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.
How Does Everything fit together?
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
NIH Draft Tribal Consultation Policy – Process

**Implementation Process: NIH Draft Tribal Consultation Policy**

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

**Internal NIH Vetting**

- 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

**Final HHS Approval**

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

We are here!
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

COVID-19 Vaccines in Late Phase Clinical Trials in the US

<table>
<thead>
<tr>
<th>Company</th>
<th>Platform</th>
<th>Planned Start</th>
<th>Eligibility</th>
<th>Number of Doses</th>
<th>Vaccines (at Factor)</th>
<th>Planned Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderna</td>
<td>mRNA</td>
<td>July</td>
<td>18+ years, healthy or medically stable, no active COVID-19</td>
<td>2 doses, 3 weeks apart</td>
<td>Blood, nasal swab</td>
<td>2 weeks</td>
</tr>
<tr>
<td>Pfizer/ BioNTech</td>
<td>mRNA</td>
<td>August</td>
<td>18-85 years, healthy or medically stable, no active COVID-19</td>
<td>2 doses, 21 days apart</td>
<td>Blood, nasal swab</td>
<td>2 weeks</td>
</tr>
<tr>
<td>Gilead/Lilly</td>
<td>Adenovirus vector</td>
<td>December</td>
<td>Healthy, 18-85 years, first, then add a 40+ years, with and without comorbidities</td>
<td>1 dose, 2 doses 8 weeks apart</td>
<td>Blood, nasal swab, saliva</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Johnson</td>
<td>Adenovirus vector</td>
<td>December</td>
<td>Healthy, 18-85 years, first, then add a 40+ years, with and without comorbidities</td>
<td>1 dose, 2 doses 8 weeks apart</td>
<td>Blood, nasal swab, saliva</td>
<td>4 weeks and 3 months</td>
</tr>
<tr>
<td>Biontech</td>
<td>Protein nanoparticles</td>
<td>December</td>
<td>18+ years, healthy or medically stable</td>
<td>2 doses, 21 days apart</td>
<td>Blood, nasal swab</td>
<td>2 months</td>
</tr>
<tr>
<td>Sanofi/GSK</td>
<td>Protein subunit</td>
<td>December</td>
<td>18+ years</td>
<td>2 doses, 21 days apart</td>
<td>Blood, nasal swab</td>
<td>12 months</td>
</tr>
</tbody>
</table>

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.

Will a COVID-19 vaccine alter my DNA?

No. COVID-19 mRNA vaccines do not change or interact with your DNA in any way.

"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 #StandUp 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
• 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.
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
Radio Media Tour with Dr. Fauci – March 2021

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

Listen!  KNNB APACHE RADIO
Goal #2 – Building Research Capacity

- 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)
Grant Writing Workshops

Grant Writing Strategies for Tribal Colleges and Universities (TCUs)

**Spring Series:** Fridays, April 30, May 7, May 14, May 21, and May 28

**Fall Series:** Fridays, Oct 22, Oct 29, Nov 5, Nov 12, and Nov 19.

Build on strengths of faculty, postdoctoral fellows, and graduate students to increase applications for research grants and career training and development support
Innovative Training for AI/AN Students

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

COVID-19 UPDATE: We are now able to share information regarding the 2021 NINDS/NIH 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: https://www.nih.gov/health-information/coronavirus

Graduate and undergraduate students selected for this fully funded summer internship
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

Notice of Intent to Re-issue RFA-RM-21-022

The purpose of this Notice is to indicate the intent to re-issue RFA-RM-21-022 “Transformative Research to Address Health Disparities and Advance Health Equity at Minority Serving Institutions (MRI).” The re-issued RFA will solicit new applications or revisions for a proposed March 25, 2022, due date. View details: https://nih.gov/spire

Pre-application Webinar Material for RFA-RM-21-021 and RFA-RM-21-022

On April 27, 2021, the NIH Common Fund hosted a pre-application webinar for Transformative Research to Address Health Disparities and Advance Health Equity (RFA-RM-21-021 and RFA-RM-21-022). NIH program officers discussed the overall scope and
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.

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

- Increase awareness of Traditional ways of healing
- Begin the conversation on how research can benefit from cultural adaption
- Educate scientific community
• 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
  o OHSRP Education Series
  o 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
  o 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
  o sIRB policy/exceptions (HHS/OHRP)
  o NIH Data Sharing Policy (NIH/OSP)
  o Consent language for biospecimen/data sharing (NIH/OSP)
  o Ethical conduct of research with Urban AI/AN populations (TAC)

➢ Podcasts and Native media outlets
  o Indian Country Today interviews
  o AI/AN case studies for PRIM&R Knowledge Center (in progress)
  o Genetics Unzipped:
    ✓ “Responsible genomics research with tribal and indigenous communities”
Clinical Trials Led by Tribal Communities

Overview of the Clinical Trial Life Cycle

1. Participant Enrollment
2. Trial Design & Registration
3. Study Completion or Termination
4. Publication

Metdata
- Registration Elements
- Data Sharing Plan
- Protocol & Amendments
- Statistical Analysis Plan and Amendments
- Analytic Code

Summary Data
- Registry Results Summary
- Lay Language Summary
- Published Articles
- Clinical Study Report (CSR)

Regulatory Application?
- No
- Yes

Raw Data
Analyzeable Dataset
Growing Investment in Tribal Health

https://report.nih.gov/

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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
Connect With Us and Learn More

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