The Biophysicist

Understanding Internal Review Boards and Their Role in Biophysics Education

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Editors

As we review manuscripts submitted to *The Biophysicist*, we sometimes encounter misconceptions regarding the need for review and oversight of education research by internal review boards (IRBs). Clarifying this important requirement will help avoid unnecessary delays in publication processing. With this editorial, we hope our authors better understand which types of educational research require prior institutional ethics approval to ensure that all stakeholders' rights are respastected and protected.

Many scientists associate medical research with human subject protection, which certainly had its origins in this realm. Countless crimes against humanity in human subject research studies conducted during the 20th century, first and foremost the human trials in Nazi Germany concentration camps, led to the formulation of the *Nuremberg Code* (1). Later on, in reaction to racist and inhuman medical experiments, such as in the Tuskegee Study (2), or questionable psychologic and behavioral trials as in the Milgram experiment (3), the *Declaration of Helsinki* (4) and the *Belmont Report* (5) were developed. These documents form the basis for our current human subject research value system, summarized in the *Common Rule* (6). Yet, frequently, when thinking about educational studies, scientists do not make a connection between the human origin of the data they plan to collect (e.g., when assessing learner performance) and the need to protect the rights and needs of those who provide the data, such as students. Nevertheless, as educational scholars, it is incumbent upon us to protect vulnerable groups involved in our work, which implies that we are aware of and apply the central principles expressed in the *Belmont Report* (5), we must do the following:

(a) Demonstrate *respect for persons* and their autonomy, including the right of participants to choose whether or not they want to be part of a research project. Moreover, we are obligated to show respect for our learners by ensuring that their privacy and confidentiality are protected by asking for informed consent.
(b) Make every effort to maximize benefits and minimize risks for and to do no harm to the study participants (principle of *beneficence*). In educational contexts, this can mean being respectful of study participants' potentially experienced psychologic stress.
(c) Fairly distribute burdens, as well as the benefits, resulting from participation in a study (principle of *justice*), which can imply that

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researchers must make sure that all students (e.g., experimental and control group) gain access to an educational innovation either during or after the study.

Essentially, decision making in educational scholarship boils down to two main questions: Is the work considered research, and are human subjects involved? If the answer to both questions is yes, some level of IRB approval will be required.

How do we know if what we are doing is research, as opposed to an internal, self-evaluative assessment of student learning, solely for purposes of course improvement? If we consider submitting results from educational work, such as structured, rigorous classroom or laboratory observations (e.g., to *The Biophysicist* for publication), this already answers the question. In that case, we have conducted a "systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (6). As defined in the *Common Rule* (6), we have classified the analysis of our classroom approach as research because we intend to *disseminate* our findings to the readers of *The Biophysicist*.

The second question pertains to whether or not human subjects are involved and count as sources of human subject data. Obtaining information through interactions with individuals (such as asking for opinions, attitudes, and feedback on teaching) and the use of existing information derived from living individuals that are not publicly available count as cases of human subject data collection. Did your students take a survey about the classroom experience? Are you accessing data about them, their classroom behaviors, and their attitudes about the subject or the lesson? Or are you collecting information about how well your learners mastered the subject matter? The data you are using to assess student progress did not arise by intuition. Individuals, most likely your students, were involved in its creation.

Although the likelihood of physical harm during data collection in an educational setting might appear considerably low in comparison to the hazards that, for example, participants in a novel drug trial would undergo, there are risks involved that cannot be neglected. For example, if you proposed to do a controlled study in which you intentionally placed some students in a learning environment where you intentionally deprived them of appropriate guidance in a course, would that be ethical? Consider the student who performed worse in such an environment and subsequently received a poor grade as a result or failed to learn the material adequately. Maybe that decreased learning was compounded in subsequent courses such that, by senior year, the student required an extra year to graduate or could not gain admission to a graduate program. One might argue that this student underwent significant psychologic and even material harm (e.g., cost of an extra year of college) in the context of the study. In today's competitive education landscape, such consequences are not beyond the realm of possibility and, thus, are of interest to IRBs.

Often underestimated in ethics approval submissions are aspects that relate to the notion of coercion or *undue influence*. Stemming from the *Belmont Report* principle of respect for persons (3), they are clearly stated in the "General Requirements for Informed Consent" of the *Common Rule* (4). In an educational setting, undue influence can refer to the undeniable power imbalance between students and instructors (e.g., if the instructor is the same person as the principal investigator of the educational research study). An example might best illustrate this somewhat abstract idea: If an instructor chooses to study a pedagogic approach in the classroom, there are numerous issues to consider. Will the instructor be aware of who has chosen to participate in the study and who has opted out? Will participation or nonparticipation bias the way grades are assigned, consciously or unconsciously? Might the students, hence, feel coerced to participate in the study to avoid anticipated disadvantages? Can the instructor be truly impartial? After all, they have a vested interest in showing that their work is successful, whether for the purposes of obtaining funding, improving reputation in the field, or achieving tenure.

To avoid or at least reduce the previously mentioned power imbalances, biases, and conflicts of interest, such situations must be managed in an ethically appropriate manner. For instance, a third party can be involved in the process, such that the individual who has designed or is implementing the pedagogy is not the one who enrolls the participants or collects the raw data. Instead, research assistants trained in human subject research can enroll volunteering participants, handle the informed consent process, and collect and deidentify the data before analysis. The study director, who may also be the course instructor, will then not know which students are participating in the study. This removes the conflict of interest, keeps the research at arm's length from the assignment of grades, and helps ensure students' privacy and confidentiality.

Speaking of privacy and confidentiality, there are several other good practice guidelines to consider when it comes to the storage and sharing of raw or processed human subject data. IRB applications, as well as most grant proposals, require information about how data obtained from human subjects will be managed. Authors submitting to *The Biophysicist* are advised to confer with the data management office of their institution for guidance if unsure how to adequately store and manage the educational human subject data collected. Additionally, the Center for Open Science (7) provides valuable guidance on data management, storage, and distribution.

The previously mentioned concerns help illustrate why IRB review is relevant to educational research. The Biophysical Society Publications Staff and Editorial Board members of *The Biophysicist* aim to help our authors proceed with the highest of ethical standards in their work. This requires careful advance planning for its publication, from the very beginning of a project and onward. Depending on the study design, the project may be deemed *exempt* from IRB review, indicating that it has been reviewed by a single member of the IRB team and deemed compliant with the ethical principles of the *Belmont Report*. Alternatively, a project may be classified as requiring *expedited* review. This designation indicates that there might be a low risk of potential harm for the study participants and that a reduced level of review is appropriate. However, should an initial IRB appraisal result in an estimation of more than just a low level of risk for human subjects, the project may undergo *full board review*.

The National Institutes of Health offers a decision tool (8) that provides initial guidance on whether one's educational project is to be considered research involving human subjects, and if yes, whether it may qualify as exempt, expedited, or requiring full board review. Regardless of the decision tree outcome, every researcher must submit documentation paperwork to their institution's IRB to receive official determination of status, council on potentially required adjustments of the study protocol, and finally project approval.

The Biophysicist has added to its ethics review instructions for authors those aspects that editors and reviewers are looking for during the ethical evaluation of an educational research manuscript. It is worthwhile to review such materials in advance of starting your pedagogic study, as it will ensure that you follow these standards from the outset. We hope that you will choose to publish your work with us and other discipline-based education research journals, which will hold you to an equivalent standard for the ethical conduct of education research. Please remember that this requires appropriate preparation in advance of launching your project.

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