



## Canadian Family Physician's new ethics guidelines

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Ethics issues have not arisen often at *Canadian Family Physician*, but there have been occasional instances of plagiarism or conflicts of interest. Until now these issues have been addressed in an ad hoc fashion. One incident of suspected plagiarism, however, prompted our Editorial Advisory Board to examine this subject in more detail, with a goal of defining our standards explicitly.

*Canadian Family Physician* has always subscribed to the principle that all research articles that use human subjects should have their protocols approved by a reputable ethics committee. This rule has been an absolute requirement for any submission we publish, and it will not change.

When scientific fraud or misconduct has occurred, however, we have not had a clear policy for addressing it. We believe that it is the responsibility of the editor to identify cases and take appropriate action. The United States Department of Health and Human Services' Office of Research Integrity, in their January 2000 publication, "Managing Allegations of Scientific Misconduct,"<sup>1</sup> quote a report from the Institute of Medicine in 1989: "Journal editors should develop policies to promote responsible authorship practices, including procedures for responding to allegations of misconduct in published research."<sup>2</sup> Having such a mechanism in place is important, and *Canadian Family Physician* is addressing its responsibility with this position paper.

### Principles of research ethics

The Nuremberg Declaration after the Second World War still forms the basis of ethical principles in research studies. In Canada, these are spelled out in detail by the Tri-Council Policy Statement issued by the three major funding bodies (Medical Research Council, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada), *Ethical Conduct for Research Involving Humans*.<sup>3</sup> It incorporates the following principles:

- respect for human dignity,
- respect for free and informed consent,
- respect for vulnerable persons,
- respect for privacy and confidentiality,
- respect for justice and inclusiveness,
- balancing harms and benefits,

- minimizing harm, and
- maximizing benefits.

### Ethics review boards

These principles are used by ethics review boards of universities and funding bodies to assess research protocols. Reviews are carried out before articles are submitted for publication. Journal editors do not have the resources or skills to investigate whether a study was carried out ethically. That responsibility falls to the academic institution or funding body with which the author is affiliated, if any. This is an important point, because the academic institution or funding body will be asked by the editor to investigate any alleged episode of scientific misconduct. These bodies need to have confidence in their ethics review procedures.

One potentially unique situation, more likely to occur in primary care, is for a researcher to be community based and not necessarily attached to an academic centre. If that researcher obtained research funding from a private source, he or she might not have gone through the usual ethics review procedure. Researchers in this situation should be aware of the requirement of most peer-reviewed journals to have ethics review before they publish and should ensure their protocols are reviewed by reputable ethics boards.

The amount of scrutiny each study undergoes should be proportional to the amount of risk involved. A study of a new, but potentially dangerous, treatment for a disease requires careful examination of all the potential harms and benefits and for patients to truly give informed consent. Other research might be described as "minimal risk," such as an anonymous survey, and it would require scrutiny mostly from confidentiality and privacy perspectives.

### Types of ethics problems in publishing

An important aspect of ethics is protection and fairness to authors and reviewers during the peer-review process. Authors need the assurance that their work will be assessed fairly by peers without biases toward their work. Reviewers need to feel uninhibited by an author's influence or academic rank to provide honest reviews. A journal should ensure that each group is protected.

Authorship itself has been the subject of considerable discussion and debate recently.<sup>4,5</sup> Guest authorship, ghost authorship, and unfairness in whose name

is included and in what order on the author list are all examples of unethical authorship practices.

Financially competing interests might occur in family medicine, although, given the meagre funding for this discipline in past years, the potential for serious financial compromise has probably been limited. With greater opportunities for large grants available from the new Canadian Institutes of Health Research, however, this might become more of an ethical problem. In addition, drug companies are now approaching community physicians (and bypassing academic centres) for drug trials with substantial funding, which opens the door to potential financial conflicts of interest.

### Scientific misconduct

Scientific misconduct is more serious and includes the following:

- deliberate falsification or fabrication of data;
- plagiarism or theft of intellectual property, where information is presented without proper citation;
- duplicate publication in which essentially the same article is submitted to more than one journal;
- publication of the “least publishable unit” or “salami science” where many papers are spun off one data set; and
- citation errors and inappropriate attribution—when the contents of a study are misrepresented.

It is important to understand that interpreting what is scientific misconduct is not necessarily black and white. Blatant fabrication or false manipulation of data is fairly clear-cut misconduct. But who is to decide whether a study is a “least publishable unit” or a genuine, new contribution to the literature? When does using another person’s idea become intellectual theft? These are much grayer areas and represent some of the dilemmas faced by editors. Editors must determine not only whether misconduct has occurred, but whether it is deliberate or just honest oversight, how it is to be investigated, and what the final judgment is to be. Editors must ultimately decide whether to publish in a situation often fraught with uncertainty.

The modest associations of fame and fortune that accompany family medicine research suggest that the degree of scientific misconduct has likely been relatively small. But pressure on academics to publish is rising, and this might lead to sloppy writing or outright cheating, and so *Canadian Family Physician*, along with other journals, needs to be sensitive and able to respond to these challenges.

