

Publication Ethics Policies for Medical Journals
Prepared by the WAME Publication Ethics Committee

The purpose of a policy on ethical principles

Medical journals aspire to select, through peer review, the highest quality science. To achieve this, the entire peer review and publication process must be thorough, objective, and fair. Almost every aspect of this process involves important ethical principles and decisions, which are seldom explicitly stated and even less often shared with the readership. Journals' reputations depend on the trust of readers, authors, researchers, reviewers, editors, patients, research subjects, funding agencies, and administrators of public health policy. This trust is enhanced by describing as explicitly as possible the journal's policies to ensure the ethical treatment of all participants in the publication process.

A comprehensive policy on publication ethics is summarized in this article, which addresses all the major areas of ethics we believe contemporary science journals should consider. Our aim is to encourage editors of journals to use these to develop such policies for their journals and make them accessible to their constituents by publishing them in print or on the web. The document makes recommendations on what we consider to be the best solutions to address these ethical problems, but we expect individual journals to customize the policies to best fit their own situations.

However, we believe that every journal should have an explicit policy on each of these issues, and that these policies should be published in each journal so they are accessible to readers, authors, and reviewers.

Study Design and Ethics

Good research should be well justified, well planned, and appropriately designed, so that it can properly address the research question. Statistical issues, including power calculations, should be considered early in study design, to avoid futile studies that produce subject risk without enrollment sufficient to answer the research question. Outcomes should be specified at the start of the study. Research should be conducted to high standards of quality control and data analysis. Data and records must be retained and produced for review upon request. Fabrication, falsification, concealment, deceptive reporting, or misrepresentation of data constitute scientific misconduct.

Documented review and approval from a formally constituted review board (Institutional Review Board or Ethics committee) should be required for all studies involving people, medical records, and human tissues. For those investigators who do not have access to formal ethics review committees, the principles outlined in the Declaration of Helsinki should be followed. If the study is judged exempt from review, a statement from the committee should be required. Informed consent by participants should always be sought. If not possible, an institutional review board must decide if this is ethically acceptable. Journals should have explicit policies as to

whether these review board approvals must be documented by the authors, or simply attested to in their cover letter, and how they should be described in the manuscript itself. Animal experiments should require full compliance with local, national, ethical, and regulatory principles, and local licensing arrangements.

Journal recommendations for preferred presentation and analysis of data should be described in the Information for Contributors or Authors. Wherever possible, recommendations should be based on evidence about methods of data presentation that are readable and most likely to be interpreted correctly by readers. Editors should keep themselves informed of this research and adapt their recommendations as it evolves.

Authorship

Journals should publish guidance about what constitutes authorship. While there is no universally agreed definition of authorship, contributors should be made aware of the guidelines developed by the International Committee of Medical Journal Editors (available at <http://www.icmje.org/#author>).

Authorship implies a significant intellectual contribution to the work, some role in writing the manuscript and reviewing the final draft of the manuscript, but authorship roles can vary. Who will be an author, and in what sequence, should be determined by the participants early in the research process, to avoid disputes and misunderstandings which can delay or prevent publication of a paper.

For all manuscripts, the corresponding author should be required to provide information on the specific contributions each author has made to the article. (Alternatively, since authors may differ on the nature and magnitude of contributions, each author may be asked to describe their own.) All authors are responsible for the quality, accuracy, and ethics of the work, but one author must be identified who will reply if questions arise or more information is needed, and who will take responsibility for the work as a whole. This description of author contributions should be printed with the article. The authors are responsible for creating all components of the manuscript. If writers are provided by the sponsoring or funding institution or corporation to draft or revise the article, the name of the writer and their sponsoring organization must be provided. Their names and contributions will be provided with the acknowledgments. Journals should discourage "honorary" authorship (when authorship is granted as a favor to someone powerful or prestigious who would not have qualified for it otherwise) and should also try to ensure that all those who qualify as authors are listed.

