PROTECT & BENEFIT:
Ethical Considerations at the National and Tribal Levels for Research Involving Tribal Peoples

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Introduction
Agenda & Session Objective

1. Overview of NCAI and the PRC
2. Federal research policy update
3. Tribal research policy and partnership
4. Tips for researchers

At the end of this session, you will be able to:

- describe the ethical, cultural, and contextual considerations important for tribal research policy.
Overview of NCAI and the PRC
National Congress of American Indians (NCAI), est. 1944

- Serves broad interests of tribal governments and communities
- Representative congress of AI/AN tribes
- Protect and enhance sovereign and treaty rights while securing our traditional laws, cultures, and ways of life
- Advance a common understanding of the rightful place of tribes in the family of American governments

[Logo of NCAI]

[Website Link: www.ncai.org]
NCAI PRC

NCAI Policy Research Center (PRC), est. 2003

• **Mission:** Provide tribal leaders with the best available knowledge to make strategically proactive policy decisions in a framework of Native wisdom that positively impact the future of Native peoples

• **Vision:** Supporting Indian Country in shaping its own future

[www.ncai.org/](http://www.ncai.org/)
The PRC Team

Yvette Roubideaux, MD, MPH, serves as the new Director of the Policy Research Center

Deana Around Him, DrPH, ScM, serves as the Postdoctoral Research Fellow

Amber Ebarb, MPP, has served as the Budget & Policy Analyst since 2003

Sarah Cline Pytalski, MPP, serves as the Policy Research & Evaluation Manager

Natasha Anderson, JD, serves as the Native Youth Strategy Coordinator
Current Projects

- **Grant funded projects**
  - Building Tribal Capacity for Data Intensive Research (NSF)
  - Implementation of National Tribal Behavioral Health Agenda (SAMHSA)
  - Supporting scholars conducting research on diabetes (NIH/WUSL CDTR)
  - Disseminating best practices in tribal-academic research partnerships (NARCH)
  - Disaggregating AIAN data to map outcomes and develop policy priorities (RWJF)
  - Hosting workshops that build tribal research capacity and oversight (NIH/CRCAIH)
  - Building systems of support for Native youth (W.K Kellogg Foundation)
  - Diabetes prevention with Native youth in Boys & Girls Clubs (IHS)

- **Other activities/resources**
NCAI PRC

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Fulfilling the Mission

Data on the problem + Data on solutions, policies + Political players take action = Policy change

Adapted from Kingdon, J. Agendas, Alternatives and Public Policies, 2nd ed. 1995
Fulfilling the Mission

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NCAI
PRC
CRCAIH Partnership

NCAI Policy Research Center

Mission: Provide tribal leaders with best available knowledge to make strategically proactive policy decisions in framework of Native wisdom that positively impacts future of Native peoples.

Collaborative Research Center for American Indian Health

Mission: Bring together tribal communities and health researchers, with a goal to build research infrastructure and transdisciplinary teams to improve health through focus on social and environmental influences on health.

Culture, Science & Bioethics Core

Mission: Facilitate ethical research that meets cultural and contextual needs of communities by bridging traditional, western/academic, and policy sciences.

CSBC Fellowship
CRCAIH Structure

Goal: Address Social Determinants of Health through Transdisciplinary Collaboration

Around Him, D. and Elliott, A. (2016, June 29). Data Access & Management: Understanding the Landscape and Fostering a Climate of Meaningful Research Data for Tribes. NCAI Mid-Year Conference. Spokane, WA.
## CRCAIH Tribal Partners’ Oversight Structures

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CRCAIH – www.crcaih.org
Federal Research Policy Update
The Common Rule & NPRM

- **Federal Policy for the Protection of Human Subjects**
  - Published in 1991
  - HHS Codification: 45 CFR 46
    - Subpart A: Federal Policy, “Common Rule” covers IRB provisions, informed consent, compliance

- **Advance Notice of Proposed Rulemaking (ANPRM)**
  - Released July 22, 2011
  - Requested comment on ethics, safety, and oversight of human subjects research

- **Notice of Proposed Rulemaking (NPRM)**
  - Released Sept. 8, 2015
  - Revisions aim to “modernize, strengthen, and make more effective”
  - 519 pages, 88 formal questions
  - 90 day public comment period

