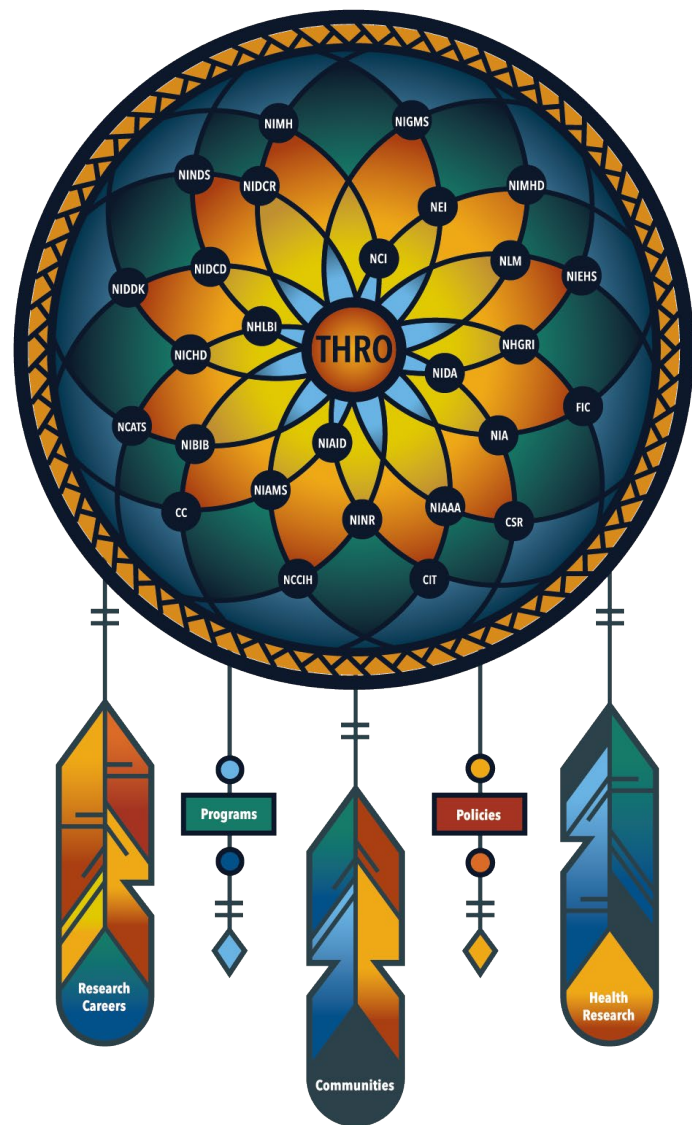

Ethical Conduct of Research with AI/AN Participants: Extending Protections through Respect for Tribal Sovereignty



David R. Wilson, Ph.D.

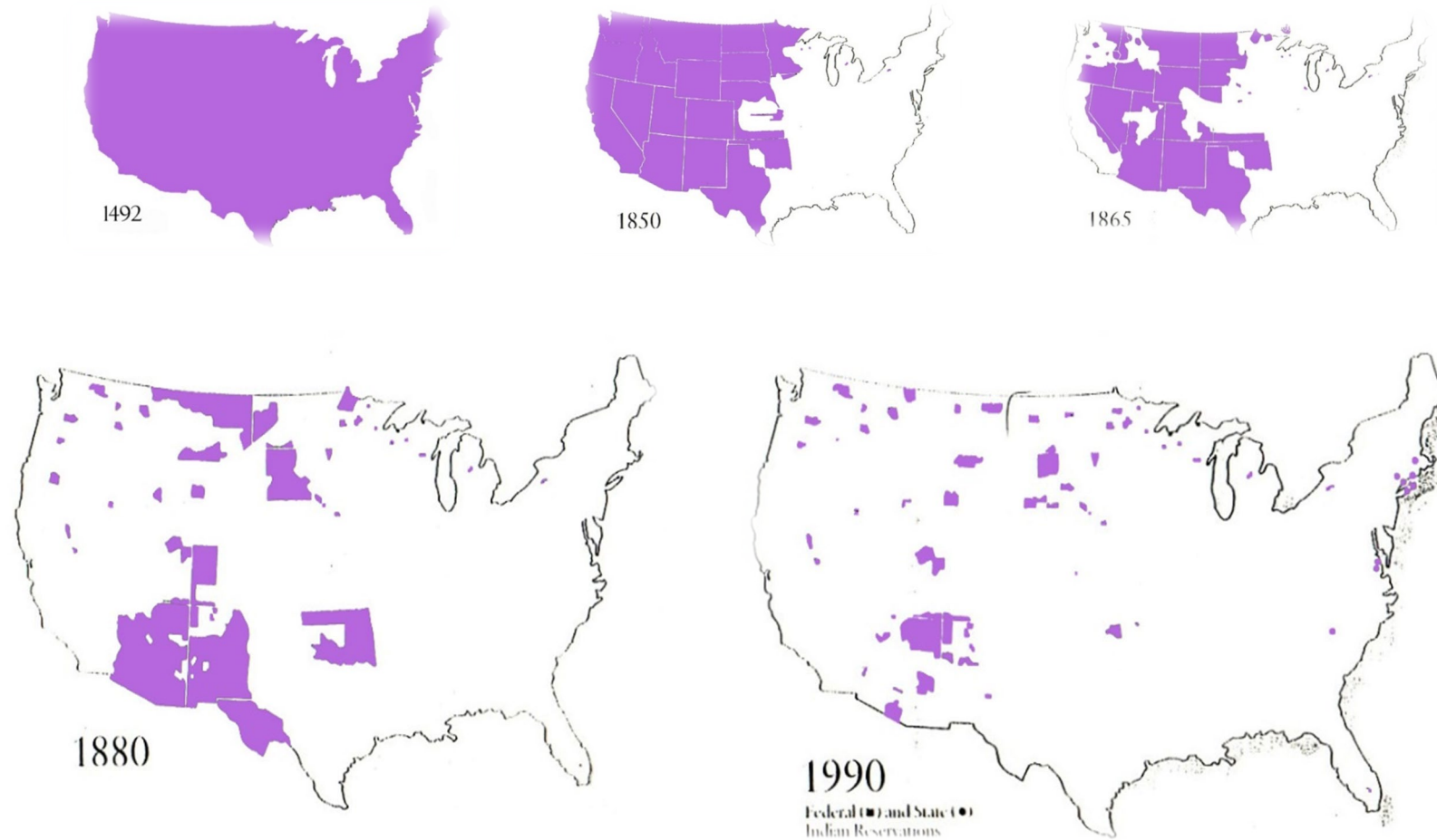
Director, NIH Tribal Health Research Office

