EASTERN ILLINOIS UNIVERSITY

Human Subjects in Research

A guide for applying for IRB review

The Protection of the Rights and Welfare of Human Subjects is an Essential Part of Research

The principles of research ethics evolved as the result of past abuses.

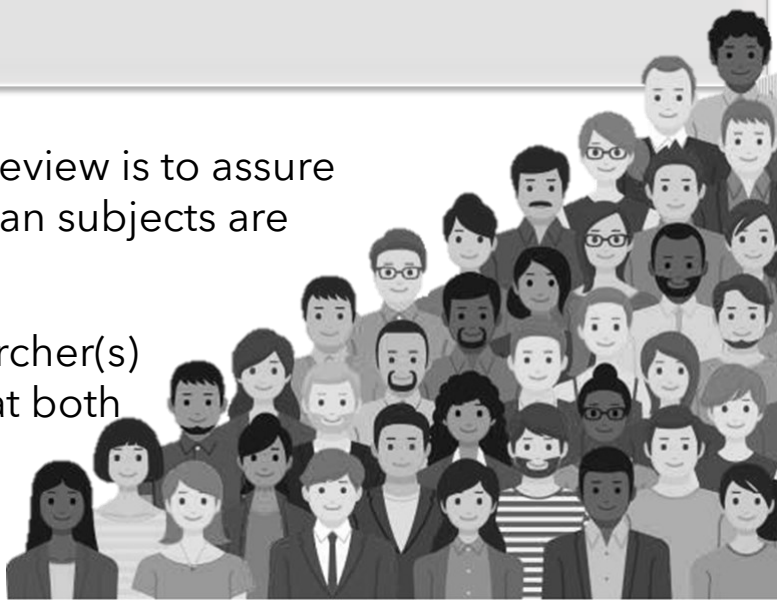
Regulatory and ethical safeguards are designed to protect the rights and dignity of participants in clinical trials and research studies.

Institutional Review Boards (IRB) were established in 1974 as part of the National Research Act.

At the highest level, they are governed by the United States Department of Health & Human Services' Office of Human Research Protections (OHRP) at 45 CFR part 46 and the Food and Drug Administration's regulations at 21 CFR part 50 and 21 CFR part 56.

The fundamental purpose of IRB review is to assure that the rights and welfare of human subjects are protected.

IRB reviews also protect the researcher(s) and the institution by ensuring that both have complied with applicable regulations.



Institutional Review Board at EIU

The Institutional Review Board (IRB) at Eastern Illinois University serves as an objective third party with the purpose of protecting and managing risk to human participants involved in research.

- The IRB is composed of at least nine members (and several alternates), representing each of the four colleges.
- Diverse representation is emphasized, and the committee is composed of members with a variety of experiences and expertise.

The IRB membership list is posted on the IRB website

Office of Research and Sponsored Programs

- The review process is coordinated by the Office of Research and Sponsored Programs (ORSP).
- ORSP is also responsible for managing human subjects research training, assisting with assurance of compliance with federal regulations, assisting in liaison with funding agencies, and record keeping.
- ORSP serves as the point of contact for any questions you may have about human subjects in research.

The Office of Research and Sponsored Programs can be contacted during regular business hours, Monday through Friday.

1102 Blair Hall
217-581-8576
eiuirb@eiu.edu

Research Personnel

Principal Investigator (PI)

- Students are the PI when conducting their own research
- Compiles/submits protocols for review
- Conducts the study in accordance with the protocol as approved by the IRB
- Informs faculty sponsor and IRB of any problems that arise during research
- Must complete CITI Training

Faculty Sponsor

- Serves as co-Investigator for student PI
- Provides guidance to student PI throughout the research process
- Attends IRB meeting when student protocol is reviewed
- Must complete CITI Training

Co-Investigator

- Any additional investigator participating in the research project in any capacity
- Must complete CITI Training

Research Ethics Training

All researchers must complete training regarding the protection of human subjects in research before beginning any research activities. EIU has contracted with the Collaborative Institutional Training Initiative (CITI) to provide on-line research ethics education.

