

# NIH Tribal Health Research Office (THRO)

Division of Program Coordination, Planning, and Strategic Initiatives Office of the Director

# NIH Tribal Advisory Committee Meeting October 26-27, 2021

David R. Wilson, Ph.D., Director, THRO



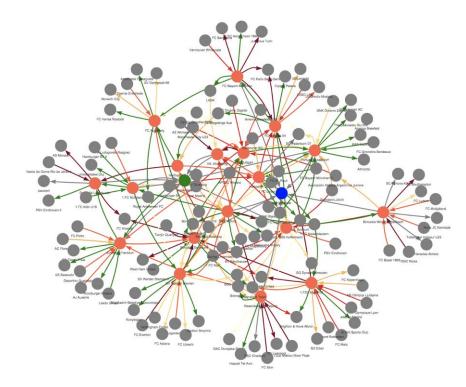
NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.



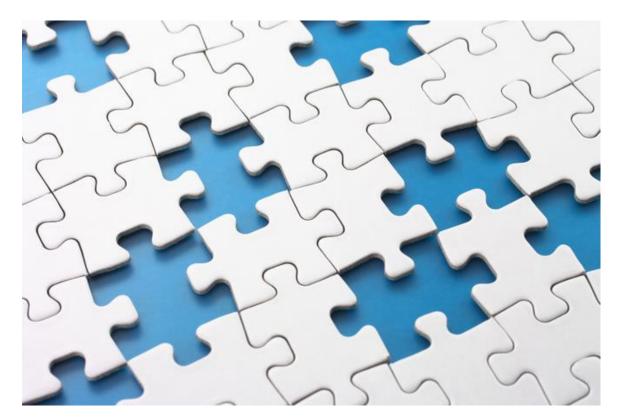
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# How Does Everything fit together?



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Building research partnerships for healthy Tribal Nations

# **New Draft Tribal Consultation Policy**

### **Draft Policy Includes:**

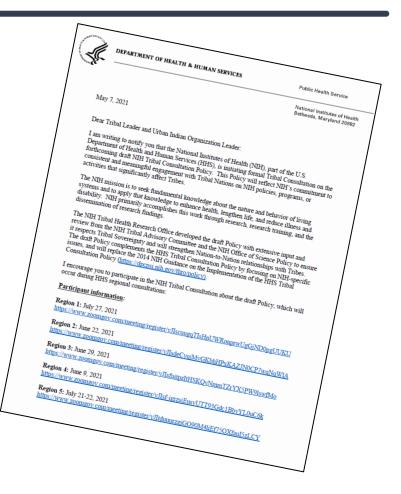
- Timelines for steps (30 days, 60 days, etc.)
- Descriptions of roles of NIH entities (Who does what, and when)
- Requirements for tracking outcomes and actions
- At least one annual Tribal Consultation

### Agency requirements to:

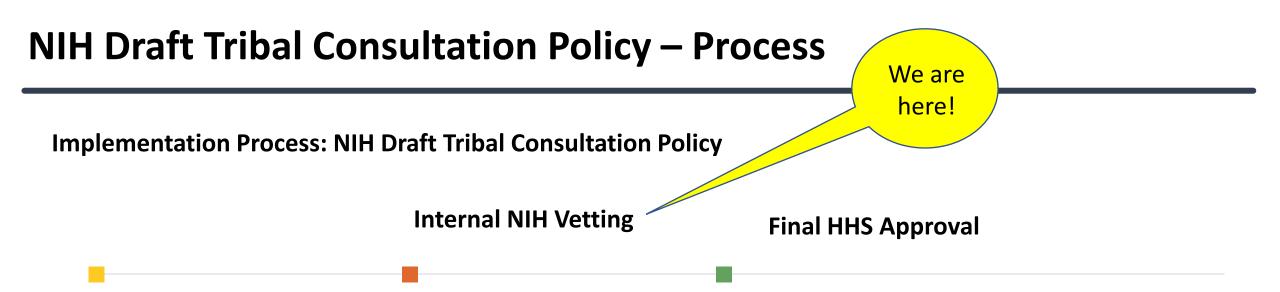
- Seek Tribal feedback
- Evaluate Policy implementation and effectiveness
- Report back (summarizing input and agency response)



