

# Objectives:



8. Discuss the history of AI/AN human subjects protections
9. Discuss the limitations of current federal regulations and research processes
10. Identify the IRB and investigator responsibilities for approval of research

IRB = Institutional Review Board



Objective 8:

Discuss the history of AI/AN  
human subjects protections

# Who are the AI/ANs?

Inhabitants of the new world for more than 12,000 years



- History
- Tradition



- Language

- Culture

- Geographic location

- Population size

- Gene flow

- Values



# Who are the AI/ANs?

- Unratified treaties
- Colonization
- Religious persecution
- Boarding schools
- Termination
- Relocation
- Sterilization



## COME TO DENVER

THE CHANCE OF YOUR LIFETIME!

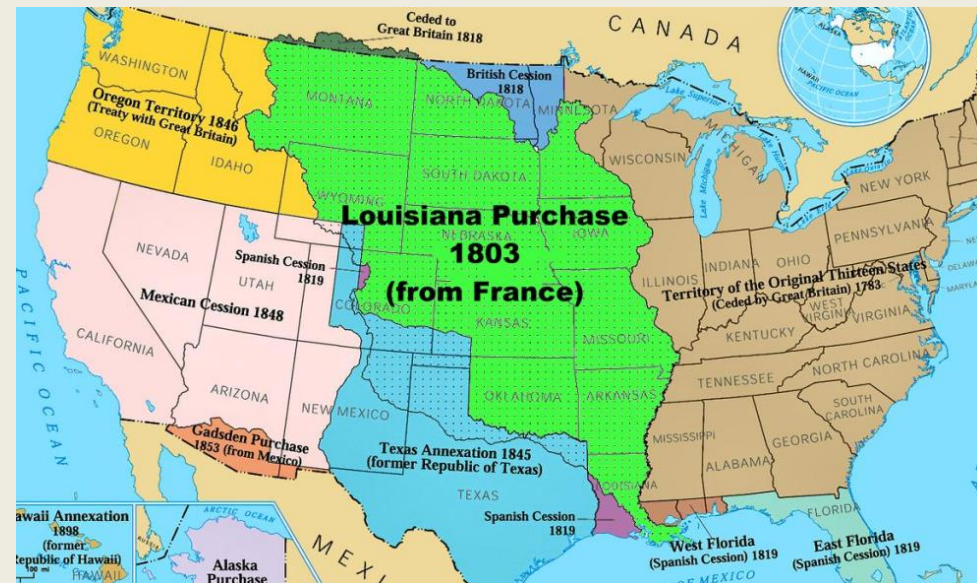
**Good Jobs**  
 Retail Trade  
 Manufacturing  
 Government - Federal, State, Local  
 Wholesale Trade  
 Construction of Buildings, Etc.

**Happy Homes**  
 Beautiful Homes  
 Many Churches  
 Existing Community Life  
 Over Half the Homes Owned by Residents  
 Convenient Streets - Shopping Centers

**Training**  
 Vocational Training  
 English, Reading, Spoken English,  
 Reading Instruction, penmanship,  
 Adult Education  
 Evening High School, Arts and Crafts  
 All implemented in home making

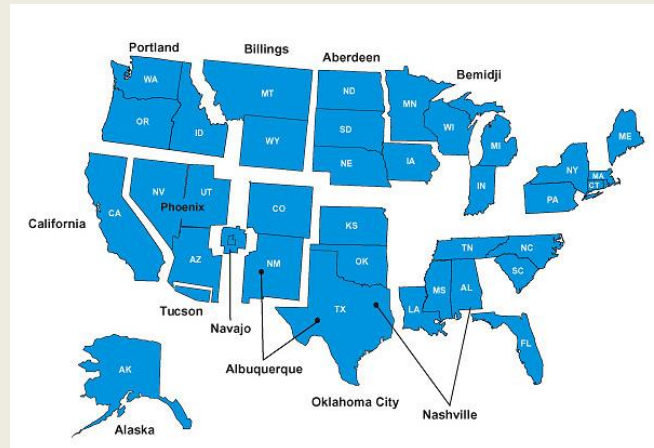
**Beautiful Colorado**  
 "Best" State, 48 Mt. Peaks Over 14000 Ft.  
 350 Days Sunshine, Mild Winters  
 2000 Markets, Mountain Parks, Drive-In  
 Picture Shows, Lakes, Amusement Parks  
 Big Game Hunting, Trout Fishing, Camping

