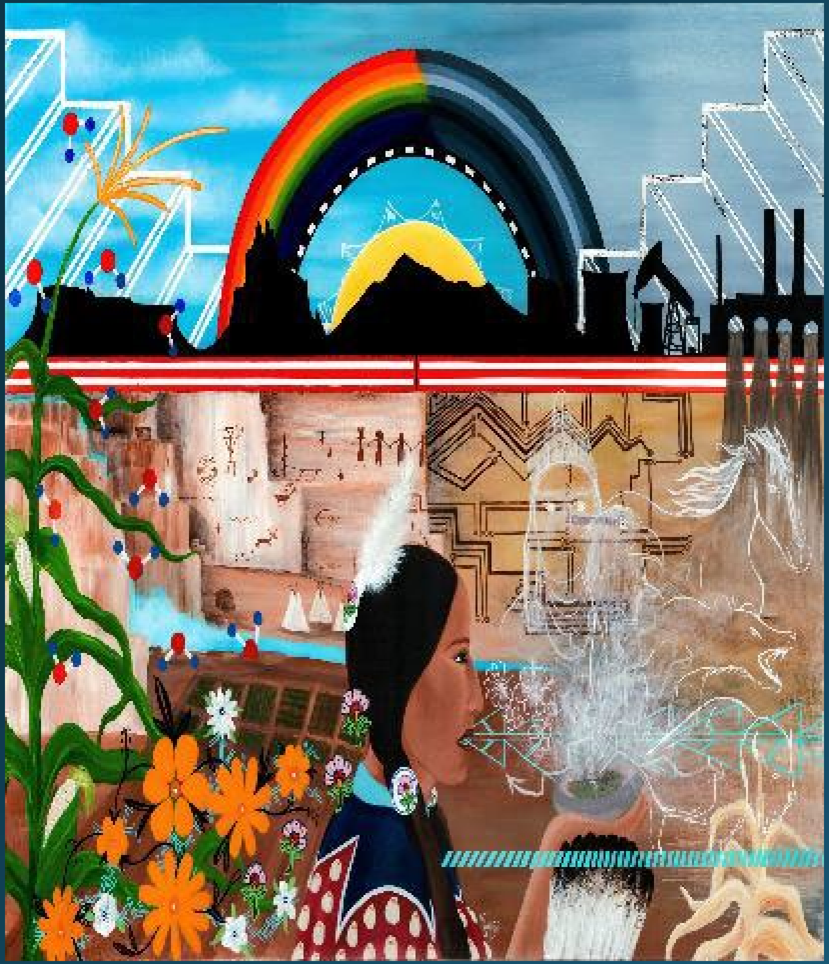

THRO Overview: Indigenous Data Sovereignty

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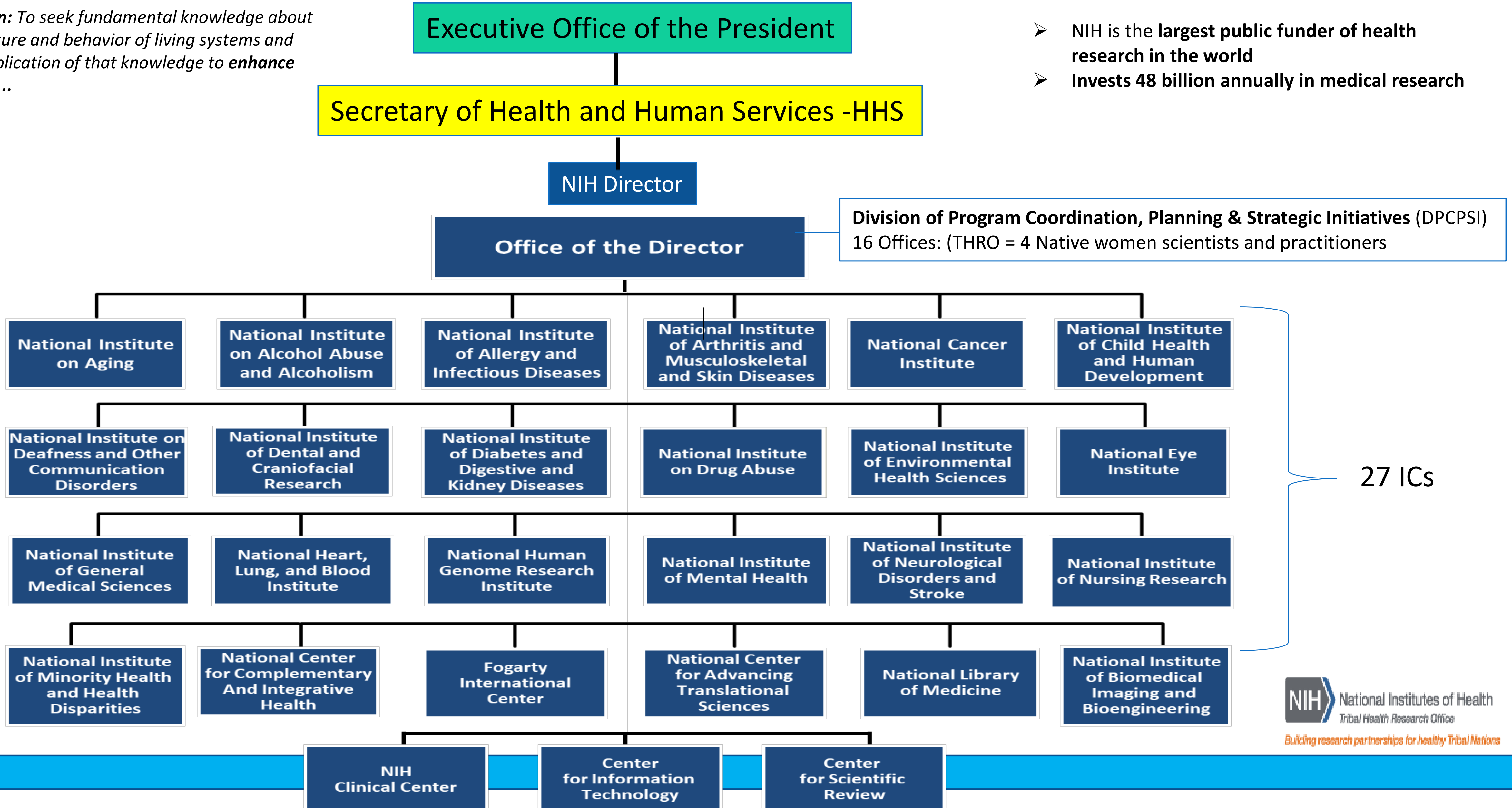
NIH National Institutes of Health
Tribal Health Research Office
Building research partnerships for healthy Tribal Nations

27 Institutes and Centers (ICs) – Each Has Its Own Mission and Budget

- ***Mission:*** *To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to* ***enhance health...***

- NIH is the **largest public funder of health research in the world**
- **Invests 48 billion annually in medical research**



Executive Office of the President

Secretary of Health and Human Services -HHS

NIH Director

Office of the Director

Division of Program Coordination, Planning & Strategic Initiatives (DPCPSI)
16 Offices: (THRO = 4 Native women scientists and practitioners

National Institute on Aging

National Institute on Alcohol Abuse and Alcoholism

National Institute of Allergy and Infectious Diseases

National Institute of Arthritis and Musculoskeletal and Skin Diseases

National Cancer Institute

National Institute of Child Health and Human Development

National Institute on Deafness and Other Communication Disorders

National Institute of Dental and Craniofacial Research

National Institute of Diabetes and Digestive and Kidney Diseases

National Institute on Drug Abuse

National Institute of Environmental Health Sciences

National Eye Institute

National Institute of General Medical Sciences

National Heart, Lung, and Blood Institute

National Human Genome Research Institute

National Institute of Mental Health

National Institute of Neurological Disorders and Stroke

National Institute of Nursing Research

National Institute of Minority Health and Health Disparities

National Center for Complementary And Integrative Health

Fogarty International Center

National Center for Advancing Translational Sciences

National Library of Medicine

National Institute of Biomedical Imaging and Bioengineering

NIH Clinical Center

Center for Information Technology

Center for Scientific Review

27 ICs

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

At THRO, we turn culturally informed discovery into health equity of Natives by…

Through:

