History of research ethics in Native communities

Lands of the Anishinaabe
and the Respective Tribal Colleges

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Hy’shqe siam (Lummi) - Thank you, respected teachers

- **Community Institutional Review Board (IRB) members**
  - Sam Deloria, Lisa Preston, Kathleen Alexis, many others

- **Native IRB leaders**
  - Francine Gachupin, Dave Oreiro, Barbara Juarez, Heather Larsen, &c

- **IRB staffs**
  - Helen McGough, Ada Sue Selwitz, Shannon Sowards, &c

- **Participants in research projects**

- **Researchers who walk their talk**
  - Tessa Evans-Campbell, Jaime Donatuto, Stacy Rasmus, Deana Around Him, &c

- **“Indigenous Research Methods in Public Health”**
  - Graduate Course U MT 595.54-34884 – by Lori Lambert

- **Wife** - Carolyn Robbins
Research atrocities by Nazis, WWII

• *In concentration camps (Dachau) and killing camps (Auschwitz)*
  – Immersed prisoners in cold water
  – until they died – *the intent of the research*
  – Decompressed prisoners in high-altitude chambers
  – until they died – *the intent of the research*
  – Injected many prisoners with typhus
  – many died

• *Nuremberg Medical Trial, 1946-47*
  – tried 23 defendants (20 physicians)
  – convicted 15
Unethical research USA: USPHS Syphilis Study

- (Public disclosure 1972 precipitated regulations)
- Natural history of untreated syphilis: 399 African American men, dirt-poor sharecroppers Tuskegee, AL 1932
- Intentionally not treated (told them “treated for bad blood”)
- Not secret! – updates published about every 5 years!
- Continued 40 years – 1932-1972
  - better Rx (penicillin) available 1945
- Highly “successful” (= “the men stayed with it”) – dropout rate only 1% over 40 years!

Q1. Why was it so “successful”?
Please “pair-share” to answer
Answers received

• Many answers:
  – *People were poor; They lacked knowledge about syphilis*

• A few answers:
  – *Incentives (decent burial if family consented to autopsy)*
  – *African American (Negro) personnel – doctors, nurse*

• IMO: *key reason for keeping 99% for 40 years:*

• *the study was “culturally sensitive”:*
  • *free burials, African American doctors & nurses, etc.*

• *LESSON: being “culturally sensitive” is not sufficient to make a research project ethical*
National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

• **By the 1974 National Research Act**

• **First, it proposed regulations:**
  – required Institutional Review Boards (IRBs)
  – for research done or conducted by HEW (now DHHS)
  – 45 CFR 46 (Title 45 Code of Federal Regulations Chapter 46)

• **Applied to all types of human research**
  – not just “experiments” or “biomedical research”
  – PHS Syphilis Study in Tuskegee: *observational* research

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
Then issued The Belmont Report

- **Basic ethical principles underlying its proposed regulations** (and their application):
  - **Respect for persons** (implication: informed consent)
  - **Beneficence** (Assessment of potential risks [harms] and benefits)
  - **Justice** (selection of people to be in the research)

- (The Belmont Report in effect asked: “Under what circumstances is research ethical?” Its answer:

- “When, & only when, the research complies with all 3 principles.”

http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm
Q2. What do you think has been the research that has caused the most harm to the most people in 20th century America?

Please “pair-share” to answer.
Answers received

• Several answers received:
  – *Tuskegee*
  – *specific Alcoholism Research [TBD]*
  – *specific Diabetes Research [TBD]*

• No “right” answer -- but in my opinion

• …

• Almost all answers:
  – *Research harmed not just the participants in the research but their communities*
  – *Most answers: Non-experimental (i.e., observational), often non-medical, research*
Implications

- All types of research — experimental & observational, medical & behavioral & educational — has caused (and can cause) major harms.

- “Harms to communities”: when community members not in the original research are directly harmed by the results of the research.

- Researchers and IRBs should have or seek expertise to assess and minimize all potential harms — individual and communities.

