

## Research Ethics

Ray Block, Jr.  
PS 585  
Research Methods

### Today's Blueprint

Last Class

Surveys and Interviews:

- Interviews
- Surveys
  - Defining them
  - Why we use them
  - How to do them
  - Strengths and Weaknesses

Today's Class

Research Ethics

1. Definitions
2. Documents, Regulations, and Guidelines
3. Roles and Responsibilities

## Definitions

### Definitions

Key Questions

- Is the activity research?
- Does the research involve human subjects?
- If the answer to each of these questions is “yes”, the research must be performed in accordance with federal regulations to assure that research participants are protected.

### Definitions

Is the activity research?

- The Belmont Report (1979):
  - “[Research is] an activity designed to test a hypothesis, permit conclusions to be drawn and thereby contribute to generalizable knowledge. Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective”

### Definitions

- Code of Federal Regulations (45 CFR\* 46):
  - [Research is] “a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge”

### Definitions

- The Belmont Report:
  - [Professional practice is] performing “interventions that are designed solely to enhance the well-being of an individual patient or client. . . . The purpose is to provide diagnosis, preventative treatment or therapy to a *particular individual*.”

### Definitions

- Practice or Research?
- Professionals such as professors, teachers, physicians, psychologists, counselors, etc. may engage in activities that, depending on the circumstances, may be either research or professional practice.
- If the intent of the activity is to contribute to generalizable knowledge, typically by publishing the results, the activity should be considered research.

## Definitions

- Does the research involve “human subjects”?
- A human subject is:
  - A living individual about whom an investigator conducting research obtains:
  - data through intervention or interaction with the individual, or
  - identifiable private information.

## Definitions

- Additional Considerations:
- Research may also involve “indirect activities”
  - Analysis of human specimens
  - Data collected by others
- These kinds of indirect activities are considered research with human subjects.

## Documents, Regulations, and Guidelines

### Documents, Regulations, & Guidelines

- Regulations = the government’s response to egregious violations of human rights and dignity
  - Nazi war crimes (1940’s)
  - “Tuskegee” experiment (1932 - 1972)
  - “Human Radiation Experiments”

### Documents, Regulations, & Guidelines

#### Overview

- Documents, regulations and guidelines dealing with the protection of human subjects derive from several sources.
- The primary responsibility of Institutional Review Boards (IRBs):
  - Protecting human research subjects by implementing various requirements

### Documents, Regulations, & Guidelines

- Important Documents, Regulations and Guidelines:
  - Belmont Report, 1979
  - 45 CFR 46, 1974 - revisions in 1981, 1998
  - Multiple Project Assurance of Compliance with 45 CFR 46
  - Food and Drug Administration (FDA) regulations (21 CFR 50 and 56)
  - FDA: Good Clinical Practice Guidelines
  - FDA: International Conference on Harmonization

### Documents, Regulations, & Guidelines

#### Belmont Report

- Articulates the boundaries between “practice” and “research”
- Articulates basic ethical principles to be applied to research involving humans
  - Respect for Persons
  - Beneficence
  - Justice
- Discusses applications of ethical principles

### Documents, Regulations, & Guidelines

#### Respect for Persons

- Researchers are required to:
  - Acknowledge the autonomy of subjects
  - Protect subjects with diminished autonomy
- An autonomous person is capable of deliberating about personal goals and acting on that deliberation

#### Documents, Regulations, & Guidelines

- Respect for Persons: Application
  - To the extent that they are able, subjects must be given the opportunity to choose what will, or will not, happen to them.
  - The process of providing information that subjects can comprehend in a manner that assures voluntary participation in the research represents the application of this ethical principle

#### Documents, Regulations, & Guidelines

##### Beneficence

- Do no harm
- Minimize possible harms and maximize possible benefits
- Creates the obligation to secure the well-being of individuals without intentionally injuring any individual

#### Documents, Regulations, & Guidelines

- Beneficence: Application
  - Avoiding harm requires learning what is harmful
  - Assessing the nature and probability of harms and benefits in a systematic manner, prior to performing the research, represents the application of this ethical principle

