ETHICAL EVALUATION RESEARCH AND THE ROLE OF INSTITUTIONAL REVIEW BOARDS IN TRIBAL COMMUNITIES

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Presentation Overview

- Historical Contexts (non-tribal and tribal communities)
- An Overview of IRB Regulations
- Tribes, tribal programs, and IRBs
Background & History

Post World War II Medical Research

- Rapid increase in research funding
  - 1945-65 there was a 17-fold increase in NIH funding
- Increased emphasis on experimentation to establish the efficacy of treatments
- Increased emphasis of research in academic medicine
Background & History

Examples of Ethical Violations

- Injection of “live cancer cells” into 22 chronically debilitated patients.
- Placebo given to men enlisted in the armed forces for the treatment of rheumatic fever when Penicillin was known to be an effective treatment.
Examples of Ethical Violations

- **Tuskegee Syphilis “Experiment”** - “studied” the effects of untreated syphilis in African American men (for 40 years)

- **Willowbrook “Study”** - systematic infection (with hepatitis viruses) of individuals with mental retardation
Background & History

Types of Ethical Violations

- 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
Background & History
A Brief History of Human Subjects Protection

- 1946: Nuremberg Codes “prevent experimental abominations in the future ...[and] increase the protection of the rights and welfare of human subjects”
  - Informed Consent
- 1964: US Signed the Helsinki Declaration
  - Careful Assessment of Risks and Benefits
  - Informed Consent
Background & History

A Brief History of Human Subjects Protection

- **1966**: Beecher reviewed 100 studies published in a prestigious medical journal - 12 seemed to be unethical
- **1972**: Tuskegee “Experiment” exposed
Background & History
A Brief History of Human Subjects Protection

- **1974**: DHHS established regulations for the Protection of Human Subjects of Biomedical and Behavioral Research (45 C.F.R. 46), including the establishment of IRB review procedures.

Examples of ways research has failed tribal communities

- Identified problems without benefit or solution
- Publication of protected cultural materials
- Served the needs of academics but not that of participating communities
- Presented inaccurate findings due to cultural misinterpretation of data

Salios et al., 2006
Background & History

Human Subject Research and Tribal Communities

Barrow Alaska Study

Eskimos Irate Over Alcoholism Study

Barrow, Alaska

Hot tempers and tension arising from a scientific report that found a high rate of alcoholism in this predominantly Eskimo community have abated somewhat after two days of meetings here at the northernmost point of Alaska.

Researchers from the University of Pennsylvania found that the Inupiat Eskimos of Alaska's North Slope were "practically committing suicide" by mass alcoholism. They said that up to 72 percent of this village's 2,000 residents were alcoholics and that violence had become the most frequent cause of death as a result of the problem.

"We definitely have a problem here with alcohol," said Acting Mayor Lloyd Ahvakana. "But our people were shocked with the report and the picture it painted. It's definitely out of line and doesn't reflect the way it is."

Mr. Ahvakana and other residents challenged the validity of the report, contending that some of the research instruments and researchers were culturally biased and that some of the findings were erroneous because of false assumptions.

About 300 residents, many of them furious, crowded into the Presbyterian Church here Wednesday night for a public hearing on the alcohol problem that lasted seven hours, ending at 3 A.M. Other meetings were held Thursday.

Only a day before the first meeting, Kim Moeller, who was instrumental in commissioning the study, was dismissed as Public Public Safety Director by Mayor Eben Hopson, who is away on a business trip.

When the results of the study were released to the press Jan. 20, Mr. Moeller traveled to Anchorage to grant interviews to the reporters in what he described as "an attempt to soften the blow." Mayor Hopson, however, accused Mr. Moeller of leading the news media to "mistakenly report most of our people are alcoholic and incompetent."

"This indiscretion and poor judgment has caused reduced confidence in our community and has angered our people," Mayor Hopson declared.

