

NIH Tribal Health Research Office (THRO)

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

David R. Wilson, Ph.D., Director

NIH Tribal Advisory Committee Virtual Meeting
December 2-3, 2020

NIH Tribal Advisory Committee Virtual Meeting

Improving how we operate:

- Rules of order
- Point of contact
- TAC leading the way

THRO and COVID-19:

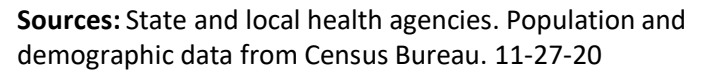
- Rapid-Response NIH Consultation
- THRO, CoVPN, OWS
- NIH CEAL
- Communicating with Tribal Nations
- Tribal participation in vaccine trials

NARCH:

- Collaborations with CSR

Strategic Plan Tracking System:

- Portfolio analysis



How THRO is Assisting Tribes with COVID-19

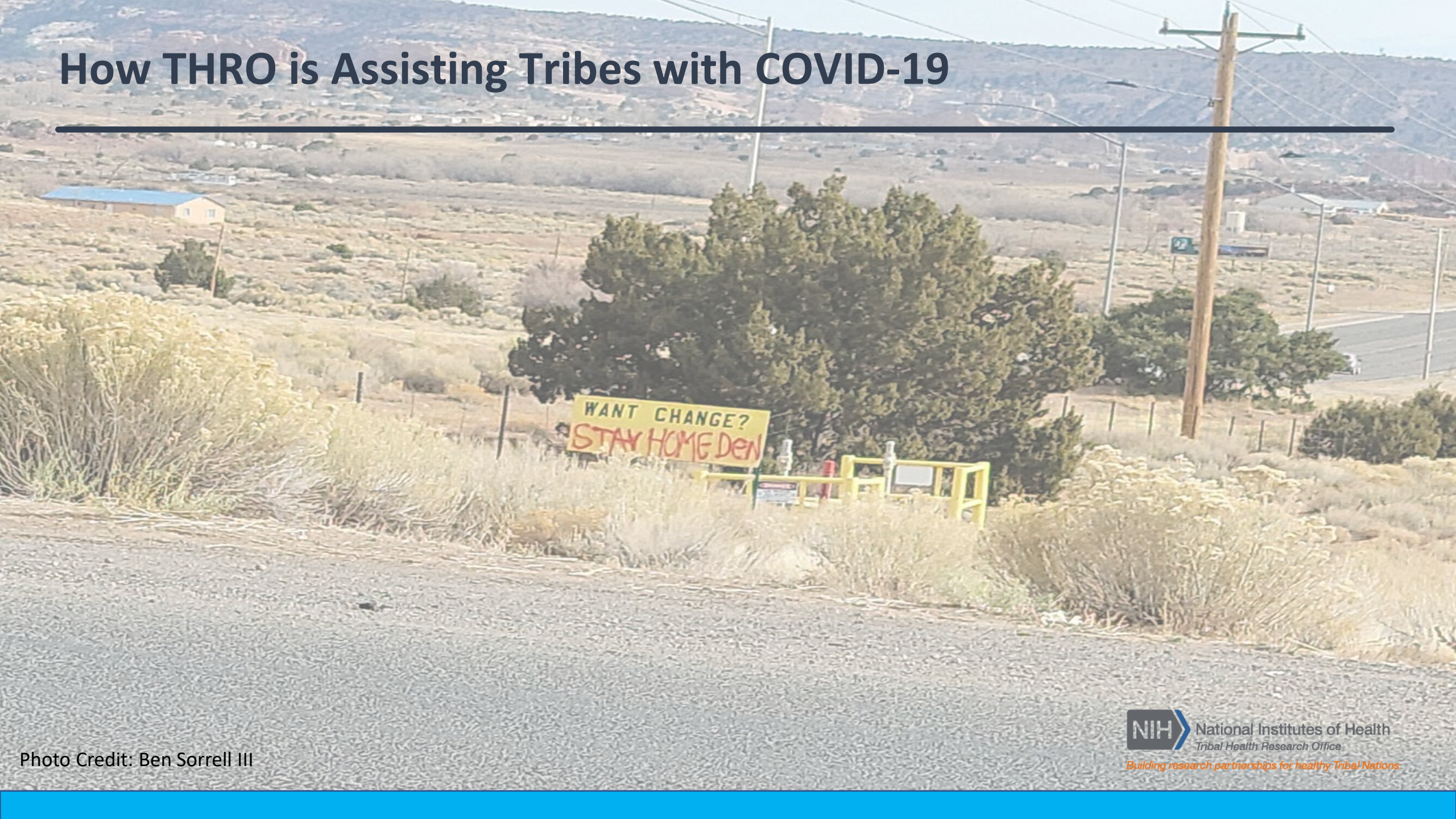
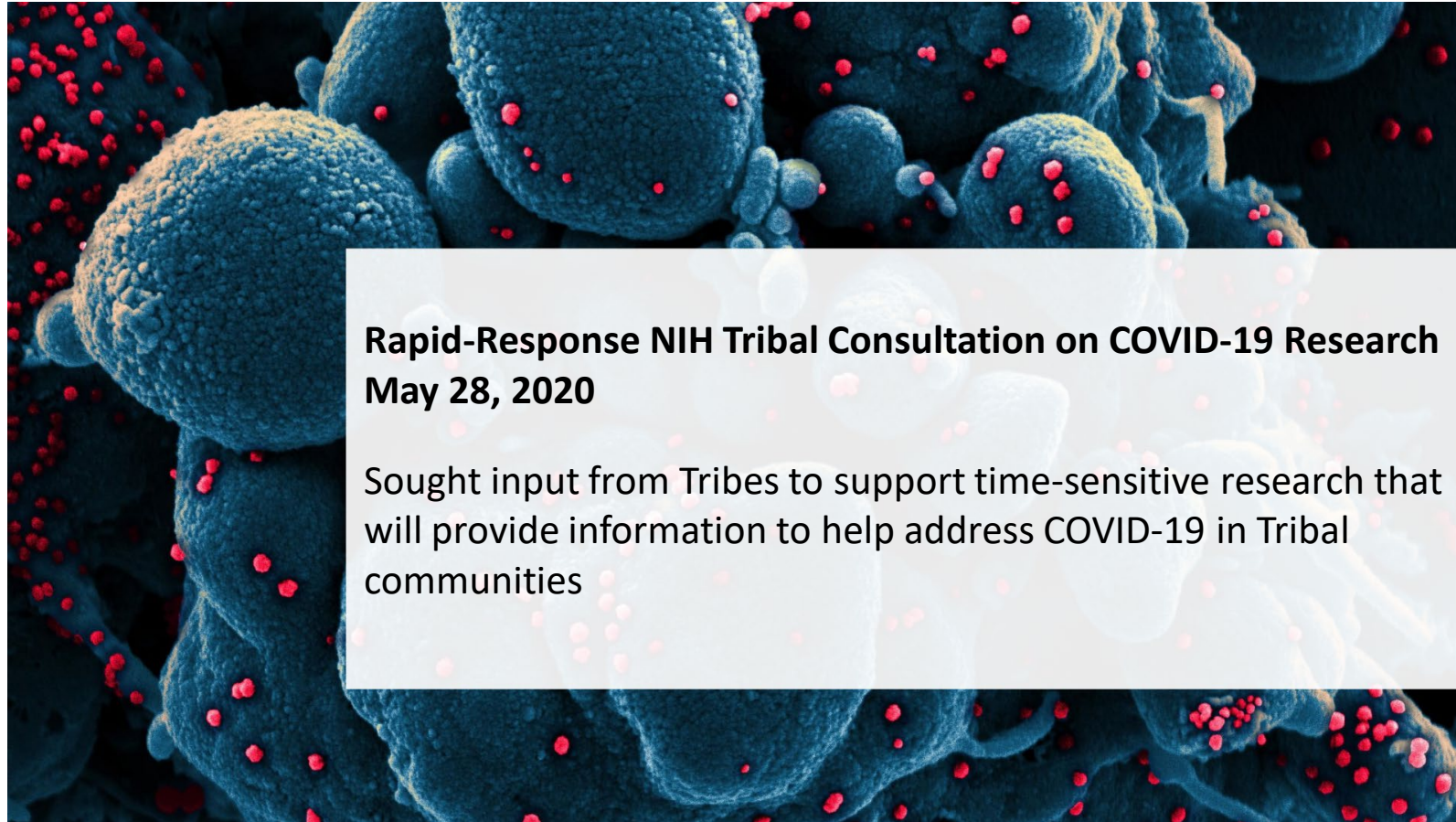