The required course, *Social/Behavioral Research Course for the Protection of Human Research Subjects*, takes approximately one hour to complete and consists of three required modules, plus one elective module of your choice. There are also three supplemental modules, which may be taken for no credit.

The course must be completed with a score of at least 80% for each module.

Social/Behavioral Research Course Modules:

Required Modules:

Assessing Risk • Informed Consent • Privacy and Confidentiality

Elective Modules:

Research with Children • Federal Regulations • Plagiarism

Health Privacy Issues for Researchers • Research with Prisoners

Research Misconduct • Basics of Health Privacy • International Research

Health Privacy Issues for Students and Instructors

Supplemental Modules:

Institutional Responsibilities as They Affect Investigators

Conflicts of Commitment and Conscience

History and Ethical Principles

The IRB Review

Any research that involves human beings as subjects must be reviewed and approved by the institution's IRB before any research activity begins

- IRB review should be sought after research is approved by the department or faculty advisor, when applicable
- Researchers will complete the Application for IRB Review and supply other required information to create a protocol, which will be reviewed by the IRB
- EIU's IRB Forms and guidelines were developed to enable researchers to provide all information needed for an IRB review
- Processing times vary by review type. Notification of status can be expected:
  Exempt Protocols: within 10 working days of receipt of the protocol.
  Expedited and Full Review Protocols: within 20 working days of receipt .

Protocols are reviewed on a continual basis in the order they are received, regardless of estimated project start date.

The Review Process:

1 **Principal Investigator compiles a protocol**
Completed forms and all required supplemental information are gathered to create a protocol

2 **Protocol is submitted**
e-mail to eiuirb@eiu.edu or deliver to Office of Research and Sponsored Programs, 1102 Blair Hall. **Do not send via Sharepoint or One Drive**.

3 **Protocol is screened by ORSP**
If modifications are required before the IRB can review the protocol, an e-mail will be sent to the PI and Faculty Sponsor to request them

4 **IRB reviews the protocol**
If the IRB member reviewer requests modifications, the ORSP will e-mail the PI and Faculty Sponsor to request the modifications

5 **IRB makes a determination**
The PI and Faculty Sponsor are notified via e-mail

Compiling a Protocol

The PI is responsible for completing all forms (with guidance from their Faculty Sponsor).

The following items **must** be included in a protocol when it is submitted for IRB review:

✓ Application for IRB Review

- All fields on the form require a complete response unless otherwise indicated
- The form must be signed by the PI and Faculty Sponsor and all boxes in the submission statement must be checked
- Each prompt will state what information is required. Please read all prompts carefully and provide all requested information. Responses should be thorough and descriptive.

✓ Informed Consent

If children are the subjects of research, include assent also

✓ Research Instruments

Questionnaires, surveys, tests, or other research instruments that will be administered to subjects.

✓ Recruitment Materials

Any advertisements, letters, flyers, e-mails, and/or social media posts that may be used.

✓ Administrator Letter (when applicable)

Written permission from other institutions or agencies involved in the research (e.g., school or hospital administrator, prison warden)

- Exempt research requires a letter from an administrator only when children are involved.

Forms and informed consent templates are located at the IRB Forms page.

Informed Consent

Mandated by Federal regulation, informed consent assures that potential subjects understand the nature of a research project and can make an informed, voluntary decision about participation.

Informed consent must contain certain basic elements presented in a way that is appropriate for the targeted subject population.

- If necessary, informed consent must be translated to the potential subjects' language.

Consent is usually documented through the use of a written form that is signed by the subject or the subject's legally authorized representative, parent, or guardian.

- When research is conducted online, informed consent can be obtained online.

Research Involving Children

When conducting research where the subjects are children, informed consent must first be obtained from parents or guardians.

Once parental informed consent is obtained, then *assent* must be solicited from subjects who are capable of providing assent.

