IRB 101:
Introduction to Protecting Human Research Subjects and the IRB Process at EKU
What is the IRB?

- Institutional Review Board for the protection of human research subjects
  - Responsible for overseeing the use of human subjects in research projects conducted at the University or conducted by University faculty, staff, or students at locations other than those owned by the University
  - Mission to ensure the safe and ethical conduct of research that ultimately will protect the rights and welfare of human subjects in an atmosphere of mutual trust and scientific integrity in the pursuit of knowledge
  - Authority to review, approve, require modifications to, or deny approval of research protocols
History: Human Subjects Research Misconduct

- Tuskegee Syphilis Study (1932-1972)
  - Long-term research using disadvantaged, rural black males as subjects to study the natural history of untreated syphilis
  - Recruited without informed consent
    - Spinal taps as “free treatment”
  - Not told about penicillin (discovered in 1940s)

- Nazi Medical War Crimes (1939-1945)
  - “Medical experiments” on concentration camp prisoners
    - Injecting people with gasoline & live viruses
    - Mutilation
    - Forcing people to ingest poisons
  - 1947: 23 physicians tried in criminal courts; 7 sentenced to death
  - Resulted in the Nuremberg Code (1949) – Basis for ethics codes internationally
History: Human Subjects Research Misconduct

- Jewish Chronic Disease Hospital Study (1963)
  - Injected live cancer cells into patients with chronic debilitating diseases
  - Patients not told - would unnecessarily frighten them

- The Willowbrook Study (1963-1966)
  - Deliberately infected children at state institution for “mentally defective” children with the hepatitis virus to understand its natural history
  - Consent - Children had to be in study to live there
  - Researchers’ defense: Most of the children would eventually contract the disease anyway because of the crowded and unsanitary conditions of the institution.
History: Human Subjects Research Misconduct

- **San Antonio Contraception Study (1971)**
  - Study of side effects of oral contraception
  - Subjects: 76 low income Mexican American women seeking contraception
  - Half of women switched to placebo at study’s midpoint without their knowledge
  - 10 unexpected pregnancies

- **Restaurant Letter Study (2001)**
  - Business faculty research on restaurant responses to customer complaints
  - Letters to restaurants falsely claiming food poisoning
  - Severe emotional distress for restaurant owners and employees
  - Lawsuit filed against University
Defining Human Subjects Research

- **Human Subject**
  - A *living individual* about whom an investigator conducting research obtains either
    - Data through *intervention or interaction*
    - OR
    - Private information

- **Research**
  - A *systematic investigation*, including research development, testing, and evaluation, *designed to develop or contribute to generalizable knowledge*
Not Human Subjects Research

- Student projects that occur in the classroom with no intention of sharing results beyond the classroom
  - Learning experience about the research process that is not conducted with the intention of contributing to generalizable knowledge about a particular subject

All thesis projects are considered research.
Regulations

  - [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm)

- EKU IRB policies and procedures:
  - [http://www.sponsoredprograms.eku.edu/institutional-review-board](http://www.sponsoredprograms.eku.edu/institutional-review-board)
The Belmont Report

- **Beneficence**: Requires that researchers maximize the potential benefits to participants, or to society, while minimizing the potential risks of harm.

- **Justice**: Requires that subjects be selected fairly and that both the risks and benefits of research are distributed evenly.

- **Respect of Persons**: Requires that researchers recognize the personal dignity and autonomy of individuals with special protection of those persons with diminished autonomy. Respect also requires honoring the privacy of individuals and maintaining confidentiality.

http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm


**Informed Consent**

- *Informed Consent*: Requires that participants are provided with information about the research project to assist in their informed decision of whether to participate, are given explicit assurances of the voluntary nature of their involvement in terms that are easy to understand, and are not pressured to serve as participants
  - See Essential Elements of Informed Consent

- *Assent*: A child’s affirmative agreement to participate in research
  - Mere failure to object to is not assent

- *Parent/Guardian Permission*: A parent/guardian’s permission for a child to participate in research
  - Permission secured prior to contacting child about study
The Application Process
Completing required training

- **Purposes**
  - To ensure that investigators are trained in protecting human research subjects
  - To document compliance with federal regulations

