Ethical Conduct of Research and Federal Regulations

What you absolutely need to know

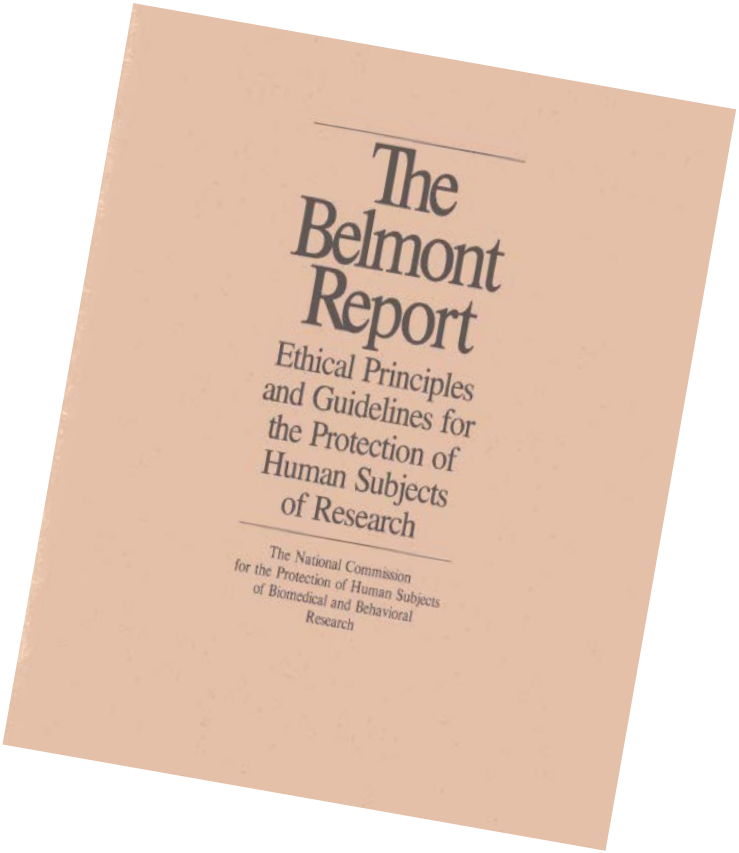
Ethical Conduct of Research

- The Belmont Report (1979)
- The Common Rule (45 CFR 46 – 15 federal agencies)
- Food and Drug Administration
  - 21 CFR 50 – Protection of Human Subjects
  - 21 CFR 56 – Institutional Review Boards

The Belmont Report

- Defines 3 ethical principles to guide the conduct of human subject research:
  - Respect for Persons
  - Beneficence
  - Justice

http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/



The Belmont Report

Practice

Interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals

VS.

Research

Activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed in theories, principles, and statements of relationships).

The Belmont Principles

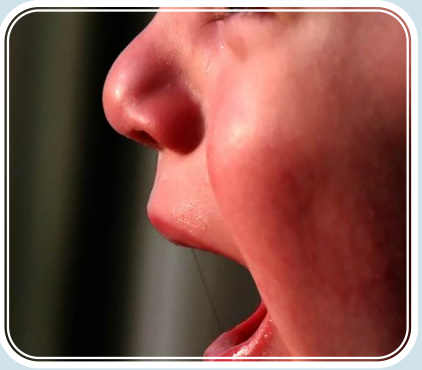
Respect for Persons	Beneficence	Justice
• Autonomy • Vulnerable Protection • Voluntary • Informed • Right to Withdraw • Privacy and Confidentiality	• Maximize benefits • Minimize harm • Justify benefits to individual or society	• Equitable selection • Who is included? • Who is excluded?

45 CFR 46: Protection of Human Subjects

- Administered by the Office for Human Research Protections (OHRP)
- Regulations guiding the conduct of federally funded human subject research **(Subpart A: The Common Rule)**
  - Applicability
  - Definitions
  - Membership requirements
  - Criteria for IRB approval, 45 CFR 46.111
  - Requirements for informed consent

http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/

45 CFR 46: Protection of Human Subjects



Subpart A: The Common Rule – Basic Protections	Subpart B: Pregnant Women, Fetuses & Neonates	Subpart C: Prisoners	Subpart D: Children

Food and Drug Administration – 21 CFR 50, 21 CFR 56

- Applies to review of human research involving FDA regulated products
  - Applicability
  - Definitions
  - Membership requirements
  - Criteria for IRB approval, 21 CFR 56.111
  - Requirements for informed consent

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56

FDA Regulations	Federal Policy Regulations
Clinical Investigation: any experiment that involves a test article and one or more human subjects	**Research**: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge
Human Subject: an individual who is or becomes a participant in research either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient	**Human Subject**: a living individual about whom an investigator (whether professionals or student) conducting research obtains • Data through intervention or interaction with the individual *or* • Identifiable private information

Possible Interview Questions

- Have you read The Belmont Report? Describe the application 3 ethical principles
- What is subject to the The Common Rule? What is included in it?
- What is a human subject?
- What types of research are regulated by the FDA?
- Are your feelings about the IRB experience positive or negative? Why?

Moving Forward

- Interviewee selections expected in late Summer
- Scheduling will occur
- Education ongoing until then and beyond
- Separate educational guidance upon request