Photo Credit: Ben Sorrell III

NIH Tribal Consultation on COVID-19 Research



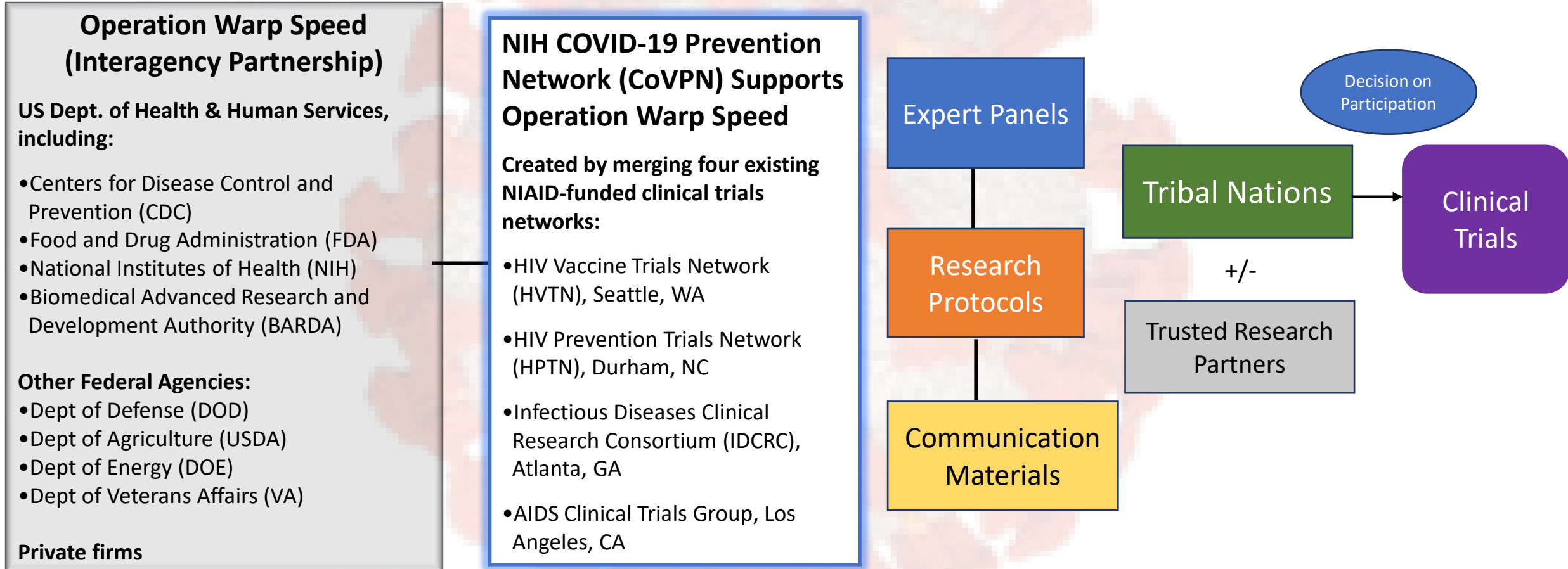
Rapid-Response NIH Tribal Consultation on COVID-19 Research May 28, 2020

Sought input from Tribes to support time-sensitive research that will provide information to help address COVID-19 in Tribal communities

Outcomes

- Informed RADx-UP funding opportunities (8 applications with Tribal focus)
- Created awareness that Consultation should not be bypassed for speed

THRO Engagement During Vaccine Development



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

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



NIH COVID-19 Community Engagement Initiative: CEAL Program

STATE CEAL TEAM MPIs (* indicated contact PI)

ARIZONA

*Dr. Sairam Parthasarathy, spartha@arc.arizona.edu
Dr. Chyke Doubeni, doubeni.chyke@mayo.edu
Dr. Sabrina Oesterle, sabrina.oesterle@asu.edu
Dr. Samantha Sabo, samantha.sabo@nau.edu

CALIFORNIA

*Dr. Arleen Brown, abrown@mednet.ucla.edu
Dr. Steven Dubinett, sdubinett@mednet.ucla.edu
Dr. Keith Norris, KCNorris@mednet.ucla.edu

LOUISIANA

*Dr. Marie Krousel-Wood, mawood@tulane.edu
Dr. Daniel Sarpong, dsarpong@xula.edu

MISSISSIPPI

*Dr. Caroline Compretta, ccompretta@umc.edu
Dr. Victor Sutton, victor.sutton@msdh.ms.gov
Dr. Michael Hall, mehall@umc.edu

NORTH CAROLINA

*Dr. Anissa Vines, avines@email.unc.edu
Dr. Goldie Byrd, gbyrd@wakehealth.edu
Dr. Al Richmond, al.richmond@ccphealth.org

CEAL Tribal Nation Interest Group Strategy

Based on CEAL Team applications, there was a need to engage with American Indian communities. The following CEAL Tribal Nation Interest Group* strategy was developed in collaboration with THRO, NIH SMEs, and CEAL Teams that identified American Indians as a community of focus.

VISION

Collaborating with Tribal Nations by providing American Indian communities with information, tools, and resources to make informed decisions about research participation related to COVID-19 and beyond.

CONSIDERATIONS AND CHALLENGES

Each Tribal Nation has unique needs and challenges. As a result, there isn't a one-size-fits-all approach and ability to move forward and show progress will vary from CEAL Team to CEAL Team.

INTEREST GROUP COLLABORATORS

THRO, CEAL Program, NIH SMEs, CEAL Team POCs

*An Interest Group differs from a Work Group in that it does not include representation from all CEAL Teams.

Short-Term Goals

- Understand unique American Indian needs per CEAL Team
- Delineate what “success” means for each CEAL Team
- Connect CEAL Teams with additional and local entities that could help facilitate Tribal Engagement
- Assist with problem-solving
- Disseminate information and provide resources
- Create a re-occurring forum for CEAL Teams to collaborate

Long-Term Goals

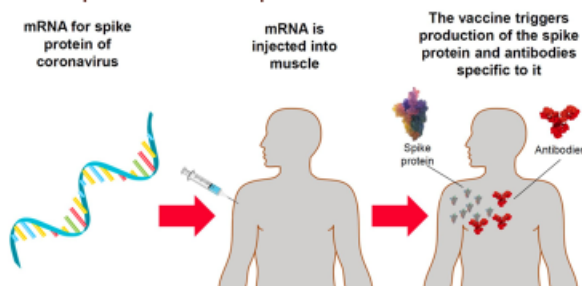
- Identify potential longer-standing community partnerships within Tribal Nations
- Codify approaches the group will develop and continue to refine for future NIH use

mRNA Based Vaccine Platform

Moderna/mRNA-1273 The COVE Study

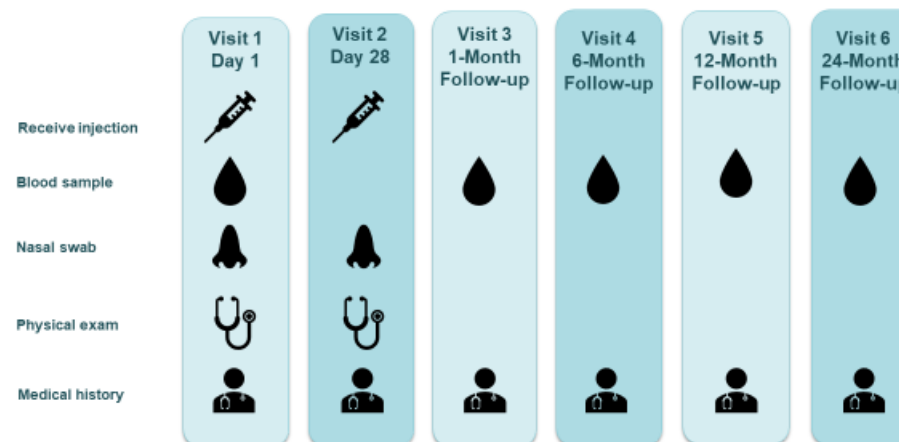
mRNA platform

- Translated in the cytosol to the coronavirus spike protein
- mRNA vaccines are not made with pathogen particles so are non-infectious
- mRNA is degraded after translation; it does not enter the nucleus or become integrated into the host genome
- RNA vaccines are much quicker and simpler to make
- Storage at -70C



