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Editorial

Is research ethics committee approval necessary for publication of prospective surgical research studies?

Research is defined as "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to knowledge". Thus clinical innovation becomes research when the intervention is undertaken according to a protocol aimed at producing knowledge.[1]

As surgeons we all know that surgery harms before it heals, accordingly we have always attempted to limit the harm we do to our patients and extend the healing power of the surgical craft. In surgical practice the implementation of any research study should be justified, well planned, properly designed and it should follow the basic foundation of biomedical research ethics, which can be usefully defined as the disciplined study of morality including respect for persons, beneficence/non-maleficence and justice.[2–5]

Ethics require that a physician or surgeon be a person of character, one who can be expected habitually to act in the patient's best interest when no one is watching. This would create trust, which is essential in the healing relationship and build up a cooperative attitude in the community. This helps in the advancement of science through funding of research studies and willingness of individuals to participate in research projects as subjects with dignity and not as guinea pigs.

Surgeons should possess a sense of justice for society and for patients by ensuring their safety when involved in a research study. The currently accepted way of documentation for a researcher who has taken the necessary steps to ensure the research subjects' safety is obtaining a biomedical research ethics committee (REC) or Institutional review board (IRB) approval. Failure to do so for whatever reason is considered as an element of misconduct, which should not be rewarded by approval for publication. However, one of us (Riaz Agha) has already shown that the incidence of ethics review board permission amongst surgical RCTs is poor.[6]

All European Union member states have legislations since 2004, which make submission of research protocols on drugs to ethical committee mandatory.[7] The Australian Code for the Responsible Conduct of Research in 2007 makes it clear that novel technology affecting clinical practice, including new diagnostic, surgical or therapeutic techniques, needs to be fully discussed by an REC before it can be carried out on patients. It is no longer ethically acceptable for surgeons to use a device or technique or modification of a technique without ethical approval.[8] This agrees with the guidelines of the International Committee of Medical Journal Editors, which recommend rejection of studies that fail to adhere to ethical guidelines.[9,10]

However is it really that simple for an editor or reviewer to reject an article he received for evaluation just because it has no ethical committee approval? Well the answer to this question is not that simple due to several reasons. First, not all countries have working research ethics committee with national guidelines for research. Second, not all medical journals consider REC approval mandatory for submission for publication. Third, failure to have an ethical approval due to logistic situations does not necessarily mean that ethical standards were not followed by the investigator and on the contrary obtaining an ethical approval does not always mean that ethical standards were followed.[11,12] On the other hand following a more lenient ethical rule with publication from certain countries whether European, African or Asian is considered a "double standard" and it violates justice, which may be one of the major foundational ethical principles.[13]

The committee on publication ethics (COPE) recommended that editors, when reviewing an article, which doesn't satisfy ethical approval requirements, should consider the following: scientific validity and whether the study contributes sufficiently to knowledge to make acceptance and publication a possibility, then ensures that the benefits overweigh harms and that the research meets international norms and standards like the declaration of Helsinki with issues like informed consent, the centrality of patient welfare and patient confidentiality covered in detail.[14,15]

Due to the above mentioned reasons, we propose a decision making policy based on a reasonable rationale, which depends on several variables including:

1) Clear statement in the instruction to authors denoting that REC approval is mandatory for consideration for publication in a peer-reviewed journal.
2) If ethical approval is not provided, the issue should be discussed with the main author in order to explain the reason for this.
3) Review the original article presented to the journal with respect to the ethics of the research study by reviewers specialized in biomedical research ethics (if the author was able to convince the editorial board with reasons for why an REC approval was not provided).
4) Any query regarding a possible ethical misconduct should be noted against the publication of the article and it should be rejected at this stage with the authors' institution or departmental head informed.
5) If the ethical standard seems to be followed by the researcher as reported by the ethical reviewers, then the article should be submitted for scientific review and if accepted it may be published with an editorial comment denoting that this research

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study was not approved by an ethical committee before the commencement of the research (rather like conflicts of interest).

Journal editors and reviewers have an important role in enhancing the quality of published studies and adhering to ethical standards of research by insisting that investigators should follow journal's policy that should be in line with COPE and other standards. This can be achieved because publication in a peer-review journal confers legitimacy and is the main method for the dissemination of scientific knowledge among professionals.[16,17]

Conflict of interest

None.

References

1. McKneally M, Daar A. Introducing new technologies: protecting subjects of surgical innovation and research. *World J Surg* 2003;**27**:930–5.
2. *International ethical guidelines for biomedical research involving human subjects*. Geneva: CIOMS and WHO; 2002.
3. Nuremberg code, http://www.Ushmm.org/research/doctors/Nurembergcode.htm; 1947.
4. Declaration of Helsinki. Human experimentation: code of ethics of the world medical association. *BMJ* 18 July 1964:177–80.
5. *The Belmont report: ethical principles and guidelines for the protection of human subjects of research*. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; April 18, 1979.
6. Agha R, Cooper D, Muir G. The reporting quality of randomised controlled trials in surgery: a systemic review. *Int J Surg* 2007;**5**:413–22.
7. Silverman HJ, Druml C, Lemaire F, Nelson R. The European Union Directive and the protection of incapacitated subjects in research: an ethical analysis. *Intensive Care Med* 2004;**30**(9):1723–9.
8. Carney S, Watson D. Human ethics and research governance: implications for surgical research. *ANZ J Surg* 2008;**78**:421–3.
9. World medical association declaration of Helsinki: ethical principles for medical research involving human subjects. Available at: http://www.wma.net/e/policy/pdf/17c.pdf; 2006.
10. International Committee of Medical Journal. Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication. Publication ethics: sponsorship, authorship, and accountability, www.icmje.org [updated October 2008].
11. Steinbrook R. Protecting research subjects: the crisis at Johns Hopkins. *N Engl J Med* 2002;**346**:716–20.
12. Ramasay S. Johns Hopkins takes full responsibility for volunteer's death. *Lancet* 2001;**358**:213.
13. Lemaire F. Do all types of human research need ethics committee approval? *Am J Respir Crit Care Med* 2006;**174**:363–6.
14. Committee on Publication Ethics (COPE). Research without ethics committee approval, www.publicationethics.org/case/; 2003.
15. Committee on Publication Ethics (COPE). Guidance for editors: research, audit and service evaluation, www.publicationethics.org; 2008.
16. Block M, Khitin L, Sade R. Ethical process in human research published in thoracic surgery journals. *Ann Thorac Surg* 2006;**82**:6–12.
17. Pitak-Arnnop P, Schouman T, Bertrand JC, Hervé C. How to avoid research misconduct – recommendations for surgeons. *J Chir (Paris)* 2008 Nov–Dec; **145**(6):534–41.

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