All authors must take responsibility in writing for the accuracy of the manuscript, and one author must be the guarantor and take responsibility for the work as a whole. A growing trend among journals is to also require that for reports containing original data, at least one author (eg, the principal investigator) should indicate that she or he had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. This helps assure that authors, and not funding sources, have final say over the analysis and reporting

of their results.

Peer Review

Peer review is fundamental to the scientific publication process and the dissemination of sound science. Peer reviewers are experts chosen by editors to provide written assessment of the strengths and weaknesses of written research, with the aim of improving the reporting of research and identifying the most appropriate and highest quality material for the journal.

Regular reviewers selected for the journal should be required to meet minimum standards (as determined and promulgated by each journal) regarding their background in original research, publication of articles, formal training, and previous critical appraisal of manuscripts.

Peer reviewers should be experts in the scientific topic addressed in the articles they review, and should be selected for their objectivity and scientific knowledge. Individuals who do not have such expertise should not be reviewers, and there is no role for review of articles by individuals who have a major competing interest in the subject of the article (e.g. those working for a company whose product was tested, its competitors, those with special political or ideological agendas, etc.)

Reviews will be expected to be professional, honest, courteous, prompt, and constructive. The desired major elements of a high-quality review should be as follows:

- The reviewer should have identified and commented on major strengths and weaknesses of study design and methodology
- The reviewer should comment accurately and constructively upon the quality of the author's interpretation of the data, including acknowledgment of its limitations.
- The reviewer should comment on major strengths and weaknesses of the manuscript as a written communication, independent of the design, methodology, results, and interpretation of the study.
- The reviewer should comment on any ethical concerns raised by the study, or any possible evidence of low standards of scientific conduct.
- The reviewer should provide the author with useful suggestions for improvement of the manuscript.
- The reviewer's comments to the author should be constructive and professional
- The review should provide the editor the proper context and perspective to make a decision on acceptance (and/or revision) of the manuscript. (Some journals may wish a recommendation on whether the article should be published; others will not, as such decisions are usually made on priorities different than the reviewer's).
- All reviewers should be informed of the journal's expectations and editors should make an effort to educate them and suggest educational materials (such as articles on how to peer review):

The editors should routinely assess all reviews for quality; they may also edit reviews before sending them to authors, or simply not send them if they feel they are not constructive or appropriate. Ratings of review quality and other performance characteristics of reviewers should be periodically assessed to assure optimal journal performance, and must contribute to decisions on reappointment or ongoing review requests (for journals that do not formally appoint reviewers). Individual performance data must be kept confidential. Performance measures such as review completion times should be used to assess changes in process that might improve journal performance.

The type of review process should be stated, such as the number of reviewers, blinded as to author or institution or not, authors blinded as to reviewer identity or not, etc. Any policy on suggesting reviewers or on requests to not use certain reviewers should be described.

The submitted manuscript is a privileged communication; reviewers must treat it as confidential. It should not be retained or copied. Also, reviewers must not share the manuscript with any colleagues without the explicit permission of the editor. Reviewers and editors must not make any personal or professional use of the data, arguments, or interpretations (other than those directly involved in its peer review) prior to publication unless they have the authors' specific permission or are writing an editorial or commentary to accompany the article. If reviewers suspect misconduct, they should notify the editor in confidence, and should not share their concerns with other parties unless officially notified by the journal that they may do so.

High-quality review is important, but equally important is that readers be able to readily determine which contents of the journal are peer reviewed. The journal should describe which types of articles are peer reviewed, and by whom (ie, only by editorial board members, by outside expert reviewers, or both). Editors should strongly consider having a statistician review reports of original research that are being considered for publication, if this feasible, since studies have shown that typical nonstatistician reviewers do not identify many major errors in research. Journals should publish annual audits of acceptance rates, publication intervals, percentage of submissions sent out for external peer review, and other performance data.

Review materials and original submitted manuscripts may sometimes be useful for educational purposes, for review by other parties in the peer review process (other than the decision editor or other reviewers of the same manuscript) or in educational products. No reviews or manuscripts should be so used without the express written permission of the reviewer or authors, respectively. (One procedure may be to have a blanket permission for autonomous internal quality assurance use included in the submission requirements for the manuscript, and the reviewer's assignment agreement).