- Standardizes process
- Educates NIH community
- Increases understanding of Tribal sovereignty
- Improves program development







➢ Initiate DTLL in May

- Engage Tribes at 10 HHS Regional Consultations May 25 - August 9, 2021
- Review and summarize comments

- THRO, Office of Science Policy and Office of General Counsel (OGC) review Tribal input
- Revise as needed
- Take draft policy to
   NIH-wide committees
- Final IC review and approval

- HHS OGC and Assistant Secretary for Legislation conduct final review
- Policy implementation



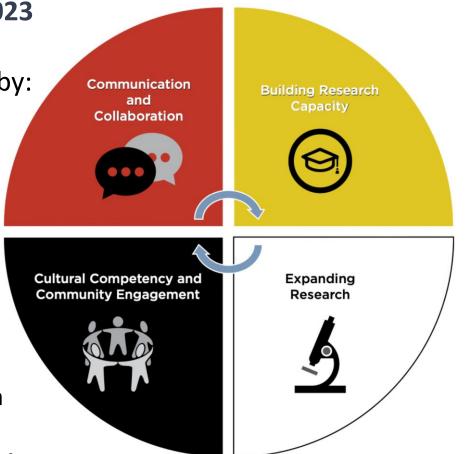
# **NIH Strategic Goals for Tribal Health Research**

The NIH Strategic Plan for Tribal Health Research, FY2019-2023 articulates the mission of NIH's relationship and collaborative efforts with American Indian and Alaska Native communities by:

- 1. Enhancing communication and collaboration
- 2. Building research capacity
- 3. Expanding research
- 4. Enhancing cultural competency and community engagement



- Agency-wide vision for implementation
- Goals and metrics to assess progress
- Lays foundation to enhance engagement





### **Goal #1 – Enhancing Communications and Collaboration**

Developer	Platform	Planned Start	Eligibility	Number of Doses	Specimens Collected	Planned Follow-up
Moderna	mRNA	July	18+ years, healthy or medically stable, no prior COVID-19	2 doses, 28 days apart	Blood, nasal swab	2 years
Pfizer/ BioNTech	mRNA	August	18-85 years, healthy or medically stable, no prior COVID-19	2 doses, 21 days apart	Blood, nasal swab	2 years
Oxford/Astra- Zeneca	Adenovirus vector	August	18+ years, healthy or medically stable	2 doses, 28 days apart	Blood, nasal swab, saliva	2 years
Janssen	Adenovirus vector	September	Healthy 18-59 years first, then add in 60+ years, with and without comorbidities	1 or 2 doses, 8 weeks apart	Blood, nasal swab, saliva	1 year and 3 months
Novavax	Protein nanoparticle	October	18+ years, healthy or medically stable	2 doses, 21 days apart	Blood, nasal swab	2 years
Sanofi/GSK	Protein Subunit	December	18+ years	2 doses, 21 days apart	Blood, nasal swab	12 months

Can vaccines cause SARS-CoV-2 infection or cause COVID-19?

#### NO!

The vaccines being tested are made from synthetic (laboratory-made) pieces copied from SARS-CoV-2, not the whole virus. Therefore, the vaccines CANNOT cause infection or cause you to get COVID-19.







"The choice to be vaccinated is an important community, family, and personal decision that we all must take seriously. I took my first opportunity to #SleeveUp because I believe in the science behind the COVID-19 vaccines and that they are safe, effective, and will **save lives**."

- David R. Wilson, Ph.D., Diné, Director, NIH Tribal Health Research Office





THERE.

