Excellence in Action

Institutional Review Board (IRB)

Overview for Students
WHY DO RESEARCH SUBJECTS NEED PROTECTION?

Trigger Events:
- Nazi Experiments
- Tuskegee Syphilis Study

Ethical Milestones

1947
Nuremberg Code
Status: International Code of Ethics
Informed consent, must be scientifically necessary and conducted by qualified personnel

1964
Declaration of Helsinki
Status: International ethical Guidelines
Clinical research should be based on animal and laboratory experiments, conducted and supervised only by qualified medical workers, careful assessment of risks/benefits

1974
National Research Act
Signed into law creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. All research funded by federal government must be reviewed by an IRB.
On April 20, 2010, Arizona State University (ASU) agreed to pay $700,000 to 41 members of the Havasupai Indian tribe to settle legal claims that university researchers improperly used tribe members' blood samples in genetic research.

Floranda Uqualla, 46, whose parents and grandparents had diabetes. She said she felt shamed by the news that the samples had been used for research that could potentially damage the tribe.

Institutional Review Board (IRB) Function

The purpose of the IRB is to:

- Review research and ensure that the rights and welfare of the human subjects involved in research are adequately protected.
- Ensure that the research is in compliance with the Code of Federal Regulations, Title 45 Part 46 (Protection of Human Subjects).
- Ensure congruency between grant proposals and IRB application.
IRB HAS AUTHORITY TO:

- **Approve** the research.
- **Require modifications** before approving research.
- **Disapprove** the research.
- **Table** the research protocol until changes are made.
EXAMPLES OF PROJECTS THAT ARE NOT CONSIDERED GENERALIZABLE

- Biographies
- Oral histories that are designed solely to create a record of specific historical events.
- Service or course evaluations, unless they can be generalized to other individuals.
- Services, or concepts where it is not the intention to share the results beyond KSU or any agency supporting the research.
- Classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices.
- Quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond KSU. (Teaching evaluations, customer service surveys).

REMEMBER: Only the IRB is able to make the determination whether or not an activity is research...not the investigator.
The IRB Process at Kent State University

**STUDENT**
- Completes required CITI online training.
- Completes IRB application electronically attaches instruments, consent forms and all applicable documents.
- Has application reviewed and signed by faculty advisor who serves as the Principal Investigator (PI)
- Attaches a copy of faculty advisor CITI online training completion certificate to application.
- Submits materials to Discipline-specific reviewer via email.
- Communicates with reviewer to revise application, if necessary.

**Discipline-specific reviewer**
- Reviews application for completeness, methods and adherence to ethical standards.
- Communicates requirements & need for revisions to the PI and student.
- Sends final version of application to the Office of Research Compliance for final review and inclusion into the IRB meeting materials.
- Makes recommendation about what Level of review is needed.

**Research Compliance**
- Notifies Investigator via email that application has arrived in our office.
- Reviews level recommendation and evaluates the application for compliance with federal regulations.
- Verifies training requirements have been met.
- Communicates with Investigator regarding any additional requirements, or revisions needed.
- Sends final written notification of IRB approval to Investigator.
All research projects are categorized into one of three categories for the IRB review process. Each category is different in the level of scrutiny and submission procedures. The IRB is responsible for making the final decision of which category a research project falls under.

- **Full review by convened IRB - (Level 3)**
  - Sensitive subjects, vulnerable subjects

- **Expedited - (Level 2)**
  - Involve children, audiotaping, research on individual or group behavior (focus groups)

- **Exempt from Annual review – (Level 1)**
  - Surveys, evaluation of service programs, educational tests, class projects, food quality, research involving existing data
TYPES OF REVIEW

- **Initial** – Level of review is determined.
- **Continuing/Annual Review** – Level 2’s and 3’s.
- **Modifications** – changes to research. Must be reviewed and approved before implemented.
- **Adverse events** - safety Information or unanticipated problems for subjects or others.
- **Noncompliance** – a participant calls Research Compliance office and reports that investigator is doing something he/she shouldn’t be.
CRITERIA FOR IRB APPROVAL

- **Risks are Minimized** - (Consistent with a sound research design and does not unnecessarily expose subjects to risk)
- **Risks are Reasonable in Relation to Benefits**
- **Selection of Subjects is Equitable**
- **Informed Consent will be Sought** - for each prospective subject unless a waiver is granted.
- **Informed Consent will Be Documented**
- **Research Plan Adequately Provides for Monitoring the Data Collected to Ensure Safety of the Subjects**
- **Research Plan Adequately Protects the Privacy of Subjects and Maintains Confidentiality**
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, **additional safeguards** need to be included in the protocol to protect the rights and welfare of these subjects.
CONSENT FORM REQUIRED ELEMENTS

- Statement that the study involves research
- Research is described
- Description of Risks
- Description of Benefits
- Disclosure of Alternatives (if applicable)
- Confidentiality
- If more than minimal risk, plans for compensation and/or medical treatment (Kent State has none).
- Participation is voluntary
- Whom to Contact (Include name and contact information for investigator, faculty advisor and KSU Institutional Review Board @ 330.672.2704)
INFORMED CONSENT PROCESS

- Informed Consent process is more than just the use of the IRB-approved consent document!

- Initial

- Ongoing
COMMON MISTAKES TO AVOID WHEN SUBMITTING IRB APPLICATIONS

- Indicating that data is anonymous when it is actually confidential.
- Stating that there are no risks involved in the activity. Even though the risks may be low, they need to be listed in the application.
- Not clearly defining the study and the involvement of participants.
- Not completing CITI online training, or completing the wrong online training.
- Faculty Advisor has not completed CITI online training.
- Signature page does not have all the required signatures.
- Consent forms, survey, or interview instruments are not attached for review.
- Not including necessary approvals or letters of support from other institutions (e.g., elementary or high school principals or superintendents).
Information

We are located on the second floor of Cartwright Hall
Website www.kent.edu/research/researchsafetyandcompliance/irb/index.cfm