### Handling scientific misconduct

According to the International Committee of Medical Journal Editors (ICMJE) in the Uniform Requirements

for Manuscripts Submitted to Biomedical Journals,<sup>6</sup> editors have a responsibility to pursue possible scientific misconduct in manuscripts submitted to or published in their journals and to publish retractions of any fraudulent papers published in their journals. Editors are not responsible, however, for conducting full investigations into matters. That responsibility lies with the institution where the work was conducted or by the funding agency. In the United States, the Office of Research Integrity sets standards and oversees this type of work.<sup>1</sup> In the United Kingdom, the Committee on Publishing Ethics (COPE) provides an informal venue for discussing cases, although it has no formal authority.<sup>7</sup> No such overseeing body exists in Canada.

Recently, the World Association of Medical Editors (WAME) ([www.wame.org](http://www.wame.org)) has suggested an on-line consultation service where editors could pose ethical dilemmas and receive comments from other editors. This would function much as COPE does in the United Kingdom. Note, however, that COPE and WAME offer only advice; an individual journal and its editor or editors are ultimately responsible for handling instances of scientific misconduct. Hence, the need for an established ethics policy for our journal.

A recent new development was a meeting of editors in Ottawa, Ont, in November 2001 hosted by the *Canadian Medical Association Journal*. It brought together editors of Canadian medical journals to decide whether there were enough publishing ethics concerns in this country to justify establishing a national body to address them in a more coherent manner. The consensus of the meeting was that we should form an association of medical editors to offer mutual support when handling scientific misconduct, to establish ethics standards for the Canadian context, and to educate researchers and authors on proper ethical practices. The Canadian Institutes of Health Research were well represented at the meeting and strongly supported this initiative. *Canadian Family Physician* took an active part in this meeting and intends to contribute to the new ethics initiative.

### Canadian Family Physician’s ethics policies

The Editorial Advisory Board of *Canadian Family Physician* therefore agrees on the following ethics policy. It is incorporated into our Instructions for Authors.

1. *Canadian Family Physician* requires that all research studies on human subjects are approved by a reputable ethics review board.
2. The peer-review process takes care to protect both authors and reviewers. Manuscripts are sent to reviewers with authors’ identities

- removed. Reviewers are not identified to authors. Although the literature on peer review does not show that reviews are better quality if they are blinded,<sup>8,9</sup> we believe that the benefits of blinding in a small research community, such as Canadian family medicine, outweigh the possible weaknesses of unblinded reviews. This is not a closed issue, however, and might be reviewed in the future with new evidence.
3. Issues of authorship are addressed in a new authorship statement<sup>10</sup> that asks each author to certify that he or she has made a substantial contribution to the paper, according to the most recent guidelines for authorship from the ICMJE, May 2000 ([www.icmje.org](http://www.icmje.org)). Authors are asked to specify their contributions and to indicate the order in which authors' names should appear.
  4. Financial conflicts of interest are addressed by asking each author whether he or she has any competing financial interests in the article when he or she signs the journal's copyright agreement. The journal also adopts the new guidelines for sponsorship from pharmaceutical companies. These guidelines insist that authors retain the right to access *all* data from a study and have the freedom to publish their findings without interference from funding bodies.<sup>11</sup>
  5. In cases of suspected scientific misconduct, the following procedure would be followed.
    - a) When a case of suspected scientific misconduct is identified, it will be given a special, confidential review in a timely manner.
    - b) The case would be reviewed by a Senior Editorial Advisory Group (SEAG), made up of the two scientific editors, the managing editor, and the chair of the journal's Editorial Advisory Board.
    - c) The SEAG will examine all the evidence available and then decide whether scientific misconduct has occurred. Its decision will be passed on to the journal's publisher for review. The publisher might wish to obtain a legal opinion and consult with the Executive Director of the College of Family Physicians of Canada, the journal's host association.
    - d) Once the publisher has completed the second review, the decision of the SEAG will be communicated to all authors of the article in question, requesting an explanation of the ethical issues raised. The authors would be asked to respond to these issues within 2 months.
    - e) If no acceptable response is received within 2 months, the authors would be informed that the article was rejected and that no further articles by them would be accepted until the matter was

satisfactorily resolved. At that point, a notification would be sent to the head of the department of the first author, with a copy to all the authors. The institution would be asked to investigate the case and report back to the journal within 3 months. If the author was not a member of an academic institution, the funding body for the research would be notified.

f) The SEAG would have to be satisfied with the explanation given by the authors or the institution regarding the alleged misconduct. If no satisfactory explanation was received, a published paper would be retracted. For unpublished papers, the journal would refuse to accept any further articles submitted by any of the authors.

g) In exceptional circumstances, *Canadian Family Physician* could request a qualified third party acceptable to both parties (*Canadian Family Physician* and the author) to review the decision-making process.

## Conclusion

Until now, *Canadian Family Physician* has dealt with ethics issues in an ad hoc manner. It is now time to address these issues in a more comprehensive and systematic way. The ethics policies described here make clear the responsibilities and rights for authors and editors to ensure that articles published in the journal are ethically sound. We look forward to participating in the new ethics initiative by Canadian medical editors. We hope these policies strengthen the integrity and reputation of *Canadian Family Physician* as the only peer-reviewed, indexed family medicine journal published in Canada. ♣

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