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## Tribal Health Research Office & Considerations when reviewing research involving Indigenous peoples

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# Water First Medicine

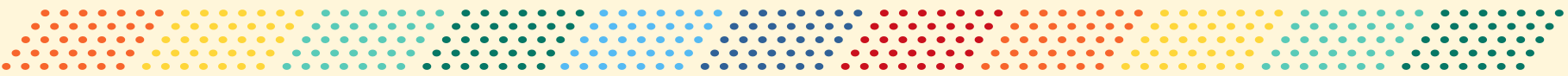
- POWER
- Vision
- Love



# Who We Are: Our Mission

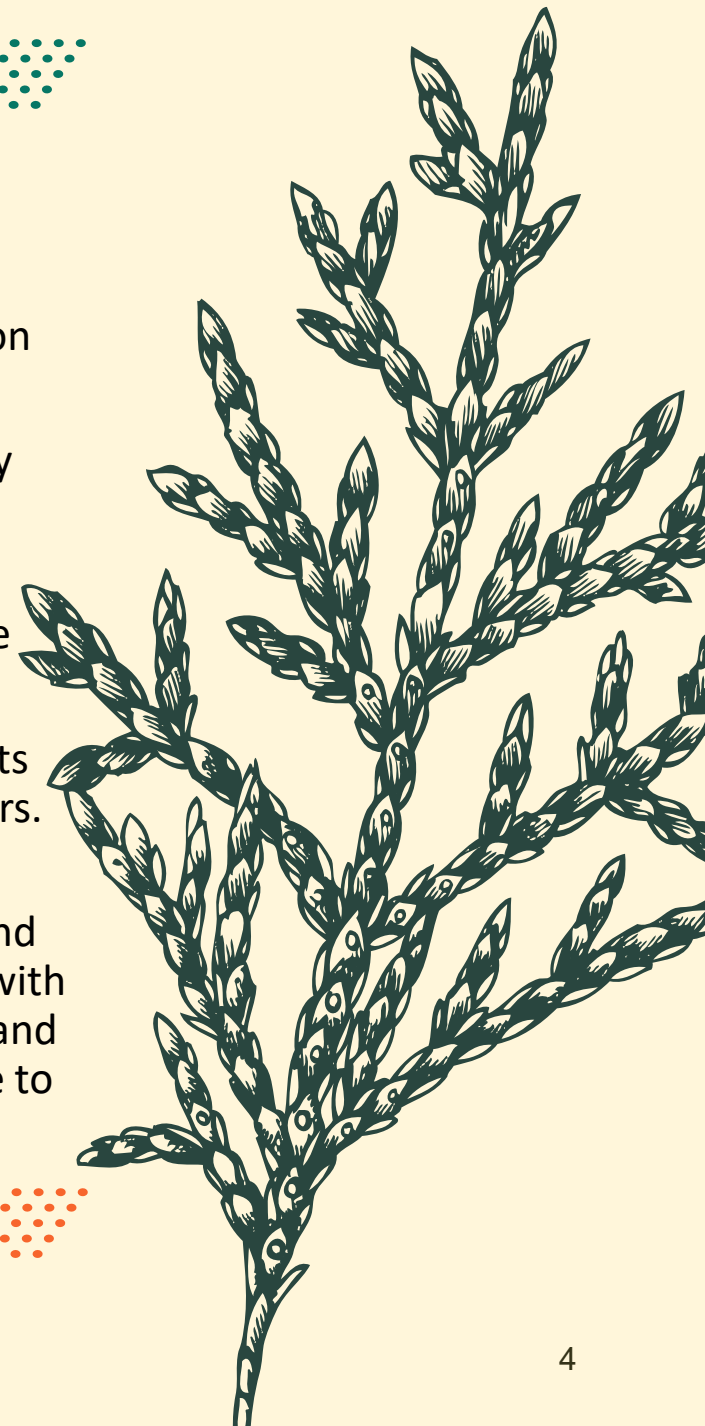
- We are one of the 16 Offices of the Office of the Director at the NIH in the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI).
- We are a **synergistic hub** for all AIAN research activities and research workforce development at the NIH.
- We strategically consult, coordinate, and collaborate with NIH Institutes and Centers as well as with Tribal partners to generate Native science and a research workforce that builds healthy lives and communities.
- Our ultimate goal is to grow Indigenous health and health equity through culturally credible and meaningful Indigenist-driven science- it is, as our theme for THRO this year suggests- about **Indigenous Knowledges Powering Science.**