The IRB Forms page contains the following resources to assist with developing informed consent:

Informed Consent Form Checklist:
A listing of requirements of elements informed consent

Informed Consent Form Template:
Phrasing and format guidance

Informed Consent Process Guidelines:

Assent Guidelines:
Phrasing and delivery format guidelines

Template Letter to Parents:
Phrasing and guidance for parent informed consent when children are the subjects of research

Informed Consent and Assent Exceptions

Federal regulations allow the IRB to waive some or all informed consent or assent requirements as long as certain criteria are met.

- In certain situations, informed consent or assent is required, however, signatures do not have to be collected. This is called *waiver of* ***documentation*** *of informed consent*.
- In other situations, informed consent or assent can be *waived*.

It is important to provide **clear** and **thorough** justification for a *waiver of documentation of informed consent* or assent as requested in the Application for IRB Review.

When requesting a *waiver of informed consent* or assent, submit the Application for IRB Review Addendum Waiver of Informed Consent or Assent form with the Application for IRB Review.

Common Protocol Mistakes

Take care to avoid some of the most common reasons why protocols are returned for modification:

Prompts are not answered completely in the Application

Read each prompt carefully to ensure you have provided **all** required information

There is no risk identified in Section F of the Application

There is always some risk in any study

Required supplemental materials are not included

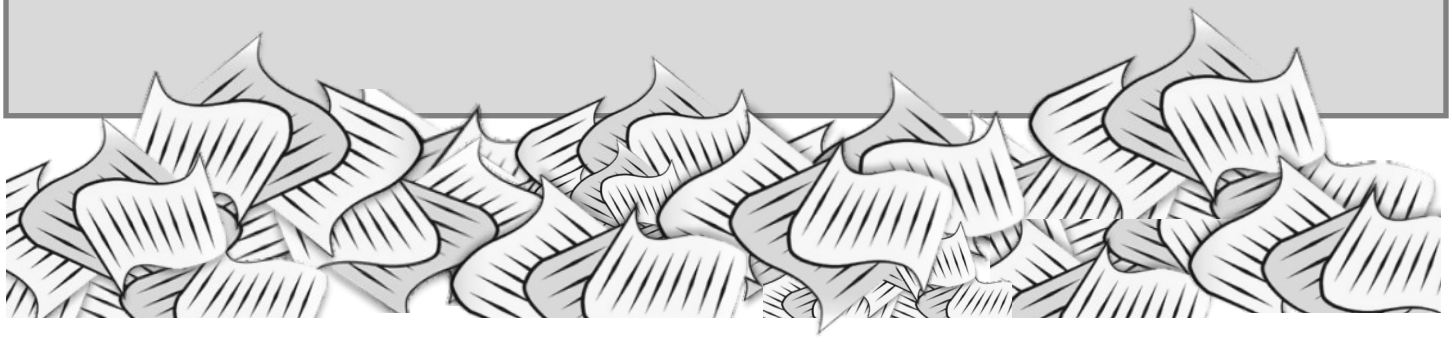
Don't forget to include recruitment materials, administrator letters, instruments, etc.

Informed Consent is missing information

Review the Informed Consent Checklist carefully

Faculty Sponsor's CITI Training has expired

CITI Training must be renewed every three years



Responsibilities After Approval

Once a protocol has been approved, researchers must conduct the study as it was approved by the IRB and adhere to the following:

Retain signed informed consent forms and research materials for at least three years after completion of research.

Funding agencies may have their own requirements; the PI is responsible for understanding and complying with those policies.

Notify the IRB **immediately** of any problems encountered that could adversely affect the health or welfare of the subjects in the study

Report of Adverse Effects or Noncompliance must be submitted within 5 business days.

Submit the *Request for Modification of Existing Protocol* form to request a review of any changes - even minor ones - to a research project.

Changes must be approved by the IRB prior to implementation.

If the project has an expiration date and research will extend beyond that date, submit the *Request for Protocol Continuation* form.

Research cannot continue beyond the expiration date until the IRB has approved it.

Submit the *Completion of Research Activities* form to report project completion if the approval letter states to do so.
