



IHS and Tribal Institutional Review Boards (IRBs) in the Oklahoma City Area

“A dialog on structure and process”

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OCA-IHS IRB**

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Chickasaw Nation IRB
Choctaw Nation IRB**

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Choctaw Nation IRB**

Objectives

- 1. To provide a brief overview of the history of the IHS and Tribal IRBs.**
- 2. To review the current processes of the IHS and Tribal IRB for research.**
- 3. To understand how IHS and Tribal IRBs in the Oklahoma City Area work together and independently.**

Mission of the IRB

- To help researchers conduct important human subjects research in a way that protects the rights & welfare of research participants.
- The IRB must determine that all of the criteria in 45 CFR 46.111 are satisfied by the investigator along with relevant principles from the Belmont Report.

Do We Need an IRB Review?

- IRB Jurisdictions in the OCA (IHS or Tribal)
 - IHS/Tribal/Urban (ITU) health facilities
 - ITU personnel
 - Individuals identified through ITU programs
 - Programs that receive 638 contract funds
 - Programs that receive regular consultation from ITU personnel
- Other IRB's may be IRB of record
 - i.e. Universities

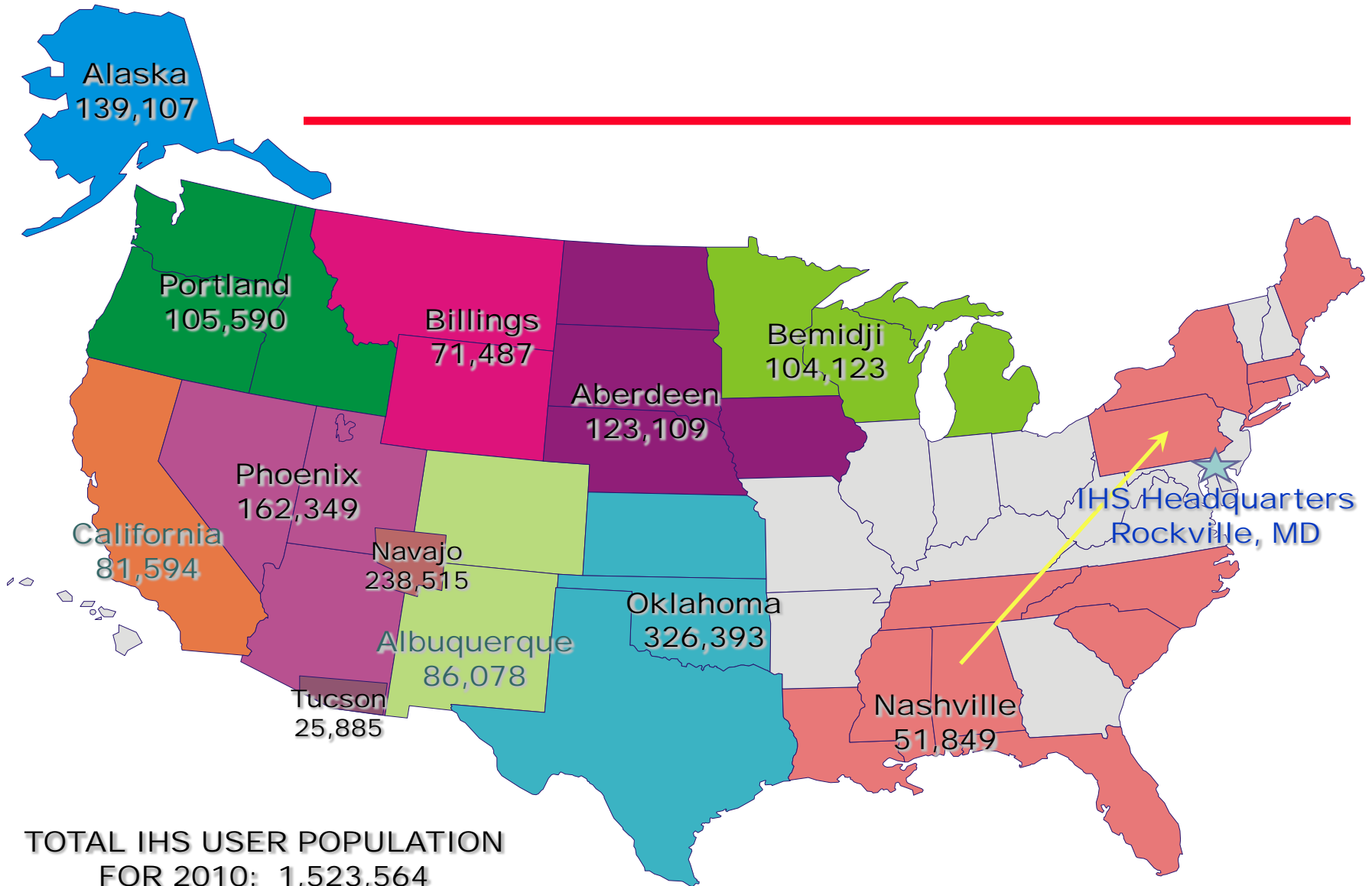




Real Diversity Among the
Many Native Tribes and
Communities



INDIAN HEALTH SERVICE USER POPULATION BY AREA



Types of Ethical Violations in History

- Lack of Informed Consent
- Failure to Evaluate the Risks and Benefits of Research
- Withholding Effective Treatment
- Harming Individuals or Placing Them at High Risk for Harm
- Taking Advantage of Vulnerable Populations