# We're Guided by Our THRO Values: CEDAR

- **Creativity**: Moving beyond conventional approaches to science, we center innovative Indigenist-centered methods and knowledges 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 Tribal 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.





Artist: Cara Romero

## Who We Serve

- **Who we serve:** 574 Federally Recognized Nations (229 federally recognized tribes in Alaska); 2.6% of population (3.7 million; 9.7 if add other races). Projected to grow to 10.1 million by 2050. Over 200 unique languages.
- We also engage Native Hawaiian and other Indigenous populations of US Territories (e.g., Chamorro of Guam; Marshallese of Marshall Islands, etc.). Approximately 1.5 million Native Hawaiians

# Tribal governments are a unique member of the family of American governments

- THRO has a mandate to serve the 574 sovereign tribal nations.
- Hundreds of treaties and laws, along with the Supreme Court, the President, and Congress have affirmed **powers of Tribal self-government** and **Tribal sovereignty**.
- The **federal Indian trust responsibility** is a moral, legal, and enforceable fiduciary obligation on the part of the US to protect **tribal treaty rights, lands, assets, and resources**, -including economic, social and health programs necessary to raise the standard of living and social well-being of AI/ANs.
- Congress requires that Federal agencies consult with Native Hawaiian organizations as the informal representatives of the NH communities.



“Sovereignty is that wafting thread securing the components that make a society. Without that wafting thread, you cannot make a rug. Without that wafting thread, all you have are unjoined, isolated components of a society. Sovereignty runs through the vertical strands and secures the entire pattern. That is the fabric of Native Society.”

*Ingrid Washinawatok El Issa*





# We are living a health reality that our ancestors did not dream for us...

- We suffer under a chronically underfunded, inaccessible and inadequate health care system.
- Structural determinants of health are the –poorest. We experience substandard/overcrowded housing, food deserts and highest rates of food insecurity (1/4), lack of clean or accessible water, electricity and disproportionate exposure to damaging environmental hazards, pollutants and toxins.
- Compounding the crisis- few of us are in higher education and as a result are underrepresented in the healthcare and research workforce- 14.5% achieve college degrees in contrast to 31.3% for general population.
- These and other structural factors have led to high multiple chronic disease burden—or syndemics-where we have multiple synergistic epidemics that lead to premature mortality.



## IMPACT...

- We now have the lowest life expectancy- worst since WWII – age 65; in fact, 25% of our population die before the age of 45.
  - Life expectancy varies by Tribe. Example-age 46 for men, 52 for women in SW Tribe.
- We are facing multiple public health crises, but few are listening.
- We are invisible to public awareness.
- It is our obligation to reconnect to that power, vision, and love now and to change the course we are on and to harness our collective scientific and Indigenist wisdom to achieve health and health equity.



**Our story at THRO is about  
harnessing our power to  
heal through science**





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

A landscape photograph showing a grassy field in the foreground. On the left, there is a large, dark, rounded tree. On the right, there is a taller, thinner tree with its branches silhouetted against a bright sunset. The sun is low on the horizon, casting a golden glow over the scene. In the background, the ocean stretches to the horizon under a blue sky with some light clouds. The overall mood is serene and contemplative.

# LAND

I am the land, the land is me --vs.-- I own the land, the land is mine

. parallel process for data dispossession and erasure...

I am the data, the data is me --vs.-- I own the data, the data is mine.