The Common Rule & NPRM

Significant Changes Proposed to the Common Rule in the NPRM*:

1. Improved informed consent
2. Broad consent for secondary use of stored biospecimens
3. Exclude certain categories of activities deemed non-research or for non-research purposes, or inherently low-risk and protected under separate mandate
4. Add categories of exempt research and a new process to determine exemption without administrative or IRB review
5. Change conditions and requirements for waiver or alteration of consent
6. Mandate use of a single IRB, with certain exceptions
7. Eliminate continuing review requirements for studies that undergo expedited review and studies that have completed interventions and are analyzing data
8. Extend scope to all clinical trials, regardless of $ source, at US institutions that receive federal $ for human subjects research

The NCAI PRC Approach

- Submit comments on behalf of NCAI
  - Build on ANPRM & NIH Genomics Data Sharing Policy comment submissions
  - Identify revisions relevant to tribal research contexts

- Raise awareness
  - Comment Resource & Template Letter
  - NCAI Broadcasts, social media, targeted emails
Tensions & Opportunities

Revision Process – Tribal Consultation

Timeline:
• Sept. 8, 2015: NPRM released, 90-day comment period
• Nov. 24, 2015: 30-day deadline extension
• Dec. 21, 2015: Tribal Consultation announced
• Jan. 5, 2016: “Tribal Consultation” conference call
• Jan. 6, 2016: NPRM public comment deadline

“...executive departments and agencies (agencies) are charged with engaging in regular and meaningful consultation and collaboration with tribal officials in the development of Federal policies that have tribal implications...”

–President Obama’s 2009 Memo on Executive Order 13175

Tensions & Opportunities

Revision Process – Timing

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- Limited even with institutional capacity
- Sovereign status of tribes may extend timeline further
- ~10 submissions from tribal bodies (nations, organizations, researchers engaged in tribal research)
- Over 2,000 comment submissions received overall

Tensions & Opportunities

Revision Content:

• Implications: secondary research with biospecimens, data from those no longer alive, role of tribal regulatory bodies, oversight for certain categories of research

• Tensions:
  1. Protections for participants counterbalanced against innovation
  2. Tradeoffs with principles of research ethics
  3. Autonomy rationale coupled with broad consent
  4. Responsibility placed on investigators rather than institutions
  5. Focus on risk rather than benefit
  6. Commitment to tribal consultation
  7. “Majority Rule” orientation
  8. Acceptance of “burden” of consent
  9. Lacking specific language regarding tribal research oversight and approval

The Outcome (so far)

ANPRM → NPRM → Final Rule → Implementation

- July 2011
- September 2015
- January 2017
- January 2018
  - Public Comment
  - Public Comment

The Outcome (so far)

The Outcome (so far) & Implications for Tribes

- Two stand-alone provisions referring to tribal authority:

- This policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects. (§ .101(f))

- Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe). (§ .102(j))

The Outcome (so far) & Implications for Tribes

• Definition of “Research” and activities deemed not to be research:

  • Scholarly and journalistic activities focused on specific individuals
  • Public health surveillance activities by a public health authority, which may be an Indian Tribe, that is responsible for public health matters as part of its official mandate.
  • Collection of information for criminal justice purposes
  • Operational activities for national security purposes

§_.102(l)
The Outcome (so far) & Implications for Tribes

Informed Consent & Broad Consent

• Additional guidance on the use of broad consent added as well as a statement that:

  “The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.” (§.116(i))

The Outcome (so far) & Implications for Tribes

Requirement for Single IRB Review

- Does not apply to:

  - Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe);
  - Whenever any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

Common Rule – Key Points

• Tribes can develop laws to ensure research benefits and protections beyond individual protections required in federal research policy.

• Tribes should review their current laws related to research and consider updates.

