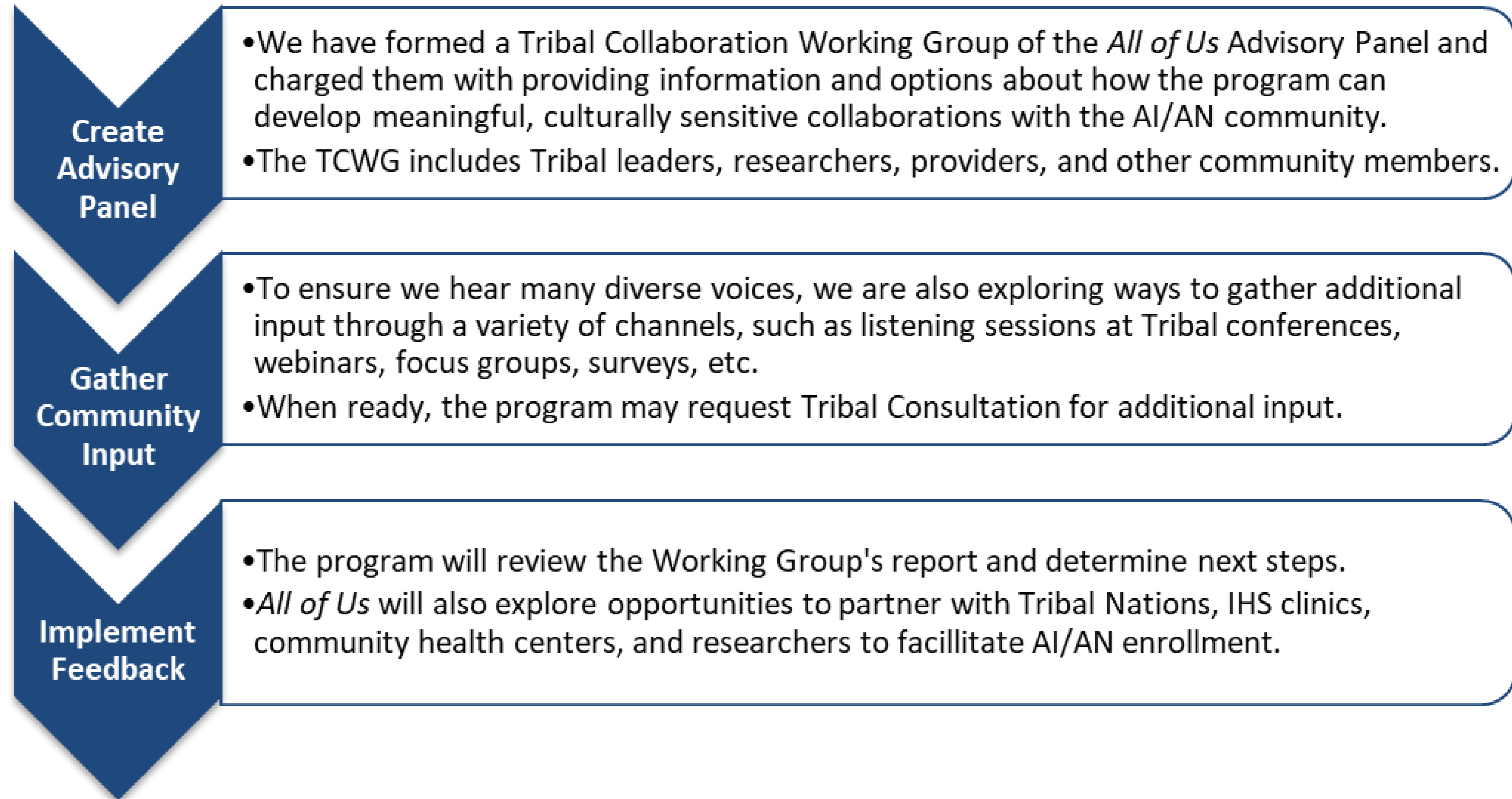
- Blood (or saliva, if blood draw is unsuccessful)
- Urine
- 28 aliquots of blood and 6 of urine stored in Biobank