NIH National Institutes of Health
Tribal Health Research Office
Building research partnerships for healthy Tribal Nations

Study timeline: Moderna/mRNA-1273 The COVE Study



NIH National Institutes of Health
Tribal Health Research Office
Building research partnerships for healthy Tribal Nations

Adenovirus Based Vaccine Platform

Astra Zeneca / AZD1222

- ChAdOx1 platform (Adenovirus Vector) non replicating
- Produces **coronavirus spike protein**
- Development of the vaccine was initiated by the University of Oxford in the United Kingdom

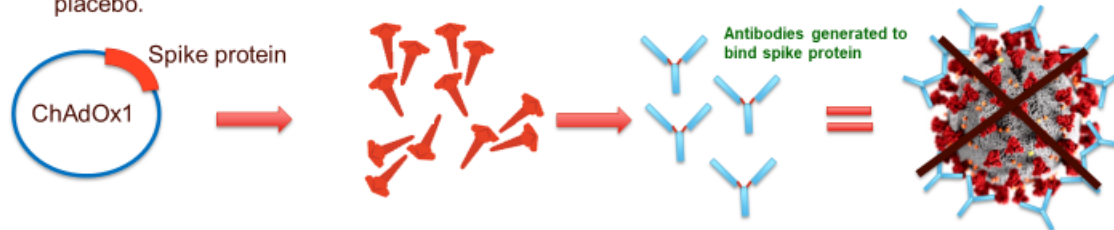
Phase 1/2 results:

Vaccine elicits **antibody** immune responses and **cellular** immunity

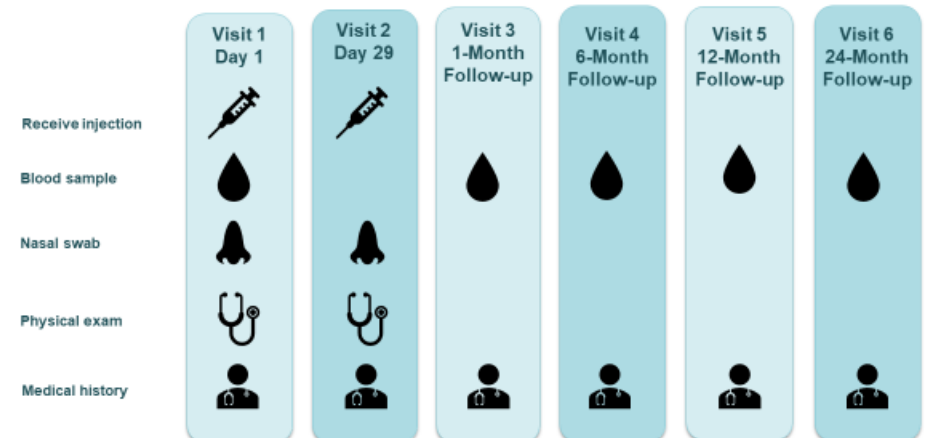
- Adverse reactions (fever, fatigue, and chills)

Phase 2/3 currently ongoing:

- The vaccine is now being tested by more than 75 clinical sites in the US.
- Approximately 30,000 participants from the United States will participate
- Participants will be randomized in a 2:1 ratio to receive either a dose of AZD1222 vaccine or placebo.



Study timeline: Astra Zeneca



Protein Based Vaccine Platform

Novavax 2019nCoV-301

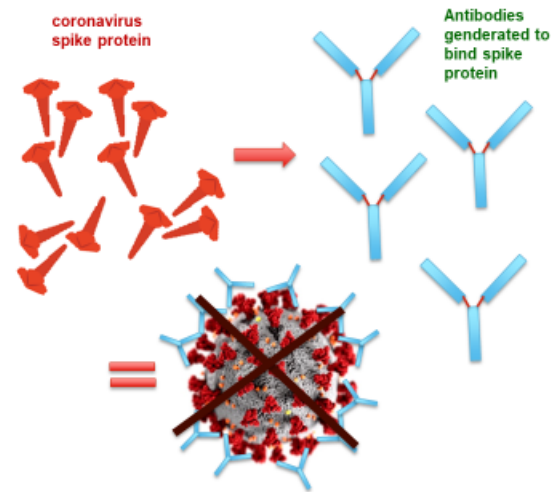
Protein platform: use part of coronavirus protein with Matrix-M1 to provoke an immune response

Phase 1/2 results: (tested on 131 people aged 18-59)

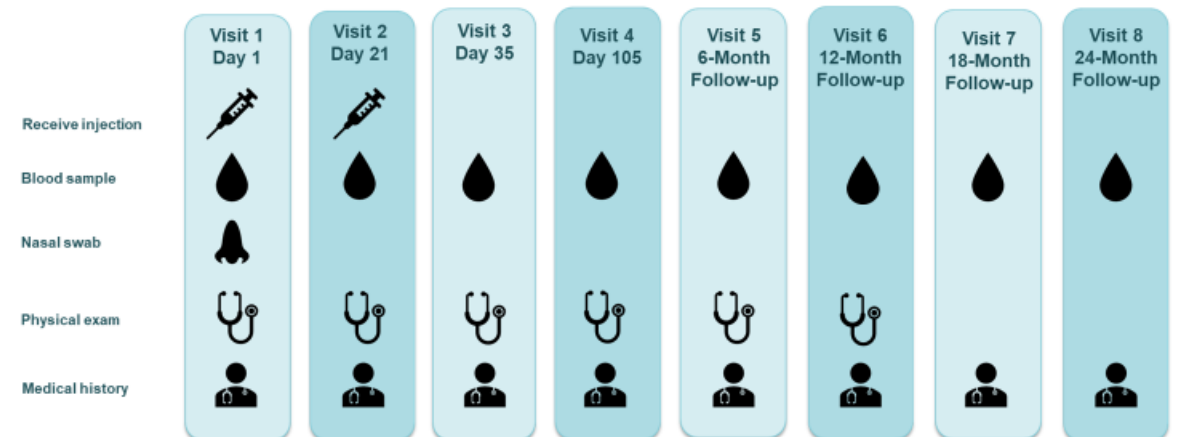
- Vaccine elicits **antibody** immune responses and **cellular** immunity
- Some adverse reactions (fever, fatigue, and chills)
- Phase 2 ongoing

Phase 3: will enroll ~30,000 people aged ≥18 years from sites globally; enrollment slated to begin in October