Sara Chandros Hull, Ph.D.

Senior Advisor, NIH Tribal Health Research Office (Detail)

Director, NHGRI Bioethics Core

Native American Lands From 1492 to Present



Tribal Nations and the U.S. – A Government-to-Government Relationship



The Treaty of Canandaigua, 1794. Parchment, ink, resin and wafer seals, ribbon. National Archives, Washington, D.C.

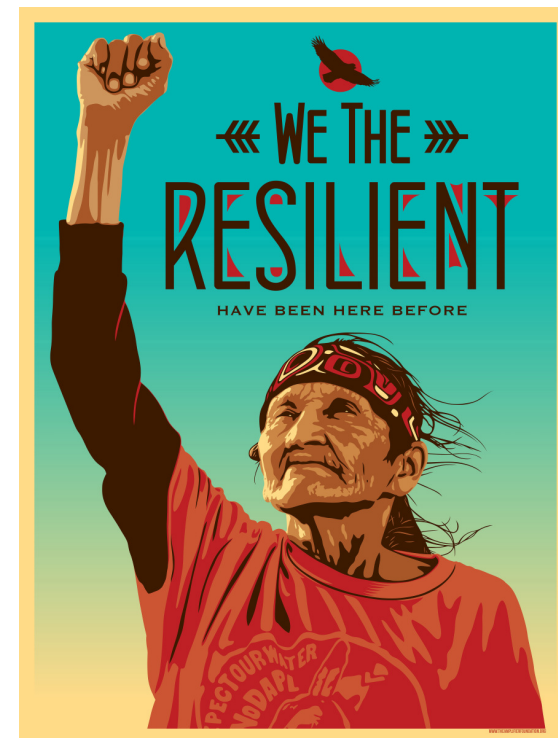
- Since the formation of the Union, the U.S. has recognized American Indian Tribes as **sovereign nations**.
- Resulted in the transfer of land under treaties
- Federal programs and services that benefit American Indians and Alaska Natives (AI/AN) are based on this **unique government-to-government relationship**.
- **The relationship is political and legal.** It is not based on race.
- The Federal government recognizes **574 Tribal Nations**, each with their own culture, language, government, and history.

2020-2021: The Changing Landscape

“It is a priority of my Administration to make respect for Tribal sovereignty and self-governance, commitment to fulfilling Federal trust and treaty responsibilities to Tribal Nations, and regular, meaningful, and robust consultation with Tribal Nations cornerstones of Federal Indian policy.”

- President Biden, Presidential Memo, January 26, 2021

Health Equity



Health Disparities

Inclusion

115TH CONGRESS
1ST SESSION

H. R. 40

To address the fundamental injustice, cruelty, brutality, and inhumanity of slavery in the United States and the 13 American colonies between 1619 and 1865 and to establish a commission to study and consider a national apology and proposal for reparations for the institution of slavery, its subsequent de jure and de facto racial and economic discrimination against African-Americans, and the impact of these forces on living African-Americans, to make recommendations to the Congress on appropriate remedies, and for other purposes.