Klamath Termination Act, 1954	
Before Termination	After Termination (1966-1980)
Fewer than 5 tribal members on public assistance.	28% of the Klamath people died by the age of 25, and 52% died by the age of 40.
Tribal member income was 93% of that earned by non-Indians.	40% of all deaths were alcohol-related.
Tribes provided jobs, per-capita payments from timber sales, medical services, land for homes, and revolving loans.	Infant mortality was 2.5 times the Oregon statewide average, and 70 percent of adults did not complete high school.
Klamath Tribes were one of the wealthiest tribes in the nation.	Tribal poverty levels were three times that of their non-Indian neighbors.



# Who are the AI/ANs?

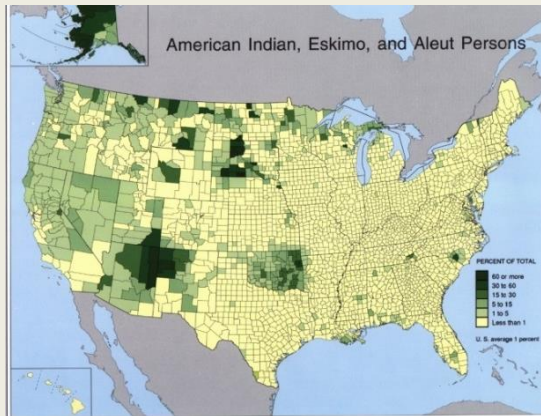
- 566 distinct federally-recognized sovereign Tribes
- According to the United States Constitution, Article I, Section 8, there is a direct Government-to-Government relationship between tribes and the federal government
- Tribes are not subordinate to state governments
- Tribes consult with federal Departments at the Secretarial level, including the Executive Office of the President



# Who are the AI/ANs?



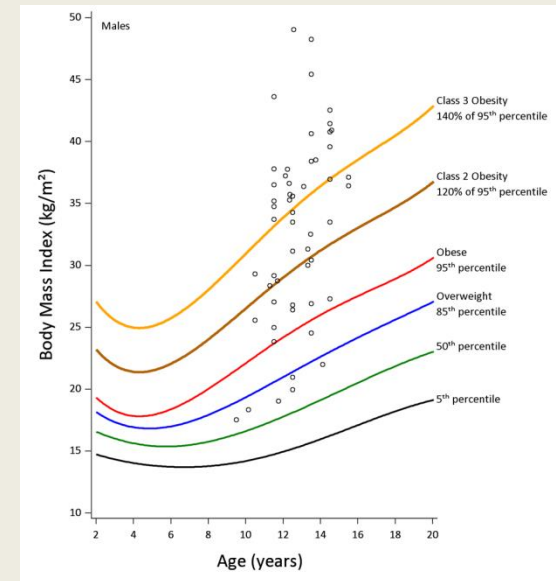
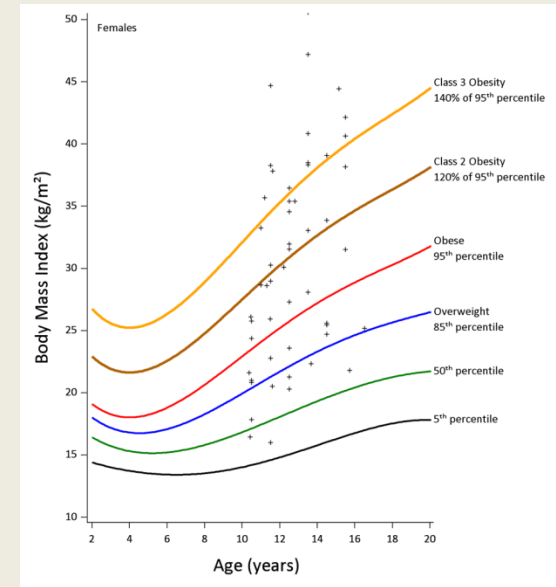
- 4.5 Million AI/AN, 1.5% of the total U.S. population
  - 1491, estimated 50 Million+
- AI/AN median age 30.7 years vs. 36.2 for U.S. All Races
- California has the largest population of AI/AN (696,600), followed by Oklahoma (401,100), and Arizona (334,700)
- Alaska has the highest proportion of AI/AN (20%), followed by Oklahoma and New Mexico (11% each)



