Challenges and Solutions from a Tribal IRB Perspective; Case Example of Oversampling
Objectives

- Ethical Principles and Guidelines for Research Involving Human Subjects
- Challenges of measurement from an IRB perspective
- Solutions of measurement from an IRB perspective
- A case example, the South Dakota Tribal Pregnancy Risk Assessment Monitoring System (PRAMS)
Ethical Principles and Guidelines for Research Involving Human Subjects¹

A. Boundaries Between Practice and Research

B. Basic Ethical Principles
   ◦ 1. Respect for Persons
   ◦ 2. Beneficence
   ◦ 3. Justice

C. Applications
   ◦ 1. Informed Consent
   ◦ 2. Assessment of Risk and Benefits
   ◦ 3. Selection of Subjects

Challenges

- Research vs. Practice
  - Harm has been done
  - Relevance questionable, focus of research oftentimes determined by others
  - Moratoriums may mean loss of benefits from research
  - Apprehension about publications contributing to limits of sharing AI/AN work, progress, efforts, ideas
Solutions

- Research vs. Practice
  - Participate in revisions to federal regulations to include tribal needs
  - Promote (require) community based participatory research
  - Enforce tribal rights and responsibilities
Solutions

- Requests for Applications – AI/AN inclusion
- AI/AN as researchers, peer-reviewers
- Oversampling
- Inclusion of AI/AN race
- Race classification verification
Solutions

- Variables
- Recruitment (mechanism)
- AI/AN as authors, analysts
- AI/AN benefits optimized
Two ethical convictions:
- that individuals should be treated as autonomous agents, and
- that persons with diminished autonomy are entitled to protection
Challenges

- Respect for Persons
  - Individual vs. Family and Community decision-making

- Beneficence
  - Assessment of risk, benefits and harms not always from tribal perspective

- Justice
  - AI/AN inclusion (limited) in federally funded projects
Solutions

- Respect for Persons
  - Individual vs. Family and Community decision-making
  - Tribal oversight

- Beneficence
  - Assessment of risk, benefits and harms from the tribal perspective

- Justice
  - AI/AN inclusion in federally funded projects
Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being.

Two general rules:
- (1) do not harm and
- (2) maximize possible benefits and minimize possible harms.
Measurement Background

- Small sample sizes (numerator)
- Denominator issues
- Inclusion of race
- Race categorization (AI only vs. AI + other(s))
- Racial misclassification
- Variables
- Recruitment (mechanism)
- Tribal variation
- Collapsing of AI/AN into “Other”
South Dakota Tribal Pregnancy Risk Assessment Monitoring System (SDT PRAMS)

Hecel Oyate Kin Nipi Kte
So That The People May Live
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A survey for mothers of young infants
Questions about the mothers experiences, behaviors, health during pregnancy
Goal: AI statewide and tribe-specific population-based surveillance data on pregnancy and early infancy

- 39 PRAMS funded across the US
- SDT PRAMS the first tribal-based PRAMS
SDT PRAMS Objectives

- To improve understanding of maternal behaviors and experiences and their relationship to pregnancy outcomes

- To develop new maternal and child health programs and to modify existing programs

- To influence public health policy at the tribal, state, and federal levels
SDT PRAMS Objectives

- To help health professional incorporate the latest research findings into their standards of practice
- To monitor progress toward tribal, state, and national health objectives and goals
SDT PRAMS Topics

- Nutrition, food security, and exercise
- Breastfeeding initiation and duration
- Attitudes and feelings about the pregnancy
- Barriers to and content of prenatal care
- Pregnancy-related violence
- Psychosocial support and stress
- Use of alcohol and tobacco before and during pregnancy
- Infant’s early development, health care, sleep position, and exposure to passive smoke