- **Collaborative Institutional Training Initiative (CITI)**
  - **Basic Course** for initial certification
  - Refresher Course required every 3 years
  - [http://www.sponsoredprograms.eku.edu/irb-training](http://www.sponsoredprograms.eku.edu/irb-training)
  - Required for principal investigators, key personnel, and faculty advisors

- **Documentation must be attached to application at time of submission**
Classifying the research: Exemption

- Application must be filed for IRB to determine exempt status
- Project must represent not greater than minimal risk and activities may only be conducted in one or more of the categories of exemption
  - Minimal Risk: the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons
  - See list of Exemption Categories
- Examples:
  - A study using surveys of adults about their beliefs on a particular topic of research interest that does not include the collection of identifiable sensitive information
  - A study using existing records if the provider of the records removes all identifying information prior to providing records to the investigator
Classifying the research: Expedited Review

- Project must represent not greater than minimal risk and activities may only be conducted in one or more of the expedited review categories
  - Minimal Risk: the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons
  - See list of Expedited Review Categories

- Examples:
  - A study involving the digital recording of a focus group session for analysis of themes among participants’ comments
  - A study using interview procedures to collect information from subjects about a sensitive topic
Classifying the research: Full Review

- Projects that do not qualify for exemption or expedited review are reviewed during a convened meeting
  - All projects involving greater than minimal risk
  - All projects involving prisoners
  - Other projects that are referred for full committee review based on the nature of the project

- Examples:
  - A study on prisoners’ childhood experiences
  - A study involving interviews with autistic children
Application procedures

Application forms and templates:
http://www.sponsoredprograms.eku.edu/irb-submission-procedures-and-application-forms

Application materials must include (as applicable):
- Completed application form signed by investigator, faculty advisor (if investigator is student), and department chair
- Training documentation for all investigators, key personnel, and faculty advisors
- Informed consent, assent, and permission forms
- Letter of support for off-campus research
- Data collection instruments (i.e., questionnaire, interview questions, or assessment scales)
- Recruitment materials (i.e., advertisements, flyers, telephone scripts, verbal recruitment scripts, cover letters, etc.)
- Grant/Contract Proposal Narrative if research is funded by grant/contract
- Forms M, P, I, and W, as applicable
Application procedures

- Submit one original of all application materials (send through campus mail to Coates CPO 20 or deliver to Jones 414)
  - Full review applications must be complete and received by deadline
    - [http://www.sponsoredprograms.eku.edu/irb-submission-deadlines-full-review-applications](http://www.sponsoredprograms.eku.edu/irb-submission-deadlines-full-review-applications)
  - Applications for exemption and expedited review may be submitted at any time and are reviewed on an ongoing basis
Application Review Process

- Exemption and Expedited Review
  - Reviewed on an ongoing basis (~2 weeks)
  - Contact is by email
  - Allowed only for projects involving not greater than minimal risk and including only activities in specific categories

- Full Review
  - Reviewed during convened meeting
  - Monthly submission deadlines and monthly meetings
  - Investigators encouraged to attend
Compliance Requirements

- Approval valid through end date of project on application, not to exceed 3 years from date of approval
  - Form E: Protocol Extension may be used to request an extension of time for an approved project
  - If project continues beyond 3 years, a new application is required

- Study must be implemented exactly as approved by the IRB unless prior approval is granted for changes (Form R: Protocol Revision)
  - Study design changes
  - Changes in subject population or number of subjects
  - Adding personnel
  - Adding research locations
  - Changes to data collection documents
  - Changes to recruitment materials or methods

- Consent forms, survey documents, recruitment flyers, etc. must be used exactly as approved by the IRB.
Compliance/Reporting Requirements

- Form C: Continuing Review required annually if approved for more than one year
- Form F: Final Report due within 30 days of project’s end
- Injuries, adverse events, or other problems reported to the IRB within 10 days of occurrence
  - Adverse event: an unexpected or serious negative event occurring in the conduct of a research project
Compliance/Reporting Requirements

- Records related to the research must be maintained for at least 3 years from the end of the project
  - Application
  - IRB approval notification letter
  - Applications and approval for any extensions or revisions
  - Signed informed consent forms
  - Completed data collection instruments
  - Digital files/recordings
  - Final report
  - Other research-related materials

- Data for student projects maintained by faculty advisors following project’s completion
Questions?
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