

JCO and the Public Trust

Daniel G. Haller, Editor-in-Chief, *University of Pennsylvania Cancer Center, Philadelphia, PA*

The *Journal of Clinical Oncology* (JCO) prides itself in publishing the highest quality research. Articles published in the *Journal* are highly cited, ranking JCO among the best peer-reviewed journals in oncology. The American Society of Clinical Oncology (ASCO) and the JCO editors take seriously the responsibility of ensuring that every published article contains trustworthy data that remain free from allegations of potential conflicts of interest in the publication process. The peer review process itself is structured to preclude editorial decisions based on potential conflicts of the reviewers and editors, but further steps are necessary to ensure the continued credibility of the *Journal* and the trust of the readership and the public.

Concerns About Conflicts of Interest

In addition to the readers, conflicts of interest can affect three participants in the publication of scientific articles: editors, reviewers, and authors. Since its inception, the JCO has had a strict conflict of interest policy that conforms to the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals," a set of standards developed by the International Committee of Medical Journal Editors (ICMJE).¹ The *Journal* has always practiced the principle of disclosure—the cornerstone of any conflict of interest policy. The Editor-in-Chief and the Associate Editors annually disclose all potential conflicts of interest relative to their journal activities; these disclosures are reviewed by ASCO leadership. When manuscripts are submitted for which an editor may have a potential conflict of interest, that editor is prevented from having any knowledge or contact with the peer review process and ultimate decision making for that manuscript. When such manuscripts are discussed on regularly scheduled conference calls, the editor is recused from the discourse. In addition, the *Journal's* electronic manuscript tracking system has been designed to prohibit assignment of a manuscript to an editor when any of the authors are from the editor's institution.

Similarly, when reviewers are solicited to review a manuscript, they are requested to decline if they recognize a potential conflict—whether personal, professional, or financial—that would prevent an objective assessment. Reviewers are required to electronically sign a statement for each review, disclosing any potential conflicts or attesting that no such conflicts exist. The editors consider these disclosures as they evaluate each review.

Authors, too, must disclose potential conflicts related to the design and conduct of the study and the evaluation of the data, and the results. Since November 2003, authors have also been required to disclose to the reviewers and editors the role each author played in the study and preparation of the manuscript; the *Journal* now publicly discloses this information at the end of each article. Readers have no

doubt also observed that the JCO publishes author disclosures at the end of every article and letter under the heading "Authors' Disclosure of Potential Conflicts of Interest."

Why "potential"? A conflict occurs when a secondary interest, such as money, the quest for fame, or publication priority, might influence a primary interest of research such as patient safety or the integrity of research data. Because everyone has multiple interests, it is not always clear—especially to readers but even to researchers themselves—when a secondary interest actually may compromise decision making. The editors realize that readers may bring varying perspectives to their evaluation of whether a secondary interest may have affected the validity of a research finding. Making these judgments is not easy, and the editors want to provide enough information for readers to decide for themselves and to make the publication process as transparent and complete as possible.

ASCO's Policy Clarified

ASCO's policy on conflicts of interest was enacted in light of "heightened awareness among both physicians and patients of the important role played by clinical trials in the comprehensive treatment of many cancer patients."² Building on the existing stringent policy of disclosure, the 2003 document required disclosure of "virtually all financial interests"² for particular activities, such as stock ownership and leadership positions in a research-related company. In addition, the policy specifies "circumstances in which disclosure alone will be insufficient,"² such as prohibition of finders' fees and bonuses for accruals to clinical trials. Most significant to JCO authors is the prohibition by principal investigators of clinical trials to engage in a number of trial-related activities.^{3,4} Among other restrictions, principal investigators should not: (1) hold stock or equity in the trial sponsor's company; (2) receive royalties or licensing fees from the product or novel treatment under investigation; (3) hold patents for the product or novel treatment under investigation; (4) hold position as an officer, board of directors member, or employee of the trial sponsor; (5) engage in travel paid by the trial sponsor to attend educational or scientific meetings; (6) receive research-related payments from the trial sponsor substantially exceeding actual research costs; (7) receive honoraria or gifts from the trial sponsor.

These restrictions do not preclude researchers from receiving support from sponsors to present their findings at widely attended meetings or serving on scientific boards as unpaid advisors. ASCO also recognizes the need for flexibility. Narrowly interpreted, these restrictions would prevent translational researchers from developing their laboratory breakthroughs into clinical innovations, or from publishing them in the JCO—outcomes that are not ASCO's intention. Similarly, many studies, including those funded by the National

Institutes of Health, have extensive oversight with data safety and monitoring committees that minimize the effects of conflicts of interest. Consequently, the revised policy incorporates exceptions to these restrictions when proper oversight is instituted and public.

Readers are advised to peruse the revised policy published in this issue of the *Journal*.^{3,4} In response to questions regarding implementation of the restrictions portion of the policy, ASCO has issued a clarified policy meant to define more specifically and narrowly to whom the restrictions apply.

Schedule of Implementation

The ASCO policy took effect 12 months after its initial publication April 29, 2003, on www.jco.org, and applies prospectively to clinical trials that *began accrual* subsequent to April 29, 2004.

As the first step in implementation, in 2004 the editors instituted a new form (see Information for Contributors) that requires disclosure of dollar ranges for each of the categories of potential conflict. Each author must provide the disclosure at the time of submission and must specify whether he or she served as the principal investigator of the study. Virtually all disclosed information is now published with accepted articles, except for dollar amounts associated with employment positions with the trial company: ASCO and the editors believe that a potential conflict arises from the employment itself, not from the salary level. In addition, upon publication of the January 20, 2006, issue, readers will be able to review the disclosure statements of the editors online at www.jco.org.

Phase two of implementation, to begin this year, will be managing the restrictions portion of the policy as it relates to the principal investigators of clinical trials. The editors encourage authors to err on the side of submitting, rather than withholding, manuscripts that authors may interpret as falling in a “gray zone” of restrictions under the policy, in order to allow the linchpins of disclosure and the peer review process to be most effective. Anticipating the need for such procedures to be infrequent, the editors will utilize the ASCO Ethics

Committee’s processes—to be announced in 2006—to assess and decide on requests for exceptions.

CONCLUSION

It is essential for the research community, including professional societies and journal editors, to maintain the highest levels of ethical behavior to ensure the safety of patients. In conjunction with the publication of the conflicts of interest policy, ASCO issued a policy statement on oversight of clinical research.⁵ As affirmed in that document, “Public trust in the integrity of research is critical not only for funding and participation in clinical trials, but also for confidence in the treatments that result from the trials.”⁵ The *Journal*, and public confidence, will be strengthened by the combined effects of more rigorous conduct of clinical trials, restrictions on remunerations from the trial sponsors to the principal investigators of those trials, as well as more detailed disclosure of potential conflicts of interest. Key to the disclosure process is that conflicts of interest of many types may arise in the conduct of clinical research, and it is the duty of ASCO and the *JCO* to ensure that sufficient information is made available to readers and the public for their ultimate judgment.

REFERENCES

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Author’s Disclosures of Potential Conflicts of Interest

The author indicated no potential conflicts of interest.

Author Contributions

Manuscript writing: Daniel G. Haller