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.

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 at EIU at all times.

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 Compliance Coordinator, who reports to the Director of 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.

Located in Blair Hall, ORSP is a department within the Graduate School.

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

- Co-Investigator for student PI
- Provides guidance for student PI
- 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 *Social/Behavioral Research Course for the Protection of Human Research Subjects* course 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.

Required Modules:

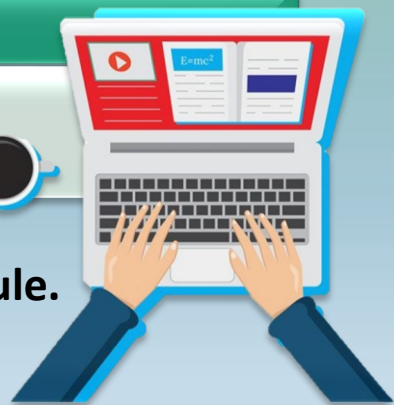
Assessing Risk • Informed Consent • Privacy and Confidentiality

Elective Modules:

Research with Children • Research with Prisoners • Basics of Health Privacy
Health Privacy Issues for Students and Instructors • Health Privacy Issues for Researchers
International Research • Plagiarism • Research Misconduct • Federal Regulations

Supplemental Modules:

Institutional Responsibilities as They Affect Investigators
Conflicts of Commitment and Conscience • History and Ethical Principles



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

The IRB Review Process

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.

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 IRB forms 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

This training will explain the process for obtaining IRB review at EIU

The IRB Review Process

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

1. **Primary 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
3. **Protocol is screened by the Compliance Coordinator**
   - If modifications are required before the IRB can review the protocol, the Compliance Coordinator will e-mail the PI and Faculty Sponsor to request them
4. **IRB reviews the protocol**
   - If the IRB member reviewer requests modifications, the Compliance Coordinator will e-mail the PI and Faculty Sponsor to request them
5. **IRB makes a determination**
   - The PI and Faculty Sponsor are notified via e-mail

Levels of Review

There are three levels of IRB review: **exempt**, **expedited**, and **full**. The type of review conducted is determined by the nature of the research being proposed.

- The PI will request one of the three types of review with their submission, however, the IRB makes the final determination based on established criteria.
- The submission process for each level of review is the same.

Exempt Review	Research activities where human subjects' participation involves no more than minimal risk and falls within one or more exemption categories. This is the most common type of review. See Form B for more details. Written notification of the status of the project can be expected within 10 working days of receipt of the protocol by the IRB.
Expedited Review	Research activities where human subjects' participation involves no more than minimal risk and falls within one or more expedited review categories. See Form C for more details. Written notification of the status of the project can be expected 10 to 20 working days after receipt of protocol by the IRB.
Full Review	Research activities where human subjects' participation involves more than minimal risk, does not fall within any exemption or expedited review categories, or involves certain vulnerable populations. Full reviews are conducted by the IRB as a committee. A full review will be scheduled for the next regular IRB meeting or a special meeting may be called.

Compiling a Protocol

The following items must be included in a protocol when it is submitted for IRB review. The PI is responsible for completing all forms (with guidance from their Faculty Sponsor).

Forms and templates are located at the IRB Forms page.

- ✓ **Form A**: New Application for Review of Research Involving Human Subjects
- ✓ If you are requesting an *exempt* review: **Form B**
- ✓ If you are requesting an *expedited* review: **Form C**
- ✓ **Informed consent**
  If you are seeking a waiver of informed consent, or a waiver of documentation of informed consent, you must include **Form I**
- ✓ Questionnaires, surveys, tests, or other research instruments that will be administered to subjects.
- ✓ Any advertisements, letters, flyers, and/or social media posts that may be used.
- ✓ If applicable, written permission from other institutions or agencies involved in the research (e.g., school board, hospital, agency, prison)

Form A

New Application for Review of Research Involving Human Subjects

Form A must be submitted for all levels of review.

The form must be signed by the PI and Faculty Sponsor

- When e-mailing a protocol, an e-mail from the Faculty Sponsor serves as signature of assurance.

All fields on the form require a complete response unless otherwise indicated.

- Each prompt will state what information is required. Please read them carefully and provide all requested information.

Form A is utilized to explain how researchers will protect the rights and welfare of the study's human subjects in the course of their research. **Be as thorough and descriptive as possible**.

Forms B & C

Exempt and Expedited Reviews

Forms B and C are checklists that contain criteria for exempt and expedited reviews.

- Form B must be submitted for **exempt** review requests
- Form C must be submitted for **expedited** review requests

Select the criteria on Form B or C that applies to your project.

- The submitted form must have at least one criterion selected, but can also have more than one criterion selected.

Informed Consent

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

Informed consent is mandated by Federal regulation and 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.

Informed 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 provided and documented online.

