

# Indigenous Data Sovereignty: Leadership and Application

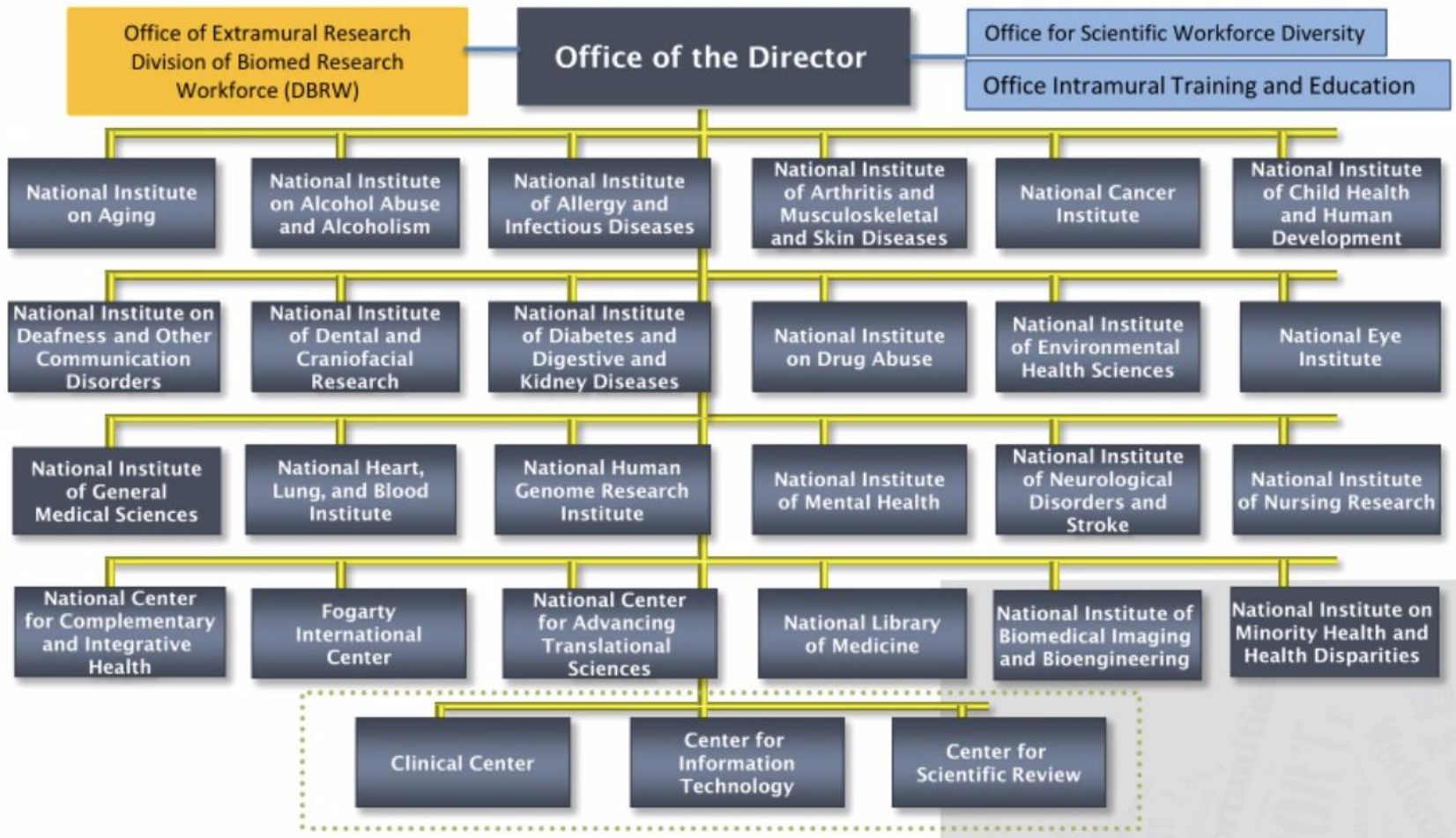


AI/AN Indigenous Data Sovereignty Series  
AKIRP  
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# NIH includes 27 Institutes and Centers



# Scientific Data and Indigenous Data Sovereignty

- **Scientific data:** the recorded factual material commonly accepted in the scientific community as necessary to validate and replicate research findings, regardless of whether the data are used to support scholarly publications
- **Indigenous Data Sovereignty:** the right of a nation to govern the collection, ownership, and application of its own data. It derives from tribes' inherent right to govern their peoples, lands, and resources

