American Indians and the Institutional Review Boards

“A Tribal Governance Perspective”

Phillip L. Smith, M.D., MPH
Indian Health Service

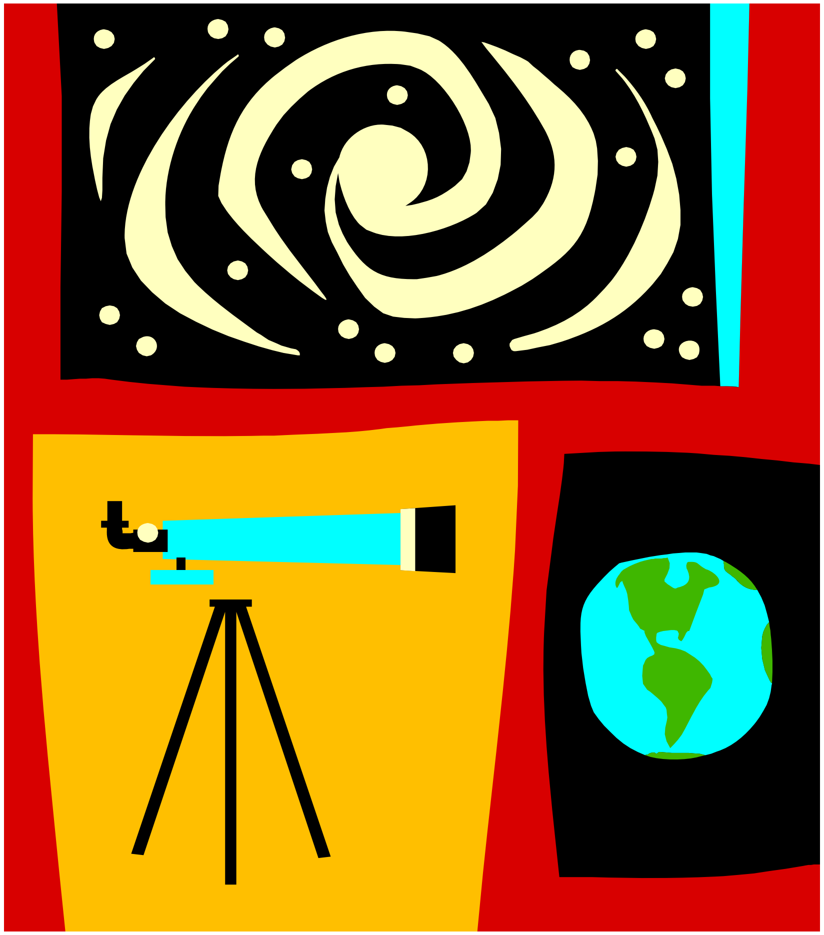
Wars, Conquest, Governance have influenced the Indian world

- **First Congress established Indian Health office in Dept of War**
- **Indian Wars – 471 treaties signed thru 1890**
- **Moved to Department of Interior 1849**
- **Indian Wars end 1890**
- **World War I**
- **Citizenship 1934**
- ***WW II - 1940's /Nuremberg***
- **Transfer Act 1955**
- **AI/AN Self-determination legislation 1970-2012**

