

Ethics and Editors: A Study of Editorial Policies and Practices

By Yvonne Brackbill and André E. Hellegers

During the last twenty-five years, there have been repeated suggestions that an effective way to ensure high ethical standards in research is to suppress publication of unethical research.¹ Editors of biomedical journals were not initially receptive to such a proposal. In 1966, William Curran reported that a survey conducted by the Boston University Law Medicine Institute had “found that most medical-journal editors did not see as one of their own responsibilities the checking or monitoring of papers submitted to assure that the researchers had followed accepted ethical practices to protect the subject's rights in experimental situations.”²

The push for prepublication ethical screening continued, however. In 1970, the Council of Biology Editors issued a three-page recommendation on “ethical experimentation and the editor.” It began by stating:

Investigators conducting biomedical, behavioral, and social studies on human subjects are expected to observe certain ethical standards designed to protect the subjects from exploitation and abuse. Since this principle is widely accepted by the scientific community, as well as by society at large, all organizations whose functions impinge on such research should, by word and deed, support adherence to ethical standards. When editors evaluate the acceptability of the report of such research for publication, they should, therefore, apply ethical as well as other criteria.³

The Council went on to recommend that editors adopt not one but two types of prepublication monitoring: ethical review at the editorial level and proof of institutional review board (IRB) approval (along with footnoted publication of proof).

In the decade following this recommendation there have been few if any such footnotes, and most “Instructions to Contributors” make no demands for proof of IRB approval. Have there been changes in other aspects of editorial policy that are effective but less visible? Have there been changes in editors’ attitudes regarding the necessity or advisability of ethical review?

A Survey of Journals

In December 1977, a questionnaire was mailed to editors of 138 core medical journals, defined as recommended periodical holdings in the *Selected List of Books and Journals for the Small Medical Library*.⁴ It contained the following five questions:

1. Do you instruct reviewing editors to judge manuscripts on the basis of ethics as well as substantive material, methodology, and style?
2. Do you require authors to submit IRB approval along with their manuscript?
3. Some ethicists have suggested that the most effective way to eliminate ethical violations in research is for editors to refuse to publish articles based on research in which there are clear ethical violations. Do you agree that this ought to be done?
4. Is it ethical for an editor to publish unethical research?
5. Do you contemplate any changes in your editorial policy with respect to any one of the points raised above?

Of the 138 editors polled, seventy-five completed the questionnaire and returned it; twelve returned the questionnaire noting that it was not applicable (because the journal does not publish original research); six returned the questionnaire with or without comment, but without answering the questions; and forty-five did not reply.

At the time the questionnaire was mailed, we undertook to survey articles published in a sample of the core journals, in order to see if the authors themselves mentioned obtaining informed consent from the human subjects of their research. The material surveyed consisted of all articles based on original research using human subjects that had been published in each journal's last volume dated 1977. Included in the survey were sixty-nine of the seventy-five journals whose editors subsequently returned a questionnaire relating to editorial policy review.⁵

Results of the Survey

Table I contains the basic tabulations from the seventy-five questionnaires that were completed and returned. Principal interest attaches to “No” responses to questions one through three and “Yes” responses to question four.

Of the forty-four “No” responses to question one, fifteen editors elaborated by stating that reviewing editors are already sensitive to ethical issues. An additional four said that review on ethical grounds was the responsibility of the editor-in-chief.

In response to question two, fifty-five editors answered that they did not require IRB approval. Four editors qualified their responses (“other”) by stating that they required IRB approval occasionally, in borderline cases or when appropriate.

The seven editors who disagreed with the proposal that unethical research should be refused publication (question three) felt either that ethics are “not sufficiently clear to justify censorship” or that ethical violations should be published and accompanied by an editorial. In addition, six editors (“other” response category) said they had no opinion, no comment, or that it is difficult to determine ethical violations.

Of the seven editors who believe it is ethical to publish unethical research (question four), one stated that “the ethical witch hunt has gone too far,” and a second defined randomized clinical trials as unethical but publishable. The nine “other” responses contained three themes: (1) determining who is to define *ethical* and how; (2) balancing the importance of scientific data against ethical considerations; and (3) interpreting failure to publish as a form of censorship.

How do editorial actions compare with editorial policy? Table 2 contains the basic survey data on informed consent for 1,575 articles published during 1977 in sixty-nine core biomedical journals. Of the 671 articles published in journals whose editors, according to their questionnaire responses, request ethical review by consultants, 30 percent actually mentioned obtaining informed consent; of the 822 articles published in journals whose editors do not request reviewers to monitor ethics, 19 percent mentioned obtaining informed consent.

A second tabulation indicates that informed consent was mentioned in 39 percent of articles published in journals whose editors require proof of IRB approval, whereas it was mentioned in 23 percent of articles published in journals whose editors do not require such proof. Finally, the survey data revealed that 35 percent of articles published in those journals explicitly mentioning informed consent in “Instructions to Contributors” actually did mention obtaining informed consent, whereas 18 percent reported obtaining informed consent without explicit instruction to do so.

Policy and Implementation

Most editors believe that the observance of ethical standards in research is a precondition for publication and that editorial responsibilities include ethical responsibilities. On the other hand, most have no policy with respect to ethical review at the editorial level or institutional level. Of the fifty-eight editors who agree that unethical research should not be published, only twenty-three instruct their reviewers to screen for ethical violations, and only nine require authors to submit IRB approval along with their manuscripts. Further, as noted above, 70 percent of articles published in journals whose editors state either that they instruct consultants to review for ethics or that they require proof of IRB approval do not mention having obtained informed consent. Finally, 65 percent of articles published in journals whose “Instructions to Contributors” require a statement of informed consent do not mention having obtained that consent.

