

Research Ethics Review Processes: Potential Teaching Tools for Health Professions Students

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Abstract

This article highlights how research ethics review processes have the potential to be used as teaching tools. Health professions students at the graduate level often conduct research involving human participants as part of their program requirements. Applying for approval from a reviewing committee may be one of their first experiences implementing a research project. Beyond their ethics application, novice researchers require additional support as they encounter the challenges of incorporating research ethics principles into practice. We argue that such support can, and should, be provided through Research Ethics Board activities such as participating in classroom teaching, providing support to research supervisors and remaining available to applicants throughout their research projects.

Keywords: Research ethics boards; Ethics review processes; Health professions graduate students

Introduction

Health professions students often conduct research involving human participants as part of their graduate program requirements. One of their first experiences implementing a research project is to submit an application for ethical review to an academic committee. The committees are most commonly referred to as Research Ethics Boards (REB's), but they may also be known as Institutional Review Boards (IRB's) or Research Ethics Committees (REC's).

As established by the 1964 *World Medical Association Declaration of Helsinki*, the primary role of an REB is to assess whether research protocols provide participants with sufficient knowledge to make an informed and voluntary consent; to safeguard participants' privacy and confidentiality; and to assess risks and benefits [1]. Once an application has been reviewed, REBs have the authority to approve projects, request revisions, reject proposed projects and terminate ongoing projects [2]. REB membership is usually multidisciplinary and decisions are generally communicated to applicants through formal memorandums.

Most REB's are governed by jurisdictional regulations. For example, in the United States, the *Federal Policy for the Protection of Human Subjects*, known as the 'Common Rule,' drawn from the Code of Federal Regulations Title 45: Public Welfare, part 46 (45 CFR 46) provides oversight to REB's [3]. Governance in the United Kingdom is provided by the *Health Research Authority* [4]; in Australia, by the *National Statement on Ethical Conduct in Human Research* [5]; and in Canada by a second iteration of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* [6].

In the health professions, researchers may require ethical approval from clinical sites as well as from community and academic REB's before they can begin projects. These institutions can all have different

reviewing guidelines. Understanding the required processes can seem complex to novice researchers. Even experienced researchers have identified that "getting through ethics" can feel like "jumping through hoops" [7]. A recent study in the United States revealed that one-third of researchers investigating innovative clinical therapies felt that the "cumbersome" ethical review processes they experienced actually limited their innovations [8].

For graduate students, the complex processes involved in the ethical review of their projects is significant for their learning and has lasting impressions on those who strive for careers as researchers [9,10]. The authors, as chairpersons of Canadian university and community REBs, believe that many of the reviewing processes REBs implement have the potential to be used as teaching tools. Beyond their duty to protect research study participants and to follow jurisdictional governance requirements, REBs are in a unique position to provide student researchers with needed education.

The purpose of this article is to identify commonly implemented research ethics review processes and highlight how these processes have the potential to be used as teaching tools. Drawing from our experiences leading and participating on academic and community REB's, we suggest innovative ideas that other reviewing committees may find useful. We invite REB members to participate in classroom teaching, to support research supervisors and to remain available to applicants throughout their projects. We call for members of REBs to go beyond reviewing and granting ethical approval, and consider possibilities for expanding the role of REBs to include intentionally offering relevant support to student researchers.

Participate in Classroom Teaching

One underutilized teaching tool that REBs can readily implement is to participate in classroom teaching at institutions they are affiliated with to address research ethics content that students require. REB's routinely engage in discussions that link ethical principles to applications submitted by researchers. During deliberations on whether applications should be approved, revised or rejected, committee members provide rationale for their decisions. In essence, the discussions bring theory to life. As a teaching tool, exemplars from these REB deliberations provide real-world examples of translating ethical theory into practice that could be shared in the classroom setting.

Work on reviewing committees is time-consuming and the practitioners and academics involved may be reluctant to take on additional teaching responsibilities. However, knowing where curriculum planners have positioned ethics content can help REB members find time-limited opportunities to participate in and to enhance classroom teaching. Most health professions programs strive to integrate content related to research ethics into their curriculum. In many programs, designated courses specifically addressing ethical issues are offered [11,12]. Information is often presented through didactic lectures, written assignments, group discussions, guest lectures, movies and videos, case study analysis, and peer presentations [13-16]. Simulations, role-play and vignettes have also been used to help students contextualize different sides of research ethics, particularly aspects that are usually invisible to research participants [15,16].

