

Human Subject Protection

Research Imperatives

History

— [World War II - Nuremberg

— [Tuskegee Study

— [Belmont Report

— [Modern Problems - Inadequacy of “Good Intentions”

Belmont Report

— [Respect for Persons - Informed Consent - Confidentiality

— [Beneficence - Risk and Benefit

— [Justice - benefits for all

subjects are given free choice to decide about participation, and the study is fully described in terms that are easy to understand. The consent form should include adequate information about the study risks and benefits that will assist subjects in deciding whether to participate in the research.

Belmont Report

In addition, respect means honoring the privacy of individuals and maintaining the

confidentiality of data obtained. Respect for minors and mentally disabled persons requires

taking extra precautions to protect those individuals who are immature or incapacitated, perhaps

even to the extent of excluding them from participation in certain research. The extent of

protection depends upon the level of autonomy the person possesses.

Beneficence:

— The principle of beneficence requires that researchers maximize the potential

benefits to the subjects and minimize the risks of harm. Benefits to the subjects, or generalized

knowledge gained from the research, should balance or outweigh the risks.

Justice:

Specific Problems

- [Coercion
- [Vulnerable Populations
- [Populations unable to give consent

Protection of Privacy

— [Recruitment of Subjects

— [Publication

— [Protection of data

— [HIPAA and protecting “Personal Health Information”

The IRB - Review, Audits

- [Facilitation
- [Required Role
- [New Problems of Internet
- [Authority for Sanctions and Referral

IRBs at Case

- [Case IRB (Behavioral Emphasis)]
- [UH IRB (Clinical Trial Emphasis) - UH patients - all med school]
- [Cleveland Clinic IRB]
- [Metro IRB]
- [VA IRB]

IRB Process

— [Exempt and Non Exempt

— [Expedited Review

— [Full Board Review

— [Role of Staff

— [Responsible Investigator

— [

Mechanics - Case IRB

- [CWRU website for application
- [Manual also available
- [Use consent templates
- [Discuss problems with staff
- [Respond to queries - you can disagree

Our Experience

- [Combined Informed and HIPAA consents
- [Separate consents for patients, and practitioners
- [Consents for parents or guardians - assents for children
- [Under 18 are children in Ohio
- [Coding and separation of consents from data