Effective and safe **COVID-19** vaccines will help to #StoptheSpread.





- Increasing use of social media for outreach
- Questions about vaccine distribution to AI/AN communities, vaccine risks for immunocompromised patients,





- Initially, reached more than 80,000 people
- Received more than 33,000 views and 1,800 engagements
- Video shared more than 480 times.
- Approximately 95% of the reactions were positive.



# Addressing Mental Health in AI/AN Communities – July 2021



- Dr. Joshua Gordon, NIMH Director, participated in a discussion about the mental health impacts of COVID-19 in AI/AN communities.
- Continued communication and resource sharing during the pandemic, and beyond.



- Responding to interests of Tribal communities
- Increased interest from other ICs about outreach to Tribes
- THRO supporting ICs to do more
- Enhancing agency interest in cultural competency



Dr. Anthony Fauci participated in a radio media tour to address COVID-19 and vaccine hesitancy in AI/AN communities.

### **Initial Highlights:**

- > Nearly 4.5 million total impressions
- 371 radio broadcasts with 2 million+ total audience
- Additional soundbite distribution with 2 million+ audience

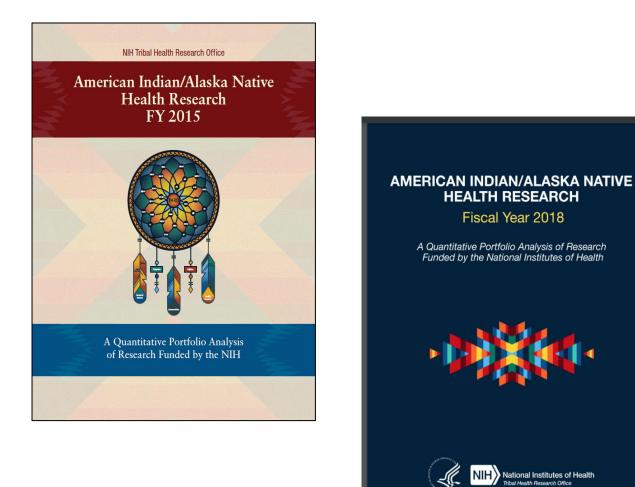








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- Forming collaborative partnerships
- Expanding support for AI/AN researchers
- Working to increase the number of • AI/AN students pursuing research careers
- Engaging ICOs to expand NIH • research with AI/AN communities



### **NIH Tribal Consultations: Gathering Tribal Input & Enabling Participation**

#### Past

1. 2020	Rapid-Response NIH Tribal Consultation on COVID-19 Research
2. 2019-2020	The NIH Draft Policy for Data Management and Sharing
3. 2019-2020	The All of Us Research Program
4. 2019	Intellectual Property in Biomedical Research
5. 2018	The Opioid Crisis in Indian Country
6. 2017	The NIH Strategic Plan for Tribal Health Research

#### Current

- 1. 2021 Native American Research Center's for Health (NARCH) Program
- 2. 2021-2022 Draft NIH Tribal Consultation Policy
- **3. 2021** RADx Initiative's Tribal Data Repository (TDR)

### Upcoming

> 2021

National COVID-19 Cohort Collaborative (N3C)



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## **Grant Writing Workshops**





Build on strengths of faculty, postdoctoral fellows, and graduate students to increase applications for research grants and career training and development support



An important NIH focus in data science is developing and testing tools located "in the cloud," instead of on individual computers, that are accessible to researchers regardless of location and resource availability.