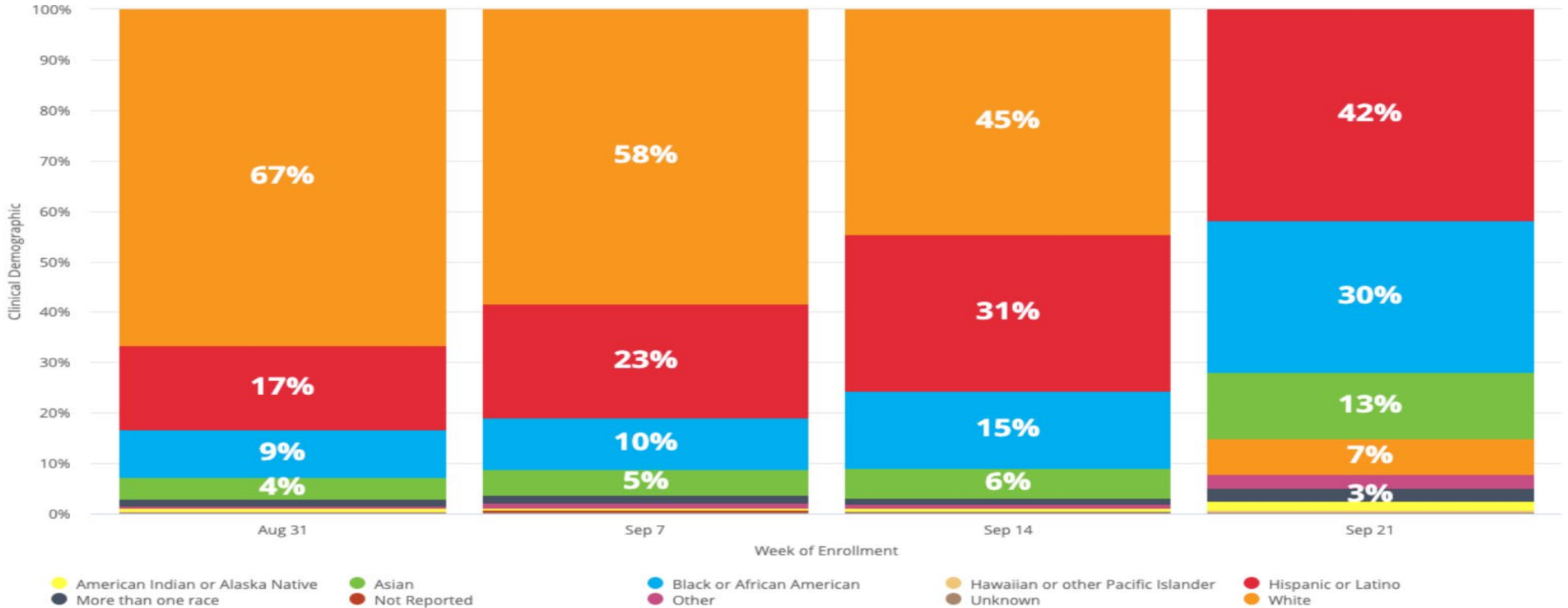
Vaccine uses antigen derived from the **coronavirus spike protein** to stimulate **neutralizing antibodies**



Study timeline: 2019nCoV-301



Minority Enrollment in Vaccine Trials Increases Substantially with Appropriately Targeted Engagement and Outreach



As of Friday, September 25, 2020, nearly 31% of participants enrolled cumulatively are from diverse communities.

<https://www.modernatx.com/cove-study>

Pfizer Study

Trial Progress



The Phase 2/3 clinical trial **has enrolled 43,661 participants** and **41,135 participants** have received their **second vaccination**

Participant Diversity

Approximately **42%** of overall and **30%** of U.S. participants have diverse backgrounds

Participants	Overall Study	U.S. Only
Asian	4.5%	5.5%
Black	10.0%	10.1%
Hispanic/Latinx	26.1%	13.1%
Native American	0.8%	1.0%
Ages 56 to 85	40.9%	45.4%

Updated as of Monday, November 16, 2020 at 9:00 a.m. ET. Updates are made on a weekly basis.

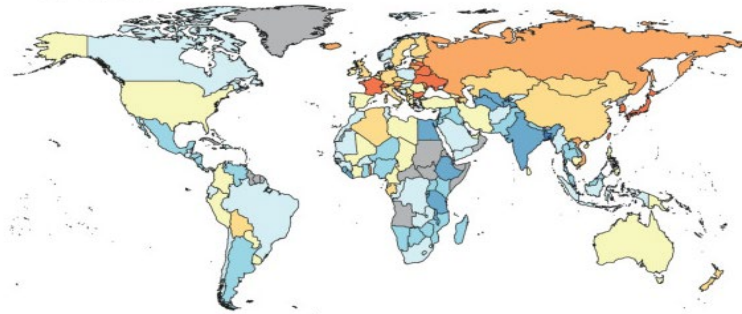
Vaccine Uptake

Respondents who strongly agree (%)

0-29.9 30-39.9 40-49.9 50-59.9 60-69.9 70-79.9 80-89.9 90-99.9

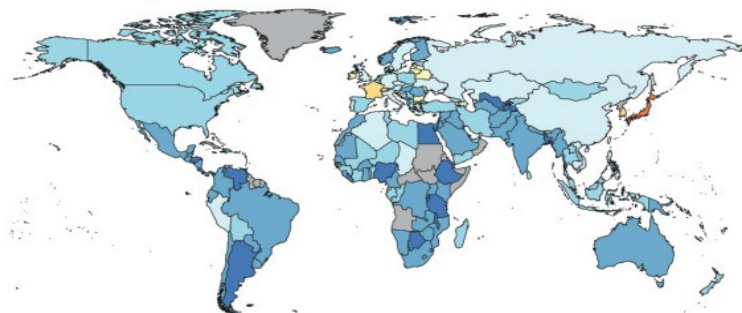
November, 2018

B Vaccines are safe

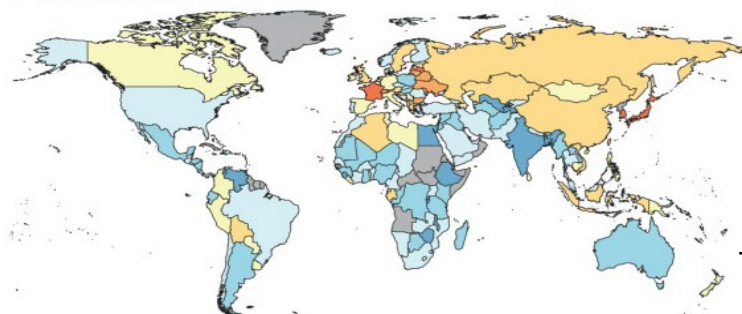


- Japan ranks among the countries with the lowest vaccine confidence in the world.
- Linked to HPV vaccine safety scares in 2013.

