

BASIC INFORMATION

IHC's Institutional Review Board (IRB)

Any organization, institution or individual conducting Research on humans or animals MUST be reviewed by a legitimate IRB before they can begin data collection in the field.

Definition of Research: A process of systematic inquiry, data collection and documentation of critical information, analysis and interpretation of that data using suitable methods from professional fields and academic disciplines.

PURPOSE of IHC's IRB: To protect all members of IHC's clinic and tribal populations from unethical research practices, incorrect or harmful interpretations of data and unethical or incorrect publications in the scientific literature.

IHC IRB Established 2004 - Deborah J. Morton, PhD, MA, Chair, **20 Year Anniversary!**

IRB MEMBERS - Chair, Chief Medical Officer, clinic staff and tribal community members of IHC's 9 tribes

GENERAL GLOBAL IRB HISTORY

IRB Principles based on the Belmont Report (1978) – related to research conducted by Nazi's in WWII.

- Nuremburg Trials – revealed the ethical standards of “civilized” society
- Nuremburg Code – Research must be;
 - Voluntary
 - Informed Consent
 - Risk/benefit analysis
 - Right to withdraw as research subject

THREE FAMOUS STUDIES – NEVER REVIEWED BY ANY IRB COMMITTEE

1) Tuskegee Syphilis Study 1932 - 1972

- 399 African American Men - Alabama
- Already infected with syphilis
 - misled – denied treatment of penicillin which cures syphilis
- Long lasting scar – African American Community – do not like to participate in research studies

2) Sexually Transmitted Infections (STIs) Experiments in Guatemala 1946 – 1948, and Their Aftermath revealed in a 2019 article in the Ethics and Human Research Journal

- Funded by NIH, US Public Health Service, Guat. gov't.
- At least 5,128 people: children, orphans, child/adult prostitutes, INDIANS, leprosy & mental health patients, prisoners, soldiers
- 1,308 purposely infected w/syphilis, gonorrhea & chancroid
- Denied treatment
- Dr. Cutler (USPHS) – same as Tuskegee Study

3) Havasupai, Arizona 1989

- 400 tribal members donated blood for diabetes research
- Instead – DNA samples (from blood) used for schizophrenia, population inbreeding & ethnic migration research not mentioned in the Consent Form
- Tribe filed lawsuit against Arizona State University and Theresa Markow (2009)
- Long lasting scar for genetic research among American Indians/Alaska Natives

3 Ethical Principles of Research

A) Respect for People;

Including dignity, autonomy, vulnerable subjects, children, voluntary & informed consent, privacy and confidentiality

B) Beneficence; “ Do Unto Others...” :

Including protection from harm, maximize benefits, minimize risks, manage conflicts of interest

C) Justice; distribution of risk/benefits must be equal across all participants

Cannot exclude women, minorities, vulnerable not targeted for convenience

IHC IRB Committee Charge: All Research Projects are Reviewed by IRB and must be;

Consistent w/3 Principles Belmont Report

Reasonable w/regard to risks & benefits

Involve vulnerable groups only with justification and safeguards

Integrate components of CBPR – IHC’s CEO & CMO must approve before IRB application

All of these components help to assure success of Research Projects at IHC

IHC IRB Members Tribal Duties

Protection of tribal members/tribal sovereignty

Approval of process for research application

Understand complete research process

Review All projects before approved to start

Request reports if needed

Return of research data be given back to IHC

Review Scientific Manuscripts prior to submitting to a journal for Publication

IHC IRB Applicant Responsibility

Must have IRB from own institution – (but does not guarantee automatic IHC IRB approval)

Tribally appropriate materials from applicant

Informed Consent – must be appropriately and clearly written

Materials in study must be tribally appropriate, example - Videos

Consent must be read aloud to potential research subjects

IHC IRB Review of Publications

Confidentiality/Anonymity – No Tribal Names

Must use Acronym SCAIHC = Southern California American Indian Health Clinic – cannot use “IHC”

Consistent use of “AIAN” vs. other acronyms for tribal people

Informed Consent – Read aloud to research subjects

Results/Discussion does not harm IHC patient population, nothing negative

20+ publications from 1 tribal health clinic – very impressive

Publication regarding IHC IRB

Morton DJ, Proudfit J, Calac D, Portillo M, Lofton-Fitzsimmons G, Molina T, Flores R, Lawson-Risso B, Majel-McCauley R. (2013) Creating Research Capacity Through a Tribally- based IRB. *American Journal of Public Health*, 103(12):2160-2164.