ORIGINAL ARTICLE

Human research review committee requirements in medical journals

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Abstract

Purpose: Independent ethical review committees safeguard participants in human research. The purpose of this study was to describe the current ethical guidelines for human research requirements in the Instructions to Authors of the English language medical journals previously studied in 1995.

Methods: The instructions to authors of English language medicine journals from the *Abridged Index Medicus* were searched for any policies regarding guidance on the ethical treatment of human subjects in research.

Results: More medical journals require independent ethics committee approval of human research now [84/101 (83%)] than 10 years ago [48/102 (47%) ($P<0.001$)], and most journals continue to require that this disclosure appear in the manuscript [71/84 (85%) vs. then 37/48 (77%) ($P=0.29$)]. Fewer medical journal instructions to authors provide no ethical guidelines for human research now [8/101 (8%)] than 10 years ago [25/102 (24%) ($P<0.001$)]. No journal required submission of the study approval letter or of the approved protocol.

Conclusions: Although medicine journals increasingly require disclosure statements of independent ethics committee approval for human research, they fail to verify such approval beyond taking authors for their word.

History provides numerous examples of harmful human research.¹ In response, distinguished

organizations (such as the World Association of Medical Editors (WAME) and the World Health Organization (WHO)) have issued ethical guidance and governments have created independent ethics committees to safeguard study participants.¹ While concerns remain regarding the performance of individual ethical review committees in fulfilling their mission,^{2,3} these committees embody an undeniable advance for ensuring patient safety. In addition, articles reporting ethics committee approval of protocols are generally of higher methodological quality than articles that do not.⁴

In 1997, Amdur and Biddle reported that only 47% of medical journal Instructions to Authors called for disclosing independent ethics review committee approval in manuscripts reporting human research and that 24% did not provide any information on human research ethics.⁵ Because ethical issues in human research are increasingly debated in both scientific forums and popular media,^{2-4,6,7} we repeated Amdur and Biddle's study to determine what changes have occurred regarding ethics committee journal disclosure guidelines over the past decade.

TABLE 1. Medical journals, grouped according to the ethical guidelines described in the journal's instructions for authors section

2006		
Ethics Review Committee		Uniform Requirements
Acad Med	Clin Orthopedics	Am Fam Physician
Am Heart J	Clin Pharmacol Therap	Am J Pathol
Am J Clin Nutr	Crit Care Med	Clin Pediatr
Am J Clin Path	Dig Dis Sci	J Am Coll Surg
Am J Obstet Gynecol	Gastroenterology	Public Health Reports
Am J Ophthalmol	Gut	
Am J Phys Med Rehabil	Heart	Declaration of Helsinki
Am J Psychiatry	J Allergy Clin Immunol	Am J Med Sci
Am J Public Health.	J Am Coll Card	Diabetes
Am J Roentgenol	J Am Diet Assoc	J Oral Maxillofac Surg
Am J Surg	J Bone Joint Surg Am	
Am J Trop Med Hyg	J Bone Joint Surg Br	Informed Consent
Am Journal Respir Crit Care Med	J Clin Endocrinol Metab	Cancer
Anaesthesia	J Clin Invest	
Anesth Analg	J Clin Pathol	No Guidelines
Anesthesiology	J Gerontol Psychol Social Sci (Series B) [†]	Am J Cardiol [‡]
Ann Emerg Med	J Fam Pract	Am J Med
Ann Intern Med	J Immunology	Ann Otol Rhinol Laryngol [‡]
Ann Surg	J Infect Dis	Heart Lung ^{††}
Arch Dermatol	J Lab Clin Med	J Gerontol Bio Med Sci (Series A) ^{‡‡}
Ann Thorac Surg	J Nervous Mental Disease	J Laryngol Otol
Arch Surg	J Neurosurg	J Nurs Admin
Arch Dis Child	J Pediatr	
Arch Environ Health	J Thorac Cardiovasc Surg	Nurs Outlook [‡]
Arch Gen Psych	J Toxicol Clin Toxicol	
Arch Intern Med	J Trauma	
Arch Neurol	J Urology	
Arch Ophthalmol	JAMA	
Arch Otolaryngol Head Neck Surg	Lancet	
Arch Path Lab Med	Mayo Clinic Proc	
Arch Pediatr Adolesc Med	Medicine	
Arch Phys Med Rehabil	N Engl J Med	
Arthritis Rheum	Neurology	
Blood	Nurs Res	
BMJ	Obstet and Gynecol	
Br J Obstet Gynaecol (BJOG)	Pediatrics	
Br J Radiol	Phys Ther	
Br J Surg	Plast Reconstruct Surg	
Brain	Radiology	
Can Med Assoc J	Rheumatol	
Chest	South Med J	
Circulation	Surgery	

