A Question of Institutional Review

A resident physician who has described use of a new technology in several cases requests that the manuscript be edited before submission to her specialty journal. When the editor asks whether institutional review board (IRB) approval for analysis of the cases has been obtained, the resident states that this is not necessary for case reports. The editor ascertains from the text that patient information was obtained from the facility's registry. Should the editor advise her that she may need to provide a letter of approval or evidence of exemption from the IRB? What recourse does the editor have if the resident declines but wants the paper edited and submitted anyway?

Solutions

There are two issues here: whether the editor is correct, and what to do if an author violates ethical principles. First, is the editor correct? In my experience, the judgment of editors is constantly challenged because authors consider themselves, by definition, "authoritative" persons—although their authority may not extend to grammar! Regardless of their attitudes, however, authors have the right to know the basis of editorial recommendations, grammatical or otherwise.

In this case, the editor is probably mistaken ("probably" because for various reasons IRBs do not all have the same procedures). The law that governs IRB procedures (Code of Federal Regulations, Title 45, Part 46) states that IRB review is required for "research", which is defined as follows: "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to *generalizable* knowledge" (emphasis added) (Code of Federal Regulations, Title 45, Part 46.102[d]; (*ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.102*). Case reports are anecdotal and thus do not meet the definition of research.

Although an editor cannot necessarily be expected to know IRB regulations, he or she should know the facts. Thus, if a challenge arises, the editor will have credibility, and the author will most likely be grateful. The authoritative sources for IRB information are the local IRB (most university IRBs have a Web site) and the federal Office for Human Research Protections (OHRP) (*ohrp.osophs.dhhs.gov*).

If IRB review had been required but the author balked, the editor could choose to be a whistleblower. Once again, for his or her own good, the editor should be certain to have all the facts. If the author attempted to publish unreviewed human-subjects research, the journal may very well detect the problem and refuse to publish the paper.

Last but not least:

- IRB review would always be required way before the time a paper is written—*before* any data are collected or any human-subjects research activities begin.
- Ironically, when the Health Insurance Portability and Accountability Act of 1996 takes effect (14 April 2003), hospitals, not IRBs, may require a review of proposed case reports, and university hospitals *may* relegate this review to IRBs.

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Federal guidelines and institutional policies are in place to protect the rights and confidentiality of the patient. As representatives of the "institution", both the IRB and the medical editor have an obligation to ensure that federal and institutional policies are followed. The editor should advise the resident that institutional policy requires either IRB approval or exemption for such a study to be done and reported. In general, case reports will be granted exemption from the full IRB approval process, assuming that the appropriate "Request for IRB Exemption" is submitted and approved. Larger studies in which institutional databanks are used to recruit or study patients usually require formal IRB approval. The resident should be educated as to the need to go through

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this process. In addition, the resident should be required to take the NIH online CME course to learn all the reasons the IRB is so careful in supervising institutional research (*cme.nci.nih.gov/*). The medical editor has several options if the resident declines.

First, the editor should contact any "supervising author" on the manuscript, who should be aware of the need for compliance. If there is none, the editor has the option of contacting the residency director, department chief, or facility chief of staff to encourage compliance.

A second question raised by the scenario relates to the resident's desire to report use of a "new technology". I believe the medical editor should try to determine whether this new technology might have required IRB approval before use. In some cases, the new technology could be an experimental device, product, or medication requiring such IRB approval.

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The editor should inform the resident why IRB approval for research is necessary. The resident needs to know that the new Health Insurance Portability and Accountability Act will almost certainly make getting IRB approval a requirement for all studies, even case reports, and that most major journals will not publish research studies that have not first been approved by the IRB. The editor may draw educational assistance from the IRB coordinator at the institution; many of them are now required by law to educate everyone who might do research, and the subject of their talks is the ethical conduct of research.

If the resident insists on continuing with her manuscript, the editor might suggest that the resident call the journal to which she wishes to send the manuscript and ask the managing editor whether her manuscript would be considered. If the answer is yes, the editor would then agree to edit the manuscript. If the answer is no, as it probably will be, such a call will save time for all involved—resident, editor, reviewers, journal editors, and readers.

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New Question:

A Question of Font

A consultant retained to work on a health-services project that includes submitting articles for publication is asked to send a completed manuscript to a journal for publication. The journal has just launched its new Web site, and the online instructions for authors ask for submission of all articles via the Web site. The consultant proceeds to cut and paste segments of the text to the sequential templates provided but finds that several special characters—for example, frequently used mathematical symbols "≥" and "≅" and Greek symbols "α", "β", and others—are not accurately reflected by the fonts available at the site. The solution of spelling these out as, for example, "greater than or equal to" and "approximately equal to" in the statistical notation or "alpha-adrenergic" and "beta-adrenergic" does not fit within the allowed word count. What recourse can the publisher or Webmaster recommend to the consultant in these instances?

The situations described as new questions in this column are not necessarily based on actual situations, and the ones that are may have been modified to focus the question. Send your responses to the new question to Della Mundy, Department of Medical Editing, Kaiser Foundation Research Institute, 1800 Harrison Street, 16th Floor, Oakland CA 94712-3429. Telephone 510-625-2373; fax 510-625-5231; e-mail *della.mundy@kp.org*.