HUMAN RESEARCH PARTICIPANT PROTECTION

Boston College, OSP Brief

October 2015

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Why the Concern and Regulations?

- An historic pattern of abuses and controversy followed by regulation
  - Nazi abuses during World War II
  - Tuskegee
  - Guatemala
  - Milgram Study
  - Jewish Chronic Disease Hospital (1963) – injection of live cancer cells into debilitated patients without their knowledge or consent
  - Beecher Paper (1965/66) – chronicled disregard for the consent process in published research

- Current (perceived?) pattern of inattention to proper procedures and policies
  - Especially concerning the consent process

The Beginning - Nuremberg

- Nuremberg War Crimes Trials of Nazi doctors
- Nuremberg Code (1945)
  - ten principles
  - http://www.hhs.gov/ohrp/references/nurcode.htm

What are the Guiding Principles, Regulations, and Policies?

Principles

- Nuremberg Code
- Helsinki Declaration
- Belmont Report
  - http://ohsr.od.nih.gov/guidelines/belmont.html

Principles of the Belmont Report (1978)

- Respect for persons
  - obligation to treat individuals as autonomous agents able to chose for themselves
  - obligation to protect those with diminished capacity
- Beneficence
  - obligation to not harm
  - obligation to maximize benefits and reduce harms
- Justice
  - obligation to be fair and equitable
  - obligation to distribute benefits and burdens fairly

What are the Guiding Principles, Regulations, and Policies?

Regulations

- Federal “Common Rule”
- Other federal regulations
  - HIPAA, FERPA
- State and local regulations
- Site regulations and policies

What are the Guiding Principles, Regulations, and Policies?

Policies

- Boston College Policy
  http://www.bc.edu/research/oric/human.html

- Standard Operating Procedures for Researchers
  http://www.bc.edu/research/oric/human.html

Definition: Research

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

- An activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to general knowledge.

Ethical Design is Good Research Design

General considerations

- Know, understand, and follow the relevant principles, regulations, policies and guidelines
- Plan research well - *before* starting
- Keep obligations in mind during the research

Ethical Design is Good Research Design

- Ask a new and relevant question
- Be sure your design can answer your question
- Anticipate and be empathic
  - anticipate possible problems and/or complications
  - try to put yourself in the participants' place

Ethical Design is Good Research Design

- Design to minimize risks and maximize benefits
  - consider psychological, financial, social, employment, and educational risks as well
  - don’t ask more than you need to know
  - design for confidentiality
  - don’t promise more than you can deliver
  - have plans to deal with possible participant distress or injury
  - maximize any direct benefits to the participants

Ethical Design is Good Research Design

- Consider participant recruitment procedures
  - Free of coercion?
  - Role conflicts? Power inequities?
  - Best population with which to investigate your question vs. the most convenient?
  - Vulnerable population? Population that may benefit?
  - Inclusive? Equitable?
  - Inclusion and exclusion criteria clear and appropriate?

Ethical Design is Good Research Design

- Consider the informed consent process
  - Fully informed of all relevant information and planned procedures?
    - Use of data? Who has access? Video or audio tapes?
  - Has information been understood?
    - Presented appropriately? Able to ask questions?
  - Able to give consent?
    - Cogently impaired? Underage?
  - Who will do the informing and witnessing of consent?

Researcher Obligations

- Informed consent is a process
  - Means to contact researcher? Continuing exchange of information and questions?
- Monitor for problems, adverse events
- File with the IRB any necessary reports (ex. adverse events), requests for amendments, annual renewals
- Respect those who volunteer to participate in your research study

Valid Informed Consent

- Fully informed
- Information understood
- Voluntary, free of coercion
- Given by competent adult

Basic Elements of Informed Consent (45CFR46.116)

- Statement that this is research - purpose, duration, procedures
- Reasonably foreseeable risks or discomforts
- Reasonably expected benefits to subject or others
- Disclosure of alternate procedures
- Extent of confidentiality that will be maintained
- Treatment if injured? Who pays?
- Whom to contact if questions, injuries
- Statement that participation is voluntary; no penalty or loss of std. benefits if decline to participate; can withdraw at any time

Possible Additional Elements of Informed Consent

- If may involve risks not currently foreseeable
- Circumstances under which subject's participation may be terminated by researcher
- Any additional costs to subjects
- Consequences of early withdrawal
- Statement that researcher will tell subject of significant new findings discovered during course of study
- Approximate number of subjects

The Consent Process: Three Parts

- Initial informing and person's consent
- Documenting Consent
- Continuing exchange of information and opportunity to withdraw from the study

Vulnerable Populations

- “Subjects likely to be vulnerable to coercion or undue influence”
- Children
- Prisoners
- Pregnant women
- Mentally disabled persons
- Economically or educationally disadvantaged persons
- Employees? Students? Clients?

For Children and Others Not Legally Able to Consent:

- **Permission** from parent, guardian, or legal representative, and
- **Assent** from individual