1. Advancing “Indigenist” research
2. Cultivating capacity- internally and externally
3. Watering seeds of engagement and consultation
4. Blazing new paths for strategic initiatives, policies, and collaborations
5. Embodying our Values at THRO: CEDAR

THRO Consultation regarding data issues

- Inconsistent application – the octopus of NIH
- Biospecimens & genetic/gene sequenced data
  - International
  - Request for return
  - No documented consent
- Scientific misconduct and biospecimens
- Data repositories
- Paleogenomic and gene sequenced data
- Clinical research data and tribal consent or not
- Urban-reservation borders
- ICOs and Programs:
  - NCI (moonshot)
  - All of Us
  - NIDDK
  - NIMHD
  - NHLBI
  - NIH Intramural IRB workgroup
  - NLM (paleogenomic)
  - CEAL NHLBI (COVID and Climate Change)

Indigenous Data Sovereignty (IDS) Policy Working Group

Co-chaired by:
Dr. Kayla Davis (Osage), DPCPSI IMOD & Mr. Michael Hahn, Branch Chief, Tribal Engagement and Outreach, All of Us Research Program

- 23 members
- Representing 10 NIH Institutes and Centers

- OD (THRO, AoU, OSP)
- NLM
- NCATS
- NIMHD
- NIAID
- NHGRI
- NHLBI
- NIDA
- NIA
- NCI

Indigenous Data Sovereignty & Governance Movement

Indigenous data sovereignty is the right of Tribal Nations to exercise their sovereign authority and govern the **collection, ownership, stewardship, sharing, transfer and re-use; and disposal and/or disposition of data** collected from and about their Tribal populations, particularly when such data has the potential to impact the social, cultural, economic and general welfare of their Tribal Nations. [1-2]

- CARE principles: Collective benefit, Authority to control, Responsibility & Ethics- all stages of data cycle

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1. Indigenous and Tribal Peoples Data Governance in Health Research: A Systematic Review. Griffiths, Blain, Vajdic, and Jorm. Environmental Research and Public Health 2021.
2. Adapted from https://nni.arizona.edu/our-work/research-policy-analysis/indigenous-data-sovereignty-governance (Native Nations Institute & Stephanie Carroll Russo)

AI/AN Research: Common Rule & Single IRB Exemption

[CFR, Title 45, Part 46, Section 46.01 (f), Subpart A]

- The 2018 update stipulates that if Tribal governments have developed laws and ordinances related to the protection of human subjects that are ***more protective*** **than the Common Rule**, then their Tribal research laws and ordinances take precedent and must be followed by federal agencies and federally funded researchers.
- Clarifies that **Tribal Governments can develop laws related to human subjects that are more protective than the Common Rule and that these laws must be followed.**

- NIH respects Tribal sovereignty in the absence of written Tribal laws or policies.

- **De-identified biospecimens are not considered human subjects research under the Common Rule** and thus, their use is generally not subject to the regulatory requirements.

- Many Tribal research laws and ordinances that extends human subjects protections to de-identified biospecimens (and other non-living) under Tribal research regulations; and, as a result, **federal agencies would be expected to accede to Tribal laws and ordinances protecting de-identified Tribal biospecimens** and any regulatory practices associated with biospecimen transfer and/or disposal.

AI/AN Data Sharing Guidance Supplement Best Practices (**NOT-OD-22-214) 9-21-2022**
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-214.html

Culture Matters

Sacred Kin: Samples living and non-living are our relations. Includes plant, flora, fauna, water, land to DNA, proteins, gene sequenced and other biological derivatives etc.

Sacred Offerings: Respect for offerings of biosamples and data- spiritual, cultural, traditional (e.g., SD offerings)

Sacred Knowledge: Indigenous knowledges, cultural protocols, etc. require traditional guardianship and responsibilities. Primary right and responsibility for holding and utilizing Indigenous Knoweldges lies with Indigenous Peoples and their leaders. Collective Responsibility example (Mamala Bark)

IDS Policy Development Takeaways

Tribal sovereignty will be honored.	- The Tribe has authority over data collected on Tribal lands or if data inferences or attributions to Tribe can be made.
Ownership and authority over Tribal data rests with the Tribe.	- Clarify with Tribe, in writing, understanding of who owns or co-owns data, who, how, and where data will be stewarded, and cultural protections for the data and communities participating.
Data management, sharing, access, re-use, transfer and disposal must be tribally approved prior to collection.	- Plans for future data transfer and de-identification of data and return to tribe. Open access and unrestricted access will not be the default, Tribes have to opt into this with clear plans and approvals in place.
Individual, collective and shared benefits should be clearly defined.	- Individual and collective benefits (including dissemination and publication strategies), and benefit sharing should be outlined in consents and data plans.
Free and informed prior consent- always.	- For both the Tribe and individual participants. (possible MOUs/IGAs) – in plain, clear language to ensure mutual understanding.