D Vaccines are important



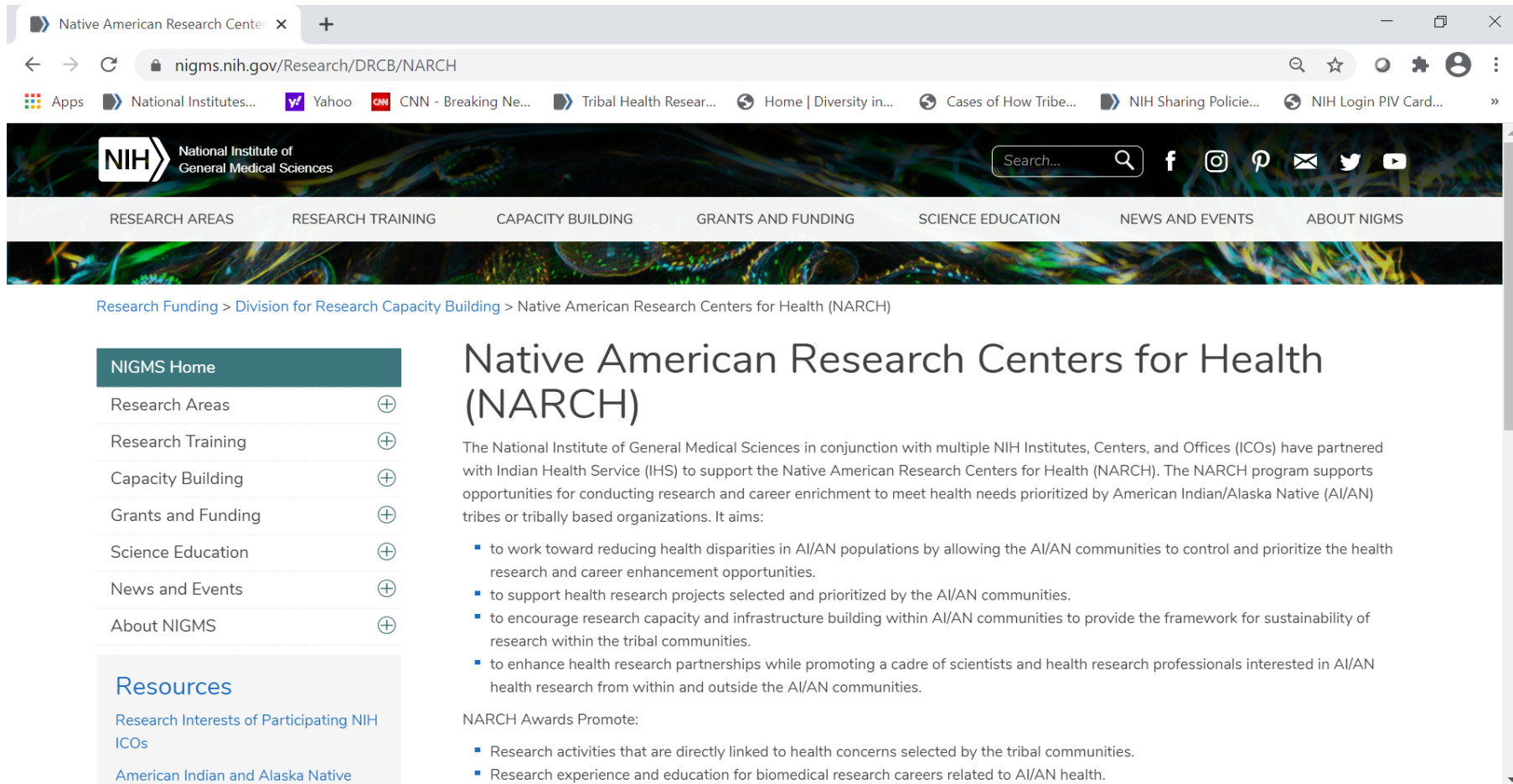
F Vaccines are effective



What should NIH do to increase vaccine uptake in Tribal communities?

Strategic Goal #2 and #4

Community Engagement and Collaboration to Expand Research



The screenshot shows a web browser window with the address bar displaying "nigms.nih.gov/Research/DRCB/NARCH". The browser's address bar and tabs are visible at the top. Below the browser window, the NIGMS website header features the NIH logo and the text "National Institute of General Medical Sciences". A search bar and social media icons (Facebook, Instagram, Pinterest, Email, Twitter, YouTube) are also present. The main navigation menu includes links for "RESEARCH AREAS", "RESEARCH TRAINING", "CAPACITY BUILDING", "GRANTS AND FUNDING", "SCIENCE EDUCATION", "NEWS AND EVENTS", and "ABOUT NIGMS". The page content shows a breadcrumb trail: "Research Funding > Division for Research Capacity Building > Native American Research Centers for Health (NARCH)". The main heading is "Native American Research Centers for Health (NARCH)". The text describes the partnership between NIGMS and the Indian Health Service (IHS) to support the NARCH program, which aims to support research and career enrichment for American Indian/Alaska Native (AI/AN) tribes or tribally based organizations. A list of aims is provided, including reducing health disparities, supporting health research projects, encouraging research capacity and infrastructure building, and enhancing health research partnerships. The page also mentions "NARCH Awards Promote:" and lists research activities and education for biomedical research careers related to AI/AN health.

Native American Research Centers for Health (NARCH)

The National Institute of General Medical Sciences in conjunction with multiple NIH Institutes, Centers, and Offices (ICOs) have partnered with Indian Health Service (IHS) to support the Native American Research Centers for Health (NARCH). The NARCH program supports opportunities for conducting research and career enrichment to meet health needs prioritized by American Indian/Alaska Native (AI/AN) tribes or tribally based organizations. It aims:

- to work toward reducing health disparities in AI/AN populations by allowing the AI/AN communities to control and prioritize the health research and career enhancement opportunities.
- to support health research projects selected and prioritized by the AI/AN communities.
- to encourage research capacity and infrastructure building within AI/AN communities to provide the framework for sustainability of research within the tribal communities.
- to enhance health research partnerships while promoting a cadre of scientists and health research professionals interested in AI/AN health research from within and outside the AI/AN communities.

NARCH Awards Promote:

- Research activities that are directly linked to health concerns selected by the tribal communities.
- Research experience and education for biomedical research careers related to AI/AN health.

Funding Opportunity Title

Native American Research Centers for Health (NARCH) (S06 Clinical Trials Optional)

PAR-16-297

Research Objectives

Due to the complexity of factors contributing to the health and disease of AI/ANs, and to their health disparities compared with other Americans, the collaborative efforts of the agencies of the Department of Health and Human Services (HHS) and the collaboration of researchers and AI/AN communities are needed to achieve significant improvements in the health status and promote wellness of AI/AN people. To accomplish this goal, the NARCH initiative will pursue the following program objectives:

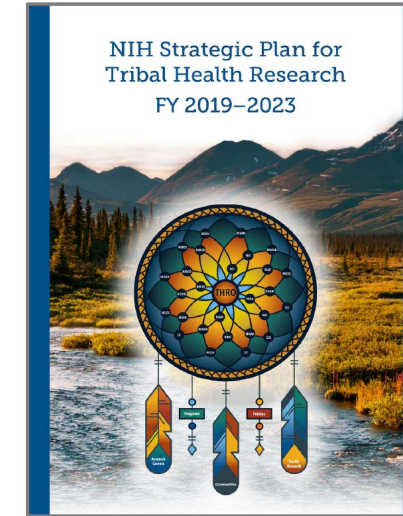
- To gain a better understanding of strengths and resiliency factors: An understanding of how to enhance the strengths and resilience factors within the AI/AN communities and individuals may help reduce health disparities. While AI/AN communities have relied on health research and medical science to promote overall healthful behaviors, they have also relied on their own psychological, organizational, and cultural assets and strengths to survive major harms and disruptions over the centuries, and to rebound from insults to health.
- Strengthen partnerships and AI/AN community engagement in health research: Fully utilizing all cultural and scientific knowledge, strengths, and competencies, such partnerships can lead to better understanding of the biological, genetic, behavioral, psychological, cultural, social, and economic factors either promoting or hindering improved health status of AI/ANs, and generate the development and evaluation of interventions to improve their health status. By ensuring that the Tribe has greater control over the research process, the AI/AN communities can dictate the scientific agenda and research priorities. Published work on community-based participatory research suggests that AI/AN communities should work collaboratively in partnership with health researchers to further the research needs of AI/AN. Helpful guidelines for community leaders and health researchers conducting research within the AI/AN communities can be found at https://dpcpsi.nih.gov/sites/default/files/Critical_Considerations_for_Reviewing_AIAN_Research_508.pdf and <http://www.ncai.org/policy-research-center/initiatives/research-regulation>.
- Promote the enhancement of student and/or faculty research scientists interested in addressing the health issues within the AI/AN communities: Opportunities are needed to enhance the cadre of scientists and health professionals engaged in health research focused on AI/AN health needs, and to conduct biomedical, clinical and behavioral research that is responsive to the needs of AI/AN communities and the goals of this initiative. Faculty/researchers and students at each proposed NARCH can develop investigator-initiated, scientifically meritorious research projects, including pilot research projects. Career enhancement projects may also be proposed to improve the research skills of investigators involved with AI/AN communities.
- Encourage research infrastructure and capacity building within AI/AN communities, ensuring sustainability of research within AI/AN communities: Supporting the research infrastructure development and capacity building within the AI/AN communities provides tools to support research from within the communities, as well as the long-term maintenance and evolution of their research agenda.

