Institutional Review Boards and the Use of Human Subjects

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Journal of Athletic Training
Charlottesville, Virginia

Panelists:
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Journal of Laboratory and Clinical Medicine
Minneapolis, Minnesota

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Journal of the American Medical Association
Chicago, Illinois

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> The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.
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> —Declaration of Helsinki, World Medical Association, 1975 revision

Canada's three government-funded agencies (similar to the US National Institutes of Health) established a Tri-Council Working Group in 1994 to decide how to deal with ethical issues in scientific research. Robert Kilgour, chair of the research ethics board (REB) of Phoenix International Life Sciences, explained that a "Code of Ethical Conduct for Research Involving Humans" was developed by the group in 1997 and endorsed by the three agencies. The code requires researchers and institutions to prove that they have applied its standards to their research, otherwise funding will be denied. It requires that all research involving living human subjects be reviewed by REBs, which have the authority to approve, reject, or modify any research proposal or to terminate any research. Potential subjects must be informed of the benefits and possible dangers of the research and be informed that they have a right to privacy and confidentiality. Prospective subjects must give free and informed consent, and consent must be maintained throughout the research. Human genetic research and research with human gametes, embryos, fetuses, and tissue must be approved by REBs, and privacy, confidentiality, and consent must be guaranteed.

Dale Hammerschmidt, director of education in research ethics and compliance at the University of Minnesota, described three cases of ethical problems or research misconduct that were detected in peer review. In the first, a paper described a novel therapy used in a comatose patient who had a life-threatening illness. The paper mentioned no institutional review board (IRB) approval. The patient was comatose and so could not give informed consent. The patient had not received standard care. Reviewer concerns revolved around why standard care was not used before the experimental therapy, why IRB approval was not obtained, and the fact that the comatose patient could not give consent; it was recommended that the manuscript be rejected.

The second case involved massive publications by one author. Referees questioned how one author, Dr Salim, could have completed so much research in such a short period and written so many manuscripts alone (49 in 3 years). Investigation of the entire body of Salim's work (not just a single paper) revealed discrepancies in time sequence and logical errors that Salim could not adequately explain. The manuscript currently under scrutiny by a journal was rejected, and the journal withdrew its aegis from the author's previous contributions.

The third case involved a report of research with a surgical technique. Reviewers were not familiar with the technique and asked the author to provide references to its safety. Investigation revealed that the technique had never been reported in a peer-reviewed journal, and the author could not document that the surgeon had specific IRB approval. The manuscript was rejected.

Peer review, Hammerschmidt said, is hit-or-miss when it comes to detecting and remedying unethical scientific behavior or publication. It is more important for journals to set standards and expectations than to police them. However, when peer reviewers and editors do detect misconduct (despite themselves), they should act.

Carin Olson, an IRB member and editor, discussed ethics from the two perspectives. IRB members see research as it is proposed; editors see the outcome of research as it is performed. Principles of research ethics, Olson said, include autonomy, beneficence, and justice. Autonomy means respecting research subjects; subjects enter research voluntarily and with adequate information that leads to informed consent. Beneficence promotes the well-being of research subjects while protecting them from harm and is ensured by IRBs. Justice means that neither the burden nor the benefits of being a research subject should fall unevenly on particular classes. Editors, Olson said, should require conformity to the rules of autonomy, beneficence, and justice in publishing research findings in their journals; Kilgour and Hammerschmidt shared this sentiment.