Editorial

Education Research and the Institutional
Review Board (IRB)

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In an effort to support better teaching and learning, faculty are often revising courses and instituting new teaching methodologies. In some instances, data collected as part of the course assessment demonstrate that the new methodology had a positive impact on learning. Is this considered education research if the faculty member now wants to share the new methodology and test scores with colleagues by publishing the results in an education journal?

The project definitely meets the definition of research, which includes “Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”[1] The project also involves human subjects. A human subject included in research is defined as “A living individual about whom an investigator (whether professional or student) conducting research: 1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or 2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”[1] As soon as the faculty member decides to share the results, they become generalizable knowledge. Collecting test scores provides important feedback for course revision and evaluation, but disseminating the information reclassifies the collection of information as education research. As education research, does this project require Institutional Review Board (IRB) review?

What is the IRB and How Does it Impact Education Research?

The IRB was developed in response to the unethical treatment of human subjects in research, including what occurred in the federally funded Tuskegee Syphilis Study, which was conducted from 1932 to 1972. Study subjects did not receive treatment and were not informed that an effective treatment for syphilis was available. In 1974, the National Research Act was signed into law and required institutions to have a board of at least five members that reviewed research on human subjects. Such boards are most commonly called IRBs. The Common Rule, which is a set of federal guidelines for the ethical conduct of human subjects, guides the review board.

IRBs vary in size and how they implement the Common Rule. An IRB must contain at least five members from varied professions whose purpose is to “protect the rights and welfare of the subjects involved in research.”[2] IRBs are composed of members who have expertise in science, one member who is not affiliated with the institution, and one member whose expertise is in a nonscientific area. The IRB has the authority to “approve research; disapprove research; modify the research; conduct continuing reviews of the research on at least an annual basis; observe, verify, and approve any modifications to the research; observe the consent process and research procedures; and suspend or terminate approval for research.”[2] IRBs are directed by the Common Rule but may vary in how they meet federal regulations and standards.

There are three types of IRB review: 1) full-committee, 2) expedited, and 3) review for exemption. Full-committee reviews are needed for studies that have risks that are more than minimal or involve vulnerable subjects. Expedited reviews are for projects that involve no more than minimal risk. Reviews for exemption pertain to studies that involve minimal risk and protect the identity of subjects. A full list of potentially exempt research can be found at the Department of Health and Human Services website along with decision-making charts to aid in determining whether potential research is exempt (https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c4).

Education research usually requires IRB review because it meets the criteria of research with intervention and human subjects. In some circumstances, education research may qualify for the exempt category. The federal guidelines do not specify who at an institution must determine that research is exempt. At some institutions, the principal investigator (PI) can determine whether a project is exempt using the decision tree. Although it may not be required, it is generally recommended that PIs ask for an IRB opinion on exemption. Many faculty have little research training and experience and can benefit from the expertise of the IRB. Education research involving students or residents as subjects may potentially put the subjects at risk due to power differentials. Subjects must participate in education research voluntarily, without coercion, and be allowed to withdraw.[3]

When in Doubt, and Even when Not, Consult the IRB

Investigators involved in education research should become familiar with the IRB protocols and policies involving education research, including subject recruitment, informed consent and confidentiality practices.[3] When planning a course or project, consider the possibility of future publication and seek guidance from the IRB while still in the planning stage. When in doubt, and even when not, consult the IRB. Additionally, journals may require IRB review of education studies before publication. IRBs must follow the Common Rule but how that is implemented may vary. It is important to know your IRB and follow all protocols.

References

1. Public Welfare, 45 C.F.R. Sect. 46.102 (2020). Electronic Code of Federal Regulations. Available from: https://www.ecfr.gov/cgi-bin/text-idx?SID=5c0f068ae8594782dcc3b5ce275135d3&mc=true&node=se45.1.46_1102&rgn=div8
2. Miser WF. Education research — to IRB or not to IRB? Fam Med. 2005 Mar;37(3):168-73.
3. Dyrbye LN, Thomas MR, Papp KK, Durning SJ. Clinician educators' experiences with institutional review boards: results of a national survey. Acad Med. 2008 Jun;83(6):590-5.

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