- Communities must protect themselves as well!
“The good, the bad, and the ugly” in research with Indigenous people

• (Not in list of unethical research leading to IRB regulations)

• (But common feeling in many tribes & tribal people: “research has harmed us”)
Social science research in service of eugenics

- In Vermont [VT], the first third of 20th century
- Surveys of "dumb" or "delinquent" children and their families
- “Dumb” or “delinquent” families were usually poor Catholic French Canadians, Abenaki Indians, or migrants

VT sterilized some “dumb” or “delinquent” children
identified research survey- “to protect the gene pool”

(Many other states sterilized such people as well

**Ugly research with Indigenous people-2**

Center for Research ... Acts of Man: effects of alcoholism in Barrow, AK

- 1960-70s, researchers from northeastern US
- Announced findings in press conference at their U.
- **Barrow was floating bonds on Wall St. -> BIG news**
  - Bond ratings on Wall Street adversely affected
- **What was the worst & longest-lasting harm?**
- **Internal stigmatization by people from Barrow & nearby communities**
- **NOTE: harms were done by dissemination of results & the researchers’ interpretations**
Recent *Ugly* AI/AN research: ASU research on diabetes at Havasupai

- early 1990, Tribe approved a diabetes study including genetic analysis, by Arizona State University researchers
- genetic markers, inbreeding, & migration genetic research also done using the specimens
- sources: (also - Paul Rubin [personal communication])
  - Pubmed: Havasupai OR Markow T[Author] OR Martin JF[Author] OR Benyshek D[Author] OR Zuerlein K[Author]
Recent **REAL UGLY AI/AN research**

- **ASU diabetes research with Havasupai** [yes, there is more]
  - concurrently with T2DM study was schizophrenia study
    - neither tribe nor individuals informed
    - information from clinic charts was obtained after hours, illegally, with no approval by anyone
    - ASU IRB did not comply with own procedures & requirements
  - research was “amateur night” against the Havasupai
    - PI was not experienced in research with human beings … much less AI/AN people and Tribes
      - her primary experience was with fruit flies
    - Should ASU IRB have allowed her to be PI?

- **Result: Fear of ugly research among AI/AN**
  - major adverse publicity in Arizona
  - major law suit by the Havasupai Tribe, settled Apr 21, 2010
  - Positive result: state established policy for AI research
**Recent **GOOD** research with AI/AN People Awakening Project, Alaska, mid-1990s**

- “What **strengths & resiliency** do AN people have regarding alcohol & alcoholism”

- Interviewed people for their life histories
  - People who had never drank *or* were in stable recovery

- Results: patterns of individual, family, & village/community strengths & resiliency

- Led **directly** to an intervention now proven effective

- An excellent example of “**Tribally Engaged and Controlled Research**”
“Other issues”: Tribe and Community values/concerns in research and CBPR

- **Protect and benefit** the Tribe/community
- **Respect elders & knowledge of** Tribe/community
- **Respect Tribe/communities, strengths, and survival**
- **Incorporate traditional spirituality into the project**
- **Promote resiliency, assist Tribe/community in its activation and problem finding/addressing/solving**
- **Have pride in community’s role in the CBPR project**
- **Have ownership in/of the CBPR project**
- **Respect/promote Tribal sovereignty/community power**
- **Express hope for the Tribe’s/community’s future**
Criteria for IRB approval of research

**REQUIRED CRITERIA:**

1. Risks to subjects are minimized
   - avoid unnecessary risks
   - use existing procedures
2. Risks are reasonable in relation to anticipated benefits
3. Selection of participants or subjects is equitable
4. Informed consent is sought from all potential participants – 46.116
5. Informed consent is documented – 46.117

**ADDITIONAL SAFEGUARDS:**

- for people vulnerable to coercion or undue influence
  [“children, prisoners, pregnant women, mentally disabled ..., or economically or educationally disadvantaged”]

6. Data collection is monitored to ensure subject safety
7. Privacy and confidentiality of subjects are protected

**Why are 1, 2, & 3, listed before 4 & 5? Please pair & share**