Institutional Review Board
Overview for Students
WHY DO HUMAN RESEARCH SUBJECTS NEED PROTECTION?

Trigger Events

The Nazi Experiments

Tuskegee Syphilis Study

Ethical Milestones

Nuremberg Code 1947

National Commission for the Protection of Human Subjects of Biomedical & Behavioral Research 1974

* Belmont Report 1978
* Common Rule 1981
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.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Members of the Commission
Kenneth John Ryan, M.D., Chairman, Chief of Staff, Boston Hospital for Women.
Joseph V. Brady, Ph.D., Professor of Behavioral Biology, Johns Hopkins University.
Robert E. Cooke, M.D., President, Medical College of Pennsylvania.
Dorothy I. Height, President, National Council of Negro Women, Inc.
Albert R. Jonsen, Ph.D., Associate Professor of Bioethics, University of California at San Francisco.
Patricia King, J.D., Associate Professor of Law, Georgetown University Law Center.
Karen Lebacqz, Ph.D., Associate Professor of Christian Ethics, Pacific School of Religion.
David W. Louisell, J.D., Professor of Law, University of California at Berkeley.
Donald W. Seldin, M.D., Professor and Chairman, Department of Internal Medicine, University of Texas at Dallas.
Eliot Stellar, Ph.D., Provost of the University and Professor of Physiological Psychology, University of Pennsylvania.

*** Deceased.
GUIDANCE DERIVED FROM THE BELMONT REPORT

➢ **Respect for Persons**
  - Informed Consent Process.
  - Respect for Privacy.
  - Provide extra protections for vulnerable subjects.

➢ **Beneficence**
  - Good research design.
  - Competent investigators/researchers.
  - Favorable risk-benefit analysis.

➢ **Justice**
  - Equitable selections of subjects and fair distribution of burdens and benefits of the research.
The “Common Rule” is the set of regulations which were developed to ensure compliance with the principles of the Belmont Report.

• The regulations fall under the Department of Health and Human Services.

• The regulations have been adopted by many other federal departments which regulate human research.

• There are many other regulations with which KSU is sometimes required to comply, such as the Food and Drug Administration, but these are all *in addition* to the “Common Rule”.

The Common Rule
WHAT’S THE DIFFERENCE BETWEEN THE BELMONT REPORT AND THE COMMON RULE?

- THE BELMONT REPORT is a guidance document that provides the basic ethical standards for researchers.
  *(Tells us why...)*

- The COMMON RULE (45 CFR 46) is a set of federal policies that Kent State University has agreed to adopt (via a legally binding document) as the standards for research.
  *(Tells us how...)*
Protective mechanisms established by The Common Rule

- Institutional assurances of compliance
- Review of research by an IRB
- Informed consent of subjects
Institutional Assurance

Kent State University has a signed agreement in place with the Office for Human Research Protections that all of the institution’s human subject research activities, regardless of funding, will be guided by the Belmont Report, will comply with the Common Rule, and other regulations as applicable.

This is referred to as a Federalwide Assurance (FWA).
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.

• help *facilitate* research for Kent State investigators.

There are two IRB committees at Kent State. Each board is comprised of 10 faculty members, two medical doctors, a community representative, a non-scientist, and an administrator.
IRB HAS AUTHORITY TO:

- **Approve** the research.
- **Require modifications** before approving research.
- **Disapprove** the research.
- **Table** the research protocol until changes are made.
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.
- 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 & revisions to Investigator.
- 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)**
  - Anonymous 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 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.
I am not sure if my project is human subjects research, what should I do?

Answer: Complete the **IRB DETERMINATION FORM**. Submit it to the Research Compliance Office and wait for a reply.
FREQUENTLY ASKED QUESTIONS

Do I really have to complete the CITI online training?

Answer: Yes, your application will not be approved until you have completed the training.
Which of the CITI courses should I complete?

Answer:
You should complete one of these courses:

STUDENTS CONDUCTING NO MORE THAN MINIMAL RISK RESEARCH – Complete this course if you are a student that is conducting a research project for a class. You should always first check with your professor however, you should complete this course if you are going to conduct a class assigned research project that will NOT:
- Be submitted for publication
- Involve audio taping, video taping or photographing of subjects.
- Include sensitive subject matter (sexual conduct, depression, drug use, underage drinking, abuse, etc..).
- Involve deception.
- Involve a vulnerable population (children, pregnant women, terminally ill).
- Involve more than minimal risk (i.e., action research, anonymous surveys).

SOCIAL & BEHAVIORAL BASIC/REFRESHER COURSE – Choose this course if you are a student and/or investigator that is conducting Social/Behavioral (sociology, anthropology, psychology, education) research on human subjects that involves more than minimal risk.

BIOMEDICAL BASIC/REFRESHER COURSE – Choose this course if you are a student and/or investigator that is conducting Biomedical (biology, physiology, clinical medicine) research involving human subjects that involves more than minimal risk. If you think you are going to collect medical information from the participants, this is the training that you need to complete.
What happens if I lose the completion certificate for the CITI training or cannot print it out?

Answer: Call or email me and I will sign into the system and obtain a copy for you.
What happens if I go to another institution and want to do research...do I have to repeat the training?

Answer: Not usually. Most institutions recognize and accept the CITI training to fulfill their requirements. The training is valid for 3 years. After that, you must complete the refresher course.
How do I find a discipline-specific reviewer?

Visit our website at www.kent.edu/research

Click on the Office of Research Safety and Compliance

Click on the Institutional Review Board – IRB
Can I begin my project without IRB approval?

No. Engaging in human subject research without IRB approval has serious ethical implications and violates university and federal policies. Students, faculty, and staff are required to submit IRB applications before embarking on any data collection. Even pilot studies must be approved by the IRB. IRBs do no have the option of granting “retroactive” approval after research is done, so you are strongly encouraged to submit your research proposal or consult with the Research Compliance office if you are unsure whether your project needs IRB approval.
How long does it take to get IRB approval for my protocol?

Answer: Plan ahead. Do not wait until the last minute to submit your application. Approval can take 1-6 weeks. The more complete your application is...the quicker you can get approval.

You will receive a “notification” email once your application reaches the Research Compliance office. The email will contain information about the number assigned to your application and who to contact with questions.
Should I keep a copy of my IRB application?

Answer: YES, definitely save an electronic copy of your application!

You should also save the notification email that our office sends to you. It contains the log number for your protocol. This is the number that you should use if you have to call/email our office with questions.
Is there somewhere where I can get a template to help me develop the consent form for my study?

Answer: YES visit the Research website at:

www.kent.edu/research/researchsafetyandcompliance/irb/forms.cfm
I am a teacher...can I do research in my classroom?

Answer: Probably. You will need written documentation from the authority at your school that is able to approve research to be conducted in a classroom (typically the principal or superintendent) and if you are doing the research as a Kent State investigator, from the KSU IRB.
Can I do international research?

Answer: Probably. There are additional issues that you may need to address like:

- Translated consent forms
- The Research requirements in the other country. You can access a link to the International Compilation of Human Research Protections from our website.
Information

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