Opportunities to contribute to these existing instructional activities may be available. For example, REB members can participate as guest lecturers or guest speakers in face-to-face and online classrooms, making recordings of the sessions available to those unable to attend. Insights from REB meeting deliberations can be included in any case studies and role-plays currently in use as well as those in development.

Similarly, course designers may value integrating REB members' experiences into self-directed learning modules for students to complete independently. When REB members seize opportunities to become involved in classrooms, to actively collaborate with educators, and to share the knowledge they have gained from their deliberations, they contribute to student success. In particular, this success is likely to be observed in stronger proposal submissions from students and perhaps from those who supervise and educate them as well.

In some instances, existing research ethics content in health professions programs can be limited. For example, students may not fully understand the theories and principles that guide ethical research practice [17,18]. Specific content topics that students view as important include research misconduct, authorship and publications, peer review, protection of human subjects, and accuracy of data management [19]. Students also identified a need for more instruction on the ethical dissemination of research findings, particularly fraud, plagiarism and undeserved authorship [20].

Many of these topics are likely to emerge during REB discussions. When REB members share different points of view that emerged during deliberations they have engaged in, they provide students and their educators with new perspectives that may not otherwise be available to them. REB members can identify what a strong research proposal should look like and they can comment on common pitfalls and elements that can easily be missed. In turn, these new ideas and practical suggestions help students gain a deeper understanding of how theoretical knowledge can guide their projects and enable them to build ethical integrity into their research.

Support Research Supervisors

Providing support to the academic and field supervisors who mentor students throughout their research projects is another potential teaching tool REB members can implement. It is common practice for REBs to include feedback with decisions rendered, particularly in situations where a proposal has been rejected or is in need of revision. In our experience, only one or two submissions per year out of 100 are approved on first submission. Likewise, approximately one or two are deferred each year for major modifications or a re-write of the proposal. The majority of submissions, >90%, receive feedback and provisos for modifications and applicants are required to re-submit with revisions before they are approved.

If students can access aspects of this feedback from their supervisors prior to submitting their proposals, the experience would be construed as more collaborative. Students could first submit their application to the supervisor who might then collaborate with the REB in some fashion if s/he is unsure about aspects of the student's application. Certainly collaborative conversations after the decision has been rendered should occur. In a study exploring graduate students' perceptions of research ethics, participants identified that they wanted the option to submit their proposal for an ethical pre-review with opportunity to make any suggested revisions, before the application was assigned for formal REB review [21].

While it is not feasible to expect REB members to respond directly to all student inquiries about projects they are working on, it may be possible for one or more designated members of the REB to communicate with research supervisors. This adaptation of an existing REB practice shifts the focus more towards an educational approach rather than solely an evaluative function. When supervisors and students view the ethical review application process as a positive, mutual process of exchanging knowledge, students are able to strengthen their research designs [22]. Further, when stronger applications are submitted, REBs will spend less time and resources reviewing incomplete work and students will experience less frustration with the process.

In addition to providing opportunities for supervisors to discuss

questions directly with a REB member, indirect strategies for making information available can also be useful. REBs can develop and update websites housing a plethora of information documents and templates. For example, frequently asked questions; guidance notes on ethical issues that researchers commonly encounter; highlights of jurisdictional requirements applicants may not be familiar with; exemplars of stellar ethics applications; and consent form templates are all very useful to novice researchers.

Further, requirements for data management including access, linkage, storage, security, retention and destruction should be specified. Recorded sessions on relevant research ethics topics can be posted for access by researchers at any time. Educational sessions benefit both students and educators [23] and the online resources developed by one REB may be of interest to researchers external to the institution as well. For example, in Canada, the Athabasca University website is informative <http://research.athabasca.ca/ethics/>. Also, community REB's affiliated with healthcare based organizations in Canada also have website resources available for their researchers, such as <https://www.interiorhealth.ca/AboutUs/ResearchandEthics/Pages/default.aspx>.

