



CONFLICTS OF INTEREST

The policies and guidelines provided here are in place to protect the quality and integrity of forms of scholarly practice and research, as well as the reputations of the publications produced by SAE International.

SAE International's full policy and ethical guidelines for authors are available [here](#).

Conflict of interest has been defined as a set of conditions in which professional judgment concerning a primary interest (such as validity of research) can be influenced by a secondary interest (such as financial gain).

If a guest editor, associate editor, or reviewer believes that his/her relationship to an author, if known, or the subject matter of an article, may constitute a conflict of interest for any reason, this must be disclosed to the journal editor.

AUTHORS

Authors must include any necessary disclaimers or declare conflict(s) of interest at the time of submission of a manuscript for possible publication in SAE International journals.

REVIEWERS

Reviewers should preview a manuscript that they have been asked to review to see if they have conflicts of interest that could complicate their review. Reviewers must disclose to editors any conflicts of interest that could bias their opinions of the manuscript and should recuse themselves from reviewing specific manuscripts if the potential for bias exists. Reviewers must not use knowledge of the work they are reviewing before its publication to further their own interests.

EDITORS, ASSOCIATE EDITORS, AND JOURNAL STAFF

Editors and Associate Editors who make final decisions about manuscripts should recuse themselves from editorial decisions if they have conflicts of interest or relationships that pose potential conflicts related to articles under consideration. Other editorial staff members who participate in editorial decisions must provide editors with a current description of their financial interests or other conflicts (as they might relate to editorial judgments) and recuse themselves from any decisions in which a conflict of interest exists. Editors should publish regular disclosure statements about potential conflicts of interest related to the commitments of journal staff. Guest editors should follow these same procedures.

Conflict of interest (COI) exists when there is a divergence between an individual's private interests (competing interests) and his or her responsibilities to scientific and publishing activities such that a reasonable observer might wonder if the individual's behavior or judgment was motivated by considerations of his or her competing interests. COI in medical publishing affects everyone with a stake in research integrity including journals, research/academic institutions, funding agencies, the popular media, and the public. Journals are interested in COI as it relates to a specific manuscript.

Everyone has COIs of some sort. Having a competing interest does not, in itself, imply wrongdoing. However, it constitutes a problem when competing interests could unduly influence (or be reasonably seen to do so) one's responsibilities in the publication process. If COI is not managed effectively, it can cause authors, reviewers, and editors to make decisions that, consciously or unconsciously, tend to serve their competing interests at the expense of their responsibilities in the publication process, thereby distorting the scientific enterprise. This consequence of COI is especially dangerous when it is not immediately apparent to others. In addition, the appearance of COI, even where none actually exists, can also erode trust in a journal by damaging its reputation and credibility.

COI policies differ among journals and are evolving over time. Every peer-reviewed medical journal¹ (herein "Journal") should have its own COI policies for authors, reviewers, and editors. Journals should make these policies readily accessible to everyone involved in the publication process by publishing them with instructions for authors.

The Editorial COI Policy that addresses editor COI should be published as well. This statement summarizes the main elements of COI policies with examples and options for disclosure and management.

Definition and Scope

Journals should publish their own definition of COI. In the context of medical publishing, COI exists when a participant in the publication process (author, peer reviewer, or editor) has a competing interest that could unduly influence (or be reasonably seen to do so) his or her responsibilities in the publication process. Among those responsibilities are academic honesty, unbiased conduct and reporting of research, and integrity of decisions or judgments. The publication process includes the submission of manuscripts, peer review, editorial decisions, and communication between authors, reviewers and editors.

Types of Competing Interests

Many kinds of competing interests are possible. Journals often have policies for managing financial COI, mostly based on the untested assumption that financial ties have an especially powerful influence over publication decisions and may not be apparent unless they are made explicit. However, other competing interests can be just as damaging, and just as hidden to most participants, and so must also be managed. The following are examples of competing interests; they do not include all possibilities and they may coexist.

