Institutional Review of Research Involving Human Participants

IRB Presentation

EASTERN WASHINGTON UNIVERSITY IRB

HEIDI HILLMAN PHD, BCBA-D, LMHC, NCC

Institutional Review Board Members

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INSTITUTIONAL Review Board (IRB)

The IRB committee established to advocate for the protection of the rights and welfare of human participants involved in research.

Review is required for all research involving human participants conducted by individuals at EWU.

Approval must be obtained prior to initiating research.

Institutional Research (IR) is **NOT** IRB

Information and Questions

IRB PURPOSE

- Review research, human subjects
- Safeguarding rights and welfare
- Review protocols
- Assist and guide researchers

IRB Responsibilities

- Evaluates new research proposals, reviews on-going research
- When reviewing, we consider:
    - Recruitment process
    - Selection and informed consent of prospective participants
    - Risks and potential benefits
    - Additional safeguards for vulnerable populations (if needed)
    - Protecting participants' privacy, maintaining confidentiality.
- For on-going research
    - Change of protocol
    - Requests for renewal (before expiration)

How do I know if a project needs IRB review?

Definition of "research"

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Definition of "human subject(s)"

How do I know if a project needs IRB review?

Research: systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

How do I know if a project needs IRB review?

human subject(s): a living individual about whom an investigator (whether faculty, staff or student) conducting research obtains: (1) Data through intervention or interaction with the individual; or (2) Identifiable private information.

Research Categories

- Research projects categorized into one of three categories
  - Exempt
  - Non-Exempt Expedited
  - Non-Exempt Full Board

*Level of risk is an important factor in determination

- Minimal risk: the probability and magnitude of physical or psychological harm normally encountered in daily lives.

Exempt
(reviewed by IRB Chair)

Select Exempt when study fits into one of these categories:

- Category 1: Research conducted in established educational settings on normal educational practices
- Category 2: Your research will use:
  - Educational tests with children or adults
  - Benign Surveys with adults (non-sensitive topics)
  - Interviews with adults on non-sensitive topics
- Category 3: Research involving observation of public behavior of adults
- Category 4: Research collecting only existing data
- Category 5: Research focusing on public benefit or service program
- Category 6: Research focusing on taste and food quality evaluation and consumer acceptance studies

Non-Exempt Expedited
(reviewed by IRB Chair and one member)

- Low-risk behavioral research (e.g., non-invasive physical or behavioral tasks; manipulation of the subject's environment and similar methods commonly used in cognitive, behavioral, social, ethnographic, educational, health, and epidemiologic research)
- Video, digital, or image recordings made for research purposes. (Audio, Zoom, focus groups)
- Noninvasive procedures routinely employed in clinical practice (e.g., weighing, muscular
- strength testing, body composition assessment, and flexibility testing).
- Minimally invasive procedures routinely employed in clinical practice (e.g., physical sensors that are applied either to the surface of the body or at a distance).

Non-Exempt Full Board (reviewed by IRB members)

- Select Non-exempt Full board in your application.
- Full board reviews require you to submit your study at least 2 weeks prior to the IRB meeting (occurs once a month; dates on IRB website)
- Plan enough time for a full board review when:
  - Your study involves more risk than ordinarily encountered in daily life
  - Any of the subjects are confined in a correctional or detention facility. **
  - Pregnancy is a prerequisite for serving as a subject.
  - Any subjects are presumed not to be legally competent.
  - Any subjects are children and are part of data gathering
- PIs and Faculty mentors (if student is the PI) are expected to attend the IRB meeting to clarify questions or concerns.

IRB HAS THE AUTHORITY TO:

- Approve
- Require modifications
- Table
- Disapprove

KEY TERMS

Anonymous

Confidentiality

Privacy

REQUIRED TRAINING

- CITI (human subjects protection training).
- Study not be approved until all Investigators submit certs to IRB application.
- Researchers complete either:
  - Students: Human Subjects Research for Student Investigators
  - Faculty:
    - Social Behavioral Researchers OR
    - Biomedical Researchers
  - https://www.citiprogram.org/


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IRB APPLICATION DOCUMENTS

- IRB Application
- Consent form
- **Assent form (if participants are under the age of 18)**
- Recruitment scripts and flyers
- CITI training certificate for all investigators

IRB WEBPAGE

- EWU IRB: https://inside.ewu.edu/irb/

Home

Human Subjects Research: Institutional Review Board (IRB)

The IRB is a federally-mandated body established under the DHHS regulations for the Protection of Human Subjects (45 CFR 46). Its purpose is to protect the rights and welfare of human subjects recruited to participate in research activities conducted under the auspices of Eastern Washington University (EWU).

Research involving human subjects must be reviewed and approved by the IRB prior to initiation of the research. This requirement applies to all human subject research conducted by faculty, staff and students, on- and off-campus, regardless of the funding support, if any, and its status as an Exempt, Non-Exempt Expedited or Full Application.

See also: EWU Human Subjects Research Policy

- **Definitions**
- **Classroom Research Guidelines**
- **Required CITI Training**
- **Applications**
- **Meetings**
- **Designated IRBs**

Addition questions? Please contact IRB chair, Heidi Hillman

Applications

New Applications

Use for Exempt and Non-Exempt applications. You will select type-Exempt, Expedited or Full-in the application.

Human Subjects Research Protocol Application

Exempt vs. Non-Exempt Research Decision Aid

Change and/or Renewal of Existing Protocol

Change and/or Renewal of Protocol Application

Templates

The following templates are meant to assist researchers in completing IRB applications. Use of these example documents does not automatically confirm that your application will be approved. Researchers may save the templates as Word documents and edit the yellow highlighted areas to reflect their research projects. When done editing, please remove all highlighting.

Consent Form Templates:

Student Primary Investigator: Consent Form for Anonymous Online Survey for Participants over 18 years of age

Faculty Primary Investigator: Consent Form for Anonymous Online Survey for Participants over 18 years of age

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Consent Form Templates:

Student Primary Investigator: Consent Form for Anonymous Online Survey for Participants over 18 years of age

Faculty Primary Investigator: Consent Form for Anonymous Online Survey for Participants over 18 years of age

Consent Form for Confidential Research with Signatures for Participants over 18 years of age

Consent Form for When Audio or Visual Recordings will be Used

Parental Consent Form for When Children are Participants

Child Assent Form

Recruitment Script Templates:

Student Primary Investigator: Recruitment Script

Faculty Primary Investigator: Recruitment Script

QUESTIONS ?