



Exposing a Loophole: Journals Not Requiring Ethics Committee Review for Published Meeting Abstracts

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Abstract

Purpose: Medical journals have become increasingly explicit in their requirements for ethics committee review of human research. However, many medical societies do not require ethics review for human research submitted as abstracts and presentations; often these abstracts are then published in affiliated journals. This study examined the requirements for ethics committee review and approval for research submitted to society meetings and published in affiliated journals.

Methods: Using a sample of 27 journals affiliated with medical societies, we examined ethics committee requirements for human research published as articles as compared to research originally submitted as abstracts to medical society meetings.

Results: Ethics committee approval requirements for human research submitted to academic journals exceeded those of abstracts submitted to affiliated medical society meetings (100% versus 37%). Twelve journals or their supplements (44%) published abstracts of research presented at the medical society meetings. Ethics committee approval was not required by a majority (58%) of medical societies prior to the publication of meeting abstracts in affiliated journals.

Conclusion: Many medical societies do not require ethics committee approval for abstracts presenting human research. Some of these abstracts are then published in the society's affiliated medical journal. Several arguments against requiring ethics committee approval exist and are addressed.

While the majority of research may be ethically sound, and journals can request approval if something appears to be out of the ordinary, -we submit that making an effort to ensure proper ethical guidelines are followed in abstract related research would be useful, even if this did require making the process of abstract submission more difficult. Acknowledging and attending to this loophole will increase transparency for those submissions that have proper approval, as well as improve accountability in those submissions that do not. Ethics committee approval should be required for all presentations at medical society meetings and all research publications within journals,

including abstracts and articles.

Introduction

Over the past half-century, the importance of sufficient ethical review of human research has received increasing attention. As a result, medical journals have become increasingly more explicit in their instructions to authors regarding ethics-related guidelines, and ethics committee approval has become standard for the publication of human research in major medical journals.^{1,2,3} To protect the rights of human research subjects, ethics committees seek to evaluate the risks and benefits that research subjects face, while taking the subject's potential vulnerable status into account.

In 1964, the Declaration of Helsinki defined standards for ethics board approval, informed consent, and the reporting of research in publication.⁶ The National Research Act, signed in 1974, created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; this Commission was responsible for defining basic ethical principles to be applied to biomedical and behavioral research involving human subjects.⁷ The three principles defined by the Commission—respect for persons, beneficence, and justice—remain prominent in contemporary research ethics. As such, researchers have a duty to uphold these principles. Ethics committees play an important role in human research by assuring that research protocols involving human subjects follow accepted ethical guidelines. In the United States, these committees, known as "Institutional Review Boards" (IRBs), are charged with the responsibility to protect the rights and welfare of human research subjects.

The assurance of ethical human research remains an iterative process; as new technology, research techniques, and loopholes are identified, the requirements should be reevaluated and updated. As such, we have identified a potential loophole which may allow for the publication of research which has not been approved by institutional human investigations or ethics committees. Many medical societies do not explicitly require ethics committee

approval for human research being submitted for presentation at society meetings; oftentimes, abstracts presented at society meetings go on to be published in journals affiliated with the society.⁸ This study aimed to determine whether research abstracts presented at society meetings are held to the same standards as research submitted directly to journals for publication.

Methods

The researchers compiled a list of the 100 medical journals with the highest SCImago Journal Rank (SJR), an open-access journal ranking resource which evaluates and ranks the scientific impact of journals based on how often and by whom the journal is cited. (<http://www.scimagojr.com/journalrank.php>).⁹ Journals not affiliated with a medical society and those not publishing human subject research were excluded. In the case that a single journal was affiliated with more than one society (or vice versa), affiliation was selected at random. The data sample was comprised of 27 widely recognized medical journals affiliated with or published by a medical society. The websites of each journal and affiliated society were accessed between January 5 and February 20, 2009 to collect information related to requirements for publication of human research. If information on the website was unclear, the authors contacted the journal or society to clarify ethics committee requirements. The "Information for Authors" and/or "Abstract Submission Guidelines" sections for each site were digitally saved and examined for the following:

Journals

* Ethics committee requirements for the publication of original research articles involving human research subjects.

* Whether documentation of such approval was required prior to publication.

Societies

* Ethics committee requirements for the submission of original research abstracts presented at medical society meetings.

* Whether documentation of such approval was required prior to the presentation of research at the meeting.

* Whether abstracts accepted for presentation at meetings are later published in affiliated journals or their supplements.

Results

All 27 journals in the sample required ethics committee

approval prior to the publication of articles containing original research with human subjects. Of the 27 affiliated medical societies, ten explicitly required ethics committee approval prior to the submission of original human research abstracts for presentation at society meetings. Twelve journals from the sample or their supplements published research abstracts presented at medical society meetings, of which seven did not require ethics committee approval for the published research abstracts (Table 1).