# Settler Colonialism



Manifest Destiny

"Manifest Destiny" by John Gast (1872)

- U.S. settler colonialism consists of the policies and practices that facilitate Native land dispossession and erasure of Native People and identity.
- It is a structure, not an event (Wolfe, 2006; Rowe & Tuck, 2017).
- Structures, policies, and values undergirding such policies (Doctrine of Discovery, Manifest Destiny) are created to:
- distort historical realities
- free future generations from guilt and accountability
- rationalize and normalize continuous rights to dispossess Native people of their lands
- erase Indigenous people from the land, contemporary society, and social discourse ....then....ERASE TO REPLACE
- replace with settler "origin" narratives that perpetuate myths while also disavowing historical and ongoing violence...

Body to cellular dispossession & data erasure/invisibility; language "gold mine" etc.

# Timeline and snapshots of research abuses

- 1860s **Army Medical Museum-** Surgeon William Hammond orders all medical officers and field personnel to “collect all specimens of morbid anatomy, surgical or medical, which may be regarded as valuable” --**Col. Chivington** of the Sand Creek massacre of Northern Cheyenne obliges and cuts off the heads of mostly women and children and ships to Army Medical Museum in compliance with the federal call (Utely, 1984).
- 1898 **Smithsonian’s National Museum of Natural History** receives over 2,000 of the 4,000 heads amassed by the AMM.
- 1920s **Trachoma eye experimental surgeries** leave hundreds blind in SW.
- 1930s **Grave robbing extends to Alaska** with Smithsonian anthropologist exhuming 800 Alaska Native remains/1000 burial offerings.
- 1950s **US Air Force’s arctic aeromedical lab** study uses radioactive iodine 131 given to Alaska Natives –without proper informed consent.
- 1970s **Alaska alcohol study-** impacts economic status of the corporation-published without consent.
- 1980s **PNW First Nation Arthritis research-** 800 tribal members consented to blood draw for arthritis biomarkers- researchers used samples to conduct further genetic research and share with other researchers without Tribal knowledge or consent.
- 1990s **Navajo hantavirus study-** Navajo asked CDC to not publish place names-they and Navajo halted research for over 13 months.
- 2000s **Havasupai-Tribal member discovered years later that DNA samples for diabetes study was used without knowledge** or consent for highly taboo and stigmatizing topics- Tribe issues banishment order and files lawsuit against the university and settled. collective harm, unequal distribution of “benefits”
- **Navajo issues a moratorium** on all genetic research that remains in effect today.
- 2015+ **International tribes (e.g., Yanomami) demand return of blood samples** collected in the 1960s –stored at various US institutions. Did not benefit Yanomami. Years delay in return –could not agree how to return and rumors of dangers in transfer.

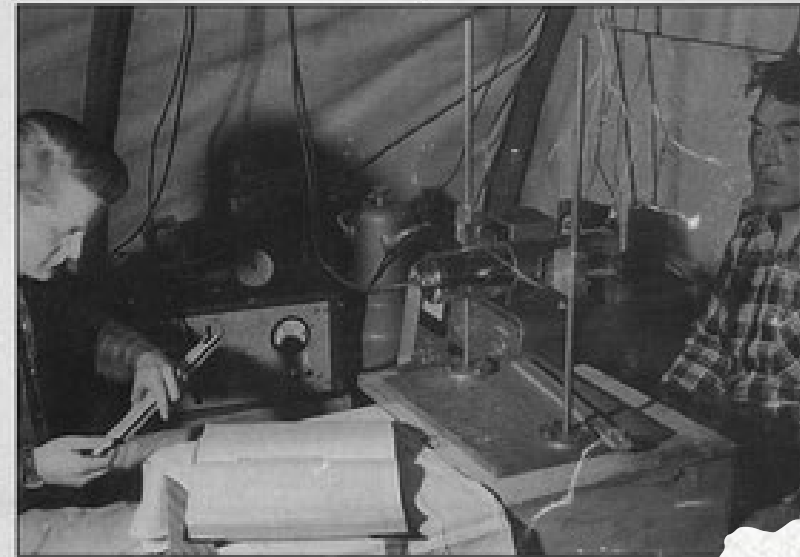
Building IDS policy  
means recognizing a  
legacy of research  
abuse

