Overview of Presentation

- Institutional Review Board (IRB)
  - Definition, History & Codification of Requirements
- Functions of an IRB
  - Types of Institutions, Requirements & Composition
- Tribal Review and Approval Processes
  - Ethical principles include community and cultural protections
- Tribal Cultural, Community, and Data Protections
  - ITCA Tribal IRB Guiding Principles

World Wide Ethical Guidance

- **Nuremburg Code**: Came about in the aftermath of the Nuremburg War Crimes Trial after WWII. **Voluntary Consent** of the human subject became “absolutely essential.”
- **Declaration of Helsinki**: Built upon the Nuremburg’s Code, took the first 10 codes and tied them to the Geneva Convention of 1948. However, “absolutely essential” was changed to “if at all possible.”
- **Belmont Report - 1978**: Established in the United States three ethical principles: (1) Respect for Persons, (2) Beneficence, and (3) Justice. This Belmont Report is the foundation of all Federal IRBs in the United States.

Definition of a Federally Registered IRB

- An Institutional Review Board is a designated group of people empowered to:
  - Protect the rights and welfare of human participants in research by-
    - Initial and continuous review of research proposals according to the ethical principles outlined in the Belmont Report (FR.979)
    - Ensuring research activities comply with federal regulations (CFR 45 part 46, 1991).
- These Federal IRB regulations, enacted in 1974, are in place because of research abuses in the United States.
Research Abuses in the United States

- In 1972, the most infamous, and longest running, American research abuse became known as the Tuskegee Experiments.

U.S. Gov’t Researchers Abuse African-American Sharecroppers for Four Decades

"For 40 years, the U.S. Public Health Service has conducted a study in which human guinea pigs, not given proper treatment, have died of syphilis and its side effects," Associated Press reporter Jean Heller wrote on July 25, 1972.

Result of Tuskegee Publicity

- Lead to the passage of the National Research Act - 45 CFR 46
- Mission of the Commission: To identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human research participants and to develop the guidelines which should be followed to assure that such research is conducted in accordance with these principles.
1979 Belmont Report or Ethical Principles and Guidelines – identified three core principles.

- **Respect for persons:** Protecting the autonomy of all people and treating them with courtesy and respect and allowing for informed consent. Researchers must be truthful and conduct no deception;
- **Beneficence:** The philosophy of “Do no harm” while maximizing benefits for the research project and minimizing risks to the research subjects; and
- **Justice:** Ensuring reasonable, non-exploitative, and well-considered procedures are administered fairly — the fair distribution of costs and benefits to potential research participants — and equally.

*These principles remain the basis for the HHS human subject protection regulations.*

**Types of Institutions & Organizations**

- Universities and Colleges
  - ASU, UA, NAU, American Medical College of Homeopathy
- Government
  - Indian Health Services
    - Area: NW Portland, Phoenix, Navajo Nation*
  - Arizona Department of Health and Human Services
- Tribes
  - Cherokee Nation & Eastern Band Cherokee
- Private
  - Western Institutional Review Board, Compass Health, Southern Arizona AIDS Foundation

*638 contract between I.H.S. and Navajo Nation*

**Federal Requirements for IRBs**

- **IRB Authority to Institutions & Organizations**
  - IRB given responsibility to ensure human subjects protection in research activities by reviewing and monitoring research activity
  - IRB are required to submit Federal Wide Assurances
  - All entities must register the IRB with the Dept. of Health and Human Services, Office of Human Research Protections
IRB – Composition of Membership

- Signatory Official, IRB members, IRB administrator, IRB support staff and investigators
- Composition of Membership
  - At least 5 members
  - At least one member "primary concerns are in non scientific areas" ie. Community member lawyer, spiritual leader
  - At least one member "primary concerns are in scientific areas" ie biomedical, social science, public health
  - Quorum must include at least one community and one scientist member
  - No meeting or decision can be made without quorum

Ethical Principles - Tribes and Federal

- Values that form the basis of Tribal review
  - Which may be formally articulated in constitution, policies, codes and ordinance.
  - Values based on protecting and promoting the wellbeing of individuals and community.
  - Values based on the protection of cultural and spiritual knowledge and practices, worldview and relationships within it.
- Values that form the basis for Federal review
  - Values based on the Belmont Report – Respect, Beneficence and Justice.