Takeaways (cont.)

Tribes have right to designate IRB of record and/or review body. Tribal assent is not consent. Clear procedures for obtaining and Tribal IRB/RRB/RRC or other designee for tribal approvals. Tribe has right to determine IRB of record or designate a non-Tribal entity for IRB review.

Tribe has right to determine single or multiple IRBs and approval process. Final approval for moving forward ultimately rests with the Tribe. Tribe still retains right to secondary review and approvals prior to engaging research and this should be determined prior to data collection.

Tribes are exempt from Common Rule. A process for ascertaining formal Tribal review and approvals should be established prior to data collection- E.g., via Tribal Council and designated review committee determined by the Tribe (e.g., historic preservation, dept. of health, AG).

Data collected from human subjects will be treated as relatives. Living and non-living data and will be accorded same rights and protections as "human subjects". Identification of cultural stewardship protocols, when relevant should be prior to data collection.

Individual rights will be honored for data disposal. Tribes must abide by individual consent for data disposal and cannot override such consent.

Legacy and dynamic re-consent plans need to be Tribally approved prior to data collection.

Disposition, transfer, and disposal plans for data associated with deceased individuals needs to be in consent plan prior to data collection. The plan should identify a person to decide this- relative, heir, family, and/or the Tribe. **Dynamic re-consent plans** for longitudinal studies should identify timeframe for re-consent (5 years post study) if disposal is not planned.

Takeaways (cont.)

Tribes have right to designate tribal preferences for how biological samples will be collected, stewarded, stored (including where stored) and disposed of.

Tribes have rights of Traditional Guardianship. - includes flora, fauna, land, culture, language etc. as well as biospecimens, tissues, cells, biogenetic molecules, DNA, RNA, and proteins, and all other substances and codes originating from bodies of tribal members and any genetic or data derived thereof.

Tribal consent will be ascertained if data analyses have implications or inferences for or to Tribe. Re-consent for secondary analyses that may identify a tribe or have impact or inference to a tribe.

Irreversible and timeless consents for biological and genetic, genomic and derived materials should stop. Clear options and consent plans (including re-consent) needs to be identified up front.

Points of Tension

What to do if urban/off rez sample?

If the study is not making inferences to a tribal community, not collected on tribal land, the respondent lives off tribal land, data is not collected at IHS urban facility, then can proceed without Tribal approval.

What if urban sample, not targeted tribe, but tribal lands/rez overlaps close to or with urban area? (e.g., Phoenix or Albuquerque)?

Same criteria as above + best practice of consultation with nearby tribes, MOU to ensure no data analyses by Tribe without tribal approval.

Bottom Line

Any planned or secondary data analyses where *inferences will be made to a specific Tribe or Tribal community, particularly because the data has the potential to impact the social, cultural, economic, and general welfare of a specific Tribal Nation, village or community-*

Tribal consent and formal approval (per the Tribe's ordinances, laws, or protocols) must be acquired to conduct the study, and/or the analyses, and/or publish or otherwise disseminate the findings.

IDS Policy Development Timeline

Future Direction

Key Practices for Indigenous Data Governance

Tribal/community based governance structures.

Support establishing mechanisms for Indigenous communities to oversee data collection, storage, and usage according to their values, cultural customary practices, and priorities.

Data sovereignty protocols.

Develop policies and frameworks that recognize and uphold Indigenous rights to data sovereignty, including data sharing agreements and ethical guidelines.

Capacity Building and Benefit Sharing.

Providing training and resources to Indigenous communities to build their capacity in data management, analysis, decision-making, and data storage/repositories.

Cultural Preservation.