AI/AN Experience is Different than other US Population

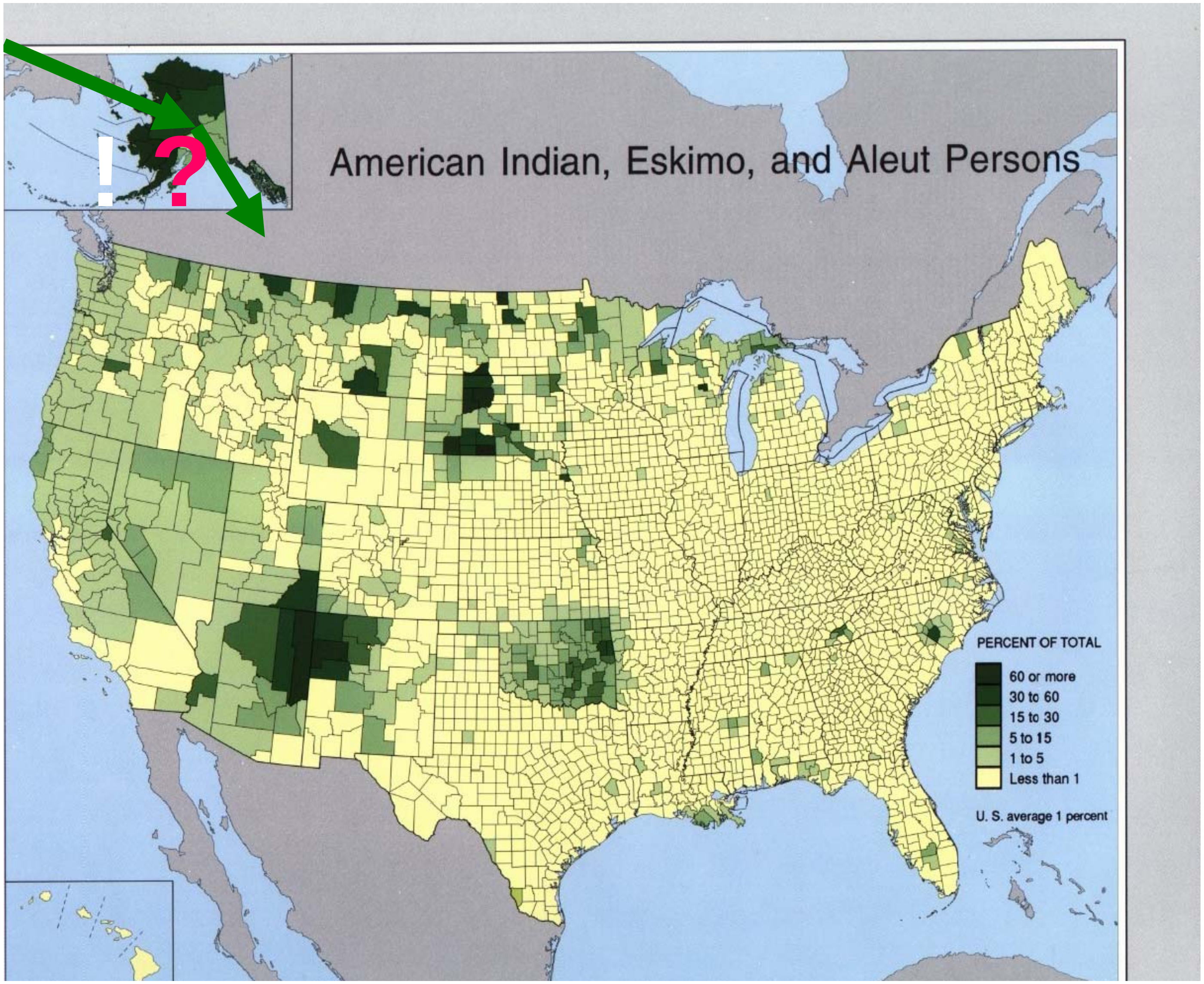
- **Historical trauma :** Colonization, forced separation of parents and children, Relocation, Boarding Schools, Termination, Assimilation, acculturation
- **Heterogeneity**:

Socio-Cultural and linguistics challenges in studies



American Indians and Alaska Natives (AI/AN)

Approximately 566 sovereign Tribes, each with distinct



- tradition
- language
- migratory history
- geographic distribution
- population size
- gene flow, and
- culture

Research INFLUENCES for Good or Bad

- **Language - Communication**
- Culture
- Diverse tribal Experiences
- Resources

Prejudices and Past Breeches of Trust (1)

Contribute to Native Peoples' Concern for the

Safety of Research Participants

Uncertain of adequate protection from potential physical, emotional, mental financial and/or social harm posed by research activities, including community stigmatization.

Uncertain of participants' understanding of the extent of participation, e.g. is consent "informed"?

- due to basic literacy and health literacy level of participants

- due to unfamiliarity with research language

Concern that participants with few financial resources may be lured by incentives, e.g. subject entrapment

Prejudices and Past Breeches of Trust (2)

Contribute to Native Peoples' Concern for the

Privacy of Research Participants

Perceived lack of respect for individual privacy

Perceived lack of respect for and understanding of cultural knowledge

Concern that individual and group identity will not be protected

Prejudices and Past Breeches of Trust (3)

Contribute to Native Peoples' Concern that Researchers

will not respect Cultural and Tribal Integrity

Research process often focuses on deficits and problems, not strengths, assets or resilience

Research results often are not applied, "put into action," do not directly benefit the people or aren't even reported back to the Tribe

Non-Native interpretation of research outcomes can misrepresent people's behaviors and may lack a ppropriate context

Unauthorized public dissemination of research can perpetuate negative stereotypes (group harm)

Undisclosed uses of information and samples collected from Native participants has led to data interpretation that conflicts with and disrespects traditional Tribal cultural knowledge

Certain samples must be returned to the subject or family for proper disposition and not just destroyed after the researcher is done

A Brief Review of American Indian Healthcare

Doubt cast on Non-Native Sincerity for AIAN Well-being

Initially, Indian health care was under the US Department of War in concern for non-Native soldiers who had contact with Natives.

In 1849, oversight was transferred to the US Department of the Interior that had little experience in health care management.

In 1955, the Indian Health Service (IHS) was established within the US Public Health Service and responsibility for health care and public health services was transferred from the BIA.