[†] *Journal of Gerontology: Psychological Sciences* manuscripts should be prepared according to the 5th edition of the Publication Manual of the American Psychological Association (2001).

[‡] Consult ICMJE Uniform Requirements for Manuscripts to Biomedical Journals for manuscript style issues.

^{††} Animal experimentation must observe the "Guiding Principles in the Care and Use of Animals" published in the Guide to Authors of the American Physiological Society, and be approved by the appropriate Animal Care Committee.

^{‡‡} *Journal of Gerontology: Medical Sciences* randomized controlled trials must follow the guidelines established in the CONSORT statement (<http://www.consent-statement.org/>).

TABLE 2. Ethical Guidelines for Research Involving Human Subjects Described in the Journal's Online Instructions for Authors Section (1997 and 2006)

Ethical Guideline	No. (%) of Medical Journals 1997	No. (%) of Medical Journals 2006	P
Institutional Review Board	48 (47)	84 (83)	<0.001
Uniform Requirements	15 (15)	5 (5)	0.02
Declaration of Helsinki	3 (3)	3 (3)	
Informed Consent	10 (10)	1 (1)	0.01
No Guidelines	25 (24)	8 (8)	<0.001
Miscellaneous†	1 (1)	0 (0)	0.32

† *Nursing Research* stated that no manuscript would be considered for publication unless it contained an explicit statement ensuring that the rights and dignity of all human subjects involved in research be protected. There was no mention of IRB, Uniform Requirements, the Declaration of Helsinki or informed consent.

Methods

Between November 25 and December 7, 2006, journal websites for English language medical journals in the 1995 *Abridged Index Medicus*⁵ were identified via the search engine Google and information for authors was digitally saved. Instructions to authors were read and extracted independently by two authors (KL, SF). Journals were segregated into the following categories regarding their requirements for human research publication:

- Ethics committee approval,
- International Committee of Medical Journal Editors (ICJME) *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*,⁸
- Declaration of Helsinki,⁹
- Informed consent,
- No guidelines listed.

If journals required independent ethical committee approval, documentation requirements were categorized:

- Copy of independent ethics committee approval letter,

- Statement of independent ethics committee approval required in the manuscript,
- Submit separate document certifying independent ethics committee approval, or
- None.

Descriptive statistics and Pearson chi-square *P* values were obtained with Pepi Programs (<http://sagebrushpress.com/PEPI.html>).

Results

Of the 102 original medical journals examined--one journal (*Western Journal of Medicine*) stopped publishing in 2002 and was not included, two journals in the original list constituted the same journal (*American Journal of Diseases of Childhood* became *Archives of Pediatrics and Adolescent Medicine* in 1993 and only the latter was included). Another later changed its name (*British Heart Journal* became *Heart* in 1996), and one divided into two (*Journal of Gerontology* split into *Journal of Gerontology: Series A* and *Journal of Gerontology: Series B* in 1995)--101 continuing journals were available for examination (Table 1).

Instructions to authors of 84/101 (83%) medical journals required independent ethics review committee approval for studies using human subjects: 8/101 (8%) made reference to other guidelines that call for approval by an independent ethics review committee [5/101 (5%) ICJME Uniform Requirements, 3/101 (3%) Declaration of Helsinki], 1/101 (1%) stated that informed consent should be obtained, and 8/101 (8%) journals did not mention human research ethics guidelines (Table 2).