# Importance of Addressing Implementation of IDS: Why now?

- Indigenous Data Sovereignty (IDS) Movements
  - E.g., Native Nations Institute, University of Arizona
  - E.g., US Indigenous Data Sovereignty Network
- NIH
  - New Data Management and Sharing Policy being introduced where broad data sharing is *encouraged*
    - This can conflict with tribal policies or accepted processes
  - Large NIH research programs have raised additional questions
    - Studies that have or will draw in a large sample of AI/AN
      - Studies that will have sensitive data
    - Tribal concerns and response
      - E.g. AoU established Tribal Collaborative Engagement Advisory Group and engaged in Tribal Consultation

# AI/AN Research Contexts: Specific Focus on AI/AN

- Studies conducted:
  - On tribal sovereign lands
    - single or small number of reservations
    - across a large number of reservations
  - Off tribal sovereign lands
    - Or combine reservation and off-reservation sites



# AI/AN Research Contexts: Studies of General Population

- Not specifically focused on AI/AN but will draw into sample
  - Off Tribal Sovereign Lands
    - Further distinguish between studies that:
      - Collect tribal affiliation
      - Have a sample large enough to produce specific findings for AI/AN
  - On Tribal Sovereign Lands
    - Draw reservation into sampling frame

# AI/AN Research Process

- Predicated on Tribal Sovereignty
- Responsive to Past Research Abuses
  - Outside of approved research area
  - Not in line with consent forms
  - Produced stigma
  - Caused community/Tribal harm
  - Challenged AI/AN worldview
    - E.g. Origin stories
- Differs from research conducted with other racial/ethnic groups

# Tribal Policies and Practices for Research

- Tribal Resolution Required
- IRB
  - Tribal IRB if infrastructure exists
  - Possibly IHS IRB
  - University IRB
- Community Engaged Research
- Community Advisory Board or Research Advisory Board





# Tangible Benefits

- Research in service to community
- Direct implications for communities and improving their well-being
- Research should build community capacity



NCAI Policy Research Center Core Values

# Selected NIH/HHS Policies or Guidance Relevant to IDS

- Common Rule (HHS Policy)
- Data Sharing Policy
- Single IRB
- Language in Funding Opportunity Announcements (FOAs)

# *Federal Policy for the Protection of Human Subjects/Final Rule: Revised Common Rule (HHS Policy 45 CFR part 46)*

- A 1981 rule of ethics (revised in 2018) regarding biomedical and behavioral research involving human subjects in the US
- Baseline standard of ethics by which any government-funded research in the US is held
  - Requirements for assuring compliance by research institutions
  - Requirements for researchers' obtaining, waiving, and documenting informed consent
  - Requirements for Institutional Review Board (IRB) membership, function, operations, review of research, and record keeping.

# Revised Common Rule Updates

- 2018 update acknowledges research laws and codes passed by a tribe's governing body, along with state and local law, in its requirements (Code of Federal Regulations [CFR], Title 45, Part 46, Section 46.101(f), Subpart A
- Clarifies that tribal governments can develop laws related to the protection of human subjects that are more protective than the *Common Rule*, and that these laws must be followed by federally funded researchers in activities involving these populations.

# Single IRB Policy for Multi-Site Research

- Establishes the expectation that a single IRB (sIRB) of record will be used in the ethical review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site
- Goal is to enhance and streamline the IRB review process in the context of multi-site research
  - Help research proceed effectively and expeditiously

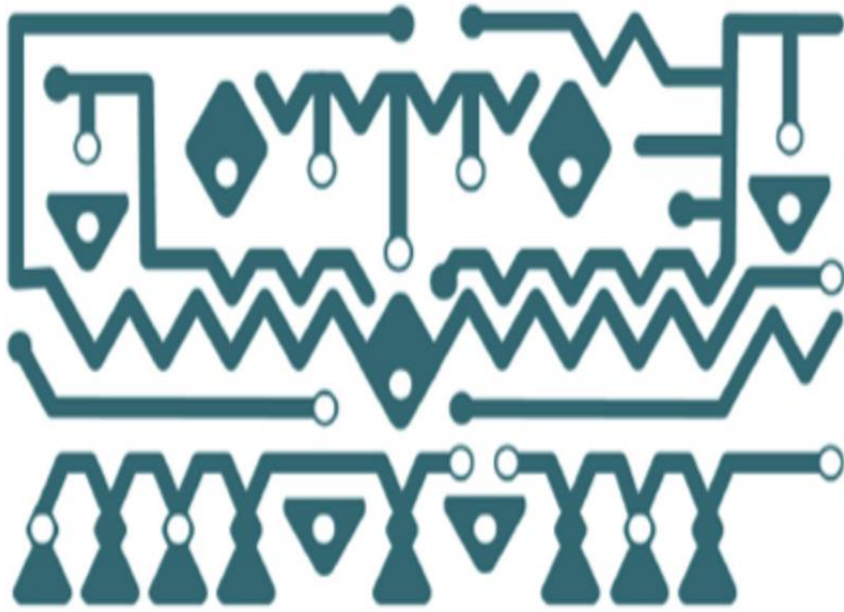
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>