Social Justice

Diversity

Shifting Legal Landscape – 2020 Landmark U.S. Supreme Court Decision

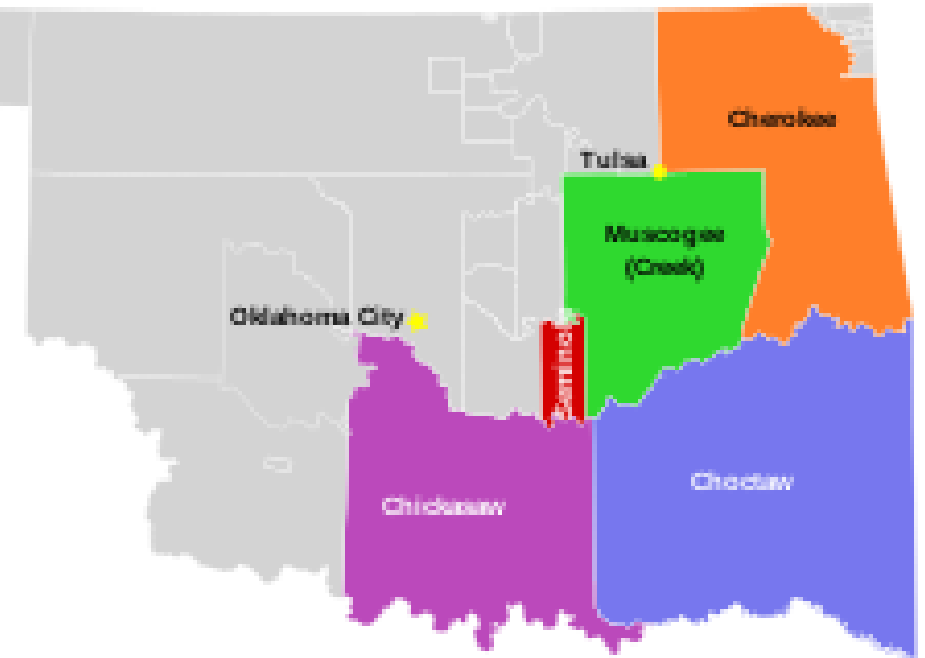
***McGirt v. Oklahoma* – Decided July 9, 2020**

- Case concerned whether Oklahoma could try a citizen of a Tribal Nation for criminal matters.
- McGirt contended that because his offenses occurred on lands guaranteed to the Muscogee Creek Nation in an 1866 treaty—one never legally extinguished by Congress—only Federal authorities could prosecute his case.

In a 5-4 decision, the Court ruled that Oklahoma remains Native Land.



Tribal rights, sovereignty, and jurisdiction are coming to the forefront in a historic way.



Former reservations of Cherokee, Chickasaw, Choctaw, Creek (Muscogee), and Seminole.

60 Minutes, The Fattest Americans



Perspective FREE PREVIEW

The Havasupai Indian Tribe Case — Lessons for Research Involving Stored Biologic Samples

Michelle M. Mello, J.D., Ph.D., and Leslie E. Wolf, J.D., M.P.H.



On April 20, 2010, Arizona State University (ASU) agreed to pay \$700,000 to 41 members of the Havasupai Indian tribe to settle legal claims that university researchers improperly used tribe members' blood samples in genetic research.¹ The settlement closes a difficult chapter for both parties but leaves open a bedeviling question for genetic research: What constitutes adequate informed consent for biospecimens collected for research to be stored and used in future, possibly unrelated studies? The case illuminates the clashing values that have driven debate in this area and the

July 15, 2010

N Engl J Med 2010; 363:204-207

DOI: 10.1056/NEJMp1005203

Print Subscriber? [Activate your on](#)

> [Am Indian Alsk Native Ment Health Res. 1989;2\(3\):7-17. doi: 10.5820/aian.0203.1989.7.](#)