Tribal Processes: Review and Approval

- Tribal Council Approval
  - Tribal Council is the sole body responsible for research review and approval for the Tribe.
- Community Advisory Board (CAB) and Tribal Council
  - A Health Board/Committee, Advisory Board, or other group, reviews the proposed research and provides recommendations for approval to Tribal Council. Tribal Council is responsible for the final review and approval decision. Any tribe using a Health Committee, Advisory Board, or group, other than Tribal Council, to review and approve research was categorized as having a CAB.

Tribal Review and Approval Processes

- Department Head and Tribal Council
  - The Department Head is responsible for reviewing the proposed research and for working directly with Tribal Council for approval.
- Tribal Institutional Review Board
  - A Tribal IRB is formally designated to approve, monitor and review biomedical and behavioral research involving human subjects with the aim to protect the rights and welfare of the research subjects – with special emphasis on American Indian cultural rights; and to protect and promote the wellbeing of individuals and community. Tribal IRBs, like all IRB, are governed by federal regulations, Title 45 CFR Part 46. (http://ohsr.od.nih.gov/guidelines/45cfr46.html)
**Tribal IRB - Role and Responsibilities**

- Educate members about human research protections and federal regulations
- Establish IRB policies and procedures
- Review each protocol or proposal carefully
- Maintain good records
- Protect and promote the wellbeing of individuals and community, and cultural rights
- Oversee data ownership and publication rights

**ITCA Regional Tribal IRB**

- It is a fundamental principle of the ITCA IRB that tribal governments have a legal right to maintain, control and protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions.
- The ITCA IRB Guiding Principles include:
  1. Respect for Tribal sovereignty and autonomy,
  2. Concern for Individual and Community Welfare,
  3. And Concern for Protection.

**American Indian Cultural Rights and Protections**

- The Tribal IRB study protocols shall include how the study and the data will protect and promote the wellbeing of individuals and community, as well as protecting cultural and spiritual knowledge and practices, worldview and relationships with in it.
- The Tribal IRB study protocols shall include community protections and confidentiality provisions. This requirement will ensure that potential study participants are informed about what they might participate in, and so that they may bring their own cultural values to bear on the decision of whether to participate or not.

**American Indian Cultural Rights and Protections**

- The ITCA IRB will require proof that the American Indian government(s) included in the study has approved the research; this might be in the form of a Tribal Council resolution or a letter of approval to participate signed by the Tribal Leader.
- For Tribes that have their own Community Advisory Committee (CAB), the research application must also include formal written approval from the CAB.
Data Ownership and Publication Rights

- It is the Tribal IRB position, that as sovereign governments, tribal communities have the authority and the responsibility of protecting their community members and their communities as a whole from harm in research.
- Tribal IRB will require specific consent for each secondary use of biological samples must be implemented and enforced.
- ITCA IRB will define each secondary use as a new study, and that neither a consent for the primary use nor blanket consent establishes the informed consent necessary for the protection of the subject American Indian’s human rights.

Data Ownership and Publication Rights

- The Tribal IRB shall have a mandatory re-consent is required for multiple uses of sample, acknowledgement of intellectual property rights, and protection of indigenous rights in cultural and sacred knowledge. Tribes have ownership interest in their data and traditions, and past experiences with genetic research have made tribes cautious of broad data-sharing agreements.
- The Tribal IRB position is that Tribes are the exclusive owners of their knowledge, biogenetic resources and culture. Tribal approval of dissemination is required beginning with an advanced review of the researchers manuscripts prior to publication. Researchers must present the study results to the community prior to any dissemination and/or publication of study results. A fundamental requirement is that study results must be used to benefit the community first.

Data Ownership and Publication Rights

The ITCA Tribal IRB will inform Tribal governments of the option to require researchers to sign a contract agreeing to specific terms about the research project:
- Such as the research protocol that will be followed,
- How data or biological samples will be handled,
- Intellectual properties considerations,
- Details on who owns the data and/or biological samples,
- Guidelines for review of publications and authorship of publications,
- And what penalties may be imposed if the contact is broken.

ITCA-AIRCH TRIBAL IRB

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