Financial ties: This conflict is present when a participant in the publication process has received or expects to receive money (or other financial benefits such as patents or stocks), gifts, or services that may influence work related to a specific publication. Commercial sources of funding, by companies that sell drugs and medical devices, are generally seen as the most concerning, perhaps because of many well-publicized examples of bias related to ties to industry. Examples of financial ties to industry include payment for research, ownership of stock and stock options, as well as honoraria for advice or public speaking, consultation, service on advisory boards or medical education companies, and receipt of patents or patents pending. Also included are having a research or clinical position that is funded by companies that sell drugs or devices. Competing interests can be associated with other sources of research funding including government agencies, charities (not-for-profit organizations), and professional and civic organizations, which also have agendas that may be congruent or at odds with research findings. Clinicians have a financial competing interest if they are paid for clinical services related to their research—for example, if they write, review, or edit an article about the comparative advantage of a procedure that they themselves provide for income. Financial competing interests may exist not just on the basis of past activities but also on the expectation of future rewards, such as a pending grant or patent application. “Insider trading,” which is the use for one’s financial gain of information obtained through participation in research, review or editing before it is available to the general public, is a special kind of financial COI that has both legal and ethical implications.

Academic commitments: Participants in the publications process may have strong beliefs (“intellectual passion”) that commit them to a particular explanation, method, or idea. They may, as a result, be biased in conducting research that tests the commitment or in reviewing the work of others that is in favor or at odds with their beliefs. For example, if research challenging conventional wisdom is reviewed by someone who has made his or her reputation by establishing the existing paradigm, that person might judge the new research results harshly. Investigators in the same field might make extra-efforts to find fault with manuscripts from competing teams, to delay publication or relegate the work to a lesser journal. While such commitments are not generally part of author’s disclosures, editors should be aware of them and their potential influence on author(s), reviewer(s), and themselves.

Personal relationships: Personal relationships with family, friends, enemies, competitors, or colleagues can pose COIs. For example, a reviewer may have difficulty providing an unbiased review of articles by investigators who have been working colleagues. Similarly, he or she may find it difficult to be unbiased when reviewing the work of competitors. Bonds to family members may be strong enough that their competing interests should be treated as if they are also present for those directly involved with a manuscript.

Political or religious beliefs: Strong commitment to a particular political view (e.g., political position, agenda, or party) or having a strong religious conviction may pose a COI for a given publication if those political or religious issues are affirmed or challenged in the publication.

Institutional affiliations: A COI exists when a participant in the publication process is directly affiliated with an institution that on the face of it may have a position or an interest in a publication. An obvious concern is being affiliated with or employed by a company that manufactures the drug or device (or a competing one) described in the publication. However, apparently neutral institutions such as universities, hospitals, and research institutes (alone or in partnership with industry) may also have an interest (or the appearance of one) in the results of research. For example, investigators may have a COI when conducting research from a laboratory funded by private donors who

could have (or appear to have) an interest in the results of the study, on a device for which the participant's institution holds the patent, when the institution is the legal sponsor of the drug or device trial, or if the institution is in litigation in an area related to the study. Professional or civic organizations may also have competing interests because of their special interests or advocacy positions.

Declaring and Managing COIs

COIs are ubiquitous and cannot be eliminated altogether. However, they can be managed constructively so that they make the least possible intrusion on journal content and credibility.

Journals' policies for disclosure and management of COI must take the following into consideration: What COI must be declared, how, to whom and when? Journals need to be as specific as possible about their definition of COI for authors and reviewers, including the kinds of competing interests they wish to have declared by those individuals, with the understanding that any operational definition will be imperfect. They should provide clear instructions about how to make declarations. It should also be clear that a journal may ask additional questions or seek clarification about declarations. For example, the journal may ask for details about future monetary gains or ask an author who works in a laboratory funded by a particular organization for written details about how their independence and research integrity was maintained.