Of the 84 medical journals with Instructions to Authors calling for ethics committee approval for human studies, 71 (85%) required that a statement disclosing independent ethics committee approval appear in the manuscript, 5 (6%) required separate documents certifying independent ethics committee approval, 8 (10%) assumed compliance and zero required a copy

TABLE 3. Documentation Requested by Journals Requiring Ethics Committee Approval of Protocols Involving Human Subjects

Journal Requirement	No. (%) [*] of Medical Journals (1997)	No. (%) [*] of Medical Journals (2006)	<i>P</i>
Copy of IRB approval letter	0	0	
Statement in the manuscript	37 (77)	71 (85)	0.29
Separate signed statement	7 (15)	5 (6)	0.10
Assumed compliance	4 (8)	8 (10)	0.82

* The denominators used for determining percentages were the 48 and 84 journals requiring ethics committee approval respectively in the original study and in this update. Percentages do not always sum to 100% due to rounding error.

of the independent ethics committee approval letter (Table 3).

Discussion

Ten years ago, 24% of the medical journal Instructions to Authors examined provided no ethical guidelines for research involving humans. This percentage has decreased to 8%. These findings reflect the growing pressure clinical investigators face in addressing ethics committee concerns regarding research design, conflicts of interest, and subject privacy.^{6,10,11} The number of journals requiring documentation of ethics committee approval, however, has not changed [7/48 vs 5/84 journals ($P=0.10$)]. A major development since Amdur and Biddle's study has been the mandatory prospective registration of clinical trials by numerous journals.¹²⁻¹⁴ While the trial registration database "ClinicalTrials.gov" requires ethical committee approval before patient enrollment and contains approved protocol information,¹⁵ documentation of ethics committee approval is not generally required by registries. For example, the International Committee of Medical Journal Editors (ICJME) asserts that "it is assumed that all registered trials will be approved by an ethics board before commencing," but does not require documentation,¹⁶ and the World Health Organization (WHO) International Clinical Trials Registry

Platform (ICTRP) recommends, but does not require, ethics approval before patient enrollment.¹⁷

To further ensure the integrity of scientific journal publications,¹⁸ medical journals should require submission and online posting of approved human research protocols and copies of independent ethics committee certification letters in an open repository. Online posting of approval letters and protocols are logical extensions of policies requiring ethics committee review; these additional measures will promote ethical conduct and foster the archiving of the experimental methods.^{19,20} International consensus on posting may be promoted by international consortia (e.g., ICJME) and organizations (e.g. the World Association of Medical Editors). Similar precedent for online access to critical information has been established with database deposition of protein crystallography, gene sequence and microarray data for publication in protein structure, genetic and gene expression publications.²¹

Concern regarding patient privacy and loss of researchers' competitive advantage may arise with the publishing of detailed experimental protocols. While the HIPAA Privacy Rule has been reported to hinder biomedical research on several fronts in the US, HIPAA was designed to protect the privacy of individually identifiable health information, striking a balance between patient privacy and the disclosure of medical data that have been properly deidentified.²² Clearly, protocols can be described without patient data being revealed. Still, investigators and pharmaceutical companies may consider protocols trade secrets, so the benefits of increased transparency will need to be weighed against any disincentive mandatory protocol registration will have on medical research.

The lengthening list of abuses of human subjects accompanying the shift of clinical research from academic centres to the less regulated private sector⁷ calls for the greater accountability that increased transparency provides. An author simply stating that ethics committee approval was obtained for their experiments involving humans is no longer sufficient. A

fact of human behaviour is that there will always be those among us who cheat. For researchers who have obtained ethics committee approval, providing a copy of the approval letter is minimal additional work. Creating such a document is much more problematic for researchers who have not received approval. Likewise subjects may expose experimenters altering posted protocols and thereby effectively supplement the work of data safety monitoring boards to protect human research. The minimal extra work involved in requiring online posting of clinical trial documents is a small price for the benefits that open review and transparency will provide.

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