Integrating IK systems and cultural protocols into IDG practices as deemed culturally appropriate by appropriate tribal knowledge keepers to ensure respect for cultural heritage, intellectual property rights and traditional ways of knowing.

Indigenous Data Sovereignty Policy and Working Group

- Will conduct at least 12 Listening sessions and 2 Tribal Consultations.
- Will hold a 1.5 day IDS Summit at the NIH (stay tuned for the date) with 30 subject matter experts and tribal leaders.
- **Listening Sessions completed to date:**
  1. IDSov Governance Summit (April)
  2. Hawaiian Researchers and Community Members (April)
  3. IRINAH PIs and Partners (June)
  4. NIH Tribal Advisory Committee (TAC) (June)
- **Future listening sessions:**
  1. Virtual Open Listening Sessions (2)
  2. NARCH & INBRE PI's and Tribal Partners (July)
  3. Johns Hopkins University Center for Indigenous Health Staff and Partners (July)
  4. NIH Intramural Internal Listening Session
  5. NIH Extramural Listening Session
  6. Native American and Alaska Native Organizations Listening Sessions
  7. Virtual Tribal Leaders Listening Session

Proposed Indigenous Data Sovereignty Policy Timeline:

April

- Meet with Indigenous scientists and data sovereignty experts in Hawaii
- Hold listening session at Indigenous Data Governance Meeting

May

- Announce policy at STAC meeting
- Develop draft ID Sov Policy
- Plan Tribal consultation 1

June

- Listening session with IRINAH PIs and Tribal Partners

July

- Hold listening sessions
- Hold Tribal Consultation 1

August

- Tribal Consultation 2 with draft policy
- IDS SME Summit

September

Revise policy

October

Publish draft policy for Public comment

Key Questions for Today

1. Urban/reservation boundaries and protocols.
2. Clinical/genetic studies for rare diseases example.
3. Nationally representative samples
4. Other questions/examples

Connect with THRO on LinkedIn

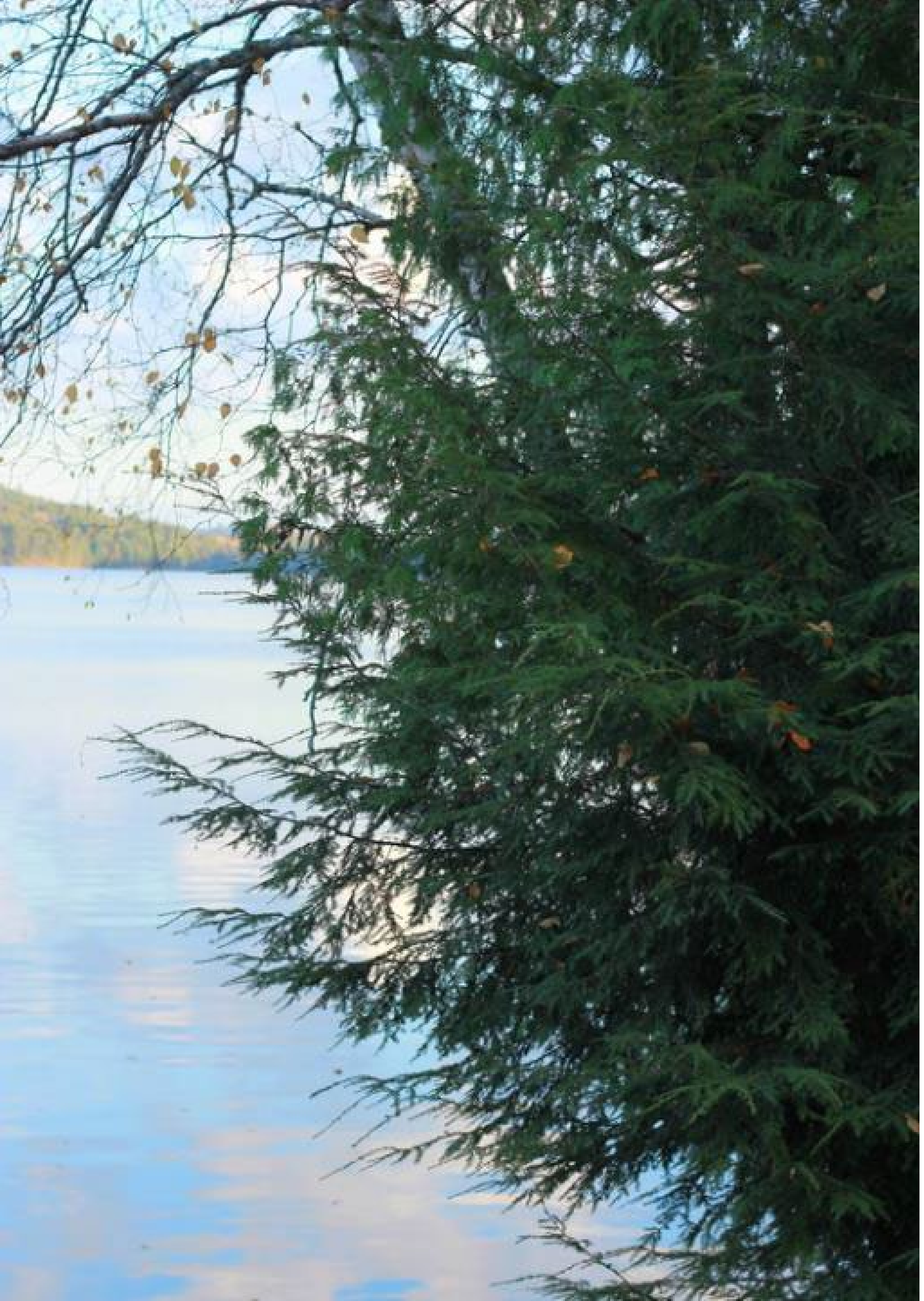
Website
https://www.nih.gov/tribalhealth