Editorial Decisions

Decisions about a manuscript should be based only on its importance, originality, clarity, and relevance to the journal's scope and content. Studies with negative results despite adequate

power, or those challenging previously published work, should receive equal consideration. There should be an explicit written policy on the procedure that will be followed if an author appeals a decision.

If a published paper is subsequently found to have errors or major flaws, the Editor should take responsibility for promptly correcting the written record in the journal. The specific content of the correction may address whether the errors originated with the author or the journal. The correction should be listed in the table of contents to ensure that it is linked to the article to which it pertains in public databases such as PubMed.

Ratings of review quality and other performance characteristics of editors should be periodically assessed to assure optimal journal performance, and must contribute to decisions on reappointment. Individual performance data must be confidential. These performance measures should also be used to assess changes in process that might improve journal performance. The handling of manuscripts that may represent a conflict of interest for editors is described under the section on conflict of interest.

The process by which candidates are nominated to the Editorial Board, and the qualities sought in candidates, should be explicitly described.

Originality, Prior Publication, and Media Relations

Journals should state their policies on what type of content they accept for publication. Journals should generally seek original work that has not been previously published. Web and other electronic publication should be considered the same as print publication for this purpose. Redundant publication occurs when multiple papers, without full cross reference in the text, share the same data, or results. Republication of a paper in another language, or simultaneously in multiple journals with different audiences, may be acceptable, provided that there is full and prominent disclosure of its original source at the time of submission of the manuscript. At the time of submission, authors should disclose details of related papers they have authored, even if in a different language, similar papers in press, and any closely related papers previously published or currently under review at another journal.

Because medical research findings are of increasing interest to the lay media, journalists attend scientific meetings at which preliminary research findings are presented, which can lead to their premature publication in the mass media. Publication of details not included in the abstract or meeting presentation is not advised until the article has appeared in a peer-reviewed journal, as this means that enough detailed evidence has been provided to satisfy peer reviewers and editors. Where this is not possible, authors should help journalists to produce accurate reports, but refrain from supplying additional data, if they wish their material to be of sufficient original interest to warrant publication in peer-reviewed journals. Authors should be discouraged from holding press conferences to publicize their abstract results, as these results are preliminary and generally the complete report has not yet undergone peer review. Journals should address these concerns in their formal policies on originality of submitted materials.

Previous publication of an abstract during the proceedings of meetings (in print or electronically) does not preclude subsequent submission for publication, but full disclosure should be made at the time of submission.

The journal's embargo policy (on release of information to the press about upcoming contents) should be made available.

Plagiarism

Plagiarism is the use of others' published and unpublished ideas or words (or other intellectual property) without attribution or permission, and presenting them as new and original rather than derived from an existing source. The intent and effect of plagiarism is to mislead the reader as to the contributions of the plagiarizer. This applies whether the ideas or words are taken from abstracts, research grant applications, Institutional Review Board applications, or unpublished or published manuscripts in any publication format (print or electronic).

Plagiarism is scientific misconduct and should be addressed as such (see prior section).

Self-plagiarism refers to the practice of an author using portions of their previous writings on the same topic in another of their publications, without specifically citing it formally in quotes. This practice is widespread and sometimes unintentional, as there are only so many ways to say the same thing on many occasions, particularly when writing the Methods section of an article.

Although this usually violates the copyright that has been assigned to the publisher, there is no consensus as to whether this is a form of scientific misconduct, or how many of one's own words one can use before it is truly "plagiarism." Probably for this reason self-plagiarism is not regarded in the same light as plagiarism of the ideas and words of other individuals. If journals have developed a policy on this matter, it should be clearly stated for authors.

Advertising

Many scientific journals derive a substantial income from advertising or reprints, creating a potential conflict of interest. Editorial decisions should not be influenced by advertising revenue or reprint potential. Editorial and advertising functions at the journal should be independent.

