EASTERN ILLINOIS UNIVERSITY

Action Research Involving Human Subjects

A guide for applying for Action Research
and Course Project Review

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

- Regulatory and ethical safeguards are designed to protect the rights and dignity of participants in clinical trials and research studies.
- At the highest level, they are governed by the United States Department of Health & Human Services' Office of Human Research Protections and the Food and Drug Administration's regulations.

The Institutional Review Board at EIU

The Institutional Review Board (IRB) 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 diverse members with a variety of experiences and expertise, representing each of the four colleges.

The Office of Research and Sponsored Programs

The review process is coordinated by the Office of Research and Sponsored Programs (ORSP).

ORSP serves as the point of contact for any questions you may have about human subjects in research. ORSP can be contacted during regular business hours, Monday through Friday.

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

Terminology

Research Protocol

Action Research Project details need to be submitted for review to ensure that federal guidelines and EIU policy will be adhered to. These details are compiled into a *research protocol*.

Course Project Review

Action research projects can be reviewed using a Course Project Review process, provided certain criteria are met.

IRB Review

Research projects that do not meet the criteria for Course Project Review are reviewed utilizing an IRB review process. There are three levels of review: Exempt, Expedited, and Full. Most research at EIU is Exempt.

Principal Investigator (PI)

Students are the Principal Investigator (PI) when conducting their own research. PI responsibilities include:

- Compiling/submitting research protocols for review
- Conducting the study in accordance with the protocol as approved
- Informing the faculty sponsor and IRB of any issue that arise during research
- Completing CITI Training prior to protocol submission

Faculty Sponsor

Serves as co-Investigator for the student PI. Responsibilities include:

- Providing guidance to the student when developing the protocol
- Providing guidance to the student throughout the research process
- Completing CITI Training prior to protocol submission

Co-Investigator

Any additional person participating in the project in any capacity

- Must complete CITI Training prior to protocol submission

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

Action Research Criteria

When an action research project is being conducted to meet the requirements of a research methods (or similar) course, it must meet the following criteria to be considered for Course Project Review:

Course Project Review is appropriate provided the action research project meets the following conditions:

- ✓ The project is not intended to contribute to generalizable knowledge
- ✓ The project place the subjects at more than minimal risk
- ✓ The project is not intended for publication

Submitting an Action Research Protocol for Review

When research meets the criteria above, the PI must submit the ***Application for Course Project Research Review***.

- Under the guidance of a faculty advisor, PIs will complete the *Application for Course Project Research Review* and supply other required information to create a protocol
- Review should only be sought after the project and research protocol are approved by the faculty advisor.

Compiling an Action Research Protocol

The student PI is responsible for completing the Application (with guidance from their Faculty Sponsor).

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

✓ Application for Course Project Research Review

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

- Each prompt will state what information is required. Please read all prompts carefully and provide all requested information. Responses should be thorough and descriptive.

The form must be signed by the PI and Faculty Sponsor and all boxes in the submission statement must be checked

✓ **Informed Consent** (and **Assent**, when applicable)

If children are the subjects of research, include assent

- If assent is being delivered verbally, include the script to be used

✓ Research Instruments

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

- Standardized assessments do not need to be included

✓ 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

- For example, a school or hospital administrator

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

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

Risk is not properly identified in the Application

There is always some risk in any study

Required supplemental materials are not included

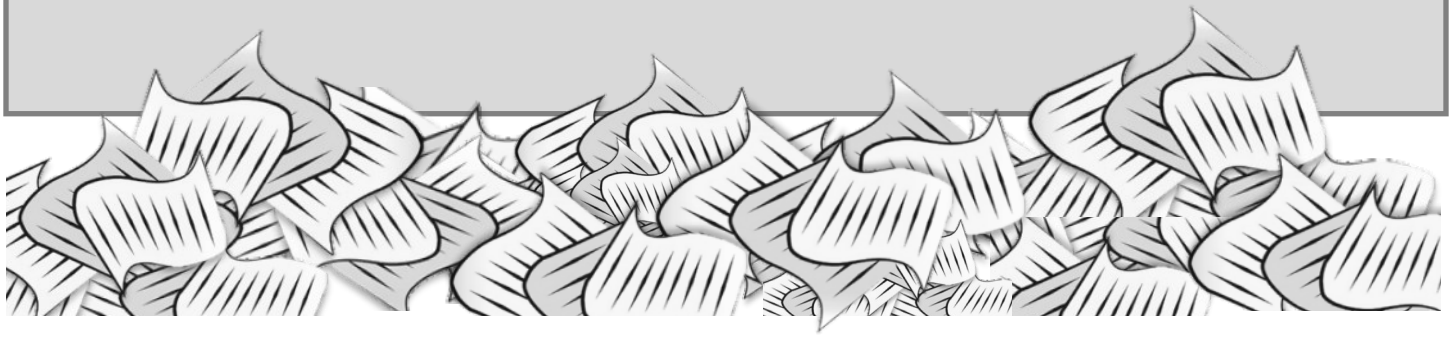
Don't forget to include recruitment materials, administrator letters, instruments, etc.

Informed Consent is missing information

See the next page for more information about informed consent and assent

Faculty Sponsor's CITI Training has expired

CITI Training must be renewed every three years



Informed Consent and Assent

Mandated by Federal regulation, informed consent assures that potential subjects or their parents understand the 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.

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

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

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 sought from subjects who are capable of providing assent.

Informed Consent and Assent Exceptions

In certain situations, researchers are allowed to provide informed consent or assent information, but consent signatures do not have to be collected. This is called *waiver of* ***documentation*** *of informed consent*.

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

The Action Research Review Process

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

1

Principal Investigator compiles the protocol

Completed forms and all required supplemental information are gathered to create a protocol.

2

Protocol is submitted

e-mail to eiuirb@eiu.edu. **Do not send via Sharepoint or One Drive**.

3

Protocol is screened by ORSP

If modifications to the protocol are required before it can be reviewed, an e-mail will be sent to the PI and Faculty Sponsor.

4

Protocol is reviewed

If the reviewer requests modifications to the protocol, ORSP will e-mail the PI and Faculty Sponsor.

5

Research project is certified to proceed

The PI and Faculty Sponsor are notified via e-mail.

Responsibilities After Approval

Once a protocol has been approved, researchers must conduct the study exactly as approved and adhere to the following:

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

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

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 prior to implementation.

If the project research will extend significantly beyond the estimated completion date, submit the *Request for Protocol Continuation* form.
Research cannot continue until the continuation is approved.

If you have any questions, contact your faculty advisor, or the Office of Research and Sponsored Programs at:

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