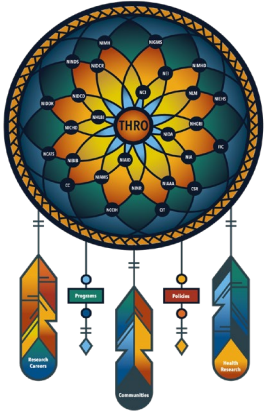
By involving the community in health research and integrating the training of researchers the pool of investigators and the scientific knowledge of the communities can be increased. This approach benefits the communities in terms of research design and sustainability. By involving the AI/AN communities in the research agenda for the proposed NARCH application, NIH is not limiting proposed projects to only Community Based Participatory Research (CBPR) projects. Research projects ranging from basic science to clinical investigation are welcome and encouraged. Projects that do not focus on health disparities can be chosen as priorities for the proposed AI/AN populations.

NIH Strategic Goals for Tribal Health Research

The **Strategic Plan** established a roadmap for the agency to address the health research needs of 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

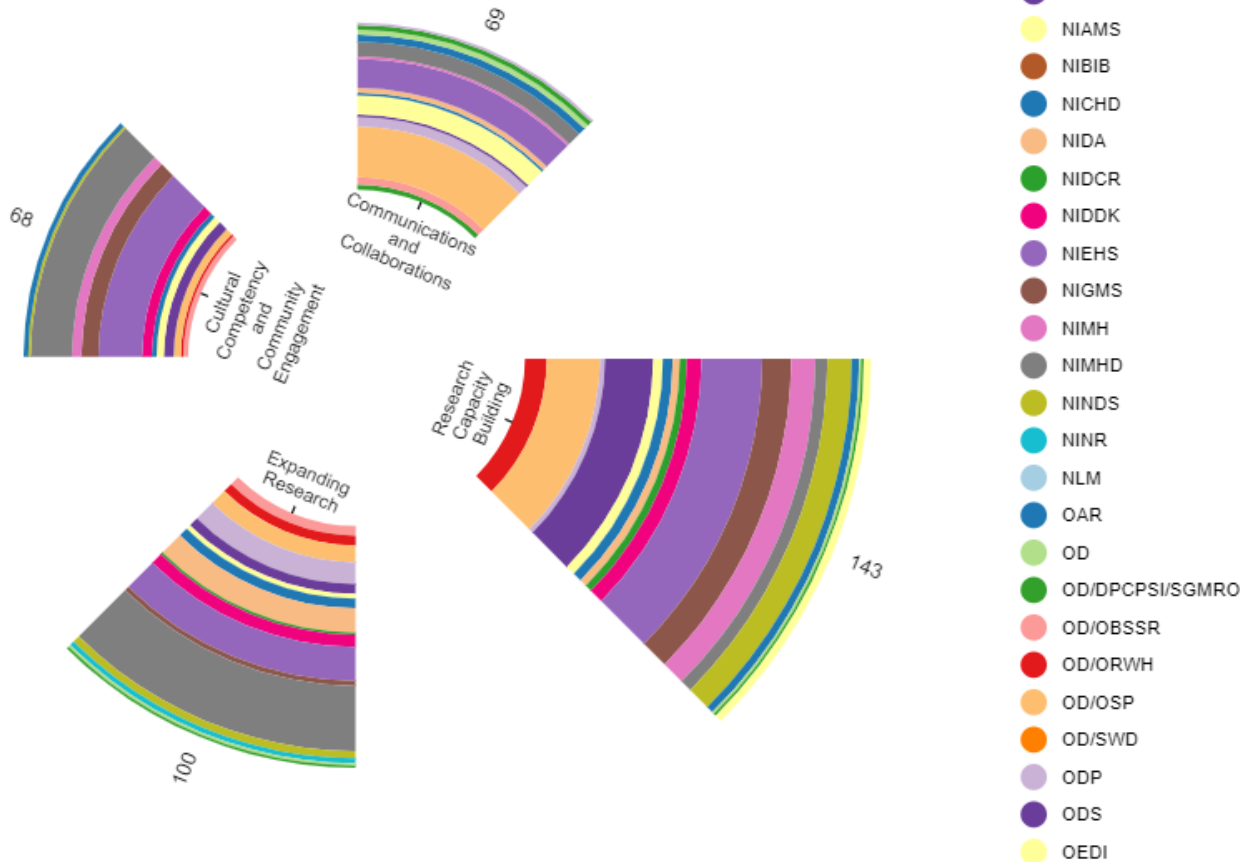




THRO Collaboration with Office of Evaluation, Performance, and Reporting (OEPR): The Strategic Plan Module

- Tool: Internal tracking system (*NIH Only*)
- Data:
 - ICO information collected by THRO and provided by THRCC members
 - RePORTER Data (*publicly available*)
- Collaboration

