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Research ethics and permission

Editorial for December 2014 issue of *The Clinical Teacher*
Michael Ross

Ethical issues are, by nature, complex and multi-faceted. Whilst most of us always want to behave ethically, when we become very focussed on one aspect of our work it may be difficult to step-back and take a broad overview, and remain confident that our intended actions would be considered ethical and appropriate by others. This is compounded when there are potential conflicts of interest, for example pressures from employers and funding bodies. Ethics committees exist precisely for these reasons, as does the Declaration of Helsinki.¹ The declaration is a set of principles which emphasises the need to carefully consider in advance the ethical issues of any medical research, including consent, confidentiality, weighing-up of potential benefits and risks, and independence from personal or financial interests, and then to submit research proposals for independent review by an ethics committee. The principles have been substantially embedded into medical and allied healthcare education, and it is now virtually unthinkable to conduct research on patients without adhering to them. Unfortunately, we cannot yet say the same for educational research involving healthcare students and trainees.

Two years ago, *The Clinical Teacher* published an editorial outlining the journal's expectations regarding ethical approval for submitted manuscripts, along with other aspects of publication ethics such as authorship and plagiarism.² Our

expectations draw heavily on the Declaration of Helsinki, and also guidance from the Committee on Publication Ethics,³ our publisher, Wiley,⁴ the British Educational Research Association,⁵ and the academic literature. Firstly, we expect manuscripts to describe ethically-justified research or evaluation. Eikelboom and colleagues highlight that such research is able to generate valuable knowledge through valid research design, demonstrates respect for participants with informed consent, maximises potential benefits and minimises risks for participants and society, and treats participants equitably.⁶ We expect similar standards for the design of evaluation studies if data are to be submitted for publication. Secondly, we expect authors to carefully reflect on the potential ethical issues related to their research or evaluation, including the need for verbal or written informed consent, and the potential for coercion in dependent relationships (e.g. between teacher and student). New researchers will find research methods books, such as those by Merriam⁷ or Cousin,⁸ helpful in explaining the features of ethical and trustworthy research. Cousin also reminds us that, “An ethical orientation supports the thoughtful conduct of the research process and the eventual credibility of the report... [and] should never be viewed as a tiresome preliminary to the real business of research”.⁸ Thirdly, we expect authors to submit their research proposals for formal ethics committee review and institutional approval from the medical school, hospital or training programme where appropriate – including proposals to re-analyse or publish evaluation or assessment data which have already been collected for educational purposes. We recognise, however, that in some situations clinical educators may not have access to a formal ethics committee, and so an opinion on the proposed research from a senior colleague who is independent of the study may be

appropriate. Finally, we expect authors to document the ethical issues considered, and provide evidence for ethical / institutional approval, in their submission to *The Clinical Teacher*.

When authors submit a manuscript to The Clinical Teacher, they must complete a free text box about ethical issues, which states:

“Ethical issues for any study involving human subjects should have been carefully considered in line with the Declaration of Helsinki. Where possible, we expect ethical approval to have been sought from an appropriate body, such as an Institutional Review Board (IRB) or Independent Ethics Committee (IEC). Please indicate from whom ethical approval was sought and the outcome (e.g. approval or deemed exempt from full review). In places where a formal body does not exist for the purposes of ethics review of educational research projects, please provide a statement confirming that the standards of the Declaration of Helsinki were maintained along with some indication of how you ensured that to be the case. If your study has been declared exempt from formal ethical review, please advise how you obtained consent from students/participants for their data to be submitted for publication”.⁹

For certain manuscripts, which are purely descriptive or based on the perspective of the authors and resources in the public domain, ‘not applicable’ is an appropriate response to this statement. Such perspectives may include personal opinions and experiences, and extend to general impressions of the opinions of others such as ‘we did this because students were asking for more

feedback', or 'the course was generally well-received'. For all other manuscripts, including those with anonymised assessment or evaluation data, 'not applicable' is not acceptable. Yet in the past year alone, since Jill and I have been co-editing *The Clinical Teacher*, we have received many such submissions. If otherwise appropriate for the journal, these are now 'unsubmitted' for being incomplete, and will only be considered again if the authors submit with adequate consideration of ethical issues. Some authors, and even research ethics committees, highlight that their work is evaluation rather than research, and so does not require ethical consideration or approval. Arguably that may be the case for local evaluation and quality-improvement activities, but it is not acceptable when participant data are submitted for publication. We also had a manuscript reporting research on medical students with the ethical statement 'Not required, no human subjects'. Clearly medical students are indeed human, and whilst educational research might not have the same risks as testing a new drug on patients, as clinical teachers and researchers we have a responsibility to protect their rights and ensure our work with them is ethical.

In this issue, there is a fine selection of original articles aimed at all clinicians who teach, many of which raise complex ethical issues. We also say 'farewell' to the last of the View From Here articles. As editors, authors and reviewers, we very carefully consider the ethical issues of every submitted manuscript. Some of the 'Ethical approval' statements at the end of these articles do not include further ethical information requested and received after the original submission, but with all new manuscripts we are trying to ensure these are also updated so this information is available to readers. It is, after all, you the reader who

decides whether an article is valuable and trustworthy. Having reflected on my own practice, and helped teach ethics to innumerable medical students, masters students and general practice trainees, I am convinced that once we understand basic ethical principles (benevolence, non-maleficence, autonomy, social justice and probity),¹⁰ the most difficult aspects of ethical practice and decision-making are recognising when there are ethical issues to consider and taking the time to do so. If you want to write for publication, you can expect to encounter ethical issues. By considering and addressing these from the planning stages of any study, we think you will find the whole process smoother and more rewarding, your manuscripts will be more likely to be accepted, and ultimately your published articles will be more valued, trusted and influential.

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