Misalliances in the Barrow Alcohol Study

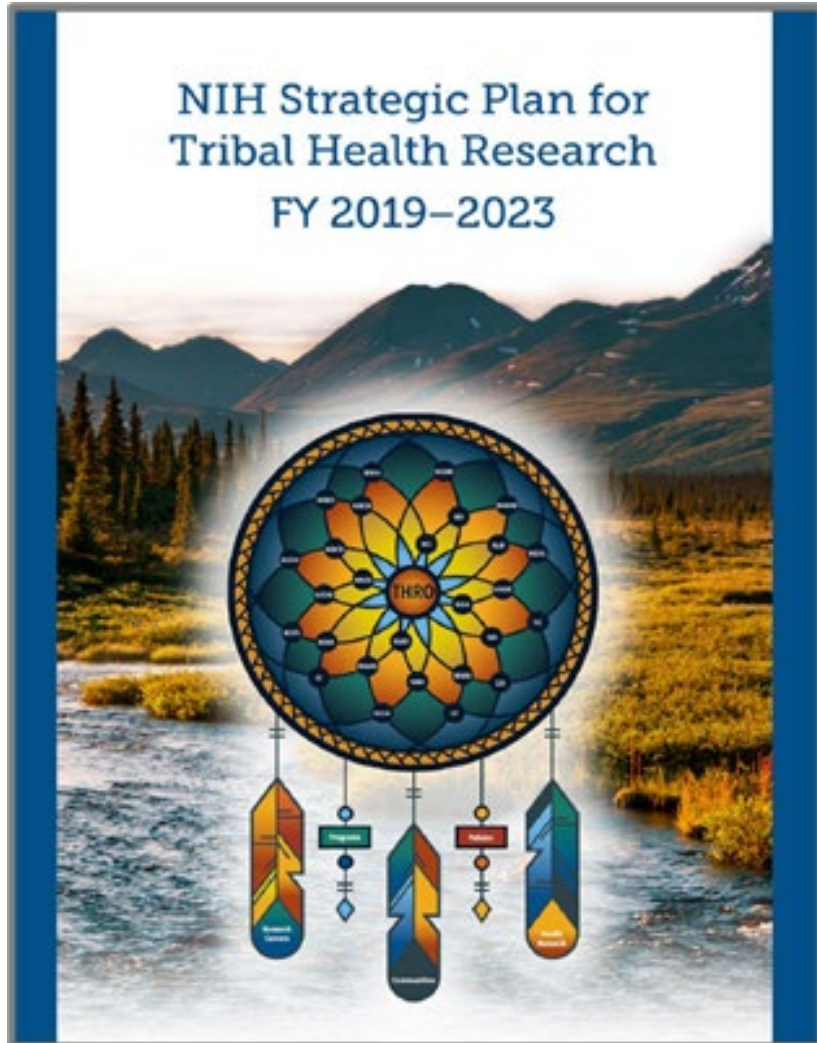
E F Foulks

PMID: 2490286 DOI: [10.5820/aian.0203.1989.7](#)

Abstract

The Center for Research on the Acts of Man conducted a survey of the use of alcohol among the Inupiat of Barrow, Alaska, in 1979. The study resulted in grievances among many individuals and institutions associated with the community. In a retrospective analysis of the factors contributing to these misalliances, the author raises important ethical and procedural questions to be considered carefully in future projects of this nature.

NIH Tribal Health Research Office (Established 2015)

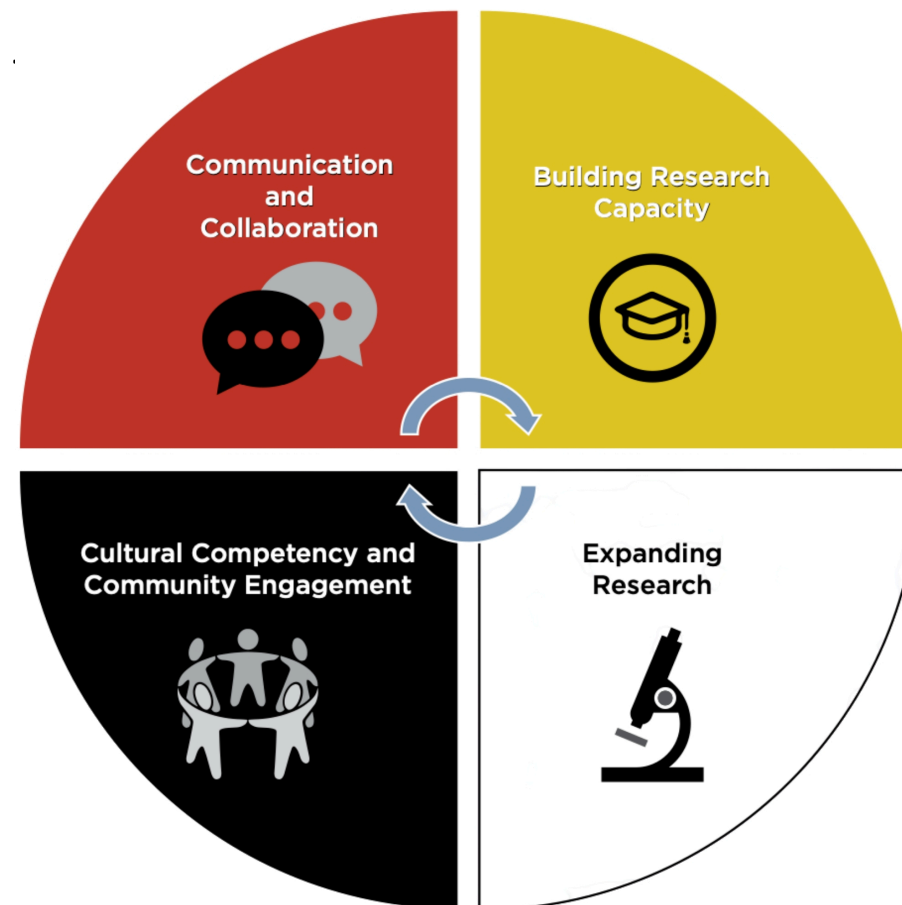


- **Central hub** for coordinating Tribal health research and AI/AN capacity building across NIH
- **Supports ICO efforts** to meet Strategic Plan Goals
 - THRO Coordinating Committee (THRCC)
 - Detail opportunities in THRO
 - Opportunities for the next generation of AI/AN researchers at NIH
- Ensures that NIH adheres to the **“NIH Guidance on the Implementation of the HHS Tribal Consultation Policy”**
- **Gathers meaningful input** from Tribal communities on NIH research policies, programs, and priorities
- Convenes **NIH Tribal Advisory Committee** with Tribal leaders from across the country

NIH Strategic Goals for Tribal Health Research

The NIH Strategic Plan for Tribal Health Research articulates 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**



NIH Tribal Advisory Committee (TAC)



- Representatives from **12 geographic areas** advise NIH and help ensure NIH policies or activities that affect AI/AN communities are shared with Tribal leaders.
- Brings together Tribal officials (or their designated representatives) and NIH officials to exchange views, share information, and seek advice.