There is justifiable mistrust

## Alaska Natives in the Nuclear Age:

The U.S. Government's Treatment of Alaska Native  
Research Subjects in a Thyroid Function Study Involving  
the Administration of Radioactive Iodine-131

January 1997



An Investigative Report Funded by the North S\*



## Choctaw Story: The Bungling Host

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





# Wind Transformation

# 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>

- ***Proactively engage AI/AN Tribes in planning for data management and sharing.***
- ***Establish mutual understandings of goals for data management and sharing.***
  - Researchers should convey relevant data management and sharing agreements in the Plan (i.e., applicable Tribal laws, regulations, and policies, etc.) and obtain Tribal letters of support, Tribal resolutions, and/or other forms of written documentation when required..
- ***Incorporate AI/AN data management and sharing practices and preferences in Plans.***
  - Prior to submitting a Plan to NIH, researchers and AI/AN Tribal partners should consider whether data generated will be stewarded by Tribal Nations, researchers, or a trusted third party..
- ***Consider additional protections and appropriate limitations to future data sharing.***
  - AI/AN Tribes have legal rights to determine the conditions by which their data are shared when data are collected within their jurisdiction, including requiring Tribal approvals or participating in research review requests...
- ***Incorporate data management and sharing plans in the informed consent process.***
  - The DMS Policy strongly encourages researchers to communicate data sharing and future use limitations to research participants in the informed consent process. This includes...oversight processes and safeguards on secondary research, plans related to return of secondary research results, and/or stipulations of the data repository used (e.g., how long data can be made available for secondary analyses).
- ***Safeguarding against future risk.***
  - The DMS Policy indicates that, in developing Plans, researchers should describe how participants privacy, rights, and confidentiality will be protected...To mitigate the potential for group harm to AI/AN Tribes, both individual and community data protections (e.g., deidentification of Tribal affiliation or other group identifiers and controlled access review) should be considered.

# 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.<sup>1-2</sup>

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



<sup>1</sup>.Indigenous and Tribal Peoples Data Governance in Health Research: A Systematic Review. Griffiths, Blain, Vajdic, and Jorm. Environmental Research and Public Health 2021.

<sup>2</sup>.Adapted from <https://nni.arizona.edu/our-work/research-policy-analysis/indigenous-data-sovereignty-governance> (Native Nations Institute & Stephanie Carroll Russo)

# Common Rule & IRB Exemptions for AI/ANs

- 2018 - Tribal research laws and ordinances take precedent and federal agencies must follow these laws if more restrictive than the Common Rule (CR).
- De-identified biospecimens are not considered “human subjects” under CR; however, most Tribal laws & cultural protocols extends human subjects protections to de-identified biospecimens- federal agencies are expected to accede to Tribal laws protecting de-identified biospecimens.
- **NIH respects Tribal sovereignty in the absence of written Tribal laws or policies.** CFR, Title 45, Part 46, Section 46.01 (f), Subpart A]





# Listening Session Takeaways for IDS Development

- **IDS Policy honors Tribal sovereignty and governance.** Tribes have authority over data collected on Tribal lands or if data inferences or attributions to Tribe will be made.
- **Ownership of and authority over data rests with Tribe.** Prior to data collection- clarify with Tribe in writing- who owns or co-owns data, who and how data will be stewarded (loan), cultural protection for data & community.



# FIRE

Honoring our Responsibilities and  
Transcending Research Traumas to Build Healthful  
and Ethical Partnerships



M... HA  
ISHT AN... HOKE.  
YOHMI ma... filemmit  
j sanali tok... laia ka  
2. Atuk o... ka tok:  
ettet iti okho... klon in  
mihmet anu... nana  
chitokaka Ba...  
chj ka ont lvs...  
3. Mihma C... hatak  
g. Wakayet, Su... hg out  
ish afama cha... on in  
chitokaka Baal-s... ?  
4. Yohmi hoke... h  
oiya tuk et, yemma...  
pulla chj hoke, ish...  
chah et ia tok.  
5. Atuk o an...  
ma, Nanta kati...  
6. Mihma, ...  
miko et hecl...  
achishke, Cl...  
kaka Baal-s...  
cho? yemolmi...  
akowa chj keyu...  
achashke, pim ac...  
7. Mihma, An...  
ha, ... pa ileppa puta ka

# Culture Matters

## Sacred Kin

Samples living and non-living are our relations. Includes plant, water, land, DNA, proteins, and other biological derivatives etc.