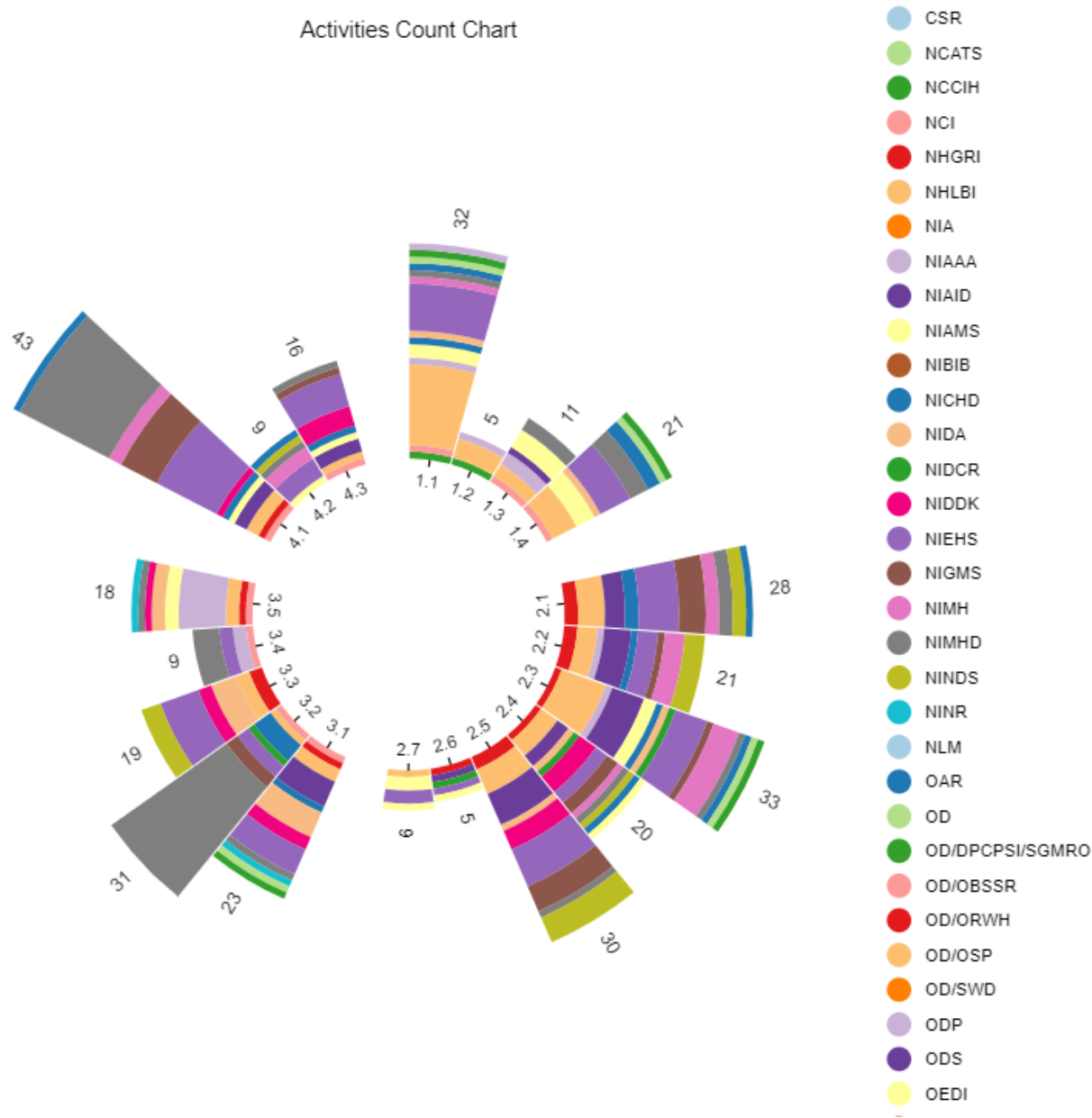
Activities Count Chart



Strategic Goals

1. Enhancing Communication and Collaboration
2. Building Research Capacity for American Indian and Alaska Native Communities
3. Expanding Research
4. Enhancing Cultural Competency and Community Engagement

Activities Count Chart



Strategic Objectives


1.1 Increase bidirectional communication and coordination among the NIH, Tribal nations, American Indian and Alaska Native researchers, American Indian and Alaska Native-serving organizations, and agency partners.

1.2 Enhance NIH Tribal Advisory Committee (TAC) input to NIH policies and activities related to American Indian and Alaska Native health.

1.3 Enhance internal trans-NIH communication to consolidate and coordinate information about American Indian and Alaska Native health needs and ICOs' research, interests, and activities.

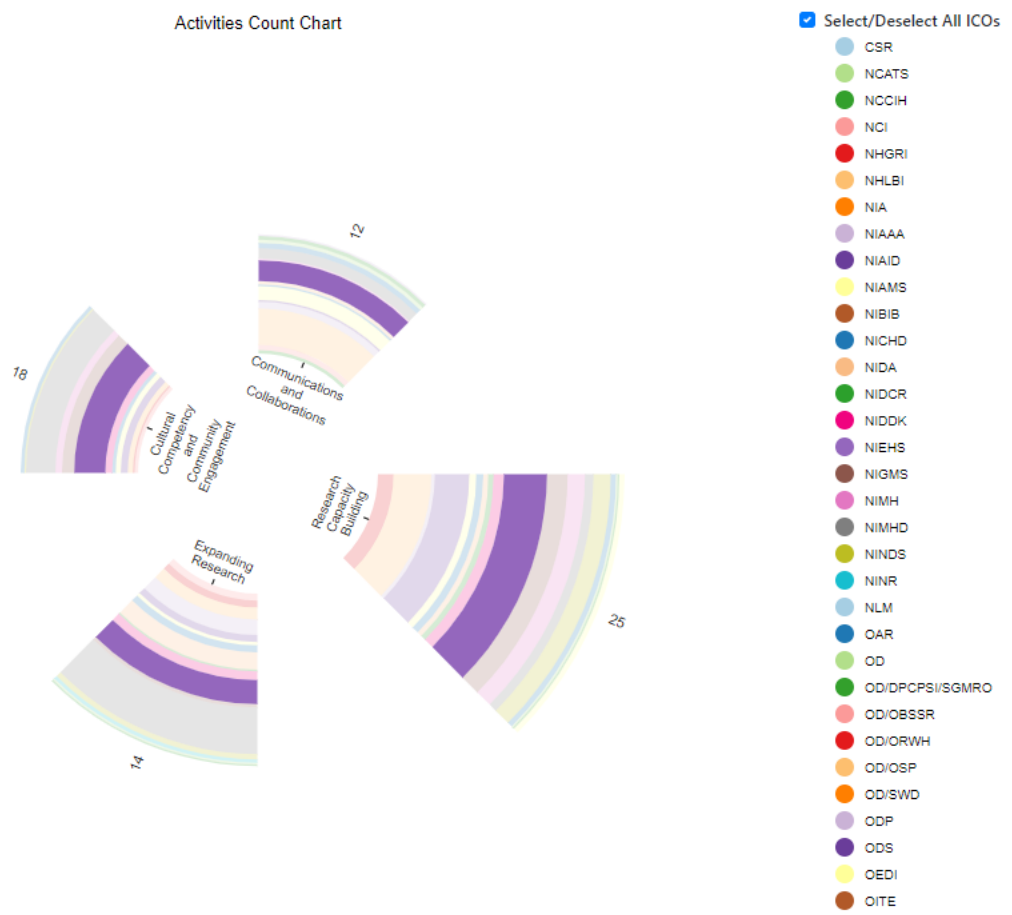
1.4 Improve trans-NIH communication with the scientific community about American Indian and Alaska Native health research, health disparities, and related ICOs' research and activities.

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Filter

View by Objective

View by Goal



ICO: NIEHS Total: 69

Communications and Collaborations 12 Activities

- Objective 1.1 7 Activities
- Time sensitive grant award that led to community teach-ins, radio broadcasts, flyers and newspaper articles, and the production of four 10-minute videos in the Navajo language. Video 1: Introduction to the Gold King Mine Dine Exposure Project. Video 2: Water Results within one Year of the Gold King Mine Spill of 2015. Video 3: Soil and Sediment Results Within One Year of The Gold King Mine Spill of 2015. Video 4: Gold King Mine Spill Dine Exposure Project Household Results.
 - U of A researchers participated in the Stories of Disasters in Tribal Communities Panel at Southwest Environmental Health Sciences Center Tribal Forum
 - Center activities include research projects (R01), pilot project program, capacity building and training for young AI investigators, cross fertilization with other EHD Centers. Focus of research on metal and particulate contamination associated with mining, arsenic update in humans and animals, water quality, radon exposures (among Hopi, Navajo and Cheyenne River Sioux).
 - Center activities include research projects (R01), pilot project program, capacity building and training for young AI investigators, cross fertilization with other EHD Centers. Focus of research on metal and particulate contamination associated with mining, arsenic update in humans and animals, and interventional study to reduce uranium exposure in humans.
 - Invited service on organizing committee and moderator for EHS session at 2018 annual AISES meeting in Denver CO
 - Invited service on organizing committee for the 2019 annual conference that focuses on increasing awareness of NIH funding opportunities and cultivating interest among AI and AN students about biomedical and environmental health sciences. Organized abstract for and invited speakers to participate in concurrent sessions on TEK and EHS and chose plenary speaker on that topic.
 - Participation in IC Director invited site visit to Navajo Nation in 2018 (invitation from and tour given by Walter Phelps)

Objective 1.2 0 Activities

Objective 1.3 0 Activities

- Objective 1.4 5 Activities
- Time sensitive grant award that led to community teach-ins, radio broadcasts, flyers and newspaper articles, and the production of four 10-minute videos in the Navajo language. Video 1: Introduction to the Gold King Mine Dine Exposure Project. Video 2: Water Results within one Year of the Gold King Mine Spill of 2015. Video 3: Soil and Sediment Results Within One Year of The Gold King Mine Spill of 2015. Video 4: Gold King Mine Spill Dine Exposure Project Household Results.
 - Tribal environmental health session at the native American research and training water institute
 - On an ongoing basis, EHP publishes a variety of content on exposures, health outcomes, and research efforts and policies that are relevant and sometimes unique to AI/AN and other Indigenous communities. In April 2019, EHP published a curated collection of AI/AN-relevant materials previously published in the journal. The Indigenous Health Collection can be found at <https://ehp.niehs.nih.gov/curated-collections/indigenous-health>. This collection demonstrates the quality and breadth of EHP's attention to Indigenous health over time and packages content in an accessible manner that can be easily shared beyond a highly specialized research audience.
 - Invited service on organizing committee and moderator for EHS session at 2018 annual AISES meeting in Denver CO
 - Invited service on organizing committee for the 2019 annual conference that focuses on increasing awareness of NIH funding opportunities and cultivating interest among AI and AN students about biomedical and environmental health sciences. Organized abstract for and invited speakers to participate in concurrent sessions on TEK and EHS and chose plenary speaker on that topic.