# Who are the AI/ANs?

Strong desire for wellness; health a priority

- Underfunded preventive care services
- Limited set budgets for contract health
- Aged and aging facilities
- Recruitment and retention of providers
- Prominent, high risk factors for disease
- High prevalence of disease
- High rates of comorbidities
- Younger age at diagnosis
- Late stage at diagnosis of disease
- High number of years of potential life lost
- Strong role of social determinants



# Human Subjects & Research Considerations

Culture and world view

Relevance of research focus

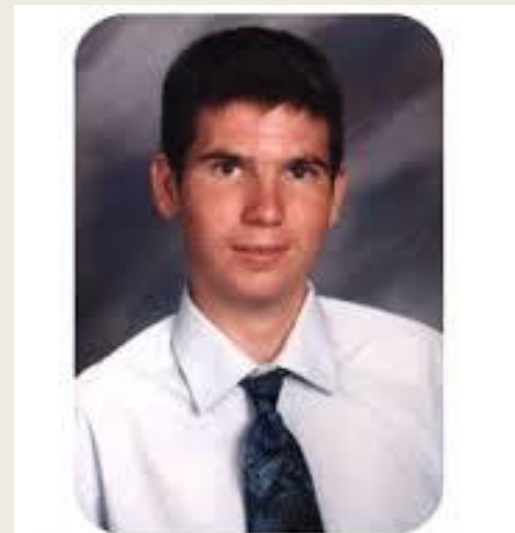
Study design or approach

Privacy and confidentiality

Custodianship and ownership

Future and secondary data uses

# Federal Regulations



Jesse Gelsinger's death from a gene therapy clinical trial in 1999 raised many questions concerning the safety of experimental gene therapy treatments.

# Research Experiences



**BOZEMAN DAILY CHRONICLE**

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## Shane Doyle links Montana tribes, international research into prehistoric boy

Evelyn Boswell | MSU News Service Posted Feb 13, 2014

On a beautiful fall day, Shane Doyle sang a somber song for a young boy who was buried some 12,600 years ago south of present-day Billings.

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**The New York Times** U.S.

WORLD U.S. N.Y./REGION BUSINESS TECHNOLOGY SCIENCE HEALTH SPORTS OPINION

## Indian Tribe Wins Fight to Limit Research of Its DNA

Edmond Tilousi, 56, who can climb the eight miles to the rim of the Grand Canyon in three hours. [More Photos >](#)

By AMY HARMON

department of **GENETICS**

Stanford University School of Medicine

Indigenous Peoples Council on Biocolonialism



1. El virus más contenido en las heces de roedores

2. Las heces infantiles serían, conteniendo en polvo, se transportan por el aire

3. Inhalación de heces por el ser humano

4. Síntomas: dolor de garganta, fiebre, dolor de cabeza y tos

5. Malosher respiratorio agudo

NATIONAL INSTITUTE OF HEALTH

CDC

**Ha-Shilth-Sa**

Canada's Oldest First Nations Newspaper - Serving Nuu-chah-nulth-aht since 1974

Vol. 31 - No. 25 - December 16, 2004 haasitsa "Interesting News"

## Nuu-chah-nulth blood returns to west coast

By David Winkler Ha-Shilth-Sa Reporter

**Akwashit** - After a 20-year journey halfway around the world, hundreds of vials of Nuu-chah-nulth blood have returned home to the west coast. And although many people welcome its return, many remain critical of the system that allowed its return in the first place.

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Dr. Richard (Dick) Wood took 853 vials of blood between 1962 and 1982 under the guise of a \$100,000 health Canada

on the study, I would like to survey every person in Akwashit so that we can be sure exactly who has a problem with rheumatic disease and who needs help." According to Wood's final report, published in 1987, his team of researchers interviewed 1,878 (82%) of all 2,300 adult Nuu-chah-nulth, in 13 different communities and territories living away from home in Port Alifan, Tofino, Nanaimo, and Victoria. Of those surveyed, 482 people (44.7%) were advised to give 30 ml of blood as research could begin on whether there was a genetically inherited aspect to rheumatic disease.

"The Canadian population has the overall prevalence of the order of 1%," Wood described in his project report. "The prevalence rates for rheumatoid arthritis in adult Native Indians are between 7% and 8%," he wrote.

After he failed to find any genetic markers in the DNA, he shelved the study, and that's where things started to go wrong.

