Ethics, Empowerment, and Education: Stories from the Trenches (or: What’s an Editor to Do?)

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Presenters:
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Karen Potvin Klein
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Faith McLellan
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This panel of distinguished editors shared their accumulated wisdom and experiences from the research trenches in the real world.

To ensure that research involving human subjects is ethical, Faith McLellan emphasized the importance of submitting protocols to an institutional review board (IRB) before the study starts. Where there is no IRB, she suggested that a regional or national committee would be helpful, stating that the Declaration of Helsinki, available at www.wma.net/e/policy/b3.htm, is the bottom line for ethics. When research is conducted in third-world countries, McLellan continued, researchers who are not from that culture must be careful to avoid “ethical imperialism”. Informed-consent documents may be written, oral, or even presented via audiovisual equipment if the subjects are illiterate.

McLellan urged author’s editors to join the research team early, go to meetings, and read journal articles to educate themselves on these issues. “And now”, she urged, “go home and spread the word.”

Flo Witte examined the sticky question of authorship. Despite written policies at many institutions, at times senior staff may insist on authorship when it is not warranted. Early negotiation for authorship can avoid problems, and editors can help to ensure that authors do enough to qualify for authorship.

When an editor suspects plagiarism, Witte advised a tactful approach to the author. Educating authors can help, and she suggested that editors create their own opportunities by leading workshops and engaging in one-on-one discussions. Take every chance to teach, remind, and explain, concentrating on junior faculty, graduate students, and postdoctoral fellows, who may be more open to editorial help.

Noting that author’s editors have little clout, Witte counseled them to educate themselves formally or informally and to obtain certificates and other “proofs” of competence. Keeping up with pertinent publications and participating in professional organizations are also beneficial.

“Make yourself an authority”, she counseled. “Active collaboration can eventually make you an indispensable part of the author’s team.”

Susan Eastwood encouraged younger editors to get an advanced degree and become familiar with statistics to build credibility with authors. She emphasized McLellan’s advice that editors join the research team and suggested that they attend their authors’ meetings, such as grand rounds and research presentations.

Noting that the National Institutes of Health (NIH) requires institutions to teach the responsible conduct of research (RCR), she suggested that author’s editors can be a rich resource for RCR education in research institutions. She wryly observed that “avoiding problems beats having to solve them” and recommended that, before problems arise, editors establish written policies and have them approved by higher levels of the administration.

Karen Potvin Klein discussed IRB review of research protocols. She noted that although protocol writers have always focused on scientific rigor, issues surrounding the safety of human subjects, informed consent, and patient confidentiality have grown in importance. The 40 general clinical research centers (GCRCs) funded by NIH in individual US medical centers also need assistance in reviewing protocols and educating staff.

Observing that many institutions have difficulty in finding qualified volunteers for their IRBs and GCRC review boards, Klein encouraged medical writers and editors to get involved. They have the skills to review the documents, linguistic expertise, scientific knowledge, and familiarity with the institution and its culture. They can help to ensure that protocols comply with institutional policies and regulatory guidelines, and they can craft appropriate language for consent forms.

Recent media coverage about unplanned negative outcomes in a few clinical trials has meant that research protocols are under increasing scrutiny. Klein encouraged medical editors and writers to share their expertise with IRBs and GCRCs—two places where ethics and editing can meet.