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Ethical approval for research in physiology education

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Kibble JD. Ethical approval for research in physiology education. Adv Physiol Educ 33: 268–269, 2009; doi:10.1152/advan.00086.2009.—The goal of this article is to reflect on the contemporary ethical standards that should be applied to the publication of physiology education research. As teachers, we are all education researchers to some degree but our appreciation of when and how regulatory requirements apply to our work is variable. A significant number of articles in Advances in Physiology Education that might be classified as “research involving human participants” do not document ethical safeguards such as Institutional Review Board approval and informed consent, which are required according to journal policy. I elaborate my personal view that we should strive to maintain the present community standards for conducting and publishing education research. And, as always, I hope the road to hell is not paved with good intentions!

Institutional Review Board; informed consent

THE PURPOSE OF THIS ARTICLE is to reflect on contemporary standards and policies regarding ethical approval for physiology education research. As a neophyte in the world of education research, I claim no special wisdom or moral high ground, and what commentary follows is humbly offered.

Advances in Physiology Education (Advances) serves a diverse audience and embraces a broad spectrum of teaching scholarship from personal reflections to original discovery research. From her vantage point sitting in the editor’s “catbird seat” in 2001, Penelope Hansen rightly noted that the 1990s was a period of increasing scholarliness in the pages of Advances (2). Subsequent editors Dee Silverthorn and Rob Carroll have continued to champion Advances as the primary conduit for scholarly communication about physiology education. But where does scholarly teaching practice end, when does discovery research in education begin, and what is the requirement for external ethical approval?

Roberts et al. (5) asked similar questions when they analyzed 424 reports published in 1988 and 1989 and in 1998 and 1999 in Academic Medicine and Medical Education. They defined research studies as those reports with a METHODS section and described six ethical safeguards [informed consent, confidentiality, institutional review board (IRB) approval, education committee review, incentives for participants, and funding source(s)]. They found that only 3% of studies mentioned an IRB and that 47% of studies “...offered no indication of ethically important safeguards or features.” Applying the same criteria to the most recent volume of Advances, I found that approximately one-third of the articles were research papers.

Among these, approximately one-third of the studies documented IRB approval, one-third documented other ethically important safeguards, and one-third made no references to ethical safeguards. I do not suggest that any of the studies I reviewed were unethical, but how do these reporting characteristics match with journal policies?

Academic Medicine recently focused on this question by issuing a new policy requiring all manuscripts to give a statement of approval by an IRB (4). A strong case was made for the policy, including the moral imperative for ethical approval, the need to be in accordance with global publication standards, and the possible enhancement of research quality. The American Physiological Society (APS) appears to be ahead of the curve since our policy already stipulates:

- That research “...must adhere to the principles of the Declaration of Helsinki (7) as well as to Title 45, United States Code of Federal Regulations, Part 46, Protection of Human Subjects ...” (6).
- “...that all investigations involving humans or animals reported in its publications be conducted in conformity with these principles, and that a statement of protocol approval from an IRB or IACUC [Institutional Animal Care and Use Committee] or equivalent is included ...”
- and that “Manuscripts reporting the results of experiments on human subjects, including healthy volunteers, must include a statement that informed consent was obtained.”

So, is there a mismatch between policy and practice? If so, should it give rise to concern? There probably is a mismatch, if we assume that the articles classified according to Robert et al.’s criteria are “research” involving human participants. Federal regulations define research as “...a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Several years ago, my own assumption was that education research was exempt from ethical review, and, anecdotally, I have found this to be a common assumption among other faculty. On the face of it this is perhaps a reasonable interpretation of Title 45, United States Code of Federal Regulations, Part 46.101b (6), which exempts:

- “Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effect of or the comparison among instructional techniques, curricula, or classroom management methods.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior,
The vast majority of studies I reviewed would likely receive an exempted status from an IRB. However, it is crucial to note that even if our work fits these criteria, federal regulations still require that an IRB make the determination of exempt status rather than the investigator. According to federal regulations, there is therefore no doubt that education researchers must engage an IRB, and, according to APS policy, statements attesting to IRB approval and the use of an informed consent process must be included in journal articles. If this is not the case, then there is indeed cause for concern. It is also worth noting that physiology education research is not always of minimal risk. For example, our research occasionally involves children (a specially defined vulnerable population), often involves the participation of students over whom we have authority, and may apply qualitative methods that can be more psychologically invasive and less predictable.

If current policies and regulations require that we engage an IRB, what is left to discuss? Well, I have two worries that relate to promoting scholarship in physiology education. The first is the risk of a “bureaucratic creep” in which local IRB procedures become a barrier for teaching faculty members to engage in education research in the first place. Dyrbye et al. (1) documented considerable variability in the timeliness and consistency among six IRBs that were considering the same medical education research project. How can this situation be improved? One possibility is for our community, for example, through the Federation of American Societies for Experimental Biology or the Association for American Medical Colleges, to develop an authoritative reference to help our IRBs in making consistent and timely decisions about education research. My second concern relates to how we support our international colleagues who may not have access to formal ethical review committees. The pages of Advances are enriched by contributions from around the world, and it is important that our policies do not exclude colleagues overseas. Given the clear policies of APS journals on the reporting of studies involving human participants, there is no need for Advances to announce a new policy on ethical standards. However, the new policy of Academic Medicine (4) offers provision for overseas researchers and now requires that manuscript submissions include descriptions of how the risks to participants were minimized, how any risks were balanced against benefits, what criteria were used to select participants, how privacy issues were managed, and how informed consent was obtained. The electronic submission process for Advances would allow such supplemental materials to be uploaded with an article. If this is done, our tradition of editorial support and the peer review process may then be extended to include the validation of published studies as ethical.

I do wonder if our present community standard of requiring ethical review and informed consent will be viewed as a dinosaur in the coming years. When my telephone can report my demographic information and even my exact location to goodness knows who, why should I be concerned about such things as confidentiality in an education research project? Well, it remains my personal view that the APS standards for publishing are crucially important to maintaining and further enhancing the scholarship of teaching as well as the place of Advances as a publishing role model.

REFERENCES