# Exceptions to Single IRB Policy

- Exceptions made where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy.
- Further clarification:
  - Also grant exceptions where the federal, state, or tribal prohibition on the use of an sIRB is established by policy, and we will consider granting an exception if a request is made and a compelling justification provided for why an exception is needed.

# Data Sharing and Ownership: NIH Goals for Responsible Data Sharing

- **Foster a culture of data stewardship**
- **Balance data management with sharing need**
- **Practices consistent with FAIR principles**
  - Findable, accessible, interoperable and reusable
- **Respect research participants' values and consent**



# CARE Principles for Indigenous Data Governance

- Collective Benefit
- Authority to Control
- Responsibility
- Ethics

The CARE Principles were drafted at the International Data Week and Research Data Alliance Plenary co-hosted event “Indigenous Data Sovereignty Principles for the Governance of Indigenous Data Workshop,” 8 November 2018, Gaborone, Botswana. Co-leads: Stephanie Carroll & Maui Hudson



# CARE Principles

- **Collective Benefit:** Data ecosystems designed and function in ways that enable Indigenous Peoples to derive benefit from the data.
- **Authority to Control:** Indigenous Peoples' rights and interests in Indigenous data must be recognized and their authority to control such data be empowered. Indigenous data governance enables Indigenous Peoples and governing bodies to determine how Indigenous Peoples, ... are represented and identified within data.
- **Responsibility:** Responsibility to share how those data are used to support Indigenous Peoples' self-determination and collective benefit. Accountability requires meaningful and openly available evidence of these efforts and the benefits accruing to Indigenous Peoples.
- **Ethics:** Indigenous Peoples' rights and wellbeing should be the primary concern at all stages of the data life cycle and across the data ecosystem.

# Tribal Policies or Expectations: Data Ownership

- Data ownership
  - Tribes often require that they own the data
  - Will share data with researchers or allow them to be steward of data for a period of time

# Tribal Policies or Expectations: Data Sharing

- Many tribes have policies or laws that prohibit broad data sharing
  - Even without policy, often do not desire broad data sharing
- Use of Secondary Data:
  - Requires specific approval for each “study”
    - Especially if topic different than what originally proposed
  - All “studies” must go through all approval steps,
    - E.g. tribal resolution, tribal IRB, manuscript approval, etc.

# Tribal Policies or Expectations: Dissemination of Research Findings

- **Any** dissemination of findings must receive tribal approval
  - Depending on infrastructure, approval provided by tribal IRB, Research Advisory Board, or Community Advisory Board
- Necessary to disseminate results to community in layman's terms

# Example of How One NIH FOA has Operationalized Appropriate Research with Tribes: IRINAH

- **Collaborations:** Collaborators should address issues of ownership, control, and storage of data and biological samples in the application. However, NIH recognizes that communities may wish to retain ownership or control of data and biological samples.
- **Community Support:** Applications are expected to include evidence of: 1) strong scientific capabilities; and 2) community involvement and support.
- **Data Ownership and Control:** If tribes seek ownership or control of all data and all biological samples, then universities and other partners should be prepared to negotiate data sharing and biological sample sharing agreements as appropriate and provide letters of agreement/partnership.

