Ethics approval for health professions education research: are we going too far down the barrel?

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It goes without saying that any research involving human subjects must respect and protect those involved. The Helsinki Declaration provides clear guidance for this foundational stance. As societies, we have therefore decided that all research involving human participants must be evaluated for its ethical soundness, a decision that has led to the creation and proliferation of institutional review boards (IRBs). As the authors of this commentary, we subscribe wholeheartedly to the use of IRBs. The processes around IRB approval, however, increasingly raise questions that we will attempt to address. In doing so, we realise that the discussion is not new. Brice et al., for example, wrote about this over 10 years ago and explained that an unabbreviated copying of the IRB process from biomedical and clinical research to medical education research and from one country and culture to another is probably not advisable.1 However, there seems to have been little further development since.

Two of the most well-known domains in ethics are deontology and utilitarianism. In deontology, the rightness or wrongness of an action is the focus of the ethical consideration, whereas in utilitarianism the usefulness of an outcome is a more important principle. If we apply these schools of thought to the ethics approval process, we have the impression that this process for health professions education (HPE) research is more understandable from a deontological than a utilitarian point of view. That is, we commonly accept the need for review because it is simply wrong to do harm to participants or to fail to respect their autonomy. To broaden our consideration of ethics review in HPE, it is compelling to apply a utilitarian viewpoint.

A first criterion to consider is the ability of the proposed diagnostic tool to detect ‘harm’ (in other words, the sensitivity and specificity of the tool). Almost all HPE research is non-invasive and psychologically non-threatening with little potential for harm. Therefore, the most likely risk refers to the wasting of participants’ time or the publishing of non-informative or incorrect results. The question then concerns how sensitive and specific IRB processes are for detecting studies without merit. Unfortunately, most review committees lack specific expertise in medical education to make sufficiently informed decisions on the merit of HPE research. If the process is unable to detect serious flaws, its validity and its power to prevent unethical research from happening are threatened. We have serious doubts as to whether the ‘diagnostic instrument’ of ethics review is sufficiently able to detect the ‘disease’ of non-merit, especially given the extensive volume of paperwork ethics committee members are required to digest.

A second criterion relates to the ‘curability’ of the disease. If an ethics approval process detects the nature of disease prevention technologies.

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disease of non-merit, the institution will still require the means and expertise to remedy the problem if it is to prevent a significant waste of money, time and energy for no positive outcome. Feedback to the researchers needs to improve the quality of subsequent applications (i.e. the disease has to be treatable for the screening to be worthwhile). In organisations with well-functioning HPE research groups, this would not be difficult, but where there is no such expertise, simply identifying non-merit is unlikely to resolve the problem.

A third criterion regards the ‘prevalence’ of the disease. Large-scale primary prevention programmes are not useful when the prevalence of the disease is low. Of course, we cannot vouch for other domains of research, but we wonder whether HPE research would produce a significant number of harmful research studies were ethics review practices not in place. Our discipline is not known for its ‘Tuskegee syphilis studies’ or ‘Milgram experiments’. Of course, closing the stable door after the horse has bolted is not a good strategy, but neither is ‘punishing’ one discipline by subjecting it to an onerous process for the past poor behaviour of other researchers in different domains.

A final criterion is the number-needed-to-treat (i.e. the number of people who must be treated for the treatment to have a particular benefit). If the prevalence of the ‘disease’ is low, the strength of the diagnostic tool is poor and the ‘disease’ cannot be cured, the number needed to treat is consequently high, meaning that a great deal of effort must be expended for fairly minimal gain. For most ethics review processes, adverse effects of the process are liable to occur inadvertently and without guaranteeing better outcome or protection from harm if the number needed to treat is high. The adverse effects of overly lengthy and bureaucratic ethics approval processes are considerable, given the time, energy and money they require. From a university business viewpoint, a research centre in an organisation with an onerous ethics approval process is put at a disadvantage compared with a competitive research centre with a more streamlined process. If researchers from both centres have the same brilliant idea for a research project, the former will have a false start in comparison with the latter, thereby contributing to declines in researcher motivation.

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An unnecessarily onerous process is likely to result in more harm than good... it might be better to decouple the process of evaluating the merit of the research proposal and the judgement of possible ethics-related harm by... allowing research centres to undertake an internal peer review process followed by a... streamlined ethics review process.

For organisations with strong HPE research groups, it might be better to decouple the process of evaluating the merit of the research proposal and the judgement of possible ethics-related harm by, for example, allowing research centres to undertake an internal peer review process followed by a rapid and streamlined ethics review process. We contend this to be defensible practice. Typically, national statements on research in human subjects in HPE state that when data are collected in the course of routine educational activities or quality audits, and when these data are de-identified, the research is deemed to be of negligible risk. It is then logical to extend this to research projects with prospective data collection that involve only activities that are equivalent to normal education or quality audit activities. After all, from a utilitarian perspective, the level of inconvenience, discomfort or harm does not differ according to whether the decision for research...
was made retrospectively or prospectively to the data collection.

For such studies, in which data collection is equivalent to normal educational processes and the project is deemed to have sufficient scientific merit, we argue that ethics committees could decide to allow for a hands-off procedure with marginal checking of the process, rather than a lengthy review of each research project. This is current practice at some IRBs, but we think it represents a safe and viable option for each organisation, and believe that it will result in a win-win situation for all stakeholders, including participants in the study, future beneficiaries of the outcomes of the study, researchers and IRB committee members. The easing of regulatory burdens (when appropriate) will increase trust and value in the system and will facilitate, rather than being detrimental to, the necessary research.

REFERENCE

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Faculty development and the growth mindset

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Everyone recognises the importance of faculty development in medical education. Every chair of a department wants his or her faculty members to participate in faculty development programmes. All educators will likewise express their interest, in theory, in participating in faculty development programmes. Yet, despite this common belief in the underpinnings of faculty development, programmes face many hurdles in their implementation, durability and ultimate success. The obvious immediate challenges include finding sources of funding and navigating the myriad of coverage issues that arise when faculty staff are away being ‘developed’. Even on the assumption that these barriers can be overcome, several more fundamental issues must be addressed: How do you promote such a programme to all your medical educators in the hope of achieving buy-in, particularly to those who are not interested in participating but need it the most? How do you impact the culture and create a community of practice that promotes continuous rather than episodic faculty development? We suspect that if leaders fail to tackle these questions, many well-intentioned programmes will fall short of their goal of enhancing the teaching skills of faculty staff.

In their paper ‘Peer-supported faculty development and workplace teaching: an integrative review’, Campbell and colleagues focus on the importance of peer support strategies in faculty development. They comprehensively review a very heterogeneous group of articles that used disparate methods including surveys, focus groups and observation to determine outcomes. Despite this inherent limitation, they do a remarkable job of promoting the themes of a successful peer support programme and are able to cogently argue that peer support strategies should form the foundation of a successful faculty development programme. They highlight four main factors that contribute to success: the model is collaborative and reciprocal; participation in the programme is voluntary; observations are made in the real workplace, and observations are made not by experts but by peer collaborators.

We also believe in peer-to-peer support strategies, but we recognise