All declarations about COI should be requested in writing as a condition of reviewing a manuscript and asked in such a way that authors will have a high likelihood of reporting their COIs related to the manuscript.

No generally accepted standard, nor evidence-based consensus, exists for precisely defining the degree of financial COI or the timeframe that creates a substantial risk of bias or damage to the journal's reputation. Judgments may be affected by many factors including, in the case of financial COI, the amount of money, goods, or services exchanged, how recently they were received and whether they are expected in the future, as well as the services provided in return. To guide authors in this decision, journals should publish their own standards for financial COI, including its standards on expiry on COI (e.g., only declare COI within last five years), as precisely as possible.

Managing COI depends on disclosure because it is not possible to routinely monitor or investigate whether competing interests are present. Disclosure is about the facts that might bear on COI; assertions of integrity are not, in themselves, helpful.

The consequences for failing to declare COI. The journal should state the steps editors will take if competing interests surface from other sources after a manuscript is submitted or published. For example, the journal may investigate allegations of COI and action may be taken if found to be true. Such investigations should be completed as quickly as reasonably possible. If a manuscript has been published and COI surfaces later, the journal may publish the results of the investigation as a correction to the article and ask the author to explain, in a published letter, why the COI was not revealed earlier.

Which COIs will result in a manuscript not being considered further? Journals must be transparent about COI situations that, if present, will result in a manuscript not being considered further. Some journals have made it explicit that they will exclude authors from writing narrative (not systematic) reviews of topics in which they have a competing financial interest, on the grounds that it is more difficult for readers to detect bias in reviews than reports of original research, where methods are made more explicit. Some journals may apply internal editorial rules about which COI situations are not acceptable but these may not be explicit to those involved in the publication process; a journal COI policy needs to articulate the journal's position.

How COI will be dealt with by the journal? Journals should publish all relevant COI disclosures with the publication. Other additional management strategies include for example:

- Not considering a manuscript further
- Exclusion of those with COI from the process (e.g., reviewer or editor)
- Abstaining from decisions where COI might arise (e.g., editors)
- Investigation by impartial observers

Some research institutions provide information about their employees' COI on their Web sites. Journals should routinely ask authors to disclose such e-links as part of their COI disclosure.

Journals have a responsibility to raise awareness and educate the research community about COI. One option to increase understanding of the concept is to ask investigators and reviewers "if my competing interest becomes known

to others later, would I feel defensive or would others in the publication process, readers or the public think I was hiding my other interests or could they feel I misled or deceived them?"

Responsibilities of Participants

Authors: All authors should be asked to report their financial COI related to the research and written presentation of their work and any other relevant competing interests. Journals should publish all COI (or their absence) reported by authors that are relevant to the manuscript being considered. In addition to financial COI, policies for authors should be extended to other types of competing interests that might affect (or be seen to affect) the conduct or reporting of the work. Journals should disclose all COIs that they themselves thought were important during the review process. Declarations should require authors to explicitly state funding sources and whether the organization that funded the research participated in the collection and analyses of data and interpretation and reporting of results.

Reviewers: Reviewers should be asked if they have a COI with the content or authors of a manuscript. If they do, they should be removed from the review process. In general, it is best to avoid reviewers from the same institution as the authors, unless the institution is so large that authors and reviewers are not working colleagues.

Editors: Editors should not make any editorial decisions or be involved in the editorial process if they have or a close family member has a COI (financial or otherwise) in a particular manuscript submitted to their journal. For example, if editors have political/religious COI or personal COI with respect to the authors or their work, the editors should remove themselves from the decision-making process. An editor may also be in a COI if a manuscript is submitted from their own academic department or from their institution (if it is small); in such situations, they should have explicit policies, made in advance, for how to manage it. When editors submit their own work to their journal, a colleague in the editorial office should manage the manuscript and the editor/author should recuse himself or herself from discussion and decisions about it.