Why the discrepancy between conviction and action? Are editors reluctant to enforce or even adopt policies regarding ethical standards if doing so increases workload or adds policing functions at the editorial level?

Our data do not support this conjecture, as there are more editors (36 percent) who shoulder responsibility for ethical monitoring than there are editors (21 percent) who hold the authors' institutions responsible. This may reflect editors' awareness that IRBs approve research proposals. They do not monitor the manner in which research is actually conducted and have no mechanisms for gauging any discrepancies between word and deed. In addition, granting agencies also tend to be unaware of deviations from proposed protocols (a situation that is exacerbated by emphasis on short-term funding). In short, there is no more all-encompassing perspective from which to view the actual ethical quality to research than an editor's; and editors are very likely aware of their potential effectiveness as ethical gatekeepers. They should also be aware, as Robert Veatch has pointed out,⁶ that they in all likelihood maintain membership in at least one of the professional groups which “impose a duty on their members to report evidence of unethical conduct to an appropriate professional board for review.”

Alternatives to Prepublication Review

Are there alternatives to prepublication ethical review? Henry Beecher felt that publishing unethical research was as unjustified as a court's accepting unconstitutionally obtained evidence. Nevertheless, the "sunshine" argument for publishing unethical research, put forth most forcefully by Jay Katz,⁸ argues that continuing appraisal of conflicting values in research involving human subjects requires high visibility of those conflicting values. The example most frequently cited in connection with this argument is the Willowbrook project in which, under proxy consent conditions that provoked considerable controversy, researchers infected mentally retarded children with hepatitis in order to test the effectiveness of experimental vaccines. Publication of the studies evoked, sequentially, laudatory editorials, objections from outraged readers, and editorial reassessments. In the end, the total number of printed words devoted to the controversy exceeded that given over to the original presentation of the research.

In the decade since Willowbrook, constraints on publication space have increased. Brevity is now regarded as a necessity rather than a virtue. Despite the recommendation of the Council of Biology Editors that manuscripts based on experimental studies should "describe the precautions taken" to ensure ethical standards,⁹ editorial policy no longer encourages sufficient detail to allow experimental replication, much less a detailed account of the conditions under which human beings agree to become subjects. Therefore, even those readers who want to sit in ethical judgment on their published colleagues find the task all but impossible. To illustrate, consider these examples, both published in 1977. "The recipients of infectious (hepatitis) material were male inmates of federal penitentiaries who . . . volunteered." "An attempt was made to transmit the illness to volunteers by oral administration of 2% bacterial free diarrheal stool filtrates." (The investigators also reported that 52 to 60 percent of their volunteers subsequently became ill.) In neither case is mention made of informed consent, nor is it easy for readers to imagine the circumstances under which sizable numbers of human beings would "volunteer" their services as subjects for these research projects.

Most scientists are under great pressure to conduct research and publish it. Publication is the sole route to professional success, to salary increases, to tenure, to promotion. Scientists, therefore, regard the terms and conditions of publication as matters of considerable importance. There is no question that ethical review as a gate to publication is an effective means of maintaining ethical standards in research. It is also the most feasible method. We urge editors to accept the recommendations of the Council of Biology Editors and evaluate manuscripts on ethical grounds as routinely as they are now evaluated on substantive and stylistic grounds.

Table 1

Editors' Responses to Questions on Ethical Policies

Editors' Responses

<i>Question</i>	<i>Yes N(%)</i>	<i>No N(%)</i>	<i>Other N(%)</i>	<i>No Answer N(%)</i>
1. Review for ethics?	27(36.00)	44(58.67)	2 (2.67)	2(2.67)
2. Require IRB approval?	16(21.33)	55(73.33)	4 (5.33)	----
3. Refuse publication?	58(77.33)	7(9.33)	6 (8.00)	4(5.33)
4. Publish unethical research?	7 (9.33)	54(72.00)	9(12.00)	5(6.67)
5. Any policy changes?	5 (6.67)	67(89.33)	----	3(4.00)

Table 2

Survey of 1,575 Articles Reporting Original Research Using Human Subjects

Editors		Authors						Total
		Mention Informed Consent		Do Not Mention Informed Consent		Mention Using "Volunteers"		
		N	%	N	%	N	%	
Question # 1:	Yes	199	29.66	405	60.36	67	9.98	671
Review for	No	155	18.86	578	70.31	89	10.83	822
Ethics?	Other	35	42.68	43	52.44	4	4.88	82
Question #2:	Yes	74	38.54	100	52.08	18	9.38	192
Require IRB	No	301	23.08	866	66.41	137	10.51	1304
Approval?	Other	17	21.52	58	73.42	4	5.06	79
Instructions	Yes	146	35.18	245	59.04	24	5.78	415
to Contributors:	No	164	18.16	633	70.10	106	11.74	903
Informed Consent?	Other	82	31.91	146	56.81	29	11.28	257

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5. The survey was carried out by one graduate student in philosophy and ethics and one graduate student in psychology. The students worked independently; any disagreement between their tabulations was subsequently resolved by consensus, including assistance from the first author. The authors are indebted to Jacqueline Miller and Kern Schroder for their assistance.
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