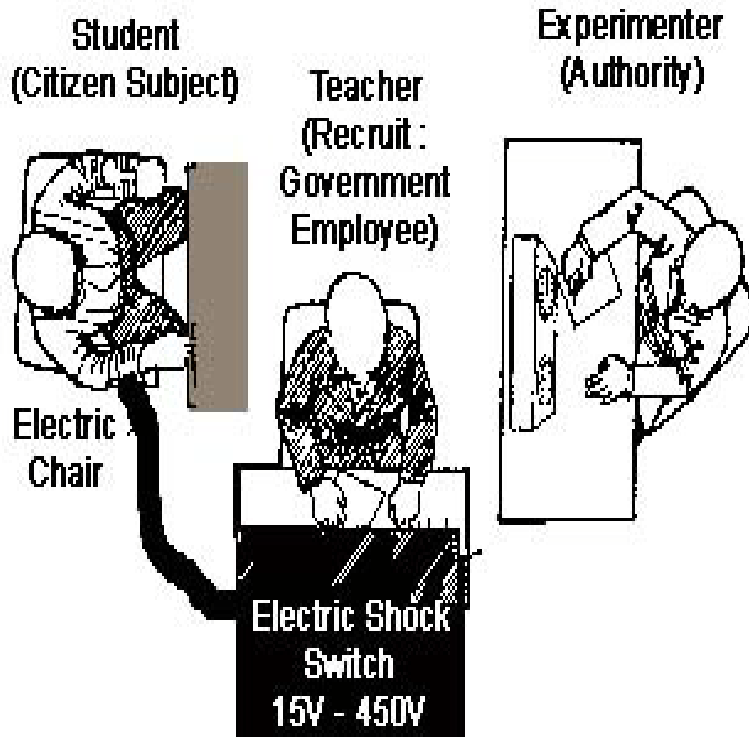
Examples of American Indian,
other minorities and famous
experiences with research...



Nazi Experiments Nuremberg Trials



Milgram Experiments Willowbrook Institute



Macon County Health Department

ALABAMA STATE BOARD OF HEALTH AND U.S. PUBLIC HEALTH
SERVICE COOPERATING WITH TUSKEGEE INSTITUTE

Dear Sir:

Some time ago you were given a thorough examination and since that time we hope you have gotten a great deal of treatment for bad blood. You will now be given your last chance to get a second examination. This examination is a very special one and after it is finished you will be given a special treatment if it is believed you are in a condition to stand it.

If you want this special examination and treatment you must meet the nurse at _____ on _____ at _____ M. She will bring you to the Tuskegee Institute Hospital for this free treatment. We will be very busy when these examinations and treatments are being given, and will have lots of people to wait on. You will remember that you had to wait for some time when you had your last good examination, and we wish to let you know that because we expect to be so busy it may be necessary for you to remain in the hospital over one night. If this is necessary you will be furnished your meals and a bed, as well the examination and treatment without cost.

REMEMBER THIS IS YOUR LAST CHANCE FOR SPECIAL FREE TREATMENT. BE SURE TO MEET THE NURSE.

Macon County Health Department

Tuskegee Havasupai



This letter is reproduced from an educational website at the University of Illinois's Poynter Center for the Study of Ethics and American Institutions (<http://poynter.indiana.edu/sas/lb/facts.html>.)