Opportunities for supervisors to increase their own knowledge by seeking advice from REB members and accessing information provided online can enhance their ability to mentor students. The relationship that graduate students have with their supervisors affects their learning and perceptions of ethical research practice. Students' self-confidence is developed through research experiences and positive mentoring [24]. Supervisors can reduce the complexity and frustration of the ethics review process for students by sharing their own experiences and by competently pre-reviewing the ethics application with them in detail [25,26]. Knowledge translation and socialization into the research community is bolstered when supervisors are able to provide credible instruction and practical guidance to students [27].

The importance of establishing 'safe spaces' in situations where ethical issues are discussed and research plans are reviewed should not be underestimated [28]. Students in health professions programs are often invested in earning high marks, providing 'correct' or 'right' answers and succeeding. And yet, ethical issues in research are seldom simply black or white, right or wrong. Research, particularly in health related disciplines, is complex with a myriad of factors to consider and students need to know how to rationalize options and understand which decision is best and why. When supervisors feel a sense of trust and openness with their REBs, they are better equipped to create the 'safe spaces' their students need to become ethically responsible researchers.

Remain Available to Applicants throughout Their Projects

A further ethics review process that can be used as a teaching tool is for REBs to remain available to applicants throughout their research projects. Students may view the experience of submitting a proposal to a review committee as one that ends once permission for the research to proceed has been granted. Regulations in some jurisdictions may require researchers to submit mid-point and final reports updating the committee. However, ongoing communication between REBs and researchers is not usually expected.

Continued REB involvement with all research projects reviewed is clearly an unrealistic goal. Yet, for some researchers, especially students who have little or no experience completing a research study from conceptualization through to dissemination, perplexing ethical questions may come up long after their proposal has been approved. Supervisors, mentors and colleagues can be of some help, but their knowledge of ethical principles may not be as robust as members of REBs. In these cases, when students and their supervisors need additional and likely unexpected support, it can be reassuring to know that they can reach out to their REB for guidance.

In order for students and their supervisors to feel comfortable disclosing concerns and discussing issues, some of which could involve negative incidents, a view of REB processes as supportive rather than punitive is important. Perceptions of REBs as punitive can intensify when members, however inadvertently, communicate ‘mission creep.’ ‘Mission creep’ occurs when REBs require applicants to re-submit their applications and include additional details related to harms that are imagined, minor or highly unlikely [29-31]. On the other hand, when REBs consistently communicate a genuine interest in strengthening the ethical integrity of students’ proposals, they are perceived as more approachable.

Approachability and a willingness to remain available to applicants throughout their projects can be projected both explicitly and implicitly. Using websites to provide specific contact information for REB members designated to respond to inquiries indicates an intention to help. On a subtler level, applicants may be sensitive to indicators such as response times and the depth of responses. In his seminal book *The Ethics Police? The Struggle to Make Human Research Safe*, Robert Klitzman urges REBs to pay careful attention to “the quality, contents and tone of memos and communication” [32]. When students and their supervisors believe that the initial review of their proposal was a positive experience, they will be more inclined to seek additional help from their REB once the project is underway.

Finally, REBs can communicate an openness to remain available, if and when they might be needed, by projecting transparency. Suggestions for doing so include making meeting minutes publicly available [32]; ensuring that at least one public representative is present at meetings [33]; and including students as members of REBs [34]. Some researchers have recommended that REB deliberations, which are usually conducted in-camera, should be opened to allow applicants to ask questions and seek clarification during the sessions [7]. More informally, REBs can contribute to continuing education activities that faculty, practitioners and researchers attend.

Conclusion

Historically, REB’s in many institutions have been perceived (whether or not the perception is warranted) as an adversary whose role is to challenge rather than support research. Efforts to demonstrate a desire to be collaborative, approachable and collegial with researchers may be a good strategy for REBs to utilize in trying to change this perception.

REBs need to go beyond reviewing and granting ethical approval of student research projects and provide more support and education on research ethics principles for novice researchers. Respecting that REBs are often under resourced and with jurisdiction limited to the institution they represent, they still have an opportunity to impact students’ knowledge related to research ethics for those who submit ethics applications to their committee. They can also supplement education provided by academic and health care institutions, and champion a culture where the core concepts of ethical research are imbedded throughout the research life cycle and not just part of an initial application for approval to proceed.

REB’s are charged with a great responsibility but also tremendous opportunities. Expanding their roles to participate in classroom activities, support research supervisors and remain available to applicants throughout their projects will create environments that foster increased confidence in the ethical conduct of research and ultimately, greater protection of human participants.

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