

Institutional Review Boards (IRB) for Indian Health Research

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Learning Objectives

- Identify elements essential to protect individuals and communities involved in research – using a case example
- Understand the procedures for approval of research in Indian Country

Three Basic Ethical Principles

Respect for Persons

Application: Informed Consent

Beneficence

Application: Assessment of Harms and Benefits

Justice

Application: Selection of Participants in Research

A Fourth Basic Ethical Principle

Respect for Communities

Application: Community involvement and participation

Case Study #1: Diabetes Screening

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- High prevalence of type 2 Diabetes
- High prevalence of behavioral risk factors – including children
- Community based screening of primary and secondary school children

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- Community, school, family, and individual assessments
- System comprehensiveness and responsibility, resources, communication
- Human subjects protection, vulnerable subjects (assent forms)

National IHS IRB

- Requires tribal approvals for all research and publications (tribal sovereignty)
- Sensitive to cultural appropriateness of study design, questions, and implementation (community-specific knowledge, norms, and world views)

National IHS IRB

- Minimize adverse impact of research by minimizing potential harms and maximizing potential benefits
- Balance ethical concerns (regulations) with promoting research

Research Approval in Indian Country

- Tribal Health Director
- Tribal Health Committee or Board
- Tribal IRB (Navajo)
- Tribal Council
- Host institution's IRB (University)
- IHS IRB Area
- IHS IRB National
- Funding Agency (NIH, CDC)

Tribal - Researcher Relationships

- understand and appreciate community research priorities
- Community partnership from inception of the ideas to project completion, and into publication
- understand and appreciate tribal interests
- Regular and timely tribal consultations
- Community capacity building, benefits to the tribe
- Help tribes understand collaborator responsibilities and requirements

Tribal - Researcher Relationships

- Make available a listing of all public health resources to tribes
- Provide technical assistance to tribes
- Develop training and linkage opportunities to ensure a better understanding of tribal and community based tribal health systems

Contact Information:

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