IRB Fundamentals for Publishing in Engineering Education

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Institutional Review Boards

Used to evaluate the use of human subjects in research

- Governed by regulations of the U.S. Department of Health and Human Services (45 CFR 46)

Subpart A of 45 CFR 46 is called the Common Rule and was modified in 2018

- Outlines the policies for human subjects research

What is research?

§46.102 l defines research as

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

If you intend to publish your findings, you are contributing to generalizable knowledge.

What is a human subject?

§46.102 e(1) defines a human subject as

> …a living individual about whom an investigator (whether professional or student) conducting research:
>
> (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
>
> (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Exempt research

Some research is exempt from IRB review

> Research, conducted in established or commonly accepted educational settings…. This includes … research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Other exempt research

Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

> (i) The information obtained is recorded … in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

Exempt research

Much of the educational research we perform will be considered exempt from IRB review

BUT

Investigator cannot make the determination that the research is exempt. IRBs have procedures by which this determination can be made.

IRB review

Falls into two categories

- Expedited – subjects exposed to no more than minimal risks
  - Expedited review categories can be found at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html
  - Review may be conducted by IRB chair or subset of IRB

- Full review
  - Must be reviewed by full IRB membership

Things to know

- There is no retroactive IRB approval. If you perform research without IRB exemption or approval, you can never use that data in publications, grant applications, etc.
- You can request approval to use archival data.
- Students who are not yet 18 years old cannot give informed consent. Consent must come from parents. Assent is required of minors.
- Research involving multiple institutions may require IRB approval from each institution.

Publications

IRB approval/exemption should be noted in all educational research publications, as allowed by the publication. Give document/ID number, as appropriate.

Examples:

This research was determined to be exempt under the MyUniversity IRB (MU E1234).

This research was approved by the MyUniversity IRB (approval number MU 7689).

Helpful tips

Get to know your IRB chair, if possible. They can provide useful information prior to an IRB proposal submission.

Take advantage of training opportunities offered by your institution.

Consider serving on the IRB. This can provide useful experience on how best to write an IRB proposal.