

Institutional Review Board (IRB)

Background

What is the IRB?

- Committee responsible for reviewing human subjects research protocols

Why do we need an IRB?

- Protect the rights of human subjects in research and minimize any potential risks and/or harms

Historical Concerns

Scientific research has historically struggled with ethical concerns

- Nuremberg – Nazi doctors charged with crimes against humanity
- Tuskegee Syphilis Study – treatment withheld
- Beecher article detailed 22 published medical studies that presented risk to subjects

Belmont Report



➤ Respect for Persons

- Respect individual autonomy
- Protect individuals with reduced autonomy
 - Informed consent
 - Protecting privacy and maintaining confidentiality
 - Safeguarding those vulnerable to coercion or undue influence

➤ Beneficence

- Maximize benefits and minimize harms
- IRB assessment of risk/benefit analysis including study design
- Ensure that risks to subjects are minimized
- Risk justified by benefits of the research

➤ Justice

- Equitable distribution of research burdens and benefits
- Ensure that selection of subjects is equitable

Definitions

1.1 Human Subject

A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information or identifiable biospecimens.

1.2 Research

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

1.3 Generalizable Knowledge

Generalizable knowledge is meant to draw conclusions, facts, or principles derived from particulars (individual subjects, medical records, etc.) that are applicable to or affect a whole category (members of a class, group, a field of knowledge) and enhance scientific or academic understanding. Activities that are disseminated with the intent to influence behavior, practice, theory, future research designs, etc. are contributing to generalizable knowledge.

Timeline for working with the UIRB