LinkedIn
https://www.linkedin.com/showcase/nih-tribal-health-research-office

EMAIL: karina.walters@nih.gov

Choctaw Story: The Bungling Host

- Bear
- Rabbit
- Dr. Buzzard
- House
- Animals capture
- Repair and Restitution



Guided by Our THRO Values: CEDAR

- **Creativity:** Moving beyond conventional approaches to data science, we employ innovative Indigenous Knowledges and methods to ensure science drives sustainable population health change.
- **Ethics**: We maintain the highest standards of professional and ethical behavior; are culturally responsive, reflexive, and aware; and demonstrate transparency and honesty in every transaction.
- **Determination**: While recognizing and respecting the diversity of our Tribal communities, we honor Tribal sovereignty and AI/AN rights to self-determination.
- **Accountability:** We hold ourselves accountable for the quality, timeliness, and lasting impacts of our work--and for the commitments we make to tribal communities and research partners. Accountability engenders trust, builds solidarity, and strengthens partnerships.
- **Respect and Relational Responsibilities**: We respect and value unique and diverse talents and experiences of our Indigenous communities and research partners. We fulfill our responsibilities with compassion, humility, dignity, and equanimity. Through our efforts, we honor past, present, and future generations; are attentive to ancestral, cultural and traditional obligations; and strive to be a healthful and good ancestor in all that we do.

Points of Consideration

- How to address the IDS policy in the data sharing and management plans in grant application process- what should be included prior to funding and/or data collection
  - Tribal letter of support with application and data sharing management plan proposal
  - During 1st year and prior to data collection- documentation of Tribal IRB of record and tribal approval (either via IRB or RRC or tribal designee) of data sharing, management, and dissemination (publication) plan
  - Include in progress report and if not by end of 2nd year, funding will be withheld until final approval from tribal partner?
- Considerations for urban AI/AN research- what do we need to require and what do we need as guidance? Challenges and opportunities?
- What are the IDS considerations (individual and collective) for participation in clinical studies, particularly for rare diseases and treatment and research in urban hospitals? (small n; not able to make inferences)

- How to address deceased or unidentifiable donors? i.e. no living donors to re-consent, family, heirs, and/or tribe is not clear?
- What if Tribe wants samples repatriated or sent to a designated biorepository?
  - We would honor that in cases where it is not in conflict with original individual consent (i.e. individual wanted destroyed).
- What are best IDS practices for consent for culturally sensitive and significant samples? (e.g., breast milk, umbilical cords, placenta, etc.)
- What are the IDS considerations for paleogenomic samples (human and non-human) ?