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Twelve tips to avoid ethical pitfalls when recruiting students as subjects in medical education research

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ABSTRACT

Medical education research has unique characteristics that raise their own set of ethical issues, which differ significantly from those commonly found in clinical research. In contexts where researchers have a dual role as teachers, free consent to participate in research may be undermined and students' data must be kept confidential from faculty who play any role in their academic or professional path. Faculty members who recruit students as research subjects within their institution for education research should pay particular attention to ensure students' consent to participate is indeed free and continuous and that their privacy is adequately protected. A good understanding of ethical standards and of the appropriate strategies to fulfill them is essential to conduct ethical medical education research and to ensure ethics approval is obtained. These twelve tips draw from the *Declaration of Helsinki*, from the ICMJE recommendations and from the example of their application to medical education research in a Canadian and North American context. They aim to act as a reminder and as a guide to address the main ethical issues which should be given proper consideration when designing a study involving students as subjects for medical education research.

Introduction

Ethical approval by a research ethics committee is most often a prerequisite for medical education research, and where it is not, evidence of compliance to ethical standards is still required for funding and publication (Eva 2009; Hally and Walsh 2016). What makes the ethical stakes in education research more challenging for health professionals who are familiar with clinical research is the discrepancy between the risks incurred by participants in both fields. The subtler risks associated with recruiting students for education research are much easier to overlook, but they are present nonetheless.

In the context of research, vulnerability is defined as a "diminished ability to fully safeguard one's own interests in the context of a specific research project", which may be "caused by limited decision-making capacity [in terms] of rights, opportunities and power" and "may occur when prospective participants are recruited by individuals in a position of authority over them (e.g. teacher/student, employer/employee)" (TCPS2 2014, p. 210). Thus, it has been suggested that we regard medical students as a vulnerable group (Walsh 2014), possibly even as a "captive population" (Ferguson et al. 2006; Shannon 1979). Their participation in research may not always be as free as it is informed, due to perceived pressure from faculty or peers, even if pressure is exerted unwillingly (Forester and McWhorter 2005).

Ethics breaches in education research usually arise out of ignorance rather than malfeasance (Brice et al. 2009), as medical education researchers may have received their

training in other disciplines and come from diverse research backgrounds (Maggio et al. 2017). Here, we present twelve tips, summarized in Table 1, which should help recognize and avoid ethical pitfalls when recruiting students as research subjects. The ethical norms that these twelve tips put forward are derived from the *Declaration of Helsinki* (WMA 2013), which the World Medical Association intended for physicians to follow in all research "involving human subjects" (art.10,18). The *Declaration* underlies the *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals* set forth by the International Committee of Medical Journal Editors (ICMJE). While country-specific regulations vary greatly regarding ethical approval of educational research, both the *Declaration of Helsinki* and the *ICMJE Recommendations* are of particular relevance for all medical education researchers. Indeed, the ICMJE (2016) requires that when a study involving human data has not been reviewed by an ethics committee, authors indicate whether their study complied with the *Declaration of Helsinki*. Moreover, regardless of whether a study has been reviewed by an ethics committee, if doubt remains "whether the research was conducted in accordance with the *Helsinki Declaration*, the authors must explain the rationale for their approach" (ICMJE 2016, p. 7). These reference frameworks are cited throughout our guidelines. Our own perspective, however, is Canadian and North American. Consequently, the twelve tips also draw from the *Tri-Council Policy Statement* (TCPS2 2014), the mandatory ethical framework for research in Canada. References are also made to American legislation pertaining to the protection of research subjects (CFR,

Table 1. An ethical framework for involving students as subjects in medical education research.

Core principle	Considerations for students	Recommendations
RESPECT	<p>Free, informed and ongoing consent</p> <p>Freedom of consent may be undermined if:</p> <ul style="list-style-type: none"> Recruited by their own teachers or a person in a position of authority Their decision to either participate or decline will be known to faculty or peers 	<ul style="list-style-type: none"> Disclose role conflicts and privacy measures from the outset Involve an independent research team member for recruitment, consent and data collection Verify need for consent for secondary use of data
WELFARE	<p>Confidentiality</p> <p>Confidentiality:</p> <ul style="list-style-type: none"> Is crucial if researchers have dual roles as faculty May be breached unintendedly if inclusion criteria match only a few individuals in a community 	<ul style="list-style-type: none"> Only gather information from students that is directly relevant to your research question Anonymize or de-identify data before analysis by faculty members Protect data against unauthorized access Ensure results will not allow identification of participants; consider multisite studies
JUSTICE	<p>Protection of vulnerable groups</p> <p>Vulnerability:</p> <ul style="list-style-type: none"> Is defined by limited decision-making capacity May stem from undue influence exerted either by faculty, peers or disproportionate incentives 	<ul style="list-style-type: none"> Avoid resorting to course credits and mandatory activities Have the study reviewed by a dedicated education research ethics committee, where available

U.S.Code). While the recommendations drawn from these sources are only compulsory in their country of origin, they remain relevant outside their borders as they propose concrete ways of putting into effect the principles brought forward by the *Declaration of Helsinki*.