The anger of residents had reached such a point that some people here were worried Wednesday about the safety of Dr. Edward Foukes, associate professor of psychiatry and anthropology at the University of Pennsylvania, a member of the research group who was here to present the study to the community.
Background & History
Human Subject Research and Tribal Communities

- Havasupai Diabetes Study

The New York Times

Indian Tribe Wins Fight to Limit Research of Its DNA

SUPAI, Ariz. — Seven years ago, the Havasupai Indians, who live amid the turquoise waterfalls and red cliffs miles deep in the Grand Canyon, issued a “banishment order” to keep Arizona State University employees from setting foot on their reservation — an ancient punishment for what they regarded as a genetic-era betrayal.
Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
Human Subjects Regulations & IRBs
45 C.F.R. 46

- Subpart A – Basic HHS Policy for Protection of Human Research Subjects
- Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates
- Subpart C – Additional Protections for Prisoners
- Subpart D – Additional Protections for Children
- Subpart E – Registration of IRBs
Human Subjects Regulations & IRBs

IRBs - Purpose

- To review whether the benefits of the proposed research outweigh the risks
  - risk of psychological harm
  - risk of breach of confidentiality
Human Subjects Regulations & IRBs

IRBs - Purpose

- To make certain that the investigators have explained all relevant issues so as to assure the subject’s informed consent.
  - child & adolescent assent with parental permission
  - right to refuse participation
  - no coercion to participate
Human Subjects Regulations & IRBs

IRBs – Purpose – Tribal Communities

- To further assure
  - Tribal participation in the development, conduct, and reporting of research findings
  - That research conducted is beneficial to the community
  - That the community (not just individuals) is protected from harm due to the research
  - That issues such as data ownership/control are fully understood by all parties
  - That publications are reviewed by the community prior to presentation and publication

NCAI Policy Research Center:  http://www.ncaiprc.org/tools
Researcher submits the following:

- **Summary of Research Protocol**
  - Settings and Participants
  - Study Design, Measures, and Analysis
  - Funding
  - Assent/Consent Procedures
  - Subject Payment
  - Review of Risks and Benefits (including special precautions)
- **Assent/Consent Forms**
IRBs – Review Process

- IRB reviews the protocol summary and consent forms.
- Requests to investigators for further clarification and revisions to assent/consent procedures and forms are typical.
- Requests for clarification and revision of the research protocol are possible as well.
IRB approves the project when it determines that all of its human subjects concerns have been fully addressed by the investigator.
Research Regulation in Tribal Communities

- IRBs (tribal, tribal college, IHS, University independent)
  - Has an “FWA” number (federal wide assurance)
  - Required for MIECHV evaluation
- Research Review Boards
- Tribal Council/Program Board of Directors
- Tribal Executive/Program CEO
- Program Director
Conclusions

- IRB’s are the bedrock for protection of evaluation and research participants.

- Major ethical goals for the type of evaluation efforts within the scope of MIECHV are as follows:
  - Obtaining full informed consent
  - Minimizing the risk of psychological harm
  - Protecting the confidentiality of individuals who participate in this evaluation
Conclusions

- In addition to the above, specific concerns for tribal communities and evaluators/researchers include:
  - Community approval
  - Community participation
    - Study design, implementation, analysis
    - Local Dissemination of results
    - Outside Dissemination of results
Resources

- National Congress of American Indians Policy Resource Center
  - http://www.ncaiprc.org/research-curriculum-guide

- Indian Health Service IRB

- National Indian Health Board Health Research Advisory Council
Planning for our next webinar

- Please send us information about your plans for evaluation approval and any questions you have about the process by Friday, July 6th. Issues that would be helpful for us include:

  - Which IRB you are planning to use? What type of IRB is it (e.g., tribal, tribal college, IHS, University, independent)? More than one IRB?
  - Are there additional approvals you need to obtain (e.g., tribal council, research review board, program CEO/board of directors)?
Questions/Comments?