Engagement Plan

Early information gathering

- Conducted an informal literature review to understand the issues
- Spoke with Tribal leaders and researchers to gather input and feedback and build relationships
- Met with leaders of tribal organizations, including NCAI and NIHB
- Presented at meetings or webinars convened by tribal organizations
- Attended and spoke at NIH Tribal Advisory Committee meetings
- Consulted with HHS and NIH colleagues
- Attended a regional conference with tribal leaders that was organized by our University of Arizona & Banner Health consortium partners
- Assembled a team of advisors to provide engagement advice and help plan the Tribal Collaboration Working Group of the AOU Advisory Panel

National engagement plan



Tribal Collaboration Working Group

Tribal Collaboration Working Group (TCWG)

◎ Purpose

To provide input on strategies for developing meaningful, culturally sensitive collaborations with American Indian/Alaska Native (AI/AN) populations. Describe challenges and unique considerations (such as tribal sovereignty, cultural beliefs/traditions, historical distrust) and solutions for consideration. Input will inform future tribal consultations.

◎ Composition – 16 members:

- Tribal leaders, researchers, providers
- Community representatives
- Consortium representatives
- AOU staff

◎ Timeline

- First meeting: October 27
- TCWG report draft: mid-March
- Input gathering from NIH TAC, tribal organizations: mid-March to late April
- Consultation: date to be determined upon completion of WG report



Your input will be appended to the TCWG report.

TCWG Roster

Co-Chairs

- **Lynn Malerba, D.N.P., M.P.A.**
Chief, Mohegan Tribe
Uncasville, Connecticut
- **Spero Manson, Ph.D.**
Associate Dean for Research, Colorado School of Public Health
Aurora, Colorado

