HUMAN RESEARCH PARTICIPANT PROTECTION

Boston College, OSP Brief
October 2015
Stephen Erickson
ericksst@bc.edu
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
Principles of the Belmont Report (1978)

- **Respect for persons**
  - obligation to treat individuals as autonomous agents able to choose 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](http://www.bc.edu/research/oric/human.html)

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