"Our family has been hit pretty hard by arthritis," said Akwashit Elder Connie Frank. "It's really, really hard to watch someone you love suffer like that when you can't do anything to help. It's hell."



## Yanomami of Brazil Honor Return of Stolen Blood

Yanomami activists fought to get their blood returned from United States anthropologists who took the samples from Yanomami people in Brazil and Venezuela in the '60s and then sent the samples to the U.S. for experiments without their leaders' consent; the blood was returned recently and then honored in a ceremony in Brazil.

Yanomami leaders returned the blood of their family members to the earth in a ceremony honoring the ancestors on Friday, April 3, a week after finally receiving the thousands of blood samples from U.S. universities that held the blood for the last several decades.

# Research Experiences



**BOZEMAN DAILY CHRONICLE**

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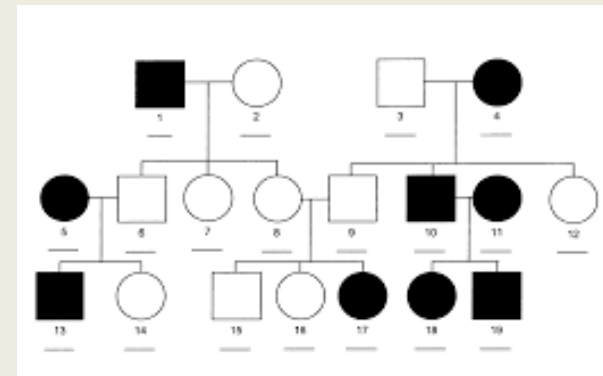
# Protecting the rights and welfare

- Culture and tradition where community and family decisions trump individual autonomy and decision
- Recognizing tribes as experts – risks, benefits
- Relevance of the research within the context of competing research needs and responsibilities
- Understanding the boundaries of world views
- Existing intra- and inter-tribal and family relationships and understandings



# Risks and Benefits from the American Indian Perspective

- Established origin stories
- No separation between the physical, spiritual, psychological entities – being is seen as a whole
- Continuum from present life to after life and the need to keep physical being intact
- Established disease and illness explanations



Objective 9:

Discuss the limitations of  
current federal regulations  
and research processes

# Federal Regulations

- **Tribal Sovereignty – review and approval**
- **45 Code of Federal Regulations (CFR) 46, Subpart A**
  - Permits consent of participants to future unspecified research
- Is this **human subjects** research? **45 CFR 46.102(f)**
  - A *living* individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.
- **21 CFR Parts 50 and 56**
  - Informed consent; therapeutic misconception; single commercial IRBs
- **Proposed changes to federal regulations**
  - Deferral; single IRBs of record
  - Broadening of exempt research categories and interpreters

# Federal Regulations

- **Risk:** Minimal Risk generally means that the probability and magnitude of physical or psychological harm anticipated in the research are not greater in and of themselves than those *ordinarily encountered in daily life*, or in routine medical, dental, or psychological examinations.
- Determination of risk level –
  - **Exempt** – below minimal risk (category specification), 1-2 IRB member review
  - **Expedited** – at or slightly above minimal risk (category specification), 1-2 IRB member review
  - **Full** – more than minimal risk, full committee review



Objective 10:

Identify the IRB and  
investigator responsibilities  
for approval of research

# Basic Elements of Respect

- Respect tribal culture and traditions
- Respect tribal sovereignty and self-determination
- Respect concerns and opinions of community
- Respect local research priorities and needs
- Respect individuals, families, and communities
- Demystify research

# Basic Elements of Respect

- Respect human participants' rights and dignity
- Respect a tribe's right to decline participation
- Respect the autonomy and decisions of the tribe
- Respect the tribe's time, be accessible
- Respect communication, provide feed-back and findings in a timely manner

# Basic Elements of Responsibility

- Ensure understanding and good communication regarding all aspects of the proposed research
- Communicate and coordinate with tribal leaders
- Maximize benefits and minimize risks
- Protect human participants and sensitive data
- Comply with informed consent process
- Obtain service unit director, tribal, IHS research committee, and IRB approval

# Basic Elements of Responsibility

- Do not begin research until all approvals are obtained
- Share results of the research with the tribes
- Protect participant and tribal identity
- Build capacity within the community
- Comply with the agreed-upon protocol specifications
- Comply with tribal and IHS publication clearance



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