# Final NIH POLICY FOR DATA MANAGEMENT AND SHARING

- **The final DMS Policy does not create a uniform requirement to share all scientific data**
- **Researchers prospectively submit a plan for managing and sharing data at the time of application**
- **Policy expectations:**
  - **Submission of a Data Management and Sharing Plan**
    - Describes how data will be managed, preserved, and shared
    - Outlines how participants' privacy, rights, and confidentiality will be protected and any potential limits to sharing
    - Indicates anticipated timelines for data preservation and access
  - **Compliance with the approved Plan**
- **Plans may be updated (with approval by NIH)**

# In Developing Policy, NIH Made the Following Commitments

- Tribal Nations are sovereign nations engaging with NIH through a government-to-government relationship
- NIH is committed to working with Tribal Nations to:
  - Increase awareness of and participation in biomedical research
  - Develop practices/ policies that respect Tribal Nations' rights and beliefs
- NIH engaged in Tribal Consultation and more broadly sought input on data sharing practices to:
  - Alleviate concerns and mitigate risk regarding data misuse
    - Ensure protection and benefit
  - Promote responsible and respectful data management and sharing practices sensitive to cultural values, practices and preferences

# How Policy for Data Management and Sharing Acknowledges Tribal Sovereignty

- *"Considerations for Scientific Data Derived from Human Participants:* NIH prioritizes the responsible management and sharing of scientific data derived from human participants. Applicable federal, Tribal, state, and local laws, regulations, statutes, guidance, and institutional policies govern research involving human participants and the sharing and use of scientific data derived from human participants. NIH also respects Tribal sovereignty in the absence of written Tribal laws or polices."

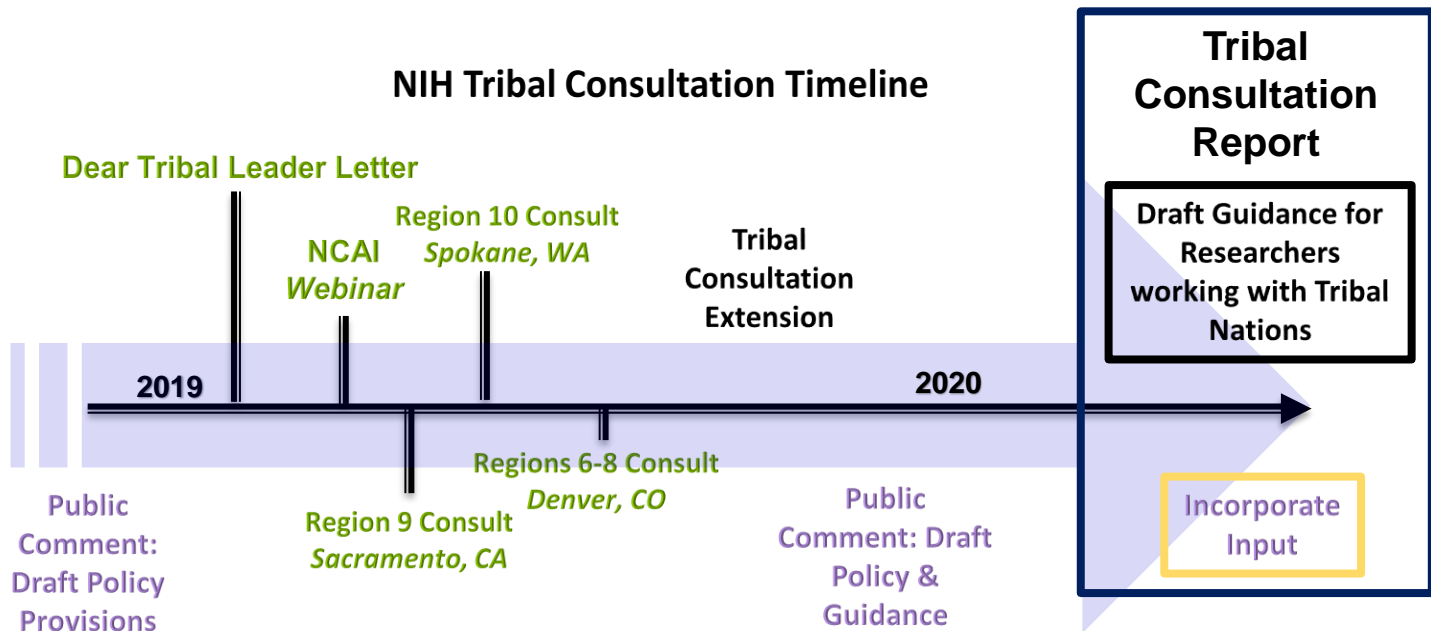


# Developing supplemental information for researchers who wish to work with AI/AN communities

- Expected to encourage researchers to (among other topics):
  - thoughtfully consider the unique data sharing concerns of AI/AN communities;
  - respectfully negotiate agreements for data use with Tribal Nations;
  - and enhance researcher awareness of processes Tribal Nations use to review prospective research.
- NIH will seek input from AI/AN communities on the development of the guidance, to ensure it serves the goals of guiding researchers while taking into account Tribal preferences and values

# NIH TRIBAL CONSULTATION ON DATA MANAGEMENT & SHARING

## Work conducted



# All of Us Final Tribal Consultation Report: Brief Summary

- Respect tribal sovereignty by engaging Tribal Nations to ensure that research using the program's biospecimens and data from tribal members is done in a way that is respectful of applicable tribal customs, culture, and laws.
- Include as much diversity of AI/AN populations as possible by partnering with tribes and with organizations with urban Indian expertise that want to collaborate.
- Will not recruit on tribal lands without first obtaining tribal approval
- Will not share information about participants' tribal affiliation without first getting approval from the tribe.

