



IRB REVIEW PROCESS



Institutional Review Board

- Protecting the rights and welfare of individuals participating in research
- Governed by federal regulations
- Overseen by Office for Human Research Protections
- Department of Health and Human Services

Belmont Report

- Published in 1979
- Establishes Ethical Principles and Guidelines for the Protection of Human Subjects of Research
- 3 Principles
 - *Respect for Persons*
 - *Beneficence*
 - *Justice*

Respect for Persons

- Individuals are autonomous agents
- Protections for individuals with diminished autonomy
- Examples
 - *Children*
 - *Adults with diminished mental abilities*
 - *Prisoners*
 - *Economically or educationally disadvantaged persons*
 - *Students, depending on situation*

Beneficence

- Wellbeing of participants as goal of the research study
- 2 principles
 - *Do not harm*
 - *Maximize possible benefits / minimize possible harms*

Justice

- Equals should be treated equally
- Who receives benefits of study / who bears burden of risks
 - *Study population should represent group who benefits from outcomes*

Definition - Research

- Systematic investigation including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge
- Key components
 - *“Systematic investigation” – using procedures to test a hypothesis*
 - *“Generalizable knowledge” – results can be widely applied*

Exclusions – Revised Common Rule

- Scholarly and journalistic activities (oral history, journalism, biography, literary criticism, legal research, historical scholarship)
- Public health surveillance activities
- Criminal investigative activities
- Homeland security, authorized intelligence, defense and national security operational activities

Definition – Human Subject

- Living individual about whom an investigator: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimen; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens
- Key components
 - *Must be a living individual*
 - *“About whom” – opinions, characteristics, or behavior of an individual*
 - *Obtain through interaction or intervention*

Types of IRB Review

- Exempt
- Expedited
- Full Board

Review of Forms

- Request for Review of Research Involving Human Subjects (Protocol Form)
- Informed Consent documents
- Other Materials (Debriefing Form, Recruitment Materials, etc.)