• Questions about the revisions?
  • Email OHRP@hhs.gov
  • Check www.hhs.gov/ohrp for additional resources explaining the revised Common Rule.
Tribal Research Policy and Partnership
Supporting Research Ethics & Partnership

**Tracking Federal Research Priorities**
- Comments in response to the Common Rule revisions

**Research Regulation**
- Curriculum - Research that Benefits Native People: A Guide for Tribal Leaders
  1. Foundations of Research: An Indigenous Perspective
  2. Managing the Design and Planning of Research
  3. Ethics as a Guide for Managing Research
  4. Conducting Research with Others
  5. Understanding Evaluation
- Walk Softly & Listen Carefully: Building Research Relationships with Tribal Communities

**Research Partnerships**
- Strengthening Tribal-Academic Research Partnerships
How do tribal values apply to research?

- The Raven & Whale

- **Tribal values can:**
  - Serve as guides in a complex research context
  - Help to choose research projects that serve your tribe’s needs
  - Provide a foundation for research projects
  - Give stability and direction in complicated decisions
  - Set terms for partnership
Five Proposed Values for Tribes

1. Indigenous knowledge is valid and should be valued.

1. Research is not culturally neutral.

1. Responsible stewardship includes the task of learning how to interpret and understand data and research.

1. Tribes must exercise sovereignty when conducting research and managing data.

1. Research must benefit Native people.
Ethical Codes

• Guiding principles from the Belmont Report
  • Respect for Persons (autonomy)
  • Beneficence (do no harm)
  • Justice (equal distribution research burden)

• People or Peoples?
  • Known cases of community harm in the southwest and Alaska

• Tribal Leader & Community Considerations
  • Akwesasne Task Force on the Environment (ATFE) Example
Partnership Principles

Keep in mind the five core values and ask would the prospective research partner:

• Value Indigenous knowledge and consider it valid?

• Be understanding and respectful of the Native peoples, cultural knowledge, and traditions?

• Work to understand and protect tribal interests in the research?

• Acknowledge the role of tribal sovereignty in all his/her activities?

• Ensure that the outcomes of the research are dedicated to benefiting Native people?
Tips for Researchers
Strengthening Research that Benefits Youth

Tribal Populations

Youth (prenatal to 24 yrs)
- 42% of total US AI/AN population
- 50% of some state AI/AN populations

Research Lifecycle

- Ideas
- Partners
- Proposal writing
- Research process
- Publication

Data Lifecycle

- Create
- Process & analyze
- Give Access
- Re-use
- Preserve

1 Adapted from: https://www.jisc.ac.uk/guides/implementing-a-virtual-research-environment-vre
2 Adapted from: http://www.bu.edu/datamanagement/background/whatisdata/
Affirming Native Youth: Making Visible, Making Valuable Project

Aims

• Create space for Native youth leaders to convene, set an agenda, learn, and network.

• Expand partnerships to ensure the collection and reporting of data on the status and experiences of Native youth; and

• Train Native youth and others involved with developing policies and practices that affect them to do so in a coordinated and effective manner.

Resource Components

• Centering Youth Voices
  • Youth are a treasured part of relationship-drive, interconnected networks

• Engaging Tribal Communities
  • Acknowledge community variation in infrastructure, norms, methods/approaches, and recruitment strategy

• The Power of Place-based, Small-scale Inquiry
  • Inquiry-driven, context-specific, small-scale efforts make contributions to immediate local change

• Expanding to Urban & National Settings
  • Complement rather than replace

Ethical Considerations

- **Confidentiality**
  - Protection of individual and, if desired, community privacy

- **Consent**
  - Role of kinship/extended family care; age of consent preferences

- **Referral Context**
  - Identification of service needs outside of study or in limited resource setting

- **Law & Jurisdiction**
  - Differences in state/tribal mandatory reporting laws; determination of oversight authority

- **Study Design**
  - Reluctance around certain designs in high-need settings

- **Sustainability**
  - Assurance when resources and human capital are limited; obligation?
Take Aways for Researchers

• **No one-size-fits-all approach to research with Native youth**

• **Wise practices include:**
  - Centering youth voices
  - Fostering relationships with youth and communities
  - Celebrating diversity of each context
  - Building mechanisms to understand shared strengths and needs across contexts
  - Committing to ethical approaches that account for needs of Native youth and communities

• **Researchers and communities have a role in strengthening research that benefits Native youth**

Wrap Up
Closing Points

- Progress has been made in federal research policy revisions, but we have to continue to engage in the implementation process.

- Tribal research oversight infrastructure and capacity is a mechanism for ensuring benefit and protection for tribal individuals and communities.

- Research involving AI/AN youth requires special ethical considerations.
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Thank You!