Speaking with TAC, Listening in Albuquerque



September, 2017



Belmont Report

- Respect for persons
 - Voluntary informed consent
- Beneficence/non-maleficence
 - Assessment of risks and benefits
- Justice
 - Fairness in recruitment and selection of subjects



Indian Tribe Wins Fight to Limit Research of Its DNA



Jim Wilson/The New York Times

Edmond Tilousi, 56, who can climb the eight miles to the rim of the Grand Canyon in three hours. [More Photos »](#)

By AMY HARMON

Published: April 21, 2010

“Helicopter” Research

“The failure to return results or focus on community benefit has been characterized as ‘carpetbagger’ or ‘helicopter’ research: the researcher drops into the community, extracts data, and is never heard from again, or at best provides information about the study in technical language that is unfamiliar to most in the community.”

Boyer et al (2011)

History of Research

Long history of research in Alaska Native communities

The Arctic Aeromedical Laboratory's Thyroid Function Study
A Biological and Ethical Analysis

1950s Air Force Aeromedical Laboratory Thyroid Function Study (Radioactive Iodine-131)

1979 Barrow Alcohol Study

What are the lessons?

- “[A] profound disconnect exists between common academic research practices and legitimate [tribal] community expectations, and justice requires that this gap be bridged.”

Goering, Holland, and Fryer-Edwards (2008) *HCR*

Revised Common Rule

“Thus, if the official governing body of a tribe passes a tribal law that provides additional protections for human subjects, the Common Rule does not affect or alter the applicability of such tribal law.”

Federal Policy for the Protection of Human Subjects
Final Rule 2017, 7158, Executive Summary II.E.2

**Beyond Belmont: Ensuring Respect
for AI/AN Communities Through
Tribal IRBs, Laws, and Policies**
Sara Chandros Hull, National Institutes of Health
David R. Wilson (Diné), National Institutes of Health

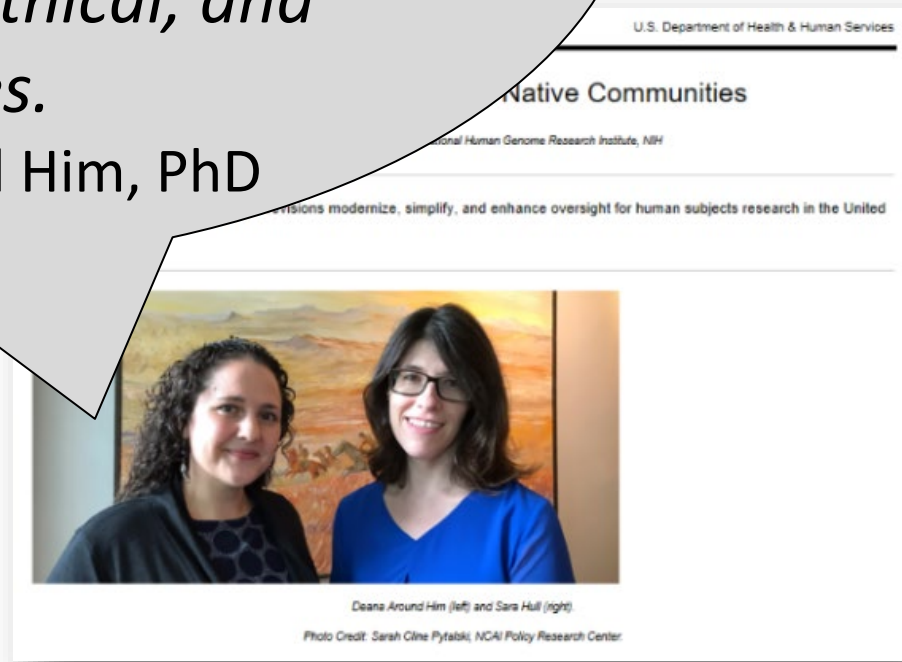
Role of Tribal IRBs

“Tribally based research ethics boards (IRBs) address issues in an area of health science research that is their own research and their people in the same way that has been accomplished through the perpetuation of sovereignty rights.”

When discussions of research ethics are inclusive of tribal perspectives...the likelihood of conducting research in a way that is meaningful, ethical, and appropriate increases.

- Deana Around Him, PhD

Morton *et al* (2013) *AJPH*



Current Landscape of Research Oversight in AI/AN Communities

- Tribal Nation
- Tribal College
- Tribally Based or Focused Organization/Department
- Indian Health Service (IHS)

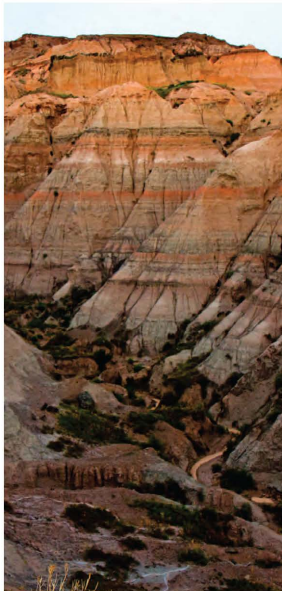
Around Him *et al* (2019)



Examples of Additional AI/AN Research Protections



Collaborative Research Center for American Indian Health
Tribal IRB Toolkit



Project is supported by the National Institute on Minority Health and Health Disparities of the National Institutes of Health under Award Number U54MD008164.