Getting a good start on your project: Do formal ethical requirements apply?

Tip 1

First determine whether your project qualifies as research or evaluation

As both research and evaluation may share the common purpose of determining the value of an educational process, one may be hard-pressed at times to determine which best applies. This distinction is crucial, however, as the respective requirements for ethical approval are not same. To determine whether a project qualifies as research or evaluation, examine the intended use and audience of your results.

Evaluation falls within the context of quality improvement and its purpose is to inform *local* curriculum development and guide in-house decisions (Morrison 2003). Accordingly, its results are intended for local stakeholders, which include primarily the institution's teachers and administrators (Cook 2010). Although curriculum committees must ensure that evaluations are carried out ethically, an evaluative process does not usually require formal approval by an ethics committee. On the other hand, research aims to develop knowledge, by producing generalizable results that can be used by the medical education community *at large*. To that end, research results are generally published in peer-reviewed literature. It is especially important that a research process be identified as such at the outset, because research must comply with formal ethical requirements and, where applicable, requires approval by a research ethics committee (Morrison 2003). While this article focuses on

research, many of its recommendations are applicable to both processes.

Tip 2

Verify need for consent for secondary use of data

In certain circumstances, you may wish to conduct a study using data which has already been collected for a different purpose. This data may have been gathered through a regular academic process, for teaching or evaluation purposes; it may also have been collected in the course of an evaluation or even of an informal survey. Because academic and quality improvement processes do not usually require formal consent (TPCS2 2014, art. 2.5), you may be faced with the more difficult task of obtaining ethical approval and participants' consent retrospectively.

A general principle is that participants' consent is always required when identifiable information is reused for research. However, regulations vary when the data does not contain any means of identifying participants. Thus, the need for consent should be verified before making secondary use of data. In Canada, for instance, researchers are not required to seek consent for the secondary use of non-identifiable information, but they must still submit the study to a research ethics committee. Consent is also required if researchers have a way of tracing participants' identity, for example through access to a key code (TCPS2 2014, art. 5.5B). In the United States, release of educational information is regulated by the *Family Educational Rights and Privacy Act* (FERPA), whereby student consent is required (20 U.S. Code §1232g).

Consent: Ensuring that it is free, informed and ongoing

Tip 3

Inform participants of all privacy measures

Freedom of consent and privacy are particularly at stake when students are recruited (Egan-Lee et al. 2011). Students could agree to participate by fear of alienating

those in positions of authority (TCPS2 2014), believing that participation will result in better grades or letters of recommendation (Forester and McWhorter 2005), or simply to please faculty with whom they have positive relationships (Ferguson et al. 2006). Such perceptions may be entirely unfounded, but even perceived pressure takes a toll on freedom of consent. Perceived role conflicts, for their part, can be detrimental to the quality of the collected data. If anonymity is not guaranteed, or if participants are not convinced that it is, this will taint their answers, which in turn may alter results. Taking measures to protect participants' right to privacy may have as much effect as not taking any if doubts remain in students' minds (Ferguson et al. 2006).

For many such pitfalls to be avoided, prospective participants must be informed from the outset that their participation and data will remain confidential from faculty and how this will be achieved. They should know from the very start who will have access to their information and to whom disclosures could be made (TCPS2 2014). They should also be informed of their right as participants to refuse to answer any question (Ferguson et al. 2006). Only then can participants determine how comfortable they are with the way role conflicts will be managed and give truly informed consent.

Tip 4

Obtain consent through an independent research team member

Double agency is defined as "fulfilling two roles simultaneously in relation to the same individual, as teachers do when they research their students", resulting in "a situation of conflicting loyalties" (Ferguson et al. 2006, p. 399). In situations where role conflicts arise, the *Declaration of Helsinki* states that "consent must be sought by an appropriately qualified individual who is completely independent" (art. 27). Indeed, involving a third party at various stages of the research process can considerably reduce the stakes associated with conflicting roles. To this end, a third party can be any member of the research team who is free from any actual or potential conflict of interest, be they research assistants or faculty who do not – and will not – play any role in students' path. Later on, an independent member could stand as an ombudsman for participants, or as a resource to handle queries (TCPS2 2014). Depending on needs and means, similar purposes can be achieved by resorting to research participant management software – such as Sona (Sona Systems 2002), or similar web-based systems – for anonymous signing up of students (Leentjens and Levenson 2013).

