IRB 101

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Does Your Project Need IRB Review?

Yes, if

a. you are systematically collecting quantitative or qualitative information to share outside your institution (eg, for publication or at a meeting)

and

b. your project involves human subjects.

Residents, fellows, students, faculty, and team members are all human subjects. Assessments, test results, focus groups, journals, needs assessments, and other education projects involve human subjects. Using previously collected evaluation data obtained from human subjects (eg, trainees) also represents research qualifying for IRB review.

Reviews, meta-analyses, or descriptions of educational materials do not involve human subjects and do not require IRB review.

Does Your Project Qualify for Exemption From IRB Review?

This determination must be made by your IRB. You are likely to qualify if your data is collected anonymously or there is minimal risk to subjects. (See http://research.fiu.edu/compliance/humanResearch/guidelineDocuments/humanSubjectsDecisionCharts.pdf for exemption categories.) Medical students are considered a potentially "at risk" population due to the power differential between faculty and students. Trainees must not be coerced into participation, and opportunities to "opt out" often must be provided. Informed consent must be obtained unless waived by your IRB.

If Not Exemption, Does Your Project Qualify for Expedited IRB Review?

An expedited review is usually performed by a single IRB panel member and is often a faster process than a full review. If your study poses minimal risk to participants, it should qualify for an expedited review. Minimal risk means that the chance and severity of harm or discomfort anticipated in the research are not more than those encountered in daily life or from routine physical or psychological examinations.

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Does Your Project Require Full IRB Review?

If your project does not meet exemption or expedited review criteria as interpreted by your IRB, your project will receive a full review by the IRB panel. Each IRB is independent and uses individual criteria to judge issues of human safety. Information is available from the IRB staff, chair, or education panel member, if one exists.

Are There Strategies for Enhancing the IRB Review Process?

Experts recommend the following:

1. Talk to the IRB chair about education research in general at your institution and the IRB's approach to this type of research. Is there a separate panel that reviews education research? Is there someone on the IRB that is knowledgeable about education research or is available via consultation for projects of this nature? Talk to this individual early, in the development stage of your proposal.
2. If there is no one knowledgeable about education research on the committee, talk to a senior education researcher, either at your institution or at another institution, about your project to identify potential ethical pitfalls.
3. Unless it is likely that your project will qualify for exempt status, leave sufficient time for approval of your IRB application, as delays are common. Your IRB office should be able to give you the usual time required for determination of exempt, expedited, or full reviews, which varies greatly from institution to institution.
4. Fill out your IRB application correctly with no unanswered questions.
5. If acceptable to your IRB, consider attaching an article about education research with human subjects that describes relevant ethical issues and practical solutions, or attaching relevant materials from the OHRP website (http://www.hhs.gov/ohrp).
6. Get the response from your IRB regarding exempt status, if applicable, in writing.
7. For multisite studies, consider having one site obtain IRB approval. Negotiate with the other sites to agree, in writing, to this.

What Are Private IRBs?

As review delays have increased, private, for-profit IRBs have grown substantially. These entities must follow the

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same OHRP requirements as your institutional IRB and often experience similar conflict-of-interest issues. Because most educational research occurs at training sites, which require approval by the local IRB, private models will not be an option.

What Is the Policy of *JGME* Regarding IRB Review?

JGME requires all submitted research manuscripts to state whether the project received IRB exemption or approval, unless human subjects were not studied (ie, reviews, meta-analyses, and descriptions of educational materials without evaluation).

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