Discussion

In 1964, the Declaration of Helsinki defined ethical standards for reporting of research, ethics board approval, and informed consent in the publication of articles.⁶ As a result, over the past forty years, journals have increasingly implemented requirements to reduce the number of published articles lacking proper ethical committee approval. Ethics committee approval reporting has increased. Whereas approval was mentioned in 69% of clinical trials published before 1997, this number has increased to 82% after 1997.¹⁰ Furthermore, between 1995 and 2005, the proportion of journals requiring ethical review board approval increased from 42% to 76%. Improvements have been made in both publication requirements and in the instructions to authors regarding ethical standards.³

However, articles with potential ethical shortcomings continue to be published.⁶ The loophole described here is significant, as it represents a process that may allow ethically unsound human research to make its way through the publishing process without being subjected to ethics committee review. Ideally, ethically unsound research would not be accepted as an abstract presentation. This specific loophole pertains to the publication of abstracts and not full articles. The authors of this article submit that, regardless of the impact or length of an abstract or article, all human subjects research should be held to certain ethical standards. Counter-arguments are outlined and dissected in the following paragraphs.

Arguments against requiring ethics committee approval include three major points: 1) lack of approval does not automatically indicate that the research is ethically unsound, 2) abstracts may not be as influential in the field as full articles, thus requiring ethics approval may not be as crucial for abstracts as for fully published research, and 3) increasing standards for ethics committee approval for human research would make the process to submit work for meetings and abstract publications even more

arduous and consequently limit the accessibility students have in submitting research and presenting at meetings/conferences.

It is important to note that the absence of specific notation of ethical review board approval within the manuscript does not necessarily indicate that ethical review was not obtained; it is likely that a substantial percentage of studies which do not explicitly discuss ethics committee review have actually undergone sufficient review at the institutional level. In these cases, review may have been obtained from the institutional review board, but not explicitly noted in the manuscript. This is supported by a study which examined prospective publications for the *Journal of the American Academy of Dermatology (JAAD)* between 2004 and 2006. Investigators found that 56 of 150 papers submitted did not include ethics panel review information—42 papers of these manuscripts were returned to the authors with a request for information regarding institutional ethics review; of these, 48% were resubmitted with confirmation of ethics review, 7% were clarified as exempt from review, 22% were withdrawn, 12% were never resubmitted, and only 12% responded that ethical review was not obtained.¹¹ These findings suggest that most research has undergone ethics committee review, even in cases when it is not specifically documented in the manuscript.¹² This finding limits the argument that requiring ethical committee review would make presenting and publishing abstracts too difficult for students. This study proves that most research has already undergone approval from an ethics committee, and the request for documentation in these cases only increases transparency. Requiring disclosure of ethical review board approval as a condition for publication holds human researchers accountable.

Finally, the impact of a paper or abstract is irrelevant to its need for proper ethics committee approval. Ethical breaches are not limited to lengthily high-impact studies with cutting-edge technologies or large sample sizes. Even a small seemingly-irrelevant case-series study may face ethical dilemmas, and as such all human subject research should undergo proper ethics committee approval.

Conclusion(s)

All of the journals in this study required ethics committee approval for manuscripts describing research on human subjects. However, a loophole was identified for the publication of abstracts presented at medical society meetings. Many

academic societies do not explicitly require ethics committee approval for presentation of human research at society meetings and some of these abstracts are subsequently published in affiliated journals. Ethics committee review should be confirmed for all human research presentations at medical meetings and resulting published abstracts, as this will increase transparency and accountability for published human research.¹³ The responsibility to require ethics committee approval should be shared by conferences, meetings, and individual institutions in addition to the journals that publish these abstracts.

Closing this loophole would require additional work from the submitting authors and could possibly make the submission process more arduous, perhaps even unachievable by some. However, by expanding the requirements surrounding the disclosure of ethical review to include all human research publications, including those initially presented at medical meetings, we will continue to improve the global research community's dedication to ethical standards in human research design and reporting.

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Illustrations

Illustration 1

Table 1: Journals Not Requiring Ethics Committee Review for Published Meeting Abstracts

Journals	Affiliated Societies	Associated Meeting	2008 Impact Factor for Journal	Location of Society Headquarters
Hepatology	European Association for the Study of the Liver	44th Annual Meeting of the European Association for the Study of the Liver	11.4	Switzerland
American Journal of Respiratory and Critical Care Medicine	American Thoracic Society	American Thoracic Society 2009 International Conference	9.8	US
Diabetes*	American Diabetes Association	ADA's 69th Scientific Sessions	8.4	US
Journal of the American Society of Nephrology*	American Society of Nephrology	Renal Week 2008	7.5	US
Arteriosclerosis, Thrombosis, and Vascular Biology*	American Heart Association	American Heart Association Scientific Sessions 2009	6.9	US
Critical Care Medicine*	Society of Critical Care Medicine	Society of Critical Care Medicine Annual Congress (2009)	6.6	US

Journal of Immunotherapy	International Society for Biological Therapy of Cancer	International Society for Biological Therapy of Cancer 2009 Annual Meeting	3.7	US
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*Meeting abstracts are printed in a journal supplement

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