Tip 5

Ensure participation itself remains confidential

The *Declaration of Helsinki* stresses that "every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information" (art. 24). While privacy concerns may refer to the data participants have shared, they may also refer to participation itself. This issue is all the more important the further advanced the students are in their training, because as

students progress and specialize, cohorts gradually become smaller. Trainees lose their anonymity while professional stakes consistently increase. Consequently, it may be increasingly more difficult for students to withhold consent (TCPS2 2014). In a study by Forester and McWhorter (2005), clinical undergraduates were almost three times more likely to feel coerced to participate than did preclinical students. Presumably, this number would be higher at the post-graduate level. Extra care should therefore be taken so that neither the researchers involved in students' training nor their peers know whether or not a specific student has agreed to participate in a study.

Data collection, analysis and dissemination: Confidentiality safeguards

Tip 6

Anonymize data prior to consultation by faculty

Once participants are involved in a study, a core principle underlying research ethics is concern for participants' welfare. It entails controlling all information *about* participants at all stages of the research life cycle, from data collection to analysis and use (TCPS2 2014; 45 CFR §46.111). An essential part of safeguarding participants' privacy relies on being very selective in determining what data will even be collected. The only personal information that should be gathered is that which is directly relevant to answering the research question. It should be stressed that even when information may seem trivial and harmless, it may have implications for participants that researchers are not aware of. Information that does not appear sensitive or embarrassing to researchers may be so for participants (TCPS2 2014). Consequently, "nonessential identifying details should be omitted" (ICMJE 2016, p. 7), both at the stage of data collection and when releasing results.

In contexts where researchers take on a dual role as teachers, only independent research team members should be involved in collecting students' information. Before it is transmitted to faculty with dual roles for analysis, data should be either anonymized or de-identified:

- *Anonymized data* is irrevocably stripped of all identifiers, both direct (e.g. name) and indirect (e.g. age).
- *De-identified data* has had identifiers removed and replaced with a code. The key code is kept by an independent member of the research team.

Anonymized data carries the least risk of re-identification, but is not always possible, if new information needs to be linked to the same participant later on in the study. Then the next best alternative is to use de-identified data. Ethical concerns regarding privacy decrease proportionally with the level of difficulty in associating information and codes with specific subjects (TCPS2 2014).

Tip 7

Protect participants' identity when disseminating findings

Our duty as researchers to safeguard information about participants becomes all the more important at the final

stage, when we report our findings. Once information is reported, we have no control over how it will spread. Therefore, careful consideration must be given when selecting the data that will be released.

When releasing results, all identifiers should have been removed. Care must also be taken to ensure that a combination of indirect data will not allow others to retrace participants. Bear in mind that when students are recruited from a very small program, inclusion criteria may in themselves suffice to allow identification of specific individuals (Christakis 1985; Forester and McWhorter 2005). When this risk is present, the scope of study may be widened to make it either a multiprogram or a multisite endeavor, or both (Ferguson et al. 2006).

In certain circumstances, participants may consent to having their identity revealed. Even then, such decisions should be made carefully. Disclosure of a participant's identity may have unforeseen repercussions for third parties or even for a group or a community (TCPS2 2014).

Tip 8

Protect data against unauthorized access

When students consent to participate in research, they consent to entrust specific members of the research team with their information. In return for this trust, our duty is to guarantee that their information will indeed remain within the boundaries to which they have consented. This means protecting data from all manners of unauthorized access, even access which we would perceive to be beyond our control, like loss or theft. This level of security can be attained through physical, administrative and technical safeguards (TCPS2 2014).

- *Physical safeguards:* They include storing research data in locked filing cabinets, and keeping computers containing research data in a secure place.
- *Administrative safeguards:* They imply developing and enforcing organizational rules about who has access to the research data.
- *Technical safeguards:* These include, but are by no means limited to, encrypting data, using computer passwords and anti-virus software.

Extra care should be taken when research data is sent by email or over the Internet. Such data should first be encrypted or denormalization software should be used (TCPS2 2014). Another frequent pitfall occurs when an electronic survey is used for research. Not all survey software and websites conform to the high security standards required for research. When choosing a survey platform, consult the security statement for mention of firewalls and encryption.