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

- *Informed Consent Form Checklist* - a listing of the basic elements that must be included in an informed consent form.
- *Informed Consent Form Template* - phrasing and format guidance

Informed Consent: Research Involving Children

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

Assent must be solicited from subjects who are capable of providing assent (typically 12 or older), in addition to parent or guardian informed consent.

In a P-12 school setting, informed consent can be presented in the form of a letter to parents. The letter must include all required elements of informed consent, plus the following:

- A statement that the researcher/teacher is conducting a project in the classroom as part of the requirements of a graduate degree
- A statement that the school has given permission for the research
- If the study results will be shared with the school, a statement that this will occur, and whether or not those results will contain individually identifying data

Exceptions to Informed Consent: Form I

In general, the process for informed consent is the same for all research. However, there are a couple of exceptions:

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

Federal regulations allow the IRB to waive some or all informed consent requirements as long as certain criteria are met. It is therefore important to provide clear and thorough justification as requested in Form I.

Research Instruments

The IRB must review all research instruments that will be administered to subjects. Include all research instrument content in your protocol.

Tests or Assessments

- Copies of standardized assessments must also be included

Questions or Prompts

- Interviews, Focus Groups, or any other conversational collection of data
- If additional questions are to be formulated as the interviews progress, indicate guidelines

Surveys or Questionnaires

- Provide survey or a list of all survey items including demographic questions
- Online surveys can be provided via a link to the survey

Rubrics or Charts

- Including Behavior Charting Tables
- Include any descriptors or guidelines that will be utilized

Media Content

The IRB must review all media or correspondence utilized in research for recruitment, debriefing, or other informational purposes. Include all media content in your protocol.

Permission from Other Institutions

When research involves other institutions or agencies, such as a school district, hospital, or prison, or other agency, written permission from that institution may need to be obtained and submitted for IRB review.

Written permission must be on agency letterhead and signed by the appropriate administrator. The letter must include the following:

- Assurance that the administrator understands the nature of the project
- A statement that the facility has adequate capabilities to perform the research
- Assurance that the research is appropriate for the institution's population

If facility personnel are involved in data collection, the administrator must provide assurance that they have appropriate expertise and will follow IRB approved procedures

If research involves protected health information, HIPAA Authorization or Waiver of Authorization is required

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

Additional Considerations

Common Protocol Mistakes

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

Incorrect type of review is requested
Many studies are submitted requesting expedited review when they are actually exempt

Prompts are not answered completely in Form A
Read each prompt carefully to ensure you have provided all required information

Form A, Prompt 9 states there is no risk
There is always some risk in any study

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

Protocol Submission and Initial Screening

Once the protocol has been compiled, it will be submitted to ORSP for initial screening. The Compliance Coordinator will verify that all required information has been provided and will send the protocol to the designated IRB reviewer(s).

Submit protocols to ORSP

- e-mail protocol as an attachment to eiuirb@eiu.edu
  Do not send Sharepoint links
- e-mail submission is preferred; unstapled paper copies will also be accepted

Protocols are reviewed in the order they are received, regardless of project start date.

- The Compliance Coordinator will screen the protocol within 10 business days of receipt

The Coordinator will contact you if your protocol is missing information or requires modification

- Revised protocols will also be reviewed in the order they are received

Be sure to check your e-mail

IRB Review of Protocols

Protocols are reviewed by the IRB on a continual basis in the order they are received, regardless of project start date. Upon review, the IRB will take one of the following actions:

Review Type	Actions		
Exempt:	**Certify the project as exempt**	**Require modification or additional information** The revised protocol can then be resubmitted for IRB review	**Require expedited or full review of application**
Expedited:	**Approve the research application** The IRB will determine the length of time the study is approved. Some protocols will not require an expiration date	**Require modification or additional information** The revised protocol can then be resubmitted for IRB review	**Require a full review of the application**
Full:	**Approve the research application** The IRB will determine the length of time the study is approved	**Require modification or additional information** The revised protocol can then be resubmitted for IRB review	**Disapprove the research application** The PI may discuss the reason(s) with an IRB member, revise the protocol, or withdraw the application

The PI (and Faculty Sponsor, when applicable) will receive e-mail notification of their project's status. The e-mail will indicate if further action is needed.

- Resubmitted revised protocols will be reviewed within 10 business days (exempt or expedited reviews), or at the next IRB meeting (full review)

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

Form F must then be submitted to ORSP within 5 business days after initial awareness of the issue.

If the project has an expiration date and research will extend beyond that date, submit Form E to request a continuation review. Research cannot continue beyond the expiration date until the IRB has approved it.

Submit Form D to request a review of any changes - even minor ones - to a research project. Changes must be approved by the IRB prior to implementation.

Submit Form G to report project completion if the approval letter states to do so.

For More Information:

If you have any questions, contact the Compliance Coordinator in the Office of Research and Sponsored Programs

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

The Office of Research and Sponsored Programs is available during regular business hours, Monday through Friday.