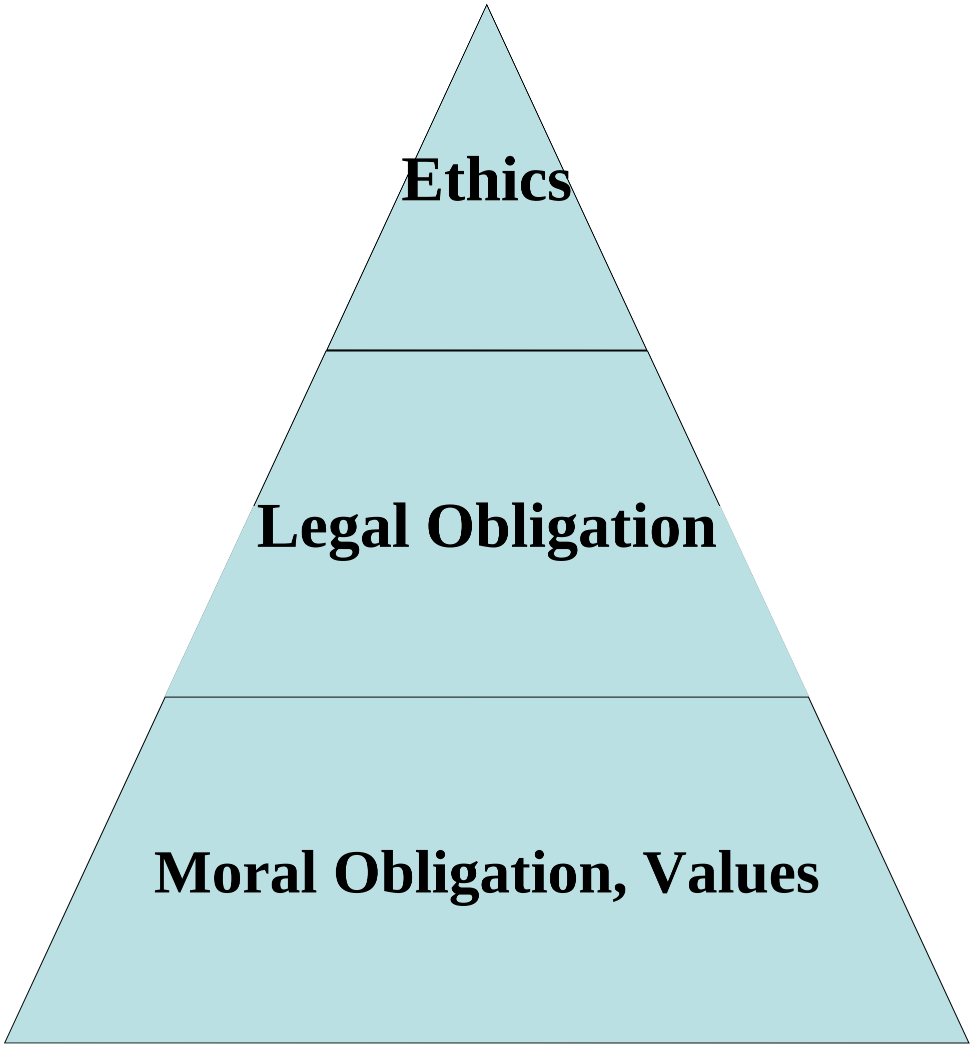
The Indian Health Service did not initiate a formal active IRB approval process until late1980s after it became an agency

Today →Major Changes as new legislation authorized AI/AN Tribes to assume full governance of their health services

Bioethics

- “ The Systematic study of the moral dimensions – including moral vision, decisions, conduct, and policies – of the life sciences and health care employing a variety of ethical methodologies in an interdisciplinary setting “

Protection of Human Subjects



Ethics

Legal Obligation

Moral Obligation, Values

Protections of Human Subjects

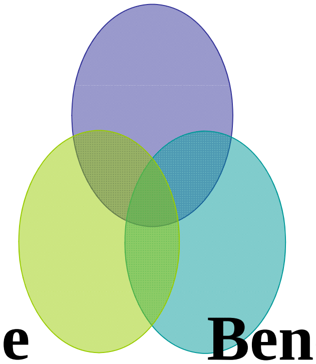
- Assessment of Risk to subjects
- Adequacy of protection against risks
- Potential benefit
- Importance of knowledge gained

Goals of IRB

1. Protect the Human volunteer involved in research activity by:
    - Minimizing potential risk
    - Maximizing potential benefit
    - Understanding the protocol
2. Ensure compliance of all regulations governing research
    - Ensure consent process fully informs volunteers
3. Assist in promoting good research
4. Provide accurate documentation of actions taken to insure full intent of 45 CFR 46

The Belmont Report

3 basic principles



Respect for Person

Justice

Beneficence

RESPECT FOR PERSONS

1. Individuals are treated as autonomous agents capable of deliberating about personal goals and acting under direction of such deliberations

2. Have a requirement to protect those with diminished autonomy

BENEFICENCE

- **Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being.**
- **“Do unto others as you would have them do unto you.”**

JUSTICE

- **The Coordinated sharing of BURDEN and pooling of the BENEFITS of research;**
  - **Distribute the risks and potential benefit of research equally among those who may benefit from the research.**

Native Nation Sovereignty and Research Activities

1) Tribes have the legal right to stop research activities; their reasons do not have to be disclosed to an outside party.