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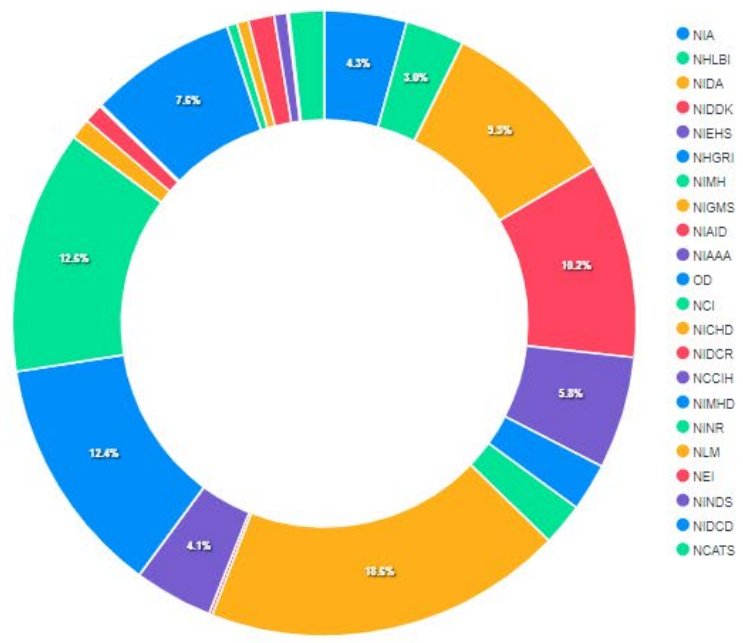
GOAL 1 GOAL 2 GOAL 3 GOAL 4

NCATS NCCIH NCI NEI NHGRI NHLBI NIA NIAAA NIAID NICHD NIDA NIDCD NIDCR NIDDK NIEHS NIGMS NIMH NIMHD NINDS NINR NLM OD

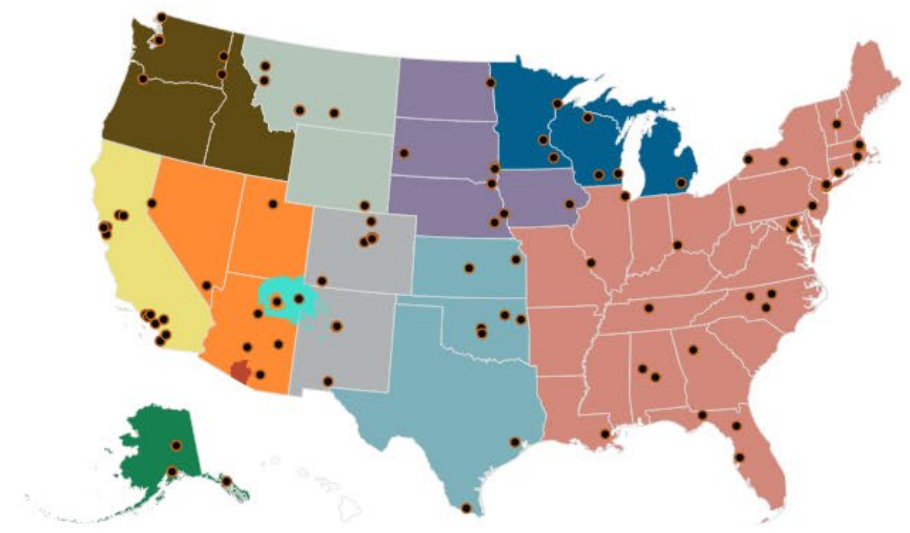
Alaska Area Albuquerque Area Bemidji Area Billings Area California Area Great Plains Area Nashville Area Navajo Area Oklahoma Area Phoenix Area Portland Area Tucson Area

Total Funding FY2019
\$206,898,454

Funding by IC



Funding by Location





National Institutes of Health
Tribal Health Research Office



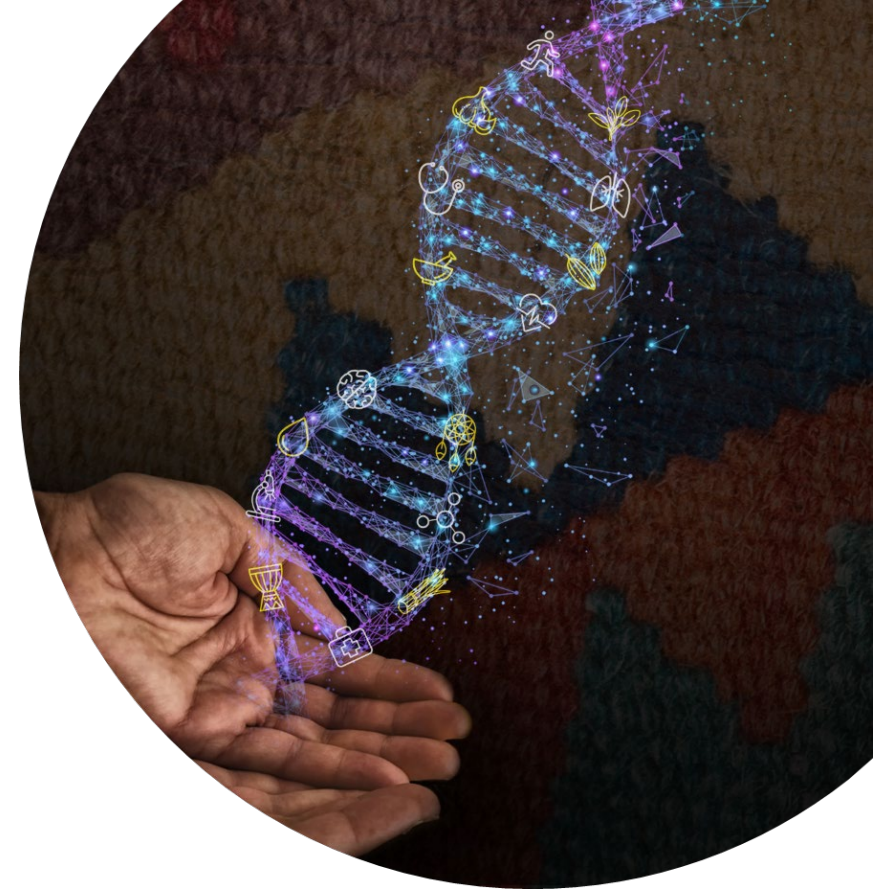
2020 NIH Rural Health Seminar

“During this challenging time, THRO is more dedicated than ever to building research partnerships for healthy Tribal Nations. In our work, we acknowledge the enduring hope, resiliency, and wisdom of American Indian and Alaska Native communities across the country, understanding these strengths are the drivers on the road to continued healing and recovery.”

– David R. Wilson, Ph.D., (Diné) Director, THRO

Other Highlighted Activities

- World AIDS Day
- **Tribal Epidemiology Centers (TECs)**
- Efforts Around HIV/AIDS, COVID-19, Maternal Health, Opioid Use
- **Native American Heritage Month**
- Alaska Native Tribal Health Consortium
- **FY 2018 AI/AN Portfolio Analysis Update**



Connect With Us and Learn More



David R. Wilson, Ph.D., Director
dave.wilson2@nih.gov

Juliana Blome, Ph.D., Deputy Director
juliana.blome@nih.gov

Website
<https://www.nih.gov/tribalhealth>

Facebook
[@NIHTribalHealth](https://www.facebook.com/NIHTribalHealth)