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 Sewards, &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 <u>most harm</u> to the <u>most people</u> 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")*

Ugly research with Indigenous people-1

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

Gallagher, Nancy L. (1999). <u>Breeding Better Vermonters: The Eugenics Project in the Green Mountain State</u>.

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*
  - Foulks EF. Am Indian Alsk Native Ment Health Res. 1989; 2(3):7-17.

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])
  - Rubin P. Indian givers. Phoenix New Times 2004; May 27
  - Dalton R. When two tribes go to war. Nature 2004; 430:500-2
  - Editorial. Tribal culture versus genetics. Nature 2004; 430:489
  - Pubmed: Havasupai OR Markow T[Author] OR Martin JF[Author] OR Benyshek D[Author] OR Zuerlein K[Author]
  - Harmon A. “Tribe wins fight to limit its use of DNA.” New York Times 2010; Apr 22.

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 <u>Controlled</u> 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

45 CFR 46.111

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

and, when appropriate

6. *data collection is monitored to ensure subject safety*
7. *privacy and confidentiality of subjects are protected*

ADDITIONAL SAFEGUARDS:

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

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