2) Tribes have the legal right to request that research activities and outcomes conducted within their jurisdiction or with reference to their community are not disclosed in oral or written form.

3) Tribes have the legal right to request exclusive ownership of research data.

4) Tribes have the right to say no.

5) Tribal Nations have sovereign Immunity for activities within their borders.

Data Collection, Use, Storage, Ownership, & Access

1) Native nations have inherent rights to control and determine their proprietary interests in the collection, use, storage, access and potential future use of data collected within their jurisdiction.

2) Collection, use, storage and future use need to be specified in the research agreement

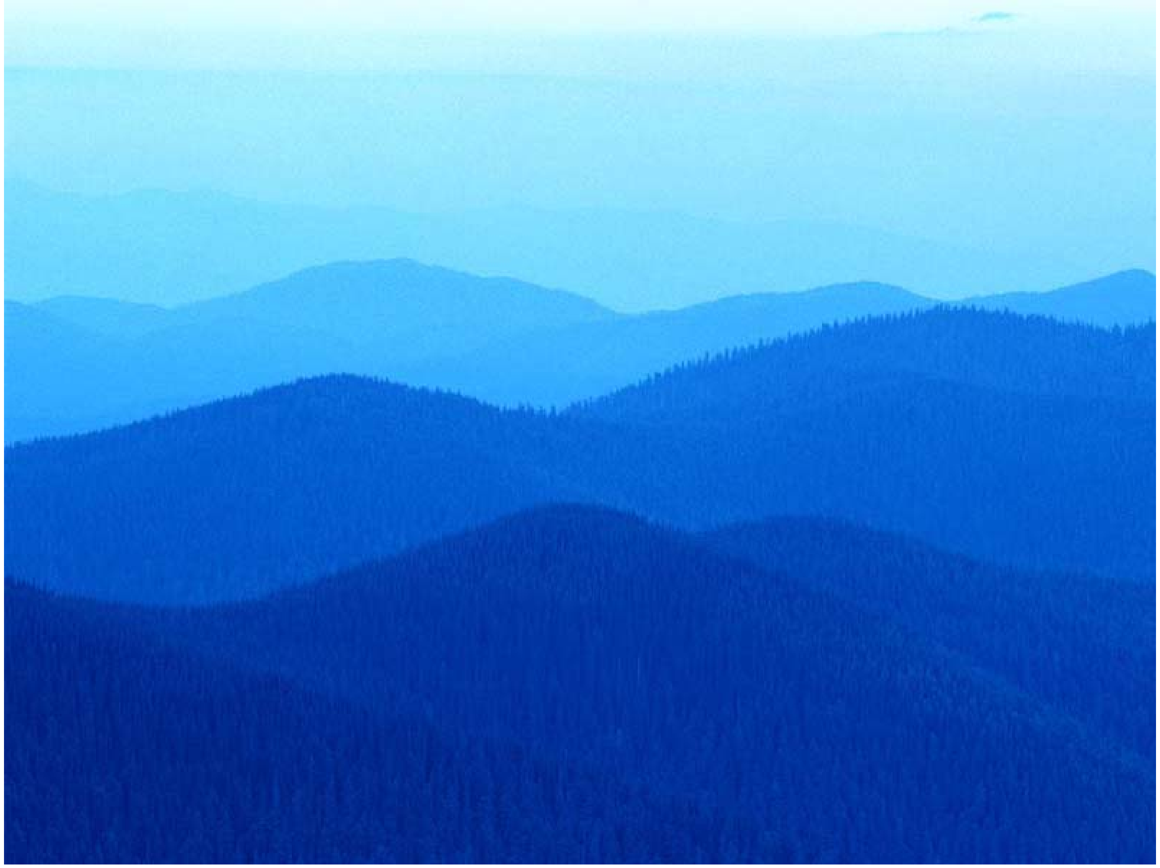
3) Secondary use of the data (including biological samples) or data use by a party not identified in the research agreement

–will need approval from approving body that awarded the initial approval

–Will need approval even if data are de-identified

Success in Applications

- Vaccine Trials
- Innovative service delivery systems
- Health Services research



QUESTIONS ??????