Approaching students as a vulnerable group

Tip 9

Resort to mandatory activities with caution

Due to the nature of interventions in medical education, researchers may be tempted to use recruitment strategies

that build on the mandatory curriculum at their institution. In such scenarios, educational interventions under study are integrated into the regular curriculum and are thus mandatory for all students. Participants' consent is only required to authorize faculty to use the data for research. Although convenient, this approach to recruitment raises certain ethical considerations. For as Eva (2007) has pointed out, "if we truly believe that some educational practices are better than others" – and this is in fact the underlying premise of most educational research – "then we must accept the very real possibility that an innovation may be worse than current practice and may, by definition, be harmful to students" (p. 725). A basic step in handling such situations is to ensure that consent truly is free and that students' participation status and data will in fact be kept confidential from faculty. We should resort to mandatory research activities with caution and aim to be creative.

Tip 10

Consider using breaks during mandatory activities

Consider using breaks during mandatory activities, while participation to research activities remains optional. One interesting solution to avoid pitfalls when interlacing research with students' regular curriculum is to take advantage of the time available within or between mandatory curricular activities, where students are all present and the schedule suggests some spare time. In this alternate scenario, regular activities are mandatory but research activities are optional. Norman et al. (2014) have illustrated how efficient this strategy can be, as they were able to recruit about a hundred participants two years in a row using this method. They took advantage of the spare time residents had after a national exam and volunteers actually exceeded capacity.

Tip 11

Avoid associating participation with course credits

A strategy that is sometimes used is to assign course credits for participation in a study. Yet, as emphasized by Leentjens and Levenson (2013), "voluntary participation is only truly voluntary if not participating has no consequences for the student" (p. 396). In the United States, the Code of Federal Regulations requires explicitly that "refusal to participate [in a study] will involve no penalty or loss of benefits" (45 CFR §46.116). Not receiving the same course credits as other students, however, puts students who refuse to participate at a clear disadvantage, which constitutes a penalty. As a consequence, undue influence is put on students to consent in such contexts. Furthermore, participants' right to "withdraw consent to participate at any time without reprisal" (*Declaration of Helsinki*, art. 26) is jeopardized when regular course credits depend on research participation. In cases where participation is associated with *extra* credits, such an incentive, in a competitive academic field, not only exerts undue influence, it may also induce a selection bias among participants, since additional course credits can preferentially encourage students with more academic difficulty to participate (Leentjens and Levenson 2013), altering the external validity of research

results. For all these reasons, course credits should not be allocated for participating in a study.

Tip 12

Get reviewed by an education research committee

Ethics reviewers and boards can play a useful role in counseling researchers as to the optimal management of ethical issues. The gold standard to avoid ethical pitfalls certainly is approval of the study by an education research ethics committee (Walsh 2014). However, a specifically dedicated ethics committee is not available at all institutions. In fact, a survey of four of the main medical education journals by Hally and Walsh (2016) revealed that only 5% of published original research in medical education has been reviewed by an education or medical education research review board.

Institutional and local ethical requirements do vary considerably. For instance, two American studies found that the very same medical education research protocol, submitted to different institutional review boards (IRBs), received an array of responses ranging from exemptions to the requirement of either expedited or full review of the protocol (Dyrbye et al. 2007; Sarpel et al. 2013). Such findings suggest inconsistent appreciation and understandings of the risk level associated with medical education research with students as subjects.

Nonetheless, the ethical requirements of medical education journals that publish original research remain the same (Brice et al. 2009; Eva 2009; Hally and Walsh 2016). To address this, members of the medical education research community are prompted to engage with their local institutions to ensure that ethical review is provided by a committee which includes at least some experts familiar with pitfalls specific to education research (Eva 2009; Hally and Walsh 2016). In the United States, such endeavors should find support in the *Code of Federal Regulations*, which states that “if an IRB regularly reviews research that involves a vulnerable category of subjects [,] consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects” (45 CFR §46.107a). Creative solutions may also be found. In one institution, a template was successfully implemented to optimize health professions education research protocols review by the IRB (DeMeo et al. 2016).

Failing such solutions, these twelve tips may serve as a reminder of the main ethical issues which should be given proper consideration when designing a study involving students as subjects.

Conclusions

Ultimately, everyone gains when proper consideration is given to ethical issues. Being aware of ethical pitfalls and acting proactively to minimize them will ensure that students are granted adequate protection as research subjects. In turn, students are much more likely to participate enthusiastically and to answer our study questions candidly. Moreover, due consideration of participants protects professional relationships in the long run, which is especially

relevant in health professions contexts where students are often future colleagues.

Acknowledgement of the ethical issues at stake will also help navigate through the ethics approval process more smoothly. Ethics reviewers wish to be reassured that researchers are aware of the risks associated with their study and that they are committed to minimizing them. In this perspective, ethical approval is all the more likely if evidence is provided that in designing an educational study, proper thought has been given to consent, privacy and confidentiality, and to the specific issues involved in recruiting students as research subjects.

Disclosure statement

The authors report no declarations of interest. The authors alone are responsible for the content and writing of the article.

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