# All of Us Final Tribal Consultation Report: Brief Summary - Continued

- Support the development of educational materials for researchers and participants, work with AI/AN researchers in partnership with AI/AN communities, and promote community-based participatory research.
- Work to ensure representation of AI/AN populations throughout all aspects of program governance.
- Give all self-identified AI/AN participants a chance to learn more about the tribal consultation and speak with their tribal leaders so they can decide whether they want to stay involved before we share any AI/AN data or samples for research.

**When research is on tribal sovereign lands, the process and requirements are mostly clear...**



**And the principles of IDS  
apply across all  
contexts, however...**



**How is IDS implemented  
when off tribal lands and  
AI AN are from many  
tribe**

**Opportunities for Leadership!**

# Will always defer to tribal law and policy....

- How is this implemented?
  - What is the process for obtaining research approval off tribal lands?
- Clarify how to seek approval
  - Health and Community Centers do not have authority derived from sovereignty
  - Currently no process or infrastructure to seek approval from multiple tribes with differing perspectives
    - Potentially introduces a barrier for individuals to participation in research
  - How proceed when laws, policies and infrastructure for research are at different stages – and are different - among tribes?



# Other Questions

- Identification
  - Self-identification and/or verify tribal enrollment?
    - Mark data as self-identified?
- Policies around collecting tribal affiliation?
  - Only with tribal approval? Must be collected? Must be verified?
- Who enforces tribal policies?
  - The NIH? Or tribes?
- How does the intersection of tribal authority and individual autonomy relate to research consent and sharing of data?

# Developing processes to ensure appropriate research engagement

- Working trans-NIH to develop a solution
- Learning from All of Us and other research programs
- Developed the NIDA AI/AN Collaborative Research Engagement Workgroup (CREW)

# Support and Tools Needed

- Guidance document (with Tribal Consultation) on AI/AN research and data ownership/sharing
- Ethics statement for all public use datasets drawing attention to unique factors to consider for AI/AN data?
- Trainings or courses on collection and use of AI/AN data?
  - E.g., NCAI board game on research decisions
- Consent forms: Practices that acknowledge tribal sovereignty and individual autonomy
  - Also address sharing of data

# Support and Tools Needed, Continued

- Specific recommendations for when collecting data off tribal lands
  - When AI/AN are the focus
  - When a large number drawn into the sample
  - When a low number drawn into the sample
- Tribal listening sessions and consultations on how to proceed across research programs/studies

What does IDS and community engagement look like in each of these contexts?

# Principles for AI AN research and AI AN Data use?

- Consider principles as perhaps better than policies right now, because contexts vary significantly
- What principles should be included?
  - Protect and Benefit
  - Data in service to tribes and AI/AN people
  - Community Engagement
  - IDS Strategies

# NIH TRIBAL CONSULTATION ON DATA MANAGEMENT & SHARING

## Tribal Consultation Themes that could inform Principles

- **Facilitate relationships built on trust between researchers and Tribal Nations**
- **Train researchers to responsibly and respectfully manage and share American Indian/ Alaska Native (AI/AN) data**
- **Ensure research practices are aligned with the laws, policies, and preferences of AI/AN community partners**

**All of Us**  
RESEARCH PROGRAM

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## ***All of Us* Research Program Releases Final Tribal Consultation Report**

<https://allofus.nih.gov/all-us-research-program-tribal-consultation-final-report>

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# AMERICAN INDIAN AND ALASKA NATIVE RESEARCH IN THE HEALTH SCIENCES:

*Critical Considerations for the  
Review of Research Applications*

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[https://dpcpsi.nih.gov/sites/default/files/Critical\\_Considerations\\_for\\_Reviewing\\_AIAN\\_Research\\_508.pdf](https://dpcpsi.nih.gov/sites/default/files/Critical_Considerations_for_Reviewing_AIAN_Research_508.pdf)





Thank you!  
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