Advertisers and donors should have no control over editorial material under any circumstances.

Reprinted articles must be published as they originally appeared in the journal (including subsequent corrections); that is, there is no alteration or revision of articles for a supplement or reprint other than corrections. The content of special supplementary issues (if any) should be determined only by the usual editorial process and not be influenced in any way by the funding source or advertisers. Limitations on how reprinted articles may be combined with advertisements or endorsements of a product or company should be explicitly addressed in journal policy. If supplements do not undergo peer review or undergo a peer review process different from the rest of the journal, that should be explicitly stated.

Journals should have a formal advertising policy and this should be made available to all constituents of the journal. Briefly, journals should require all advertisements to clearly identify the advertiser and the product or service being offered. In the case of drug advertisements, the full generic name of each active ingredient should appear. Commercial advertisements should

not be placed adjacent to any editorial matter that discusses the product being advertised, nor adjacent to any article reporting research on the advertised product, nor should they refer to an article in the same issue in which they appear. Limitations on how reprinted articles may be combined with advertisements or endorsements of a product or company should be explicitly addressed in journal policy. Ads should have a different appearance from editorial material so there is no confusion between the two. Similar limitations (for the regular journal as well as supplements) may include placement of ads for related products on the front, rear, or inside cover pages of an issue that carries an editorial or original article on that topic. Policies on these issues should be explicit, and published in print or on the Web.

Products or services being advertised should be germane to (a) the practice of medicine, (b) medical education, or (c) health care delivery.

Advertisements may not be deceptive or misleading. Exaggerated or extravagantly worded copy should not be allowed. Advertisements should not be accepted if they appear to be indecent or offensive in either text or artwork, or contain negative content of a personal, racial, ethnic, sexual orientation, or religious character.

Journals must have the right to refuse any advertisement for any reason. The decision as to acceptance (and any questions about eligibility raised by readers or others) should be made in consultation with the journal's editorial content team and the editorial team should be regularly informed about the evaluation of advertising, especially those that are refused due to non-compliance with the journal's guidelines.

Responding to Allegations of Possible Misconduct

Journals should have a clear policy on handling concerns or allegations about misconduct, which can arise regarding authors, reviewers, editors, and others. Journals do not have the resources or authority to conduct a formal judicial inquiry or arrive at a formal conclusion regarding misconduct. That process is the role of the individual's employer, university, granting agency, or regulatory body. However, journals do have a responsibility to help protect the integrity of the public scientific record by sharing reasonable concerns with authorities who can conduct such an investigation.

Deception may be deliberate, by reckless disregard of possible consequences, or by ignorance. Since the underlying goal of misconduct is to deliberately deceive others as to the truth, the journal's preliminary investigation of potential misconduct must take into account not only the particular act or omission, but also the apparent intention (as best it can be determined) of the person involved. Misconduct does not include unintentional error. The most common forms of scientific misconduct include (the following are taken with minor modification from the ORIpublication Analysis of Institutional Policies for Responding to Allegations of Scientific Misconduct [<http://ori.dhhs.gov/html/polanal2.htm>], full report in PDF format<http://ori.dhhs.gov/html/publications/studies.asp>, accessed 3/13/04]):

- ♣ Falsification of data: ranges from fabrication to deceptive selective reporting of findings and

omission of conflicting data, or willful suppression and/or distortion of data.