- Additional stages of review
 - Concept clearance to publication review
 - Limited use of exempt and expedited categories
 - Review of research areas beyond health (e.g., environmental, natural resources, education)
- Tribal data ownership and control, constraints on sharing
- Evidence of community involvement/CBPR, council approval
- IRB membership includes AI/AN community members

Kelley et al (2013) *AJPH*

Around Him, Gachupin, Freeman (2021)

AI/AN Research Checklist - NIH Study Application Form

5.2 * Does this study include any of the following:

(select all that apply)

- Take place on American Indian/Alaska Native (AI/AN) land or territory
- Take place at an Indian Health Service (IHS) or other tribal AI/AN facility
- Use IHS resources (staff, funding, space or other support)
- Access non-research data collected at an IHS facility
- Target enrollment of any AI/AN population
- Involve specimens or data from American Indian/Alaska Native populations that was initially collected for other purposes
- None of the above

* Has the protocol been reviewed and approved by an Indian Health Service IRB and/or a tribal IRB?

Yes

No

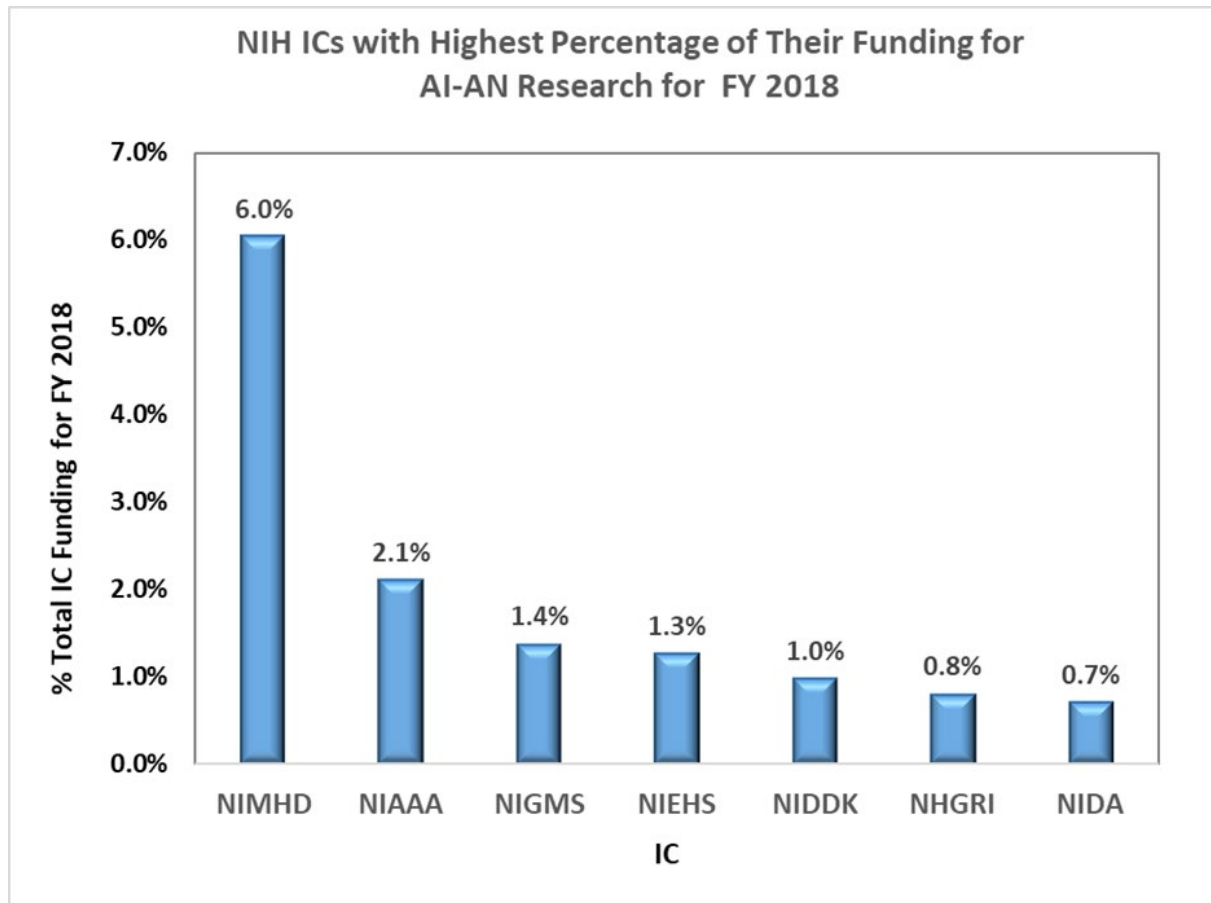
(attach documentation with the submission form)

AI/AN Enrollment in NIH Intramural Research in 2017

- 32,409 of 4.5 million participants (0.71%) identified as AI/AN
- 19 clinical studies were AI/AN specific (4) or enrolled >33% AI/AN (15)
 - 17 sponsored by NIDDK, 2 by NCI
 - 13 in Arizona, 6 in high density areas (e.g., New Mexico, California, Hawaii, Washington, and Mexico)
 - Focused on: diabetes (8); weight, diet, and/or lifestyle (5); obesity (4); cancer (1); and thermogenesis (1)

Vigil, Sinaii, Karp (2021) *EHR*

NIH's AI/AN Research Portfolio – FY2018 Investment of \$180M



- Supported **254** research base projects specifically focused on AI/AN health or community resource needs in FY18
- **10 ICs and the OD** provided approximately \$141M or 78% of the funding
- Funding level has remained relatively constant since FY15.
- **43% - Research**
30% - Infrastructure and community outreach
28% - Workforce development
- 16% of the NIH AI/AN funding fell under umbrella funding opportunities, like **NARCH** and **IRINAH**.