#### Documents, Regulations, & Guidelines

- Justice
- Consider the following questions:
  - Who receives the benefits of the research?
  - Who bears the burdens of the research?
- There should be a fair sharing of burdens and benefits

#### Documents, Regulations, & Guidelines

- Justice: Application
  - Selecting subjects by fair procedures that take into account who may benefit from the research represents the application of this ethical principle

#### Documents, Regulations, & Guidelines

- Department of Health and Human Services Regulations .45 CFR 46
  - Codifies the manner in which ethical considerations are applied to research involving human subjects by requiring institutions receiving federal funding to have the research reviewed *prospectively and on a continuing basis* by Institutional Review Boards (IRBs)
  - Referred to as “the Common Rule”

#### Documents, Regulations, & Guidelines

- Multiple Project Assurance of Compliance (MPA) M-1238
  - A document negotiated between the Department of Health and Human Services and the OSU Vice President for Research, which assures compliance with 45 CFR 46.
  - The MPA outlines principles and guidelines that govern the institution, faculty and staff in the discharge of responsibilities for protecting human subjects taking part in research conducted at or on behalf of OSU, *regardless of the source of funding.*

#### Documents, Regulations, & Guidelines

- FDA Regulations .21 CFR 50 and 56
- Codify FDA regulations pertaining to human subjects research including the requirement of informed consent and prospective and continuing review of research by IRBs
- FDA regulations govern sponsors and investigators, as opposed to Health and Human Services regulations, which govern institutions.

#### Documents, Regulations, & Guidelines

#### Additional FDA Guidelines

- The Good Clinical Practice (GCP) and International Conference on Harmonization (ICH) guidelines:
  - Help investigators and sponsors meet the FDA regulations by articulating standards for performing research involving human subjects. (see in particular [E6](#) )

#### Documents, Regulations, & Guidelines

##### Roles and Responsibilities

###### Investigators

- Responsible for conducting the research properly and maintaining adequate records, which includes:
  - Seeking approval prior to initiating the research
  - Obtaining legally effective informed consent from subjects and documenting the consent using an IRB-approved consent form, unless specifically waived by the IRB

##### Roles and Responsibilities

- Investigators also responsible for:
  - Reporting adverse events or unexpected occurrences to the IRB promptly
  - Requesting changes to the protocol and receiving permission from the IRB before implementing them
  - Requesting continuation of IRB approval if the duration of the research extends beyond the period of initial IRB approval (which, by regulation, is a maximum of 365 days)

##### Roles and Responsibilities

###### Institutional Review Boards (IRBs):

- Determine that the risks of participation in the proposed research are reasonable in relation to the anticipated benefits
- Ensure that legally effective informed consent will be obtained and documented in a manner that meets federal requirements
- Have the authority to review and approve, require modification in, or disapprove all research activities, including proposed changes in previously approved research

##### Roles and Responsibilities

###### Office of Research Risks Protection (ORRP)

- Provides administrative support to IRBs and investigators
- Maintains official institutional records regarding human subjects research
- Determines, in consultation with the IRB Chair, whether applications meet federal requirements for exemption from IRB review
- Determines, in consultation with the IRB, whether applications meet federal requirements for expedited review
- Is responsible for procedural and record-keeping audits

##### Roles and Responsibilities

###### Vice President for Research

- Assures institutional compliance with 45 CFR 46 and other federal, state or local laws
- Assures sufficient resources to support the IRBs

##### Roles and Responsibilities

###### Shared Responsibilities/Accountabilities

- Failure of any party to comply with the MPA when performing or administering research involving human subjects can result in:
  - Harm to research participants
  - Harm to the reputation of the institution and its faculty
  - Federally imposed suspension of all research, and/or
  - Disciplinary actions

## Roles and Responsibilities

### Allegations of Noncompliance

- Allegations of suspected noncompliance should be reported to the IRB or the OSU Office of Research Risks Protection.
- The process for reporting and responding to these allegations is described in the Human Subjects Violations Policy.

## References

- FYI:
  - Web-Based course on research ethics: [http://www.orrp.ohio-state.edu/educ\\_intro.html](http://www.orrp.ohio-state.edu/educ_intro.html)