A Brief History of Human Subjects Protection Regulations

- **Nuremburg Code (1945-1949):** First true human protections came into play after Nazi experiments - basis for all protections and all IRBs do.
- **45 CFR 46 (1974):** DHHS established regulations for Protection of Human Subjects of Biomedical and Behavioral Research (45 C.F.R. 46), including the establishment of IRB review procedures. “The Common Rule”.
- **Belmont Report (1979)**



The Belmont Report (1979)



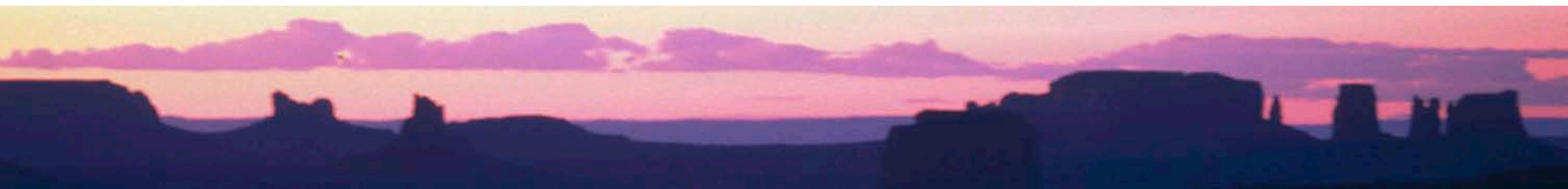
1. Respect for Persons

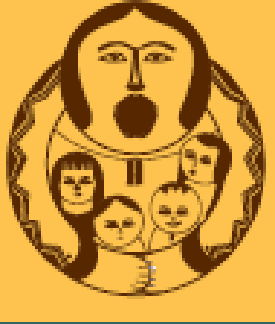


2. Beneficence



3. Justice





RESPECT FOR PERSONS

Rules derived:

1. Informed consent
2. Respect privacy & confidentiality
3. Consider additional protections for limited autonomy



BENEFICENCE

Rules derived:

1. Use procedures of least risk (benefits outweigh risks).
2. Gather data from procedures/activities already being performed for non-research reasons.
3. Requirement to maintain confidentiality.
4. Requirement to monitor data to ensure the safety of subjects (for greater than minimal risk of harm).



JUSTICE

Rules derived:

1. Requirement to select subjects equitably.
2. Requirement to avoid exploitation of vulnerable or convenient populations.

IHS or Tribal IRB Review Responsibility?

- IHS (National and Area) acceptance of decisions of Area/Tribal IRBs.
- If it is in Tribal Jurisdictional Area, falls under Tribal IRB, if one exists.
- For Area IHS IRB - secondary review of of all protocols (at national level IHS IRB) with:
 - High Risk
 - Unproven Clinical Therapeutic trials
 - Efficacy of new pharmaceutical products
 - Request by investigators or by research volunteers
 - Multiple Area cross-over of projects

IHS/Tribal IRBs in Oklahoma City Area

- Oklahoma City Area IHS IRB
- Cherokee Nation IRB
- Chickasaw Nation IRB
- Choctaw Nation IRB
- Creek Nation IRB



Federal Wide Assurances

IRB Purpose

1. To determine if benefits outweigh risk to subjects who participate in the research
 - Assessing risk of psychological/physical harm
2. To ensure investigators have explained issues so and assure informed consent.
 - Child & adolescent assent with parental consent
 - Right to refuse participation
 - No coercion to participate
 - Tribal IRBs have the added responsibility to protect the unique culture of the tribes they represent.



IRB Submission Process

- OCA-IHS submissions go to julie.erb-alvarez@ihs.gov & require:
 - Tribal leadership approval
 - Facility CEO approval
 - Protocol
 - Grant application
 - Consent document
 - Feel free to call first to discuss: 405-951-3946
- Difference in Tribal IRBs?



IRB Review Process

1. Researcher submits protocol, assent/consent forms and application.
2. IRB reviews.
3. IRB requests clarification/revisions to assent/consent procedures and forms – typical (requests for clarification/revision of protocol are also possible).
4. IRB approves project once human subjects concerns have been fully addressed by investigator.



IRB Review Process

- Determinations include:
 - Exempt, expedited, Full board review
- Reviews occur within 3 months



IRB Composition

- Minimum of 5 members
- Quorum to vote
- 1 non-scientific member (must be at meeting)
- Scientist member
- 1 unaffiliated member
- Meets as needed to conduct business
- Qualifications
 - Racial diversity/cultural diversity
 - No IRB may consist entirely of one profession
- Expert consultant



Presentation and Publication Committees

- Presentations or publications based on research approved by the IRB(s) must also be approved by the same IRB(s) or by the Publication Review Committee.
- Applications for publication/presentation approval with findings about specific Tribes must be accompanied by approval from the relevant Tribal government(s), even if the Tribes are not named in the manuscript.



Thank You!

LCDR Julie A. Erb-Alvarez, MPH

Area Epidemiologist

Institutional Review Board Co-Chair

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