- ♣ Plagiarism: The appropriation of the language, ideas, or thoughts of another without crediting their true source, and representation of them as one's own original work.
 - ♣ Improprieties of authorship: Improper assignment of credit, such as excluding others, misrepresentation of the same material as original in more than one publication, inclusion of individuals as authors who have not made a definite contribution to the work published; or submission of multi-authored publications without the concurrence of all authors.
 - ♣ Misappropriation of the ideas of others: an important aspect of scholarly activity is the exchange of ideas among colleagues. Scholars can acquire novel ideas from others during the process of reviewing grant applications and manuscripts. However, improper use of such information can constitute fraud. Wholesale appropriation of such material constitutes misconduct.
 - ♣ Violation of generally accepted research practices: Serious deviation from accepted practices in proposing or carrying out research, improper manipulation of experiments to obtain biased results, deceptive statistical or analytical manipulations, or improper reporting of results.
 - ♣ Material failure to comply with legislative and regulatory requirements affecting research: Including but not limited to serious or substantial, repeated, willful violations of applicable local regulations and law involving the use of funds, care of animals, human subjects, investigational drugs, recombinant products, new devices, or radioactive, biologic, or chemical materials.
 - ♣ Inappropriate behavior in relation to misconduct: this includes unfounded or knowingly false accusations of misconduct, failure to report known or suspected misconduct, withholding or destruction of information relevant to a claim of misconduct and retaliation against persons involved in the allegation or investigation.
- Deliberate misrepresentation of qualifications, experience, or research accomplishments to advance the research program, to obtain external funding, or for other professional advancement.

Responses to possible misconduct

Journals should have an explicit policy describing the process by which they will respond to allegations of misconduct. In drafting such a policy, the guidance provided to editors by a publication of the US Office of Research Integrity may be useful (ori.dhhs.gov/multimedia/acrobat/masm.pdf, accessed 12/2/03). The process described in the following 2 paragraphs is an example of a policy for an individual journal:

All allegations of misconduct will be referred to the Editor-In-Chief, who will review the circumstances in consultation with the deputy editors. Initial fact-finding will usually include a request to all the involved parties to state their case, and explain the circumstances, in writing. In questions of research misconduct centering on methods or technical issues, the Editor-In-Chief may confidentially consult experts who are blinded to the identity of the individuals, or if the allegation is against an editor, an outside editor expert. The Editor-In-Chief and deputy editors will arrive at a conclusion as to whether there is enough evidence to lead a reasonable person to believe there is a possibility of misconduct. Their goal is not to determine if actual misconduct occurred, or the precise details of that misconduct.

When allegations concern authors, the peer review and publication process for the manuscript in question will be halted while the process above is carried out. The investigation described above will be completed even if the authors withdraw their paper, and the responses below will still be considered. In the case of allegations against reviewers or editors, they will be replaced in the review process while the matter is investigated.

All such allegations should be kept confidential; the number of inquiries and those involved should be kept to the minimum necessary to achieve this end. Whenever possible, references to the case in writing should be kept anonymous.

Journals have an obligation to readers and patients to ensure that their published research is both accurate and adheres to the highest ethical standard. Therefore, if the inquiry concludes there is a reasonable possibility of misconduct, responses should be undertaken, chosen in accordance with the apparent magnitude of the misconduct. Responses may be applied separately or combined, and their implementation should depend on the circumstances of the case as well as the responses of the participating parties and institutions. The following options are ranked in approximate order of severity:

- ♣ A letter of explanation (and education) sent only to the person against whom the complaint is made, where there appears to be a genuine and innocent misunderstanding of principles or procedure.
- ♣ A letter of reprimand to the same party, warning of the consequences of future such instances, where the misunderstanding appears to be not entirely innocent.
- ♣ A formal letter as above, including a written request to the supervising institution that a investigation be carried out and the findings of that inquiry reported in writing to the journal.
- ♣ Publication of a notice of redundant or duplicate publication or plagiarism, if appropriate (and unequivocally documented). Such publication will not require approval of authors, and should be reported to their institution.
- ♣ Formal withdrawal or retraction of the paper from the scientific literature, published in the journal, informing readers and the indexing authorities (National Library of Medicine, etc), if there is a formal finding of misconduct by an institution. Such publication will not require approval of authors, should be reported to their institution, and should be readily visible and identifiable in the journal. It should also meet other requirements established by the International Committee of Journal Editors(www.icmje.org/#correct, accessed 12/2/03). It is recommended that editors inform readers and authors of their reservation of the right to publish a retraction if it meets these conditions, thereby helping decrease arguments with authors. Editors or reviewers who are found to have engaged in scientific misconduct should be removed from further association with the journal, and this fact reported to their institution.

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