Partnering on Programs and Problem Solving

NCATS



National COVID-19 Cohort Collaborative (N3C)

NHLBI



Strong Heart Study (SHS)

NIAID



Navajo Nation Town Hall
Facebook Live: COVID-19 Research/Vaccines
Great Plains Tribes and NIH
CFARs and Tribal Epidemiology Centers

OAR



HIV Prevention in Tribal communities

NIGMS



Formal Consultation on NARCH Program

NIMHD



Tribal Epidemiology Centers

NINDS



Regional Training Hubs for AI/AN students

What are the best ways to increase Tribal participation in Clinical Trial Studies?

Tribal Consultation at NIH: The Process

Phases:

Critical Event



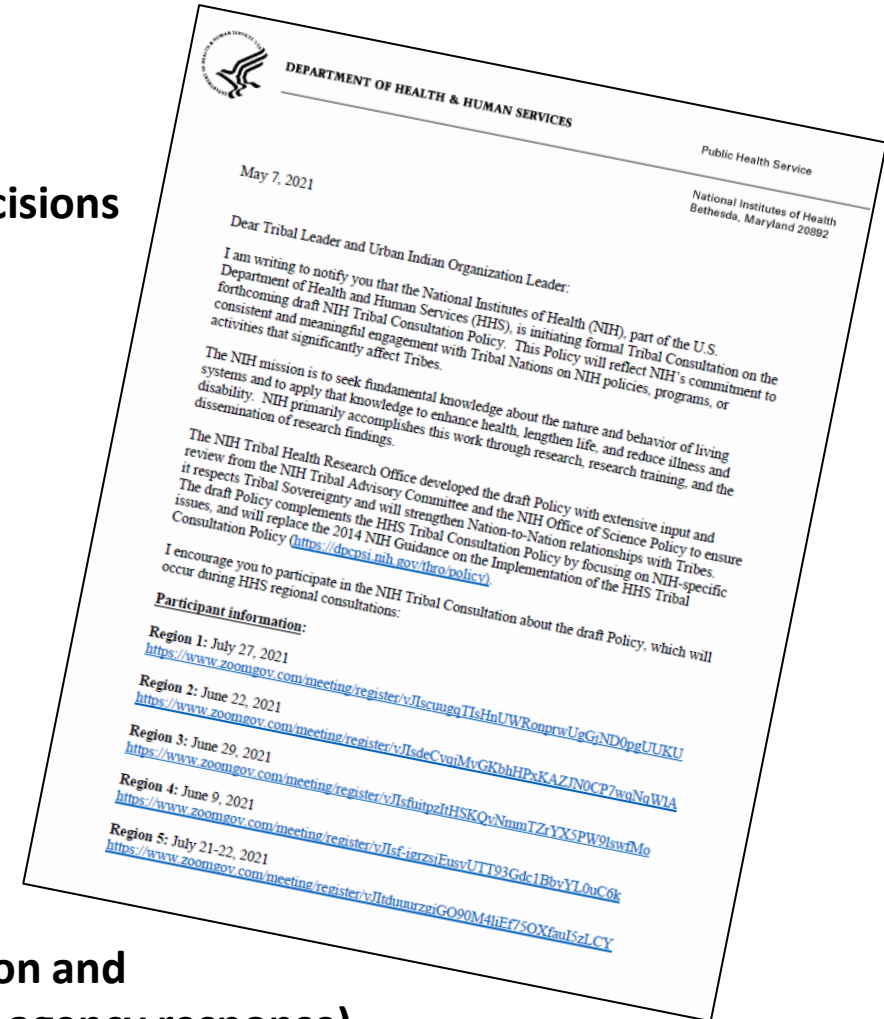
Hold Consultation



Report Outcomes/Decisions

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**
- **A standard process** for all NIH components to follow
- Agency requirements to **seek Tribal feedback, evaluate Policy implementation and effectiveness, and report back (Consultation Report summarizing input and agency response)**



NIH Tribal Consultations: Honoring Commitments, Building Relationships

Past

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

Current

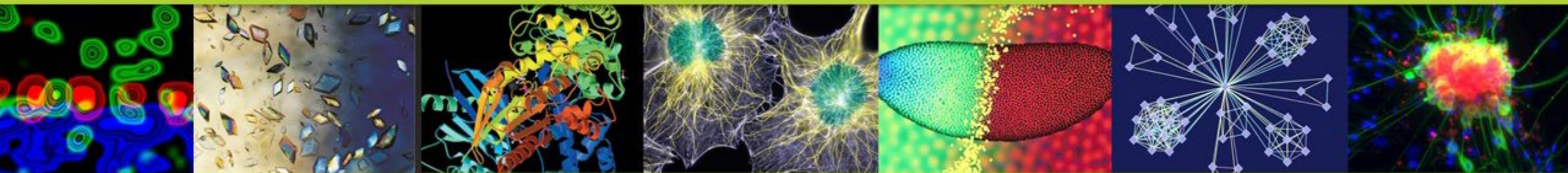
- 2021 Native American Research Center's for Health (NARCH) Program
- 2021-2022 Draft NIH Tribal Consultation Policy
- 2021 RADx Initiative's Tribal Data Repository (TDR)