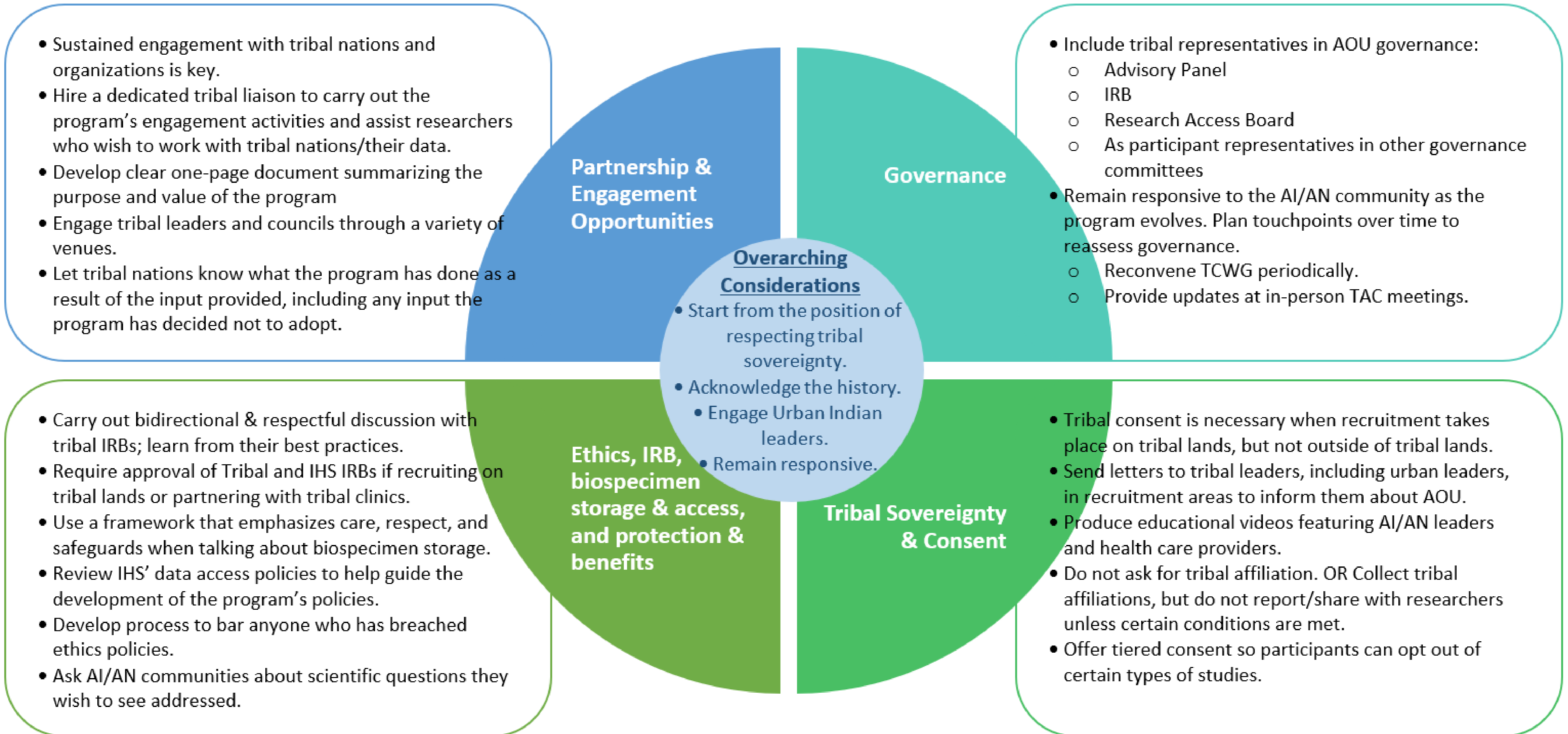
Working Group Members

- **Murray Brilliant, Ph.D.**
Director, Center for Human Genetics, Marshfield Clinic Research Institute
Marshfield, Wisconsin
- **Denise Dillard, Ph.D.**
Director of Research, Southcentral Foundation
Anchorage, Alaska
- **Abigail Echo-Hawk, M.A.**
Chief Research Officer, Seattle Indian Health Board
Seattle, Washington
- **Kevin English, Dr.P.H.**
Director, Albuquerque Area Southwest Tribal Epidemiology Center
Albuquerque, New Mexico
- **Karen Maschke, Ph.D.**
Research Scholar, The Hastings Center
Garrison, New York
- **John Molina, M.D., J.D., L.H.D.**
Corporate Compliance Officer, Native Health
Phoenix, Arizona
- **Kelly Moore, M.D., J.D., FAAP**
Associate Professor, Colorado School of Public Health
Aurora, Colorado
- **Marcia O’Leary**
Manager, Missouri Breaks Industries Research
Eagle Butte, South Dakota
- **Liana Onnen**
Chairperson, Prairie Band Potawatomi Nation
Mayetta, Kansas
- **Dara Richardson-Heron, M.D.**
Chief Engagement Officer, AOU
Bethesda, MD
- **Bobby Saunkeah, RN, MSHCE, CIP**
Manager, Division of Research and Population Health, Chickasaw Nation Department of Health
Ada, Oklahoma
- **Rachael Tracy, MPH**
Research Director, Indian Health Service
Rockville, Maryland
- **Malia Villegas, Ed.M.**
- **David Wilson, Ph.D.**
Director, Tribal Health Research Office, NIH
Bethesda, Maryland

TCWG Topic Areas

- ⦿ **Governance**
- ⦿ **Tribal sovereignty & consent**
- ⦿ **Ethics considerations**
- ⦿ **Biospecimen handling & storage**
- ⦿ **Institutional review board**
- ⦿ **Partnership opportunities & best practices for engagement**
- ⦿ Verification of tribal membership
- ⦿ Research & data access
- ⦿ Responsible return of information
- ⦿ Scientific vision
- ⦿ Other topics the TCWG would like to address

A schematic of our input...



TCWG Input – Overview

- ◎ A research program on the scale of *All of Us*, with its focus on environmental and lifestyle factors in addition to biological makeup, could be of potential benefit to tribal nations and individuals.
- ◎ If done right, *All of Us* could become a model of positive, bidirectional partnership on research between the NIH & tribal nations.
- ◎ In order to succeed, *All of Us* will need to:
 1. Start from a position of attention to and **respect for tribal sovereignty**.
 2. **Acknowledge the history** that American Indians and Alaska Natives have experienced with the government and keep in mind how that shapes AI/AN perceptions about participating in government research. Special approaches will be necessary to overcome the mistrust and fear. Also, if the program makes any mistakes or missteps, they should be acknowledged as well.
 3. Since many of the participants will be Urban Indians, in addition to reaching out to tribal leaders, **engage with the organizations that represent Urban Indians**.
 4. **Remain responsive** to the AI/AN community as the program evolves.

