Human Subjects Protection

Southern Illinois University Carbondale

Institutional Review Board

Response to Research Abuses

- Nazi atrocities in World War II drew attention to the lack of international standards on research with human participants and led to the formulation of the Nuremburg Code (1948).
- The Declaration of Helsinki drafted by the world Medical Association in 1964 built on the Nuremberg Code.

Response to Research Abuses

- The thalidomide disaster led to the adoption of the Kefauver-Harris Amendment (1962) to the Food, Drug and Cosmetic Act, requiring drug manufacturers to prove to the FDA the safety and effectiveness of their products and physicians to obtain informed consent from potential subjects before administering investigational medications.

Response to Research Abuses

- The National Research Act (1974) was passed primarily in response to the Tuskegee syphilis study, codified the requirement that human participants in research must be protected and set the stage for the issuance of the Belmont Report.

Belmont Report

- Respect for Persons
  - Individuals should be treated as autonomous agents
    - Informed, voluntary consent
  - Persons with diminished autonomy are entitled to protections
    - Children
    - Physically or mentally ill
    - Prisoners

Belmont Report

- Beneficence
  - Do no harm
    - Investigators and society at large must decide when benefits justify risks and vice versa
  - Maximize benefits while minimizing risk
    - The nature and scope of risks and benefits must be assessed in a systematic way

Belmont Report

- Justice
  - The benefits and risks of research must be distributed fairly
    - There must be fair procedures and outcomes in the selection of research participants
    - Representative sampling

Institutional Review Board

- The Institutional Review Board reviews all research that involves human subjects if:
  - Sponsored by SIUC
  - Conducted by SIUC employee/student in connection to their responsibilities
  - Conducted by SIUC employee/student using SIUC resources
  - Involves the use of SIUC's non-public information to identify or contact potential subjects

Key Definitions

- **Human Subject:** Any living individual about whom an investigator obtains information through interaction or intervention, and uses, studies, or analyzes the information.
- **Research:** Systematic investigation, testing and evaluation of information designed to develop or contribute to generalizable knowledge

Publication/Presentation

- Human subjects data that is disseminated or collected outside of the classroom setting typically meets the definition of *research*!
  - Includes thesis, research papers and dissertation projects
  - The Graduate School will require documentation for clearance to graduate

Application Process

- The application processes is done with an MS Word or PDF form.
- orc.siu.edu-The form is online to download. Submit the form to siuhsc@siu.edu
- Call 618-453-4534 or email siuhsc@siu.edu with ANY questions or to **schedule** a meeting!

Standard Application

- Form A
  - Must be signed by the PI (can be a student) and, *if* PI is a student, their faculty advisor must sign off on form A as well
- Form B-1
  - You must use your siu.edu email address.
  - List all Key Personnel and their training, including your faculty advisor
    - Training is a requirement for all IRB applications.

Training Requirements

- Training Requirements
  - Includes all Categories of research and all NIH funded research
    - Collaborative Institutional Training Initiative (CITI)
      - Social & Behavioral Research – Basic/Refresher

Standard Application

- Form B-1 (continued)
  - Be practical with your estimations of dates and participant numbers
    - Remember that your advisor must approve and sign before the application goes to the IRB, this takes time!
  - Special requirements checklist
    - Audio/video recording
    - Email solicitation – see page 21
    - Protected Health Information
    - Non-English materials

Standard Application

- Form B-2 – screening questions
  - Answers determine the level of review and adherence to federal regulations required
  - Answers determine which subsequent form you will need to complete

Standard Application

- Form C – for Category I (exempt)
  - Be specific! Use more pages, if necessary, but do not attach a prospectus/thesis proposal. Complete the application with the IRB as your audience.
  - Questions 5-14: any answer with “Explain” underneath requires further information
  - Attach all necessary documents: cover letter, phone script, email recruitment letter, Social media, consent form, survey/interview questions…

Standard Application

- Form D – Category II and III
  - Details details details!
    - Justify subject pool
    - Adequately and thoroughly assess risks and benefits
    - Protection of confidentiality
  - Copies of all associated materials

Informed Consent

- Must contain basic elements
  - Identify yourself, purpose, voluntary, duration, how confidentiality will be protected, contact information, risks and benefits, signature, statement of approval
  - Elements are listed in the form page 16.
- Additional requirements as relevant
  - Audio/video recording
  - Focus group

Informed Consent

- Appropriate level of comprehension
  - 8th grade for adults, 3rd-4th for ages 7-12
  - No jargon

Vulnerable Populations

- Children (under 18), Persons with limited capacity, Prisoners, Persons in residential program, Clients of human service program
  - Consent from parent/legal guardian
  - Assent from participant
    - Assent: an affirmative agreement to participate in research

Application Review

- Levels of Review – **Decided by the IRB**
  - Category 1 – Exempt (minimal risk)
  - Category 2 – Expedited
  - Category 3 – Full Committee review
- Research that has begun or is completed cannot be reviewed
- Modifications to protocols must be approved
- Approval for Category 3 is for one year

IRB

- Located in Woody Hall Office 373
- Sarah Kroenlein, Research Compliance Director
- Emily Bell, Human Subjects Coordinator
- Daniel Becque, Chair
- VCRGD Constantinos Tsatsoulis, IO
- siuhsc@siu.edu –for questions, communications, revisions, modifications, scheduling a meeting, electronic submission.