### **Summer Internships at the NIH**

#### TRAINING & CAREER DEVELOPMENT

 High School, Undergraduate, &

 Post-Baccalaureate

 Predoctoral Fellows

 Postdoctoral Fellows

 Clinician-Scientists

 Faculty

 Diversity Awards

 Individual Fellowships

 Career Development Awards

 Institutional Grants

 Other Training-Related Programs

LATEST UPDATES

Strategic

Planning

NINDS Strategic Plan 2021-2026

### NINDS Health Disparities in Tribal Communities Summer Internship Program (SIP)

**COVID-19 UPDATE:** We are now able to share information regarding the 2021 <u>NINDS/NIH</u> Summer Internship Program (SIP), High School Summer Internship Program (HS-SIP) and the Health Disparities in Tribal Communities Summer Internship Program. Unfortunately, it is clear that we still face uncertain times with continuing difficulty integrating trainees who started during the pandemic. Therefore, we want to let you know that all **2021 NINDS Summer programs will be fully virtual this summer.** The 2021 Summer Program Cohorts has been selected. We look forward to the next application cycle starting in mid-November 2021.

For information about COVID-19, visit the following link: <u>https://www.nih.gov/health-information/coronavirus</u>



Graduate and undergraduate students selected for this fully-funded summer internship

### Contact

<u>Angel de la Cruz Landrau, PhD</u> 301-496-0899 <u>ninds-sip@ninds.nih.gov</u>⊠







# **AI/AN Regional Training Hubs**

### Locations: Pacific Northwest, Northern Arizona, Great Plains





- Gives research experience close to home with community support
- Increases student interest in research
  - Provides research experience of multiple disciplines



### **Goal #4 Expanding Research**



### **NIH Common Fund Programs**

#### COMMUNITY LISTENING SESSION FOR TRIBAL COMMUNITIES AND ORGANIZATIONS

#### HELP IDENTIFY NEW SOLUTIONS AND INFORM THE DEVELOPMENT OF INTERVENTIONS TO ADDRESS HEALTH DISPARITIES AND ADVANCE HEALTH EQUITY

**NOVEMBER 4, 2021** 

2:00 - 3:30 P.M. ET

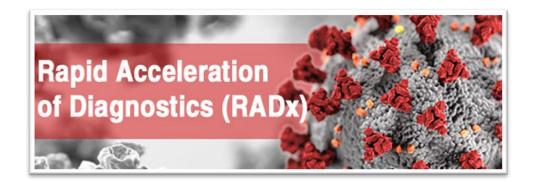
Sponsored by the NIH Common Fund's Transformative Research to Address Health Disparities and Advance Health Equity Initiative Working Group



National Institutes of Health Turning Discovery Into Health



### **Tribal Voice in Big Data for Healthy Tribal Nations**



The RADx-UP initiative aims to understand the factors associated with disparities in COVID-19 morbidity and mortality and to lay the foundation to reduce disparities for those underserved and vulnerable populations most at risk for complications or poor outcomes from the COVID-19 pandemic.



The All of Us Research Program is part of an effort to advance individualized health care. The program aims to reflect the diversity of the U.S. and to include participants from groups that have been underrepresented in health research in the past.

National COVID Cohort Collaborative (N3C) 

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**The N3C is a national partnership** in which collaborators will contribute and use COVID-19 clinical data to **answer critical research questions to address the pandemic**.



# **Goal #4 Enhancing Cultural Competency & Community Engagement**







U.S. NATIONAL INSTITUTES OF HEALTH 2019 Traditional Medicine Summit Report Maintaining and Protecting Culture Through Healing



Held November 20-22, 2019

Nighthorse Campbell Native Health Building University of Colorado Anschutz Medical Campus | Aurora, Colorado





Increase awareness of Traditional ways of healing Begin the conversation on how research can benefit from cultural adaption Educate scientific community



### **Publications and White Papers**





- Increase awareness of how to ethically and respectfully conduct research with Tribal communities
- Influence training of grant reviewers
- Educate scientific community



