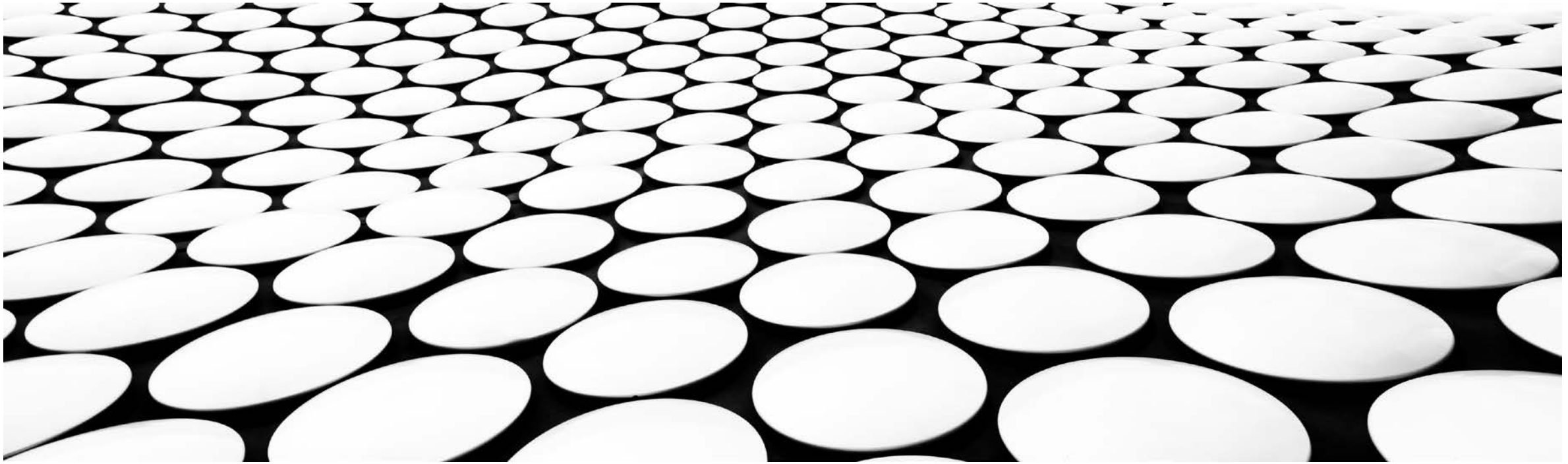
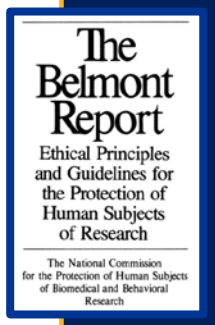
ETHICAL CONDUCT OF RESEARCH AND FEDERAL REGULATIONS GOVERNING RESEARCH

WHAT YOU ABSOLUTELY NEED TO KNOW



ETHICAL PRINCIPLES AND REGULATORY ADHERENCE

The University subscribes with the ethical principles and complies with the following regulations as appropriate for the research being conducted



Identifies the basic ethical principles underlying the conduct of human subject research

Respect for persons

Beneficence

Justice

Regulates research involving human subjects in order to protect the rights and safety of subjects

45 CFR 46 – Protection of Human Subjects (The Common Rule)

OHRP
OFFICE FOR HUMAN RESEARCH PROTECTIONS

Other regulations pertaining to specific scenarios:
types of records, locations (state & local laws), populations

FDA

Establishes regulations that govern FDA materials in research

21 CFR 50 – Protection of Human Subjects

21 CFR 56 – Institutional Review Boards

Other parts of 21 CFR dependent on the research

Enforces HIPAA: Provides data privacy and security for medical information

45 CFR 160

45 CFR 164 (A)(E)

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA
Office for Civil Rights

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).

ETHICS: THE BELMONT REPORT (1979)

Cornerstone of ethical principles and foundation of federal regulation
http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

Belmont Principles

Respect for Persons:

- Autonomy
- Vulnerable Protection
- Voluntary
- Informed
- Right to Withdraw
- Privacy and Confidentiality

Beneficence

- Maximize benefits
- Minimize harm
- Justify benefits to individual or society

Justice

- Equitable selection
- Who is included?
- Who is excluded?

45 CFR 46: PROTECTION OF HUMAN SUBJECTS

The Common Rule: Published in 1991 and codified in separate regulations by 15 Federal departments and agencies

Administered by the Office for Human Research Protections (OHRP) 45 CFR 46 are the regulations guiding the conduct of federally funded human subject research (Subpart A: The Common Rule) contains:

- Applicability
- Definitions
- Membership requirements
- Criteria for IRB approval, 45 CFR 46.111
- Requirements for informed consent

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

Includes The Common Rule as well as regulatory protections for the noted special populations. Researchers adhere to each subpart based on the subject population

FOOD AND DRUG ADMINISTRATION

21 CFR 50: PROTECTION OF HUMAN SUBJECTS
21 CFR 56: INSTITUTIONAL REVIEW BOARDS

- Applies to review of human research involving FDA regulated products (e.g. food, dietary supplements, drugs, medical devices, some medical apps)
- Applies when the investigation intends to “treat, cure, mitigate, diagnose, or prevent disease in humans”
- Contains:
  - Applicability
  - Definitions
  - Membership requirements
  - Criteria for IRB approval, 21 CFR 56.111
  - Requirements for informed consent
- Other FDA regulations may apply based on research being conducted (e.g. 21 CFR 812: Investigational Device Exemptions, 21 CFR 312: Investigational New Drug Application)

DEFINITION DIFFERENCES

FDA Regulations	The Common Rule
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 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 and investigator conducting research obtains: • information or biospecimens through interaction or intervention Or • obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

POSSIBLE INTERVIEW QUESTIONS

- Have you read The Belmont Report?
  - How were you educated about it and when?
  - What are the principles?
- What is The Common Rule and what is its purpose?
- What types of research are regulated by the FDA?

QUESTIONS?

SPECIALIZED EDUCATION AVAILABLE UPON REQUEST: ASKIRB@PITT.EDU