TCWG Input – Governance

- ◎ Include a tribal representative in *All of Us* governance areas:
 - **Advisory Panel** – outside experts who provide oversight & advice on vision, scientific goals, and operations
 - **Institutional Review Board** – dedicated single IRB; reviews protocol, informed consent, & participant-facing materials
 - **Research Access Board** – oversees operationalizing program’s data access policies
 - **Other governance groups** – *All of Us* is working to include participants in their governance committees, boards, and task forces; AI/AN participants should be included in these opportunities

- ◎ Gather ongoing input from tribes & tribal members:
 - Periodically reconvene TCWG
 - Provide updates at TAC’s in-person meetings, potentially as a standing agenda item
 - Also ask TAC for assistance to share information about the program with tribal nations and address any issues that arise as the program enrolls AI/AN participants.
 - Provide updates to major organizations – IHS, epidemiology centers, NCAI, NIHB, NCUIH, UIHI, USET, etc.

TCWG Input – Tribal Sovereignty & Consent

- ◎ Obtain tribal consent when recruiting & enrolling participants within tribal lands/jurisdiction
- ◎ Tribal consent is not required for enrollment of Urban Indians
 - However, send courtesy letters to tribal leaders, including Urban Indian leaders, to inform them of the program in any region where the program is recruiting participants
- ◎ Produce educational videos featuring tribal leaders, providers, researchers, and community members/potential participants discussing their opinions about the program
- ◎ Varied input regarding collection of tribal affiliation, including:
 - Do not ask about tribal affiliation
 - Or allow participants to provide tribal affiliation, but do not make the information available to researchers unless certain conditions are met
 - Tag the data as “self-reported”
 - Require researchers obtain tribal permission before conducting/publishing a study naming a tribe; specific permission not required for broader studies of the AI/AN population
- ◎ Offer tiered consent, so participants can opt out of certain types of studies

TCWG Input – Ethics

◎ IRB

- Engage in respectful, bidirectional discussion with tribal IRBs to learn from their best practices
 - Ask tribal IRB representatives to provide cultural sensitivity training for *AOU* IRB & Research Access Board
- Single IRB requirement does not apply when partnering with tribal nations
 - Tribes and their tribal IRB have jurisdiction when research takes place on tribal lands
 - IHS IRB has jurisdiction when research is conducted with IHS staff or resources, or within IHS facilities

◎ Biospecimen storage and access

- Use a framework that emphasizes care, respect, and safeguards when talking about biospecimen storage
- Review IHS' data access policies to help guide the development of the program's policies, recognizing that some may not translate well given the unique nature of the *All of Us* Research Program

◎ Protection and benefits

- Ensure tribal representation on the Research Access Board
- Develop process to identify and bar organizations or individuals who have breached ethics policies
- Ask communities about scientific questions they want to see addressed

TCWG Input – Engagement and Partnerships

- ◎ Sustained engagement with tribal nations and organizations is key
 - Hire a dedicated tribal liaison – ideally a native individual with a deep understanding of AI/AN culture
 - Reach out to & have conversations with tribal nations in the region, even if recruitment is targeted at Urban Indians
 - Since *AOU* has enrollment sites in Arizona & Wisconsin, prioritize meeting with tribal leaders in these two states

- ◎ Develop clear one-page document summarizing the purpose and value of the program

- ◎ Engage tribal leaders and councils through a variety of venues:
 - Ask AI/AN organizations to help disseminate materials through their website, contacts, listservs
 - Create an interactive webpage to provide information and updates to tribal leaders
 - Launch a blog or email account for tribal leaders to send questions
 - Hold webinars after national launch to answer questions, address concerns
 - Engage with tribal epidemiology centers
 - Organize a symposium or listening session with tribal leaders & researchers
 - Conduct periodic visits and two-way conversations with tribes, tribal communities
 - Hold consultation with tribal nations

- ◎ Let tribal nations know what the program has done as a result of the input provided, including any input the program has decided not to adopt

We want to hear your input!

In addition to sharing your feedback today,
we welcome written comments to:

Daozhong Jin: daozhong.jin@nih.gov