### Training, Facilitating the Ethical Conduct of Tribal Research

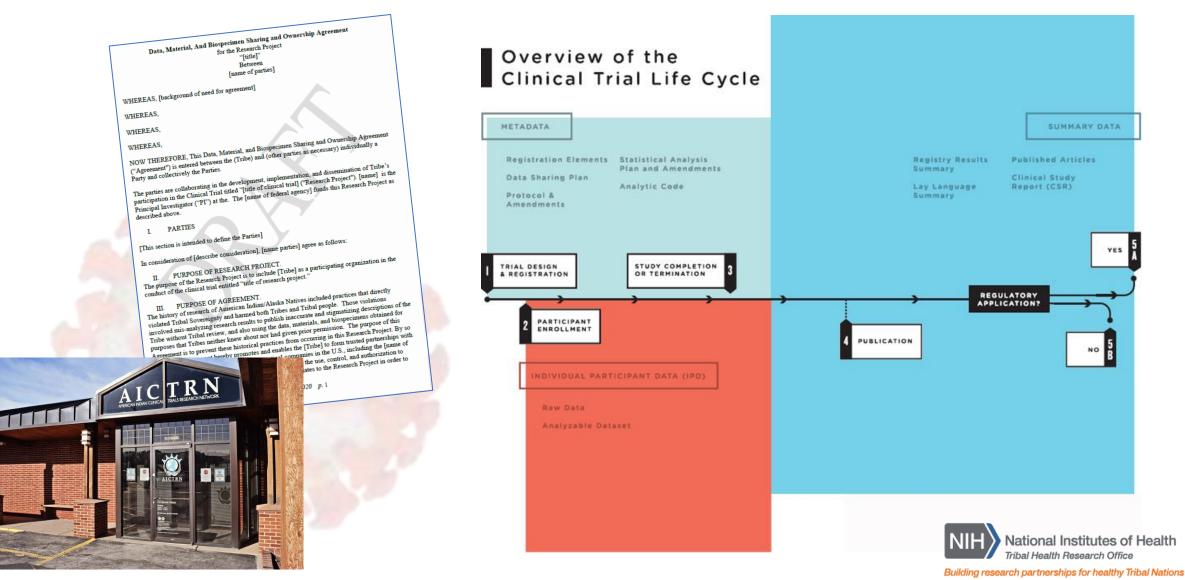
- Teaching/mentorship of NIH Investigators, trainees, IRB staff
  - OHSRP Education Series
  - NIH/Bioethics Ethical and Regulatory Aspects of Clinical Research Course
- Partner with NIH IRB to facilitate engagement between Intramural investigators and Tribal leadership prior to initiation of American Indian and Alaska Native (AI/AN) research
  - Development of IHS/NIH Memorandum of Understanding regarding IRB review of collaborative research (in progress)
- Provides input on emerging policies/guidance affecting AI/AN research
  - sIRB policy/exceptions (HHS/OHRP)
  - NIH Data Sharing Policy (NIH/OSP)
  - Consent language for biospecimen/data sharing (NIH/OSP)
  - Ethical conduct of research with Urban AI/AN populations (TAC)
- Podcasts and Native media outlets
  - o Indian Country Today interviews
  - AI/AN case studies for PRIM&R Knowledge Center (in progress)
  - Genetics Unzipped:
    - <u>"Responsible genomics research with tribal and indigenous communities"</u>