Upcoming

- 2021 National COVID-19 Cohort Collaborative (N3C)

Jon R. Lorsch, Ph.D.
Director
NIGMS

Tribal Consultation on the NIH Native American Research Centers for Health (NARCH) Program



Feedback in Action – NARCH Tribal Consultation, June 2021

- NIH Tribal Consultation on the Native American Research Centers for Health (NARCH) Program Evaluation
- The NARCH program provides research and career enrichment opportunities to meet the specific health needs identified and prioritized by AI/AN Tribes and Tribally based organizations.
- Direct community feedback is critical to optimize the program.



- ***Program Structure***
- ***Application process***
- ***Community input is valuable and necessary.***



COVID-19 is an emerging, rapidly evolving situation.

- Get the latest public health information from CDC »
- Get the latest research information from NIH »
- NIH staff guidance on coronavirus (NIH Only) »

Tribal Health Research Office (THRO)

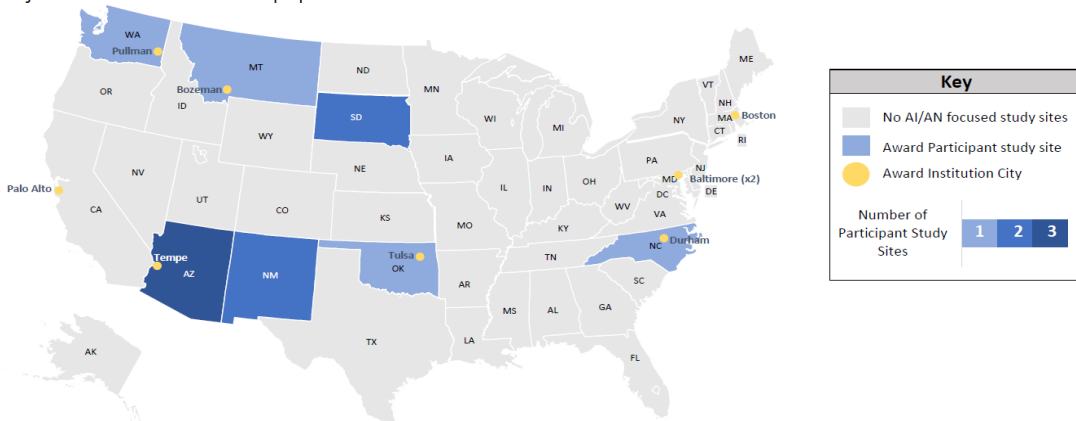
NIH Tribal Consultation on COVID-19 Research

[Learn more »](#)



RADx-UP Awarded Projects with a Focus on American Indian or Alaskan Native Populations (10 total)

The awarded projects include the RADx-UP Phase I and Return to School Program awarded projects. This map shows projects that focus on AI/AN populations.



Note: Four projects have studies across multiple states; the total number of participant study sites does not add up to the total number of projects represented



RADx Underserved Populations (RADx-UP)

The overarching goal of the RADx-UP initiative is 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 who are disproportionately affected by, have the highest infection rates of, and/or are most at risk for complications or poor outcomes from the COVID-19 pandemic. \$512M expanded \$45M

THRO Engagement During Vaccine Development

Operation Warp Speed = Interagency Partnership

US Dept. of Health & Human Services, including:

- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- National Institutes of Health (NIH)
- Biomedical Advanced Research and Development Authority (BARDA)

Other Federal Agencies:

- Department of Defense (DOD)
- Department of Agriculture (USDA)
- Departments of Energy (DOE) & Veterans Affairs (VA)

Private firms

NIH COVID-19 Prevention Network (CoVPN) Supports Operation Warp Speed

Created by merging four existing NIAID-funded clinical trials networks:

- HIV Vaccine Trials Network (HVTN), Seattle, WA
- HIV Prevention Trials Network (HPTN), Durham, NC
- Infectious Diseases Clinical Research Consortium (IDCRC), Atlanta, GA
- AIDS Clinical Trials Group, Los Angeles, CA

Expert Panels

Research Protocols

Communication Materials

Tribal Nations

+/-

Trusted Research Partners

Decision on Participation

Clinical Trials

What we have learned so far

- Tribal Consultation is an important formal process to request Tribal input and participation
- A true partnership is needed to have greatest Tribal participation
- Tribal IRBs
- Data sharing
- Data ownership
 - Secondary analysis
- Biological specimen handling and storage

Improving the Health Status of American Indians and Alaska Natives Together

Partnering with OHSRP

- How can we create more awareness on American Indian and Alaska Native research?
- **Do our policies and procedures adequately protect underserved communities in NIH research?**
- Are we training the next generation of AI/AN policy analysts?
- **large-scale programs with data collection are the future and we need to think about their impact on Tribes?**



In our every
deliberation, we
must consider the impact
of our decisions on the
next seven generations.

Great Law of the Iroquois



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

Sara C. Hull, Ph.D., Detail
shull@mail.nih.gov

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

Facebook
@NIHTribalHealth