## Sacred Offerings

Respect for offerings of biosamples and data (e.g., SD)

## Sacred Knowledge:

Indigenous knowledges, cultural protocols, etc. require traditional guardianship and collective responsibility lies with IP and their cultural leaders. (Mamala Bark)



# Guiding Principles of Indigenous Data Sovereignty & Research Ethics

**Honoring Tribal sovereignty and self-determination.** Indigenous communities have the inherent right to determine how their data is collected, managed, and utilized.

**Ownership and Stewardship.** Indigenous Peoples retain ownership, authority, and control over their data, including intellectual property rights and cultural protocols and knowledges.

**Consent.** Data collection and sharing must be based on free, prior, and informed consent, respecting Indigenous Knowledge systems and cultural/customary practices. Tribal consultation does not equal consent.

**Benefit.** Data practices should prioritize the well-being and empowerment of Indigenous communities, fostering positive outcomes, equitable partnerships, and advancing community capacity.

# IDS Policy Development Takeaways

## **Tribal sovereignty honored.**

- The Tribe has authority over data collected on Tribal lands or if data inferences or attributions to Tribe can be made.

## **All data practices (management to disposal) must be tribally approved prior to collection.**

- Plans for future data transfer, open or restricted access, dynamic re-consent, and de-identification of data and return to tribe should be outlined. Open access, irreversible and unrestricted access-not default.

## **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-for both individuals and Tribe.**

- For both the Tribe and individual participants. (possible MOUs/IGAs) – in plain, clear language to ensure mutual understanding.

# Takeaways (cont.)

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## **Tribes have right to designate IRB of record and/or review body.**

Need procedures for 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.

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## **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 review and approve prior to data collection.

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## **Individual rights will be honored for data disposal.**

Tribes must abide by individual consent for data disposal-cannot override consent.

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## **Legacy 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.

# Takeaways (cont.)—Tribal Rights and Requests



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



**Tribal consent or re-consent will be ascertained** if secondary data analyses identifies a Tribe or may impact or make inferences to a Tribe.



**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.



**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.



## Examples of Research Protocols in Action

- **Principle of Confidentiality.**

Recognizes that the Tribal Nation has the right to exclude from publication and/or to have kept confidential any information concerning their culture, traditions, sacred stories, songs or texts, or spiritual beliefs.

Furthermore, researchers and other potential users shall guarantee such confidentiality.

## Research Protocols in Action



**Principle of Traditional Guardianship.** All TRIBAL cultural and spiritual knowledge, including written, oral, visual, etc. are the sole traditional intellectual property rights of the Tribal Nation and should not be used without explicit permission from appropriate cultural authorities.

All non-tribal partners are expected to respect this knowledge when it is shared and not to misuse or appropriate it for personal gain or otherwise inappropriate purposes.

## Points of Consideration:

## NIH Grant Applications- what should be included?

- Tribal letter of support or Council resolution should be submitted with application –establishing support and preliminary support for proposed data sharing management plan
- During 1<sup>st</sup> year and prior to data collection- documentation of Tribal IRB of record and formal tribal approval (either via IRB or RRC or tribal designee) for data sharing, management, and dissemination (publication) plan.
- Formal Tribal IRB approval or designee is not needed prior to the application or award being made--the award can be made with human subject restrictions while PI finalizes Tribal IRB approval.
- Include every 2 years an updated Tribal approval with progress report
- If no Tribal approval for study by end of 2<sup>nd</sup> year, should funding be withheld until final approval from tribal partner?