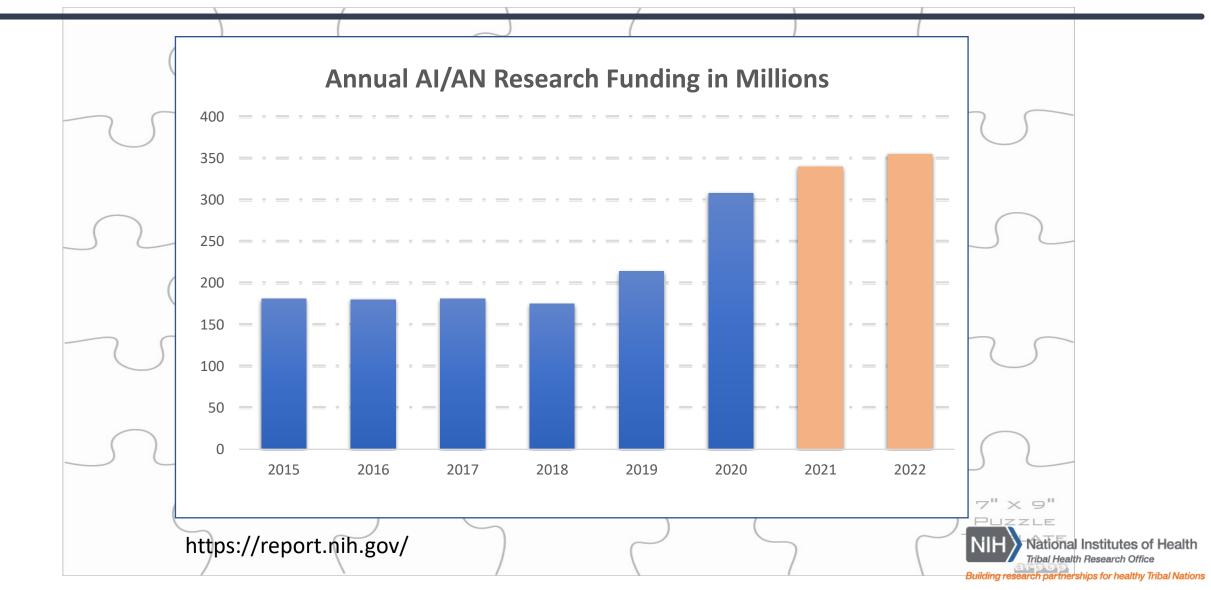
OHSRP Education Series: Ethical Conduct of Research with American Indian and Alaska Native Participants: Extending Protections through Respect for Tribal Sovereignty

Thursday, September 2, 2021	
Dr. Sara Hull, NIH and Dr. Dave Wilson, NIH	
Read more 248 views (206 live, 42 VOD) - Ru	untime: 01:01:08
THE AMERICAN JOURNAL OF BIOETHICS 2021, VOL. 21, NO. 10, 14–17 https://doi.org/10.1080/15265161.2021.1965258	Taylor & Francis
OPEN PEER COMMENTARIES	R Check for updates
Solidarity as an Aspirational Basis for Partnership with Triba	al Communities
Sara Chandros Hull, F. Leah Nez (Diné), and Juliana M. Blome	

### **Clinical Trials Led by Tribal Communities**



### **Growing Investment in Tribal Health**



### **Ethical Inclusion of Urban AI/ANs in Biomedical Research**





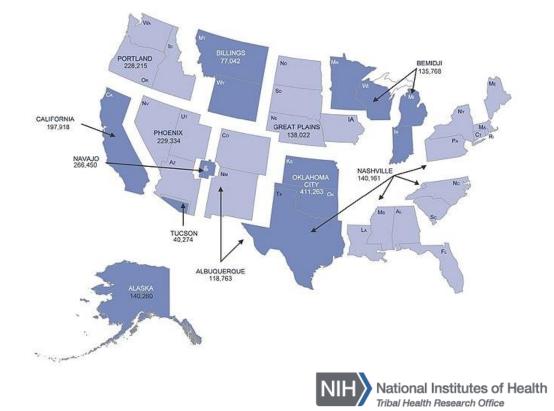
**SMALL BUSINESS INNOVATION RESEARCH PROGRAM** These programs congressionally require eligible governmental agencies to set aside a percentage of their extramural budget so that domestic small businesses can engage in R&D that has a strong potential for technology commercialization.

### Advances in Aging and Alzheimer's Research

Since its inception in 1974, NIA has conducted and supported research designed to improve quality of life for aging Americans and identify strategies to effectively prevent, delay, or slow age-related diseases, including dementia.

NIH

National Institute on Aging



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### **Connect With Us and Learn More**



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