# IRB Points of Consideration:

- There may be up to three IRB's or Two IRBs of record (e.g., IHS and University/Intramural). Single IRB rule is not in compliance with Tribal laws and ordinances.
- Tribes have authority to designate who will provide Tribal research oversight- health committee, IRB, RRC, etc.
- If IHS staff, facility, or clients involved- then IHS IRB needs to be involved.
- Some Tribes require "permits" to access Tribal lands and to conduct research with Tribal communities.
- Need to familiarize with Tribal laws and ordinances for Tribes one is working with- they vary in strength and oversight.
- In absence of Tribal laws and ordinances, we rely on most stringent best practices and contemporary Tribal laws and ordinances such as for GRIC or Navajo Nation as guidelines.
- Potential for AIAN IRB Panel at NIH for intramural research.
- Dissemination strategies is a critical issue in Indian Country- this is where many harms have manifest and Tribes must weigh in and guide dissemination strategies
- Research Protocol Codes, data sharing agreements, MOUs/IGA examples and other supplemental materials are needed

# 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 NIH protocols that recognize and uphold Tribal research laws and ordinances and Indigenous rights to data sovereignty-including data management and sharing agreements as well as ethical guidelines.



## **Capacity Building and Benefit Sharing.**

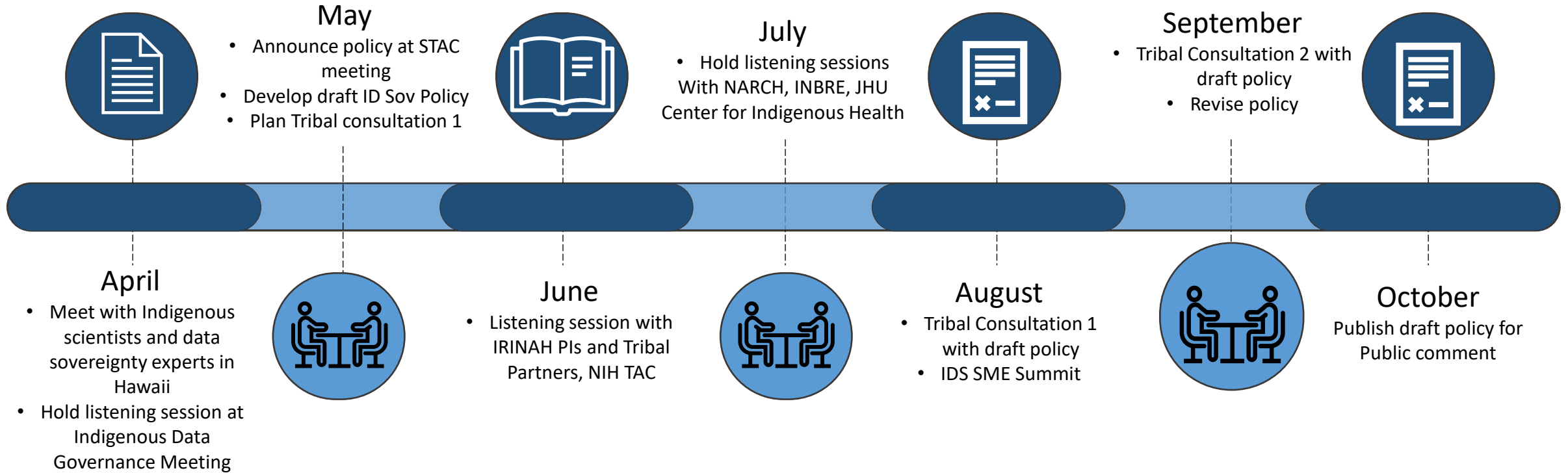
Provide training and resources to Indigenous communities to build their capacity in data management, analysis, decision-making, and data storage/repositories. Provide training and resources to NIH to build capacity in promoting IDS practices.



## **Cultural Preservation.**

Integrate IK systems as culturally appropriate (Tribe determines this) to ensure respect for cultural heritage, intellectual property rights and traditional ways of knowing.

# Proposed Indigenous Data Sovereignty Policy Timeline:



IDS Policy Development Timeline

Future Directions: